

LEGISLATIVE HEARING ON THE SAFE CHEMICALS ACT

JOINT HEARING

BEFORE THE

SUBCOMMITTEE ON SUPERFUND, TOXICS AND ENVIRONMENTAL HEALTH

OF THE

COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS

UNITED STATES SENATE

ONE HUNDRED TWELFTH CONGRESS

FIRST SESSION

NOVEMBER 17, 2011

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ONE HUNDRED TWELFTH CONGRESS
FIRST SESSION

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**OVERSIGHT HEARING ON THE
BROWNSFIELD'S PROGRAM - CLEANING UP
AND REBUILDING COMMUNITIES**

WEDNESDAY, OCTOBER 19, 2011

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

The committee and subcommittee met, pursuant to notice, at 10 a.m. in room 406, Dirksen Senate Office Building, Hon. Frank Lautenberg [chairman of the subcommittee, presiding.

Present: Senators Lautenberg, Inhofe, Crapo, Carper, Cardin, Whitehouse, Barrasso, Udall, Merkley, and Gillibrand.

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

Senator LAUTENBERG. We welcome the witnesses. Obviously, I guess we all think that when we have an issue before the public, that we all think it is very important. Needless to say, I am not going to differ with the usual routine here.

I will start off on what I hope will be a good setting for the birthday of my colleague and friend, Senator Inhofe. He is younger than I by a few years. It is not noticeable, I know, but take my word for it. There is a degree of envy, and we wish him happy birthday. We have had I won't say it is a unique relationship, but it is one that we don't agree necessarily on all the subjects, but we agree on respect for one another and it is always great to work with Senator Inhofe.

During the past 2 years, this Committee and the Subcommittee have held five hearings that identified serious problems with the Toxic Substance Control Act, known as TSCA. And today, we are starting to look for our solutions to those problems and discuss them publicly.

In our previous hearings, we uncovered dangerous and costly deficiencies in TSCA and this Committee heard from CDC officials who told us their scientists found 212 industrial chemicals, including six carcinogens coursing through America's bodies. Twice, we have heard from EPA Administrator Lisa Jackson, who told us under current law that her agency lacks the tools it needs to regulate high-risk chemicals.

And we heard from others who shared their anxiety about having no system for determining which everyday chemicals might hurt them or their children.

TSCA is so severely flawed that the nonpartisan Government Accountability Office testified that it is a “high-risk area of the law.” Our hearings also revealed the status quo does not work for the chemical industry either. In the hearing last February, executives from Dow and DuPont, two major chemical companies, testified in support of reform in part because of the difficulties their companies face operating under different rules and in different States.

We heard similar messages earlier from the chemical maker BASF and S.C. Johnson, the global consumer product company. We heard from colleagues on both sides of the aisle who agree that TSCA must be revised to work better for businesses and the health of our citizens.

Now, I first introduced legislation to address TSCA’s shortcomings in 2005. Since then, my legislation has evolved through scientific advances and feedback from various other sources, including the chemical industry. At a hearing nearly 2 years ago, I told this Committee the bill should be considered an invitation to all to play a part, and I meant it seriously. I invite colleagues with whom we might have some sharp differences, let’s sit down and talk about it. This is important enough that we want to keep the door open and we will listen to ideas or views that others have.

Many Members on our side offered ideas that are included in the newest version of my bill and I am pleased that most of the Committee’s Democrats are now co-sponsored. We also heard from Senator Vitter, who said that TSCA reform legislation must be based on sound science and called for more input from the National Academy of Sciences on chemical risk assessment.

So this year’s version of the Safe Chemicals Act mandates that EPA use the best available science, as defined by the ongoing work of the National Academies. Last summer, Senators Inhofe and Barrasso raised concerns about inadvertently depriving our economy of chemicals that are essential to daily life. And I mentioned something here that was, as they say, up front and personal. When I had six courses of chemotherapy last year and I was mighty glad to meet the chemicals, I can tell you, and they treated me nicely.

So we know that there is lots of value that comes from chemicals, and we want to be sure that we don’t get in the way of availability of those products, but we do want to watch out for those that might bring harm instead.

As a result, we have included provisions to ensure the continued availability of chemicals for critical or essential uses. Concerns were also raised about our proposal for prioritizing certain chemicals for safety review, so we completely overhauled that section of the bill.

Earlier this year, Senator Inhofe and I met about trying to make this bill bipartisan. And he suggested a process for getting more ideas from industry and others on the table. Throughout the summer, our staffs held 10 meetings with representatives from industry, from labor and environmental groups on different sections of the Safe Chemicals Act. Those meetings increased understanding of the bill’s strengths, as well as areas that could be improved.

Today's hearing is an opportunity for the witnesses and Members of the Committee to take the next step toward a bipartisan bill. And if there are concerns with something in the Safe Chemicals Act, I hope that you will either offer a suggestion for improving it or commit to working through the details with us in the next 2 weeks.

The bottom line is this: This legislation establishes a strong, but practical system for guaranteeing the safety of chemicals, many of which end up in our bodies and the bodies of our children and we remain open to other ways of achieving our shared goal of a system that improves safety and encourages continued innovation and growth in the chemical industry.

But we have got to get going. We have to act soon. I plan to call for a vote in this Committee in the near future and I hope that we will be able to address any concerns that might be raised today so we can approve a bipartisan bill that encourages the use of chemicals that help and protect our children from the chemicals that harm.

Senator LAUTENBERG. Is Senator Crapo going to be here shortly, do you know?

Senator INHOFE. I am sitting in for him.

Senator LAUTENBERG. Oh, OK, a birthday treat for Senator Inhofe. He can fill in.

Senator INHOFE. Thank you. Thank you.

As I understand it, Mr. Chairman, this is a joint full Committee and Subcommittee, so that would be appropriate.

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

Senator INHOFE. I appreciate the comments you made, and I know that it isn't only on my birthday that I get those comments because it surprises a lot of people that Senator Lautenberg and I are very good friends. We have a mutual respect, and we know the areas where we disagree. And I think it is appropriate the way he is doing this.

The stakeholders meetings were very thoughtful. We learned a lot from the participants as efforts to modernize TSCA continue in the future. These discussions will undoubtedly help to build a foundation for eventual reforms. The participants were candid and forthcoming with their unique viewpoints and I look forward to building an agreement around that. And I think that is a good start, bringing the people in to talk about these things.

While we often heard very conflicting ideas from stakeholders on how TSCA should be modernized, we also identified a few areas of potential common ground and I think that that warrants further discussion. Although our hearing today is on S. 847, which is not incorporated in what we have learned from the stakeholders process, it is a starting point, I recognize that.

It is a battle, given the unemployment rate hovering around 9 percent and numerous costly new regulations coming from this Administration that we make sure that any toxic reforms help to not only protect human health, but jobs and the economy. That has got to be part of the consideration as we develop this thing.

My interest in TSCA modernization, which I have said before, is in large part due to TSCA's broad reach over chemical manufacturing and its potential and real impacts on the economy. TSCA regulates the manufacturing, the distribution, use and disposal of chemicals, authority that covers thousands of transactions and decisions by thousands of people every day, and I have consistently said that TSCA must be accomplished with a broad base of support, including industry up and down the value chain. It also must take into account the small-and medium-size businesses that could be affected the most if the law is updated improperly.

Our witnesses today represent a few of the stakeholders we heard from in the course of our meetings that we had. They possess a wide range of perspectives on TSCA modernization and its implementation, but we must not forget that there are plenty of other groups that have strong interest in this, other stakeholders as well.

At this time, I would like to ask unanimous consent to place into the record the statements from the American Cleaning Institute, the Grocers Manufacturers Association, the Society of Chemical Manufacturers and affiliates, and the National Petrochemical and Refiners Association.

Senator LAUTENBERG. Without objection.

[The referenced documents follow:]

Senator INHOFE. While I believe it is time to bring this 35 year old statute into the 21st century, it is also important that we do it right, and I am sure that this is a good start in that, Mr. Chairman.

Thank you.

[The prepared statement of Senator Inhofe follows:]

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

I would like to begin by thanking Senator Lautenberg for scheduling a legislative hearing on S. 847 the Safe Chemicals Act of 2011. I would also like to thank him and his staff for inviting us to co-host a series of listening sessions, which included not only our staffs, but representatives from industry and the environmental community.

The stakeholder meetings were very thoughtful and we learned a great deal from the participants. As efforts for modernizing TSCA continue in the future, these discussions will undoubtedly help to build a foundation for eventual reforms. The participants were candid and forthcoming with their unique viewpoints and I look forward to building agreement around some of the many challenges facing TSCA reform moving forward.

While we often heard very conflicting ideas from stakeholders on how TSCA should be modernized, we also identified a few areas of potential common ground, and I think that warrants further discussions. Although our hearing today is on S. 847—which has not incorporated what we learned in the stakeholder process or addressed many longstanding concerns—I am encouraged that this bill helped begin a constructive dialog that may help lead to a workable bill which down the road could pass both the House and Senate and become law.

It is vital—given an unemployment rate hovering around 9 percent and numerous costly new regulations coming from this administration—that we make sure any TSCA reforms help to not only protect human health, but jobs and the economy. My interest in TSCA modernization—which I have said before—is in large part due to TSCA's broad reach over chemical manufacturing and its potential, and real, impacts on the economy. TSCA regulates the manufacturing, distribution, use, and disposal of chemicals—authority that covers thousands of transactions and decisions by thousands of people every day.

I have consistently said that TSCA modernization must be accomplished with a broad base of support, including industry up and down the value chain. It also must take into account the small and medium size businesses that could be affected the

most if the law is updated improperly. Our witnesses today represent a few of the stakeholders we heard from in our meetings. They possess a wide range of perspectives on TSCA modernization and its implementation but we must not forget that there are plenty of other groups that have a strong vested interest in this effort and need to be considered as well.

At this time I would like to ask unanimous consent to have statements from the American Cleaning Institute, the Grocery Manufacturers Association, the Society of Chemical Manufacturers and Affiliates, and the National Petrochemical & Refiners Association—all of whom also participated in the stakeholder meetings—inserted into the record.

While I believe it is time to bring this 35 year old statute into the 21st Century, it is equally as important that we do it the right way without harming American innovation or shipping jobs overseas.

My principles for reform remain the same: any modernization of TSCA should be based on the best available science; use a risk-based standard for chemical reviews; include cost-benefit considerations; protect proprietary information; and must prioritize reviews for existing chemicals.

These are principles I have stood by for many years and I think are vital to a successful TSCA modernization process that is appropriately protective, predictable, efficient, and revives confidence in our Federal chemical management system.

Again, I appreciate Sen. Lautenberg's work on this issue and his willingness to gather information in a constructive, bipartisan nature. I look forward to hearing from the witnesses today.

Senator LAUTENBERG. Thanks very much.

Senator Carper.

OPENING STATEMENT OF HON. THOMAS CARPER, U.S. SENATOR FROM THE STATE OF DELAWARE

Senator CARPER. Thank you, thank you. And I want to join all of our colleagues in wishing Jim happy birthday. It is a joy to here with you today. And I think a great gift that gets him out of the conversations between—of both our Chairman and Senator Inhofe on, and with your staffs, it would be a great gift for our Country.

I just want to commend you for the time and energy that you and your staffs are putting into this. These are important issues that I care a lot about. I know others do as well.

Every day in this Country, manufacturers use, as we know, various chemicals to make everything from carpets to cosmetics, cars, water bottles, dishwashing soap, and we need these chemicals to keep our manufacturing base strong. We also need to make sure that we are using and disposing of them safely.

As others have said, it has been more than 30 years since we revisited the Toxic Substance Control Act, and that is far too long when we consider how much more we manufacture and use chemicals today and how much more we understand today about those chemicals.

Industry, environmental and public health leaders, the Obama administration, several of our colleagues in Congress, including me, all agree that current law is not sufficient and it is time that the Toxic Substance Control Act is modernized.

From what I understand, the principles for TSCA reform that have been outlined by the chemical industry, the NGO community and other stakeholders are remarkably similar, and that is encouraging. I believe that there is a path forward to reforming TSCA that we can address, that will enable us to address the needs of our diverse stakeholders on this issue, including our constituents.

Senator Lautenberg has introduced, as we know, a bill to strengthen our chemical safety law that has gone through several

iterations. I think it is not just a good start, but it is a good process that is underway. And I just want to say to Senator Inhofe that I look forward to working with both of you and with our colleagues here in the Senate in our efforts to try to pass strong chemical safety legislation.

I look forward to hearing from our witnesses today, especially the guy in the middle, with whom I was pleased to serve in the House 10 those many years ago. Cal, it is especially nice to see you. Welcome one and all.

Thanks so much.

Senator LAUTENBERG. Thanks very much, Senator Carper.

We will proceed with the witnesses. Welcome. Each of you brings experience and obviously a point of view.

Oh, my goodness, surprise.

Senator Gillibrand I think was the next arrival and we look forward to hearing from you.

**OPENING STATEMENT OF HON. KRISTEN GILLIBRAND,
U.S. SENATOR FROM THE STATE OF NEW YORK**

Senator GILLIBRAND. Thank you, Senator Lautenberg, for your leadership on such an important issue, one that very deeply affects our constituencies and the whole Country. I appreciate that the Committee is going to examine the Safe Chemicals Act which aims to modernize TSCA. And I, too, have read the studies and reports that have found toxic chemicals in everyday products.

Since TSCA became law more than 30 years ago, we have seen an unacceptable rise in childhood cancers, learning disabilities, birth defects, allergies, asthma, autism and infertility. Our children are being exposed to hundreds of chemicals before they are even born. Umbilical cord blood samples show exposure to over 200 chemicals from BPA, which is found in plastic bottles, flame retardants which are used in electronics and in furniture, and PCBs, a known carcinogen that has remained in our soil and water decades after it has been banned.

Congress can no longer afford to ignore the failures of TSCA to prevent public health any longer. The issue of the effectiveness of our Nation's chemical regulations is extremely important to all Americans and in particular to mothers like me. We must stand with parents across the Country who have joined together to demand better from their elected leaders.

It is just not good enough for the Federal Government to sit on the sidelines while States are forced to fill in the void and take matters into their own hands. In my home State of New York, the State legislature passed critically needed reforms, like protecting babies from toxic chemicals, BPA in baby bottles and other cancer-causing chemicals found in nursing pillows and in baby carriers. In all, 25 States across the Country have passed 80 chemical safety laws in 9 years, with overwhelming majorities and strong bipartisan support.

I applaud this action at the State level, but we need a national policy that ensures chemicals in products are safe in every State and for every family.

The legislation we are examining today, the Safe Chemicals Act, changes the current paradigms to put the burden on proving a

chemical is safe on industry and provides that our regulators need to finally allow this law to work as it was intended. As the legislation moves forward, it is essential that the final product make meaningful reforms that will give comfort to consumers that the products that they purchase for their families are safe.

Mr. Chairman, earlier this year, I heard the story of Mira Brouwer, a young girl from Ithaca, New York, who at the age of just 4 years old passed away as the result of complications in the treatment for brain cancer. Faced with the loss of her young daughter, her mother, Chistine Brouwer, founded Mira's Movement. It is an organization to raise awareness of pediatric cancer.

[Audience interruption.]

Senator GILLIBRAND. I agree. I agree with you.

[Laughter.]

Senator GILLIBRAND. Mira's mother shared her story and her questions and concerns about what could have contributed to her daughter's cancer. She pored through study after study that identified the potential links between chemicals in our environment and such cancers, just like the one that took Mira's life. We owe it to Mira and thousands of the children who are facing similar ailments to ensure that the products that we produce in this Country and that we purchase for our families are safe.

Thank you, Mr. Chairman, for looking at this important issue.

Senator LAUTENBERG. Thank you very much.

Senator Merkley.

**OPENING STATEMENT OF HON. JEFF MERKLEY,
U.S. SENATOR FROM THE STATE OF OREGON**

Senator MERKLEY. Thank you, Mr. Chair. Senator, your leadership on this issue has been extremely important, and your commitment to modernizing the Toxic Substance Control Act so we can protect our families from exposure to dangerous toxins is terrific. So thank you for doing that.

Oregon has been a leader among the States in attempting to limit toxic chemicals, ranging from flame retardants to mercury, cyanide and so forth. But we are not satisfied. Our families are not satisfied with the protection from dangerous chemicals that exist currently.

Oregon is among the top five in the Nation for adult asthma rates, the top 10 for breast cancer, near the top for autism, and these kinds of diseases are linked to toxic chemicals in our environment.

The shocking part for me is that the Environmental Protection Agency has been unable to protect our families from exposure because the Toxic Substance Control Act does not provide EPA with the necessary tools to collect data on chemical risk and effectively regulate the most toxic chemicals.

And who are most impacted by this? It is consumers and families across America who don't know if they are using products that could be harmful to their health.

Reforming TSCA makes common sense. We know that many American companies currently have to prepare to abide by the REACH law in Europe, which requires much higher control of chemical toxins. We know that many States, as my colleague just

referred to, have gone out on their own to try to pass laws, as New York has, as Oregon has, as so many have, because of the vacuum in Federal policy. It makes sense to have a Federal policy to regulate toxic substances that actually works.

So I look forward to the hearing today and to doing all I can to help take this important bill forward to protect the health of Americans across this Nation.

Senator LAUTENBERG. Thank you very much, Senator Merkley.

And now we ask our witnesses to make their statements. Today, we are going to hear from a range of experts who have significant experience in chemical safety: Mr. Ted Sturdevant, Director of the Washington State Department of Ecology; Charlotte Brody, Director of Chemicals, Public Health and Green Chemistry for the BlueGreen Alliance, a national partnership of labor unions and environmental groups; and Mr. Cal Dooley, President and CEO of the American Chemistry Council; Mr. Robert Matthews, a partner in the law firm of McKenna Long & Aldridge, and counsel to the Consumer Specialty Products Association; and Dr. Richard Denison, Senior Scientist for the Environmental Defense Fund.

And we welcome you.

And Mr. Sturdevant, you are the first, and please give us your testimony.

**STATEMENT OF TED STURDEVANT, DIRECTOR, DEPARTMENT
OF ECOLOGY, STATE OF WASHINGTON**

Mr. STURDEVANT. Thank you, Chairman Lautenberg, Ranking Member Inhofe and Members of the Committee for this opportunity to testify. I am Ted Sturdevant, the Director of the Washington State Department of Ecology.

It is very significant that this Committee is willing to open the conversation on TSCA reform and I applaud you for the open and inclusive dialog that you have had to date. And I want to particularly recognize the leadership of Senator Lautenberg for offering this legislation, and to Senator Inhofe for supporting such an inclusive dialog.

This is a critical issue for the States and I appreciate the chance to share our perspective.

So today, what I would like to do is talk about why States care so much about TSCA reform; what we have had to do in the face of an outdated TSCA; and speak just a little bit about the preemption of States' authority in this arena.

So why do States care about TSCA? As State environmental agencies around the Country, part of our job is to protect people and the environment from harmful exposure to toxic chemicals. When those chemicals come from a pipe or a smokestack, we know what to do. We have the tools to deal with that. But when they come from ubiquitous products like foam and furniture or the plastic casings of a television or toys, we don't have the tools to deal with those.

We can't intercept chemicals that leave products and get into our public waterways via wastewater or stormwater runoff with potential human exposure along the way. We are just not good at that.

So as we grow concerned about a particular chemical or chemicals in our States, we face a very difficult choice. And that is, do

we tackle that chemical or chemicals with inadequate tools and resources or do we look the other way? And more and more, what you are seeing are States deciding to act and step up to this. So even with those inadequate tools, that is the pattern we are seeing in the States.

But our preference is for a third option, and that is for a Federal system that works. So I want to share an example of what we face and really how ill-equipped we are to deal with this kind of thing. In Washington State, we are undertaking a massive effort to restore and protect Puget Sound, the Nation's second-largest estuary. And in the city of Tacoma, which sits on Commencement Bay in the Sound, we have spent over \$100 million cleaning up contaminated sediments in the bay. And last year, for the first time, we started to see improved health in those sediments, which was great news.

But at the same time, we are seeing phthalates come in via stormwater runoff and settle on top of those sediments. Phthalates are plasticizer chemicals that are used in a wide variety of consumer products. And they are endocrine disrupters which can have harmful reproductive and development effects.

So I don't mean to open the debate about the science of phthalates, but we are concerned about these things getting into the food chain in Puget Sound and concerned about impacts on people that harvest food from Puget Sound.

So the problem here is that we don't know what to do about it. We don't have the tools. We don't have any means of really doing anything about that particular source of pollution. And we don't have any means of protecting that investment that we have made in the bay. And I think that this is exactly the kind of problem that should be addressed by TSCA and don't have confidence that it will be.

So even without the right tools, as I said, States are tackling these challenges more and more. In the last 8 years, 18 States have passed chemical policy legislation and I think it is fair that we will continue to see those kinds of efforts in the upcoming legislative session.

And it is important to note that this has not been a partisan issue at the State level. The votes on these things have been strongly bipartisan because it is a public health issue.

Now, before I conclude, I want to speak briefly to the issue of preemption of States' authority. Given the patchwork of regulations that is taking hold across the Country in States, some people believe that absolute preemption of States' authority is necessary. I understand the concern, sympathize with the concern, but disagree with that approach for two reasons.

First, as you said, TSCA has not been reformed for 35 years, so the States have been the folks that have filled that gap in the meantime and we need to have the authority to do our job, to deal with the unanticipated challenges of the future that TSCA may not address, even a reformed TSCA may not address.

And second, we are not doing this because we don't have anything better to do. We are doing this because we think we have to, because these challenges exist that are not getting addressed.

So I believe that if there is a national solution to this problem, preemption of States' authority really becomes a non-issue because we will then direct, I think, our scant resources elsewhere. And we appreciate that the proposed bill preserves States' authority.

We also appreciate the sensible approach of requiring minimum data-sets on chemicals and showing that they meet safety standards. The bill's provisions for sharing data with States, while maintaining confidentiality and enabling EPA to deal with the highest-risk chemicals are also appreciated.

So TSCA reform is a big deal for the States. Last year, the Environmental Council of the States unanimously passed a resolution calling for TSCA reform, and that represents the environmental agencies of all the States across the Country. I don't believe we have ever seen such broad agreement that TSCA needs to be fixed, whether your aim is to protect public health or the environment, or to have a more consistent, predictable playing field for businesses across the States. The solution to all these things I think is modernizing TSCA.

Senator LAUTENBERG. Your full statement will be included in the record, so please forgive me because we want to move quickly.

Mr. STURDEVANT. I was done and I appreciate the opportunity.

Senator LAUTENBERG. Your testimony was excellent to this point. We look forward to having it in the record.

[The prepared statement of Mr. Sturdevant follows:]

Testimony of Ted Sturdevant

Director

Washington State Department of Ecology

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

Legislative Hearing on the Safe Chemicals Act

November 17, 2011

First I want to say thank you for the opportunity to testify on this very important issue. TSCA reform is an issue whose time has come, and it is very significant that this committee is willing to open this conversation. I applaud the committee for the open and inclusive effort to bring stakeholders together over the past year to inform this debate, and I want to particularly recognize the leadership of Senator Lautenberg for offering this bill, and of Senator Inhofe for supporting such an inclusive dialogue. This is a critical issue for the states and we appreciate the opportunity to share our perspective.

Today, I'd like focus on why states care about modernizing TSCA, what we have had to do in the face of an outdated and ineffective federal chemical policy, and briefly address the issue of preemption of states' authority.

So why do states care about TSCA?

It is the job of state environmental agencies around the country, ours included, to protect people and the environment from harmful exposure to toxic chemicals. When those chemicals come from a pipe or a smokestack, we have the tools and the know-how to do our job. But when they come from ubiquitous products like the plastic casing of a television, or the foam in our furniture, we haven't had the tools or the know-how to do our job. We can regulate direct dischargers, we can

clean up contaminated soils, but we can't intercept toxic chemicals that escape products and get into public waterways via wastewater or stormwater runoff, with potential human exposure along the way.

As we better understand the consequences of human or environmental exposure to certain chemicals, we in the states face a tough choice: either tackle those chemicals with imperfect tools and inadequate resources, or look the other way. In Washington and in more and more states around the country, we have chosen to act. But our preference is for a third option: a federal system that works.

Let me share an example of what we face, and how ill equipped we are to deal with it.

In Washington State, we are undertaking a massive effort to restore the Puget Sound, the nation's second largest estuary, just behind Chesapeake Bay. In the city of Tacoma, we spent over \$100 million to clean up contaminated sediments in Commencement Bay from its industrial past. Last year, we finally started seeing improved sediment and fish health in the Bay. But at the same time, we are now seeing phthalates pour into the bay in polluted stormwater runoff and settle on top of those clean sediments. Phthalates are used as plasticizers in a variety of everyday products such as flexible piping, soft plastic toys or packaging for consumer products, and they are considered endocrine disruptors.

According to the National Institute of Environmental Health Sciences, many of these substances have been associated with developmental, reproductive and other health problems in wildlife and laboratory animals. Some research suggests that these substances are adversely affecting human health in similar ways.

I am concerned about what phthalates might mean in the food chain in Puget Sound, and for the people that harvest its food. But I don't know what to do about it. We don't have any means of stopping or reducing this pollution stream, or protecting our investment in the Bay. I believe this is exactly the kind of problem that should be addressed by TSCA, but is not.

States across the country are confronting similar problems, but more and more, we're developing our own solutions, state by state.

Let me share another example.

In 2008, Washington became the first state in the nation to ban all forms of PBDEs, a commonly used flame retardant used in foam and plastics that posed unacceptable neurological risks to children. This effort took significant time and resources at taxpayer expense, and it was strongly opposed by industry. Since then, several other states have banned PBDEs, and the EPA recently announced their phase-out nationally.

But now we are learning about a chemical that was just listed on the California Office of Environmental Health Hazard Assessment's Proposition 65 list of chemicals as a known carcinogen. This chemical is known as Chlorinated Tris or "TDCPP," a flame retardant added to polyurethane foam in furniture. The challenge is that after a years-long effort to improve the safety of chemical flame retardants in furniture, we may now have to start over, but with a new chemical.

There are three problems with this. First, it reveals that the system is not designed to move us toward safer chemicals. We have to wage long, bitter fights over controlling a specific chemical, but with no effective inducement to then shift to safer alternatives.

Second, we have to recreate these efforts state by state, expending precious resources to do so.

And third, this leads to a patchwork of chemical regulations that industry understandably fears.

But this approach, however imperfect, is preferable to inaction. During the past eight years 18 states have passed legislation ranging from comprehensive chemical safety laws to bans on specific hazardous chemicals, and I'm sure we'll see many more such efforts in upcoming legislative sessions around the country.

It's important to note that this is not a partisan issue at the state level. Most of these votes have been strongly bipartisan, because public health is at stake.

The current system doesn't work for anyone. I shouldn't have to spend my resources on Washington-specific efforts that are better made at the national level. Citizens expect to be protected from harmful toxic exposures that could be avoided. And businesses shouldn't be subject to an increasingly complex maze of regulations across the country.

For those reasons, I believe there is broad support for TSCA reform, and I think this is the right bill, at the right time.

Let me briefly speak to the issue of preemption of states' authority before I conclude.

Given the patchwork of regulations taking hold in the states, some believe that absolute preemption of states' authority is needed. I understand the concern, but disagree with this approach for two reasons. First, TSCA has not been updated

in 35 years, even while our understanding of the human and environmental impacts of many chemicals has grown by leaps and bounds.

In that time, the states have been the leaders and the innovators in protecting our citizens and their environment. Had states not been able to act, I don't believe we'd be having this conversation today, and we'd be stuck with an antiquated, ineffective system. Even if you pass strong TSCA reform today, we still need the authority to do our jobs and confront the unanticipated challenges of the future that TSCA may not address.

And second, states are not undertaking these efforts because we want to. We're doing it because we have no other choice. If the federal system worked, we wouldn't have to do it ourselves. If you create a national solution to this problem, states can focus our scant resources elsewhere, and I believe preemption will become a non-issue.

I think the proposed bill strikes a good balance on this issue.

The second issue I'd like to address is information sharing. Better access to information would help us all – government, industry and consumers. We should build a system for sharing information about chemicals between EPA, the states, manufacturers and downstream users of chemicals. We can and should do this without asking companies to give away trade secrets.

I'm confident we can figure that out. I see no reason that modernizing TSCA should conflict with industry's ability to innovate and create jobs.

The comments I've made here reflect collective statements state leaders have made in recent years on the need for TSCA reform. Most recently this included a group of nine states submitting comments on this bill. In 2009, 13 states issued

a set of principles for TSCA reform, and in August, 2010, the Environmental Council of the States, representing the leadership of all state environmental agency commissioners, unanimously passed a resolution urging Congressional reform of TSCA.

I don't believe there has ever been such broad agreement that TSCA needs to be fixed. Whether your aim is to better protect the American people, or provide a more predictable, consistent playing field for business – or both – the answer is TSCA reform. Let me again offer my gratitude to you for inviting this conversation, for engaging the states in it, and for allowing me the privilege of testifying today.

Attached are more detailed comments on the Safe Chemicals Act of 2011 that were submitted to Senator Lautenberg and Senator Inhofe on behalf of nine state environmental commissioners from California, Colorado, Delaware, Massachusetts, Maryland, Michigan, Oregon, Vermont, and Washington.

**STATE ENVIRONMENTAL COMMISSIONERS
COMMENTS ON THE
SAFE CHEMICALS ACT OF 2011
S. 847 (April 15, 2011 Version)**

Summary

These comments were submitted to Sen. Lautenberg and Sen. Inhofe on August 23, 2011, by nine environmental commissioners from California, Colorado, Delaware, Massachusetts, Maryland, Michigan, Oregon, Vermont, and Washington.

Reforming the Toxic Substances Control Act of 1976, (TSCA) is a key issue for states. In 2010, the Environmental Council of States (ECOS) passed a resolution calling for responsible TSCA reform to cover both new and in-use chemicals, and provide for quick action when needed, assessment of safer alternatives, and collaboration and information-sharing between federal and state programs. As of today, 30 states have passed chemical policy laws that include comprehensive chemical programs, bans on specific high-risk chemicals, and resolutions that call for TSCA reform. These are overwhelmingly bipartisan efforts. Through our work, we have learned many lessons about what has worked and what has not in the Federal TSCA law. Our comments address the key issues for states, which are that TSCA reform should:

- Preserve states' ability to protect public health and the environment.
- Require minimum data for all chemicals and require manufacturers to show that chemicals meet safety standards.
- Require United States Environmental Protection Agency (EPA) to define criteria for safer alternatives using a hazard and risk-based approach that considers the entire chemical life cycle, and encourage use of safer alternatives through market incentives and other means.
- Give EPA authority to take immediate action to reduce threats from the most harmful chemicals, especially Persistent, Bioaccumulative and Toxic chemicals (PBTs) and other chemical substances determined to require immediate risk management, including chemical bans where needed.
- Reward innovation and help safer chemicals and alternatives get to the marketplace faster.
- Share information and coordinate between state and federal programs to maximize use of resources and ensure a predictable regulatory environment for all stakeholders.

We appreciate the opportunity to submit these comments and respectfully ask for their consideration. We would welcome the opportunity provide additional information, answer questions, engage in discussion and provide suggested language on any or all of these issues.

1. Preservation of State Authority.

We support the express preservation of state authority in §18 of Safe Chemicals Act of 2011 (S. 847) and urge the bill's sponsors to retain this language.

The retention of state authority as it is described in S. 847 is one of the most important issues in the TSCA reform debate. Many Federal environmental laws expressly preserve state authority. For example, many states have programs that contain requirements in addition to those specified in the Resource Conservation and Recovery Act (RCRA). Washington State has enacted toxic chemical cleanup legislation that is more restrictive than the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA). States also have state cleanup programs in addition to CERCLA. The Clean Air Act authorizes California to establish more stringent vehicle emission standards, which can then be adopted by other states in lieu of the federal standards. These are only a few examples where state authority has been maintained without disruption of a federal program. Preservation of state authority is both workable and necessary. The states strongly recommend that this provision be retained in its current form.

2. Enhanced State Coordination Role.

Section 24 (State Programs) amends TSCA § 28 to require EPA to establish a state coordination process for data sharing and prioritization as it relates to management of chemical substances and mixtures. The language from last year's House discussion draft does not appear in S. 847. Last year, the states worked with House Committee staff to strengthen federal coordination and cooperation with state programs and provide an enhanced consultative role in areas of particular importance to the states. At a minimum, the states request that §24 be revised to strengthen consultation and coordination with the states and local governments to:

- Provide for advance consultation and coordination on the design and development of the electronic database established under § 9(d).
- Provide for advance consultation and coordination on the development of a streamlined process for sharing confidential business information with the states under § 14.
- Provide for consultation and coordination prior to: (1) establishing conditions on the manufacture, processing, use, distribution, or disposal of a chemical substance or mixture; and (2) granting an exemption or providing for public notice under § 6(e) to determine if related states have taken a similar action under state law.
- Provide for consultation and coordination before initiating any rulemaking and for meaningful opportunities for input throughout any rulemaking process under TSCA including efforts to define "safer alternatives" and establish criteria for alternatives assessment.
- Provide for advance consultation and coordination on the development of Hot Spot action plans under § 34.

- Provide for grant funding to the states to support activities related to §§ 5-9, 14, 18, 23, 29, and 34, in addition to grant funding provided for states to promote and support activities in § 31.
- Provide for state representation, appointed by ECOS, on the Interagency Science Advisory Board on alternative testing methods and the Interagency Prioritization and Testing Committee.

3. Risk Based Safety Standards and the Role of Hazard Assessment.

Section 3 (Findings, Policy and Goal) amends TSCA § 2(b) (3) to add new policy language related to meeting a risk-based safety standard that protects vulnerable populations and the environment. States recommend addition of the term *hazard* so that, consistent with the approach taken by many states, Federal policy is based on a *hazard* and risk-based approach to protect vulnerable populations and the environment.

Chemical policy reform should shift chemical use from chemicals that possess a high intrinsic hazard to chemicals with lower hazard. In many cases, there are equally effective and safer alternatives to hazardous chemicals. Manufacturers should be required to conduct safer chemical alternative assessments, as part of a safety standard determination, prior to implementing any other proposed risk control measures. In instances where safer alternatives are available, chemical policy should help shift uses towards these alternatives. When faced with a choice between implementing control measures and reducing intrinsic hazard, the states have often found that the cheapest and most effective option is reducing hazard. Protection of public health and the environment requires identification and substitution of safer alternatives, irrespective of current known risks.

4. Minimum Data Set.

Section 5 amends the Minimum Data Set and testing requirements of TSCA §4. The states are concerned with the proposed language relating to the minimum data set, particularly the requirement that each minimum data set include the minimum amount of information necessary for the Administrator to conduct a screening-level risk assessment. This limitation appears to be open to a variety of interpretations, depending on the definition of screening level risk assessment. Many chemicals, particularly those produced at high volumes or chemicals with particular hazard traits, should receive a comprehensive risk assessment; the minimum data set should contain all of the data needed to conduct these types of assessments. The current language appears to limit the scope of the minimum data set in such a way as to preclude a thorough assessment of chemical substances without relying on additional testing orders. It is important to have a minimum data set that actually provides the information needed to make good decisions. When additional data may be needed beyond the minimum data set, there should be specific pre-established criteria and processes to quickly obtain this data without relying on additional testing orders.

In addition, S. 847 requires that each minimum data set include information on the characteristics, toxicological properties, exposure, and use of chemical substances. States recommend that the following changes be made: characteristics changed to physical characteristics; exposure changed to potential exposure; and that information pertaining to environmental hazard be specifically added to this section.

5. Chemical Substances in Priority Class 1.

States support the definitions for Persistent and Bioaccumulative in S. 847. Section 7 (Prioritization, Safety Standard Determination, and Risk Management) amends TSCA § 6 to require the Administrator to assign a chemical substance to priority class 1 if it is determined that the chemical substance is, or is degraded and metabolized into, a PBT with the potential for widespread exposure to humans or other organisms.

In addition to PBTs that meet the above findings, the Administrator should be given the authority to add any other chemical substance that is determined to require immediate risk management to priority class 1. This should not be limited to PBTs.

The term widespread should be replaced by the term significant. Significant exposure may occur even though that exposure may not be widespread.

Additionally, the draft SCA requires the Administrator to determine, based on any more than theoretical concern, that there is uncertainty whether a chemical substance would satisfy the safety standard. The phrase more-than-theoretical is vague and unclear and should be refined or deleted. The States recommend that the language be made clear that the Administrator may ban PBTs and other chemicals in priority class 1 if, after an alternatives assessment, safer alternatives have been identified, regardless of whether measures are proposed to reduce exposure.

6. Safety Standard Determination

Section 7(b) places the burden of proof on the manufacturer and processor of a chemical substance to prove that a chemical substance meets the applicable safety standard. The EPA Administrator then determines whether the chemical substance meets the safety standard, using the best available science, which shall be based on the recommendations of a National Academy of Sciences (NAS) report entitled Science and Decisions. At a minimum, a timeframe should be established for the Administrator to develop guidance on the application of the NAS methodology to the data to be collected by the manufacturers for the purpose of EPA's Safety Standard Determination, and for the manufacturer's requirement to indicate whether a chemical substance meets the safety standard.

The requirements of the Safety Standard proposed for TSCA § 6(b) (1) (C) should be modified to include consideration of the most vulnerable ecosystems in addition to the health of vulnerable human populations.

In addition, Section 7 amends TSCA § 6 to provide a process for determining whether chemicals of concern meet a safety standard and conditions under which chemicals may be exempted from the requirement to meet a safety standard. The public participation

procedures as they relate to safety standard and exemption determinations are not adequate. While the bill authorizes a petition requesting EPA to reconsider a determination that a chemical *continues* to meet the safety standard, it does not provide for state input or public comment on initial safety standard determinations. A determination that a chemical meets the safety standard should be subject to a public notice and comment process. Similarly, while a determination to *renew* an exemption from the safety standard is subject to notice and public comment, initial determinations on such requests are not. Last year's House discussion draft provided for notice and comment on initial exemption requests. We submit that this is the better approach as it provides an opportunity for the broadest exchange of information on these two key determinations, which have public health and environmental impacts.

7. Data Sharing—Confidential Business Information.

Section 14 (Disclosure of Data) amends TSCA § 14 to provide for sharing of confidential information with states, tribes and local governments, upon request, for the purpose of administration or enforcement of a law and in accordance with one or more applicable agreements to ensure that confidentiality is maintained. We suggest two revisions to this section to facilitate a streamlined data sharing process and strengthen the state/federal partnership. First, access to confidential information should not be conditional on its use for administration or enforcement of an existing law. A growing number of states have taken, or are considering, action to regulate various toxic chemicals now in commerce. Unfettered state access to information on chemical substances is important, not only to administer and enforce existing laws, but also to inform state decision-making on the need for further regulation or restrictions on chemical substances.

Second, the reference to applicable agreements in § 14 is not clear. As an alternative, we suggest that state access to confidential information should be provided so long as the state agrees to safeguard the information under procedures that are equivalent to those utilized by EPA. We also suggest that EPA be required to coordinate and consult with the states in establishing a streamlined information sharing process.

8. Green Chemistry, Safer Alternatives and Market Incentives.

The development of safer alternatives to existing hazardous chemicals is an important tool to facilitate a shift away from the use of hazardous chemicals in commerce. S. 847 should encourage manufacturers and processors to evaluate whether functionally equivalent alternatives are available, especially for those chemicals identified in priority class 1, new chemical substances, or existing chemicals substances with new uses. EPA should be given the authority to ban these chemical substances to reduce the level of hazard posed by the chemical substance if a functionally equivalent alternative exists. Currently, the bill only requires a manufacturer or processor to evaluate whether feasible alternative exists if they are applying for an exemption to an EPA imposed prohibition. EPA, the States, formulators and the public should have access to identified safer alternatives to hazardous substances. The states strongly support the creation of market incentives for the development of safer alternatives, such as expedited EPA review of

new chemicals that include a safer alternatives analysis, as provided in § 31, but this is not sufficient to ensure a systematic approach to determine if functionally equivalent, safer chemical substances are available.

S. 847 is silent on criteria for evaluating chemicals and their alternatives. The bill should require that, within a year of enactment, EPA define and establish criteria for safer alternatives through rulemaking. At a minimum, safer alternatives should be identified based on risk assessment throughout the life cycle of a chemical substance. Other criteria that EPA might include are product function or performance, useful life, materials and resource consumption, water conservation, water quality and air emission impacts, transportation-related energy usage, greenhouse gas emissions, waste and end-of-life disposal impacts and public health, environmental and economic impacts. EPA could benefit from the states' experience in these areas and with these types of evaluations, and we have identified this as one of the recommended areas for enhanced state coordination. Public outreach and perhaps labeling explanation also will be needed to help people understand that safer alternatives mean less risk, not no risk.

9. Development of Hot Spot Action Plans.

Section 34 requires EPA to identify localities that are disproportionately exposed to toxic chemicals and mixtures (the Hot Spot list), and after consultation with applicable state and local governments and elected officials, to publish the list. Subsection (f) further requires EPA to develop Hot Spot plans for EPA action to reduce disproportionate exposure in the identified localities.

Addressing exposures using public health as the end rather than media-specific cleanup standards is strongly needed; however, this section does not provide for a state or local government role in developing or implementing such plans, a process for prioritizing the most severely impacted localities, or an identified source of funding to implement action plans. A collaborative relationship between the federal, state, and local governments in this regard, as well as adequate funding, is essential to successful implementation of these important environmental justice provisions. The States recommend that these additions be made to § 34.

10. Coordination between Federal Agencies with Chemical Oversight Responsibilities.

States support formal, ongoing and strong coordination between all federal agencies with responsibility for oversight of chemicals, including FDA, FIFRA, OSHA and CPSC. There also should be strong coordination within agencies, particularly EPA, so that decisions about chemical safety made in the TSCA program are considered in the media programs.

11. Funding for Technical Assistance to Business through State Environmental Agencies.

The bill does not currently provide any state funding to facilitate the use of safer chemicals. Grant funding should be provided for State programs to reduce the use of and

exposure to hazardous chemicals, including technical assistance to businesses seeking information on chemical use and exposure reduction strategies and pollution prevention and green chemistry, including onsite technical assistance to facilitate development of state and local toxic use reduction and pollution prevention plans; state chemicals clearinghouse data and information sharing to facilitate collaboration between state and local jurisdictions on chemicals information and data, product information, and safer alternatives outreach and education; training in chemical use and exposure reduction strategies and programs; reporting of state performance output and outcome measures; state recognition programs for reduction in toxic chemicals or implementation of voluntary programs; and monitoring of chemicals in the environment, animals, and humans to assess persistence and bioaccumulation.

12. Regulation of PCB Waste and Residuals.

TSCA Section 6 should be amended to provide for regulation of the management and disposal of polychlorinated biphenyl (PCB) waste and residuals under the appropriate provisions of RCRA and CERCLA. Currently, the management and disposal of PCB wastes and residuals are subject to overlapping regulation under three separate federal environmental statutes-TSCA, RCRA, and CERCLA. PCBs are identified as a hazardous constituent under RCRA and as a hazardous substance regulated under CERCLA. The existing regulatory authority under RCRA and CERCLA governing the management and disposal of hazardous and toxic wastes and residuals is broader in scope than the authority under TSCA. The coordination of management of PCB wastes and residuals under these overlapping authorities often requires substantial time and effort between the three regulatory programs, resulting in a redundant, cumbersome approval process that impedes the timely and efficient remediation of contaminated properties and management of PCB wastes and residuals.

**Follow-up Questions Resulting from the November 17, 2011,
U. S. Senate Committee on the Environment & Public Works Hearing
on the Safe Chemical Act of 2011**

Questions from Senator Barbara Boxer:

1. *Mr. Sturdevant, can you describe the benefits to states from passage of federal legislation that reforms the Toxic Substances Control Act by creating strong standards to protect public health and the environment from dangerous chemicals?*

Response: The ultimate benefit to states is reduced costs, improved public health and environmental protection. Passage of a TSCA reform bill that includes a preventative approach will put us on the path towards less chemical exposures that will improve public and environmental health, reduce the number of toxic chemical cleanup sites, and provide businesses with more regulatory certainty. Another benefit of TSCA reform is the opportunity to enhance economic competitiveness and innovation for businesses and communities in our states.

The benefits to states from comprehensive TSCA reform include:

- A stronger, more protective federal system.
- Improved public health and environment by preventing harmful chemical exposures.
- Lower costs and risks to states, especially for states that do not have adequate tools or resources to tackle toxic chemical pollution.
- A more predictable regulatory system across all the states; less of a patchwork of regulation.
- Better data and information on chemical toxicity, including improved transparency.
- States/federal partnership to address the most problematic chemicals on the market.
- Economic opportunity for states through expanding markets for safer chemicals and products.
- Sustaining the U.S. chemical industry and growing new jobs in our states.

States action is growing in this area that can help inform a reformed national system. Over the past nine years, there have been at least 81 state chemicals policies in 18 states related to chemicals of concern. Results from the states' experience can provide Congress with "on the ground" experiences and the practical aspects of running chemical management programs.

One aspect of these states' actions is a concern from industry about the patchwork of state regulations. While I agree that a strong federal program is critical, the states will continue to respond to local problems and concerns as needed.

2. *Mr. Sturdevant, can you describe the difficulties that states may encounter by the lack of federal legislation reforming the Toxic Substances Control Act in a way that creates strong standards to protect public health and the environment from dangerous chemicals?*

Response: Without a strong federal system, the states will continue to pursue legislative and administrative action on a state-by-state basis. This will cost states more in the future to implement our own chemical management programs.

Lack of federal action on chemicals of concern will lead to future chemical contamination and cleanup sites. The cost of these sites is expensive and places a burden on taxpayers and businesses.

It is difficult and expensive for states to take action on individual chemicals. Many states don't have the technical expertise or resources to address these challenges through a chemical-by-chemical approach.

Removing toxic chemicals from stormwater pollution, drinking water, and consumer products is expensive and sometimes impossible. Until we make the necessary reforms, our current pollution control practices force us to focus on detection and control, management methods, and treatment once the chemicals are in the environment. Without changes, our current regulatory system cannot prevent the creation of future contamination and cleanup sites, negative impacts on the economic vitality of local communities and expected increased healthcare costs.

Another problem is interstate commerce. States don't have the authority to regulate commerce across our boundaries. Without TSCA reform, it's increasingly difficult for businesses in our states to harmonize with other countries that are reforming their own chemicals management systems. This reduces our competitiveness in the states for chemical producers and formulators that are selling into international markets.

States cannot adequately address the international nature of the global chemicals market. States do not have the authority to restrict the international use of chemicals that may end up in products that are produced in foreign markets, but re-enter through the states. One example is the production of perfluorinated chemicals (PFCs). These chemicals are used in global manufacturing and industrial applications, but are restricted on a voluntary basis in the U.S. Although the U.S. EPA and eight major companies established the 2010/15 PFOA Stewardship Program in 2006, there are no international restrictions that prevent the use of these chemicals that may end up in products that re-enter through the states and into commerce. This is an example where EPA needs to have the tools to address this type of problem in a modernized TSCA. This is necessary to move away from the most problematic chemicals on the market. International harmonization is also necessary to effectively phase out or ban problematic chemicals, which will otherwise end up back in the U.S.

3. *Mr. Sturdevant, you are the Director of the State of Washington's Department of Ecology. Could you please describe the importance of maintaining states' authority to address the threats to public health from dangerous chemicals, and the need to ensure that the federal TSCA reform legislation does not take this authority away from states?*

Response: I support the express preservation of state authority in §18 of the Safe Chemicals Act of 2011 (S. 847) and urge Congress to retain this language. TSCA reform should set the floor, not the ceiling, on protecting public health.

Many federal environmental laws expressly preserve state authority. For example, many states have programs that contain requirements in addition to those specified in the Resource Conservation and Recovery Act (RCRA). Washington State has enacted toxic chemical cleanup legislation that is more restrictive than the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA). States also have state cleanup programs in addition to CERCLA. The Clean Air Act authorizes California to establish more stringent vehicle emission standards, which can then be adopted by other states in lieu of the federal standards.

These are only a few examples where state authority has been maintained without disruption of a federal program. Preservation of state authority is both workable and necessary.

However, if done correctly, a modernized TSCA will establish a strong federal chemical regulatory system that reduces the potential for individual states' action.

Unfortunately, given that we cannot predict the future chemicals market, it is necessary that we expressively preserve the authorities of states to take action. Federal legislation will likely be a product of consensus, which means that it may not entirely fill the needs of states. As outlined in the Safe Chemicals Act of 2011, priority 1 chemicals will be the initial focus, which will likely be a limited number of chemicals to be addressed by U.S. EPA. States may wish to augment this approach based on individual state needs.

It is now 2012, and most agree that TSCA reform is long overdue. For the past several years, as Americans became aware of shortcomings in federal protections, they have demanded change. It has been the states who have provided that change. Given industry's proven ability to block reform, the American people should not be deprived of future protection in their home states.

A reformed TSCA that allows states to bring forward chemicals of concern would provide additional safeguards for federal regulators. One new model is the approach currently authorized in the European Union's REACH regulations. REACH provides for identifying Substances of Very High Concern (SVHCs), meeting the criteria referred to in Article 57 and for establishing the "candidate list" for inclusion into the Authorization List. A key provision of this Article is that these substances are identified on the basis of proposals submitted by Member States or by the European Chemicals Agency (ECHA). Substances included on the candidate list are subject to information and notification requirements and can be prioritized and included in Annex XIV of REACH, which lists the substances subject to authorization.

Reforming TSCA to allow states to bring forward the chemicals of concern in our states should be continued as a principle in TSCA reform. This will create additional accountability of the overall system and provide for an enhanced states/federal partnership on chemicals management.

4. *Mr. Sturdevant, do you believe that the bill establishes the right policy by ensuring that chemical manufacturers and processors have the duty to show that a chemical meets the safety standard?*

What benefits does this policy have for agencies that are charged with protecting public health from dangerous chemicals?

Response: Yes, absolutely, but it all depends on getting the standard right - which is challenging, but can and must be done. Requiring chemical manufacturers and processors to show that a chemical meets the safety standard will improve consumer confidence with the industry's current practices.

The Safe Chemicals Act of 2011 should be amended to include the option of an alternatives assessment in the safety standard determination methodology. This would allow EPA to use the best available science when conducting an assessment of risk.

The benefits to agencies protecting public health include improved data and transparency, and fewer threats to public health.

5. *Mr. Sturdevant, do you believe that it is important for the federal government to help promote innovation in the development of safer alternatives to toxic chemicals through the development of a green chemistry program?*

If so, do you believe that S. 847's provisions on green chemistry can help to promote such innovation?

Response: The goal of green chemistry is to reduce or eliminate the use and/or generation of hazardous substances or processes. Green chemistry and TSCA reform go hand in hand, but they are not the same thing. TSCA reform will drive the demand for safer alternatives, but the science of green chemistry will ultimately provide the solutions and economic prosperity.

The green chemistry provisions in S. 847 recognize the importance of incentives, research, education, and workforce development as the cornerstones for the advancement of green chemistry science. Additional green chemistry education provisions should be added to provide funding to k-12 and higher education academic institutions. This funding will enhance our state and private educational institutions' abilities to attract and teach green chemistry. Providing foundational funding will jumpstart innovation and economic development.

I also recommend adding state "green chemistry research and development" grant programs to foster state, university and industry green chemistry partnership research and education programs. For example, Michigan has established a Green Chemistry Clearinghouse Program that brings together industry, government, and educators to advance the science of green chemistry. There are similar efforts in New England, Minnesota, Oregon and Washington State. Adding state grants for green chemistry economic development and commercialization will spur new business development.

However, given that green chemistry is not going to happen overnight, it is critical that TSCA reform address the demand to identify safer alternatives to existing hazardous chemicals. I believe that S. 847 should require manufacturers and processors to evaluate whether alternatives are available for problematic chemicals, especially those identified in priority class I.

EPA should be given the authority to ban these chemical substances to reduce the level of hazard posed by the chemical substance if a safer and functionally-equivalent alternative exists. Currently, the bill only requires a manufacturer or processor to evaluate whether a feasible alternative exists if they are applying for an exemption to an EPA-imposed prohibition. EPA, the states, formulators and the public should have access to identified safer alternatives to hazardous substances. The states strongly support the creation of market incentives for the development of safer alternatives, such as expedited EPA review of new chemicals that include a safer alternatives analysis, as provided in § 31, but this is not sufficient to ensure a systematic approach to determine if functionally-equivalent, safer chemical substances are available.

S. 847 is silent on criteria for evaluating chemicals and their alternatives. The bill should require that, within a year of enactment, EPA define and establish criteria for safer alternatives through rulemaking. At a minimum, safer alternatives should be identified based on risk assessment throughout the life cycle of a chemical substance. Other criteria that EPA might include are product function or performance, useful life, materials and resource consumption, water conservation, water quality and air emission impacts, transportation-related energy usage, greenhouse gas emissions, waste and end-of-life disposal impacts and public health, and environmental and economic impacts. EPA could benefit from the states' experience in these

areas and with these types of evaluations, and we have identified this as one of the recommended areas for enhanced state coordination. Public education will be needed to help people understand that safer alternatives mean less risk, not zero risk.

Questions from Senator Tom Carper:

1. *What do you believe is the biggest outstanding issue that the environmental and public health communities, the chemical industry, and others engaged in efforts to reform the Toxic Substances Control Act need to come closer together on in order to further strengthen the Safe Chemicals Act and gain even more support for reforming the country's chemical safety laws?*

Response: Addressing the data safety standard is probably the biggest outstanding issue at the moment, but confidential business information, state preemption, and the role of states are critical as well. I recommend that continued dialogue with all the stakeholders is needed to further refine the issues and to identify solutions. I am particularly interested in hearing more specifics from industry representatives on concerns with S.847 and opportunities for improvement.

2. *Over the last several years, Europe, Canada, Australia, Korea, China, and other countries have undertaken reforms of their nations' chemical safety laws. What can we learn from these countries' efforts to improve the safe use of chemicals? How can these lessons inform the work of the Senate Committee on Environment and Public Works in proceeding with the Safe Chemicals Act?*

Response: The most significant concept in the EU REACH Program is the concept of "no data, no market" for chemicals in commerce. This is the underpinning of the regulations that requires industry to provide chemical data information to the government. Another important lesson is the opportunity for global harmonization and sharing of data to improve efficiencies for government and industry. Canada and other jurisdictions have undertaken chemicals prioritization to address chemicals of concern.

I recommend the Committee staff reach out to these jurisdictions in order to inform the TSCA reform process, since chemicals are part of a global market. Efforts to harmonize, share toxicity information, identify and take action on high priority chemicals should be incorporated into TSCA reform.

Another key provision in REACH Article 55 is the goal of authorization to "ensure the good functioning of the internal market, while assuring that the risks from substances of very high concern (SVHS) are properly controlled, and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable."

The use of the "substitution principle" promotes the replacement or reduction of hazardous substances in products and processes by less hazardous or non-hazardous substances, or by achieving an equivalent functionality via technological or organizational measures. The substitution principle should be applied whenever safer alternatives are available at an acceptable socio-economic cost to replace persistent, bioaccumulative and toxic chemicals (PBTs) and other chemicals of concern.

Japan issued updated regulations under its Chemical Substances Control Law (CSCL). Companies manufacturing and importing chemicals in Japan were required to submit notifications on June 30, 2011, for chemicals produced in volumes over one ton (metric ton), as well as for 88 "Priority Assessment Chemicals" (PACs) produced at any volume. PACs are those chemicals deemed to be of particular concern based on a combination of exposure and hazard information.

The Japanese Ministry of Economy, Trade and Industry (METI) will use information from the CSCL notifications to develop an expanded list of PACs. These chemicals will then undergo risk assessments. The prioritization process will ultimately allow METI to request hazard data on chemicals that raise significant concerns. The first list of PACs was published on April 1, 2011, and METI forecasts the addition of approximately 1,000 PACs by March of 2012.

China recently unveiled its 12th Five-Year Plan for Environmental Protection. In the section that addresses chemicals management, the plan sets out to establish two priority chemical lists: one "Phase-out List of Hazardous Substances" under the 12th Five-Year Plan and one "List of Key Hazardous Substances for Priority Environmental Management," under the recently released Measures for the Registration of Dangerous Chemicals for Environmental Management.

Australia's National Industrial Chemicals Notification and Assessment Scheme (NICNAS) and Environment Canada and Health Canada signed an agreement in December 2011 to enhance technical cooperation and share information on existing industrial chemicals. This replaces an earlier agreement between the countries that only covered new chemicals.

Senator Inhofe's Questions:

1. *Mr. Sturdevant, in your testimony, you state that under the current TSCA, the "system is not designed to move us toward safer chemicals" and that states have "to wage long, bitter fights over controlling a specific chemical, but with no effective inducement to them to shift to safer alternatives." One major concern that we have heard about this bill as written would be that it might stifle the ability to bring new chemicals to market. Even many critics of TSCA feel the current new chemicals program has been very successful and protected the public. Wouldn't putting additional barriers to bringing new chemicals to market equate to barriers to bringing less toxic chemicals to market?*

Response: S. 847 includes incentives to bring less toxic chemicals to market under Section 31 of the bill. This section requires EPA to establish a program to create market incentives for the development of safer alternatives, including a provision for expedited reviews and recognition.

One example is EPA's pesticide registration program that places a high priority on registering new pesticides that are safer than pesticides currently on the market, those with public health benefits, and pesticides that are of particular economic importance to producers. This might be a potential model to review, or perhaps there are other good examples in other federal agencies.

Providing the government with necessary data provides a "level playing field" for industry to compete in the growing market for safer chemical alternatives and green chemistry. Providing the right signals and incentives in TSCA reform will spur the development of safer chemicals and create a demand that businesses will jump to fill. Providing for market innovation that allows industry to embrace the principles of green chemistry at the design phase will create a market advantage for those companies seeking new market opportunities and growth. TSCA reform

should provide an opportunity to move from the status quo where existing grandfathered toxic chemicals have a market advantage over new chemicals.

2. *In your testimony, you also mention that Washington was the "first state in the nation to ban all forms of PBDEs." Was this a total ban or does your state recognize exemptions? If there are exemptions, why were they enacted and do you support them? If there are exemptions, and EPA was to ban all forms of PBDEs under S. 847 authorities, what effects would losing those exemptions have on the state of Washington's economy?*

Response: The Washington ban (RCW 70.76)¹ passed in 2007 encompassed most uses of the penta- and octa-BDE mixtures. The legislation also included a ban on the third PBDE mixture, deca-BDE, in mattresses and allowed a further ban in electronics and residential upholstered furniture if a safer alternative could be identified. We supported legislation that essentially banned all three *forms* of the chemical, but allowed for particular *uses*.

A unique aspect of this legislation involved the creation of a fire safety committee to review the alternatives. In November 2008, the agencies presented our recommendations to the Fire Safety Committee, made up of five fire safety experts, and they unanimously approved the alternatives presented. The State Fire Marshal determined that the alternative met applicable fire safety standards as required by the law.

On January 20, 2009, Ecology submitted a report to the Legislature describing how Ecology and Health evaluated alternatives for technical feasibility, toxicity and fire safety. It also explains how the agencies were able to identify safer alternatives. The report triggered the state ban on the manufacturing, sale and distribution of televisions, computers and residential upholstered furniture containing Deca-BDE by January 2011.

The banning of deca-BDE in electronics and residential upholstered furniture covered more than 80% of the traditional deca-BDE use prior to the ban and has substantially restricted the use of this toxic flame retardant. Other uses of deca-BDE are not currently banned within Washington State.

Specific exemptions were included by the Legislature in the original PBDE legislation. RCW 70.76.020 identifies a list of specific exemptions including military and space applications, FAA fire worthiness requirements and recommendations, transportation applications, sales by non-profit organizations, etc. It is my understanding that these exemptions were included because specific industries were able to make a case to the Legislature that alternatives do not currently exist or that a ban was unreasonable in certain cases. The result is a ban on the most wide-spread uses, significantly reducing the risk of exposure, while exempting lower volume uses for which alternatives were not available, or where a ban was not feasible. I support this policy as a good, common sense solution.

3. *You mention multiple forms of flame retardants in your testimony as examples of chemicals that are being regulated at a state level and in some instances pose "unacceptable" risks. If this legislation is enacted and EPA is unable to find a suitable alternative which meets a "reasonable certainty of no harm" finding, is there any "unacceptable" risk from products not protected from flammability?*

¹ Chapter 70.76 RCW Polybrominated diphenyl ethers—flame retardants, available at: <http://apps.leg.wa.gov/RCW/default.aspx?cite=70.76&full=true#70.76.020>, accessed 12/30/2011.

Response: I support regulations that create an evaluation and approval process for continued use of a toxic chemical in certain situations. This would include a peer-reviewed scientific evaluation to determine, after a rigorous review and approval process, that no viable alternative exists or is likely to exist. The evaluation should also address if the risk posed from continued use of the toxic chemical is greater than the risk posed by its discontinued use. In some cases (perhaps many) it may make sense to continue such a chemical's use.

I recommend that this process include a full life cycle assessment of the impacts upon human health and the environment and not just the impact from the use of a specific product. Our current risk management paradigm does not generally take into consideration the impacts from manufacture, transport, use, removal, disposal, etc. of a chemical throughout the entire value chain. The process should also recognize that non-chemical, product redesign and pollution prevention methods may be preferred to continued uses. For example, my staff and our partners at the Washington State Department of Health determined that, for residential upholstered furniture, the preferred alternative was to redesign the furniture using barriers that maintained fire safety. In this example, fire safety could be maintained through product redesign and toxic flame retardants such as deca-BDE were not needed.

4. *When you mentioned the PBDEs posed an "unacceptable" risk, how did you come to that calculation? Should federal chemical management recognize an acceptable level of risk? Is there a way to calculate "unacceptable" risk as you have categorized it without some sort of cost-benefit analysis?*

Response: The process Ecology used to determine risk is well documented in our report to the Washington Legislature: *"Alternatives to Deca-BDE in Televisions and Computers and Residential Upholstered Furniture."*² Our approach can be summarized as an optimized risk reduction methodology.

This approach allows us to identify a universe of chemicals that are potential replacements for a toxic chemical. As risk is a function of hazard and exposure, these alternatives are reviewed for the hazard they pose to human health and the environment using principles established by the Environmental Protection Agency's Design for the Environment Program. Those chemicals that are identified as posing less of a hazard are subjected to additional filters including exposure, economic feasibility (including cost benefit review), functional feasibility, etc. At the end of this process, an alternative is identified that has both the lowest possible risk, as identified by optimizing hazard reduction and exposure concerns, while maintaining economic viability.

Our approach includes chemical elimination and product redesign options. If no chemical avoidance and product redesign options are available, chemicals with significantly reduced hazard are identified for further evaluation. After evaluating exposure scenarios, chemicals that are optimized for risk reduction inherently include the lowest possible acceptable risk. Further evaluations and determinations may be necessary if no suitable alternatives can be met.

Determining "acceptable" and "unacceptable" risk is ultimately a judgment call based on a careful weighing of costs and benefits. In the case of PBDE's, the science showed significant cause for concern, particularly to young children. On the other hand, no one wants inadequate protection from fires. In the end, it was the fact that fire safety could be maintained without deca-BDE that led to our conclusion that the risk was unacceptable.

² Ecology publication Number 09-07-041, Published January 2009, available at: <http://www.ecy.wa.gov/biblio/0907041.html>, accessed 12/30/2011.

Senator LAUTENBERG. Ms. Brody, welcome.

STATEMENT OF CHARLOTTE BRODY, DIRECTOR OF CHEMICALS, PUBLIC HEALTH AND GREEN CHEMISTRY, BLUEGREEN ALLIANCE

Ms. BRODY. Chairman Lautenberg, Ranking Member Inhofe and Members of the Committee, thank you for the opportunity to appear before you. I am Charlotte Brody, a registered nurse, a mother, and the Director Chemicals, Public Health and Green Chemistry for the BlueGreen Alliance, a unique partnership of 11 labor unions and four environmental organizations.

We bring together 15 million Americans in pursuit of good jobs, a clean environment, and a green economy. We support the passage of the Safe Chemicals Act because it can create some of the middle-class manufacturing jobs that our Country so desperately needs. Between 1992 and 2010, more than 300,000 chemical manufacturing jobs disappeared in the United States. Employment fell 38 percent in the chemical industry at a time when all manufacturing declined by 24 percent.

Among the union partners of the BlueGreen Alliance, the steelworkers represent the majority of organized workers in the chemical industry. Two other BlueGreen Alliance union partners also include some chemicals workers in their ranks. These unions and their members depend upon the existence of an American chemical industry. We need more Americans making chemicals and more people using chemicals made in America.

We support the Safe Chemicals Act because we believe it will spur innovation and the invention of a new generation of safer chemicals that can be produced in the United States.

I started practicing as a registered nurse around the time that TSCA became law. If I had practiced nursing the way I did then, I would be in prison for gross negligence and malpractice. That is how much we have learned about disease and treatment since then.

What have we learned about human disease and chemicals? Let me just use the example of Agent Orange. Decades ago, I worked with young soldiers coming back from Vietnam. Those who had been exposed to Agent Orange were informed that their skin rash, core acne, was the only problem they would have from their exposure. That is what the science told us then. But over the last 40 years, new knowledge keeps showing us how wrong we were.

Now, Vietnam veterans who were exposed to Agent Orange, even those who didn't have the skin rash, can be compensated for one kind of leukemia, two kinds of lymphoma, four other kinds of cancer, as well as diabetes, a type of heart disease and Parkinson's disease. The V.A. also recognizes as compensable spina bifida, a defect of the developing fetus that results in incomplete closure of the spine in the children of Vietnam veterans born decades later. One chemical; so many diseases, including in children born decades later.

Forty years ago, we simply didn't understand that chemicals could do that. Allowing our Nation's chemical management system to remain lost in the 1970's is its own form of negligence. The punishment for this negligence is cancer, birth defects, infertility, asthma, and nervous system disorders. But the sentence is being doled

our indiscriminately to workers, babies in utero, the people who live at the fence-line of chemical plants, and millions of other chronically ill Americans, including people each of you were sent here to represent.

The Safe Chemicals Act would modernize TSCA to reflect what we have learned about chemicals and human health since the 1970's. The bill's safety standard of reasonable certainty of no harm from aggregate exposure captures the way good science works and underscores the legislation's intent to make chemicals safe.

Especially important for the members of the BlueGreen Alliance is that workers are identified as part of the vulnerable populations protected under that standard. The prioritization system and tiered use of data do a good job of tackling the huge problems created by decades of unregulated chemicals and starting to solve that problem with a worst-first approach.

I represented the BlueGreen Alliance in the stakeholder process that Senators Inhofe and Lautenberg co-hosted this year and I comment both of you and your staffs for creating a careful, reasoned and reasonable dialog.

I was trained as an OB/GYN nurse and I still think like a nurse. I know that the Senate has become a deeply partisan place and the proposal that would give the EPA more power to protect are not popular in every office. But the Safe Chemicals Act is fundamentally not about politics. It is about mercury in breast milk. It is about phthalates in newborn babies cord blood. And it is about the creation of new set of American manufacturing jobs making chemicals that are 21st century safe. Doing nothing is a negligent act.

Thank you.

[The prepared statement of Ms. Brody follows:]

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Testimony of Charlotte Brody BlueGreen Alliance before the

**U.S. Senate Committee on Environment and Public Works and
Subcommittee on Superfund, Toxics and Environmental Health
Joint Legislative Hearing on the Safe Chemicals Act
November 17, 2011
Washington, DC**

Chairman Boxer, Chairman Lautenberg, Ranking Members Inhofe and Crapo and members of the committee, thank you for the opportunity to appear before you this morning. I am Charlotte Brody, a registered nurse and the Director of Chemicals, Public Health and Green Chemistry for the BlueGreen Alliance.

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I know I look more like the old nurse that I am than the typical image of a Steelworker. But I am a proud-dues paying member of Local 2002-22 of the Steelworkers and a Safety and Health Advisor to the Steelworkers' Health, Safety and Environment Department. Among the union partners of the BlueGreen Alliance, the Steelworkers represent the majority of organized workers in the chemical industry, as well as hundreds of thousands of workers who use chemicals on the job. Two of the BlueGreen Alliance's other union partners, the United Food and Commercial Workers and the IUE-CWA also include some chemical workers in their ranks. These unions and their members depend upon the existence of an American chemical industry. We need more Americans making chemicals and more Americans using chemicals made in America. But we won't be able to achieve that vision if we're just producing and using the same chemicals that were in production 40 years ago. We support the Safe Chemicals Act because we believe it will spur innovation and the invention of a new generation of safer chemicals that can be produced in the United States.

I started practicing as a registered nurse around the time that TSCA became law. If I practiced nursing the same way I did then, I would be in prison for gross negligence and malpractice. The science about disease and treatment has changed so much since then.

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What have we learned about human disease and chemicals? It's hard to cram 40 years of science into 5 minutes of testimony. So let me just use the example of Agent Orange. Decades ago I worked with young soldiers just back from Viet Nam. Those who had been exposed to Agent Orange were informed that the skin rash, chloracne, was the only problem they would have from their exposure.

That's what the science told us then. But over the last 40 years new knowledge keeps showing us how wrong we were. Every few years the Institute of Medicine looks at the new science and learns more about how this one chemical can cause multiple kinds of harm, even to people who had no acute effects. Now Vietnam veterans who were exposed to Agent Orange can be compensated one kind of leukemia, two kinds of lymphoma (Hodgkin's Disease, non-Hodgkin's lymphoma) and four other kinds of cancer as well as diabetes, a type of heart disease and Parkinson's Disease. The VA also recognizes as compensable spina bifida, a defect in the developing fetus that results in incomplete closing of the spine in the children of Vietnam veterans. One chemical. So many diseases, including in children born decades later. So many years after exposure. Four decades ago we simply didn't understand that chemicals could do that.

Allowing our nation's chemicals management system to remain lost in the 1970s is its own form of negligence, especially when we have the opportunity to modernize the law. The punishment for this negligence is cancer, birth defects, infertility, asthma and nervous system disorders. But the sentence is being doled out indiscriminately to workers, babies *in utero*, the people who live at the fence line of chemical plants and millions of other chronically ill Americans, including people each of you were sent here to represent.

The Safe Chemicals Act would modernize TSCA to reflect what we've learned about chemicals and human health since the 1970s. The bill's safety standard of reasonable certainty of no harm from aggregate exposure captures the way good science works and underscores the legislation's intent -- to make chemicals safe. Especially important for the members of the BlueGreen Alliance is that workers are identified as part of the vulnerable populations protected under that standard. The prioritization system and tiered use of data do a good job of tackling the huge problem created by decades of unregulated chemicals and starting to solve that problem with a worst first approach. I represented the BlueGreen Alliance in the stakeholder process that Senators Inhofe and Lautenberg co-hosted this year and I commend both of you and your staffs for creating a careful, reasoned and reasonable dialogue.

I was trained as an OB-GYN nurse -- a baby nurse -- and while I've had lots of different jobs with different responsibilities over the years, I still think like a nurse. I know the Senate has become a deeply partisan place and that proposals that would give the EPA more power to protect are not popular in every office. But the Safe Chemicals Act is fundamentally not about politics. It's about mercury in breast milk. It's about phthalates in newborn babies' cord blood. And it's about the creation of a new set of American manufacturing jobs making chemicals that are 21st century safe. Doing nothing is a negligent act. Thank you.



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January 3, 2012

Jonathan Aronchick
Senate Committee on Environment and Public Works
410 Dirksen Senate Office Building
Washington DC 20510

Dear Mr. Aronchick:

Thank you for the opportunity to answer these questions from Chairman Boxer, Ranking Member Inhofe and Senator Carper. Here are my answers:

Answers to Questions from Chairman Boxer

1. *Can you describe the benefits to workers from passage of deferral legislation that reforms the Toxic Substances Control Act by creating strong standards to protect public health and the environment from dangerous chemicals?*

The passage of federal legislation to reform TSCA would benefit workers in two critically important ways:

First, TSCA reform can reduce the rates of cancer and other diseases that come from occupational exposures to toxic chemicals. Last April, in a speech commemorating the 40th anniversary of the Occupational Safety and Health Administration (OSHA), Assistant Secretary of Labor for OSHA David Michael estimated that "every year more than four million workers are seriously injured or are sickened by exposure to toxic agents." This is a conservative but sizable estimate of harm, at 800 times the well-documented annual workplace fatality rate. Meaningful TSCA reform will result in better identification of the exposures that are contributing to occupational disease and to the creation of exposure limits and safer alternatives that will protect workers' lives and health.

Second, as we showed in *The Economic Benefits of a Green Chemical Industry in the United States* (done by the University of Massachusetts, Amherst's

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Political Economy Research Institute for the BlueGreen Alliance), TSCA reform can create jobs in the U.S. chemical industry and staunch the dramatic job loss that has already taken place. More than 300,000 American jobs have been eliminated in the U.S. chemical industry since 1992.

2. *Can you describe the difficulties that workers may encounter by the lack of federal legislation reforming the Toxic Substances Control Act in a way that creates strong standards to protect public health and the environment from dangerous chemicals?*

The lack of TSCA reform means we don't know what we need to know about the hazards of chemicals. An absence of information is not the same as the absence of harm. But when workers try to obtain all the information they need to protect their health, the absence of information means that there are no warnings on the Material Safety Data Sheets that are supposed to give workers the information they need to determine the appropriate safety measures.

When adequate information about a chemical's hazards, does exist, that information too often results from a tragedy in which many workers lives were lost. As the Steelworkers Union (USW), the labor organization representing the largest number of chemical workers in the United States, explained in their letter to the EPW committee, chemical workers are the first to be exposed when a chemical goes into production. And both chemical workers and other workers who use chemicals on the job are most likely to suffer the highest exposures. So much of what we now know about chemicals is the result of testing these chemicals in the bodies of workers and their families for decades and waiting for the epidemiological studies -- for the body count -- to determine their danger. Meaningful TSCA reform will move the testing of chemicals to laboratories and away from worker and their families.

The Economic Benefits of a Green Chemical Industry in the United States describes how the lack of TSCA reform has discouraged innovation and promoted the chemical industry pattern of staying profitable by cutting research and development costs and workers' jobs. Done right, TSCA reform can promote innovation, ensure access to global markets, help meet the growing consumer demand for safer products, protect shareholder value by reducing the risk of environmental disasters, and -- most important for workers -- create tens of thousands of new jobs in the chemical industry and the industries which use its products.

Answers to Questions from Senator Carper

1. *What do you believe is the biggest outstanding issue that the environmental and public health communities, the chemical industry and others engaged in efforts to reform the Toxics Substances Control Act need to come closer together on in order to further strengthen the Safe Chemicals Act and gain even more support for reforming our country's chemical safety laws?*

I believe the biggest outstanding issue is the proper role of government and regulation. The TSCA reform negotiations table is being severely tilted by a political climate in which all existing public protections on our air, food and water and products are under attack. That tilt makes it difficult to come together on answers to complicated questions like the proper language for the Safe Chemicals Act safety standard or how to write legislation that will provide some certainty for businesses but allow adaptation for the surprises that new science sometimes creates.

2. *What can we learn from Europe, Canada, Australia, Korea, China and other countries efforts to improve the safe use of chemicals? How can these lessons inform the work of the Senate Committee on Environment and Public Works in proceeding with the Safe Chemicals Act?*

In each of these countries and in the 18 states that have passed 80 chemical safety laws in the last 9 years, the American Chemistry Council did what they could to oppose and weaken reform. This experience suggests that the Senate Committee on Environment and Public Works should not wait for the support of all chemical manufacturers in the United States before proceeding with its deliberations on the Safe Chemicals Act.

The United States can also turn the embarrassment of being a laggard in chemical policy reform to good use by crafting a law that harmonizes and builds upon earlier national reform efforts, creating efficiencies and cost-savings for what is a global industry. There are lessons to be learned from the implementation of the European Union's REACH and other efforts that can now be used to strengthen the regulatory methodology of the Safe Chemicals Act.

Answers to Questions from Senator Inhofe

1. *Are you suggesting that EPA currently is not regulating chemicals?*

I am suggesting that the EPA is not adequately regulating chemicals and that TSCA does not give them the authority to do so. EPA Administrator Lisa Jackson said as much in her 2009 testimony before the committee in which she described her ambitious plan to utilize the EPA's full existing authority under TSCA but stated, "this is no substitute for meaningful reform of the underlying law." In her testimony, Administrator Jackson described one of the fundamental reasons for TSCA's inability to properly regulate chemicals:

However, when TSCA was enacted, it authorized manufacture and use, without any evaluation, of all chemicals that were produced for commercial purposes in 1976 or earlier years. Thus, manufacturers of these "grandfathered" chemicals weren't required to develop and produce the data on toxicity and exposure that are needed to properly and fully assess potential risks. Further compounding this problem, the statute never provided adequate authority for EPA to reevaluate existing chemicals as new concerns arose or as new scientific information became available.

2. *Are you aware that according to the EPA, the number of PMNs that have been submitted to the New Chemicals Program since 1979 – some 30 years ago – is approximately 50,000? How would you reconcile those numbers with your testimony?*

Approximately 22,000 new chemicals have been added to the TSCA inventory that began with the 62,000 chemicals that were grandfathered in when TSCA was enacted. The 50,000 figure in this question represents applications rather than approved chemicals. We can compare both numbers to the quantity of patent applications and approved patents. In 2010, according to the US Patent and Trademark Office, there were 520,277 patent applications and 244,341 patents granted ---more than 10 times both the application and granted patents in a single year that the chemical industry has had in total over 31 years.

3. You mentioned a few times the idea that "doing nothing is a negligent act." Has anyone been advocating for "doing nothing" with regards to TSCA? With EPA's recent efforts to expand information gathering and other actions under current TSCA authority, so you think they are "doing nothing?"

There is a large gap between taking a position that reform is needed and putting that reform into place. My testimony suggested that we needed to move beyond advocacy into action. My comments were focused on Congress needing to "do something" rather than the US EPA. I applaud the recent efforts of the EPA to do what they can under their current authority but as Administrator Jackson has said and as I quote above, "this is no substitute for meaningful reform of the underlying law."

Please let me know if you have any further questions or if I can help in any other way.

Sincerely,

A handwritten signature in cursive script, appearing to read "Charlotte Brody".

Charlotte Brody, RN
Director of Chemicals, Public Health and Green Chemistry
BlueGreen Alliance

Senator LAUTENBERG. Thanks very much.
Mr. Dooley, we look forward to hearing your testimony.

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

Mr. DOOLEY. Thank you for the opportunity to testify on behalf of the American Chemistry Council, our member companies and their nearly 800,000 employees about the need to modernize the Federal system that regulates chemicals. We appreciate the efforts of Senators Lautenberg, Inhofe and other Members of this Committee, and we appreciate the chance to discuss our views about the Safe Chemicals Act.

As I told this Committee in February, ACC strongly supports efforts to reform the 35 year old Toxic Substance Control Act. Over the years, public confidence in TSCA has diminished, contributing to misperceptions about the safety of chemicals, ill-conceived State laws, unnecessary product de-selections, and baseless litigation. Safety is a top priority of our Member companies. We need an effective and reliable chemical regulatory system that will instill in policymakers, our business partners, and the public the same level of confidence in the products that we have.

Over 2 years ago, ACC released 10 principles for modernizing TSCA. These principles created a road map to a modern chemical regulatory system that will protect public health and the environment, while preserving the ability of American chemicals companies to drive innovation, grow jobs, and compete in the global marketplace.

In recent months, ACC and other stakeholders have engaged with bipartisan Committee staff to discuss our respective positions about legislation to update TSCA. We appreciate and would like to commend Ben Dunham from Senator Lautenberg's staff, and Dimitri Karakitsos from Senator Inhofe's staff for their professional management of these discussions.

Unfortunately, though, today we are discussing a bill that remains very similar to the bill that was introduced in 2010, which we consider unworkable. As we discussed during that process, there are several fundamental flaws in the legislation.

No. 1, the safety standard. The bill's standard for reasonable certainty of no harm from aggregate exposure for all chemicals would be virtually impossible to meet. If EPA were required by TSCA to consider the aggregate exposure to substances from every industrial, commercial and consumer product use of a chemical substance, regulatory paralysis would ensue.

No. 2, new chemicals. There is a broad consensus even among TSCA critics that the program to evaluate new chemicals is working. In spite of this, the legislation would prescribe significant new data requirements for all new chemicals before they could come to market. It would also extend EPA's time to evaluate this data, keeping these chemistries in a State of limbo.

If EPA is unable to complete its work in a timely manner, and this is an agency that is known to struggle with deadlines, the chemical would effectively be barred from entering the market. Manufacturers are certain to seek more manageable regulatory environments and produce new chemicals, including green chemistry

developments and other potentially revolutionary new products, in other countries to avoid prohibitive costs and uncertainty.

No. 3, minimum data-sets. The bill would create an enormous burden on EPA and on the manufacturers, with little benefit, by requiring a minimum data-set for all chemicals. Instead, EPA should collect data that is needed on specific types and classes of chemicals, as well as to take advantage of the massive amount of data that the agency already has access to.

No. 4, prioritization. The bill's prioritization proposal lacks rigorous criteria and makes no mention of integrating current knowledge about hazards, risk and exposure, three factors that are critical to informed regulatory decisions. ACC recently proposed a transparent and scientifically sound prioritization process to determine which chemicals should receive full safety assessments, so EPA can focus its resources where they are most needed. We believe our prioritization proposal would be more effective than what has been proposed in S. 847 and have the details in our written statement.

Reform of TSCA is an important priority, but one that must be done right. Chemistry will be the source of clean energy, improved infrastructure, efficient transportation, medical advancement, and a strong defense, among a lot of other applications. An ill-conceived regulatory system such as that which would be created by S. 847 would undermine America's ability to develop and produce these transformational technologies and would put the jobs of today and tomorrow at risk.

Even though S. 847 is not the answer, ACC and the industry remain fully committed to TSCA reform. We believe we can develop legislation that will give consumers confidence, that learns from the success and mis-steps of reforms undertaken by other countries, and that fosters innovation and job creation.

Thank you for the chance to express our views on this critical subject and we look forward to continued collaboration on this issue.

[The prepared statement of Mr. Dooley follows:]



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

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

"Legislative Hearing on the Safe Chemicals Act"

November 17, 2011





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Thank you for the opportunity to testify on behalf of the American Chemistry Council, our member companies and their nearly 800,000 employees. We appreciate the efforts of Senators Lautenberg, Inhofe and other Members of this committee, and we appreciate the chance to discuss our views about S. 847, the “*Safe Chemicals Act of 2011*.”

ACC strongly supports efforts to reform the 35-year old Toxic Substances Control Act (TSCA). Over the years, public confidence in TSCA has diminished, contributing to misperceptions about the safety of chemicals, ill-conceived state laws, unnecessary product de-selection, and baseless litigation.

Safety is the top priority of our member companies. We need an effective and reliable chemical regulatory system that will instill in policymakers, our business partners and the public the same level of confidence in our products that we have.

Over two years ago, ACC released *10 Principles for Modernizing TSCA*. These principles create a roadmap to a modern chemical regulatory system that will protect public health and the environment, while preserving the ability of American chemical companies to drive innovation, grow jobs, and compete in the global marketplace.

In recent months, ACC and other stakeholders have engaged with bipartisan committee staff to discuss our respective positions about legislation to update TSCA. We have appreciated the opportunity for our views to be heard and would like to commend Ben Dunham from Senator Lautenberg’s staff and Dimitri Karakitsos from Senator Inhofe’s staff for their professional management of the discussions. Unfortunately, though, today we are discussing a bill that remains very similar to the bill introduced in 2010, which we consider unworkable.

There are fundamental flaws in the legislation, including:

Safety Standard: The bill’s standard of “reasonable certainty of no harm... from aggregate exposure” for all chemicals would be virtually impossible to meet. If the U.S. Environmental Protection Agency (EPA) were required by TSCA to consider the aggregate exposures to a substance from every industrial, commercial, and consumer product use of a chemical substance, regulatory paralysis would ensue.



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New Chemicals: There is broad consensus, even among TSCA critics, that the current program to evaluate new chemicals is working. In spite of this, the legislation would prescribe significant new data requirements before new chemicals could come to market, as well as extend EPA's time to evaluate this data, potentially keeping these chemistries in a state of limbo. Manufacturers are certain to seek more manageable regulatory environments and produce new chemicals, including "green" chemistry developments and potentially revolutionary new products, in other countries to avoid prohibitive costs and uncertainty.

Minimum Data Set: The bill would create an enormous burden on EPA and on manufacturers with little benefit by requiring a minimum data set for all chemicals. Instead, EPA should take advantage of the massive amounts of data and information that the Agency already has access to.

Prioritization: The bill's prioritization proposal lacks rigorous criteria and makes no mention of integrating current knowledge about hazard, use, and exposure – three factors that are critical to an informed regulatory decision. ACC recently proposed a transparent and scientifically-sound prioritization process to determine which chemicals should receive full safety assessments so EPA can focus its resources where they are most needed. We believe our prioritization proposal would be more effective than what has been proposed in S. 847, and have attached the details for your review.

We also believe that S. 847 would compromise the protection of confidential business information, inappropriately expand EPA's authority into the jurisdiction of other federal agencies such as the U.S. Food and Drug Administration (FDA), further complicate issues surrounding national uniformity of standards, and fail to adequately consider animal welfare.

Reform of TSCA is an important priority, but one that must be done right. Chemistry will be the source of clean energy, improved infrastructure, efficient transportation, medical advancements, and of a strong national defense. An ill-conceived regulatory system, like that which would be created by S. 847, would undermine America's ability to develop and produce these transformational technologies and would put jobs of today and of tomorrow at risk.

Even though S. 847 is not the answer, we remain fully committed to TSCA reform. We believe we can develop legislation that will give consumers confidence, learns from the success and missteps of reforms undertaken by other countries, and fosters innovation and job creation.

Thank you for the chance to express our views on this critical subject, and I look forward to answering your questions.





10 Principles for Modernizing TSCA

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

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

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

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



- The priorities should reflect considerations such as the volume of a chemical in commerce; its uses, including whether it is formulated in products for children; its detection in biomonitoring programs; its persistent or bioaccumulative properties; and the adequacy of available information.
3. EPA should act expeditiously and efficiently in making safe use determinations.
 - Since a chemical may have a variety of uses, resulting in different exposure potentials, EPA should consider the various uses and focus on those resulting in the most significant exposures.
 4. EPA should complete safe use determinations within set timeframes. 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.

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- 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.



ACC Prioritization Screening Approach

I. Introduction

This document provides background on ACC's approach to chemical prioritization screening. The approach is based on the following general principles:

- The purpose of this approach is to identify substances as priority to receive more detailed evaluation and assessment which, when conducted, could possibly lead to risk management measures.
- Apply a science- and risk-based approach, considering both the degree of hazard and extent of exposure potential in setting priorities.
- Include criteria applicable to the range of chemicals being screened. Apply this principle through a two-step process rather than just those information elements available only for subsets of chemicals.
- Leverage available data and existing hazard classification frameworks already in use across industry and agreed by regulators.
- Incorporate relevant science advances where there is broad acceptance in the scientific community, e.g. improvements in how persistence and bioaccumulation considerations are addressed.
- Allow for the incorporation of significant new information to ensure prioritization decisions remain current.
- Adopt a simple, transparent screening method.
- Include opportunity for public review and comment to ensure the best available data and information is used in prioritization decisions.
- Allow professional judgment to be applied where appropriate, e.g. in hazard classification and second-tier ranking.

II. Applying Initial Screening Step in ACC's Prioritization Approach

The first step in applying ACC's prioritization approach is to apply criteria on human health and environmental toxicity potential to chemical substances.

A. Hazard Potential

The U.N. Globally Harmonized System of Classification and Labeling (GHS) was developed and internationally agreed to by many governments to provide criteria and a consistent approach for hazard classification of chemicals. It can also provide a recognized and generally accepted method for sorting chemicals in a prioritization process. The GHS framework has been used by international bodies, such as the OECD and WHO, and was endorsed by EPA's National Pollution Prevention and Toxics Advisory Committee (NPPTAC) to support prioritization.

The GHS system applies to both human health and ecological endpoints. It includes criteria for both human and ecological health. For human health, criteria are available for both acute and chronic classifications, as well as CMR categorization. For ecological

endpoints, criteria are similarly available for both acute and chronic classification. The use of one common system allows for appropriate assessment of all substances. GHS classification information is readily available for all substances, as U.S. manufacturers have developed GHS classifications for their products to meet international requirements.

ACC's support of the GHS criteria for purposes of this prioritization tool is not a categorical endorsement of the GHS criteria for any other purpose. ACC has been an active participant in the development of GHS and supports the system in principle. The GHS has not been broadly implemented to date in the U.S., although the Occupational Safety and Health Administration (OSHA) has indicated an intent to publish a regulation applying GHS in the workplace. ACC's December 29, 2009, comments on OSHA's proposed rule to modify the existing Hazard Communication Standard (HCS) to reflect the GHS urged that implementation of the GHS adhere to certain principles (e.g., continued application of the "Building Block Approach" of the Purple Book). ACC made specific recommendations concerning details of the Hazard Classification definitions, cut-off values, among others. ACC stands behind those comments. In ACC's view, the use of GHS criteria in a screening-level prioritization of chemicals can materially assist in determining which chemicals receive additional evaluation by the Environmental Protection Agency, but does not necessarily preclude the use of other appropriate, applicable criteria developed under other systems.

To classify a chemical in a hazard based priority ranking where there is not direct data on the chemical, EPA can employ the full range of approaches, such as QSAR, SAR, read-across and other modeling tools in which EPA has confidence based on molecular structure. In those situations where there still remains insufficient information on either environmental or human health hazards, the chemical would be classified as "high" for its environmental or health ranking.

1. Environmental Ranking

Table 1 provides a summary of how GHS criteria could be logically used for chemical management prioritization.

Table 1. Environmental Safety - Hazard Ranking

GHS Classification - Environmental	Ranking	Environmental Rank Score
Acute I or Chronic I or Insufficient Information to Classify	High	4
Acute II or Chronic II	Medium High	3
Acute III or Chronic III/IV or none	Medium	2
Not classified	Low	1

2. Human Health Ranking

Table 2. Human Health - Hazard Ranking

GHS Classification - Human Health	Ranking	Health Rank Score
GHS CMR Cat 1a, 1b; OR Repeat Dose ≤ 10 mg/kg/day (oral); ≤ 20 mg/kg/day (dermal); ≤ 50 ppm/6hr/day (gas inhalation); ≤ 0.2 mg/l/6h/day (vapour inhalation); ≤ 0.02 mg/l/6h/day (dust mist fume inhal). OR insufficient information to classify	High	4
GHS CMR Cat 2; OR Repeat Dose 10 - 100 mg/kg/day (oral); 20 - 200 mg/kg/day (dermal); 50 - 250 ppm/6hr/day (gas inhalation); 0.2 - 1.0 mg/l/6h/day (vapour inhalation); 0.02 - 0.2 mg/l/6h/day (dust mist fume inhal).	Medium High	3
Not carcinogen/mutagen/repro/develop; OR Repeat Dose 100 - 1000 mg/kg/day (oral); 200 - 2000 mg/kg/day (dermal); 250 - 1000 ppm/6hr/day (gas inhalation); 1.0 - 5.0 mg/l/6h/day (vapour inhalation); 0.2 - 1.0 mg/l/6h/day (dust mist fume inhal).	Medium	2
Not carcinogen/mutagen/repro/develop; OR Repeat Dose >1000 mg/kg/day (oral); > 2000 mg/kg/day (dermal); > 1000 ppm/6hr/day (gas inhalation); >5.0 mg/l/6h/day (vapour inhalation); > 1.0 mg/l/6h/day (dust mist fume inhal).	Low	1

It is important to note that specific concerns about children's health (specifically potential hazards and adverse effects on the nervous system) and those caused by endocrine disruption mechanisms are addressed in this prioritization process:

- The GHS CMR "R" classification includes specific evaluation of effects on development in utero and upon growth, maturation and reproduction. ("R" stands for reproductive toxicity and includes adverse effects on sexual function and fertility, as well as developmental toxicity in offspring).
- Endocrine activity is not a distinct toxicological hazard per se, but rather a measure of a compound's ability to interact with components of the endocrine system. The prioritization process evaluates data and information on relevant apical tests, including tests for reproduction and developmental toxicity (potential

effects, which can be mediated by endocrine pathways). Thus, even if specific screening for potential endocrine activity has not yet been conducted on certain compounds, hazard identification based on observable outcomes from apical toxicity tests (e.g., outcomes such as pathologic states indicative of disease conditions) covers all modes of action, including endocrine pathways.

- The toxicity information evaluated (CMR and repeat dose toxicity) is directly relevant to evaluating potential hazards to all individuals, including children. Such data typically includes: 1) identification and definition of possible hazards upon all major organ systems from both acute and repeated exposures, including the nervous system; 2) detection of potential hazards arising from in utero exposures, including possible effects on the nervous system; 3) evaluation of potential of a substance to affect reproduction; and 4) evaluation of the potential of a substance to damage DNA.

Integration of Hazard Elements:

Each of the environmental and human health classifications is assigned a numeric value based upon its ranking, with 1 being the lowest value and 4 the highest. The greatest ranking (highest hazard potential score) of either Environmental or Human Health is used in a substance-specific priority ranking. The numeric value does not imply relative weighting, but rather a numerical order of priority.

B. Exposure Potential Ranking

The screening method allows for an initial indication of the extent of exposure potential by considering:

1. The chemical's uses and use pattern(s).
2. Production volume as a first pass indicator of relative emission/release potential since magnitude and route (i.e. air, water, soil) of emissions is not available for all substances.
3. Persistence and bioaccumulation characteristics of the substance.

Together the 3 elements are used to rank exposure potential.

1. Use Patterns

The proposed approach applies the most current 2006 TSCA Inventory Update Reporting rule (IUR, now called the Chemical Data Reporting rule (CDR) data. To keep the initial prioritization simple and transparent, the approach "bins" different use patterns to align with general exposure potential – intermediates, industrial use, commercial use and consumer use. These patterns are the same as those reported in the IUR and are consistent with REACH exposure categories (intermediates, worker, professional, consumer). Chemicals with consumer product use are likely to have widespread potential for general population exposures and are given high priority ranking within the approach. For the initial prioritization approach, child specific products are captured under general consumer products and all consumer products are weighted equally (see additional

discussion below under Second Tier Considerations). Intermediates will have low general population exposures, since these substances are consumed, by definition, within the workplace. Therefore, they are given the lowest priority ranking within the approach. In the context of the proposed approach, the intermediates category includes both intermediates and non-isolated intermediates. A chemical used in multiple use patterns is assigned the priority of the highest use, e.g., a chemical in both industrial and commercial uses would be assigned the commercial Medium-High rank.

Table 3. Use Patterns - Exposure Ranking

Use Pattern	Ranking	Use Pattern Score
Consumer	High	4
Commercial	Medium-High	3
Industrial	Medium	2
Intermediates	Low	1

The IUR Definitions of these terms are (40 CFR 710.3, 710.43):

- “consumer use” means the use of a chemical substance or a mixture containing a chemical substance (including as part of article) when sold to or made available to consumers for their use.
- “commercial use” means the use of a chemical substance or a mixture containing a chemical substance (including as part of an article) in a commercial enterprise providing saleable goods or services.
- “industrial use” means use at a site at which one or more chemical substances or mixtures are manufactured (including imported).
- “intermediate” means any chemical substance:
 - which is intentionally removed from the equipment in which it is manufactured, and
 - which either is consumed in whole or in part in chemical reaction(s) used for the intentional manufacture of other chemical substance(s) or mixture(s), or is intentionally present for the purpose of altering the rate of such chemical reaction(s)
- “non-isolated intermediate” means any intermediate that is not intentionally removed from the equipment in which it is manufactured, including the reaction vessel in which it is manufactured, equipment which is ancillary to the reaction vessel, and any equipment through which the substance passes during a continuous flow process, but not including tanks or other vessels in which the substance is stored after its manufacture.

2. Production Volume

Recognizing that detailed exposure information will not be available for all substances to be screened, the proposed approach uses production volume as an indicator of exposure, which is widely used in many prioritization schemes. As production volume is just a rough surrogate of emissions, ACC suggests only very broad categories, covering about

two orders of magnitude each. It may be useful to consider how additional exposure estimates may be applied in the second tier assessment.

Table 4. Production Volume as Emission Surrogate - Exposure Ranking

Production Volume as Emission Surrogate	Ranking	Volume Score
>= 100,000,000 lbs national aggregate	High	4
1,000,000 lbs to < 100,000,000 lbs national aggregate	Medium – High	3
>= 25,000 lbs to < 1,000,000 lbs national aggregate	Medium	2
< 25,000 lbs (below IUR site reporting limit)	Low	1

3. Persistence and Bioaccumulation

Persistence and bioaccumulation are viewed as indicators of exposure, and therefore are considered under the exposure axis of the approach. A persistent substance that is emitted to the environment at the same rate as a non-persistent substance with similar partitioning properties will result in higher exposure to humans and the environment. In fact, multimedia modeling clearly indicates that environmental persistence in the compartment to which a substance partitions is a good indicator of human exposure potential (MacLeod & McKone et al. 2004). Similarly, substances that are not subject to biotransformation by higher organisms will exhibit a high bioaccumulation potential that results in higher exposures via the food chain (Arnot et al. 2010). Therefore, it is recommended to apply the proposed persistence and bioaccumulation criteria in assessment of exposure potential as described below.

The persistent and bioaccumulative (P&B) criteria of the proposed approach are targeted toward organic chemicals. Separate assessment criteria are likely needed for P&B evaluation for inorganics/metals, as in the approach taken by Canada's Chemical Management Program (CMP).

For assessing persistence, based upon recent expert consensus (Boethling et al., 2009) it is recommended to distinguish persistent from non-persistent chemicals using the following criteria:

- Volatile chemicals can be defined using a vapor pressure cut-off (i.e., > 1000 Pa)
 - For volatile chemicals, persistent versus non-persistent chemicals are differentiated using a half-life cut-off in air (e.g., a substance is not persistent if air half life is < 2 days).
 - For non-volatile chemicals, non-persistent substances can be defined as substances that are deemed:
 - readily or inherently biodegradable using standard biodegradation tests (OECD 301, 302, 306 test guidelines) or SAR or read across from measured data on a related substance,
 - show an equivalent degree of degradation (i.e. >20% in 28 days) via an abiotic degradation mechanism such as photolysis (OECD 316) or hydrolysis (OECD 111),

- evaluation of simulation data from transformation in soil, marine water/sediment, brackish water/sediment, surface water/sediment, oceanic water die away (e.g. OECD 308/309) have half lives below 180 days, OR
- if data are lacking, evaluation via BOWIN model (EPIWEB 4)
- Non-volatile substances that are not biodegradable or subject to abiotic losses based on the above criteria would be considered persistent.

For assessing bioaccumulation, the key question for screening is the potential for biomagnification based on recent expert consensus (Gobas et al. 2009). To determine if a substance has the potential to biomagnify the following metrics have been agreed:

- Trophic Magnification Factor (TMF)>1, fish Biomagnification Factor (BMF)>1, fish Bioaccumulation Factor (BAF)/Bioconcentration Factor (BCF) > 5000. These metrics can be derived using lab or field measurements (where available) or recently improved computational models that are included in EPA's EPIWEB model that can be freely downloaded at www.epa.gov/oppt/exposure/pubs/episuite.htm.

This approach allows all organics to be addressed and is a scientifically updated version of the approach used in Canada's CMP.

Based on the above recommendations, substances can be grouped with regard to persistence and bioaccumulation as follows:

Table 5. Persistence and Bioaccumulation - Exposure Ranking

Persistence and Bioaccumulation	P&B Ranking	P&B Score
Persistent and Bioaccumulative	High	5
Persistent and Not Bioaccumulative OR Not Persistent and Bioaccumulative	Medium	3
Not Persistent and Not Bioaccumulative	Low	1

Integration of Exposure Elements:

As demonstrated in the tables, each factor (use pattern, P&B, and production volume) would be assigned a numeric score based upon its ranking. All 3 factors are added to arrive at an overall value. These values are then separated into categories from low to high exposure potential. A proposed "banding" approach is illustrated in Table 6.

Table 6. Integration of Exposure Rankings

Combined Score – All 3 elements	Exposure Rank	Exposure Ranking Score
11 – 13	High	5
9 – 10	Medium High	4
7 – 8	Medium	3
5 – 6	Medium Low	2
3 – 4	Low	1

Overall Priority Grouping:

In the overall approach, both hazard and exposure elements are considered when placing a substance in a risk-based prioritization ranking. The overall prioritization score for priority grouping and risk evaluation is based on the combined consideration of the hazard and exposure rankings. Priority Groups 7, 8, and 9 are deemed High Priority; Priority Groups 4, 5, and 6 are Medium Priority; and Priority Groups 2 and 3 are Low Priority.

Review and Comment:

It is important that screening be done in an open and transparent way and that the best available information be used. When screening for thousands of chemicals, EPA may not have access to all available information. The process should provide an opportunity for review and comment on initial rankings and an opportunity to submit additional relevant data and information to update proposed rankings with improved information.

III. Second Tier Considerations:

After the initial screening, some substances within individual priority groupings may require further rank ordering, particularly where a large number of chemicals are in the same priority group. Listed below are the types of information that will be useful to consider in this Second Tier rank ordering:

Biomonitoring/Environmental Monitoring Data:

Mere detection of chemicals in humans or the environment, i.e., "found in biomonitoring (CDC), found in water (NCOD), and found in air", while providing an indication of exposure, does not provide a useful criterion for exposure potential because almost any industrial or commercial chemical could be detected at trace levels, given increasingly sensitive analytical methods. Therefore, detection alone primarily reflects only the fact that a specific chemical was included in a measurement program. This criterion will also tend to bias the prioritization of chemicals for which well-established analytical methods are available. Consequently, this criterion is not used in the initial prioritization scheme. However, within a particular priority grouping, reliable monitoring information should be considered for Second Tier rank ordering within a quantitative process that assesses if the data is above a level of concern (i.e., places it in a risk context).

Use in Children's Products:

Protection of children's health is a top priority and, in the initial ranking, child-specific products are captured under general consumer products and all consumer products are weighted equally. The specific IUR reporting of information on chemical use in products intended for children would be considered further within a particular priority grouping for Second Tier rank ordering, noting the following points:

- the IUR definition is based upon use in a child specific product rather than child specific exposure potential¹ (see below). Without knowing a specific product type, it is difficult to understand if potential child exposure is greater than for a non-child specific product. For example, how does child exposure to a general use cleaner compare to exposure from use in a child's raincoat. In the VCCEP assessments, there are examples for inhalation exposures where estimates of passive child exposure during adult product use exceeded conservative estimates of child exposure during active use of a child-specific product (such as a hobby product) – differences were related to the amount of product used and substance concentration within the product (MEK VCCEP Submission).
- the IUR definition targets children age 14 and younger. Younger children may be exposed to a variety of non-child specific products that are in general household use. Older children may be exposed to a variety of additional products.
- the IUR information request is targeted to manufacturers, which may not have direct knowledge of all uses, particularly the presence in products for specific subpopulations, such as children. Therefore, it is not clear that the information requested for the IUR information would be consistently available across all substances being screened. Ideally, this information should be requested from formulators of child-specific products.

Therefore, for the initial prioritization approach, which represents a broad, unrefined categorization, child specific products are captured under general consumer products and all consumer products are weighted equally. The IUR information on child specific use would be utilized within a particular priority grouping for Second Tier rank ordering. If the IUR information is utilized, it is important that the limitations above be considered in its application.

¹ IUR definition (Federal Register Volume 75, Number 156, Friday August 30, 2010, p. 49686): Intended for use by children means the chemical substance or mixture is used in or on a product that is specifically intended for use by children age 14 or younger. A chemical substance or mixture is intended for use by children when the submitter answers "yes" to at least one of the following questions for the product into which the submitter's chemical substance or mixture is incorporated:

- (1) Is the product commonly recognized (i.e., by a reasonable person) as being intended for children age 14 or younger?
- (2) Does the manufacturer of the product state through product labeling or other written materials that the product is intended for or will be used by children age 14 or younger?
- (3) Is the advertising, promotion, or marketing of the product aimed at children age 14 or younger?

Emissions Data:

Production volume, which is readily available for substances, is used in this proposed approach, but only serves as a surrogate for environmental emissions. For further prioritization, data or estimates of environmental emissions can be used to refine prioritization. Estimates of environmental emissions will be available for some substances (e.g., TRI data). When TRI data are utilized it should be recognized that it addresses only emissions that result from industrial and not wide dispersive uses. In other cases, emissions estimates can be developed as a percentage of production volume based upon consideration of use categories. Within a particular priority grouping, available emissions information can be considered for Second Tier rank ordering, with the understanding that emissions information is not an indicator of actual exposure.

Similarly, non-isolated system intermediates, by definition, would have de minimis exposure potential. Therefore, this IUR information could be considered within a particular priority grouping for Second Tier rank ordering.

International Risk Management Actions:

An initial screening approach for chemical prioritization should be based upon consistent application of specific hazard and exposure science elements that define risk potential. The hazard and exposure elements should be applicable across all substances being evaluated. For initial screening, existence of international risk management action plans should not be a factor that determines priority grouping. Risk management plans may be based upon many factors, including political drivers. It is unclear how factors, their relative weighting, and the rigor of the evaluation may vary across agencies and substances. For initial screening purposes, the same science-based criteria should be used to rank all substances. Consideration of existing international risk management plans could be utilized to check the functioning of the approach and could be considered within a particular priority grouping for Second Tier rank ordering with the possible effect of moving a chemical up in a grouping if actions are being taken internationally.

IV. Summary

ACC's prioritization approach is an example of a risk-based screening prioritization process that implements the general principles outlined at the outset of this document. It is based upon widely available information that can be utilized to understand the relative priority of chemicals for further evaluation from a risk perspective, i.e., integrating both hazard and exposure elements. Implementation of the screening framework will be most effective when utilizing the best available information. When conducting screening for thousands of chemicals, EPA may not have access to all available information. An open and iterative process that includes an opportunity for review and comment on initial rankings, together with the information that led to the result, and an opportunity to update the ranking with improved information will create a transparent and scientifically sound process.

V. References

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Proposed Prioritization Approach

DRAFT May 6, 2011

Exposure Elements				
Use Pattern	intermediate	Industrial - not intermediate	commercial	consumer
Use Score	1	2	3	4
Persistence - Bioaccumulation (PB)	not P, not B		P & not B OR B & not P	P & B
PB Score	1		3	5
Tonnage	<25,000 lbs (below IUR site reporting limit)	25,000 - <1MM lbs IUR aggregate	1MM - <100MM lbs IUR aggregate	≥ 100MM lbs IUR aggregate
Tonnage Score	1	2	3	4
SUM (Use + PB + Tonnage Scores)	range 3 - 13			

PRIORITY GROUPING = Hazard + Exposure Rankings				Exposure Ranking = Based on Sum (Use + PB + Tonnage Scores)				
				3-4	5-6	7-8	9-10	11-13
				low	med-low	medium	med-high	high
Hazard Ranking = Higher Score from Environmental and Human Health Hazards				1	2	3	4	5
		Environmental Hazard	Human Health Hazard					
1	low	not classified	Not carcinogen/mutagen/repro/develop. OR Repeat Dose >1000 mg/kg/day (oral); > 2000 mg/kg/day (dermal); > 1000 ppm/6hr/day (gas inhalation); >5.0 mg/l6hr/day (vapour inhalation); > 1.0 mg/l6hr/day (dust mist fume inhal).					
2	medium	Acute III OR Chronic III/IV ; [not acutely toxic and no chronic data]	Not carcinogen/mutagen/repro/develop. OR Repeat Dose 100 - 1000 mg/kg/day (oral); 200 - 2000 mg/kg/day (dermal); 250 - 1000 ppm/6hr/day (gas inhalation); 1.0 - 5.0 mg/l6hr/day (vapour inhalation); 0.2 - 1.0 mg/l6hr/day (dust mist fume inhal).					
3	med-high	Acute II or Chronic II	GHS CMR Cat 2; OR GHS Repeat Dose Cat 2; Repeat Dose 10 - 100 mg/kg/day (oral); 20 - 200 mg/kg/day (dermal); 50 - 250 ppm/6hr/day (gas inhalation); 0.2 - 1.0 mg/l6hr/day (vapour inhalation); 0.02 - 0.2 mg/l6hr/day (dust mist fume inhal).					
4	high	Acute I OR Chronic I OR Insufficient information to classify	GHS CMR Cat 1a, 1b; OR GHS Repeat Dose Cat 1; Repeat Dose <= 10 mg/kg/day (oral); <= 20 mg/kg/day (dermal); <= 50 ppm/6hr/day (gas inhalation); <= 0.2 mg/l6hr/day (vapour inhalation); <= 0.02 mg/l6hr/day (dust mist fume inhal). OR Insufficient information to classify					

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Hazard and Exposure Criteria for Prioritization Approach

HAZARD

Environment and Human Health Classifications based upon GHS

Environmental:
From GHS classification guidance document:

Table 4.1.2: Classification scheme for substances hazardous to the aquatic environment

Classification categories:				
Acute hazard (Note 1)	Long-term hazard (Note 2)			
	Adequate chronic toxicity data available		Adequate chronic toxicity data not available (Note 1)	
	Non-rapidly degradable substances (Note 3)	Rapidly degradable substances: (Note 3)		
Category: Acute 1 $L(E)C_{50} \leq 1.00$	Category: Chronic 1 NOEC or EC ₀₁ ≤ 0.1	Category: Chronic 1 NOEC or EC ₀₁ ≤ 0.01	Category: Chronic 1 $L(E)C_{50} \leq 1.00$ and lack of rapid degradability and/or BCF ≤ 500 or, if absent $\log K_{ow} \leq 4$	
Category: Acute 2 $1.00 < L(E)C_{50} \leq 10.0$	Category: Chronic 2 $0.1 < \text{NOEC or EC}_{01} \leq 1$	Category: Chronic 2 $0.01 < \text{NOEC or EC}_{01} \leq 0.1$	Category: Chronic 2 $1.00 < L(E)C_{50} \leq 10.0$ and lack of rapid degradability and/or BCF ≤ 500 or, if absent $\log K_{ow} \leq 4$	
Category: Acute 3 $10.0 < L(E)C_{50} \leq 100$		Category: Chronic 3 $0.1 < \text{NOEC or EC}_{01} \leq 1$	Category: Chronic 3 $10.0 < L(E)C_{50} \leq 100$ and lack of rapid degradability and/or BCF ≤ 500 or, if absent $\log K_{ow} \leq 4$	
	Category: Chronic 4 (Note 4) Example (Note 5) No acute toxicity and lack of rapid degradability and BCF ≤ 500 or, if absent $\log K_{ow} \leq 4$, unless NOECs $> 1 \text{ mg/l}$			

Human Health:
As above, based upon GHS

EXPOSURE

Use Elements - based upon IUR

intermediate consumed during industrial processing
industrial (not intermediate) - used in an industrial setting
commercial occupational use in nonindustrial setting
consumer general population residential use

Persistence:

Volatile substance (VP > 1000 Pa): Not Persistent if air half life < 2 days
Nonvolatile (VP < 1000 Pa): Not Persistent if:
a) ready biodegradability (OECD 301)
b) inherent biodegradability (OECD 301, 302, 306)
c) read across from measured data on a related substance.
d) equivalent degree of degradation (i.e. >20% in 28 days) via an abiotic degradation mechanism such as photolysis (OECD 316) or hydrolysis (OECD 111)

OR, a substance is Not Persistent if:
e) evaluation of simulation data from transformation in soil, marine water/sediment, brackish water/sediment, surface water/sediment, oceanic water die away (e.g., OECD 308/309) have half lives below 180 days.

OR, if data are lacking:
f) evaluation via BIOWIN model (EPIWEB 4)

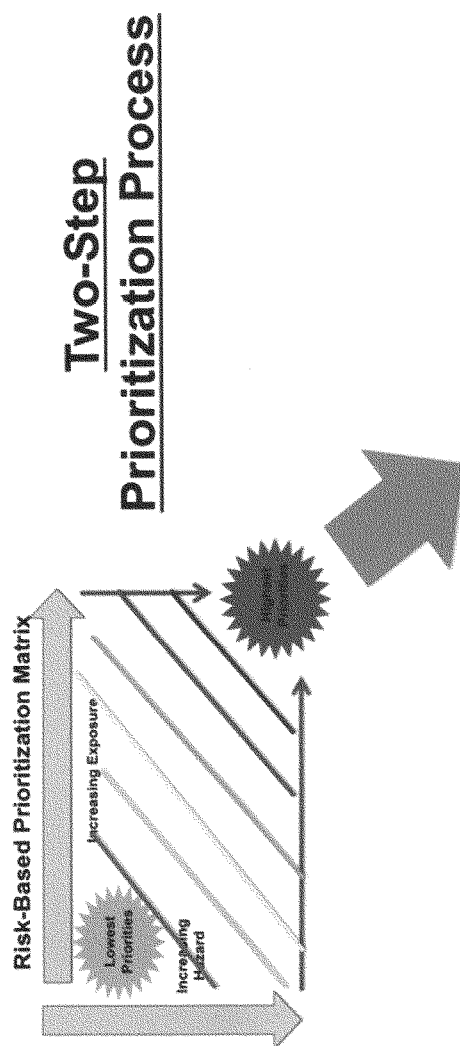
Bioaccumulation:

A substance is not bioaccumulative if:
a) measured TMF < 1 (field study)
b) measured fish BMF < 1 (lab study)
c) measured fish BCF < 5000 (lab study)
d) predicted BCF < 5000 using the BCFBAF model included in EPIWIN 4

The above order reflects the preference for use in decision-making
NOTE -- P&B CRITERIA ARE FOR ORGANICS

Tonnage - based upon IUR reporting ranges

< 25,000 lbs (below IUR site reporting limit)
25,000 - <1 MM lbs national aggregate
1MM - <100 MM lbs national aggregate
 ≥ 100 MM lbs national aggregate



Second Tier

Rank Ordering within Priority Groups

- Biomonitoring / Environmental Monitoring
- Use in Children's Products
- Emissions (e.g. TRI)
- International Risk Management Actions

RESPONSES OF CAL DOOLEY
PRESIDENT AND CEO, AMERICAN CHEMISTRY COUNCIL
TO QUESTIONS FROM SENATORS CARPER AND INHOFE

Questions from Senator Carper:

1. **What do you believe is the biggest outstanding issue that the environmental and public health communities, the chemical industry, and others engaged in efforts to reform the Toxic Substances Control Act need to come closer together on in order to further strengthen the Safe Chemicals Act and gain even more support for reforming our country's chemical safety laws?**

ACC strongly supports the modernization of TSCA consistent with the principles we first announced in 2009. We appreciate the Committee's efforts to modernize the Act and we are committed to working on a bipartisan basis to find a solution that protects health and the environment, enhances public confidence in the chemical management system, and protects jobs, innovation and U.S. competitiveness.

Unfortunately, as I stated in my oral and written statements for the November 17, 2011 hearing, Senator Lautenberg's Safe Chemicals Act (S. 847) raises numerous serious concerns, calling into question, if it were enacted, EPA's ability to implement the program, industry's ability to comply with it, and the continued ability of the business of chemistry to innovate and create jobs in the United States. We have discussed many of these concerns in detail, and offered specific solutions, during the stakeholder dialogue process convened by Senators Lautenberg and Inhofe in mid-2011. Our chief concerns include the bill's ill-conceived safety standard, its approach to regulating new chemicals that is divorced from the realities of the marketplace, its poorly defined process for prioritizing chemicals for review, its unprecedented expansion of EPA's scope of authority under TSCA to areas regulated by other federal agencies, and its failure to adequately protect confidential business information.

Perhaps the most fundamental flaw in S. 847 is the safety standard. That standard is based on the Food Quality Protection Act of 1996 (FQPA), which was designed to regulate pesticides that have a limited number of uses, specific applications, and narrow exposure pathways. Furthermore, pesticides are designed to be biologically active -- that is, to kill pests. Industrial chemicals regulated under TSCA, by contrast, are designed for a myriad of industrial, commercial, and consumer product functions and uses and are not designed to be biologically active. Requiring "reasonable certainty of no harm...from aggregate exposure" to such chemicals, as set forth in S. 847, is unworkable and disproportionate to the risks suggested by the nature of these chemicals and their potential exposures.

Further, the S. 847 safety standard requires an examination of the aggregate exposure to all existing and new TSCA chemicals. This means that every possible exposure scenario from all uses would have to be determined to quantify estimates of total human exposure to a chemical. The time and resources required to evaluate all potential uses and exposures of all new and existing chemicals would be overwhelming and wasteful for both government and the regulated community. It would also dramatically impede the innovation and job growth that is taking

place today in the American chemical industry, which is experiencing resurgence in the United States due to the emergence of shale gas and other emerging energy sources.

As stated in previous testimony before the Committee, ACC supports establishing a new standard as part of a modernized TSCA program, but it must be one designed to regulate industrial chemicals, not pesticides. As discussed in detail with Committee staff in the stakeholder dialogue, we recommend a “negligible risk” type of standard similar to that in the Occupational Safety and Health Act. Such an approach would ensure a strong level of protection, place the burden on manufacturers to demonstrate the safety of their products, and provide EPA with flexibility to determine appropriate risk levels and risk assessment approaches for the numerous and varying types of risks and exposures associated with industrial chemicals.

2. Over the last several years, Europe, Canada, Australia, Korea, China, and other countries have undertaken reforms of their nations’ chemical safety laws. What can we learn from these countries’ efforts to improve the safe use of chemicals? How can these lessons inform the work of the Senate Committee on Environment and Public Works in proceeding with the Safe Chemicals Act?

There are two key areas that Congress could benefit from when examining the regulatory efforts of other countries – the importance of prioritization and the value of information sharing.

ACC believes there is much the U.S. can learn from Canada’s Chemical Management Plan (CMP), particularly in the area of prioritization of chemicals for safety reviews. Canada’s program to prioritize its review of chemicals in commerce was comprehensive, science-based and transparent. Canada completed the entire prioritization process before it began performing risk assessments. Canada used an iterative process, engaging industry and other stakeholder input and feedback at multiple stages, making further prioritization refinements along the way. At each stage of the process, rankings were shared publicly together with supporting information. Health Canada and Environment Canada were open to accepting data and updating the rankings (e.g., replacing modeled information with study data).

The result of this process was a data-driven and scientifically-based list of priorities presenting the greatest hazard and exposure potential, a result that the United States should drive for in a modernized TSCA program. Of the approximately 23,000 substances on Canada’s Domestic Substances List (an inventory of substances manufactured in, imported into or used in Canada on a commercial scale, similar to the U.S. TSCA Inventory), Health Canada and Environment Canada ultimately set aside 18,700 chemicals as not requiring further assessment and are now engaged in a systematic process to assess the risks of 4,300 high, medium and low priority substances.

In the stakeholder dialogue process convened by Senators Lautenberg and Inhofe, ACC put forward a detailed proposal for prioritizing chemicals for safety determinations, similar in many key respects to the one used in Canada. We also provided our proposal to EPA as part of the Agency’s stakeholder dialogue on chemical prioritization, and we appended it to our written statement for the November 17 Subcommittee hearing.

In contrast to the Canadian approach to chemicals management, ACC believes that Europe's program on Registration, Evaluation, and Authorization of Chemicals (REACH) is far too slow, inefficient and bureaucratic. Under REACH, the European Chemicals Agency (ECHA) will receive dossiers on new and existing chemicals, but to date the registration deadlines have only applied to new chemicals, very high volume substances, and substances that have particular hazard characteristics. Registrations for the remaining substances in European commerce are due in June 2013 and June 2018, depending on production or import volume. Perhaps the most significant problem with REACH is that it prioritizes substances for regulatory action based only on hazard. According to the European Commission, only some 5% of all REACH dossiers will be reviewed, despite the significant expense and burden of compiling these data-intensive registrations.

Australia, Korea and China are also looking at ways to strengthen how they evaluate and assess chemicals. Australia is considering an approach to addressing existing chemicals similar to that used by Canada. Korea has proposed changes to its chemicals program but progress appears to have slowed, while China recently revised its new chemicals program.

Importantly, any chemical regulatory system adopted in the U.S. should leverage the data, information and assessments on chemicals that have been generated by the chemical safety laws of other jurisdictions to the full extent allowed. Everyone will be well served by ensuring that a modernized U.S. TSCA law does not impose duplicative and unnecessary testing and data generation requirements.

3. How do you suggest we improve the treatment of new chemicals coming onto the market in the Safe Chemicals Act so that the concerns of consumers around safety and companies around efficiency are met?

ACC believes that the new chemicals program already in place in TSCA is fundamentally sound. We are not aware of any chemicals that have come through the existing PMN process that have later been found to cause significant health/environmental concerns, nor are we aware of any problems EPA has had in exercising appropriate regulatory control and oversight over chemicals reviewed in the new chemicals program.

Moreover, TSCA's new chemicals program does not inhibit American innovation. More new chemical applications have been filed in the United States than in any other country or region of the world. That fact, and the significant number of new U.S. patents granted every year in chemistry, is evidence of the innovation that TSCA has allowed. It is critical that a modernized TSCA program continue to allow the U.S. chemical industry to innovate, compete and create jobs.

In contrast with the current program, the provisions of S. 847 would impose a significant burden on new chemical development that would stifle innovation. Ironically, the burdensome requirements of S. 847 (including its heavy data burden and ill-conceived safety standard) would likely hamper the very innovations in "greener" chemistry its proponents believe should be promoted in the U.S. and that are making their way into commerce today through the forces of the marketplace.

When I testified before the Committee in February of 2011, I stated that ACC believes that TSCA's new chemicals program is already working and does not require an overhaul. I was joined by former EPA Assistant Administrator, Dr. Lynn Goldman, in that belief. She stated: "Over the years, the new chemicals program has made wonderful efforts to inform the chemical industry about the criteria used to assess chemicals. These efforts have encouraged development of safer chemicals, and I believe have caused the industry to screen out 'bad actors' before presenting them to EPA in the first instance."

ACC has long held the view that the initial pre-manufacturing notice (PMN) submissions for new chemicals under TSCA should be tailored to the information needs of a substance, consistent with its physical characteristics, potential hazards and the use and exposure patterns of anticipated markets. It is generally not well understood that the typical approach for EPA's evaluation of a PMN includes review of all existing relevant information/data coupled with use of both EPA's "Chemical Categories" read-across process and EPA's Sustainable Futures models and methods.

The Sustainable Futures models are not traditional toxicity tests that rely on laboratory animals, but instead are modern-day computerized tools developed to be able to predict the potential of a chemical to cause systemic toxicity, cancer and ecotoxicity with an adequate degree of scientific certainty. These models are designed to be very conservative. When critics of TSCA's new chemicals program claim that new chemicals are being approved by EPA without toxicity tests, they fail to either acknowledge or understand the true and full extent of EPA's evaluation process, which by design is built upon use of advanced screening techniques that can reliably predict toxicities without requiring extensive animal testing. Such advanced approaches are efficient, cost-effective and scientifically sound decision making tools for evaluating new chemicals to assure that PMN decisions are protective of both human health and the environment. They also minimize the need for animal tests.

Questions from Senator Inhofe:

- 1. Mr. Dooley, testimony was presented at the hearing that the way to grow American jobs in your industry is to enact Sen. Lautenberg's bill. What are your thoughts on that?**

We disagree with that statement in the strongest terms. In ACC's view, the concerns we have identified with S. 847 would severely and perhaps irreparably damage American innovation and job growth in the U.S. chemical industry. Further, this negative impact on our industry would produce a ripple effect throughout the US economy as other manufacturing sectors are dependent on the business of chemistry. Any new TSCA program must be workable – for consumers, workers, the regulated community, and EPA. Restoring the public's confidence in the U.S. chemical regulatory system must be about efficient, cost-effective and smart regulation that prioritizes chemicals for review, provides for safety, and allows for innovation in new technologies and products and does not impede job growth. ACC's numerous suggestions for TSCA modernization put forward in the stakeholder dialogue convened by Senators Lautenberg and Inhofe try to strike a necessary balance

between protecting public health and the environment and allowing for innovation and job growth. In our view, S. 847 misses that mark by a wide margin.

- 2. It appeared at the hearing a coordinated effort was made to discredit ACC's sincerity and meaningful participation in TSCA efforts that have been underway. Would you like to comment on not only the discussion at the hearing but also ACC's level of engagement in efforts to modernize TSCA?**

ACC appreciates the opportunity to clarify for the record the extent of our engagement and leadership in TSCA modernization efforts.

Despite the tone of the November 17 hearing, ACC remains committed to working on a bipartisan basis to find a solution to modernizing TSCA to provide for safety, innovation and jobs. We respectfully encourage the Committee to begin afresh with a clean slate.

The American business of chemistry – both the manufacturers of chemicals and our upstream and downstream value chain that touches virtually all of the technologies and products of our society – is unified in the goal of modernizing TSCA and providing constructive solutions that will create a program that provides for safety, innovation and jobs. In August 2009, ACC made the first public declaration of basic principles for TSCA modernization – even before the Environmental Protection Agency, which followed a few months later. Even before that, we were active in discussing TSCA with President Obama's transition team, and we have followed that discussion with periodic meetings with EPA, encouraging scientifically-based positions from the Administration to help promote thoughtful, effective reform.

In 2010, ACC was fully engaged in the discussion the House Energy and Commerce Committee hosted on its discussion draft of legislation very similar to Senator Lautenberg's. We not only participated in every one of the eight individual discussion sessions, we submitted over 40 pages of written comments on concepts in the draft and suggestions for appropriate revisions. Because our comments on the House discussion draft are relevant to much of S. 847, we have attached a copy of that submission for the Committee's information.

In addition, we engaged fully in the stakeholder dialogue sessions convened by Senators Lautenberg and Inhofe in mid-2011, and met separately and periodically with the Senators' staff. The dialogue sessions focused on particular provisions in S. 847, via a schedule and order established by the Committee. The Committee also set ground rules of confidentiality to encourage constructive and transparent dialogue by both industry and NGO stakeholders. We brought experts in toxicology, risk assessment and TSCA law and policy to those meetings and to meetings with other Congressional offices in an attempt to educate staff and Members about our views of the complexities of chemical assessment, regulation and commerce. We also put forward in detail in the dialogue sessions both our concerns with S. 847 and proposed solutions (for example, see our response to Senator Carper's first question, summarizing our safety standard recommendation put forward in the stakeholder dialogue).

From May through November 2011, ACC was also engaged in an ongoing confidential dialogue directly with public interest representatives on details concerning TSCA modernization. ACC

believes those discussions were especially useful because they occurred outside the context of S. 847.

ACC categorically rejects the repeated suggestion by certain Senators during the hearing that our reluctance to provide the Committee with specific legislative text has contributed in any way to delays in the consideration of S. 847. As noted elsewhere in this response, despite a continuing series of discussions on concerns and problems in S. 847 and offers of solutions, we have yet to have any indication of how those concerns will be addressed in modifications to the bill, nor have we seen any meaningful changes to the bill or its earlier version dating back to the previous Congress.

Finally, several suggestions were made in the hearing and especially afterwards that the business of American chemistry does not share a unified view of S. 847, and that one segment of the industry in particular has a different view of the legislation. ACC points to the response of the Consumer Specialty Products Association (CSPA) to the Committee's additional questions to that group. When answering a question about whether a divide exists, CSPA clearly stated, "We do not believe that there is a 'divide' between CSPA and ACC.... [W]e are strongly aligned on the principles we have set forth for TSCA modernization and on a continued process of working jointly as an industry coalition to support and work toward bringing TSCA in the 21st Century." Furthermore, when asked if they could support S. 847, CSPA expressed concerns about the bill similar to those put forward by ACC. "CSPA could not support S.847 if the only changes made to the bill were the provisions worked out with the NGOs as part of our discussions. There are other sections of the bill that are important to us, including the adoption of a workable safety standard and data requirement, the provisions relating to new chemical review, and, very importantly, how a chemical will be screened and identified for priority review."

3. During the hearing you had a very interesting visual analogy about how risk would be treated under S. 847. Could you please explain that in more detail?

The analogy was used in my demonstration of the so-called "risk cup," using the chemical chlorine as the example, a key component in implementation of S. 847's safety standard. Under that standard, a TSCA substance would be found to meet the safety standard only if EPA finds "there is a reasonable certainty that no harm will result to human health or the environment from aggregate exposure to the chemical substance."

That standard, by its terms, suggests zero risk and is very similar to the safety standard for setting tolerances for food-use pesticides under the FQPA, as discussed earlier. While it may be an appropriate standard for food-use pesticides, it is not a correct standard for protecting human health/environment from exposure to industrial chemicals under TSCA. More to the point: it is a standard that is not feasible for industrial chemicals regulated under TSCA.

The "reasonable certainty" standard is not necessary to protect human health/environment from TSCA chemicals because TSCA chemicals are not designed to be biologically active, as pesticides are. Instead, TSCA chemicals are generally designed for very broad industrial, commercial and consumer product functions and uses. Industrial uses include things like reactants to make other chemicals; commercial uses include things like fuel additives and

lubricants; and consumer product uses include things such as household glues. So the FQPA's "no harm" standard is misaligned with TSCA chemicals which are designed for industrial, commercial and consumer applications, not for biological activity.

In addition, the FQPA standard is not feasible to apply to TSCA chemicals. The reason for that is grounded in both the number of TSCA chemicals in commerce and the number of uses of those chemicals. There are about 600 pesticide active ingredients regulated under FIFRA and the FQPA. In contrast, TSCA chemicals in commerce range in number between 15,000 and 30,000 chemicals (depending on how you count chemicals, based on volume). In contrast to pesticide chemicals with specific uses and applications, there can be hundreds if not thousands of different uses of TSCA chemicals.

For example, the TSCA chemical chlorine has hundreds of uses. These range from pharmaceuticals to disinfectants for public water supplies to plastic manufacturing. Requiring a determination of "no harm" based on consideration of the aggregate exposure to chlorine, from its hundreds of different uses, would impose a virtually impossible requirement. The S. 847 safety standard's aggregate exposure requirement means every possible exposure scenario from all of these uses would have to be determined to quantify estimates of total human exposure to the chemical. The time and energy required to evaluate all these potential uses and exposures would be incredibly inefficient and a waste of resources.

There are also important questions about how EPA would implement an "aggregate exposure" approach. I used the "risk cup" analogy in my testimony to describe how EPA determines whether aggregate exposure to a pesticide from its specific uses and applications would cause harm.

If the "risk cup" represents the total risk from aggregate exposures to a pesticide chemical, then additional exposures to that pesticide chemical from additional uses of it might cause the risk cup to "overflow". In the more limited universe of pesticide chemicals and applications, EPA has been able to use this sort of analysis to restrict certain uses of certain pesticide chemicals.

Applying the "risk cup" approach in the TSCA context, however, would require an understanding of all of the exposures from use of the chemical in all of its multiple (hundreds/thousands) functions and products, as well as from all natural sources, e.g. natural sources, ambient air, and how much exposure a person might have over an entire lifetime. For a single chemical, such as chlorine, this would involve gathering data on thousands of uses and products and would require EPA to conduct an aggregate exposure assessment from every industrial, commercial and consumer product use of the chemical substance.

Assuming EPA could even conduct such an aggregate exposure assessment of chlorine, then how would EPA enforce a finding that the aggregate exposure to chlorine posed harm? How would EPA determine which uses were acceptable and could continue, and those that could not? Would EPA simply impose a moratorium on any new uses of chlorine, at the risk of hindering innovation in untold new technologies or life-saving drugs? How would EPA identify "winners and losers" in the marketplace for chlorine chemistry? Should EPA even have this authority?

Setting aside that policy question, it is certain that if EPA were required by TSCA to consider the aggregate exposure to a substance from every industrial, commercial and consumer product use of a chemical substance, the TSCA chemical management system would quickly break down. Paralysis in regulation would result. Public confidence in federal regulation of chemicals would be even less than it is today.

Instead of the FQPA standard, the TSCA safety standard must be one that is both protective of human health and the environment and one that can be applied in a practical way. Aggregate exposure assessments should only be required in a modernized TSCA on a case by case basis for substances when the need is indicated by certain triggers, such as a small margin of exposure.

4. Do you feel that S. 847 is the proper starting point for a bipartisan TSCA modernization?

ACC strongly supports efforts to modernize TSCA and appreciates the efforts of Senators Lautenberg, Inhofe and other Members of the Committee to address TSCA reform. However, throughout our engagement with Senator Lautenberg's office on S. 847, and particularly through ACC's participation in the dialogue Senators Lautenberg and Inhofe convened on the bill, we have made clear that we do not believe the proposal is the basis for a bipartisan agreement on TSCA modernization. We expressed similar views to the House Energy and Commerce Committee when it considered a related proposal in 2010 (see the attachment appended to this response). At this point in time, we respectfully encourage the Committee to begin with a fresh slate in an effort to craft a modernized TSCA program that provides for safety, innovation and jobs.

TSCA is a complicated statute. Chemistry, and the appropriate regulation of the business of chemistry to ensure that health and the environment is protected, is similarly complicated. Europe's new chemical regulatory system, REACH, was the subject of considerable discussion before it became final, and even then, we believe the result was flawed in many respects. Further, REACH is only now in the initial implementation stages.

ACC has been a constructive participant and industry leader in the discussion of S. 847 and similar proposals. We have made clear our industry's commitment to TSCA modernization and to appropriate statutory and regulatory measures designed to protect health and the environment as well as the competitiveness of U.S. industry. Although the proponents of S. 847 have acknowledged some of our concerns with the bill, we have yet to see any indication of what changes, if any, will be made to address those concerns.

5. The National Academy of Sciences Report "Toxicity Testing in the 21st Century" discussed methods of evaluating chemicals including in vitro testing and computational toxicology. Do you think this legislation provides a clear path forward for development, validation and use of these rapidly emerging tools within a tiered testing framework?

Certain sections of S. 847 speak to "varied or tiered data" and encourage "the use of alternative testing methods and testing strategies." Although on their face these concepts appear to be

consistent with certain aspects of the report from the National Academy of Sciences “Toxicity Testing in the 21st Century,” greater clarity is needed.

Adequate characterization of advanced approaches for hazard profiling is key to their practical application. S. 847 does not clearly articulate how, when or by whom the performance attributes of these methods, including relevance, reliability, sensitivity, and specificity, will be assessed. Presumably, the bill’s proposed Interagency Science Advisory Board on Alternative Testing Methods (ISABATM) would play an important role, but the bill does not include specific provisions to ensure that these advanced profiling tools are adequately characterized in terms of performance (the ability of a method to predict “true” positives and “true” negatives and its reliability in labs over time), applicability (the range of chemical structures that can be reliably evaluated by a method, and those that cannot) and mechanistic relevance (the step in the sequence of the process of induction of toxicity that is being measured by a given method).

In addition, certain activities of the proposed ISABATM appear to overlap the existing Interagency Coordinating Committee for Alternatives to Animal Testing (ICCVAM, established by the ICCVAM Authorization Act of 2000 (P.L. No. 106–545 (Dec. 19, 2000), codified at 42 U.S.C. § 2851-3). As a result, S. 847 does not provide a clear path forward for the development, validation and use of these tools or methods within an appropriately tiered integrated testing and assessment framework. These advanced tools and methods have to be appropriately characterized in terms of performance and biological context, and then an informed decision can be made whether the level of uncertainty associated with the results of a particular tool/suite of tools is sufficient for its intended use. If these tools are not appropriately characterized prior to being used it will convey a false sense that the data have a demonstrated ability to predict downstream events of concern for human health.

S. 847’s reference to the NAS Report also raises questions about some of the practical applications of its recommendations. For example, many of the high throughput (HT) and high content (HC) advanced screening techniques that are currently being applied in programs such as ToxCast™ and Tox 21 have been taken directly from the pharmaceutical field. In that arena, screening agents with potent biological activities is a routine part of the drug candidate development process.

By contrast, commodity chemicals are typically orders of magnitude less active than pharmaceutical agents since commodity chemicals are designed to impart physicochemical effects (not biological effects) that cause or improve the specific performance of a product. This begs the question of whether such assays are even capable of delivering meaningful information to inform risk-based decision making in the TSCA commodity chemical context. Obviously testing commodity chemicals at artificially high concentrations in HT/HC assay systems simply to elicit measurable responses will have little real world significance. A critical element will be to “anchor” the test systems with sufficient knowledge a) of the biological context within its associated mode of action and key biological events, and b) to enable a translation between test dose concentrations and real life exposures.

In this regard, the National Academy of Sciences “Toxicity Testing in the 21st Century” report concludes that a coordinated effort and significant resources over the next several decades will

be required. The report specifically recommends that a new institution be created to “foster the kind of cross-disciplinary research that will be required to achieve the vision” that will involve “government, industry, universities, consulting laboratories, and the public interest community.” S. 847 does not address these findings and recommendations of the NAS Committee.

ACC fully supports utilization of tiered integrative testing and assessment approaches to determine potential hazards and risk of chemicals in a modernized TSCA. 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.

Importantly, a modernized TSCA needs to leverage the use of existing data and information in EPA’s safe use determinations, including data and information from other mandatory and voluntary programs such as Canada’s CMP, Europe’s REACH and the U.S. High Production Volume challenge program.

As ACC has testified before the Committee, ACC is firmly committed to minimizing the use of laboratory animals for testing and is equally committed to assuring that animals used for testing are treated humanely. ACC has supported the development and validation of alternative and non-animal methods. We have participated in a number of new/revised and alternative methods validation efforts, including participation in studies and serving on expert peer review panels. ACC has, and will continue to encourage the use of alternatives to animal testing when these alternatives are scientifically valid and predictive and acceptable to regulatory bodies.

Senator LAUTENBERG. Thanks very much, Mr. Dooley.
Mr. Matthews, I'd like to hear from you.

**STATEMENT OF ROBERT MATTHEWS, COUNSEL, CONSUMER
SPECIALTY PRODUCTS ASSOCIATION**

Mr. MATTHEWS. Thank you, Senator. My name is Bob Matthews. I am with McKenna Long & Aldridge, where I have the privilege to serve as counsel for CSPA. Indeed, it is a privilege to testify on their behalf before this Committee.

I want to make it clear, I think it already is, that CSPA supports TSCA modernization and it does so for several reasons. I will list three of them.

First, as has been echoed by several of the Senators in their comments, there is an erosion of public confidence, and that comes back to CSPA more than most industries because we are the branded companies. It is our products that are on retail shelves. It is our products which are in all of our homes, in our kitchens in our bathrooms and so on. And so when consumers are not confident about chemicals in their products, we feel that directly.

Second, we think that the Federal Government should reestablish its role as the primary source of chemical management regulation in this Country. I echo comments previously stated in that regard.

Third, we think there is an opportunity for the United States to reestablish its global leadership in chemical management. A chemical management system should be based on risk-based analysis of chemicals and establishing standards on the basis of risk should not be limited to considerations only of hazard, as we have seen in other jurisdictions.

I do want to say a word about the process that we have been involved in, and we have been involved in multiple stakeholder discussions, including not the least of which is the process that Senators Lautenberg and Inhofe have led and directed. We appreciate that. We think those discussions have been positive and constructive. We salute your staffs who have done an excellent job in moving that process along. They are very good at what they do.

And we have had similar processes with the NGO's. Richard Denison to my left and others from the NGO community have reached out to us and we to them and productive discussions are going on there as well.

We aren't there, Senator, I must say. We are trying hard. We have moved. They have moved. And the key to those discussions has been, and I think it is a word, I apologize if I forgot who used it, but one of the Senators used it this morning. The key is to find solutions. And to do that, we have to understand what is the Safe Chemicals Act? What are its goals? And are there, where we have problems or we have concerns about the way it is written, are there alternative approaches that can solve those same problems and achieve those same goals?

In that spirit, those discussions have been productive and I believe we have made progress. We still have a ways to go, and that is clear.

I want to talk about two issues that our trade association, our member companies have focused on in particular. And the first

falls directly out of the notion that this should be a risk-based system. Well, if you are going to do risk analysis, you need more than just hazard data. You need to understand how those chemicals are being used, where they are being used, and what exposures are being created by those uses. That information comes right back to our industry because we are the companies who are placing those products with those substances on the marketplace.

So the issue of use and exposure information is one that CSPA understands must be part of a modern TSCA, and indeed, we have for several years promoted the idea that this industry should come forward with additional information. And we have said so in our position papers and in the discussions with the stakeholders and with Senate Staff, we made clear that we are prepared to step forward under new legislation. And indeed, we have very specific proposals in that regard that we have placed on the table.

And the last issue I want to briefly address, Senators, is sort of the natural fallout from that last point, which is we understand we need to come forward with substantial additional information under a modern TSCA. Inevitably, however, when we do that, some of that information will be confidential. And the protection of confidential information is critical to this industry.

The examples we typically throw around, I am not smarter than these examples, so I will just use them: Coke and its formula; WD-40; PostIt Notes. Those formulas have been held proprietary by those companies who developed those formulas for decades. In the case of Coke, I think it is probably a century by now. It is just as important to those companies today as it was then to protect those interests.

So we are concerned that there are not enough rigorous protections in the proposed legislation. Here again, however, we think there are ways to come at that issue where we can find solutions and provide the right balance on both the submission of information to the agency and the protection of that information to protect the interests of our member companies.

I will be pleased to discuss any of those issues further during question and answer.

Thank you.

[The prepared statement of Mr. Matthews follows:]



Testimony of

**Robert A. Matthews, Esq.
McKenna, Long & Aldridge
Of Counsel to, and on behalf of,
The Consumer Specialty Products Association**

**Before
The Committee on the Environment and Public Works
and
Subcommittee on Superfund, Toxics and Environmental
Health**

**Joint Legislative Hearing on the Safe Chemicals Act
United States Senate
Washington, D.C.**

November 17, 2011



Testimony of

**Robert A. Matthews, Esq.
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Of Counsel to, and on behalf of,
The Consumer Specialty Products Association**

**Before
The Committee on the Environment and Public Works
and
Subcommittee on Superfund, Toxics and Environmental
Health**

**Joint Legislative Hearing on the Safe Chemicals Act
United States Senate
Washington, D.C.**

November 17, 2011

The Consumer Specialty Products Association (CSPA) greatly appreciates the opportunity to provide input at this legislative hearing on behalf of our approximately 235 “consumer-facing” companies who are engaged in the manufacture, formulation, distribution and sales of approximately \$80 billion annually in the U.S. of hundreds of popular brand name formulated products. CSPA members are committed to manufacturing and marketing safe, innovative and sustainable products that provide essential benefits to consumers while protecting human health and the environment.

My name is Bob Matthews, and I serve as counsel to the CSPA. I am an environmental attorney with almost forty years of experience representing clients in counseling and litigation matters across a broad spectrum of international environmental laws and regulations.

The products we represent are in every home and institution around the country. Our company names are on every one of their products. Product safety is the foundation of consumer trust and that the consumer products industry devotes substantial resources to achieving this goal.

Like EPA, ACC and other stakeholders, CSPA has previously introduced principles for TSCA modernization. Some common ground put forth by these diverse groups includes:

- The U.S. needs a modern chemical regulatory law that reflects more than three decades of scientific and technological advances since TSCA was enacted.
- The system needs to be risk-based, and must allow EPA to review and assess the safety of chemicals in commerce through a process of prioritization, with the chemicals of highest concern for immediate agency review.
- The system must include a means by which EPA can obtain reasonable and appropriate use and exposure data from companies like those CSPA represents to better assess safety.
- The system must protect public health and the environment while also protecting confidential business information (CBI), thereby preserving the ability of American companies to drive innovation, grow jobs and compete in the global marketplace.

Establishing a Process for Dialogue

Senate stakeholder discussions

Senator Lautenberg and Senator Inhofe, we want to thank you for initiating the recent series of Senate staff meetings with key stakeholder groups to discuss in detail views on whether and how the TSCA statute should be changed. As one of six trade associations invited to participate in these sessions, CSPA is committed to the process of engaging in

dialogue with all stakeholders to work through questions and issues in an effort to narrow our differences on TSCA issues. We commend the productive and professional approach undertaken both by your staff in organizing and directing these sessions, and by all of the stakeholders whose contributions were substantive and meaningful. Your leadership in this process is greatly appreciated.

Industry dialogue

Senator Lautenberg, you have noted the positive input which has been provided by TSCA-regulated companies, including Procter & Gamble, SC Johnson and others. Notably, P&G and SC Johnson serve as co-chairs of the CSPA Chemical Policy Management Team (CMPT), which operates as a leadership team of member company representatives within the association, and a group with which I am closely engaged as counsel to CSPA, particularly as it relates to our discussions about modernizing TSCA. Also notably, these works groups include representatives from the Downstream Coalition of trade associations that includes the CSPA, American Cleaning Institute (ACI) and Grocery Manufacturers Association (GMA).

Under the guidance of the CMPT, the Downstream Coalition has been working now for more than three years on TSCA modernization issues. Six TSCA work groups that involve a committed group of technical and regulatory experts have taken on the task of reviewing key program issues to, first, understand their impacts on our industry, and second, to develop recommendations on how TSCA might be modernized to better address critical shared concerns in these key areas.

Our approach in these discussions continues to seek a balance to ensure—

- EPA's ability to review and assess chemical safety in the protection of public health and the environment;
- Companies can continue to innovate and that CBI is protected; and
- Consumer confidence in the protection of human health and the environment.

EPA dialogue

CSPA is committed to TSCA modernization. We understand and accept our role in providing use information which may be needed to better inform EPA's prioritization and safety assessment decisions in the years ahead. To this end, the Downstream Coalition is also working with the EPA in an effort to better understand the types of information the agency needs to prioritize chemical review and to evaluate chemical use, exposure and risk. This dialogue will also include looking at how this information can be submitted to the Agency in a timely and meaningful way.

NGO dialogue

Two years ago, CSPA was asked by representatives in the NGO community to meet in an effort to better understand their priority concerns and calls for legislative reform of TSCA. A goal was to reach consensus to try to make progress on some of the challenging areas of TSCA modernization that most impact the downstream formulators.

Over the past six months, CSPA has participated in several meetings with the Safer Chemicals Healthy Families Coalition and Environmental Defense Fund. In these sessions, we have provided ideas and recommendations developed by the TSCA Work Groups. We believe this process has succeeded in narrowing our differences in several critical areas, for example, on the timing, process, and content of reporting use and exposure information.

As we have worked through this process, we have identified some common ground on two key TSCA elements of significance to CSPA: providing a system for EPA to receive more robust information on how chemicals are used for the purposes of both prioritizing and assessing the safety of chemicals; and balancing the need for more information with the need to protect proprietary and confidential business information. Both sides have come to the table with proposed solutions, and while we are not there yet, we are making progress.

The bipartisan approach established by this Committee has served well to motivate that dialogue.

Motivators for TSCA reformEnhancing consumer confidence on chemical safety

Developing reasonable and necessary revisions to update the TSCA statute is tremendously important for CSPA member companies, who are, in many respects, the public face of the U.S. chemical industry. The products we produce are in every home and institution around the country. Our company names are on every one of their products. Therefore, maintaining a high level of consumer confidence in the safety of the chemicals used in their products is a responsibility that all CSPA member companies take very seriously.

Consistent Regulation of Commerce in All 50 States

Companies in the chemical industry face a multiplicity of regulations at the state level, as legislative and regulatory entities seek to develop and implement their own chemical management programs in the absence of action at the federal level. These various state actions have created a patchwork of requirements for evaluating, assessing and managing chemical use—making it extremely difficult and costly for companies to

market products in all 50 states. Fifteen states have introduced resolutions asking Congress to reform TSCA. A modernized federal TSCA statute will reduce the need for regulation of chemicals by states, while providing assurances and assistance in partnership with state regulators in their efforts to address specific and priority needs in their communities.

Supporting Global Leadership for a Risk-based Approach to Chemical Review and Assessment

Chemical regulation is changing rapidly and significantly around the globe. Many of our member companies operate in the international marketplace—and are facing costly and burdensome requirements to comply with the rigorous hazard-based approach taken under Europe’s REACH regulation. It is essential for the U.S. chemical management system to keep pace with global developments and that our government resume its role as a global leader in chemical regulatory policy on behalf of all U.S. citizens and U.S. industry. The U.S. chemical industry is unified in its support for the adoption of a risk-based system under TSCA—which means the EPA will consider *both* hazard and exposure criteria in its assessment of a chemical’s safety for its intended uses.

Examining the provisions of S. 847

CSPA acknowledged in April that the new bill, S. 847, has started to move in the right direction in several key areas, such as prioritization and minimum data set. CSPA recognizes the need for EPA to obtain additional reasonable and appropriate information on consumer product exposures to refine the categorization of those chemicals for further assessment. Such an approach needs to be based on sound science and must be practical, objective, and predictable in order to quickly and efficiently narrow the large chemical universe to a smaller, more meaningful, subset of chemicals that would receive further assessment.

However, CSPA has serious concerns about sections of the bill, including, but not limited to, provisions that would:

- Significantly expand requirements for Reporting, including through a burdensome Declarations section; and
- Restrict and limit the protection of CBI.

With regard to Reporting and Declarations, it is very important to ensure that information is collected as needed and does not impose an across-the-board requirement for every chemical user to identify every chemical use. We believe that it is neither necessary nor productive to require that the same amount of information be generated for low priority chemicals as that which may be needed for a high priority chemical. We also believe that EPA should focus their limited resources on chemicals

which represent the highest hazards and highest potential for exposure and risk to human health and/or the environment.

Providing Use and Exposure Information in Support of a Risk-based Approach

CSPA recognizes that our companies are in a unique position to provide use and exposure information and are committed to undertaking a new reporting requirement to provide this information. This type of information is needed to better inform EPA's decisions in the prioritization and assessment of chemical safety.

Therefore, CSPA supports the involvement of our chemical users in providing EPA certain use information with which the Agency can make well informed screening-level prioritizations. This reporting would include an indication of use in products intended for children and information about the concentration range of the chemical in the product. Reporting under these provisions can provide EPA with a current understanding of the use and exposure of chemicals in commerce without resorting to an inflexible use registration/declaration requirement for every chemical user to report every chemical use. This reporting must be tied directly into the overall framework of priority setting which will consider existing and available information to screen chemicals to identify chemicals for further review.

Finally, while downstream users are committed to providing use and exposure information as needed by the Agency, it must be recognized that this may include information on chemicals in our products that is proprietary CBI. Intellectual property is a company's most valuable intangible asset, and represents a substantial investment of time and dollars that result more sustainable and innovative products entering the market. It must be carefully safeguarded from competitors. CSPA has indicated our support for revisions under the Safe Chemicals Act to require upfront substantiation of claims and appropriate sharing of CBI with state governments, and other appropriate authorities, but only with assurances of appropriate safeguards.

The updated TSCA, which can only be enacted with bi-partisan support, will touch thousands of companies in the U.S. and around the globe. If done right, a modern TSCA can drive innovation and sustainable products.

Mr. Chairman and Members of the Committee, while there is still much work to be done to reach bipartisan consensus on updating the TSCA law, CSPA is committed to this process. Along with other stakeholders, our industry can help to provide recommendation on these and other issues a part of a modern chemical regulatory framework.

About CSPA

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



January 3, 2012

Via electronic transmission

The Honorable James Inhofe, Ranking Member
 The Honorable Tom Carper
 United States Senate
 Washington, DC 20510
 Attn: Jonathan Aronchick
Jonathan_Aronchick@epw.senate.gov

Subject: Response to Questions Related to Testimony Presented at a Joint Legislative Hearing
 on the Safe Chemicals Act (Nov. 17, 2011)

Dear Senators Inhofe and Carper:

On behalf of the Consumer Specialty Products Association (CSPA), and of Mr. Robert Matthews who appeared for CSPA at the hearing before the Committee on Environment and Public Works on November 17, 2011, we are pleased to respond to the follow-up questions you have posed. Our responses, set forth below, provide further support for the bipartisan efforts to develop a modernized TSCA that provides EPA with the tools it needs to implement a sound, risk-based chemicals management system while at the same time meeting the needs of industry that new legislation facilitate, rather than impede, innovation. We look forward to continuing to work with the Committee members and their staffs towards achieving these goals.

Questions from Senator Tom Carper:

1. What do you believe is the biggest outstanding issue that the environmental and public health communities, the chemical industry and others engaged in efforts to reform the TSCA need to come closer together on in order to further strengthen the Safe Chemicals Act and gain even more support for reforming our country's chemical safety laws?

Answer: For industry as a whole, the most significant outstanding issue is the definition of the safety standard. It is difficult to see how industry can support reforming our chemical safety laws without resolving this most fundamental issue.

For the consumer products industry, it is vitally important that a modernized TSCA provide adequate protection for companies' trade secrets and confidential business information (CBI). CSPA believes that a reasonable balance can be developed to achieve the parallel goals of: (1) providing EPA with the information it requires to make informed, risk-based chemical safety and management decisions; and (2) protecting CBI,

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which is necessary to ensure continued innovation and is essential for American businesses to continue to compete successfully in a highly competitive global economy.

CSPA member companies believe that all stakeholders are aligned around the shared goal of chemical safety, and that this principle should be the foundation for modernizing TSCA. Part of that process is improving the information provided to EPA by companies that use TSCA regulated chemicals in products and, to the maximum extent possible, sharing appropriate information with the public. Consumer product manufacturers agree that certain information provided to EPA must be afforded protection from disclosure to the public and business competitors in order to protect innovation.

In conclusion, while CSPA believes that there are major outstanding issues related to modernizing TSCA, we believe that these concerns can be solved through a bipartisan effort.

2. Over the last several years, Europe, Canada, Australia, Korea, China and other countries have undertaken reform of their nation's chemical safety laws. What can we learn from these countries' efforts to improve the safe use of chemicals? How can these lessons inform the work of the Senate Committee on EPW in proceeding with the Safe Chemicals Act?

Answer: The Canadian program has sought to develop a regulatory review of chemicals based on prioritization of chemicals for further review and assessment. This process has involved stakeholder input and generally, has been widely viewed as an effective and productive approach to focus attention first on highest priority chemicals. Canada is now moving into a next phase of the process to begin to review a list of the next identified priorities.

In contrast, the European approach is based on the collection of enormous amounts of data on large numbers of chemicals and chemical mixtures in phase 1, with a goal of the regulators then taking that information to review and identify chemicals for further action. The end result is an overload of data, much of which is unnecessary for a chemical safety review; this has only served to delay the process and increase the level of uncertainty for both consumers and industry with regard to chemicals used in products. Another lesson learned from the European approach is the need to rely upon a risk-based review of chemicals versus a hazard based approach. Again, the purpose is to identify the chemicals that may present a risk to human health and/or the environment. Exposure is a necessary part of this review. The European approach is also unnecessarily complex, creating obligations on data generation and sharing that are burdensome and ineffective. CSPA's approach to modernizing TSCA, which would require that the consumer product manufacturers provide meaningful use and exposure information on chemicals as they become prioritized, is a much more direct and efficient approach.

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3. Are there improvements to the Safe Chemicals Act that could better ensure that the processes the bill would put in place for bringing newer, greener chemicals to market support advancements in green chemistry and innovation?

Answer: The chemical industry is highly innovative in the development of newer, more effective formulations for use in millions of products worldwide. Again, we believe that the most important part of this equation is to clearly and affirmatively provide direction to the EPA on the need to recognize and support the protection of CBI related to new chemicals, as well as formulations as they are developed and introduced in the marketplace. Even before they commit to investment in a new chemical or process, a company needs to know they can adequately protect their investment from disclosure to their competitors. Strong protections of confidential and proprietary information as part of TSCA will not only assure that this information is provided to the EPA, but, in combination with a meaningful risk-based process for prioritization of chemicals, will also serve to encourage and support innovation.

The following CSPA member companies have won the Presidential Green Chemistry Challenge Award:

- BASF Corporation
- Bayer Corporation
- The Dow Chemical Company
- E. I. du Pont de Nemours and Company
- Eastman Chemical Company
- Nalco Chemical Co. (now Ecolab, Inc.)
- Novozymes North America, Inc.
- The Procter & Gamble Company
- Rohm and Haas Company (now The Dow Chemical Company)
- S.C. Johnson & Son, Inc.
- The Sherwin-Williams Company

These companies expended a tremendous amount of time, money and effort to develop groundbreaking new technologies. The practical reality is that no company will invest in future Green Chemistry breakthroughs unless there is adequate protection for their investment in these new technologies. Thus, CSPA believes that it is essential that a modernized TSCA ensure continued innovation by providing necessary and appropriate protection for these companies' intellectual property.

Questions from Senator James Inhofe:

1. During the hearing we heard testimony that states are "ill equipped" to deal with chemical regulation and that regulating chemicals is an unnecessary drain on state resources. We also heard that state regulation of chemicals creates a "complex maze of regulations across the

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country.” If TSCA is modernized to strengthen federal protections, how important is it from a business standpoint to at a minimum maintain the current levels of preemption in TSCA?

Answer: We believe chemical regulation should be a federal responsibility largely because of this costly and duplicative regulation at the state government level. Chemicals and products are produced, marketed and sold in multiple jurisdictions--and a federal system will ensure that customers--both commercial and consumer--are assured the same level of access to chemicals and products, as well as assurance of safety in all 50 states. The United States should provide leadership on chemical safety as our companies represent the global leaders in innovation and productivity. The federal approach will also serve to reduce costs on manufacturers by eliminating duplicative and/or conflicting compliance under parallel regulatory systems. We agree that, at minimum, the Congress should ensure that current TSCA provisions that provide that, if the federal government has reviewed a chemical for safety, a state cannot take separate action that would conflict with the federal regulation. In the absence of regulation on a chemical, as appropriate, a state may take action. However, we believe it would be reasonable and practical to impose some period of moratorium on State action as part of TSCA to provide time for the EPA to update and implement their program.

We appreciated the comments of the State of Washington at the Senate hearing that it was the preference of state governments for a federal regulatory system for TSCA versus a 50-state approach. During the 2011 legislative session, 15 states introduced resolutions asking Congress to reform TSCA. A modernized federal TSCA statute will reduce the need for states to regulate chemicals, while providing assurances and assistance in partnership with state regulators in their efforts to address specific and priority needs in their communities.

In conclusion, the distribution and sale of consumer products (*e.g.*, electronics, household products) through our Nation's retail marketplace is extremely complex; thus, it is nearly impossible to manufacture products that comply with differing state statutory and regulatory requirements. That is why CSPA believes that a bipartisan comprehensive federal chemical management policy is vitally important.

2. A major interest of industry in modernizing TSCA is to create regulatory certainty and not force businesses to deal with a patchwork of regulation on their products. Does modernization of TSCA without preemption properly address the issue of creating certainty?

Answer: While we appreciated the comments of the State of Washington that states would be unlikely to take additional action on chemical regulation if an effective federal program was established, this is not sufficient to create the level of certainty necessary to encourage research and development of innovative new products. We believe a better approach is to include preemption, with appropriate provision for additional state actions where the federal government has not made a safety determination.

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3. Since the hearing, there have been efforts to highlight a perceived divide between industry groups such as CSPA and ACC. Could you speak to your organizations view of that "divide?"

Answer: We do not believe that there is a "divide" between CSPA and ACC. We understand that the final details of the law may impact our industry segments differently, and agree that it is incumbent on all of us to be engaged to ensure our interests are protected. But we are strongly aligned on the principles we have set forth for TSCA modernization and on a continued process of working jointly as an industry coalition to support and work toward bringing TSCA into the 21st century.

4. You mentioned the efforts of CSPA and others in industry to try and find common ground around major TSCA modernization issues with environmental groups. Could you describe to me where you see CSPA's role in this effort and how that fits into the bigger picture of overall TSCA modernization?

Answer: CSPA, as well as other members of the consumer products industry, has worked in parallel with manufacturers, most notably ACC, in seeking common ground with NGOs on the modernization of TSCA. For example, while ACC has focused on the safety standard and new chemical issues, CSPA, as explained above, has focused on the provisions of a modern TSCA under which consumer product formulators will be required to provide information to EPA on use and exposure of chemicals prioritized under TSCA. This is a new burden on our industry that we have accepted in order to ensure that the EPA adopts a risk-based approach for the review and assessment of chemicals. It is incumbent on us to protect the interests of our companies in these discussions. Our discussions with the NGOs were initiated to provide us a better understanding of their goals and objectives and, in turn, to improve their understanding of how these objectives could be met in a workable process without imposing unnecessary burdens on industry and to protect trade secrets and confidential business information. Again, providing meaningful information on use and exposure of chemicals under TSCA is the only way to support a risk-based approach--which is a priority for all industry stakeholders.

5. Absent any other major substantive changes to S. 847, if CSPA's negotiations with environmental groups yielded a compromise, would CSPA be supportive of the bill?

Answer: No, CSPA could not support S. 847 if the only changes made to the bill were the provisions worked out with NGOs as part of our discussions. There are other sections of the bill that are important to us, including the adoption of a workable safety standard and data requirement, the provisions relating to new chemical review, and, very importantly, how a chemical will be screened and identified for priority review. We look forward to engaging with all stakeholders on further discussions in these areas.

In conclusion, CSPA would like to thank you for the opportunity to present input at the legislative hearing on behalf of our approximately 235 "consumer-facing" companies who are

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engaged in the manufacture, formulation, distribution and sales of approximately \$80 billion annually in the U.S. of hundreds of popular brand name formulated products.

Respectfully submitted,



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Dimitri Karakitsos, Dimitri_Karakitsos@epw.senate.gov
Phil Klein, PKlein@cspa.org

Senator LAUTENBERG. Thanks very much.
Mr. Denison, we look forward to hearing from you now.

STATEMENT OF RICHARD DENISON, SENIOR SCIENTIST, ENVIRONMENTAL DEFENSE FUND; SAFER CHEMICALS, HEALTHY FAMILIES COALITION

Mr. DENISON. Thank you, Mr. Chairman, Ranking Member Inhofe. I am testifying today on behalf of both Environmental Defense Fund and the Safer Chemicals Healthy Families Coalition, a broad coalition of over 300 health, environmental and environmental justice organizations and leading businesses that represent more than 11 million Americans, including the very young voices you heard in the back of the room a bit earlier.

Mounting evidence of problems calls into question the safety of thousands of chemicals that we encounter in our everyday lives. Here are but a few examples of these problems.

Scientific researchers increasingly link chemical exposures to serious diseases that are becoming more prevalent, including childhood leukemia and brain cancers, which have risen more than 20 percent since 1975; and fertility problems, which now affect 40 percent more women than they did in 1982.

Eighty percent of all new chemicals reviewed by EPA are reviewed without access to any health or environmental information. That is because the U.S. is virtually the only developed Country in the world that does not require a minimum set of safety information to accompany a new chemical.

Residents in low-income communities and communities of color like Mossville, Louisiana, which is surrounded by 14 different chemicals plants, are routinely exposed to far higher levels of deadly chemicals like dioxin, vinyl chloride and benzene than is the general population. And yet such disproportionate impacts are not required to be accounted for when the government assesses the risks of those chemicals.

These problems can be ascribed to the failures of TSCA. They would also be ameliorated by the adoption of the Safe Chemicals Act. It provides a framework for a systematic solution to a set of problems that will only be addressed, if at all, through piecemeal actions. We support the legislation because it strikes a balance between the need to fully protect public health, including the most vulnerable among us, with the need to encourage innovation and safer chemicals, and the needs of the chemicals marketplace and consumers and the public for better information, with the need to protect legitimate confidential information.

Since the Act was first introduced in 2010, it has evolved substantially to reflect input from a variety of stakeholders. Changes have been made that both boost its health protections and make it more workable and ease its implementation. I give a number of examples of those positive changes in my written testimony. I also detail how the reforms of the Safe Chemicals Act would fix the major flaws of TSCA.

But let me now turn and emphasize in my oral statement the opportunity we see to capitalize on what is a truly remarkable consensus among a broad array of stakeholders that Congress must reform this law. The need is urgent because it is not only failing to

provide health protections, it is failing to provide industry with a stable environment in which to conduct its business, and its customers with confidence in the safety of its products.

We recognize that reform must meet the needs of a variety of stakeholders, and that is why our coalition has been deeply engaged in dialog with the industry. We have ongoing dialogs with the American Chemistry Council, with the Consumer Specialty Products Association and its members. We have met for many days over the past 6 months to narrow our differences. Eight members of our coalition traveled to the headquarters of both the Dow Chemical Company and Procter and Gamble to hear first-hand about their businesses and understand their perspectives for TSCA reform.

We strongly have endorsed and support the bipartisan leadership shown by Chairman Lautenberg and Ranking Member Inhofe to convene a process of stakeholders to explore how we can move this bill forward in a way that is truly bipartisan.

Let me say that while the details of many of the dialogs we are involved in are confidential, we have made substantial progress. In our dialog with CSPA, we are on the cusp of agreeing to recommendations for legislation to deal with the issues that Bob just mentioned: confidential business information and reporting of robust information on the use of chemicals.

Based on my deep involvement in these dialogs, I believe there is not a single issue that we cannot find the solution to. EDF and our Coalition would welcome the opportunity to share the bridging concepts we have identified, along with the companies with whom we have engaged.

We urge the Members of this Committee to act now to forge and advance bipartisan reform legislation in this Congress. It represents a once-in-a-generation opportunity to create a new chemical management system that sustains our health, our environment and our economy.

Thank you very much.

[The prepared statement of Mr. Denison follows:]



STATEMENT OF

RICHARD A. DENISON, Ph.D.
SENIOR SCIENTIST
ENVIRONMENTAL DEFENSE FUND

BEFORE
THE U.S SENATE

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

AT A LEGISLATIVE HEARING ON
S. 847, THE SAFE CHEMICALS ACT OF 2011

17 NOVEMBER 2011

I am testifying today on behalf of both the Environmental Defense Fund (EDF) and Safer Chemicals, Healthy Families, a coalition of over 300 organizations that speak for more than 11 million Americans. The coalition includes groups representing health professionals and health-affected populations and communities, environmental justice organizations, leading businesses, and state and national environmental groups – all of whom came together to urge Congress to fundamentally reform the Toxic Substances Control Act of 1976. A list of members of the coalition is attached to my written testimony.

THE PROBLEM

Over the past decade, a litany of serious concerns has emerged that calls into question the safety of the thousands of chemicals we use and encounter in our everyday lives:

- Lead has shown up in a host of children's products, imported and domestic, finally prompting Congress to impose a ban – only to see another toxic heavy metal, cadmium, immediately take its place, in a most deadly version of the kids' game "whack-a-mole."
- The science of biomonitoring has revealed that virtually all Americans, including newborns, carry in our bodies hundreds of toxic synthetic chemicals, many derived from everyday products – yet no one can tell us how they got there or what effects such a mixture of chemicals is having on our and our children's health, because they have not been adequately tested or assessed for safety.
- Persistent, bioaccumulative and toxic (PBT) chemicals that we were told we would never be exposed to – such as those used as flame retardants in furniture and TV casings, in stain-resistant coatings on textiles and food packaging, and as plastics additives – are now routinely detected in the dust in our homes, in our environment, in marine mammals, and even in people living in the remotest parts of the globe.
- Our scientific understanding of how chemicals affect our biology has grown dramatically over the last decade. We now know that the timing of exposures, especially during early development, is critical; that even very low doses of certain chemicals can have adverse effects; and that it is the cumulative effects of long- as well as short-term, real-world exposures to multiple chemicals that matter most.
- A large and growing body of scientific evidence¹ is linking chemical exposures to several serious chronic diseases and disorders that are becoming more prevalent, including:
 - leukemia, brain and other childhood cancers, which have increased more than 20% since 1975;
 - breast cancer, which went up by 40% from 1973 to 1998;
 - asthma, which almost doubled in prevalence from 1980 to 1995;
 - autism, diagnoses of which have increased 10-fold in the last 15 years; and
 - difficulty in conceiving and maintaining a pregnancy, which affected 40% more women in 2002 than in 1982.
- EPA is forced to perform Google searches to try to identify all uses of chemicals like the hormone-disrupting bisphenol A. That is because it lacks authority to ensure accurate

¹ Summarized in *The Health Case for Reforming the Toxic Substances Control Act*, 2010, available at <http://healthreport.saferchemicals.org/>.

reporting of chemical uses. And even though people are exposed to such chemicals from many different sources, EPA lacks a mandate to assess the aggregate risks.

- EPA cannot provide even a rough approximation of the actual number of chemicals in commerce today or how and where they are used. That is because EPA is severely constrained in collecting even the most basic information from companies that make and use chemicals. Many companies are not even required to notify EPA when they begin to produce a chemical or use it in a new way.
- 80% of all new chemical notices submitted to EPA include no health or environmental data. That is because the U.S. is virtually alone among all developed countries in not requiring a minimum data set to be submitted for new chemicals. While EPA can in theory require subsequent testing, the burdens are so high that it has done so for only a few percent of new chemicals.
- Residents in low-income communities of color like Mossville, Louisiana (which is surrounded by 14 chemical plants) are routinely exposed to deadly chemicals like dioxin, benzene and vinyl chloride in amounts that far exceed general population exposures. Yet such disproportionate impacts need not be accounted for when the government conducts risk assessments on such chemicals, and actions to reduce the exposures are few and far between.
- The public, state governments and even workers who may be directly exposed to chemicals are denied access to the great majority of chemical information that companies submit to EPA. That is because the companies have been given wide latitude to claim it as confidential, and EPA lacks resources to review the claims to determine if they are legitimate.

All of the problems I just described can be attributed, in whole or in part, to the failures of our country's main chemical safety law, the Toxic Substances Control Act (TSCA).

THE SOLUTION

All of these problems would be largely or entirely ameliorated by adoption of legislation introduced this year, S. 847, the Safe Chemicals Act of 2011. It provides the framework for a comprehensive, systematic solution to a set of problems that until now have only been addressed – if at all – through reactive, piecemeal actions.

EDF and the Safer Chemicals, Healthy Families coalition support S. 847 because it strikes the right balance: It fully protects human health and the environment (including the most vulnerable among us), while also encouraging and rewarding innovation toward safer chemicals and products; and it informs the chemicals marketplace as well as consumers and the public, while protecting legitimate confidential business information.

The Safe Chemicals Act would:

- promptly reduce exposure to the "worst of the worst" toxic chemicals, those that persist and build up in the food chain;
- ensure basic health and safety information is available for all chemicals as a condition for entering or remaining on the market;

- reduce the high burden of toxic chemical exposures on people of color and low-income and indigenous communities;
- upgrade methods used to test and evaluate chemical risks to reflect the best available science, based on recommendations of the National Academy of Sciences; and
- provide the tools and resources needed to identify and address those chemicals posing significant health and environmental concerns.

Attached to my written testimony is a more detailed description of the many ways in which the Safe Chemicals Act would make vitally important reforms to TSCA.

Since first introduced in 2010, the Act has incorporated many significant changes that reflect input from a broad range of stakeholders. Another attachment to my written testimony lists the many improvements made in the 2011 bill. Here are a few highlights of changes that both boost health protections and ease implementation and workability:

- An orderly process is set forth that categorizes chemicals into high-, some- and low-concern classes and directs those chemicals toward specific actions or to be set aside.
- Action is to be taken to immediately reduce exposure to chemicals of high concern – those that are persistent, bioaccumulative and toxic (PBT) to which people are exposed.
- Chemicals would be prioritized and for those requiring safety determinations, the pace of that activity would be matched to EPA's capacity and resources.
- Minimum information requirements would be tailored to different types or classes of chemicals, while still ensuring that basic safety information is provided in a timely manner for all chemicals.

THE OPPORTUNITY

At this moment, there is a truly remarkable consensus among the full range of stakeholders that Congress needs to reform the Toxic Substances Control Act. TSCA is not only failing to provide the health protections that Americans need and expect, it is also not providing industry with a stable environment in which to do business, nor its customers at home and abroad with confidence in the safety of its products.

We recognize a reformed TSCA must meet the needs of a diverse set of stakeholders, including the regulated community. That is why our coalition is directly engaging with a broad range of companies that produce, use, buy and sell chemicals and chemical products, to understand their perspectives and identify the best ways to deliver better information and critical health protections effectively and efficiently.

We have ongoing dialogues with the American Chemistry Council (ACC) and the Consumer Specialty Products Association (CSPA) and more than a dozen of their member companies; these have involved many days of substantive meetings on key issues in TSCA reform over the past six months. Eight members of our coalition traveled to the Headquarters of both The Dow Chemical Company and Procter & Gamble, meeting for two full days with each company to learn about their businesses and approaches to chemical safety, and to share perspectives on

TSCA reform. And we have met with dozens of other companies from all levels in the chemicals supply chain to understand their needs for information about chemicals in the products they make, buy and sell.

We have also been extremely encouraged by the leadership of Chairman Lautenberg and Ranking Member Inhofe in convening a series of meetings of key stakeholders to explore ways in which TSCA reform could be advanced in a bipartisan manner. Our coalition enthusiastically participated in all of those meetings.

All of these exchanges have convinced us that we have a huge opportunity to forge a legislative path forward that is truly bipartisan and meets the needs of both industry and the health and environmental communities. In our dialogues with industry, enormous progress has been made due to efforts made by both sides to gain a better understanding of each other's needs and perspectives, to narrow differences, and to find creative solutions that are both practical and effective.

While confidentiality agreements preclude me from discussing details, let me say that in our dialogue with CSPA we are on the cusp of agreement on recommendations to consider in the legislation that would address two key needs in TSCA reform: balancing public access to chemical information with the need to protect legitimate confidential business information; and designing a system to provide EPA with more robust information on how chemicals are used for purposes of both prioritizing and assessing the safety of chemicals.

I have come away from my deep involvement in these dialogues with the belief that there is not a single major issue in TSCA reform for which, working together, we cannot find a solution. EDF and the Safer Chemicals, Healthy Families coalition would welcome the opportunity to share these bridging concepts, along with companies with whom we have been engaged. We urge the members of the Committee to act on this major opportunity to forge and advance a legislative vehicle that is bipartisan.

Public opinion research consistently shows that Americans do not see this issue in partisan terms, and that, whatever their political persuasions, they want a system that gives them confidence that the products and materials they buy and use every day are safe for their families and their environment and good for business and the economy.

I strongly urge the Committee to advance TSCA reform legislation in this Congress. It represents a once-in-a-generation opportunity to create a chemicals management system that sustains our health, our environment, and our economy.

Thank you for the opportunity to testify today at this important legislative hearing.

MEMBERS OF THE SAFER CHEMICALS, HEALTHY FAMILIES COALITION

Public Health Organizations

Agent Orange Legacy - Children of Vietnam Veterans
 American Public Health Association - Public Health
 Nursing Section
 Asbestos Disease Awareness Organization
 Association of State and Territorial Directors of
 Nursing
 Bladder Cancer Advocacy Network
 Breast Cancer Action
 Breast Cancer Fund
 Citizens for Health
 Consumers Union
 The Endometriosis Association
 First Focus
 Institute for Agriculture and Trade Policy
 Lung Cancer Alliance
 Massachusetts Breast Cancer Coalition
 National Center for Environmental Health Strategies
 National Disease Clusters Alliance
 National Healthy Nail Salon Alliance
 National Pediculosis Association
 Partners in Healthy Communities
 Oregon Public Health Association
 Rachel's Friends Breast Cancer Coalition
 Women's Cancer Action
 Women's Community Cancer Project
 Women's Health & Environmental Network
 Women's Voices for the Earth

Health Care Providers/Research Institutions

Alliance of Nurses for Healthy Environments
 American Nurses Association
 Birth Defect Research for Children
 The CRS Institute
 Delaware Nurses Association
 DrGreene.com
 Health Care Without Harm
 Marine Environmental Research Institute
 Mount Sinai Children's Environmental Health Center
 National Medical Association
 Nurses for Global Health
 North Carolina Chapter of the American Academy of
 Pediatrics

Ohio Nurses Association
 Physicians for Social Responsibility
 Physicians for Social Responsibility - Austin
 Physicians for Social Responsibility - Chicago
 Physicians for Social Responsibility - Colorado
 Physicians for Social Responsibility - Greater Boston
 Physicians for Social Responsibility - Los Angeles
 Physicians for Social Responsibility - Maine
 Physicians for Social Responsibility - Oregon
 Physicians for Social Responsibility - Sacramento
 Physicians for Social Responsibility - San Francisco
 Bay Area
 Physicians for Social Responsibility - Tampa Bay
 Science & Environmental Health Network
 Washington Physicians for Social Responsibility
 Washington State Association of Occupational
 Health Nurses
 Washington State Nurses Association
 Yale School of Medicine, Environmental Health
 Group

Learning/Developmental Disabilities Organizations

American Association on Intellectual and
 Developmental Disabilities
 American Network of Community Options and
 Resources
 Association for Children's Mental Health
 The Arc of Massachusetts
 The Arc of the U.S.
 The Autism Society
 CHADD - Children and Adults with Attention
 Deficit/Hyperactivity Disorder
 Developmental Disabilities Nurses Association
 Institute of Neurotoxicology & Neurological
 Disorders
 Learning Disabilities Association of America
 Learning Disabilities Association of Maine
 Learning Disabilities Association of Michigan
 Learning Disabilities Association of Minnesota
 Learning Disabilities Association of New York State
 Minnesota Association for Children's Mental Health
 SafeMinds

National Environmental Organizations

American Bird Conservancy
 Center for Health, Environment & Justice
 Center for International Environmental Law
 Clean Water Action
 Commonweal
 Earthjustice
 Emerald Coastkeeper, Inc.
 Environmental Defense Fund
 Environmental Health Fund
 Environmental Law & Policy Center
 Grassroots Environmental Education
 Green America
 Greenguard Environmental Institute
 Greenpeace
 Jean-Michel Cousteau Ocean Futures Society
 League of Conservation Voters
 Natural Resources Defense Council
 North American Hazardous Materials Management Association
 Pesticide Action Network of North America
 Rachel's Network
 Sierra Club National Toxics Committee
 Teens Turning Green
 Union of Concerned Scientists
 US Public Interest Research Group

Environmental Justice Organizations

Advocates for Environmental Human Rights
 Air Alliance Houston (TX)
 Alaska Community Action on Toxics (AK)
 Black Women for Wellness
 BURNT (TN)
 Connecticut Coalition for Environmental Justice (CT)
 Don't Waste Arizona (AZ)
 The Earth Cause Organization (AR)
 Environmental Community Action Inc. (ECO-Action) (GA)
 Environmental Justice Action Group (AZ)
 Environmental Justice Advocates of Minnesota (MN)
 For a Better Bronx (NY)
 Galveston Baykeeper (TX)
 Indigenous Environmental Network (MN)
 Just Transition Alliance (CA)
 The JustGreen Partnership (NY)
 Kalpulli Izkalli

Kentucky Resources Council, Inc. (KY)
 REACT - Rubbertown Emergency ACTION (KY)
 Rural Coalition (DC)
 Safer Pest Control Project (IL)
 Southwest Worker's Union (TX)
 T.E.J.A.S. (Texas Environmental Justice Advocacy Services)
 UPROSE (United Puerto Rican Organization of Sunset Park) (NY)
 Voices for Earth Justice (MI)
 WE ACT for Environmental Justice (NY)

Mom Bloggers for Safer Chemicals

Alexandra Zissu at Alexandrazissu.com
 Anna Hackman at Green Talk
 Deanna Duke at Crunchy Chicken
 Diane MacEachern at Big Green Purse
 Donielle Baker at Natural Living Moms
 Jeanne Blaisdell at The Green Samaritan
 Kathy Scoleri at The Safe Mama
 Katy Farber at Non-Toxic Kids
 Linda Anderson at Citizen Green
 Lori Alper at Groovy Green Livin
 Sommer Poquette at Green & Clean Mom
 Tracy Himes at Verde Mom

Parent Organizations

EcoMom Alliance
 Growing Green Child Development Center
 Healthy Child Healthy World
 healthy-kids.info
 Holistic Moms Network
 Moms Rising
 Making Our Milk Safe
 National Green School Coalition
 Parents for Nontoxic Alternatives
 Styrofoam Out of School/Fund for City of New York

Reproductive Health Organizations

The American Fertility Association
 Asian Communities for Reproductive Justice
 Association of Reproductive Health Professionals
 National Asian Pacific American Women's Forum
 Physicians for Reproductive Health and Choice
 Planned Parenthood Federation of America
 Reproductive Health Technologies Project

State Advocacy and Community Organizations

Action for Children North Carolina (NC)
 Alaska Community Action on Toxics (AK)
 Allergy Kids Foundation (CO)
 Alliance for a Clean and Healthy Maine (ME)
 Alliance for a Clean and Healthy Vermont (VT)
 Alliance for Sustainability (MN)
 Anti Uranium Coalition (CO)
 Arkansas Community Organizations (AR)
 Basel Action Network (WA)
 Bay Area Healthy 880 Communities (CA)
 Berkshire Environmental Action Team (BEAT) (MA)
 Buckeye Environmental Network
 Butte Environmental Council (CA)
 California Healthy Nail Salon Collaborative (CA)
 Californians for Pesticide Reform (CA)
 Cancer Prevention Coalition Los Angeles
 Center for Environmental Health (CA)
 Chehalis River Council (WA)
 Citizens' Environmental Coalition (NY)
 Citizens for the Chuckwalla Valley (CA)
 Clean New York (NY)
 Coalition for a Safe & Healthy Connecticut (CT)
 Delawareans for Social and Economic Justice (DE)
 Duwamish River Cleanup Coalition (WA)
 Earth Ministry (WA)
 Earthology Institute (WI)
 Earthrose Institute (FL)
 East Michigan Environmental Action Council (MI)
 Ecology Center (MI)
 Environment California (CA)
 Environment Illinois (IL)
 Environment North Carolina (NC)
 Environmental Health Strategy Center (ME)
 Families Against Cancer & Toxics (AZ)
 Florida Public Interest Research Group (FL)
 Glynn Environmental Coalition (GA)
 Great Lakes United (NY)
 GreenCAPE (MA)
 Green Cleaning Network (IN)
 Healthy Legacy (MN)
 Hilltown Anti-Herbicide Coalition (MA)
 Huntington Breast Cancer Action Coalition, Inc. (NY)
 Indiana Toxics Action Project (IN)
 Kentucky Environmental Foundation (KY)
 Kids for Saving Earth (MN)
 LocalMotionGreen (MI)
 Lutheran Public Policy Office of Washington State (WA)
 Maine Association of Certified Professional Midwives (ME)
 Maine Children's Alliance (ME)
 Maine League of Conservation Voters (ME)
 Maine League of Young Voters (ME)
 Maine Organic Farmers and Gardeners Association (ME)
 Maine Parent Teacher Association (ME)
 Maine People's Alliance (ME)
 Maine Women's Lobby (ME)
 Mainely Girls (ME)
 Maryland Public Interest Research Group (MD)
 Massachusetts Breast Cancer Coalition
 Massachusetts Parent Teacher Association (PTA) (MA)
 Mercury Awareness Team of Washington (WA)
 Michigan Environmental Council (MI)
 Minnesota Center for Environmental Advocacy (MN)
 Minnesota Pesticide Awareness (MN)
 Minnesota Public Interest Research Group (MN)
 Natural Resources Council of Maine (ME)
 Neighbors for Clean Air (OR)
 New Jersey Environmental Federation
 New Jersey Environmental Justice Alliance
 New York City Environmental Justice Alliance (NY)
 New York Lawyers for the Public Interest (NY)
 North Carolina Conservation Network (NC)
 Northwest Coalition for Alternatives to Pesticides (OR)
 Ohio Conference on Fair Trade (OH)
 Ohio Environmental Council (OH)
 Ohioans for Health, Environment, and Justice (OH)
 Olympic Environmental Council (WA)
 Omaha Healthy Kids Alliance (NE)
 Oregon Center for Environmental Health (OR)
 Oregon Environmental Council (OR)
 Oregon Toxics Alliance (OR)
 PAWS (WA)
 Pesticide Watch Education Fund (CA)
 Preventing Harm Minnesota (MN)
 Project SafeYard (NC)
 Projects for Environmental Health, Knowledge, & Action, Inc. (NJ)

Rainier Audubon Society (WA)	Green Depot
Restaurant Opportunities Center of New York (NY)	Green Health Project TX
Restaurant Opportunities Centers United	Green Maid, Inc.
River Network (OR)	The Green Stork
Roman Catholic Diocese of Portland Maine (ME)	Greener Country
Safer States	Healthy Building Network
San Francisco Asthma Task Force	Healthy Family, Healthy World
Seattle Tilth (WA)	Healthy Planet Fundraising
Spokane Riverkeeper (WA)	Herban Lifestyle, LLC
Stephen Foster Neighborhood Protection Group (FL)	IceStone LLC
Sustainable Sudbury (MA)	Informed Green Solutions, Inc.
Take Back the Air (MN)	InTandem Integrative Therapies
Texas Campaign for the Environment (TX)	Jocelyn Anker
Texas Impact (TX)	Laro Baby
Toxic Free North Carolina (NC)	Maid Naturally
Toxics Action Center (ME)	Main Street Martial Arts
Washington Public Interest Research Group (WA)	Melaleuca - The Wellness Company
Washington Toxics Coalition (WA)	myEARTH360.com
Women for a Healthy Environment (PA)	My Online Trainer
Women's Environmental Institute (MN)	Naturepedic
Women's Lobby of Colorado (CO)	Navan Foods: The Allergy Free Food Shop
World Team Now (CA)	New Harmony
	Organic Valley
Businesses/Analysts	PioMu Kids & Toys
American Sustainable Business Council	Priscilla Woolworth
Babies 411 LLC	Q Collection
Buttercup Naturals LLC	Quality of Life
Catholic Healthcare West	Seventh Generation
Chez Sven Bed & Breakfast	Simply Toddler LLC
Citizenpip	Smart Green Media, LLC
Clean Production Action	Squishy Press
CleanWell Company	The Soft Landing, LLC
Creative Health Connections	Sound Earth
Dapple Baby	Stonyfield Farm
Debra Lynn Dadd	Subra
DNP Green Technology	SUST
Dream2Clean, Ltd.	Sustainable Party
DriftAwaySoap	Sustain LA
Duck Duck Green	Sustainability Associates
Ely Organics	Texas Green Clean
Fezal Naturally, LLC	Toxic Baby
Fire Belly Lawn Care	Toxic Justice
Grace Naturals	Wise Solutions, Inc.
green age	Zoe Organics

**How the Safe Chemicals Act of 2011 (S. 847)
would fix the major flaws of the Toxic Substances Control Act (TSCA)**

Prepared by Richard A. Denison, Ph.D., Senior Scientist, Environmental Defense Fund

Currently under TSCA	Under the Safe Chemicals Act of 2011 (S. 847)
SAFETY DATA	
Few data call-ins are issued, even fewer chemicals are required to be tested and no minimum data set is required even for new chemicals.	Up-front data call-ins for all chemicals would be required. Minimum data sets (MDSs) on all new and existing chemicals sufficient to determine safety would be required to be developed and made public.
BURDEN OF PROOF	
EPA is required to prove harm before it can regulate a chemical.	Industry would bear the legal burden of proving their chemicals are safe.
ASSESSMENT OF SAFETY	
No mandate exists to assess the safety of existing chemicals. New chemicals undergo a severely time-limited and highly data-constrained review.	Both new and existing chemicals would generally be subject to safety determinations as a condition of entering or remaining on the market, using the best available science that relies on the advice of the National Academy of Sciences. Chemicals designated by EPA to be intrinsically safe would not require assessment or further action unless new information altered their designation.
SCOPE OF ASSESSMENT	
Where the rare chemical assessment is undertaken, there is no requirement to assess exposure to all sources of exposure to a chemical, or to assess risk to vulnerable populations. No guidance is provided on how to determine whether a chemical presents an "unreasonable risk."	The safety standard would require EPA to account for aggregate exposures to all uses and sources of a chemical, and to ensure protection of vulnerable populations that may be especially susceptible to chemical effects (e.g., children, the developing fetus) or subject to disproportionately high exposure (e.g., low-income communities living near contaminated sites or chemical production facilities).
CHEMICALS AND EXPOSURES OF HIGH CONCERN	
No criteria are provided for EPA to use to identify and prioritize chemicals or exposures of greatest concern, leaving such decisions to case-by-case judgments.	EPA would be required to develop and apply criteria to identify toxic chemicals to which people are exposed that persist and build up in the environment and people (PBTs). "Hot spots" where people are subject to disproportionately high exposures would be specifically identified and addressed.

Currently under TSCA	Under the Safe Chemicals Act of 2011 (S. 847)
REGULATORY ACTION	
Even chemicals of highest concern, such as asbestos, have not been able to be regulated under TSCA's "unreasonable risk" cost-benefit standard. Instead, assessments often drag on indefinitely without conclusion or decision.	PBTs to which people are exposed would be moved directly to mandatory exposure reduction. The remaining chemicals would be prioritized for assessment against a health-based standard, and deadlines for decisions would be specified. EPA would have authority to restrict production and use or place conditions on any stage of the lifecycle of a chemical needed to ensure safety.
INFORMATION ACCESS	
Companies are free to claim, often without providing any justification, most information they submit to EPA to be confidential business information (CBI), denying access to the public and even to state and local governments. EPA is not required to review such claims, and the claims never expire.	All CBI claims would have to be justified up front. EPA would be required to review them, and only approved claims would stand. Approved claims would expire after no more than five years, except for types of claims for which EPA determines the five-year term would not apply. Other levels of government would have access to CBI.
RULEMAKING REQUIREMENTS	
To require testing or take other actions, EPA must promulgate regulations that take many years and resources to develop. EPA must show potential for a chemical to cause harm in order to require testing, a <i>Catch-22</i> .	In addition to the MDS requirement, EPA would have authority to issue an order rather than a regulation to require reporting of existing data or additional testing, and need not first show evidence of harm.

Summary of Changes in the Safe Chemicals Act of 2011 vs. 2010

Prepared by Richard A. Denison, Ph.D., Senior Scientist, Environmental Defense Fund

2010 bill	2011 bill (S. 847)
Sec. 3: Definitions	
Defines "adverse effect."	Defers definition of this term to EPA.
Defines "aggregate exposure" to include certain non-TSCA uses of chemicals.	Clarifies that exposures arising from TSCA as well as non-TSCA uses are to be considered in assessing "aggregate exposures."
Defines "bioaccumulative" based on EPA's limited PBT criteria developed in 1999 for the New Chemicals Program.	Defines "bioaccumulative" to provide for consideration of monitoring and other types of data indicating actual or potential accumulation of a chemical in people or other organisms.
Defines "cumulative exposure" to include chemicals associated with "an adverse effect."	Clarifies that cumulative exposures are from multiple chemicals that relate to "the same or similar adverse effect."
Defines "persistent" based on EPA's limited PBT criteria developed in 1999 for the New Chemicals Program.	Defines "persistent" to provide for consideration of monitoring and other types of data indicating actual or potential persistence of a chemical in various environmental media.
Defines "reasonable certainty of no harm" to require assessment of both aggregate and cumulative exposures.	Establishes (in Sec. 6) that the safety standard is to be based "solely on considerations of human health and the environment, including the health of vulnerable human populations." Clarifies that cumulative exposures are to be considered only "to the extent practicable" and where information is available that allows such consideration.
Sec. 4: Minimum data sets and testing of chemical substances	
"The rule may provide for varied or tiered testing for different chemical substances, mixtures or categories of chemical substances and mixtures."	<p>"May" is changed to "shall" and minimum data sets (plural) are to be developed, to clarify that the minimum information required may differ among different types or classes of chemicals.</p> <p>MDSs must provide sufficient "information necessary for the Administrator to conduct a screening-level risk-assessment."</p> <p>MDS development is to "encourage and facilitate the use of alternative testing methods and testing strategies to generate information quickly, at low cost, and without the use of animal-based testing, including toxicity pathway-based risk assessment, in vitro studies, systems biology, computational toxicology, bioinformatics, and high-throughput screening."</p>

2010 bill	2011 bill (S. 847)
Minimum data sets [MDSs] are due within 18 months after prioritization for existing chemicals, and at the time of filing notification for new chemicals.	MDSs are due within the earlier of 18 months of assignment to a priority class (see Sec. 6 below) or 5 years of enactment, for existing chemicals; and at the time of filing notifications, for new chemicals.
Sec. 6: Prioritization, safety standard determination, and risk management	
Chemicals are to be prioritized for safety determinations, based on production volume, use, hazard and exposure. [Categorization is provided for in Sec. 8 but is not tied to other actions.]	Chemicals are to be categorized as: <ul style="list-style-type: none"> • Priority Class 1: Chemicals requiring immediate risk management (PBTs with potential for widespread exposure; list to include 20-30 such PBTs); • Priority Class 2: Chemicals requiring safety determinations (chemicals for which there is "more than a theoretical concern" as to whether the chemical would meet the safety standard); or • Priority Class 3: Chemicals requiring no immediate action (chemicals with inherent properties indicating no risk based on robust data).
A priority list of not less than 300 chemicals is to be established as the basis for the order in which safety determinations are to be conducted. [Sec. 29, Expedited action on chemicals of highest concern, is limited to a single sentence: "The Administrator shall act quickly to manage risks from chemical substances that clearly pose the highest risks to human health or the environment."]	<ul style="list-style-type: none"> • Priority Class 1 chemicals would be subject to conditions EPA deems needed "to achieve the greatest practicable reductions in human or environmental exposure." A safety determination for remaining sources of exposure would subsequently be conducted. • Priority Class 2 chemicals would be prioritized for safety determinations. The number of substances assigned to this class at a given time would be based on EPA's capacity to expeditiously conduct safety determinations. • Priority Class 3 chemicals could be subject to a safety determination if new information is developed that calls into question or changes their categorization.
Burden of proof (BOP) is not separately delineated from duties of companies and EPA.	A clear statement that industry bears the legal BOP, and a separate clear statement of industry's duty to provide information sufficient to determine safety, and EPA's duty to make safety determinations, are provided.
In making safety determinations, EPA is to "consider" recommendations of the National Academy of Sciences (NAS).	EPA is to base determinations on the best science, which in turn is to be based on "the recommendations of the National Academy of Sciences in the report

<i>2010 bill</i>	<i>2011 bill (S. 847)</i>
	entitled 'Science and Decisions'." EPA's methodology for determinations is to be reviewed no less than every 5 years and revised "to reflect new scientific developments or understandings."
Sec. 14: Disclosure of data	
Sharing of confidential business information (CBI) with state governments would be subject to any applicable agreements to maintain confidentiality.	Clarifies that CBI may only be shared where an agreement is in place to ensure the information is kept confidential.
All CBI claims would be subject to a five-year expiration.	EPA would be required to designate types of information for which the five-year term would not apply.
	A new provision is added clarifying that nothing in this section limits EPA's authority to determine that particular information, previously considered entitled to CBI protection, is no longer so entitled.
Sec. 18: Preemption	
Actions taken under TSCA would not preempt State laws that are <u>more stringent than</u> TSCA.	Actions taken under TSCA do not affect the right of a State to adopt requirements or standards that are <u>different from or in addition to</u> those under TSCA, unless compliance with both the TSCA and the State requirement or standard is impossible.
Generally applicable provisions	
EPA may prohibit production/use of a chemical in case of a violation of a requirement under the Act. (<i>appears in several sections</i>)	EPA may impose any condition listed under section 6(c) in case of a violation under the Act. (<i>replacement made in those same sections</i>)
Retains references throughout current TSCA to EPA's authority to require testing, reporting or regulation of mixtures.	Consolidates references to mixtures (in Sec. 26) and clarifies that "any action authorized or required to be taken by the Administrator or any other person under any provision of this Act with respect to a chemical substance is likewise also authorized or required with respect to a mixture, if the Administrator determines that such extension is reasonable and efficient."

**Environment and Public Works Committee Hearing
November 17, 2011
Follow-Up Questions for Written Submission**

Responses prepared by
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Submitted in January 2012

Questions from:

Senator Barbara Boxer

1. *Mr. Denison, S. 847 prioritizes actions to address threats to chemicals that persist in the environment, can accumulate in people's bodies, are toxic and that people are exposed to in their everyday lives.*

Could you describe the public health need for focusing on these types of dangerous chemicals?

RESPONSE: Urgent attention is needed to address the class of chemicals known as Persistent, Bioaccumulative, and Toxic Chemicals, or PBTs. This class includes many of the most notorious chemicals ever studied – chemicals such as dioxins, mercury, lead, cadmium and polychlorinated biphenyls (PCBs), the dangers of which we have known for some time, as well as relative newcomers such as polybrominated diphenyl ethers (PBDEs) widely used as flame retardants and a variety of perfluorinated chemicals (PFCs) used to impart stain or moisture resistance to textiles and paper packaging or to produce nonstick cookware.

PBTs are uniquely dangerous because they pose a triple threat. They persist in the environment for long periods of time and can be transported long distances; they accumulate in living organisms and increase in concentration as they move up the food chain; and, they are highly toxic, often at very low levels of exposure.

Because they exhibit all three of these hazardous properties, PBTs are inherently unsafe. And because releases of even small amounts of PBTs will eventually lead them to build up to very high levels and in locations often far removed from their point of use or release, traditional risk assessment methods cannot be used to effectively support regulatory action on PBTs. Because risk assessments require a quantification of exposure levels, they cannot adequately evaluate the harm posed by PBTs, the levels of which will continue to rise in people or other organisms, even after the contaminant ceases being released into the environment.

The special nature of the risks posed by PBTs has been noted by EPA: “These PBT chemicals are of particular concern not only because they are toxic but also because they remain in the environment for long periods of time, are not readily destroyed, and build up or accumulate in body tissue. Relatively small releases of PBT chemicals can pose human and environmental health threats.”¹

S. 847 appropriately requires evidence of actual or potential exposure to a PBT as a basis for its identification and targeting for expedited action to reduce exposure; this avoids targeting PBT chemicals to which there is no likelihood of exposure. S. 847 also appropriately provides for time-limited,

¹ Environmental Protection Agency, “Fact Sheet on EPCRA Section 313 Rulemaking: Persistent Bioaccumulative Toxic Chemicals.” (www.epa.gov/tri/lawsandregs/pbt/pbtrule-fs.pdf)

renewable exemptions for specific uses of targeted PBTs that serve critical or essential uses for which there are not available alternatives or which provide net health, environmental or safety benefits relative to available alternatives. Even for such exempted uses, S. 847 requires disclosure of such uses so that consumers and the public are aware of and can act to protect themselves from exposures to such chemicals.

Can you also describe your views on S. 847's process for prioritizing the assessment of chemicals?

RESPONSE: The prioritization process in S. 847 represents a substantial improvement over that in earlier versions of the bill by providing an orderly, transparent procedure EPA is to use to place chemicals in different priority classes for which different subsequent actions are prescribed. Among the changes are the ability for EPA to identify chemicals of very low concern where sufficient data exist to do so – which is responsive to industry concerns that some chemicals can be set aside based on existing information and need not be subject to any further action unless new warranting information arises.

S. 847 also ensures that the pace of safety determinations for chemicals that EPA determines require them is set so as to match available EPA resources, and the order of conduct of such determinations is prioritized based on relative risk. These provisions are also responsive to concerns of industry as well as other stakeholders that EPA be able to efficiently and effectively assess chemicals for which safety determinations are needed, and use risk as the basis for deciding which chemicals most need safety determinations.

2. *Mr. Denison, S. 847 tiers the amount of information that industry must be provided on the safety of chemicals in order to demonstrate that the chemical is in fact safe.*

Could you please describe the benefits of this type of tiered information requirement and the importance of ensuring that adequate information is provided on all chemicals to ensure that they are safe?

RESPONSE: A major deficiency in TSCA has been that it has failed to generate the health and environmental information needed for EPA, the market and the public to make well-informed decisions on chemicals, even those in widespread use. Legal and procedural barriers have severely constrained EPA's authority and practical ability to require adequate testing of chemicals, both those already on the market and new chemicals prior to their market entry. (The U.S. is virtually the only developed country in the world that does not require a minimum set of safety information to be provided on a new chemical as a condition for entering the market.)

Hence, a requirement that such information be developed for all chemicals by their manufacturers is a critical need for TSCA reform. Indeed, the stated policy established under the language of TSCA itself in 1976, unfortunately not realized, states just that:

*"It is the policy of the United States that adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such data should be the responsibility of those who manufacture and those who process such chemical substances and mixtures."*²

² TSCA §2(b)(1). Emphasis added.

In implementing that policy, however, it should be recognized that not all chemicals require the same level or extent of information to determine their safety. For example, information needed to show the safety of a chemical used solely in industrial settings as an intermediate to make other chemicals is likely to be less than that needed for a chemical used in a widely sold, dispersive consumer product such as a household cleaner. For this reason, S. 847 appropriately mandates that EPA develop tiered information requirements for different chemicals and groups of chemicals.

Another significant departure of S. 847 from a “one-size-fits-all” approach is that it provides for various types of information to be used to meet information requirements, as long as such information is scientifically reliable and sufficient to effectively screen chemicals for safety. The allowable information types extend well beyond traditional test methods to include “the use of alternative testing methods and testing strategies to generate information quickly, at low cost, and without the use of animal-based testing, including toxicity pathway-based risk assessment, in vitro studies, systems biology, computational toxicology, bioinformatics, and high-throughput screening.”

3. *Mr. Denison, S. 847 references a National Academy of Sciences report, “Science and Decisions,” to establish the best currently available science for determining the risks from chemicals.*

Can you please describe the benefits of using the methods presented in this report and the strength of S. 847’s overall approach to assessing a chemical’s risks, compared to the way such risks are currently assessed under TSCA?

RESPONSE: The primary means by which chemical risks are to be judged under S. 847 is through risk assessment – a key demand of industry. Traditional risk assessments have often fallen short of protecting public health and have sometimes taken decades to identify a “safe” level to certain chemicals. As a result, public and community confidence in risk assessment is very low. There are also major technical deficiencies in current risk assessment methodologies that must be addressed if it is to serve as a credible basis for determining chemical risks. For example, we now know that there are many chemicals for which any level of exposure poses some risk, yet traditional risk assessment assumes a safe level exists for nearly all chemicals.

S. 847 therefore includes provisions to ensure that EPA’s use of risk assessment incorporates the best available science, initially by being required to rely on the recent recommendations of the nation’s foremost scientific body, the National Academy of Sciences, as to how EPA can improve its practice of risk assessment. The recommendations, many of which are already being implemented by EPA and other federal agencies, are critical to restoring the credibility of and public confidence in risk assessment.

A key recommendation of the NAS is to reverse the common practice used by EPA of assuming that there is a level of exposure to a chemical below which there is no risk. Science tells us that many chemicals have effects even at very low doses; moreover, even where such a “threshold” may be seen for a chemical in a highly controlled study of genetically homogeneous laboratory animals, the extent of variability in the human population as a whole effectively erases such a threshold. Hence NAS recommends that only if EPA has strong affirmative evidence for a threshold in the human population should it assume there is a wholly “safe” level of exposure. A second key recommendation is that EPA needs to assess risk so as to ensure protection of vulnerable populations, including developing fetuses and children that are typically more susceptible to the effects of chemical exposures. Third, EPA needs to assess “aggregate” exposures to a chemical, accounting for the often multiple sources of exposure to a given chemical. Finally, where science allows, EPA risk assessments would need to identify groups of chemicals to which people may be exposed that act similarly or produce the same or similar health effects, and assess the “cumulative” exposures to all of those chemicals.

Senator Tom Carper

1. *What do you believe is the biggest outstanding issue that the environmental and public health communities, the chemical industry, and others engaged in efforts to reform the Toxic Substances Control Act need to come closer together on in order to further strengthen the Safe Chemicals Act and gain even more support for reforming our country's chemical safety laws?*

RESPONSE: Recent dialogues among stakeholders has significantly narrowed substantive differences and identified considerable common ground, to the point where I was able to state in my written testimony that I believe there is not a single major issue in TSCA reform for which, working together, we cannot find a solution.

The most difficult issue in my view is how to ensure the safety of new chemicals before they become ensconced in our economy, but do so in a manner that does not overly impede the ability of American industry to innovate and meet market demands. Even here, I think an appropriate balance can be struck by tailoring initial data and assessment requirements applicable to most new chemicals to reflect their likely limited initial production and use, and providing an effective means whereby those requirements can be increased as such a chemical's production and use expands.

I must say I also believe that policies that place too much emphasis on speed-to-market considerations and the like are short-sighted and risk putting U.S. industry at a competitive disadvantage by failing to ensure they will be able to meet what is arguably the primary market driver for innovation today: demonstrated health and environmental safety and sustainability. Any consideration of arguments about innovation and competitiveness needs to be viewed from this starting point: All too often, a chemical's safety has been at best a tangential consideration. A major goal of TSCA reform should be to ensure that *innovation toward safety* is an integral part of how chemicals are produced and used in this country. That necessarily means imposing some data and safety assessment requirements on new chemicals, *before* they are so embedded in our economy that the costs to industry, consumers and society to dislodge them are so high.

I have written extensively on this topic; see, for example, "Raising the bar for chemical safety will spur, not stifle, innovation."³

2. *Over the last several years, Europe, Canada, Australia, Korea, China, and other countries have undertaken reforms of their nations' chemical safety laws. What can we learn from these countries' efforts to improve the safe use of chemicals? How can these lessons inform the work of the Senate Committee on Environment and Public Works in proceeding with the Safe Chemicals Act?*

RESPONSE: The scope of this question is huge, so I will provide a very brief response and provide some references for more information. The bottom-line lesson to be learned from the efforts of other countries is that they have acted to address a problem that we are not acting to address, and hence they are well ahead of us in moving their chemical and related industries toward a more sustainable footing in today's global economy.

Another observation is that the policies of these nations have a great deal in common and seek to address the very same problems that have plagued chemical safety efforts in the U.S. under TSCA: the lack of

³ Available at <http://blogs.edf.org/nanotechnology/2010/05/09/raising-the-bar-for-chemical-safety-will-spur-not-stifle-innovation/>.

sufficient information on both new and existing chemicals, which impedes prioritization and identification of chemicals of concern; the slow pace of assessment of existing chemicals; the need to provide greater access to information within chemical supply chains, in the marketplace and to the broader public; and the need to ensure sufficient governmental authority to efficiently and expeditiously identify and restrict production and use of the most dangerous chemicals.

Finally, most of these policies mirror all or substantial parts of the European Union's REACH Regulation, which is increasingly becoming a de facto global standard. Much of the chemical industry is already complying and learning to live with REACH. While REACH is not perfect and it is only at the early stages of implementation, it can and must serve as a critical reference point for TSCA reform.

For more information, see:

- my 2007 report, *Not That Innocent*, comparing in detail the chemicals policies of the U.S., Canada and the European Union;⁴
- my 2009 paper, published in *Environmental Law Reporter*, titled "Ten Essential Elements in TSCA Reform;"⁵ and
- our numerous analyses of policy developments in other countries, posted on our Chemicals and Nanomaterials blog.⁶

3. *In reforming the Toxic Substances Control Act, how do you think Congress can strike the right balance between ensuring that the public has adequate information related to the safety of chemicals and chemical products and ensuring that American companies are not required to submit public information to the Environmental Protection Agency that might put them at a competitive disadvantage in a global market? Do you think the Safe Chemicals Act in its current form strikes this balance? How might the bill be improved to ensure that the confidential business information of U.S. companies is sufficiently protected so that the U.S. maintains its position as an innovator and job-creator in the chemical industry?*

RESPONSE: There is clearly a need to balance the legitimate claims of companies to protect certain confidential business information (CBI) from public disclosure with the legitimate need for the market, consumers and the public to have access to information they need to make sound decisions about chemicals that are in commerce. Unfortunately, TSCA's provisions and their implementation by EPA have skewed this balance radically in the direction of denying the public's right to know and creating an ill-informed chemicals marketplace.

The core problem is two-fold, constituting a vicious circle: Too many CBI claims are made, and each of the infrequent examinations of such claims done by EPA has found a large fraction to be illegitimate, i.e., not meeting the well-established criteria for what constitutes a legitimate trade secret. And because of the large number of claims made, EPA has lost the ability to review claims to ensure they are in fact legitimate and remain so over time; this lack of review has led directly to more claims being made, thereby completing the vicious circle.

Under TSCA companies are free to claim, often without providing any justification, most information they submit to EPA to be CBI, denying access to the public and even to state and local governments.

⁴ Available at <http://www.environmentaldefense.org/article.cfm?contentid=6147>.

⁵ Available at http://www.edf.org/documents/9279_Denison_10_Elements_TSCA_Reform.pdf.

⁶ See <http://blogs.edf.org/nanotechnology/category/reach/>.

Even the identity of chemicals that are the subject of health and safety studies – which TSCA expressly forbids from being claimed CBI except in very limited circumstances – has been routinely masked under policies in place at EPA until recently. CBI claims remain in place until and unless challenged by EPA, yet EPA is not required to review the claims, and they never expire.

S. 847 would go far to restore the right balance. All CBI claims would have to be justified up front. EPA would be required to review them, and only approved claims would stand. Approved claims would expire after no more than five years, except for types of claims for which EPA determines the five-year term would not apply. Other levels of government would have access to CBI.

Many in industry have acknowledged the need for substantial reform of TSCA's policies toward information disclosure. There is widespread agreement, for example, on the need for up-front substantiation both to reduce the number of claims asserted and better ensure the legitimacy of those claims that are made.

One key to striking the right balance is to recognize that it is often information that links a specific chemical to a specific company or product that is most sensitive. Many disclosures, for example of a health and safety study on a chemical which in my view is information for which the public has a right to know, can be done in a manner that does not disclose such linkages and hence avoids the concern.

The most difficult area is with new chemicals, where companies understandably have a greater need to protect the identity of the chemicals in which they've invested. Here, I think a viable approach may be to provide a time-limited allowance for some types of protections on information concerning new chemicals, but with clear exceptions made for such chemicals where a potential hazard has been identified.

One specific improvement to S. 847 would be to amend the provision limiting CBI claims to a single five-year period, to allow such claims to be extended upon a showing by the claimant that the conditions for granting CBI status in the first place remain. Another would be to specify up front certain types of information that are always eligible for CBI protection, such as a company's list of customers or detailed information about the precise process it uses to make a chemical.

Senator James Inhofe

1. *Dr. Denison, in your view, what kind of additional resources would EPA require in order to implement S. 847 in a way that is sufficiently protective while not compromising speed to market or industry's innovative abilities?*

RESPONSE: The key kinds of additional resources needed include expanded and more modern information technology capabilities to manage and share information received from industry and other stakeholders; and increased staff resources to develop implementing regulations, policies and procedures, to ensure efficient processing of received information, to conduct safety determinations, and to review claims for protection of confidential business information claims.

One of the key drivers for the chemical industry in wanting TSCA reform is to ensure that EPA has the ability to assess the safety of their chemicals, and where they are found to be safe, vouch for their safety so as to restore market and public confidence. That is why many companies support measures, and have expressed a willingness to provide resources themselves, to ensure EPA has sufficient resources and authority to get the information it needs, make decisions and take needed actions as efficiently as possible.

ACC's principles for TSCA modernization, in particular #s 3 and 9, encompass these points:

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*.
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.⁷

Given the extremely limited extent of activity that has taken place under TSCA over the past several decades, and the enormity of the task of addressing the tens of thousands of chemicals that were grandfathered in under TSCA that have not been adequately tested or assessed for safety, a substantial increase in resources will be needed. That in my view is in everyone's interest, given how vital it is to both our economy and our health that the public, consumers, the domestic market, our trading partners and the global market all have confidence in the safety of the products of the U.S. chemical industry and related industries.

2. *What has been the effect of EPA's Chemical Data Reporting Rule on the level of information on chemicals available to the agency?*

RESPONSE: The short answer is that it is too early to tell, because the rule was only finalized late last year, the first reporting cycle will start in February of this year (with data not available until the second half of the year at the earliest), and many of the key enhancements will not be introduced until the next cycle of reporting that doesn't occur until 2016.

EDF strongly supports the enhancements made in the CDR, although we are disappointed that their full implementation will not be realized for an additional four years. The CDR goes far to address a key

⁷ See <http://www.americanchemistry.com/tscapprinciples>; emphases added.

deficiency in the Inventory Update Reporting Rule (IUR) it replaced: The infrequent reporting (once every five years) of only a single year's manufacturing data. Both EPA and our own analyses of data from past IUR reporting cycles demonstrates that, because of major year-to-year fluctuations in chemical production and import, such infrequent reporting has led to a highly inaccurate picture of what chemicals are actually in U.S. commerce and in what quantities. Unfortunately, we will have to wait until late 2016 to get annual production data because implementation of that feature of the CDR was delayed until then.

Another key improvement in the CDR is to require reporting of available information on chemical use for a larger number of chemicals than was the case under the IUR. Especially in a risk-based system for assessing chemical safety, good use information is essential to predicting exposure, and the lack of such information has been an Achilles heel of TSCA.

Unfortunately, a key deficiency of the IUR was retained in the CDR: The restriction of reporting obligations only to those chemicals produced at 25,000 pounds or more per year per site. Evidence indicates that the use of such a high threshold means that many, likely a significant majority of, chemicals actually in commerce will not be required to be reported and hence that EPA, the public and the market will not have any access to needed information on them. When EPA raised the IUR threshold from 10,000 to 25,000 pounds per year per site a number of years ago, the number of organic chemicals reported fell by about two-thirds. In comparison, the thresholds for reporting information under REACH and other global chemicals management systems are much lower, approximately 2,200 pounds per year.

Another deficiency is the lack of any requirement under the CDR for companies to promptly report significant changes in the production or use of a chemical, changes that could dramatically affect exposure and risk.

By requiring declarations for all chemicals produced, S. 847 would go a significant way to address these deficiencies and ensure that, at the outset, EPA is able to get a full picture of chemicals in commerce, and better prioritize those chemicals and the resources it needs to devote to assessment of their safety. And by calling on companies to promptly inform EPA of major changes in a chemical's production or use, S. 847 would ensure EPA has a current picture and is able to adjust the priority of a chemical, whether up or down, to reflect its actual production or use.

3. *We have heard from multiple witnesses in numerous TSCA hearings before the committee that EPA's New Chemicals program is working effectively and not in need of any major overhaul. If EPA had a greater ability to review existing chemicals that were grandfathered into the inventory or after they went through the PMN process, do you feel EPA could still appropriately work within the current framework of the new chemicals program?*

RESPONSE: I would agree only that EPA's new chemicals program works better than its existing chemicals program, because TSCA gave EPA the authority and mandate to review such chemicals prior to their market entry.

I do not believe that EPA receives adequate health and safety data to conduct a safety assessment of new chemicals that is robust and protective of health and the environment. EPA lacks adequate authority to do so under TSCA, and the compensatory approaches it has developed, while in many ways representing a valiant effort driven by necessity, are insufficient, especially with respect to predicting impacts on human health and long-term impacts on both human health and the environment.

I will note all of the following deficiencies in EPA's new chemicals program, about which I have written in detail.⁸

- **No data, no problem:** No up-front testing requirement or minimum data set applies to new chemicals, in contrast to the requirements of virtually every other developed country in the world.
- **Guessing game:** EPA is forced to heavily rely on limited models and methods to predict the toxicity or behavior of a new chemical.
- **Catch-22:** While EPA can require testing of a new chemical on a case-by-case basis, it must first show the chemical may pose a risk - not an easy task without any data in the first place!
- **One bite at the apple:** EPA typically gets only a single opportunity to review a new chemical.
- **Crystal-ball gazing:** EPA has to try to anticipate a new chemical's for-all-time future production and use.
- **Black box:** New chemical reviews lack transparency.
- **Anti-precaution:** In deciding whether to require testing or controls for a new chemical, EPA equates lack of evidence of harm with evidence of no harm, largely owing to its limited authority under TSCA.

Many of these same conclusions have been drawn by both the Government Accountability Office⁹ and the EPA's Office of Inspector General.¹⁰

4. *Do you think that screening level testing is appropriate for new chemicals or should all new chemicals be required to go through a safety standard determination?*

RESPONSE: I think that the bar for data requirements and for assessing a new chemical does not necessarily need to be set as high as for an existing chemical, depending of course on its level and nature of production and use. I think an appropriate balance can be struck by tailoring initial data and assessment requirements applicable to most new chemicals to reflect their likely limited initial production and use, and providing an effective means whereby those requirements can be increased as such a chemical's production and use expands.

5. *Would you agree that most if not all safety standard determinations will require more information than simply a "minimum data set"?*

RESPONSE: I think it will depend to some extent on the level of assessment EPA decides is needed to inform the safety determinations for particular chemicals or groups of chemicals. S. 847 specifies that the various minimum data sets EPA is to develop are to "include the minimum amount of information necessary for the Administrator to conduct a screening-level risk-assessment of the chemical substance or category of chemical substances" (Sec. 4(a)(1)(B)(iii)). Certain chemicals – such as those used only in relatively closed industrial settings – may require no more than a screening-level risk assessment to serve as the basis for their safety determinations, in which case the applicable minimum data set should suffice.

⁸ See my extensive analysis included in a blog post on EDF's *Chemicals & Nanomaterials* blog: <http://blogs.edf.org/nanotechnology/2009/04/16/epas-new-chemicals-program-tsca-dealt-epa-a-very-poor-hand/>.

⁹ See Government Accountability Office, Report GAO-05-458, *Chemical Regulation—Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program*, 2005, p. 5, available at www.gao.gov/new.items/d061032t.pdf.

¹⁰ See USEPA Office of Inspector General, "EPA Needs a Coordinated Plan to Oversee Its Toxic Substances Control Act Responsibilities," Report No. 10-P-0066, February 17, 2010, available online at <http://www.epa.gov/oig/reports/2010/20100217-10-P-0066.pdf>.

My expectation and desire would be that EPA establishes minimum data sets for specific types or groups of chemicals that it expects will be sufficient to conduct safety determinations; that approach will be more efficient and provide a more predictable business climate in which companies can operate with clear expectations of what data they will be required to provide. Nonetheless, there will be circumstances where closer examination of a chemical will lead EPA to conclude more data are needed; in those cases, EPA needs to have authority it can readily apply to get the additional data it needs for the safety determination.

6. *The National Academy of Sciences Report, "Toxicity Testing in the 21st Century," discussed methods of evaluating chemicals including in vitro testing and computational toxicology. Do you think this legislation pays enough attention to using these rapidly emerging and effective tools?*

RESPONSE: I do think S. 847 sufficiently provides for and encourages use of such methods. A requirement EPA must meet in establishing minimum data sets is to "encourage and facilitate the use of alternative testing methods and testing strategies to generate information quickly, at low cost, and without the use of animal-based testing, including toxicity pathway-based risk assessment, in vitro studies, systems biology, computational toxicology, bioinformatics, and high-throughput screening" (Sec. 4(a)(1)(B)(iv)). These are precisely the types of methods described in the NAS report to which your question refers.

Moreover, an entire section of the bill (Section 30) is specifically designed to spur the use of such tools where they provide information of sufficient scientific quality.

It is important to note that the approaches identified by the NAS are for the most part still under development, and that report notes it will take many years and a major increased research investment to realize its vision of a new toxicology that largely or exclusively relies on such approaches.

I am optimistic about the potential capabilities of emerging methods in understanding the effects of chemicals. They offer a number of potential benefits: They are efficient; geared toward understanding the biological activities of chemicals at a mechanistic level; potentially allow for the testing of chemicals in different cell types and over a wide range of doses; offer an innovative potential approach for evaluating the effect of a chemical at early stages of development; and may have particular relevance to humans because of the ability to use human cell cultures and human enzymes in the assays. Additionally, new assays may aid in understanding and evaluating the effects of chemical mixtures.

However, there are also cautions at present concerning the accuracy of the new methods at this early stage. First, the current battery of tests only targets a subset of adverse effects on biological pathways, and hence will not assess the full range of potential adverse effects. Second, most HTS assays lack the ability to generate – and therefore assess the toxicity of – potential metabolites of chemical substances. Third, these assays typically use immortalized cell lines and consequently may give results that are not truly reflective of cellular behaviors in living organisms. Fourth, the potential for false positives and false negatives is worrisome and raises concerns for all stakeholders. Fifth, there are challenges in extrapolation between outcomes observed *in vitro* and *in vivo*.

If the new methods are not validated prior to reliance on them as substitutes for conventional tests, EPA may improperly exonerate hazardous chemicals or penalize low-risk chemicals. These are only a few of the many issues that must be addressed before EPA relies exclusively on them for decisions with potential or actual regulatory consequences.

My view is that EPA can and should allow for the integration of such methods at this point primarily as a supplement, not a wholesale replacement for, conventional testing methods. This will have the added benefit of yielding data that will aid in the validation of the newer testing methods.

Senator David Vitter

1. *Low Dose: Analysis of human data has so far failed to provide firm evidence of direct causal associations between low level exposure to chemicals with endocrine disrupting properties and adverse health outcomes. The World Health Organization and the International Union for Pure and Applied Chemistry have both concluded this. EPA also concluded in 2003 that until there is improved scientific understanding of the low dose hypothesis, it was "premature" to require routine testing of substances for low-dose effects in the Endocrine Disruptor Screening Program. Yet, your testimony levels the charge that it is matter of fact even very low doses of certain chemicals can have adverse effects. It appears that this is not scientific fact. That being the case, shouldn't the issue of low doses of chemicals having adverse effects be an issue for scientific research and not legislation?*

RESPONSE: My testimony stated as follows: "We now know ... that even very low doses of certain chemicals can have adverse effects." It made no reference in this context to endocrine-disrupting or any other specific group or type of chemical, in contrast to your question.

Many chemicals are well-established to have adverse effects at very low doses. Examples include lead, mercury, cadmium, benzene and many others. Just this month, the CDC's Advisory Committee on Childhood Lead Poisoning Prevention, the expert committee that advises the Department of Health and Human Services and the Centers for Disease Control on lead affirmed that the latest and best science demonstrates there is no safe level of exposure to lead.¹¹

2. *Biomonitoring: We have heard your concern that the science of biomonitoring has revealed that virtually all Americans, including newborns, carry in our bodies hundreds of toxic synthetic chemicals, yet no one can tell us how they got there or what effects such a mixture of chemicals is having on our and our children's health, because they have not been adequately tested or assessed for safety.*

However, the CDC's 2009 Fourth National Report on Human Exposure to Environmental Chemicals states that "The presence of an environmental chemical in people's blood or urine does not mean that it will cause effects or disease... Small amounts may be of no health consequence, whereas larger amounts may cause adverse effects. Research studies...are required to determine the levels of a chemical that may cause health effects and the levels that are not a significant health concern."

As the CDC notes, scientific research and interpretation tools are key to understanding whether the detection of chemicals in our body is a problem. But the mere presence of a chemical does not by itself mean that there is any problem. Science is what is needed to address this issue – not legislation. Why does EPA need to address biomonitoring data any differently than any other piece of hazard or environmental data or information?

RESPONSE: The converse of the statements you cite is equally true: The presence of an environmental chemical in people's blood or urine does not mean that it will **not** cause effects or disease. The facts that we now know that people are exposed to chemicals to which we were told we would never be exposed, that many hundreds of such chemicals have been identified, and that the more we look for, the more we find, should in my view flip any presumption of safety or lack of effect.

¹¹ See report titled "Low Level Lead Exposure Harms Children: A Renewed Call for Primary Prevention," approved at January 4, 2012 meeting, p. 16, lines 19-20, available at <http://www.cdc.gov/nceh/lead/ACCLPP/activities.htm>.

In order to assess risk, EPA needs to understand whether and to what extent people are exposed to chemicals in commerce; the science of biomonitoring can help enormously in that regard by directly measuring chemicals in people. In contrast to predictive models or assumptions about release, environmental fate and the like that are often used to estimate exposure, biomonitoring provides direct, empirical data and can usefully serve as a means of “ground-truthing” models and assumptions.

Recent biomonitoring data on both phthalates and poly-brominated diphenyl ethers amply illustrate this point. Phthalates are very widely used in products ranging from plastics to cosmetics and other personal care products. They exhibit a range of toxicity, including to the liver, kidney, and male reproductive system. The first CDC National Report demonstrated surprisingly high levels of di-butyl phthalate (DBP) and di-ethyl phthalate (DEP) in U.S. residents in general, and for DBP, in women of child-bearing age in particular. Indeed, these data demonstrated high-end levels of DBP that were *an order of magnitude* higher than a prior estimate that had been developed based on industry-provided use data and expert judgment.¹² In part as the result of these biomonitoring data, the CDC has placed a high priority on investigating potential phthalate exposure routes in more detail.¹³

Polybrominated diphenyl ethers (PBDEs) are widely used flame retardants. Different species of PBDEs are used in products ranging from plastics (such as computer cases) to upholstery foam. Toxicological studies indicate that they can disrupt thyroid metabolism and may have effects on other organs, including the liver. Because PBDEs are not very volatile or water soluble, they were assumed to more or less stay in place in products, and were not believed to have a high potential for exposure. However, biomonitoring studies from around the world have demonstrated that levels of PBDEs in peoples’ bodies have been dramatically increasing over the past two decades, with the highest levels currently reported in the United States.¹⁴ This finding has prompted a number of responses, including the voluntary withdrawal of two types of PBDE (penta- and octa-bromo diphenyl ethers) and a ramped-up research effort to characterize the toxicity, metabolism, kinetics and environmental fate and transport of these substances.

I believe biomonitoring data should be one key source of information EPA considers, alongside “other pieces of hazard or environmental data or information” to which your question refers. Far more research and testing are needed to understand the effects of both individual chemicals and combinations of chemicals to which people are potentially or actually exposed; these are the kinds of data that S. 847 would required be developed and assessed.

I note that S. 847 requires EPA to rely upon the recommendations of the NAS Science and Decisions report in determining the “best available science” that EPA must use in making a

¹² National Toxicology Program Center for the Evaluation of Risk to Human Reproduction (CERHR). (2000) NTP-CERHR Expert Panel Report on Di-n-Butyl Phthalate. Available at cerhr.niehs.nih.gov/chemicals/phthalates/dbp/dbp-final-inprog.pdf. Accessed on January 12, 2006. David RM. (2000) Exposure to phthalate esters. *Environ. Health Perspect.* 108(10):979-982. Kohn MC, Parham F, Masten SA, et al. (2000) Human exposure estimates for phthalates. *Environ. Health Perspect.* 108(11) A495.

¹³ Agency for Toxic Substances and Disease Registry. “ATSDR’s Substance-Specific Priority Data Needs (PDNs).” Available at www.atsdr.cdc.gov/pdns/unfilled.html. Accessed January 10, 2006.

¹⁴ Petreas M, She J, Brown FR, Winkler J, Windham G, Rogers E, Zhao G, Bhatia R, Charles MJ. (2003) High body burdens of 2,2',4,4'-tetrabromodiphenyl ether (BDE-47) in California women. *Environ. Health Perspect.* 111(9):1175-1179.

safety determination. Don't you think it would be a mistake for Congress to "lock in" the science of 2008 in a modernized TSCA? Also, being that it sets forth a recommendation to assume "no threshold" for all toxic effects induced by chemicals – one that is highly controversial, and that does not follow the standards of professional practice used to assess the safety of chemicals, consumer products, food contact materials and pharmaceuticals under a variety of US laws and regulations, why should this radical departure from best risk assessment practices be applied in regulatory decision-making?

RESPONSE: The recommendations presented in a fully documented and reviewed report of a prestigious, highly qualified panel of scientists convened by nation's foremost scientific body, the National Academy of Sciences, can hardly be described as "radical." Your own initiatives in recent months have demanded far greater involvement of the NAS as a source of objective, independent review of EPA's scientific methods and practices.

The report you cite was commissioned precisely to address long-standing deficiencies in the practice of risk assessment by EPA and other federal agencies – and, far from locking in old science, to modernize it. What has been locked in for decades are the "standards of practice" to which your question refers, namely the state of risk assessment science that dates back to the 1984 NAS Red Book; the NAS' 2009 "Science and Decisions" report, called the Silver Book, was specifically intended to break the lock and bring the practice of risk assessment into the 21st century.

Of course, science will continue to evolve, and we should not "lock in" even the most up-to-date science in a law in a manner that does not allow practices and regulatory decision-making to evolve along with advances in science. I would strongly support a requirement under a reformed TSCA that EPA periodically, no less often than once every five years, be required to review its methodology in light of advancements and to make needed enhancements in its risk assessment methodologies and practices.

3. *We have heard your testimony that EPA is forced to perform Google searches to try to identify all uses of chemical because it lacks authority to ensure accurate reporting of chemical uses. Furthermore, we have heard from you that EPA cannot provide even a rough approximation of the actual number of chemicals in commerce today or how and where they are used.*

Isn't this a gross overstatement at best? Just visiting the EPA's own website – one can learn about how much information EPA has at its fingertips. Under TSCA authority as it exists today, EPA, through the Inventory Update Rule, received reports on 6,200 chemicals, from a total of 3,827 sites, representing 1,541 companies in 2006. More than 95 percent of the total production volume reported is manufactured in the United States. For organic chemicals manufactured in quantities of 300,000 pounds or greater at a given Site, submitters also reported downstream uses. These submitters reported nearly 1 trillion pounds of organic chemicals. The 2006 IUR data contained industrial processing and use information that accounted for 72 percent and commercial and consumer use information that accounted for 22 percent of the nearly 1 trillion pounds.

While the 2006 IUR data does not include chemical substances manufactured or imported in amounts of less than 25,000 lbs. per site, it surely captures by far most of the chemicals in commercial production today. EPA will have more use information in the 2012 CDR reports as it has dropped the use reporting threshold to 100,000 lbs, and will drop it to 25,000 beginning in 2016.

Also, EPA does have external resources available - OECD's eChemPortal provides access to reports and datasets maintained by some 30 member countries, the US among them, containing 657,802 chemicals and 560,920 endpoints.

And, changes to TSCA are not needed for EPA to get use information. Section 8(a) of TSCA authorizes EPA to require reporting by manufacturers (including importers) and processors (other than small manufacturers and processors) of the categories or proposed categories of use for each such substance or mixture. EPA does collect use information through the former Inventory Update Rule and the new Chemical Data Reporting Rule. The new CDR Rule has reporting codes for 48 industrial sectors, 35 industrial function categories, and 33 consumer and commercial product categories. Furthermore, EPA has authority to ask processors to submit use information, but has chosen not to do so.

Section 8(a) authorizes EPA to collect numerous pieces of information from manufacturers (including importers) and processors (other than small manufacturers and processors, such as: the common or trade name, the chemical identity, and the molecular structure of each chemical substance or mixture for which such a report is required; the categories or proposed categories of use of each such substance or mixture; the total amount of each such substance and mixture manufactured or processed, and reasonable estimates of the total amount to be manufactured or processed; a description of the byproducts resulting from the manufacture, processing, use, or disposal of each such substance or mixture; all existing data concerning the environmental and health effects of such substance or mixture; and the number of individuals exposed, and reasonable estimates of the number who will be exposed, to such substance or mixture in their places of employment and the duration of such exposure. To get this information, there is no requirement that EPA make any showing of unreasonable risk or findings beyond that the information is "reasonably required".

So, in sum, EPA does not need Google, or the provisions of this bill to get the chemical information it needs. So where are the actual gaps you claim exist?

RESPONSE: Your statement that the IUR (now CDR) “surely captures by far most of the chemicals in commercial production today” is simply not the case. Unfortunately, a key deficiency of the IUR was retained in the CDR: The restriction of reporting obligations only to those chemicals produced at 25,000 pounds or more per year per site. Evidence indicates that the use of such a high threshold means that many, likely a significant majority of, chemicals actually in commerce will not be required to be reported at all, and hence that EPA, the public and the market will not have any access to needed information on them. Consider the following:

- When EPA raised the IUR threshold from 10,000 to 25,000 pounds per year per site a number of years ago, the number of *organic* chemicals reported fell by about two-thirds.
- The former, long-time Director of EPA's Office of Pollution Prevention and Toxics, which administers TSCA, has estimated that on the order of 50,000 chemicals are presently in U.S. commerce.¹⁵
- The European Commission estimated that 30,000 chemicals would need to be registered under its REACH Regulation, which has a threshold of one metric ton, or 2,200 pounds per year per producer. Moreover, when they estimated how many chemicals would be subject to each of REACH's four tiers of data requirements, they found that the number of chemicals per tonnage

¹⁵ Testimony of Charles M. Auer, President, Charles Auer & Associates, LLC, Submitted on August 3, 2010 to Subcommittee on Commerce, Trade and Consumer Protection, U.S. House of Representatives, Committee on Energy and Commerce, for a Hearing On H.R. 5820 - The Toxic Chemicals Safety Act of 2010.

band constituted a pyramid, with many more chemicals produced at the lower tonnage bands than at the highest:

- >1,000 metric tons/year: 2,700 substances, plus 1,700 transported intermediates with reduced registration requirements;
 - 100-1,000 metric tons/year: 2,460;
 - 10-100 metric tons/year: 4,980; and
 - 1-10 metric tons/year: 17,500.¹⁶
- The IUR data you cite has two other major features that lead to significant underestimates of the actual number of chemicals in U.S. commerce.
 - There are many exemptions from IUR reporting. For example, polymers are exempt and not included in the counts you provide, yet 30,000 of the roughly 84,000 chemicals on the TSCA Inventory are polymers.
 - The IUR has required only very infrequent reporting (once every five years) of only a single year's manufacturing data. Both EPA's and our own analyses of data from past IUR reporting cycles demonstrate that, because of major year-to-year fluctuations in chemical production and import, such infrequent reporting has led to a highly inaccurate picture of what chemicals are actually in U.S. commerce and in what quantities. Unfortunately, while this deficiency has been addressed in the CDR, we will have to wait until at least late 2016 to get annual production data because implementation of that feature of the CDR was delayed until then.

EPA's analysis of data from multiple cycles of reporting under the IUR prior to 2006 – and before EPA added reporting of inorganic chemicals and raised the reporting threshold from 10,000 to 25,000 pounds per year per site – found that *nearly 14,000 chemicals* had been reported above 10,000 pounds per year per site in one or more reporting cycles between 1990 and 2002, many more than are reported in any single cycle because of the year-to-year fluctuations.¹⁷

Use reporting under the most recent (2006) cycle of the IUR was exceedingly disappointing, due to a variety of limitations in the program.¹⁸ The paucity of use information EPA received from companies led it to propose major changes to this aspect of the IUR, some of which were incorporated into the final CDR rule issued last year. As your question points out, however, EPA will have to wait until 2016 to obtain use information on the chemicals subject to CDR reporting – again, limited only to that minority of chemicals in commerce produced above the 25,000 pounds per year per site reporting threshold.

With respect to the part of your question regarding TSCA Section 8(a), EPA does have authority to issue mandatory reporting rules – though each rule must be limited to specified chemicals, and only requires one-time reporting of already available information. In addition, “small manufacturers” are exempted by statute from being subject to such a rule. Section 8(a) rules also generally require EPA to go through full

¹⁶ See European Commission, Joint Research Center, “Assessment of additional testing needs under REACH,” September 2003, Table 1, p. 12, available at http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/testing_needs-2003_10_29_en.pdf.

¹⁷ See “How can EPA more efficiently identify potential risks and facilitate risk reduction decisions for non-HPV existing chemicals? Developed by Broader Issues Work Group (BIWG), National Pollution Prevention and Toxics Advisory Committee (NPPTAC), October 6, 2005, p. 4, available at <http://www.epa.gov/oppt/ppptac/pubs/finaldraftnonhpvpaper051006.pdf>

¹⁸ See USEPA, TSCA Inventory Update Reporting Modifications; Proposed Rule, 75 Federal Register, Friday, August 13, 2010, p. 49646; and Denison, R.A., et al., 2010, EDF comments on EPA's proposed rule, available at http://blogs.edf.org/nanotechnology/files/2010/10/EDF_comments_on_IUR_Proposed_Rule_10-12.pdf.

notice-and-comment rulemaking, a process that can take years. The time and resource burden on EPA to develop such rules has effectively limited their use under TSCA, and they simply do not provide a viable means for EPA to obtain the kind of comprehensive data on all chemicals in commerce needed for prioritization and risk assessment.

Finally, your question also asserts that there are ample hazard data on chemicals in commerce. If the numbers you cite from the OECD portal – 657,802 chemicals and 560,920 endpoints – are correct, that means that, on average, *less than one endpoint* per chemical are available. Even the basic “minimum” hazard data set prescribed by the OECD has about *two dozen endpoints* regarded as necessary to conduct a screen-level hazard assessment of a given chemical.

It is widely accepted that there are major gaps in the data available to assess the risks of even the most widely used chemicals.¹⁹ EPA examined the extent to which basic screening-level hazard data were publicly available on chemicals that had recently reached the high-production-volume (HPV) level of production of one million pounds per year, and found the following:²⁰

- Of 235 chemicals that were manufactured at HPV levels in 1998 and 2002 (but not 1990):
 - 115 (49%) had no publicly available hazard data for any of the six major hazard endpoint groups examined.
 - Only 2% of them had publicly available screening-level hazard data for at least one endpoint in each of the six major hazard endpoint groups examined.
- Of 286 chemicals that were manufactured at HPV levels in 2002 but not earlier:
 - 166 (58%) had no publicly available hazard data for any of the six major hazard endpoint groups examined.

These findings indicated data gaps even larger than those of EPA’s 1998 data availability study²¹ conducted on chemicals identified as HPV in 1990 – data that led to the launch of the voluntary HPV Challenge program.²² For those chemicals, EPA found that:

- 43% had no publicly available hazard data for any of the six major hazard endpoint groups examined.
- 7% had publicly available screening-level hazard data for at least one endpoint in each of the six major hazard endpoint groups examined.

¹⁹ See for example, Dix, D. et al., The ToxCast Program for Prioritizing Toxicity Testing of Environmental Chemicals, *Toxicological Sciences* 95(1), 5–12 (2007), available at <http://www.ncbi.nlm.nih.gov/pubmed/16963515>.

²⁰ 58th (2006) and 56th (2005) *Reports of the TSCA Interagency Testing Committee to the Administrator, U.S. Environmental Protection Agency*, available at tsc-a-ite.syrres.com/Reports/; and personal communication to the author from John D. Walker, EPA Office of Pollution Prevention and Toxics, December 2006. Note that, if anything, these numbers overstate the extent to which a full screening-level hazard data set is available, because the search method employed groups together multiple endpoints and scores the endpoint category as having data available if even a single study for a single endpoint was found. Hence, a chemical that has a single algae study but no fish or *Daphnia* study would still be scored as having ecotoxicity data available.

²¹ See EPA’s 1998 Data Availability Study, available at www.epa.gov/chemrtk/pubs/general/hazchem.htm.

²² Unfortunately, the HPV Challenge fell far short of its promise to develop and make public a basic set of hazard data for this earlier batch of HPV Chemicals. See Richard A. Denison, *High Hopes, Low Marks: A final report card on the High Production Volume Chemical Challenge* (Environmental Defense Fund 2007), at www.edf.org/documents/6653_HighHopesLowMarks.pdf.

4. *You expressed a concern that the public, state governments and even workers who may be directly exposed to chemicals are denied access to the great majority of chemical information that companies submit to EPA because the companies have been given wide latitude to claim it as confidential. However, that is not accurate: under section 14(b) of TSCA, no confidentiality claims are allowed for health and safety studies, other than narrow categories of information. Thus, virtually all the safety data itself is made public to all. Furthermore, under OSHA requirements, manufacturers must provide hazard information even for chemicals whose identity is claimed confidential. And, CBI protections are needed to ensure that the United States can remain the center of research and development for new chemistries – including greener ones. So does a problem really exist with the protections afforded to confidential business information today?*

RESPONSE: First, the scope of my statement was much broader than the health and safety studies addressed under section 14(b) to which your question refers, and includes information on use and exposure that is collected by EPA. I, for one, believe there are legitimate bases on which certain types of information should be eligible for protection as CBI under TSCA; the problem has been that far more information has actually been claimed as such by industry, and EPA simply lacks the resources to review the claims, which must be done on a case-by-case basis; without a review and challenge, the claim remains in place indefinitely, whether or not it is legitimate.²³

Your question states that “under section 14(b) of TSCA, no confidentiality claims are allowed for health and safety studies, other than narrow categories of information. Thus, virtually all the safety data itself is made public to all.” However, for decades EPA has routinely allowed companies to claim – and maintain – the identity of the chemical to which a health and safety study pertains to be masked. The result is that the public only knows that some mystery chemical may cause a health or environmental effect – information that is truly useless.

Despite TSCA’s explicit language making clear that data from health and safety studies are not protected from disclosure by CBI claims, EPA has typically accepted CBI claims without review even as to health and safety data, thereby preventing disclosure of health and safety information, including chemical identity, for example in Section 8(e) substantial risk notices. These notices describe health and safety studies or data that reasonably support the conclusion that certain chemical substances or mixtures present a substantial risk of injury to health or the environment. Though all Section 8(e) notices are posted on EPA’s website, companies frequently assert that the names of the chemicals at issue constitute CBI, and EPA typically accepts these claims without question unless someone seeks the information through a request under the Freedom of Information Act (FOIA). Thus specific chemical names are redacted from a significant number of Section 8(e) notices posted on EPA’s website, including a majority of the chemicals covered by the notices received during some months, replaced with “generic” names that provide no means of identifying the chemical in question.²⁴ EPA statistics indicate that, for fiscal years 2006 through

²³ For a more detailed analysis of the problems with CBI under TSCA, see the posts on EDF’s Chemicals blog: “Worse than we thought: Decades of out-of-control CBI claims under TSCA,” at <http://blogs.edf.org/nanotechnology/2010/02/12/worse-than-we-thought-decades-of-out-of-control-cbi-claims-under-tsca/>; and “How should the problem of ‘secret chemicals’ be addressed?” at <http://blogs.edf.org/nanotechnology/2010/01/05/how-should-the-problem-of-%e2%80%9csecret-chemicals%e2%80%9d-be-addressed/>.

²⁴ See, for example, See <http://www.epa.gov/opptintr/tscas8e/pubs/8monthlyreports/2009/8nov2009.html>.

2009, nearly 70% of Section 8(e) notices submitted to EPA contained CBI claims, and for more than 40% of them the chemical identity was specifically claimed as CBI.²⁵

Absent specific chemical names, the health and environmental risk information provided in Section 8(e) notices is of little or no public value. As a recent report by the Congressional Research Service stated, the value of 8(e) submissions and EPA's website making the studies available to the public "is greatly reduced by the confidentiality claims of the submitters: in most cases, the identity of the chemical is concealed."²⁶

Critical health and safety information has been shielded from public view because of both submitters' assertion of excessive and often unfounded CBI claims and the failure of EPA routinely to review and reach determinations as to the legitimacy of those claims. Eighteen years ago, EPA identified "inappropriate confidentiality claims" as impairing "the dual goals of public education about chemical substances and public participation" that were enshrined in TSCA.²⁷ The EPA's Final Action Plan stated, "The unmistakable purpose behind the participatory opportunities provided in TSCA is to afford the public the chance to contribute meaningfully to the regulatory process" and indicated that inappropriate CBI claims were thwarting the legislative purpose of TSCA (see pp. 3, 5). Nonetheless, industry claims of CBI protection for health and safety information and, in particular, for chemical identity, have continued unabated and virtually unchecked.

A study undertaken by the U.S. Governmental Accountability Office (GAO) in 2005 acknowledged the problem, recognizing that under TSCA "chemical companies claim much of the data submitted as confidential."²⁸ The GAO noted the relevance of information provided under TSCA to the general public:

"Individual citizens or community groups may have a specific interest in information on the risks of chemicals that are produced or used in nearby facilities. For example, neighborhood organizations can use such information to engage in dialogues with chemical companies about reducing chemical risks, preventing accidents, and limiting chemical exposures."

At the time of its study, the GAO reported that although "EPA has the authority to evaluate the appropriateness of these confidentiality claims," the agency stated that it lacked the resources to challenge large numbers of claims. Indeed, EPA's reluctance to review claims was related to the scale of the problem, noting that a 1992 EPA study "indicated that problems with inappropriate claims were extensive."

EPA has recently proposed a new policy, under which it is beginning a general practice of reviewing confidentiality claims for chemical identities in health and safety studies and data from those studies and, by which it announced that it does not expect such chemical identities to be entitled to confidential

²⁵ See EPA, *TSCA Statistics for Congressional Briefing (Documents Received from FY 06 through FY 09)* (received from EPA by OMB Watch pursuant to FOIA request) (undated).

²⁶ See Linda-Jo Schierow, Cong. Research Serv., CRS RL 34118, *The Toxic Substances Control Act (TSCA): Implementation and New Challenges* 12 (July 28, 2009).

²⁷ See Office of Pollution Prevention and Toxics, U.S. EPA, *Final Action Plan: TSCA Confidential Business Information Reform 5* (1994) (Final Action Plan).

²⁸ See GAO, GAO-05-458, *Chemical Regulation: Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program*, at intro (2005).

treatment unless they explicitly contain process information or reveal portions of a mixture.²⁹ If fully implemented, this new policy will begin to bring practice into line with the statute. Unfortunately, the chemical industry has indicated it may mount a legal challenge to EPA's new policy. This is why clarifying and codifying a prohibition under TSCA from making CBI claims for health and safety studies, including for the identity of the subject chemical, is a necessary part of TSCA reform, as reflected in S.847.

Finally, your question states: *"Furthermore, under OSHA requirements, manufacturers must provide hazard information even for chemicals whose identity is claimed confidential."* This statement refers primarily to OSHA's hazard communication standard and related requirements for manufacturers to provide Material Safety Data Sheets (MSDSs). Unfortunately, MSDSs fall far short of providing an effective and comprehensive means of providing hazard information to workers or other stakeholders. First, only available information need be provided, and hence the major gaps in hazard information available for the great majority of chemicals in commerce mean that even where MSDSs incorporate the most current information, most of them will fail to provide even a basic hazard profile of their subject chemical. Second, many studies have found MSDSs to be notoriously incomplete, out of date and inaccurate; see, for example OSHA's own summary of studies published that examined the quality of MSDSs;³⁰ and a 2008 meta-analysis of 24 published, peer-reviewed studies that have examined MSDS quality,³¹ which concluded:

"Despite the fact that these studies varied in methodology and spanned a period of more than 15 years, a number of common themes emerged regarding inaccuracies, incompleteness, incomprehensibility and overall low use of MSDSs. The results of the literature review suggest that there are serious problems with the use of MSDSs as hazard communication tools."

²⁹ See "Notice of General Practice of Reviewing Confidentiality Claims for Chemical Identities in Health and Safety Studies and Data from Health and Safety Studies Submitted Under the Toxic Substances Control Act," 75 Federal Register 29,754 (May 27, 2010), available at <http://edocket.access.gpo.gov/2010/pdf/2010-12646.pdf>.

³⁰ OSHA (2004) "Hazard Communication in the 21st Century Workplace: Appendix re: Studies/Investigations re: Hazard Communication," available at <http://www.osha.gov/dsg/hazcom/finalmsdsreport.html#appendix>.

³¹ Nicoll, A.M. et al., "Accuracy, comprehensibility, and use of material safety data sheets: a review," *Am J Ind Med.* 2008 Nov;51(11):861-76, available at http://www.ncbi.nlm.nih.gov/pubmed/18651574?ordinalpos=1&itool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.Pubmed_DefaultReportPanel.Pubmed_RVDocSum.

Senator LAUTENBERG. Thanks very much, Mr. Denison.

And I thank each one of you.

It is interesting to hear some divergent views, not unexpected. This is a complicated subject, but it is I think less than help to solve our problems as to look at unenforceability, that kind of thing. I mean, I believe, and it was summarized by a couple of you, and that it is the number of people who have expressed concern, the number of conditions that violate our sense of what is right in terms of our responsibilities.

There is no doubt in my mind and minds of responsible scientific units, scientific bodies that there are problems lurking out there. And in the design for us to try to deal with those, does a single child's endangerment require a bill passed in here, a piece of legislation? Probably not, but when you start to see it all over the Country and the statistics tell you that there are problems with fertility and problems with this, and exposure, of course, Ms. Brody, to Vietnam, that is a classic in American history and the chemical business.

But, look, my mission, and I said it earlier, and I think that Senator Inhofe and I have set the kind of a platform that says say what you want; say what you believe. But keep an open ear to what is going on. Keep you eyes open as to what is going on with the fright that exists over the condition of children.

There is one statement that wasn't really a statement. It was the child's voice. We loved hearing that. I have 13 grandchildren.

So I ask Ms. Brody, the chemical industry employs more than 70,000 people in my State of New Jersey. I want to protect these employees, their jobs and their health. And you are a member of the United Steelworkers Union and a representative of other unions that work with chemicals. How many people are in the steelworkers union?

Ms. BRODY. The steelworkers union has about 1 million members right now.

Senator LAUTENBERG. And the total membership of your allied groups?

Ms. BRODY. Between the 11 unions and four environmental organizations, 15 million people all together.

Senator LAUTENBERG. How might reforming TSCA, as we propose, affect employment in these industries?

Ms. BRODY. Earlier this year, Senator Lautenberg, we did a study of the economic benefits of a green chemical industry in the United States. And we commissioned the University of Massachusetts-Amherst to really tell us what was going on in the chemical industry and what could TSCA reform do positively or negatively to impact that industry.

Because first and foremost, we need each of our members working and we need to do something about the economic crisis in the United States. And what we found is that unemployment in the chemical industry didn't start to go down during the great recession of 2008, but actually has been dropping since 1992. So that 38 percent of the jobs that used to be there aren't there anymore, and that this happened while the chemical industry stayed profitable at 4 percent per year during that entire time.

And that what had been going on is that the chemical industry had stayed profitable by cutting costs, by cutting research and development costs so that they were less than half of industry overall, and by cutting labor costs and putting people out of work.

And the TSCA reform actually, by moving us from a time when the smart money in the chemical industry is on making the stuff you were making 40 years ago, to a new day when making safer chemicals lets you create more market share; could actually put people back to work and turn those numbers around.

Just one point that we noticed in this, the only part of the American chemical industry that has been growing jobs and growing in profitability is the most regulated part, the part of pharmaceutical chemicals, including a lot of people working in your State who actually are employing more people every year in the one part of the industry where companies have to prove that their products are safe before they are put on the market.

Senator LAUTENBERG. Thank you.

Mr. Dooley, over the summer, the American Chemistry Council suggested alternative language for one small, but important, part of the Safe Chemicals Act. Providing that kind of specific proposal increases the odds that we can find a bipartisan middle ground. Now, are you willing to commit to providing specific alternatives to all the other sections of the Safe Chemicals Act that you strongly criticized?

Mr. DOOLEY. We have been involved in constructive discussions through the process that was sponsored with you, as well as with other stakeholders. And I think that we have seen progress at a very high level in terms of general concepts on a host of issues.

But unfortunately, we think that this is an issue of such complexity that it is going to take a significant period of time to really resolve all those very, very complex and difficult issues. And we have provided the example, one of the most recent examples was attached to our testimony, was I think the most comprehensive proposal for a prioritization process that we submitted to the Committee, as well as to EPA.

We are committed to do that on a host of issues.

Senator LAUTENBERG. Yes, but again, will you provide your specific alternatives?

Did you hear my question?

Mr. DOOLEY. Yes, I did. We will provide the information and our ideas in the appropriate fashion.

Senator LAUTENBERG. Thank you very much.

Senator Inhofe.

Senator INHOFE. Thank you, Mr. Chairman.

I have just two questions, one that I am going to ask Mr. Dooley. It is nice to be with you again. You have a lot of people up here with whom you have served in the past.

I am concerned, and you have addressed this, but not thoroughly enough, about how this could adversely affect new products. That is what I am concerned about. I have always taken great pride that we try to be ahead of the rest of the world, and could you address that for me?

Mr. DOOLEY. I would be delighted to. I would like to use maybe our greatest concern about the underlying bill, with the safety

standard which would require us to provide with a reasonable certainty and no harm a chemical from all aggregate exposures.

Basically, what the intent of this legislation is to adopt the same policy and procedures that we use for pesticides, where you actually have a risk cup. I was a farmer prior to coming to Congress. I dealt with pesticides. And when you registered a pesticide, you had a limited number of applications on a limited number of crops for a product that was going to be biologically active and try to kill either a bug or a weed. You could define those pathways of exposure.

That process does not work on industrial chemicals that have thousands and thousands of pathways of exposure. And I will provide this to the Committee at an appropriate time, but we have a chlorine tree here, which shows the hundreds and hundreds of different products that chlorine is used in. Now, if you use the proposal of the safety standard that is under this legislation, it would require anyone that was going to be making a new products or a new mixture that had chlorine in it, they would have to do an aggregate assessment of the exposures resulting from not just their new product, but from all uses in commerce today.

And so if you think about it for a minute, chlorine is in this water. It is an integral part of trying to make sure it is pure. Chlorine is in the varnish that is on your desk. Chlorine is in the semiconductors that are in your phone.

So does chlorine, if you had this risk cup perspective, does the chlorine that is in the water, does it fill it up this much? In the ink, does it fill it up this much? In the semiconductors, does it fill it up this much? Maybe in the batteries in your pacemaker, does it take it up to the top?

And so you have a new innovative company out there that has a new application for chlorine that might be the cutting edge technology that is going to ensure that the U.S. manufacturers are going to be the lead in solar cell technology, yet the risk cup is full. And so where do they go? How do they ensure that they can get approval from EPA? How can even a startup company that has limited resources and capacity, how do they even have the ability to assess the aggregate exposure?

This bill with this safety standard is a prescription to deny the U.S. manufacturers' ability to be at the forefront of innovation and creating jobs.

Senator INHOFE. Thank you, Mr. Dooley. This might be my birthday, but I don't have a pacemaker.

[Laughter.]

Senator INHOFE. One last question, a little bit over our time, but I just want to ask Mr. Matthews, because I have heard it stated very times that States are ill-equipped to deal with these things. And the term that has been used is "a complex maze of regulations across the Country."

Could you address that?

Mr. MATTHEWS. I would be pleased to do that. I think Senator Gillibrand indicated numbers I hadn't even seen before. There were something like 25 States that have adopted 80 different chemical management laws over the last 9 years. And I think we heard testimony from Mr. Sturdevant that that is a difficult issue for States

to take on because they don't necessarily have all the tools to address the toxicity of chemicals and to understand the use and exposure information that I referred to.

And that this would be best done at the Federal level where we can marshal resources one time in this Country, not duplicate that, and assure that at whatever the standard actually is, we have uniformity in that regard so that a company like a S.C. Johnson or a Procter and Gamble, which has products in all the retail shelves and in all of our homes, can have one 50-State strategy, instead of a strategy across multiple States, now 25 and growing, for formulation, for labeling and so on.

So I think on both sides of the issue, it is both unburdening the States in a very difficult area. It is reducing the resources in this Country that are being applied to doing that from potentially 50 down to one Federal Government role. And it is industry that will be able to, in our industry in particular, to market their products knowing that if they meet the Federal standard, they will have provided a safe product to the marketplace.

Senator LAUTENBERG. Senator Cardin, please.

Senator CARDIN. Well, first, Senator Lautenberg, let me thank you for your leadership on this issue. You have been incredible in pointing out the risk factors and putting a face on it as to the individuals who are impacted by what we do, by our failure to provide adequate protection. So I thank you very much and I thank you for holding this hearing.

Mr. Dooley, it is nice to see you again. I respect very much your views. I was interested in your oral response, but I read your written statement also where you point out that the Toxic Substance Control Act needs to be changed. I looked at what happened in my own State of Maryland with BPA, where because of the inability of the national government to provide safety standards, the State had to act.

It is not the ideal circumstance. The ideal circumstance is to have the Federal Government provide the blanket protection we need for the Nation, allow States to be able to push the envelope if they can, but to know that there is the backstop at the national level. We don't have that today.

So I very much value your judgment, and I want to followup on the Chairman's point, that we need to work together. We need to make sure that we encourage innovation. I am all for that. But I was disappointed by your response to Chairman Lautenberg because you said it could take a lot of time. Too many people are affected by this. We have to get this moving. We can't say let's wait another decade for a study to come back and then determine what we should be doing at the national level.

This is a safety issue. And we need your help and we don't have time. And we need to do this in a bipartisan manner. I agree with that. But you have the expertise, but you also have the credibility so that we could get something done sooner rather than later that will help the people of this Country and help job growth in this Country.

So I just encourage you to have a greater sense of urgency than at least I interpreted from your reply.

Mr. DOOLEY. Well, I guess, Senator, I would respond is that I think it is unfortunate that we are having a hearing on this legislation today; a bill that is very similar to that which was introduced 2 years ago; a bill that we have been involved in extensive discussions with Senator Lautenberg and his staff, explaining what our concerns and objections were; that we have had extensive conversations with the NGO community, telling them what our concerns and objections were, as well as some ideas in terms of how they can improve it.

And when we are faced with a situation, if we would have seen maybe another iteration that showed some progress, the tenor of our comments might be a lot different.

Senator CARDIN. And I would point out, if we had your bill before us so that we could take a look at it and compare it, I think it would be more constructive. The Chairman challenged you to come forward with recommendations. It is not one-sided here.

Mr. DOOLEY. And we have provided significant recommendations. I would be delighted to meet with you and your staff and explain. And in terms of the safety standard that you have proposed here that we object to, we have an alternative.

Senator CARDIN. The question is this. Here is the point. You say in your statement that the current law needs to be reformed. If the industry truly believes that, then you need to come forward with what you believe is necessary, and respond point by point to what Senator Lautenberg has put in his bill so that we can sit down here and try to make some sense out of this.

But if your objective is to defeat legislation, if that is your objective, then I understand what you are doing. But if your objective is to get legislation enacted, I don't understand what you are doing.

Mr. DOOLEY. Our objective is to see the modernization of TSCA in a way that provides the appropriate level of safety, ensuring the safety of the chemicals that are used for their intended purposes that are in commerce. And ensuring that we can do so in a manner that allows this U.S. chemical industry to continue to be at the forefront of innovation.

Senator CARDIN. I accept that.

Mr. DOOLEY. They are not mutually exclusive.

Senator CARDIN. I accept that. Then I just urge you to be more forthcoming on your recommendations so that we can try to get to where the real problems are, and try to get the ability at the national level to provide the safety standards that allow innovation, which is what the industry needs and what the American public needs.

That is why I just urge you to be more open so that we can get answers to the issues that have been raised. We don't want to continue under the current system that puts such a burden on States to act because of the failure of the Federal Government to provide the basic protection that is needed.

Mr. DOOLEY. The only thing I will conclude, this is my last comment. Sometimes I would say we have been providing answer. We have been providing solutions to what the industry likes and would like to see, which we think would be appropriate.

Unfortunately, they are not the answers that some of the authors and some of the proponents of the legislation, supporters of the leg-

isolation that we are testifying on today want to hear. And so just because they are not embodied in this legislation doesn't mean that this industry hasn't been offering what we think are concrete solutions and proposals.

Senator CARDIN. I appreciate that. I will make one final observation here. It is clear in this political environment, the way we get legislation enacted is for both sides to come together. This Committee has a history of working together on issues. We just passed out a surface transportation bill by an 18 to zero vote. It contains some things in there I don't like. It contains some things in there Senator Crapo doesn't particularly like, but we were able to get it done.

If there is a good-faith effort to get legislation enacted, then participate with us. If your objective is to make sure nothing gets through this Congress, then I understand what you are saying. But be straight with us as to what your objective is.

Your testimony leads me to believe that you want to see reform passed by the U.S. Congress and signed into law. If that is the case, I don't know where you are on this issue. I know Senator Lautenberg's bill. I have read Senator Lautenberg's bill. I would welcome specifics, rather than just saying no, this doesn't work; this doesn't work; this doesn't work. What works?

And I will just conclude by saying, Ms. Brody, I appreciated your response to say that regulation does create jobs if we do it in the right way. Thank you for that point.

Senator LAUTENBERG. Thanks very much.

Senator CRAPO.

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

Again, I want to thank you for holding this hearing today, and specifically, I want to convey my thanks to you for being willing to work with us in a bipartisan fashion.

Senator Cardin is right. We have an incredibly toxic political environment here in Congress right now, but this Committee is one of the committees where that brutal toxicity has not yet been able to rear its head. We have some fights and obviously we have some different points of view, but we have, I think, a good-faith intention on the parts of all of the Members on this Committee to try to find the common ground and build the consensus to make progress in the ways that will benefit our Country on all of these issues.

And I just want to relay that message to all of the stakeholders on this issue. I believe that the Members of this Committee are sincere. And I will say to my colleagues on the Committee, I think that the stakeholders whom I have worked with are sincere and want to find a solution to the problems that we face. And so I will tell you, that is the only way that we will be able to move forward, particularly in this political climate.

So I just wanted to make that comment. I wish Senator Inhofe was here so I, too, could wish him happy birthday, but I will do that privately as I get a chance to do so a little bit later.

With regard to the questions I have, I think I will start, Mr. Matthews, with you. TSCA was designed to be a chemical management statute, and we are moving into a focus now on approaching it in the light of protecting workers and first responders and so forth, at least in one context of the discussion.

Could you discuss those dynamics as to how do we try to move forward and achieve that re-focus?

Mr. MATTHEWS. Yes, Senator, thank you.

Yes, I agree with the premise that TSCA is a chemical management statute. It is worth reflecting on the fact that there are other statutes and other agencies besides EPA who have a role in some of the issues which are being or would propose to be addressed through the Safe Chemicals Act, and that is an area of concern that there would be overlapping and inconsistencies.

It is a big job to define the right standard, to run chemicals through the criteria that would be adopted for safety, and to define what a safe use of those chemicals is.

And Senator, you may have been absent when I was talking about what we think is needed here is substantial additional use and exposure information, and to some extent that will cover some of the areas that you have identified of concern.

So I don't think there is an inconsistency in the notion that this law can and perhaps should provide enough data so that there is a fuller picture of where it is being used, how it is being used, and the exposures that are being created.

But at some point, I would say, Senator, that the line has to be drawn where while that is true, if we start to regulate workplace exposures we are going to run into conflict with OSHA, and that is probably, I will say in my judgment, more trouble than it is worth. I think OSHA is a robust statute and can and is being administered appropriately.

One other specific you mentioned I think was emergency workers. And I will say this, we have discussed that issue. It is a little down in the weeds, if I may say that, but it is an important issue, but it is below the level of trying to find common ground. That is not the driver.

But it has come up, for example, in the context of confidential business information. And in that context, we have talked about there will be circumstances where speed and the disclosure of information is critical, and are there ways in which that can be accomplished while, again, still protecting proprietary considerations.

And I think we have begun to identify some of those alternatives. And again, I would use the word, as other Senators have here, it is all about finding solutions to the problem which we mutually agree must be addressed through this law.

Senator CRAPO. Well, thank you. And let me just raise another issue. It kind of relates to the unintended consequences issue, but right now we are seeing, in my opinion, in the Federal Government, at the Federal level across many different industries and issues, an explosion of regulatory activity.

Now, I understand that there are different points of view about the impact of that activity on the economy and on safety and soundness and other factors. One concern that I have is that as we move forward in looking at what the proper statutory and then ultimately regulatory climate should be, is that we have a multiplicity of agencies with jurisdiction over same or similar activities.

Not in this area, but we have been doing a lot of activity in the financial arena recently in terms of regulatory activity, and there are some companies who deal with as many as five or six or seven

regulators. And in some cases, they actually have different definitions of the same kinds of activities and different requirements on the same activities that are impossible to meet. In other words, they can't meet one without failing to meet the other. And we run into these inconsistencies in the regulatory world.

I don't know the answer to this question, but do we face that kind of risk here in terms of the potential for not identifying accurately where the jurisdictional boundaries are between different agencies?

Mr. MATTHEWS. Senator, if that question is directed to me, I would be pleased to say yes, we do face that. I think earlier testimony about the States stepping into the vacuum and creating many different rules for similar chemicals and similar products is one example of that.

I think at the Federal level, as we just mentioned, the notion that a substance may be used in different products and suddenly that implicates OSHA; that implicates FDA considerations and other agencies. It is a reality. There is no perfect solution to that. But I do think that care needs to be taken in adopting a reform TSCA that we don't, with respect, that Congress does not go too far in creating additional conflicts where, again coming back to the purpose and goal, this is chemical management legislation and I think that that needs to remain the focus.

But I must underscore again, at the risk of repetition, that the information that will come to the agency will be substantial; will have implications elsewhere; and certainly this law as drafted, if I recall, permits under defined circumstances the sharing of that information with other agencies which have the appropriate authorities to address some of those other issues.

So I do agree that this is a consideration and we just need to keep our eye on that ball as we go forward.

Senator CRAPO. Thank you. I know some of the others may want to respond to this, but my time is up, so maybe in a next round I can get further into that.

Senator LAUTENBERG. Thanks very much.

Senator Udall?

Senator UDALL. Thank you, Senator Lautenberg. And I thank you for holding this hearing and know that you are always looking out for your children and grandchildren and concerned about these kinds of impacts, chemicals on them; and also looking out for consumers. So I appreciate your laying a bill out there.

I also am concerned about this matter that was brought by first the Chairman and then by Senator Cardin. And I think there is definitely an issue of urgency. Maybe I should just approach this a little different way because I think the thrust of the question is still the same, though.

While EPA maintains a list of chemicals under TSCA, which is nearly 80,000 chemicals that are out there, only 200 have ever been examined under the Act and only five banned. Testing by the Centers for Disease Control and Prevention has found more than 212 industrial chemicals in the bodies of most Americans.

And there have been a lot of television programs. I remember one Bill Moyers did where he went and got his blood tested and he said, "I'm walking around with all these chemicals and I am a

guinea pig." And I think people have seen that and they know that is out there and they are concerned about that.

And of these 212 industrial chemicals in the bodies of most Americans, including at least six known carcinogens and dozens have been linked to cancer, birth defects and other adverse health effects, GAO has called TSCA a high-risk area of law ripe for reform."

So my question is, Mr. Dooley and Mr. Matthews, are you advocating for our body burden of chemicals to go up over time? So are you saying 10 years from now, instead of 212, we should have 400? It is kind of a simple question, yes or no.

Are you pushing for, because that is what the urgency is here is to try to say we are in an unacceptable situation. There is I think some suggestion here that we may mark up this bill. If you are marking up a bill, you want to see language. And I think it is very urgent that we see something more than just criticism of the particular language that is in the bill.

But please, on the body burden question. That is just a yes or no question, Cal.

Mr. DOOLEY. It is a no.

Senator UDALL. So you are not advocating for it to go up? OK.

Mr. DOOLEY. No. The issue, Senator, is that we have to have a system in place.

Senator UDALL. And are you concerned about it?

Mr. DOOLEY. We are absolutely concerned about it, and we think, and that is what we are advocating for the modernization of TSCA. There has to be a system in place that ensures that we can do an evaluation of the safety resulting from a combination of evaluating the hazard and exposure of a particular chemical; understanding in terms of what is the exposure resulting from use of that chemical for its intended purposes; understanding at what level and threshold that chemical might pose a risk to health and safety.

And then when we make a determination through the regulatory process and EPA having the authority there, they determine that this risk of exposure is too high, well, then we have to put in place controls. We totally support that. And we are doing that today when we are engaged with EPA in submitting new chemicals for approval. EPA has a lot of authority to do this today. And we work with them, trying to ensure that we are responding appropriately.

But it is, you know, I will be honest. I take offense when anyone would even insinuate that our industry is supporting an increase in the body burden of chemicals over a period of time.

Senator UDALL. Well, that is where we are headed right now. Where do you think we are headed? Because it has been going up year after year. We put TSCA in place in 1976 and what has happened since then? TSCA and the regulatory agencies don't have the ability. You know that. They do not have the ability to pull chemicals off. One of the most dangerous chemicals was asbestos. We had a failure to regulate under TSCA. It is a carcinogen, outright carcinogen.

So I don't think you can sit there at the table and say, oh, yes, we want to see them pulled off. They are going up and up and up.

Mr. DOOLEY. There needs to be a process in place, which we support, where you would have a scientific evaluation of the exposures

of the chemical that we have determined that pose a safety or environmental risk. There needs to be a process in place that ensures that the industry can manage those exposures in a fashion that ensures that the threshold of that exposure and the amount of those, the body burden of those does not pose a health and safety risk.

Senator UDALL. I am really sorry. I have run over time here. Mr. Chairman, I wish I could stay and hear more of the testimony and hear Senator Carper, who I know is a great champion for consumers on this. I am going to have to leave, but you need to pursue this bill. We need to mark up this bill. We need to move forward with this.

Thank you.

Senator LAUTENBERG. Thanks. And while you are still here, Senator Udall, the conclusion from our friend Mr. Dooley, I think it is summarized broadly that this is a prescription for failure. And when we give it that kind of an umbrella, the sun is not going to shine through there, but we will talk more.

Please, we are anxious to hear from Senator Carper.

Senator CARPER. Thanks, Mr. Chairman.

I am not going to pick on former Congressman Dooley. His reputation in the House was actually somebody who was pretty good at working across the aisle and pretty good at coming to consensus.

And I am going to ask you, and then I am going to ask the other four witnesses as well, to join in just answering a couple of questions. And one of those is what would you say is maybe the largest outstanding issue that the environment and public health communities and industry need to come together on in order to further strengthen this proposal, but to also get it passed? At the end of the day, we need to enact something.

And would you just respond to that? And I will ask our other witnesses to do the same.

Mr. DOOLEY. I would contend that really the most important issue that we need to come to grips on and find a consensus on is on the safety standard, is where we contend that the reasonable certainty of no harm from aggregate exposures we think will lead to paralysis on the regulatory agency. It is not conceivable for industry to meet, and so we need to see some modification of that for a workable solution.

Senator CARPER. All right. Let me ask Mr. Sturdevant.

Mr. STURDEVANT. I would echo that. I think getting the right safety standard that ensures that, A, it has to be a safety standard that can be met; but B, just flipping this paradigm where we put chemicals out there and then see what happens over the course of year, I think moving that up front so we know that these chemicals are safe before going into commerce is the right thing.

Senator CARPER. All right.

Ms. Brody.

Ms. BRODY. I agree it is the safety standard. But I have been doing this long enough that I remember when the American Chemical Council and its previous names was opposed to TSCA reform. And it is only under Mr. Dooley that that position has changed. So I appreciate the leadership that has created that, but I have sat in too many rooms like this where the chemical industry said that

TSCA was working perfectly well and that all chemicals in use were safe.

So I think the safety standard is a really important conversation, but I think we have to actually sit down and say if reasonable certainty of no harm from aggregate exposure isn't the right standard, what other words give the American people what this law is supposed to do, a way of knowing that chemicals in use are safe.

Senator CARPER. OK. Thank you for those comments.

Mr. Matthews.

Mr. MATTHEWS. Senator, I agree that the safety standard is at the heart of it all. I would just add that for this statute to work, it has to be, we think, a risk-based approach. And for risk-based determinations to be made, the system needs better use and exposure information. Our industry has said we understand that and we are prepared to come forward and provide that information, and we think that will make a substantial difference.

Second, having said that, we are extremely concerned about the provisions in the proposed legislation on confidential business information. We are concerned that it will be a disincentive to innovation; that it sets artificial timelines for the expiration of proprietary information that in many cases is unrelated to a timeline. And so that, and that are other aspects of the CBI issue that concern us.

And on one related point, I would like to say a word about new chemicals. While that is primarily an issue that ACC has championed, there is a very direct affect on the downstream community. And that is that if they can't innovate, we can't innovate. We rely on our suppliers to help us find the right products that our customers and consumers are interested in buying, and we don't want to stay with the same products that have been on the shelves, I think, for the last 40 years was the reference.

And so we echo the concern that the new chemicals program if it is working should not be so radically changed as to make it a disincentive to develop newer, greener, safer chemicals. Those are my thoughts.

Senator CARPER. All right. Well said. Thanks.

Mr. Denison.

Mr. DENISON. Thank you, Senator. In my view, the most important issue is to ensure that a reformed TSCA uses the best available science to make decisions about chemicals. Many of the issues that are in contention are actually recommendations of this Nation's highest scientific body, the National Academy of Sciences, that calls on EPA to assess the aggregate risks of chemicals, that we are constantly looking at one use of a chemical at a time and we are looking at an average population exposure, rather than protecting the most vulnerable populations that may be more susceptible or more highly exposed; and rather than understanding that people are being exposed to chemicals from multiple sources.

I think we have to find a way to make a workable approach to dealing with aggregate exposure, because I would agree with Mr. Dooley that it is more complicated than it is in the pesticide area. But the notion of pretending like we can look at one use of a chemical at a time and not look across those uses and aggregate it is

simply inconsistent with the best available science today as it is being even practiced today by the USEPA.

Senator CARPER. OK. Thank you all for responding.

Mr. Chairman, my time is expired, and I don't have time to ask this question or at least get answers for it. But I at just want to put it on the table and then will followup in writing.

But over the last couple of years, several nations, I think among them Canada, Australia, maybe Korea, China, parts of Europe, and some other countries have undertaken reforms of their own nation's chemical safety laws. And the question I will ask you to answer for the record is: What can we learn from them? What should we drill down on and take away from those experiences?

I used to say when I was Governor that some other, whatever issue we are working on in Delaware, I used to say some other State has solved this issue. They figured it out. They solved it. What we have to do is find them and figure out what they did. And so I think that might be helpful as well.

I have a couple of other questions. That is one of them, but thank you all very much for coming here. We need to address this. We need to find a way to come together. And my hope is that under the leadership of our Chairman and Senator Crapo, Senator Inhofe and a lot of people's good will, we can do this.

Senator LAUTENBERG. Yes, we will keep the record open for some time and would ask that anything submitted to you in writing, please as prompt as you can, as fully as you can.

Now, we are pleased to have Senator Whitehouse with us.

Senator.

Senator WHITEHOUSE. Thank you, Chairman Lautenberg and Ranking Member Crapo. I am delighted to be here with you and I appreciate the work that you both have done to try to come together on a TSCA reform bill.

My question is for Mr. Dooley about the American Chemistry Council. It is my understanding, correct me if I am wrong, that the American Chemistry Council has not yet come up with proposed statutory language that would propose the changes that you think are necessary; that your contribution so far has been more that of a critique of the existing language than a proponent of an alternative.

My specific question is, if I am correct about that, would you provide the Committee with a detailed redline of the Safe Chemicals Act this year so that we can see specifically what your proposal is and have that to work with as we try to move forward.

Mr. DOOLEY. We would be prepared, as we have been engaged in substantive conversations on how we think that we can most effectively move forward with a modernization of TSCA. And we can offer suggestions in terms of how we think the legislation should be constructed.

Senator WHITEHOUSE. Would you put those suggestions in writing in legislative format so we can be specific about them?

Mr. DOOLEY. In terms of serving in Congress and now serving in the outside world, we obviously have some concerns about what is the prerogative of the institution, versus an outside entity in terms of responsibility. My view is that it is your prerogative and the Committee's and Congress's prerogative in terms of actual drafting

of legislative language. But we are certainly committed to be a partner to help ensure that in your construct of that language it would reflect our policy priorities would be.

Senator WHITEHOUSE. This is nobody's first rodeo here, and we have all certainly been involved in legislative matters in which the private sector has a very specific point of view. Indeed, from time to time, we are presented with legislation that has actually been drafted by industries.

So I think the question about the prerogative is one that really by the boards and it is really more a matter of willingness. And I would urge you to do what you can to try to put your desires and wishes into a redline markup format. I think that is the most effective way for you to engage. I believe you want to be constructive. I think if you don't put ideas forward, but are simply sniping from the woods on the sides, it doesn't create the image of somebody who is trying to be constructive.

People can say no and move the ball around all day long, but it is a positive effort to go through the trouble, as we have all discovered when we are drafting legislation, to try to put something in writing. And I think it would be an important sign of good faith and good will and a desire to make progress on the part of the industry if you would reconsider that and put something into writing.

I think it puts you in a much better position and a much fairer position, and it lets the other interests who are engaged in this discussion have a sense of where you really stand and that you are not just kind of in the weeds saying no to things. And I don't think that is the place you want to be, but I think unless you do that, that is the place where you end up being.

Mr. DOOLEY. I just think it is kind of interesting that it was over a year ago, I guess, that there were a lot of folks concerned that we would be working with some Members of Congress that we thought would be more aligned with our interests and having them introduce a bill that would reflect our interests. And I think a lot of folks determined that that would be counterproductive to a process going forward.

Senator WHITEHOUSE. That is not our process. We now have a bill and we are simply asking for a redline proposal.

Mr. DOOLEY. And I guess this where there is just a note of frustration. We have met with Members of this Committee staff on the majority side. They are pretty aware of what we think needs to be, and we have given them ideas and suggestions. We haven't given them legislative language, but they are not reflected in the draft that we have today. And that is not necessarily because of a lack of specific suggestions that we have offered, but it is a fundamental disagreement on the direction to go.

So I don't want people to think because we haven't necessarily provided specific legislative language that we haven't engaged in offering some pretty specific solutions, but there could be that they are not reflected in the legislation because there is a fundamental disagreement.

Senator WHITEHOUSE. Well, my time has expired, but I continue to believe that it would be both advisable and helpful to the process if you would take your wishes for this legislation and actually

make them public and write them down in a way that everybody can look at and comment on them.

Thank you.

Senator LAUTENBERG. Thanks very much, Senator Whitehouse. You weren't here before, but we are still planting what I will say is old ground here.

Mr. Dooley, you have been here. You know it isn't, and the reason you don't get to pick out the people that you want to do these things, you don't have the votes. That is fairly simple. And you are a smart fellow and you know that as much of a bite of the apple as you would like to take, that it is never going to be a majority.

So please do what you can to respond, and where we fail, you know, point that out in more specific terms, but be as I think you see running through here, a little more constructive instead of unenforceable and that kind of thing. Figure out ways to get it done. You have a powerful organization there and we are happy to see you here, but with your compliments about my staff and the other Members' staffs here, I thought we were maybe going to clean house. But I have thought it through, and they are really very good, as you described them in the beginning.

[Laughter.]

Senator LAUTENBERG. So we will go on with a couple of questions that I have, and Senator Merkley is back, and Senator Crapo is still here.

I would like to ask Mr. Denison a question. The Safe Chemicals Act as prescribed would require the industry to demonstrate the safety of new chemicals before they enter the market. And some have criticized that that requirement is too burdensome and have suggested preserving TSCA's current approach to new chemicals.

What is needed in terms of new chemicals to have some strength in this program?

Mr. DENISON. Thank you, Senator.

I think given the limited authority and capacity that EPA was given under TSCA, it has done as good a job as it can in trying to address new chemicals coming onto the market; 1,500 notices are received every year. EPA has to process those within 90 days. And one of the major flaws is that it has, in almost all cases, no data that is submitted along with those chemicals by which it can make a decision about whether to allow that chemical on the market or impose conditions.

The other countries in the developed world require a minimum set of safety information to come in when a chemical is filed. And that is something that the Safe Chemicals Act would address by requiring a level of information.

Now, the bill indicates already that the level of information ought to be tiered and varied based on the nature of the chemical, how much is produced, how it is going to be used, and what else is known about it. So I want to emphasize, it is not a one-size-fits-all requirement. It would set an extremely high bar for any new chemical to get on the market, but there needs to be sufficient information for EPA to make a reasoned decision.

Moreover, TSCA fails to have a mechanism by which EPA can readily revisit a new chemical after it is on the market should its production or use pattern change significantly. Only if it goes

through an onerous regulatory process for each and every chemical can it get that kind of look-back provision, the ability to look again at a chemical if its use has expanded, for example, into a consumer product category that it wasn't used in before.

The bill would provide an ability for EPA to look at those chemicals, and again this is consistent with the approach taken in other countries. Canada, which the American Chemistry Council and other industry players have often pointed to as a model program, actually does have a process by which chemicals as they enter into commerce and their use expands, more data are required and the government is required to re-review those chemicals in a tiered fashion.

We think that kind of an approach could balance the need to ensure that you are not stifling innovation and overly impeding the introduction of new chemicals, but at the same time ensure there is some significant degree of safety assured of those chemicals before they get embedded in our economy, when it is very hard to do anything about it.

We need that gate to be at the beginning of the process and not wait until we find some problem 10, 20 years later to actually ensure the safety.

Senator LAUTENBERG. Mr. Sturdevant, the Safe Chemicals Act would preserve the ability of a State to go beyond the Federal standard on chemical safety to protect our citizens. How would establishing the strong Federal system on chemical safety affect the ability to establish the State-level regulations? Where might the States come in there, because we are trying to preserve an option for the States that they see a greater need for supervision?

Mr. STURDEVANT. I think with the changes envisioned in the bill, with a stronger Federal system, the need for the States to engage in these activities would decline I am sure. I think that there would still be cases where the ability to address problems that are occurring in particular States should be maintained. But I think that what we would see instead is just sort of a more normalized State-Federal relationship like we see with a whole bunch of other statutes where there is good Federal backstops and then States can tailor regulations accordingly in their own States.

So I think that we would see that kind of normalized relationship where States address problems if and when they are needed, as opposed to trying to address the fundamental challenges that we have all been talking about here today that really need to be addressed at the Federal level.

So I think that a result from me and my agency would be we would end up spending less time and energy on these efforts because we know that they are being addressed at the Federal level.

Senator LAUTENBERG. Thank you.

Senator CRAPO, do you have something?

Senator CRAPO. Yes, Mr. Chairman.

I just wanted to make an observation, a comment, and the witnesses can comment on this if they would choose. But it seems to me that there is sort of a consistent message point coming from the Democratic side of the aisle to the Chemistry Council here that they have to come forward with statutory language or their response is not acceptable.

Although it is not unheard of for participants or stakeholders on an issue to propose statutory language, I don't know that I recall very many cases in which a Committee has demanded that and sort of set that bar as the bar of proper participation on an issue.

I would tell you that if the effort is to create the impression that failure to come forward with a proposed alternative statutory proposal is the only acceptable way to engage on that issue, I think that is wrong. I can say that the American Chemistry Council and other stakeholders have been in my office many, many times to discuss this issue. I know that they are sincere about wanting to move forward.

As far as I am aware, their concerns have been very, very well expressed. And I believe that every Member of this Committee knows what the conflicts are in terms of disagreements about the issues with regard to the statute.

So I just felt like I had to say that because I felt like there was an impression being created that there was not an engagement or that there was not a willingness to try to work toward finding a solution and that has certainly not been my experience.

Senator LAUTENBERG. If I might, just a quick response. I think that if you have a chance to look through Mr. Dooley's testimony and his commentary, I got the impression that it was thought by Mr. Dooley that we weren't paying enough attention to what they were offering. So my response was to say, OK, give us some statutory language here. But that isn't intended to be a word-for-word kind of thing. It is, OK, give us the challenge to what you see.

And we invite the participation of Mr. Dooley just because we have some differences here. And I think that it is fair for you to voice your organization's views, but on the other side, you have seen the run-through here, including friends on both sides of the aisle, as to, OK, don't like it.

Be more specific about what it is and maybe even do an evaluation that says, OK, we are willing to dismiss the fact that science says that there are some episodes of health problems as a consequence of fairly active use of some chemical here or there.

What we are trying to do, and trying very hard to do, is begin. I started off in my comments this morning with we want an open process and you are included in that opening, obviously. But I think it has to be more specific as to not only what you don't like, but how would you fix it. And I think that is a reasonable request.

Senator CRAPO. My only comment was to the effect that it has been my impression that there has been very aggressive and extensive engagement from all sides. This is an issue on which I have seen a tremendous amount of activity. And I thought that there was an impression being created that was not accurate and I don't want that impression left in this hearing, that any of the participants and stakeholders have not been very engaged in trying to help make their positions and their proposed approaches known to the Committee.

Senator LAUTENBERG. Fair enough.

Senator WHITEHOUSE. If I might add, I don't doubt for a moment that there has been heavy engagement. I think it helps with the transparency of the engagement when there is actual language that is produced. That is my only point.

Senator LAUTENBERG. Senator Merkley.

Senator MERKLEY. Thank you, Mr. Chair.

I wanted to explore a little bit the interaction between American companies and the current chemical regulation regime in the European Union. And I was wondering, Ms. Brody and Mr. Sturdevant, if you could describe succinctly some of the distinctions between the European system and the current American system? Of course, recognizing that our American companies are already engaged in, if you will, working with or within the framework that is laid out in Europe.

Ms. BRODY. Let me just start. Thank you for the question, Senator.

Virtually all of the major players in the American chemical industry are global companies and are selling to the European Union and other markets.

You would agree with me, Cal?

And so all of them are looking at the new law in Europe, REACH, and figuring out how to test their chemicals and if their chemicals will meet the REACH safety standard. So I think it actually adds to this discussion about if the Safe Chemicals Act as written isn't the right language for the American Chemistry Council, what is? Because we have this statute moving in Europe and in other countries that is new and provides a place to start with in thinking about how can American chemical law add to what is already going on in other parts of the world.

And I think it is very appropriate to look at how much money the American chemical industry is already spending to test their chemicals for the European market and to figure out how every single dollar that is being spent there can add information to what we could do to get the kind of exposure, information and use information that we need about chemicals in the United States, and to do that in an important new way.

I think it is important to add, though, that European chemicals law was as broken as American chemicals law still is. And the European Union and its new Parliament took strong action with the opposition of the American Chemistry Council hard and heavy against REACH being enacted. But now that it is the law of the European Union, there is a whole lot we can learn from that and build on in what we do in TSCA reform.

Senator MERKLEY. OK, great.

Mr. Sturdevant.

Mr. STURDEVANT. My knowledge of REACH is quite general so I won't go into specifics. But one thing that has come out of REACH that I think is both worth looking at very hard and has already been beneficial is the amount of information that is coming out of the reporting required there. So that has been one of the key challenges for us at the State level is gaining access to information. So REACH is actually providing us information that we haven't had access to before.

And I certainly understand the concerns expressed by Mr. Matthews about information and sharing too much information, and that inhibiting innovation. I think that there is a lot of room for improvement in the current law on confidential business informa-

tion, how that is kept confidential. I think that there is a happy medium to be found here and REACH could perhaps inform that.

Senator MERKLEY. Thank you.

And to anyone on the panel who would like to comment on it, my impression is that the effort has been made to craft this bill that is before us in a fashion that the information prepared on chemicals for Europe would satisfy the U.S. law. Do you all share that view or do you have a different view? It would be helpful.

Mr. DENISON. I think there has been a concerted effort to ensure that we not reinvent the wheel or create a system that requires duplicate testing, et cetera. There is absolutely information coming from REACH that will be directly relevant in the U.S. and we should make sure that our EPA has the authority to get access to that information and that it is used in informing and meeting the requirements that industry faces in providing minimum information.

So the bill I think goes very far in describing a variety of types of information, including existing information being developed under other jurisdictions that could be used to satisfy the data requirements under this bill. So it would only be the gaps that remain after that other information is factored in that would be a new burden, if you will, on the American industry.

We have an advantage in going second here because the European Union has gone first. And they are taking a lot of arrows in the back because of that. But that actually makes the lift for the U.S. under TSCA reform that much easier.

Senator MERKLEY. Mr. Matthews and Mr. Dooley, I think both of your associations have members who export products to Canada, which has yet a different structure, and to Europe. Any insights on how those reporting requirements are going? And also the degree to which essentially as information is developed for that market, whether that also then largely would address the requirements that we are seeking here in this Act?

Mr. DOOLEY. Just a couple of comments. One on the REACH. Obviously, all of our companies are participating, complying with that. There is the data that we are providing to meet those requirements. I would say that based on our analysis of the legislation, the 847, it is unclear whether or not that data would be similar or identical. And obviously, we would be interested in seeing to the greatest extent possible a harmonization of those data requirements.

But I would also cite that we would look to the Canadian model as being the preferred model over the REACH in that it does embrace a much more of a prioritization process where you would focus the resources of EPA, as well as the private sector, on those chemicals of the greatest concern, that we think would then lead to greater, more positive developments ensuring safer chemicals in commerce.

So we think the Canadian model is actually one which is, from our perspective, would work better from a regulatory context, achieving a similar level of safety outcomes, and would also be more cost-effective and efficient from the industry perspective.

Senator MERKLEY. Thank you.

Senator LAUTENBERG. The record will be kept open.

Before closing the hearing, I ask unanimous consent to have Senator Boxer's statement to be put in the record.

[The prepared statement of Senator Boxer was not received at time of print.]

Senator LAUTENBERG. And the letter from the United Steelworkers, from the American Nurses Association, and a statement from the Procter and Gamble Company.

[The referenced documents follow:]

November 17, 2011

Hon. Barbara Boxer
Chair, U.S. Senate Committee on Environment and Commerce

Hon. Frank Lautenberg
Chair, Subcommittee on Superfund, Toxics and Environmental Health

Dear Senators Boxer and Lautenberg:

Thank you for holding today's hearing on the Safe Chemicals Act. Of course, Charlotte Brody, a member of the United Steelworkers, is scheduled to testify. Our union fully supports her remarks.

We also want to thank you, your staff, and your counterparts in the House who are working hard to reform the Toxic Substances Control Act. You have our complete support.

Our union represents the majority of unionized chemical workers in the United States. We make plastics, fertilizers, pesticides, synthetic rubber, pharmaceuticals, fibers, cosmetics, paints, pigments, solvents, acids, bases and the thousands of organic and inorganic chemicals that our society depends on. We also represent hundreds of thousands of workers who use chemicals on the job.

Our members have a huge stake in chemical safety. When a new chemical goes into production, we are the first to be exposed, and as the makers of that chemical we suffer the highest exposures. Our families, like all American families, are exposed to chemicals in the air they breathe, the water they drink, the food they eat, the products they use. TSCA reform is sometimes described as requiring more chemical testing. However, all chemicals get tested even now. We test them in the bodies of our workers, our children, ourselves. All too often, the hazards of a chemical are uncovered through epidemiological studies – literally by counting the bodies – decades too late. Most of those studies are done on workers. We think chemicals ought to be tested in the lab, not in people. We are sick of being guinea pigs.

Our union also has a huge stake in the economic health of the chemical industry, and all the industries which use chemicals to make the products and provide the services that form our economy. As a matter of fact, we have the greatest stake of all. When a firm crashes or a plant closes, top management goes elsewhere or floats gently down on their golden parachutes. Investors take a hit, but find other opportunities. We are the ones in the unemployment lines.

We hear a lot today about “job-killing regulations.” It seems that every proposed rule, every piece of legislation designed to protect the health, safety, or financial security of ordinary Americans gets attacked as “job-killing.” Frankly, we just don't buy it.

Let us consider the cost of doing nothing. A study in the May issue of the journal “Health Studies” estimates the medical costs of childhood environmental disease – disease caused by chemical pollution – at 77 billion dollars a year. And that was only for the hazards we know but

don't yet adequately control, not for the thousands of chemicals we foist on our children, chemicals whose hazards we do not know.

Another study – this one a 2005 review by the National Institute for Occupational Safety and Health – puts the annual cost of occupational disease between 128 and 155 billion dollars a year. Not all of that is from chemical exposures, of course, but much of it surely is.

Of course these are rough estimates at best. The true economic burden may be lower or it may be higher. We don't really know, and we can't really know until we know more about the hazards of the chemicals in commerce, and we will only know that through a modernized TSCA law.

Let us look at the benefits of TSCA reform. The Blue-Green Alliance is an organization founded by my union and the Sierra Club. It now includes more than a dozen unions and environmental organizations. In a recent study sponsored by the Alliance, James Heintz and Robert Pollen of the University of Massachusetts in Amherst, looked at production and employment trends in the U.S. Chemical Industry. They concluded that a shift to a safer, greener industry could promote innovation, ensure access to global markets, meet the growing consumer demand for safer products, protect shareholder value by reducing the risk of environmental disasters, and – most important for us – create tens of thousands of new jobs in the chemical industry and the industries which use its products.

The issue of competitiveness is especially important. Europe has adopted a strong new system known as REACH (Registration, Evaluation and Authorization of Chemicals) designed to assure that chemicals and products made with chemicals are safe to manufacture and use. Unless the United States follows suit, consumers around the world will ultimately come to trust European products more than they trust American products.

In short, we reject the claim that safer chemicals and greener chemistry will kill jobs. We believe they will, in fact, create jobs and protect the long-term future of the chemical industry. We represent chemical workers. We would not support your legislation in its present form if we thought it would put our members out of work.

Thousands of our members work in the chemical industry. They want to make things that are safe for them, safe for their kids, and safe for the planet. They know that in the long run, their jobs depend on that as well.

Thank you again for holding today's hearing and for your continuing effort to protect the health, safety, and economic security of the American people.

Sincerely yours,

Leo W. Gerard
International President

**Grocery Manufacturers Association Statement before the Senate Committee on
Environment and Public Works and Subcommittee on Superfund, Toxics, and Health's
Hearing on the Safe Chemicals Act**

November 17, 2011

GMA appreciates the leadership of Chairman Frank Lautenberg (D-NJ) and Ranking Member James Inhofe (R-OK) in their efforts to more fully understand the broad scope of stakeholder perspectives on reform of the Toxic Substances Control Act (TSCA). Their constructive leadership has continued to increase the understanding necessary to move a difficult issue such as this one forward.

While S.847 is unworkable in its current form – unmodified since introduction – and contains many serious problems that would need to be resolved, GMA believes the goal of modernizing TSCA is achievable and stands ready to work with policymakers to modernize the law.

GMA supports modernizing TSCA in a manner that will promote innovation and protect American jobs while ensuring consumer confidence in our chemical management system. Specifically, among others core principles, GMA supports legislation that will:

- **Promote Innovation** – TSCA reform should boost confidence in government chemical management and promote even greater innovation by chemical manufacturers and users.
- **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.
- **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.
- **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.
- **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.
- **Use the Best Available Science** – Policymakers should ensure that EPA relies upon the best available science regardless of its source.

GMA looks forward to continuing the dialogue with government, public health, environmental and industry representatives to reach a responsible policy solution on this critical issue.

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Written Statement of
The Procter & Gamble Company
Before
The Committee on the Environment and Public Works
And
Subcommittee on Superfund, Toxics and Environmental Health
Joint Legislative Hearing on the Safe Chemicals Act (S 847)
United States Senate
Washington, D.C.
November 17, 2011

The Procter & Gamble Company's (P&G) Purpose – to touch and improve lives, now and for generations to come – inspires everything that we do. P&G is committed to manufacturing and marketing safe, innovative and sustainable products that provide essential benefits to consumers, while protecting human health and the environment. We have over 700 scientists and regulatory compliance specialists in our comprehensive product safety management organization who ensure all our products are safe for consumers and the environment before they go to market and monitor the products while in the market.

The Procter & Gamble Company is the world's leading consumer products company operating in more than 80 countries worldwide. Our portfolio of recognized brands includes numerous household and industrial products, the ingredients of which are directly subject to EPA regulation under the Toxic Substances Control Act (TSCA). Our chemicals division, P&G Chemicals, is a global leader in the manufacture and marketing of oleochemicals. We have a committed interest in working with Congress and all stakeholders to ensure that legislation to modernize TSCA results in a workable regulatory program that effectively protects the public and the environment while retaining the ability for us to innovate and introduce sustainable products to the market.

P&G recognizes that consumers are concerned about chemicals used in everyday products and fully supports efforts to improve public confidence in the safety and management of chemicals through the modernization of TSCA. P&G takes pride in the work that we do to understand our consumers' needs, habits, practices, and suggestions that allow us to deliver product innovations that delight our consumers and improve their lives. Our work to understand consumers' interests in strengthening the US chemical management system is no different. P&G has actively engaged in discussions with Safer Chemicals Healthy Families (SCHF) because we know that by working to understand each other's interests, concerns and positions we can collectively develop informed solutions that will establish an effective, workable and comprehensive chemicals management policy. We appreciate Senator Lautenberg and Senator Inhofe's similar efforts in conducting a dialogue over the last 6 months with stakeholders. Today's legislative hearing further allows stakeholders to express the need for TSCA modernization, outline how such reform should occur, and work towards a collaborative process that will ultimately deliver a modernized TSCA built from the foundation of stakeholder interests.

Because of our commitment to ongoing dialogue, P&G recently hosted at our corporate headquarters in Cincinnati, Ohio, members of SCHF for a two day discussion on chemical management in commerce and TSCA. Our objective was to demonstrate our chemical and product safety assessment processes, show how we've built TSCA compliance into the rhythm of our daily business, and share ideas on how TSCA can be modernized. We were able to highlight in practice several of our chemical safety programs which demonstrate the following principles we have embraced for TSCA modernization:

- Promote human health (with particular focus on children's health) and the environment through a risk-based chemicals management program, administered by the EPA.
- Protect and promote sustainability through innovation.
- Establish an efficient risk-based process that uses hazard, use and exposure information to identify and prioritize chemical substances for timely assessment and (when needed) proportionate risk management actions.
- Set an updated, appropriate safety standard that can easily be applied in chemical assessment to inform EPA decisions. The process/framework by which EPA determines acceptance of priority chemicals substances against this standard must reflect key principles of risk-based decision making.
- Encourage mutual acceptance and effective use of existing information provided to other governments' chemical management programs and promote further development, validation and acceptance of evolving alternative test methods and assessments to reduce reliance on unnecessary animal testing.
- Provide EPA with sufficient Congressional funding, resources and empowerment to achieve clearly outlined policy objectives and timelines.
- Protect legitimate confidential business information to maintain a competitive and innovative marketplace.

After this visit, P&G and SCHF agreed to continue dialogue on specific aspects of S 847 that are critically important to our business. These detailed discussions have provided valuable insights and revealed opportunities for common ground solutions that could contribute to an updated TSCA.

P&G supports the intent of Congress to implement legislation to modernize TSCA with a purpose of ensuring the protection of human health and the environment and enhancing public confidence in the US chemical management program. TSCA modernization needs to preserve and protect the ability of industry to bring sustainable innovations to market and to maintain the competitiveness of the US economy in the global marketplace. We look forward to continuing engagement with Congress to ensure TSCA modernization achieves an effective, workable and comprehensive US chemical management policy.

Julie Froelicher
U.S. Regulatory Affairs Manager
The Procter & Gamble Company

Chuck O'Hara
Senior Manager, Global Government Relations
The Procter & Gamble Company

Senator LAUTENBERG. And with that, I thank all of you. I thought it was certainly an interesting meeting, but I think it is one that will help us move our legislation along.

And Mr. Dooley, we wait to hear from you and any of you who have further comments you would like to make in writing.

Thank you very much.

The meeting is closed.

[Whereupon, at 11:55 a.m., the committee was adjourned.]

[Additional material submitted for the record follows.]

STATEMENT OF HON. MAX BAUCUS,
U.S. SENATOR FROM THE STATE OF MONTANA

Chairman Lautenberg, thank you for holding this important hearing today on S. 847, the Safe Chemicals Act of 2011.

The Toxic Substances Control Act (TSCA) needs to be reformed. There is a broad consensus that it is outdated. And this bill is an appropriate starting point for that effort.

I have heard many times in recent years from Montanans who are passionate about improving chemical safety. Parents from across Montana, and mothers in particular, are worried about the products that surround their children. Montanans who suffer acute chemical sensitivity would lead better lives with a more transparent system. And I never forget the many Montanans touched by the nightmare of the asbestos contamination of the town of Libby, Montana—and the clear failure of TSCA to address the toxicity of asbestos.

TSCA is not adequately protecting Americans, and it is our obligation to fix it. Congress should give EPA better tools to keep our families safe, including strong up-front requirements for obtaining data about chemicals and the ability to prioritize the risk of different chemicals.

Looking forward, the more we can do to promote green chemistry innovation, the more new jobs we will create, technology we will export, and families we will keep safe. Rivertop Renewables in Missoula, Montana, is a perfect example of this kind of innovation. A balanced bill ought to ensure that homegrown companies like Rivertop can continue to lead the chemical industry.

Thank you again for your hard work in crafting this bill and keeping the process inclusive. I look forward to working with you toward an agreement in this committee.

**BUSINESS ALLIANCE COMMITTED TO FINDING THE RIGHT
APPROACH TO UPDATING TSCA**

WASHINGTON, D.C. (November 17, 2011) -- *The American Alliance for Innovation, an alliance of trade associations representing a broad spectrum of the economy, issued the following statement regarding today's joint legislative hearing on the "Safe Chemicals Act" before the full Senate Committee on Environment and Public Works and the Subcommittee on Superfund, Toxics and Environmental Health:*

"We appreciate the efforts of Chairman Lautenberg and Ranking Member Inhofe to tackle the numerous and complex issues involved with updating the Toxic Substances Control Act (TSCA) so the law ensures the safe use of chemicals, encourages innovation, and protects American jobs.

"The recent discussions amongst certain stakeholders were constructive and can help provide a foundation to bring TSCA into the modern world of chemical management. While these discussions have led to a greater understanding of the differing viewpoints on important aspects of reforming TSCA, there are still many serious issues that need to be resolved and much more work to be done.

"We think the *Safe Chemicals Act*, as written, is not the answer. However, we are committed to continuing to work with all stakeholders — regulators, downstream users, raw material suppliers, distributors, retailers, and environmental, consumer, animal welfare and labor groups — to help Congress find the right approach for updating TSCA. Since TSCA impacts every corner of our economy, we believe that both industry and consumers need to have confidence that any changes to the law lead to a more effective and efficient system of regulating chemicals."

#

The American Alliance for Innovation represents businesses both large and small in industries including the following sectors: aerospace, agriculture, apparel, automotive, building materials, chemical and raw material production, consumer and industrial goods, distribution, energy, equipment manufacturers, electronics, healthcare products and medical technology, food and grocery, information technology, and retail.

Adhesive and Sealant Council
 Alliance of Automobile Manufacturers
 American Apparel & Footwear Association
 American Chemistry Council
 American Cleaning Institute (ACI)
 American Coatings Association
 American Coke & Coal Chemicals Institute
 American Forest & Paper Association
 American Iron and Steel Institute
 American Petroleum Institute
 Automotive Aftermarket Industry Association
 Consumer Specialty Products Association
 Corn Refiners Association
 CropLife America
 Edison Electric Institute
 Fashion Accessories Shippers Association (FASA)
 Fashion Jewelry & Accessories Trade Association
 Flexible Packaging Association
 Grocery Manufacturers Association
 Industrial Minerals Association – North America (IMA-NA)
 International Diatomite Producers Association
 International Fragrance Association North America
 International Sleep Products Association
 Juvenile Products Manufacturers Association (JPMA)
 National Association of Chemical Distributors (NACD)
 National Association of Manufacturers
 National Association for Surface Finishing
 National Association of Printing Ink Manufacturers
 National Electrical Manufacturers Association (NEMA)
 National Industrial Sand Association
 National Mining Association
 National Oilseed Processors Association
 National Petrochemical & Refiners Association
 National Retail Federation
 North American Metals Council
 Personal Care Products Council
 Pine Chemicals Association

Plastic Pipe and Fittings Association
Portland Cement Association
Responsible Industry for Sound Environment (RISE)
Society of Chemical Manufacturers and Affiliates (SOCMA)
Specialty Graphic Imaging Association
SPI: The Plastics Industry Trade Association
Textile Rental Services Association
The Fertilizer Institute
The Vinyl Institute
Travel Goods Association (TGA)
Treated Wood Council
Utility Solid Waste Activities Group



american cleaning institute®
for better living

November 17, 2011

Honorable Frank Lautenberg
Chairman
Subcommittee on Superfund, Toxics & Environmental Health
Committee on the Environment & Public Works
United States Senate
Washington, DC 20510

Honorable James Inhofe
Ranking Member
Committee on the Environment & Public Works
United States Senate
Washington, DC 20510

**RE: Full and Subcommittee on Superfund, Toxics and Environmental Health Joint Hearing:
"Legislative Hearing on the Safe Chemicals Act (S. 847)"**

Dear Chairman Lautenberg and Ranking Member Inhofe:

The American Cleaning Institute® (ACI) is the trade association representing the \$30 billion U.S. cleaning products market. ACI members include the formulators of soaps, detergents, and general cleaning products used in household, commercial, industrial and institutional settings; companies that supply ingredients and finished packaging for these products; and oleochemical producers. ACI and its members are dedicated to improving health and the quality of life through sustainable cleaning products and practices. ACI's mission is to support the sustainability of the cleaning products industry through research, education, outreach and science-based advocacy.

ACI and its members support the modernization of TSCA. ACI has previously written to the Committee that a modernized TSCA would help improve public confidence that the chemicals used to manufacture consumer products and packaging are safe. ACI members believe that product safety is the foundation of consumer trust, and the consumer products industry devotes substantial resources toward achieving this goal.

In many ways, TSCA has been at the forefront of innovative developments in the U.S. and globally. Our members are committed to manufacturing and marketing innovative and sustainable products that provide essential benefits to consumers while protecting human health and the environment. A modernized TSCA has the potential to promote even greater innovation in furtherance of sustainable cleaning products.

Improvements in the law should recognize changes in science and technology and advance innovation. The U.S. Environmental Protection Agency (EPA) needs to take full advantage of information and data in chemical management programs undertaken by other nations. The Agency needs sufficient information to better inform Agency chemical management and assessment decisions.

ACI has called for improvements in TSCA since well before the current Congressional efforts to amend the law. ACI commends the stakeholder meetings process undertaken by your offices over the last several months. ACI appreciates engaging as a direct participant with your staff on the most critical issues related to updating the law. ACI remains concerned, though, that the whole of S. 847 would create

high hurdles to American manufacturing, particularly when it comes to product and process innovations, and ACI suggests the development of new legislation. This can occur through the stakeholder process which has been valuable and constructive for ACI member companies, and the process should continue.

ACI remains committed to a bipartisan, bicameral dialogue to fashion a reasonable approach to updating TSCA in order to promote the safe use of chemicals; build public confidence in the chemical management system; protect American jobs, and maintain the U.S. global leadership role in chemical innovation.

Respectfully submitted,

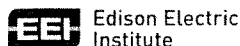


Ernest S. Rosenberg
President & CEO

cc: Members of the U.S. Senate Committee on Environment & Public Works

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202.508.5555 | Fax: 202.508.5766 | tkuhn@eei.org

Power by Association™



Thomas R. Kuhn
President

November 17, 2011

The Honorable Barbara Boxer
Chairman
Committee on Environment & Public Works
United States Senate
112 Senate Hart Office Building
Washington, DC 20510-0505

The Honorable James Inhofe
Ranking Member
Committee on Environment & Public Works
United States Senate
205 Senate Russell Office Building
Washington, DC 20510-3603

Dear Senators Boxer and Inhofe:

In anticipation of the legislative hearing scheduled for November 17 on S. 847, the Safe Chemicals Act, the Edison Electric Institute (EEI) would like to alert you to a specific concern with the text of S. 847. As currently drafted, we believe a provision of the bill would inadvertently upset the federal regulatory program for PCBs that has worked well for the past 30 years in ensuring the safe use of PCBs in electric and natural gas pipeline equipment.

Through the Utility Solid Waste Activity Group (USWAG), EEI has worked successfully with EPA during the Agency's implementation and administration of a robust and mature PCB regulatory program under TSCA § 6(e). Pursuant to TSCA § 6(e), EPA has developed a regulatory program requiring that the use of PCBs in electric and gas pipeline equipment does not pose an unreasonable risk to human health or the environment.

This federal PCB regulatory program is working well. An August 2010 technical report, "Inventory and Cost Estimates for PCB-Containing Electrical Equipment Owned/Operated by U.S. Electric Utilities," prepared by ENVIRON International Corp., found that the "amount of PCB-containing electrical equipment in use by U.S. electric utilities has been reduced by approximately 78%" since the last equipment survey in 1981 and that the amount of PCB-containing equipment still in service now constitutes less than 3% of all electrical equipment in use throughout the country.

November 17, 2011

Page 2

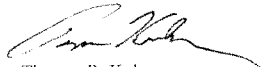
Given the success of the federal PCB program, we are concerned that, as currently drafted, S. 847 could throw the implementation and status of this program into chaos. This problem stems from the text in S. 847 that would replace the entirety of TSCA § 6(e), which is the statutory basis for the existing PCB regulations. The new text in S. 847 would require EPA to find, prior to authorizing the use of PCBs in electric equipment and natural gas pipelines, that such uses do not "present a substantial endangerment to human health or the environment." As explained above, the existing statutory text in § 6(e) already requires that such uses be based on a finding that they do not pose an "unreasonable risk to health or the environment."

While it is unclear precisely what the difference is between these two standards, a literal reading of the text in S. 847 would mean that the use of PCBs in electric and natural gas pipeline equipment would be prohibited until EPA made a finding that such uses do not "present a substantial endangerment to human health or the environment." Upon enactment of the bill and until such a finding is made, one could read the legislation as creating an immediate prohibition on the continued use of certain transmission and distribution equipment still in service in the United States.

Our second concern is with the text in S. 847 directing that, upon ratification by the United States of the Stockholm Convention and other international conventions, the text of those conventions shall apply to the use and disposal of chemical substances in the United States, "notwithstanding any other provision of law." With respect to PCBs, this would mean that the PCB phase-out and disposal directives in the Stockholm Convention would supersede the existing federal PCB regulations, which would again throw into regulatory uncertainty the use of certain transmission and distribution equipment still in service in the United States.

Based on preliminary discussions with Committee staff, we do not believe that the drafters of S. 847 intended for the legislation to produce the above complications for the federal PCB regulatory program. As this important legislation moves forward, we look forward to working with you towards a resolution of our concerns.

Sincerely,



Thomas R. Kuhn

cc: The Honorable Senator Lautenberg

TRK: mh



November 17, 2011

Dear Senator Lautenberg:

We thank all who are making protection of God's children and God's Creation a priority by taking action to reform our nation's broken chemical policy. As people of faith from diverse traditions, we affirm that reforming current chemical policies is vital to protecting people and life on God's Earth.

We have worked to educate people of faith about protecting our bodies as temples of the Holy Spirit. Thousands of Christians have signed our Christian Principles for a Healthy Body and Spirit, and many more interfaith friends have signed our Interfaith Statement on Chemical Policy Reform.

For years, in our work with our member communions as well as state councils of churches, we have emphasized the importance of better understanding and attending to the needs of babies and children's health. Any good chemical policy law should have mechanisms to do this.

We also take very seriously the Biblical mandate to care for the "least of these" (Matthew 25). In the case of chemical policy reform, this means communities that are historically disproportionately exposed in chemical hotspots are cared for. It also means having better protections for workers who are exposed to toxic chemicals each day. Any effective chemical policy must ensure communities of color and low-income communities do not bear a disproportionate burden and that existing harm is mitigated. It should also offer means for proper protection for workers.

We urge Congress to take immediate action to update our nation's chemical policy that will ensure the safety of both existing and new toxic chemicals so that we can protect vulnerable populations such as children, women, the elderly, communities of color, low-income communities, and workers, as well as God's Creation, from the negative health impacts of toxic chemicals.

Sincerely,

Cassandra Carmichael

Director, Eco-Justice Programs of the National Council of Churches



**WRITTEN STATEMENT OF THE
NATIONAL PETROCHEMICAL & REFINERS ASSOCIATION (NPRA)
AS SUBMITTED TO THE
FULL AND SUBCOMMITTEE ON SUPERFUND, TOXICS AND ENVIRONMENTAL
HEALTH
Committee on Environment and Public Works
United States Senate
For a Joint Hearing entitled,
“Legislative Hearing on the Safe Chemicals Act”
November 17, 2011**

NPRA, the National Petrochemical & Refiners Association, appreciates the opportunity to submit this written statement for the record for the full Senate Environment & Public Works Committee and the Subcommittee on Superfund, Toxics and Environmental Health joint legislative hearing on *the Safe Chemicals Act of 2011*.

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

NPRA would like to thank Chairman Lautenberg of the Subcommittee and Ranking Member Inhofe of the full Committee for inviting NPRA to recently participate in a series of stakeholder discussions on the Toxic Substances Control Act (TSCA) reform. During these discussions, several issue areas have been identified as possible areas for stakeholders to find middle ground. However, there is much work to be done and the *Safe Chemicals Act of 2011*, as written, does not meet our shared goal of responsible TSCA modernization. NPRA would like to see these important discussions continue. NPRA would also find value in opening up the format—allowing all stakeholders to discuss the issues together. To be clear, NPRA supports further bipartisan discussion and welcomes opportunities to delve deeper into potential areas for TSCA modernization.

NPRA is of the firm belief that Congress provided a solid, rational framework when it created TSCA back in 1976. The original statute provides the U.S. Environmental Protection Agency (EPA) with a suite of legal tools with which to collect and assess information about chemicals, ultimately enabling the agency to use that information in its mission to protect human health and the environment. The intent of Congress was to strike a balance between EPA's authority to regulate chemicals and the interests of the U.S. manufacturing economy. This balance is evident in the particular authorities granted to EPA, as well as the requirements Congress placed on the agency before it could take specific actions that could disrupt the manufacturing supply chain and, subsequently, the domestic manufacturing economy.

With the solid chemicals management foundation created decades ago, Congress has the opportunity to modernize TSCA and address some of the difficulties EPA has experienced when implementing certain sections of the statute. Our industry supports the reasonable modernization of TSCA, but we also believe that any modernization must be tiered, targeted, and risk-based. Furthermore, TSCA modernization must take into consideration domestic innovation, the ease of entry into the marketplace, American competitiveness, and information protection.

The *Safe Chemicals Act of 2011* has served as a focal point for current discussions, but NPRA does not support the enactment of the bill, as written, due to its breadth and potential economic impact on American manufacturers. The scope of the legislation would dramatically expand chemical control law to the point at which it would disrupt the manufacturing supply chain and impede innovation. The bill gives EPA nearly unfettered authority to collect whatever information it wants, without respect to potential burden or cost. It also allows EPA to take economically disruptive actions with little checks or balances. Furthermore, the bill would also

hand over valuable American intellectual property to other manufacturing regions that are targeting innovative American companies.

NPRA recommends a more targeted legislative approach to TSCA reform rather than a comprehensive rewrite approach. Stakeholders have identified specific challenges that EPA is not meeting and those should serve as the focus for statute updates. If a comprehensive rewrite of TSCA happens instead, then the chances of meaningful reform in the near future would be minimized. NPRA is ready and willing to find solutions to TSCA implementation challenges, including targeted updates to legislation. In principle, NPRA supports the following and will continue to work with other stakeholders to find common ground:

1. **Legislative language should require EPA to conduct a tiered and targeted prioritization scheme, conceptually a sieve-based approach, which considers hazard and exposure throughout the process.** The system employed by Canada under the Canadian Chemical Management Plan should serve as a model because it is the only system that has been proven to prioritize a large number of chemicals within a well-defined time period. Legislative language should reflect what was learned from the experience in Canada, especially with regard to realistic time frames.
2. **A new safety standard should be appropriate for industrial chemicals and not attempt to mimic standards used for pesticides, food contact materials or other substances that have a higher potential for ingestion-based exposures.** There is nothing more important to NPRA's members than the safety of the products they produce. However, industrial chemicals that are not intended for food contact or as pesticide active ingredients should not be regulated in a manner that reflects those product uses. Industrial chemicals should meet a standard that considers hazard and the potential for exposure, and should be based on an existing standard that has a strong legal precedent.
3. **A safety assessment process should be tiered and targeted, and consider hazard and the potential for exposure throughout. The process should also have a voluntary on-ramp for a chemical user who wishes to have a particular product or ingredient assessed and is willing to shoulder the burden for meeting the safety standard.** The safety assessment process should follow traditional hazard, exposure and risk assessment approaches, which are typically tiered and targeted. The process should begin at a screening level, using existing information and conservative models, using hazard information to determine the level of detail in an exposure assessment, and using the potential for exposure to drive information requirements on hazards. EPA should be required to develop a transparent and science-based safety assessment process, with thorough descriptions of each tier and the expected outcomes of each step in the process.
4. **EPA should be required to develop a system by which it can employ a transparent and science-based process for evaluating and weighing data and scientific studies.** Current risk assessments at EPA lack transparency and stakeholders are often left wondering how EPA came to its conclusions in particular assessments. EPA has never

devised a systematic, transparent, science-based approach to weight-of-the evidence, which is essential for appropriate chemical regulation.

5. **TSCA modernization should ensure the protection of American intellectual property.** It is important that detailed information about American chemical products is not publicly available. Otherwise, it would greatly impair American innovation by enabling overseas competitors to easily discover the formulations and chemical compounds of American products through government databases. Overseas firms would then be able to manufacture these products, possibly at a lower price, and export them to the United States, placing American companies at a competitive disadvantage. Data could be shared with state and international governments so long as the appropriate security requirements are in place.
6. **Hazard, use and exposure information available to and used by EPA should be enhanced and driven in a tiered, targeted and risk-based manner.** EPA needs certain information to ensure the protection of human health and the environment. The burden should be on industry to provide information to the agency. The information requirements should be appropriate to meet EPA's needs for assuring safety, with requirements for hazard information being driven by the potential for exposure (i.e., evidence that exposure will occur) and exposure information being driven by relevant hazard endpoints (i.e., exposure pathways that reflect the hazard information). In addition, the burden of information reporting should be shared along the manufacturing supply chain to maintain economic efficiencies and not overburden any particular sector.
7. **EPA should be held to reasonable schedules and time lines when developing the processes, guidance and other items called for in the revised statutory language.** Historically, EPA has been slow or hesitant to develop transparent regulatory processes subject to public comment. In the past three years the number of public meetings on TSCA implementation has dwindled considerably. TSCA modernization should consider holding the agency to well-defined time lines for the development of items required by the statute.
8. **TSCA modernization should include preemption provisions to avoid a patchwork of different state laws that disrupt the flow of interstate commerce.** Some stakeholders point to a lack of confidence in the current TSCA statute and EPA's reluctance to use certain authorities as key drivers for state-level regulatory activity. Appropriate TSCA modernization should restore confidence in the federal chemicals management system, require EPA to use its authorities in an appropriate manner and make the perceived need for state action moot.

Chemical control laws are not like other environmental laws, where the federal government sets a baseline for performance. Rather, chemical control laws directly affect the commercial activities associated with chemicals, which directly affects the interstate flow of goods. There is a strong legal history protecting interstate commerce and federal preemption of state chemical control laws is consistent with legal precedents that pertain

to interstate commerce. Federal preemption of state regulations is a critical part of any TSCA modernization package.

9. **Congress should maintain the scope of TSCA and not attempt to create a legal umbrella that addresses issues outside of chemicals in commerce.** The U.S. has a multitude of laws that address environmental and other issues associated with chemicals. When modernizing TSCA, Congress should not attempt to resolve issues with other statutes – e.g., environmental justice, right-to-know, recycling, etc.
10. **TSCA modernization should maintain the risk and use based exemptions currently in TSCA regulations.** These include existing exemptions for non-isolated intermediates, impurities, byproducts, and research & development substances. These exemptions were developed through careful deliberations by EPA with public input, and have worked well over the years to achieve practical implementation of the requirements while maintaining protection of human health and the environment.

NPRA reiterates its support for rational modernization of TSCA and commends Senators Lautenberg and Inhofe on their efforts to create a bipartisan discussion on a path forward. The discussion is still in the beginning phases and should be allowed to evolve in a manner that maximizes the potential of reaching middle ground. Because chemical control laws can directly impact the entire manufacturing supply chain, NPRA believes great care and deliberation are necessary.

NPRA appreciates the opportunity to submit this statement for the record and is willing to work with the Committee to contribute to more detailed discussions on how to find a middle ground on TSCA reform.



November 16, 2011

The Honorable Barbara Boxer
Chairman
Senate Committee on Environment and Public Works
112 Hart Senate Office Building
Washington, DC 20510

The Honorable James Inhofe
Ranking Member
Senate Committee on Environment and Public Works
205 Russell Senate Office Building
Washington, DC 20510

Re: Full and Subcommittee on Superfund, Toxics and Environmental Health Joint
Legislative Hearing on the Safe Chemicals Act

Dear Chairman Boxer and Ranking Member Inhofe:

On behalf of the members of the Society of Chemical Manufacturers and Affiliates (SOCMA), I would like to share with you our perspective on the subject of your hearing this week: S. 847, the Safe Chemicals Act of 2011. Since 1921, SOCMA has served as the leading trade association representing the batch, custom and specialty chemical industry. SOCMA has over 200 member companies, most of which are small to medium-sized businesses with less than \$100 million in annual sales. Despite their typically small size, our members make a \$60 billion annual impact on the U.S. economy and contribute to the chemical industry's position as one of the nation's largest exporters.

SOCMA would like to thank the Committee and Subcommittee for their efforts to keep this issue on the Congressional radar. We would particularly like to thank Senators Lautenberg and Inhofe, along with their staff, for all the hard work they have put into convening stakeholder discussions, in which we participated, over the course of the year on the issues addressed by this legislation. Our belief is that those discussions made very substantial progress in identifying those aspects of TSCA that most warrant improvement and those that actually work (or can be made to work) effectively in their current form. As those discussions revealed, there is broad stakeholder agreement that TSCA needs to be modernized, and potentially significant agreement on aspects of how that modernization should occur. Because the Safe Chemicals Act was introduced seven months ago, it necessarily could not benefit from those discussions. Instead, it reflects an unworkable solution to the concerns – and misconceptions – that have been associated



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with TSCA. Most important, it fails to sufficiently accommodate the vital engine of chemical innovation, or to balance assessing chemical safety with maintaining continued manufacturing in the U.S.

In our meetings with staff we have pointed out the safety standard in S. 847 would be arguably impossible to meet for the universe of chemicals and uses that fall under TSCA jurisdiction. It will be extremely important to distinguish the difference in this regard between the TSCA program and the federal pesticide and food and drug programs if we are ever to get TSCA modernization right.

We believe EPA's current new chemicals program should be maintained. For several decades, it has managed to protect human health and the environment without impeding innovation, and has thus received broad support. This program is particularly important to our highly innovative membership, which as just noted consists mostly of small and medium-sized businesses. If Congress really wants to incentivize the development of "greener" chemicals and uses, it simply cannot hamstring the chemical industry with substantial upfront product development costs. On balance, new chemicals are "greener" than existing chemicals, and so Congress should not further tilt the playing field against new chemicals – or against new uses of existing chemicals, which could also produce greener results.

The bill's minimum data set requirement is a one-size-fits-all approach that is unnecessary and would result in delays in getting low-risk chemicals to market. The Committee and Subcommittee should look closely at EPA's protective modeling tools, which have proven to be highly predictive of risk, along with some of EPA's recent enhancements to its existing chemicals program. The Committee and Subcommittee should also seek to understand how much health effects data the Agency already has in its files and the amount of data maintained elsewhere that EPA can leverage.

We fundamentally disagree with the bill's prioritization process, which would impose technology-based management measures, without any safety assessment, on Priority 1 chemicals. We also cannot see how the bill's approach to Priority 2 chemicals responds to concerns about the current existing chemicals program, since it would set no deadlines for EPA review of these chemicals and would leave them in prolonged states of regulatory limbo. The Committee and Subcommittee should look to how Canada managed to review the 23,000 chemicals on its Domestic Substances List in seven years.

Protection of confidential business information (CBI) is another one of SOCMA's highest priorities. Because our Nation's resource and labor costs are higher than most of our competitors', our only remaining hope of competitive advantage is our creativity. We simply cannot compete globally if we give our intellectual property away to our competitors. Yet the bill provides another blanket approach that would be particularly harmful to specialty batch chemical manufacturers: CBI is only protected for 5 years and chemical identity is not adequately protected. Given the complexities of our industry, CBI claims should be reviewed on a case-by-case basis. We support requiring up-front substantiation and giving EPA meaningful authority to assure compliance with CBI requirements. These provisions, accompanied by a mechanism to produce better methodologies for developing generic chemical names, would redress justifiable concerns about the current system of CBI protection.



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EPA has ample opportunity to exercise its existing authority more fully, so that it can carry out TSCA as was intended. As the stakeholder discussions revealed, many of the criticisms of the status quo actually stem less from the existing statute and more from the way EPA has implemented it. A prime example is EPA's existing chemicals program, where critics commonly complain about EPA's delay in promulgating test rules. Interestingly, the agency has actually demonstrated that it can, in fact, more expeditiously issue test rules. The timeframes for EPA to finalize its series of High Production Volume (HPV) test rules are as follows:

- First HPV Test Rule - 63 months from proposal to final
- Second HPV Test Rule - 30 months from proposal to final
- Third HPV Test Rule - 20 months from proposal to final

Even the most recent rulemaking seems slow in our opinion, given that there was no organized opposition to these rules – the chemical industry has called on EPA to issue them.

The Agency has also enhanced its information gathering tools with its recently finalized chemical data reporting (CDR) rule, formerly known as the inventory update reporting (IUR) rule. This tool allows EPA to get periodic information on chemicals in commerce that it can use for a variety of purposes. EPA could actually have gone further and required chemical processors to supply use and exposure data – its failure to do so is not a shortcoming of the statute. While Congress could enhance Section 8 to authorize collection of such information from non-consumer users, such enhanced authority will only be as useful as EPA's implementation of it.

We believe these examples give some idea of the range of ways that EPA could make fuller use of its existing TSCA authority. They also show that EPA has not received proper acknowledgement for the progress it has made.

The Committee and Subcommittee can and should revise the Safe Chemicals Act in light of the recent stakeholder discussions. In doing so, it should be guided primarily by how the costs and delays associated with increased data submission or review requirements will impact innovation in the chemical industry. There has been profoundly insufficient discussion of this concern to date. Congress will also have to ensure that it is informed by facts. Far too often we have heard misleading, and flat-out false, statistics regarding EPA's implementation of TSCA. This misinformation should not be the legislative driver that it has been. More reliable information on industrial chemicals in commerce can be found at www.chemicalsincommerce.com.

Again, we appreciate the attention that you are bringing to understanding the implications of TSCA modernization and the dedicated work of your staff in recent months. We are disappointed, nevertheless, that this hearing missed an opportunity to learn from the sector of the chemical industry, represented by SOCMA, that may very well be most impacted by this proposed legislation. We believe that the stakeholder discussions have demonstrated that the TSCA modernization debate is a more a complex issue than it has been portrayed as. We also believe that carefully tailored changes to TSCA are appropriate and warranted. A complete



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SOCMA

rewrite is not, and would stifle the innovation and Green Chemistry that we are sure you also want to promote.

Sincerely,



Lawrence Sloan
President and CEO, SOCMA

cc. Senate Committee on Environment and Public Works



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Testimony of Dr. Paul A. Locke
Associate Professor at John Hopkins Bloomberg School of Public Health,
Department of Environmental Health Studies, Center for Alternatives to Animal Testing

**Submitted to The Senate Committee on Environment and Public-Works,
 Subcommittee on Superfund, Toxics and Environmental Health joint hearing entitled,
 "Legislative Hearing on the Safe Chemicals Act."**

Thursday, November 17, 2011

10:00 AM EST

EPW Hearing Room - 406 Dirksen

Good morning Chairwoman Boxer, Chairman Lautenberg, Ranking Member Inhofe, and members of the committee. I am Dr. Paul Locke and I am an environmental health scientist and attorney. I am an associate professor at the Johns Hopkins University Bloomberg School of Public Health in the Department of Environmental Health Sciences, Division of Toxicology. I am also a member of the faculty of the Johns Hopkins' Center for Alternatives to Animal Testing.

Introduction

Passed in 1976 to correct the indiscriminate use of chemicals in the environment, the Toxic Substances Control Act (TSCA) is the principal US law governing industrial chemicals. However, over the past 35 years, it has become clear that a considerable toxicological information gap exists about chemicals in commerce. The current provisions of the TSCA law have failed to fill and perhaps have even exacerbated that gap.

For the past several years, bills have been introduced in Congress to reauthorize TSCA. Filling the toxicological information gap has been one of the driving forces for this call for substantial change.

I want to commend Senator Frank Lautenberg who has been a long-time advocate for TSCA reform and is the primary sponsor for "The Safe Chemicals Act of 2012." As a public health professional, I recognize the importance of strengthening TSCA and improving toxicity testing of chemicals. This bill is a major step in that direction. The Safe Chemicals Act of 2011 is ambitious, and would amend TSCA by adding or changing over 34 sections, including adding new findings, policies, and goals; reforming provisions on disclosure of data; requiring minimum data sets; and incorporating green chemistry provisions. The bill would shift the burden of proving the safety of existing chemicals from EPA to industry. It would also require companies to develop and submit minimum data sets for chemicals; require EPA to prioritize chemicals based on risk; expedite risk reduction for high concern chemicals; provide greater public access to reliable chemical information; and promote innovation and green chemistry.

Rather than a complete analysis of this proposed legislation, my testimony here is focused on the provisions of the bill that most directly impact toxicity testing or seek to fill the toxics information gap described earlier. In particular, I want to stress that unless the Safe Chemicals Act incorporates a replacement-first approach for toxicity testing, it cannot meet its critical goal of filling the toxics information gap. A replacement-first approach to testing is one that would utilize testing techniques such as computational toxicology and other in vitro methods to collect data ahead of traditional animal-based toxicity testing. These replacement tests, which have been evolving rapidly, are generally faster and more efficient than animal tests. I will focus on four key areas where a replacement-first approach would greatly aid in carrying out the proposed purposes of the bill. These key areas are:

- A. Adding findings, policies and goals, and a changed definition of toxicity
- B. Minimum data set requirements, especially tiered data
- C. Prioritization and classification of chemicals
- D. Specific requirements to reduce animal-based testing

A. Added findings, policies and goals, and a changed definition of toxicity

The current toxicology testing scheme for chemicals in commerce in the US has left much to be desired. This view was substantiated by an external review of EPA toxicity testing commissioned by the EPA and carried out by the US National Academy of Sciences (NAS), National Research Council (NRC). In 2007, the NAS/NRC published a report, *Toxicity Testing in the 21st Century: A Vision and a Strategy* (NRC, 2007). This report set out a new paradigm for how chemicals should be tested based on advances in toxicology. Over the next two decades, the NAS/NRC envisions the emergence of a system of toxicity testing that will utilize high throughput methodologies, human cell lines, and the study of the perturbation of pathways of toxicity that underlie the progression toward disease endpoints. It also envisions the abandonment of the current animal-intensive, low throughput, patchwork system in favor of a program that will be more predictive, cheaper, faster, and more scientifically robust. Federal agencies, including EPA, have embraced the NAS/NRC vision and strategy.

Sections 3 and 4 of the Safe Chemicals Act of 2011 address many of the existing problems with the current TSCA law. Taken together, these new provisions show explicitly that the Safe Chemicals Act of 2011 was meant to take on the toxic ignorance problem that has been so clearly documented in scientific, policy, and legal literature. Specifically, section 4 of the Safe Chemicals Act of 2011 would amend section 3 of TSCA, by adding several new definitions and changing currently existing ones. This clause is very broad, and indicates that the bill intends for EPA to cast a wide net in assessing the potential harm that could result from chemical exposure. The comprehensive list of endpoints is followed by a final clause that seems targeted at the pathways and perturbations approach advocated by the NAS/NRC vision and strategy. Specifically, adoption of the pathways and perturbations concepts from the NAS/NRC report as part of this definition would improve and sharpen it.

B. Minimum data set requirements, especially tiered data

TSCA currently does not require testing of any compound, or set out a minimum data set. The Safe Chemicals Act of 2011 would amend section 4 of TSCA to add a specific requirement that EPA establish, by regulation, a minimum data set for chemical substances for which testing is required. The changes in this section would require that the minimum data set provide for varied (or tiered) data so that a screening-level risk assessment could be carried out. This amendment to TSCA specifically states that EPA must “encourage and facilitate the use of alternative testing methods and testing strategies to generate information quickly, at low cost, and without the use of animal-based testing, including toxicity pathway-based risk assessment, *in vitro* studies, systems biology, computational toxicology, bioinformatics, and high-throughput screening.” Other changes to this section discuss testing methodologies, and specifically include “*in-vitro* tests” in the list of test methods that the EPA can demand.

If the bill, as currently written, were enacted into law, these new provisions might be helpful in moving chemical testing in a replacement focused direction. However, a major weakness exists in these provisions and in the bill generally, which should be corrected. The bill merely states that EPA should “encourage and facilitate” replacement alternatives. This phrasing stops short of what is needed. To reach the goals of this new TSCA law, EPA should be required to develop and use alternatives in regulatory decision making. More specifically, the bill should require EPA to implement the NAS/NRC vision and strategy fully. (Later in the bill, another NAS/NRC report is specifically referenced, so adding an additional reference to the Toxicity Testing report would not be new or unprecedented.) The language in the bill focusing on disease endpoints would benefit from redrafting so that the pathways underlying the endpoints, instead of the endpoints themselves, were emphasized.

C. Prioritization

The Safe Chemicals Act of 2011 would add a provision to TSCA section 6 focusing on prioritization and risk management (Safe Chemicals Act of 2011, section 7, amending TSCA section 6). Under this new section, EPA would be required to develop and publish a list of compounds divided into three priority classes. Priority class 1 would contain chemicals that EPA determines require immediate risk management. Priority class 2 would consist of chemicals that EPA determines require a safety standard determination. The third priority class would contain chemicals that require no immediate action. A US interagency committee would be established to make recommendations to EPA regarding prioritization.

This new prioritization requirement is central to resolving one of the key problems of the current TSCA program, and directly confronts the toxics information gap. Replacement alternatives are well suited to the prioritization decisions that will be needed if this provision were to become law, for the same reasons that replacement alternatives are well suited to tiering and sorting. A successful prioritization program will require replacement alternatives, which can be deployed inexpensively, quickly, and in a high throughput format to aid in decision-making.

Replacement alternatives will also be very useful for manufacturers, who bear the burden of providing information to EPA to carry out safety standard determinations on those compounds placed in category 2. EPA will thus need to be ready to accept these alternatives in evaluating chemical safety. This section of the bill could benefit from a specific provision or provisions that

acknowledge the need for replacement alternatives in assuring success in prioritization, and also by adding a specific requirement that the interagency committee contain at least one member with expertise in replacement alternatives for toxicity testing.

D. Specific requirements to reduce animal-based testing

Section 30 of the Safe Chemicals Act of 2011 addresses the need to minimize the use of animals in testing chemical substances and mixtures. Section 30 is divided into four major subsections:

The first subsection (subsection a) requires EPA to take action to minimize the use of animals in testing, including: encouraging and facilitating the use of existing data; reducing or replacing animal testing methodologies; grouping chemicals (if scientifically appropriate) so that the testing of one chemical substance can serve as a surrogate for decision-making about the group; forming industry consortia to avoid duplicative testing; submitting parallel data from animal and non-animal tests; and funding replacement-first research and validation studies.

The second subsection (subsection b) establishes an interagency science board on alternative testing methods. This board will be composed of members of various federal agencies. Its purpose is to provide independent advice and peer review to Congress and EPA on the use of alternatives and the implementation of this section. This group must issue a report one year after it is formed that lists testing methods for reducing animal use. This report must be updated and reissued every three years.

The third subsection (subsection c) requires EPA to consult with the interagency board established in section 30(b) to develop a strategic plan to improve the development and implementation of alternatives. The report is to be focused on test methods that can be used to carry out safety standard determinations. Every two years, EPA must submit to Congress a report that describes progress and discusses studies undertaken to implement this section.

The fourth and last subsection (subsection d) contains provisions for adapting or waiving required animal-based testing at the request of a chemical manufacturer. To waive animal testing, it must be shown that the animal test is not applicable because the chemical substance does not have the property for which the animal test is given, the specific endpoint is not technically practical, or the chemical substance cannot be tested at a concentration that does not cause pain, distress, severe irritation, or corrosion.

If enacted in its current form The Safe Chemicals Act of 2011 would be the first environmental law provision to explicitly include a section addressing the reduction of animal-based testing. For US law, it represents a changed approach to testing that, for the most part, is aligned with a replacement-first approach. To more effectively implement a replacement-first approach, however, this section should be changed so that EPA is required to do more than “encourage and facilitate” non-animal testing. It should require the development and use of non-animal tests and provide funding for EPA and other federal governmental agencies to strengthen their programs in computational and *in vitro* toxicology. In other words, the bill should contain “technology-forcing” provisions to chart a clear path to the use of non-animal toxicology as soon as the development of science allows. Also, the criteria contained in subsection d should be expanded

so that replacement alternatives can be substituted for animal toxicity tests based on scientific rationales, such as validation, or a demonstration that a replacement test, or series of tests, is as, or more, predictive than the animal-based test.

Conclusion

From the perspective of protecting public health and creating an environment in which the best scientific testing is utilized, a replacement-first strategy is consistent with improving toxicity testing and reducing the toxics information gap. It also offers the best chance to achieve those goals. In particular, section 30 of this bill is an important and ground-breaking provision that acknowledges the desirability of reducing animal testing and using the toxicological tools of the twenty-first century for decision making.

Still, the bill needs to be strengthened so that the move toward a replacement-first approach is clear. More assertive language is necessary to both (1) implement the vision and strategy of the NAS/NRC toxicity testing report, and (2) incorporate the replacement-first approach that the vision and strategy contains. Without these changes, it is not likely that TSCA reauthorization efforts will be able to fulfill one of their key goals – reducing the gap in toxicity information that has plagued public health decision-making for more than 30 years.

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TESTIMONY OF
PHYSICIANS COMMITTEE FOR RESPONSIBLE MEDICINE
BEFORE THE
SENATE COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS
AND
SUBCOMMITTEE ON SUPERFUND, TOXICS, AND ENVIRONMENTAL HEALTH
ON
THE SAFE CHEMICALS ACT, S.847

November 17, 2011

SUBMITTED November 22, 2011

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The Physicians Committee for Responsible Medicine is a national non-profit group of over 125,000 doctors and laypersons advocating for preventive medicine and ethical standards in research and testing. We appreciate the opportunity to submit written testimony for the record.

We have provided legislative language aimed at ensuring that the legislation moves forward on the basis of the best available science. The use of cell-based, tissue-based and computational methods for chemical testing, rather than the use of animals, is critical to the legislation's ability to protect public health. Non-animal methods have the potential to provide more accurate and human-relevant information, much more quickly and affordably. While the extensive use of animals for chemical testing is a significant concern, it is one that has been largely ignored in the discourse on this legislation. We believe the language suggested below will help decrease reliance on animal use, and in turn, increase protection of public health.

SUGGESTIONS FOR S. 847:

SEC. 3. FINDINGS, POLICY, AND GOAL

CHANGE:

(b) POLICY. It is the policy of the United States that—

(6) to reduce the reliance on animal testing in hazard assessment;

(67) to guarantee the right of the public and workers to know about the hazards and uses of chemical substances that the public and workers may be exposed to by maximizing public access to information on chemical safety and use; and

(78) to strengthen cooperation between and among the Federal Government and State, municipal, tribal, and foreign governments

JUSTIFICATION: This is a goal of many in and outside Congress and is linked hand-in-hand with the ability to collect new human-relevant hazard data on thousands of substances in a timely manner.

SEC. 5. MINIMUM DATA SETS AND TESTING OF CHEMICAL SUBSTANCES

CHANGE:

'(d) Exemptions.-

'(2) Action by administrator. In accordance with paragraph (3) or (4), the Administrator shall exempt an applicant under paragraph (1), if, on receipt of the application, the Administrator determines that-

'(A) the chemical substance for which the application was submitted is equivalent to a chemical substance for which-

'(i) data has been submitted to the Administrator in accordance with a rule or order under subsection (a) or (b); or

'(ii) data is being developed in accordance with the rule or order; or
 '(iii) data is being developed in accordance with another regulatory purpose; and
 '(B) submission of data by the applicant for the substance would be duplicative of data that-
 '(i) has been submitted to the Administrator in accordance with the rule or order under
 subsection (a) or (b); or
 '(ii) is being developed in accordance with the rule or order; or
 '(iii) is being developed in accordance with another regulatory purpose.

JUSTIFICATION: All data, including that developed for other regulatory agencies, countries, or purposes outside of this Act, should be brought to bear to prevent duplicative testing.

SEC. 6. MANUFACTURING AND PROCESSING NOTICES.

CHANGE:

'(a) New Chemical Substances and New Uses of Chemical Substances.-
 '(3) New uses of existing chemical substances that meet the safety standard.-
 '(A) In general. For an existing chemical substance for which the Administrator has determined under section 6(b) that the manufacturers and processors of the chemical substance have established that the substance meets the applicable safety standard, no person may manufacture or process the chemical substance for uses, at production volumes, or in manners other than those the Administrator specified in the safety standard determination, unless-
 '(i) the manufacturer or processor submits to the Administrator-
 '(I) a notice of the intention of the manufacturer or processor to manufacture or process the substance for a new use, at a new production volume, or in such other manner as is inconsistent with a specified condition or term for that substance; and
 '(II) all any necessary updates to the minimum data set as determined by the Administrator ~~relevant to the new use, new production volume, or other new manner of manufacturing or processing~~;

JUSTIFICATION: This language makes it more likely that companies will enter into a conversation with the Agency about what new testing might be required, instead of assuming some tests must be done when, depending on the new use or production volume, this may not be the case. The goal is to avoid "one-size-fits-all" data collection.

CHANGE:

'(b) Submission of Data.-
 '(1) In general. A person shall submit to the Administrator data in accordance with the rule or order at the time that notice is submitted under subsection (a), except as provided under subsection (b)(2), if the person is required to submit to the Administrator-
 '(A) under subsection (a), a notice prior to beginning the manufacture or processing of a chemical substance; and
 '(B) under section 4(b), test data for the chemical substance prior to the submission of the

notice.

'(2) Exceptions to minimum data set.-

'(A) A person may, upon application, request exception from specific requirements of the minimum data set described in section 4(a), either before or concurrent with submission of notice under subsection (a).

'(B) The administrator shall determine whether such exception(s) will be granted within 30 days of receipt of application, and make such this determination in accordance with section 30(b)(1) and section 30(e).

'(3) Availability. Subject to section 14, the Administrator shall make any test data submitted under paragraph (1) available on a publicly accessible Internet site.

JUSTIFICATION: This absolutely crucial change clarifies that Congress's intent is to avoid "one-size-fits-all" testing schemes in the new substances sector, just as is provided for in this Act for existing substances. It allows companies to apply for testing exceptions if there is reason to believe certain test are unnecessary for any relevant reason, such as existing data already in the EPA's possession, characteristics of the new substance, or information about related substances. As the Act is written now, companies must submit, animal- and resource-intensive toxicity data at the same time as they notify the EPA of their intent to manufacture the substance, prompting companies to conduct potentially unwarranted testing. This language creates an opportunity for dialog between the company and the EPA regarding the generation of data. At the same time it provides quick turnaround for both the agency and the company, and allows some flexibility to companies who wish to bring newer, potentially safer, chemicals to market but are concerned about the up front costs of traditional toxicity data generation.

CHANGE:

'(c) Content and Availability of Notice.-

'(1) Content. Notice under subsection (a)(1) shall include-

'(A) the declaration described in section 8(a)(2);

'(B) the minimum data set described in section 4(a) and considering subsection (b)(2); and

'(C) a statement that the chemical substance will meet the applicable safety standard.

JUSTIFICATION: Referring to changes in 6(b).

CHANGE:

'(d) Exemptions.-

'(2) ~~Equivalent~~ Similar chemical substances.-

'(A) In general. The Administrator shall, upon application, fully or partially exempt any person from the requirement to submit data under subsection (a) if, on receipt of an application, the Administrator determines that-

'(i) the chemical substance for which the application was submitted is ~~equivalent~~ structurally or toxicologically similar to a chemical substance for which data has been submitted to the

Administrator as required by this Act; and

'(ii) submission of data by the applicant on the chemical substance would be duplicative of data which has been submitted to the Administrator in accordance with this Act.

JUSTIFICATION: Scientific support can be provided to show that two or more structurally or toxicologically very similar, but slightly different (i.e., not equivalent) substances have very similar toxicological properties, making testing of such substances duplicative.

SEC. 30. REDUCTION OF ANIMAL-BASED TESTING.

CHANGE:

'(a) In general. Tests on animals shall not be performed if another scientifically satisfactory method of obtaining the information sought, not entailing the use of an animal, is reasonably and practicably available. Testing on animals for the purpose of this Act shall be undertaken only as a last resort when all other data sources have been exhausted. Where adequate animal test data exist for a toxicological or ecotoxicological endpoint, further animal testing for the same endpoint shall not be required.'

JUSTIFICATION: Such a requirement is the best incentive to develop and use non-animal methods, which is crucial for ethical, scientific, and practical reasons alike. This language is similar to that enacted in other chemicals legislation worldwide (such as REACH in the European Union), and will help implement the National Academies' vision for "Toxicity Testing in the 21st Century", which envisions faster, cheaper, and more human relevant tests instead of currently relied-upon animal tests. More focused, strategic testing and the generation of more human-relevant data will also save EPA resources.

CHANGE:

'(cb) Interagency Science Advisory Board on Alternative Testing Methods.-

'(1) Establishment. Not later than 90 days after the date of enactment of the Safe Chemicals Act of 2011, the Administrator shall establish an advisory board to be known as the 'Interagency Science Advisory Board on Alternative Testing Methods' (referred to in this subsection and subsection (de) as the 'Board').

'(2) Composition. The Administrator shall-

'(A) appoint the members of the Board, including, at a minimum, representatives of-

'(i) the National Institute of Environmental Health Sciences;

'(ii) the Centers for Disease Control and Prevention;

'(iii) the National Toxicology Program;

'(iv) the National Cancer Institute; and

'(v) the National EPA-Tribal Science Council; and

'(vi) not fewer than 3 non-agency members with expertise in alternative testing methods; and

'(B) ensure that at least ½ of the members of the Board have specific scientific or practical expertise in the development or implementation of test methods that replace or reduce animal-based testing; and

'(CB) ensure that no individual appointed to serve on the Board has a conflict of interest that is relevant to the functions to be performed, unless-

'(i) the individual promptly and publicly discloses the conflict; and

'(ii) the Administrator determines that the conflict is unavoidable.

JUSTIFICATION: The public sector contains individuals with years of expertise in the development and use of non-animal methods and alternatives to animal tests, and it is essential that the EPA consult this expertise in addition to federal agency representatives

CHANGE:

'(5) Report. Not later than 1 year after the date of enactment of the Safe Chemicals Act of 2011, and every 23 years thereafter, the Administrator, in consultation with the Board, shall publish in the Federal Register a list of testing methods that reduce the use of animals in testing under section 4.

JUSTIFICATION: The fast-developing scientific fields related to the development of non-animal toxicity tests require updates of a list of accepted testing methods more frequently than every 3 years.

CHANGE:

'(de) Implementation of Alternative Testing Methods. To promote the development and timely incorporation of new testing methods that are not animal-based, the Administrator shall-

'(1) in consultation with the Board, and after providing an opportunity for public comment, develop a strategic plan to promote the development and implementation of alternative test methods and testing strategies to generate information used for safety standard determinations under section 6(b) that do not use animals, including toxicity pathway-based risk assessment, in vitro studies, systems biology, computational toxicology, bioinformatics, and high-throughput screening;

'(2) beginning on the date that is 2 years after the date of enactment of the Safe Chemicals Act of 2011 and every 2 years thereafter, submit to Congress a report that describes the progress made in implementing this section; and

'(3) fund and carry out research, development, performance assessment, and translational studies to accelerate the development of test methods and testing strategies that are not animal-based for use in safety standard determinations under section 6(b); and

'(4) after an opportunity for public comment, establish policies within the administration of this Act that create incentives for the development of alternative test methods and the use of such methods, testing strategies, and other measures to reduce animal-based testing as described in this section.

JUSTIFICATION: Market and other incentives to develop and use non-animal toxicity tests, and the increased uptake of those tests, will save company and EPA resources, protect human health by allowing the collection of data more quickly, and accomplish ethical societal goals.

SEC. 32. COOPERATION WITH INTERNATIONAL EFFORTS.

CHANGE:

(a) 'In cooperation with the Secretary of State and the head of any other appropriate Federal agency (as determined by the Administrator), the Administrator shall cooperate with international efforts as appropriate-

- '(1) to develop a common protocol or electronic database relating to chemical substances; or
- '(2) to develop safer alternatives for chemical substances; or
- '(3) to harmonize testing methods and procedures.

JUSTIFICATION: International cooperation to harmonize testing methods and procedures saves businesses and governments millions of dollars and saves thousands of animals by preventing duplicative testing. Cooperating with other regulatory agencies' efforts to replace animal tests also saves research resources and encourages scientific progress.

Statement for the Record
Submitted by S. C. Johnson & Son, Inc.
Legislative Hearing on the Safe Chemicals Act of 2011
Senate Committee on Environment and Public Works
November 17, 2011

S. C. Johnson & Son, Inc. (SC Johnson) is pleased to submit these comments for the record following the November 17, 2011, legislative hearing on the Safe Chemicals Act of 2011 held jointly by the Committee on Environment and Public Works and the Subcommittee on Superfund, Toxics, and Environmental Health. SC Johnson appreciated the opportunity and invitation by Subcommittee Chairman Senator Frank Lautenberg (D-NJ) to testify before the Subcommittee in February of this year in support of modernizing the current Toxic Substances Control Act (TSCA), and respectfully submits these comments to convey our continued support for updating the 35-year old statute and to reiterate what we believe are the essential "building blocks" of effective TSCA modernization.

SC Johnson has been a family-owned and managed business for 125 years. Fisk Johnson, the family's fifth generation Chairman and CEO, is dedicated to delivering innovative, high-quality products to consumers, excellence in the workplace, and a long-term commitment to the environment and the global communities in which we operate. Based in Racine, Wisconsin, where it was originally founded, SC Johnson is one of the world's leading manufacturers of household cleaning, home storage, air care, shoe care, and insect control products. We market well-known leading brands such as GLADE®, OFF!®, PLEDGE®, RAID®, SCRUBBING BUBBLES®, SHOUT®, WINDEX®, ZIPLOC®, and KIWI® in the U.S. and beyond, and among the brands we market outside the U.S. are AUTAN®, BAYGON®, and MR. MUSCLE®. We employ approximately 12,000 people globally and operate in virtually all countries around the world. You can learn more about SC Johnson by visiting our public website at www.scjohnson.com.

SC Johnson wishes to acknowledge and thank Senator Lautenberg and his staff for their willingness to reach out to and engage numerous stakeholders involved in the TSCA modernization debate, including our company, trade associations representing the downstream formulator industry of which we are an active member (e.g., CSPA, ACI and GMA), and the leading non-governmental organizations (NGOs) that have long supported updating U.S. chemical management policies, most notably the Environmental Defense Fund and the Safer Chemicals, Healthy Families Coalition. Directly and through CSPA, SC Johnson has actively participated in an informative dialogue with these NGOs on specific aspects of the Safe Chemicals Act of 2011 – a process that not only has helped the parties to better understand each other's perspectives on key TSCA modernization topics, but also to identify areas of *potential* consensus that could form the basis of meaningful and successful legislation.

We also wish to commend both Senator Lautenberg and Ranking Member Senator James Inhofe (R-OK) for initiating a series of substantive stakeholder meetings this past summer in which many of these organizations were invited to share their perspectives on key elements of the Safe Chemicals Act of 2011 and to discuss potential solutions. We believe this kind of open, honest dialogue is essential to developing sound public policy and represents a commitment by well-intentioned legislators to understand differing viewpoints on TSCA modernization and to work through the challenging issues and policy questions, so as to ultimately arrive at a workable and effective legislative end-product. We trust the Committee's leadership will seek to continue this productive dialogue as the debate further evolves.

As we testified at the Subcommittee's February 2011 hearing, SC Johnson strongly supports modernization of TSCA and is committed to playing a constructive role in helping to develop workable changes to the current statute. As a consumer-facing company, maintaining a high level of consumer confidence in the safety and performance of each one of our products is a responsibility we take quite seriously. We believe updating TSCA for the 21st Century will, in part, help improve consumers' confidence in the products they purchase for their homes and families. While we still consider TSCA to be primarily a chemical-based vs. a product-based statute, we believe TSCA can be responsibly updated to achieve three very important goals: (1) enhancing consumer confidence in the safety and performance of consumer products; (2) achieving consistent chemical management policy across the 50 states; and (3) keeping pace with global chemical regulatory developments. To that end, there are a few essential principles for TSCA modernization that we will continue to advocate, which are described in more detail in our February 2011 testimony:

- Balanced transparency: SC Johnson strongly supports transparency in the U.S. chemical management program in a way that balances our genuine desire to inform, and thus empower our consumers, with the need to protect legitimate CBI, which helps ensure continued innovation and success in the competitive marketplace.
- Informing a risk-based system: We urge EPA to work with chemical manufacturers and downstream product formulators to ensure that the Agency has sufficient information on chemical hazards, exposures, and uses, including uses in children's products. By committing to provide such exposure and use information, formulators like SC Johnson are agreeing to a new reporting obligation, but one we believe is necessary to properly inform a risk-based safety evaluation process.
- Promoting greener chemistries: Any TSCA modernization effort should promote the transition to more sustainable alternatives, and not hinder manufacturers' ability to formulate out of one ingredient and into another with a more beneficial environmental and human health profile.
- Industry needs sufficient time to respond to new regulatory requirements: It is vitally important for policymakers to ensure that the chemical industry throughout the "value chain" has sufficient time to transform itself and implement the technological and scientific tools needed to accomplish the mission of a modernized TSCA.
- Promoting innovation: Any changes to current TSCA should promote sustainable innovation by chemical manufacturers and their customers by emphasizing simplicity, flexibility, and protection of intellectual property.

Further, SC Johnson believes meaningful TSCA modernization must also embrace the following principles:

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

- Update the safety standard: EPA should establish a risk-based methodology to determine whether a priority chemical is reasonably expected to be safe for its intended use. This will entail the use of exposure data in conjunction with hazard data to make risk-based determinations. Safety determinations should consider the likelihood and potential exposure to the intended population, including children and other sensitive sub-populations, as well as the anticipated benefits from use of a chemical and the availability of suitable alternatives.
- Leverage and integrate chemical reviews: Policymakers should leverage chemical management programs and reviews undertaken by other nations and integrate the patchwork of national laws governing chemical management, when it makes sense to do so. This includes accepting valid data generated to meet another country's requirements, so as to minimize duplication of animal-based testing.
- Use the best available science: It is essential for policymakers and regulators alike to rely on the best available, scientifically valid data and information, employing well-documented methodologies and meeting reasonable quality control standards, regardless of its source, and to discourage the kind of hype and misleading information that we have seen in recent years.

We believe the incorporation of these principles will lead to legislation that will effectively modernize and strengthen current TSCA, and thereby enable consumers to use chemically-formulated products with confidence that they are safe for the environment and their families. SC Johnson pledges to keep working with Chairman Lautenberg, Ranking Member Inhofe and other Committee members to develop a TSCA modernization proposal that reflects the above-mentioned principles and results in an effective, confidence-inspiring, and workable U.S. chemical management system.

SC Johnson appreciates having the opportunity to provide these comments for the hearing record.