

# REVISITING THE TOXIC SUBSTANCES CONTROL ACT OF 1976

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## HEARING BEFORE THE SUBCOMMITTEE ON COMMERCE, TRADE, AND CONSUMER PROTECTION OF THE COMMITTEE ON ENERGY AND COMMERCE HOUSE OF REPRESENTATIVES ONE HUNDRED ELEVENTH CONGRESS

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<sup>1</sup> Mr. Corbin-Mark did not respond to submitted questions for the record.

<sup>2</sup> Mr. Wright did not respond to submitted questions for the record.

## **REVISITING THE TOXIC SUBSTANCES CONTROL ACT OF 1976**

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**THURSDAY, FEBRUARY 26, 2009**

HOUSE OF REPRESENTATIVES,  
SUBCOMMITTEE ON COMMERCE, TRADE,  
AND CONSUMER PROTECTION,  
COMMITTEE ON ENERGY AND COMMERCE,  
*Washington, DC.*

The subcommittee met, pursuant to call, at 10:15 a.m., in Room 2123 of the Rayburn House Office Building, Hon. Bobby L. Rush (Chairman) presiding.

Members present: Representatives Rush, Schakowsky, Sarbanes, Sutton, Gordon, Stupak, Butterfield, Barrow, Castor, Space, Braley, Waxman (ex officio), Radanovich, Stearns, Terry, Murphy, Gingrey and Scalise.

Staff present: Robin Appleberry, Counsel; Dick Frandsen, Counsel; and Jerry Couri, Minority Counsel.

### **OPENING STATEMENT OF HON. BOBBY L. RUSH**

Mr. RUSH. The committee will now come to order.

First of all, I want to welcome the members of the subcommittee to our first hearing on the 111th Congress. I am honored to chair this distinguished subcommittee and I will strive to serve all its members in an honorable way. I truly look forward to working with everybody on a productive legislative and oversight agenda.

In this regard, our first hearing of the 111th Congress is an ambitious one and represents a new addition to the subcommittee's vast jurisdiction. Today's hearing will explore the major issues surrounding the Toxic Substances Control Act, also known as TSCA. TSCA was enacted in 1976 and originally consisted of one title, which today remains at the heart of the statute. While Congress over the years has added additional titles to TSCA addressing individual chemicals and substances, Congress has done very little with regard to Title I. TSCA and Title I have never been reauthorized nor has it been reformed, and very little oversight has been conducted on the statute's effectiveness. Today I hope to start a deliberative process that reverses this Congressional inaction of the past.

By most accounts, TSCA is badly in need of reform. While opinions may vary on the degree and nature of the reforms needed, there is a broad consensus among a diversity of stakeholders that TSCA needs to be reexamined. The scope of TSCA is very broad and its intent is indeed very ambitious. TSCA is meant to provide adequate data on potential health and environmental risk of all

chemical substances and mixtures in the United States. Furthermore, the statute is supposed to provide EPA with adequate regulatory tools to protect the public from unreasonable risk of injury to health or the environment. It is unfortunate that the statute has seemingly been a failure on both of these basic policy goals and objectives. Critics contend that TSCA has failed to generate data on the health risks of approximately 80,000 chemicals currently in use and the approximately 700 new chemicals that are introduced into commerce each and every year.

Even though sections 4 and 5 authorize EPA to force companies to test their chemical products and generate data, the hoops that the EPA must jump through in order to exercise this authority have been much too burdensome. Rulemaking takes years to finalize, costs hundreds of thousands of dollars and is subject to constant legal action by companies who do not want to comply. As the former EPA assistant administrator once said, it almost that we have to first prove that the chemicals are risky before we have the testing done to show whether the same chemicals are indeed risky.

Furthermore, once EPA has made a determination that a chemical poses a health and environmental hazard, they have been unable to act on this determination. Section 6 of TSCA provides EPA with broad authority to regulate and ban chemicals but the burden of proof for action has been so high that banning a chemical is virtually impossible, and I think most Americans would be very surprised to learn that asbestos, a known carcinogen that kills 8,000 Americans each and every year, has not been banned by the EPA under TSCA because the courts have ruled that EPA did not meet its evidentiary burden of proving that asbestos is an "unreasonable risk to the public." If TSCA is incapable of providing EPA with the regulatory tools to ban asbestos, then the statutes seem to be in dire need of serious repair, and I want to make it clear that reexamining TSCA is not only good for the public health but it is also good for business.

I do not believe that this hearing should reflect public health versus business or environment versus business, and I appreciate the innovative spirit of the American businesses and further recognize the importance of fostering that innovative spirit, especially during these perilous times. The public's faith in the safety of its product and chemicals that make up those products has been shaken and I believe that reforming TSCA and reestablishing that faith will ultimately be a boon for American businesses of every stripe, and today's hearing is only the first in a series on TSCA. Today we will kick off the process in a deliberative manner and I sincerely hope that we all can work together in a bipartisan manner.

I yield back the balance of my time

Mr. RUSH. And now I recognize the ranking member, my friend, the gentleman from California, Mr. Radanovich, for an opening statement.

#### **OPENING STATEMENT OF HON. GEORGE RADANOVICH**

Mr. RADANOVICH. Thank you, Mr. Chairman, and I appreciate the fact that you called this hearing today and would like to thank all of our witnesses for taking the time out of your busy schedules to appear before this subcommittee. This is my first hearing as

ranking member of the subcommittee and I am very excited to work with you, Mr. Chairman, and the rest of the members of the subcommittee on the broad range of issues that falls under this committee's jurisdiction.

One of those issues is the regulation of industrial chemical manufacturing in what I understand will be the first in a series of discussions of the Toxic Substances Control Act, TSCA, which was signed into law in 1976. It was revolutionary at the time of its passage because it bestowed sweeping authority on the Environmental Protection Agency, just 6 years old at the time, to regulate interstate commerce and the lifecycle of chemicals manufacturing. Congress has barely touched the core of TSCA Title I since it was enacted. Obviously we all want to make sure that the chemicals produced, imported and used in this country are safe. I think it is reasonable for us to take a look at TSCA but I would urge extreme caution about any efforts to touch what is in the law since TSCA authorities are quite sweeping. It could be that the law is fine and that more funding and enforcement would cure various criticisms. If that is the case, let us be surgical. We should not seek out perfectly functioning laws in an effort to improve or modernize them when neither is needed. Conversely, if something more is needed, we should not use an elephant gun to kill a mosquito.

A timely example of legislative overkill is the recently enacted Consumer Product Safety Improvement Act. Members of Congress like myself who supported the underlying reason behind the legislation are now left scratching our heads in frustration as small businesses, thrift stores and boutique shops in our districts are being forced out of business by the unintended consequence of this otherwise well-intentioned law, a terrible situation in any economy, but particularly during this recession. Unintended consequences are difficult to avoid but when the potential for unintended consequences is foreseen, Congress should move cautiously.

That being the case, a major revision of TSCA, as some of our panelists might suggest today, does pose the potential for a significant threat to small- and medium-sized chemical manufacturers. We should be careful to ensure that all of the regulated entities will be able to reasonably comply with whatever changes we might make. In retrospect, neglecting the ability of all entities to reasonably comply with new regulations was a major mistake of the toy bill and is something that this committee should look at rectifying.

Some folks want to point to States that have already acted to regulate chemicals. It is well known that my home State of California often brags of leading the Nation in a variety of progressive environmental and consumer protection laws and regulations. Those same folks forget to tell the flipside of the story, because as California desperately tries to claw their way out of a \$42 billion budget deficit, which was resolved the other day but in May will be back into deficit spending, Congress should think twice before using any of California's progressive models as a national standard.

My experience has been that California's environmental regulations have increasingly been a hindrance to the success of small businesses and family farms which have had a detrimental impact on the State's overall economy. Unfortunately, the European model

of toxic substance regulation is far worse, which is exactly what some of us would like to see in this Congress adopt.

Currently TSCA operates as a risk-based statute and tries to mitigate potential problems based on a number of relative factors. The European model operates under assumed hazard or precautionary principle which assumes every chemical is harmful until proven otherwise. To me, this is backwards, bureaucratic and a time-consuming way to regulate anything. Appropriately prioritizing chemicals based on risk is a vital component to effective and efficient EPA regulation. In addition to the correct context and risk prioritization, we must be sure that sound, safe and reliable science is guiding regulatory decisions at the EPA.

There are some who want to regulate industrial chemicals similar to how we regulate pesticides under the Federal Insecticide, Fungicide and Rodenticide Act, or FIFRA. My Congressional district is one of the largest agriculture-producing districts in the Nation, and because of this distinction I am well aware of the increasing difficulty farmers face when trying to obtain specialty pesticides. Certain specialty pesticides have a greater risk placed on them because they are applied directly to food that we will eventually touch and put in our mouths and digest. However, it is important that we appreciate the context and the exposure under which industrial chemicals are regulated. Under normal use, and unlike FIFRA-regulated chemicals, the general public will rarely ever be in a position to ingest the vast majority of industrial chemicals. Otherwise Congress is mixing apples with oranges.

Mr. Chairman, there is quite a bit more I would like to add as this has been 3 decades since this Congress has seriously reviewed this law. I think this hearing is going to be very useful and I am looking forward to hearing suggestions on how we can improve TSCA's performance while doing so in the least burdensome fashion. And with that, I yield back and want to thank you, Mr. Chairman.

Mr. RUSH. I want to thank the ranking member and I want to thank him for agreeing with me right at the start.

Our next speaker is my friend, the gentlewoman from Illinois, Ms. Schakowsky, for 2 minutes of opening statements.

#### **OPENING STATEMENT OF HON. JANICE D. SCHAKOWSKY**

Ms. SCHAKOWSKY. Thank you, Mr. Chairman, for holding this very important hearing.

When President Ford signed the Toxic Substances Control Act into law in 1976, it was a major victory for environmental protection. For the first time in our Nation's history, tens of thousands of chemicals in commerce would be tested to determine their long-term effects on human health and the environment. However, as we review this law 33 years after enactment, it is clear that TSCA needs to be updated and strengthened. In fact, the law presents so many problems that since 1991 the EPA has not attempted to ban a single chemical under the TSCA statute. In a report published last month, the GAO reported that without significant reforms to TSCA, "the nation lacks assurance that human health and the environment are adequately protected."

Perhaps more troubling about TSCA is the strict burden of proof the law requires the Environmental Protection Agency to satisfy in order to ban toxic substances. As interpreted by the courts, the lengths the EPA must undertake to meet the burden of proof are so onerous that chemicals known to be extremely hazardous to public health for decades remain outside the scope of TSCA. The perfect example is asbestos. Eight thousand Americans die each year from complications associated with exposure to asbestos. In 1989, EPA attempted to use TSCA to issue a rule to ban the use of asbestos, citing the strong evidence of hundreds of studies that conclusively found that asbestos was extremely hazardous to workers and the public as a whole. Despite the overwhelming evidence, the U.S. Court of Appeals reversed the decision, saying the EPA had not fulfilled the necessary burden of proof under TSCA. The fact that EPA cannot use the law to ban a substance as clearly hazardous as asbestos underscores the need for reform. I look forward to hearing from both panels today, who will share their research and direct experience in dealing with TSCA.

Mr. Chairman, thank you for holding this hearing. I yield back.

Mr. RUSH. Thank you.

Our next opening statement will be from the gentleman from Nebraska, Mr. Terry.

#### **OPENING STATEMENT OF HON. LEE TERRY**

Mr. TERRY. Thank you, Mr. Chairman. I appreciate this opportunity. I think as we progress to see what reforms are necessary, the philosophical differences will be lightest touch versus heaviest touch.

I want to relay an experience I had over the district work period when I met with a small business owner, a couple, a married couple that employed his brother, and it was truly one of those family-owned business called Wes and Willie's. I don't know if any of you know of this company but they are a kids' apparel maker. They have the coolest tee shirt designs and they are very popular in a lot of the catalogs that some of us may get. This is an example of when we go too fast and don't think through our legislation enough, but as a result of the lead-based toys we included other chemicals or additives that also have to be tested before they are allowed to come back in. Unfortunately, this company had to make a decision in order to survive that they have offshored some of their apparel making and silk screening of the paint design on the tee shirts. Under the new rules, every different design is treated as a different product and has to be tested at hundreds of dollars per shirt. But amazingly, while that is a financial hardship to do that on every different design and every different size, there is one of the chemicals that is inherent into the paint that is used and it is such a light level that it barely reads when tested. So the tester said because it is so light, what you have to do is produce 10 tee shirts and we will add them up to see if they accumulate to a level that would be banned. Now, the silliness of that is, how many of us as parents buy 10 of the same tee shirts for our kids and that that child wears all 10 at the same time, but that is what we cause when we rush into something.

So Mr. Chairman, you are on the right path, it is the right idea. Let us make sure that we don't make the mistakes that we did in the toy bill.

Mr. RUSH. I want to thank the gentleman.

Our next speaker is the gentleman from Maryland, Mr. Sarbanes, for 2 minutes of opening statement.

#### **OPENING STATEMENT OF HON. JOHN P. SARBANES**

Mr. SARBANES. Thank you very much, Mr. Chairman. Thanks for holding this hearing. I am looking forward to serving on the subcommittee.

I think obviously there is a need for this review of the Toxic Substances Control Act, as we have heard in the testimony already. There is a staggering number of chemicals in the EPA inventory, 80,000, but of course the data that we have on those chemicals and others that are introduced each year, some 700 additional introduced each year, does not match the degree of hazard that is posed by the chemicals. So just getting the basic data collected and made available is going to be critical, and of course we have heard about the burden of proof issues that need to be addressed. All those are going to come to light, I think, in these hearings. I appreciate your conducting them and I look forward to it.

Thank you, and I yield back.

Mr. RUSH. The chair thanks the gentleman.

Our next member of the committee is Mr. Murphy of Pennsylvania for 2 minutes of opening statement.

#### **OPENING STATEMENT OF HON. TIM MURPHY**

Mr. MURPHY. Thank you, Mr. Chairman, for holding this hearing on the Toxic Substances Control Act. I look forward to hearing testimony from the witnesses on this issue.

But before I begin, I would like to personally welcome two witnesses from the greater Pittsburgh area, Maureen Swanson from the Learning Disabilities Association of America, whose headquarters are in my district, and Michael Wright of the United Steelworkers from Pittsburgh too. Thank you for taking the time to come up here. I am looking forward to hearing your testimony and your thoughts on protecting children and workers, which are two of my top priorities and I am sure the priorities shared by all my colleagues but these are not mutually exclusively concepts as proper regulation can do both.

My district is home to many chemical companies that directly employ about 8,300 people. These are high-paying jobs with the average employee making a family-supporting wage of over \$73,000 a year. As America continues in this recession, these are the kinds of jobs America needs now more than ever, high-tech, high-paying jobs for the future, and we should deal with new legislation that deals with chemicals but we should also be careful that we are doing this in a way that keeps these jobs here in this country and not drives them overseas where there are no regulations to deal with these issues.

Just about everything we come into contact with throughout the day can be traced to chemical companies that help improve our lives and make them better. However, we know there are some



harmful chemicals that are harmful to people, animals and the environment and proper controls must be in place. We must understand that effects may not always be immediately visible and that all necessary precautions must be practiced at all times. So I look forward to hearing more about the specifics of what we need to do with the Toxic Substances Control Act and your thoughts on what we can do to make this environment safer for all.

With that, I yield back, Mr. Chairman.

Mr. RUSH. The chair thanks the gentleman.

The next member recognized is my friend, the gentleman from Michigan, Mr. Stupak, the chairman of the Oversight Subcommittee, for 2 minutes of opening statements.

Mr. STUPAK. Thank you, Mr. Chairman, and congratulations on your chairmanship, and I will waive my opening statement and ask for extra time for questions.

Mr. RUSH. Thank you very much.

Our next speaker is the gentleman from my birth State, Mr. Gingrey, recognized for 2 minutes of opening statement.

#### **OPENING STATEMENT OF HON. PHIL GINGREY**

Mr. GINGREY. Mr. Chairman, thank you and thank you for holding this hearing, and I also thank Ranking Member Radanovich. Obviously these are important issues that come before the subcommittee. I have some prepared written remarks. It probably would take a little more than 2 minutes and I think I will skip those and just speak off the cuff.

Mr. Chairman, I have a bachelor of science in chemistry from Georgia Tech and I am a medical doctor, as my colleagues know. I can remember as a youngster seeing Dupont ads on television. I think their slogan was "Better Living through Chemistry." I believe it was Dupont. But I think what I have heard so far in the opening statements of my colleagues is that there are concerns and that this is a 30-year-old law and it needs to be looked at very carefully and possibly updated. From my side of the rostrum, I think what you are hearing is, we don't want to overshoot, and I can think of so many things since I have been here in my three terms like this Community Reinvestment Act back in the late 1970s and the unintended consequences of that in light of our current economic situation.

Mr. Chairman, I am very happy as a new member of the subcommittee and the committee to be here at this type of hearing. I want to hear very carefully from both panels and try to learn, but again, I think I agree with my colleagues on this side that we really want to make sure that we keep in mind the unintended consequences, and if we make some changes that we do it in the right way and make sure we strike a proper balance.

With that, Mr. Chairman, I will yield back.

Mr. RUSH. The next speaker will be the gentleman from Ohio, Mr. Space, recognized for 2 minutes of opening statement.

#### **OPENING STATEMENT OF HON. ZACHARY T. SPACE**

Mr. SPACE. Thank you, Mr. Chairman.

I represent a district of small towns and villages in a very rural part of Ohio, the hills of Appalachia, in fact, and perhaps the best

phrase to describe those folks that I represent is decent and hard-working, and they I think have a right and we have an obligation to ensure that their workplaces are safe, their children are not exposed to hazardous chemicals, and at the same time that we encourage and promote a business environment that will allow some degree of profitability. The statement has been made by I believe the ranking member that we should not use an elephant gun to kill a mosquito, and I certainly couldn't agree more, but at the same time we should not use a bug light to kill an elephant, and I appreciate the opportunity to hear from our witnesses today on TSCA because doing so allows this subcommittee to move forward in improving what is at best an outdated law and at worst a risk to public health, environmental safety and business innovation. I look forward to exposing exactly what is needed to bring our toxic substance regulatory policy into the 21st century and I am also looking forward to being a part of this committee in a proactive approach to this issue.

Thank you, Mr. Chairman.

Mr. RUSH. The chair thanks the gentleman.

The chair now recognizes the chairman of the full committee, my friend, the gentleman from California, Chairman Waxman.

#### **OPENING STATEMENT OF HON. HENRY A. WAXMAN**

Mr. WAXMAN. Thank you very much, Mr. Chairman. I want to commend you for holding the subcommittee's first hearing in the 111th Congress on the incredibly important issue of reforming the Toxic Substances Control Act of 1976, or TSCA.

This is an important day for consumers, businesses, workers and especially for kids who are most vulnerable to the effects of toxic chemicals. Today marks the beginning of a much-needed national conversation on the use of chemicals in our communities. This conversation is long overdue. For years it has been clear that TSCA is not living up to its intent. For example, in 1991 the Environmental Protection Agency tried to ban the use of asbestos, a known human carcinogen, but EPA's efforts were struck down on the grounds they didn't satisfy the statute's requirements. The Government Accountability Office first recommended changes to make TSCA more effective in 1994. Now 13 years later, GAO has added EPA's assessment and control of toxic chemicals to its high-risk series list of the government programs most at risk for failure. GAO added only three issues to its high-risk list this year. The other two were the entire financial regulatory system and the safety of medical devices and drugs, so that gives you a sense of just how urgent GAO believe this problem is.

This hearing is a good beginning to address the challenge of TSCA reform. In the coming months we will look closely at the specific provisions of the statute and their implementation. We will learn from what has been done in the States and in other countries to create a more effective system of protecting against the dangers of toxic chemicals. In order to be successful, however, we will have to work cooperatively to ensure that a reformed TSCA achieves its essential goals to protect human health and the environment, to make decisions based on sound science and to encourage American innovation and leadership.

We need to get this right. We owe it to our children and our grandchildren to protect them from the dangers of toxic chemicals, and I look forward to meeting this challenge with Chairman Rush, Ranking Member Radanovich, Ranking Member Barton and all the members of the committee.

And finally, let me just say, I know this subcommittee will tackle many other important issues this Congress as well, and I want to commend Chairman Rush for his leadership on all these issues. Thank you, Mr. Chairman.

Mr. RUSH. Thank you, Mr. Chairman.

The chair now recognizes the gentleman from Iowa, Mr. Braley, for 2 minutes.

#### **OPENING STATEMENT OF HON. BRUCE L. BRALEY**

Mr. BRALEY. Thank you, Mr. Chairman, and thank you for holding this important hearing. It is an honor to serve on this subcommittee, and I think it bears mentioning that the title of this subcommittee includes the words "consumer protection." That is the most important responsibility we have when it comes to issues of safety, and I can think of no greater indictment than what we included on page 3 of the memorandum prepared for every member of the committee where it says that in the entire period of time that this Act has been in effect, EPA has not attempted to ban a single chemical under this bill. And then when you see the reference in here to first President Bush's former director of EPA general counsel, if after thousands of deaths from asbestos exposure it is virtually impossible for EPA to regulate any chemical under section 6, what does that say about the impact of this legislation.

It is important for us to have balance, it is important for us to rely upon scientific-based regulation, but it is also important for us to understand the basic purpose of this subcommittee. That is to protect consumers. It is long overdue that we take another look at this Act and provide meaningful opportunities to protect consumers despite the fact that thousands of people have died from exposure to toxic substances since 1991, and I yield back.

Mr. RUSH. The chair now recognizes my friend, the chairman of the Committee on Science, Mr. Gordon, for the purpose of 2 minutes of opening.

Mr. GORDON. Thank you, Mr. Chairman. I will waive my statement so that we can start hearing from our witnesses.

Mr. RUSH. Thank you. Now the chair recognizes the gentleman from Florida for the purposes of 2 minutes of opening statements, Mr. Stearns.

#### **OPENING STATEMENT OF HON. CLIFF STEARNS**

Mr. STEARNS. Thank you, Mr. Chairman, and I look forward to the next 2 years and the hearings we are going to have, and I appreciate you bringing up this topic, a somewhat controversial issue of industrial chemicals and the way they are currently regulated in the United States under the Toxic Substances Control Act. I know when you look through this, it is going to be pros and cons on both sides of this but I think it is important we have these witnesses and I appreciate them being here.

The long and short of it is, we probably have to look at other models to see if they are working. If we move towards a purely European approach to regulate chemicals such as what the Europeans are doing with their REACH program, regulation, evaluation, authorization and restriction of chemical substances, we will have to carefully consider that.

I serve as the lead Republican on the transatlantic dialog with the European Union. Ms. Shelley Berkley from Las Vegas is the chairwoman and I am co-chair and we have been actively involved with this issue and have to impress upon our European counterparts to ensure that the United States cosmetic industry, which is a \$2 billion industry, was not taken off the shelves in Europe due to their new overly burdensome REACH requirements and so I put that into perspective, Mr. Chairman, because a lot of U.S. industry would be hurt by this REACH program that the European Union has implemented.

So I think we have an opportunity to have a constructive discussion today on this very important issue and I thank the chairman for this hearing. I yield back.

Mr. RUSH. The chair thanks the gentleman. At this time the chair would like an unanimous consent request to enter the opening statement of the chairman emeritus, John Dingell, for the record. Not hearing any objections, so approved.

[The prepared statement of Mr. Dingell follows:]

Statement of  
Representative John D. Dingell  
Committee on Energy and Commerce  
Subcommittee on Commerce, Trade, and Consumer Protection  
Hearing on "Revisiting the Toxic Substances Control Act of 1976"

February 26, 2009

Thank you, Mr. Chairman. I commend you for holding today's hearing. When the Congress passed the Toxic Substances Control Act (TSCA) in 1976, it was our intention to give the Environmental Protection Agency (EPA) the authority to restrict the use of a chemical if it posed an unreasonable risk to public health or the environment. In the intervening 32 years, however, it has become apparent that this authority is in need of reevaluation and revision, so that EPA can more capably perform the duty entrusted to it at TSCA's inception.

Advocates for strengthening TSCA emphasize that the Act requires producers neither to conduct health and safety testing of chemicals, nor to generate original data about such chemicals before seeking EPA's approval for their release in commerce. Moreover, such advocates remind us that the Act permits EPA to require producers to provide further health and safety data on new and existing chemicals only in the case that EPA determines there is significant evidence that a chemical poses or may pose an unreasonable risk. Similarly, TSCA obliges EPA, and not producers, to demonstrate a chemical is unsafe in order to prevent its being introduced in commerce. Court cases subsequent to TSCA's enactment have made this burden very difficult to meet, and consequently, EPA has not banned a single chemical under TSCA since 1991. Finally, some call for a weakening of TSCA's confidentiality provisions to allow for greater availability of information about chemicals to serve consumers' rational interest in protecting their health and that of others.

In light of the fact that over 700 new chemicals are developed and enter in commerce each year, these criticisms of TSCA are not without merit. We must take heed of them, as it is our obligation to guard the health and well being of the Nation's citizens. Nevertheless, in our work to amend TSCA, we must consider the potential consequences of rash changes to the Act, lest the pursuit of the perfect good yield unintended consequences. For example, we would do well to examine the financial burden that will be imposed on producers if they are required by law to test chemicals and submit original data to EPA for review. We observe that new testing requirements for lead and phthalate content of children's products mandated by the Consumer Product Safety Improvement Act have caused financial duress disproportionately for small businesses. The import of this should not be lost on anyone in such economically difficult times as these. Additionally, in contemplating the publication of more detailed information about chemicals approved for circulation in commerce, we must be wary of compromising business confidentiality and, in a more extreme extension of logic, facilitating the exploitation of such information by terrorists for nefarious ends.

All of this in mind, I stand ready to work with you, Mr. Chairman, to achieve common-sense and forward-thinking improvements to TSCA and urge you and members of this Subcommittee to proceed in this task with careful deliberation.

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

Mr. RUSH. Now we are privileged to have a fine array of panelists to appear before this subcommittee, and we want to thank them beforehand for taking the time out from their busy schedules to make this first appearance before the 111th Congress on this particular issue.

I want to introduce the witnesses first and then we will ask them to have opening statements for 5 minutes of opening statements. To my left, to your right, Mr. John Stephenson is the director of Natural Resources and Environment of the Government Accountability Office, GAO. Mr. Stephenson has been the director of the environmental protection issues within GAO's natural resources and environment team since October 2000. Seated next to him is Mr. J. Clarence (Terry) Davies, senior fellow, Resources for the Future. Mr. Davies was an EPA assistant administrator for policy in the Administration of President George H.W. Bush. Seated next to Mr. Davies is Ms. Maureen Swanson of the Healthy Children Project, and she is coordinator of Learning Disabilities Association of America. Seated next to Ms. Swanson is Cecil Corbin-Mark, who is the deputy director and the director of policy initiatives for WE ACT for Environment Justice, and that stands for the West Harlem Environmental Action Group, and Mr. Cecil Corbin-Mark is a lifelong resident of Hamilton Heights in Harlem, New York, where his family has lived for the last 6 decades. Seated next to him is Mr. Michael Wright, who is the director of health and safety for United Steelworkers.

With those introductions, I would ask the panel to begin now with their opening statements, and please limit your opening statements to 5 minutes and please pull the microphone directly in front of you as you speak. The chair recognizes Mr. Stephenson.

**TESTIMONY OF JOHN STEPHENSON, DIRECTOR, NATURAL RESOURCES AND ENVIRONMENT, GOVERNMENT ACCOUNTABILITY OFFICE; J. CLARENCE (TERRY) DAVIES, SENIOR FELLOW, RESOURCES FOR THE FUTURE, AND FORMER EPA ASSISTANT ADMINISTRATOR FOR POLICY, ADMINISTRATION OF PRESIDENT GEORGE H.W. BUSH; MAUREEN SWANSON, HEALTHY CHILDREN PROJECT COORDINATOR, LEARNING DISABILITIES ASSOCIATION OF AMERICA; CECIL CORBIN-MARK, DEPUTY DIRECTOR/DIRECTOR FOR POLICY INITIATIVES, WE ACT FOR ENVIRONMENTAL JUSTICE (WEST HARLEM ENVIRONMENTAL ACTION); AND MICHAEL WRIGHT, DIRECTOR OF HEALTH AND SAFETY, UNITED STEELWORKERS**

#### **TESTIMONY OF JOHN STEPHENSON**

Mr. STEPHENSON. Thank you, Mr. Chairman and other members of the subcommittee. I am pleased to be here today to discuss our work supporting the need to improve the Toxic Substances Control Act.

Congress passed TSCA, as many of you have mentioned, in 1976 to enable EPA to obtain more information on the risk of commercially used chemicals and to control those that EPA determines may pose unreasonable risk. However, TSCA's cumbersome regulatory structure and its high legal evidentiary standards have proven difficult for EPA to use to obtain the information it needs to ef-

fectively assess and control toxic chemicals. While TSCA authorizes EPA to review existing chemicals, it generally provides no specific requirement, timeframe or methodology for doing so.

Significantly, chemical companies are not required to develop and submit toxicity information to EPA on existing chemicals unless the agency finds that a chemical may present an unreasonable risk of injury to human health or the environment. This structure places the burden primarily on EPA to demonstrate that a chemical poses a risk rather than on the company that produces it to demonstrate that it is safe. The procedures EPA must follow to obtain test data from companies can take from 2 to 10 years and hundreds of thousands of taxpayer dollars to complete. As a result, in 30 years of TSCA has used its authorities for only about 200 of the roughly 80,000 existing chemicals to require testing. Moreover, TSCA does not require chemical companies to do toxicity tests for the approximate 700 new chemicals introduced into commerce annually and companies generally do not voluntarily provide such testing. In contrast, the European Union's control legislation called REACH generally places the burden on companies to provide health effects data on the chemicals they produce.

Our reports include recommendations that the Congress consider giving EPA more authority to obtain data from the companies producing chemicals and that remains one of the most viable options for improving the effectiveness of TSCA, in our opinion. While TSCA authorizes EPA to issue regulations that may, among other things, limit the production or use of toxic chemicals or ban their use, the statutory requirements EPA must meet to do this presents a legal threshold that has proven difficult for EPA and discourages the agency from using these authorities. For example, EPA must demonstrate unreasonable risk, which requires it to conduct extensive cost-benefit analysis to ban or limit chemical production. Since 1976, EPA has issued regulations to control only five existing chemicals, and one of these, a 1989 regulation phasing out most uses of asbestos, was vacated by the federal courts in 1991 because it did not meet the test of substantial evidence. In contrast, the European Union and a number of other countries have banned asbestos, a known human carcinogen that can cause lung cancer and other diseases.

GAO has previously recommended and continues to believe that Congress should consider amending TSCA to reduce the evidentiary burden EPA must meet to regulate toxic substances. EPA has also limited ability to provide the public with information on chemical production and risk because of TSCA's prohibitions on the disclosure of confidential business information. About 95 percent of the required notices companies have provided to EPA on new chemicals contain some information claimed as confidential. Evaluating the appropriateness of confidentiality claims is time consuming and resource intensive, and as a result EPA does not challenge most claims. State environmental agencies and others have told us that information claimed as confidential would help them in such activities as better preparing emergency response personnel to deal with high-toxic substances at manufacturing facilities and their localities.



The European Union's chemical control law generally provides greater public access to chemical information it receives. GAO has previously recommended that Congress consider providing EPA additional authorities to make more chemical information publicly available.

In numerous reports over the past several years, we have recommended both statutory and regulatory changes to, among other things, strengthening EPA's authority to obtain additional information from the chemical industry, shift more of the burden to chemical companies for demonstrating the safety of their chemicals and enhance the public's understanding of the risk of chemicals to which they may be exposed but little has changed. As a result, in January 2009 we added EPA's processes for assessing and controlling toxic chemicals to GAO's list of high-risk programs in need of broad-based transformation. This list is updated every 2 years and released at the start of each new Congress to help in setting oversight agendas.

Mr. Chairman, we applaud you for holding this hearing and hope it is a first step toward bringing much-needed changes to the way we control toxic chemicals in this country. That concludes my summary, and I will be happy to take questions at the appropriate time.

[The prepared statement of Mr. Stephenson follows:]

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United States Government Accountability Office

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GAO

Testimony  
Before the Subcommittee on Commerce,  
Trade, and Consumer Protection,  
Committee on Energy and Commerce,  
House of Representatives

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Expected at 10:00 a.m. EST  
Thursday, February 26, 2009

## CHEMICAL REGULATION

### Options for Enhancing the Effectiveness of the Toxic Substances Control Act

Statement of John Stephenson, Director  
Natural Resources and the Environment



GAO-09-428T

February 26, 2009



Highlights of GAO-09-428T, a testimony before the Subcommittee on Commerce, Trade, and Consumer Protection, Committee on Energy and Commerce, House of Representatives

### Why GAO Did This Study

Congress passed the Toxic Substances Control Act (TSCA) in 1976, authorizing the Environmental Protection Agency (EPA) to obtain information on the risks of industrial chemicals and to control those that EPA determines pose an unreasonable risk. However, EPA does not have sufficient chemical assessment information to determine whether it should establish controls to limit public exposure to many chemicals that may pose substantial health risks. In reports on TSCA, GAO has recommended statutory changes to, among other things, provide EPA with additional authorities to gain health and safety information from the chemical industry and to shift more of the burden to chemical companies for demonstrating the safety of their chemicals. The most important recommendations aimed at providing EPA with the information needed to support its assessments of industrial chemicals have not been implemented—a key factor leading GAO in January 2009 to add transforming EPA's process for assessing and controlling toxic chemicals to its list of high-risk areas warranting attention by Congress and the executive branch.

This testimony, which is based on prior GAO work, addresses EPA's implementation of TSCA and options for (1) obtaining information on the risks posed by chemicals to human health and the environment, (2) controlling these risks, and (3) publicly disclosing information provided by chemical companies under TSCA.

To view the full product, including the scope and methodology, click on GAO-09-428T. For more information, contact John B. Stephenson at (202) 512-3841 or stephensonj@gao.gov.

## CHEMICAL REGULATION

### Options for Enhancing the Effectiveness of the Toxic Substances Control Act

#### What GAO Found

TSCA generally places the burden of obtaining data on existing chemicals on EPA, rather than on the companies that produce the chemicals. For example, the act requires EPA to demonstrate certain health or environmental risks before it can require companies to further test their chemicals. As a result, EPA does not routinely assess the risks of the roughly 80,000 industrial chemicals in use. Moreover, TSCA does not require chemical companies to test the approximately 700 new chemicals introduced into commerce annually for their toxicity, and companies generally do not voluntarily perform such testing. Further, the procedures EPA must follow in obtaining test data from companies can take years to complete. In contrast, the European Union's chemical control legislation generally places the burden on companies to provide health effects data on the chemicals they produce. Giving EPA more authority to obtain data from the companies producing chemicals, as GAO has in the past recommended that Congress consider, remains a viable option for improving the effectiveness of TSCA.

While TSCA authorizes EPA to issue regulations that may, among other things, ban existing toxic chemicals or place limits on their production or use, the statutory requirements EPA must meet present a legal threshold that has proven difficult for EPA and discourages the agency from using these authorities. For example, EPA must demonstrate "unreasonable risk," which EPA believes requires it to conduct extensive cost-benefit analyses to ban or limit chemical production. Since 1976, EPA has issued regulations to control only five existing chemicals determined to present an unreasonable risk. Further, its 1989 regulation phasing out most uses of asbestos was vacated by a federal appeals court in 1991 because it was not based on "substantial evidence." In contrast, the European Union and a number of other countries have largely banned asbestos, a known human carcinogen that can cause lung cancer and other diseases. GAO has previously recommended that Congress amend TSCA to reduce the evidentiary burden EPA must meet to control toxic substances and continues to believe such change warrants consideration.

EPA has a limited ability to provide the public with information on chemical production and risk because of TSCA's prohibitions on the disclosure of confidential business information. About 95 percent of the notices companies have provided to EPA on new chemicals contain some information claimed as confidential. Evaluating the appropriateness of confidentiality claims is time- and resource-intensive, and EPA does not challenge most claims. State environmental agencies and others have said that information claimed as confidential would help them in such activities as developing contingency plans to alert emergency response personnel to the presence of highly toxic substances at manufacturing facilities. The European Union's chemical control legislation generally provides greater public access to the chemical information it receives, and GAO has previously recommended that Congress consider providing EPA additional authorities to make more chemical information publicly available.

United States Government Accountability Office

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Mr. Chairman and Members of the Subcommittee:

I am pleased to appear today before the Subcommittee on Commerce, Trade, and Consumer Protection, House Committee on Energy and Commerce, to discuss our work on the need to improve the Toxic Substances Control Act (TSCA). As you know, tens of thousands of chemicals are currently in commercial use in the United States and hundreds of new chemicals are introduced into commerce each year—some of which may be toxic and adversely affect human health or the environment. The Congress passed TSCA in 1976 to enable the Environmental Protection Agency (EPA) to obtain information on the risks of commercially used chemicals and to control those that EPA determines may pose unreasonable risks. However, TSCA generally places the burden of obtaining information about the roughly 80,000 chemicals already on the U.S. market on EPA, rather than on the companies that produce the chemicals. The act requires EPA to demonstrate certain health or environmental risks before it can require companies to further test their chemicals. As a result, EPA does not routinely assess the risks of the industrial chemicals that are already in use. Further, for the approximately 700 new chemicals introduced into commerce annually, chemical companies are required to provide EPA with certain information in “premanufacture notices,” and EPA can ban or limit a chemical’s use if it finds, among other things, that this information is insufficient to allow evaluation of the chemical’s health and environmental effects. Although 85 percent of the notices lack any health or safety test data, EPA does not often use its authority to obtain more information.

In previous reports on TSCA, we have recommended both statutory and regulatory changes to, among other things, strengthen EPA’s authority to obtain additional information from the chemical industry, shift more of the burden to chemical companies for demonstrating the safety of their chemicals, and enhance the public’s understanding of the risks of chemicals to which they may be exposed. In part because the most important recommendations aimed at providing EPA with the information needed to support its assessments of industrial chemicals have not been implemented, in January 2009, we added transforming EPA’s processes for assessing and controlling toxic chemicals to our list of areas at “high-risk” for waste, fraud, abuse and mismanagement or in need of broad-based transformation.<sup>1</sup>

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<sup>1</sup>High Risk Series: An Update. GAO-09-271. Washington, D.C.: Jan. 22, 2009.

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My testimony today is largely based on our prior work involving TSCA that identified the challenges associated with implementing the act and some of the legislative options available to address these challenges.

Specifically, my statement addresses EPA's implementation of TSCA and options for (1) obtaining information on the risks posed by chemicals to human health and the environment, (2) controlling these risks, and (3) publicly disclosing information provided by chemical companies under TSCA. In addition, my testimony will also highlight the results of our 2007 report assessing the key differences between the approach to chemical regulation under TSCA and the chemical control policy the European Union adopted in 2006 under legislation known as Registration, Evaluation and Authorization of Chemicals (REACH). (See Related GAO Products following this statement.)

In summary, EPA lacks adequate scientific information on the toxicity of many chemicals in the environment. TSCA generally places the burden of obtaining data on chemicals on EPA, rather than on the companies that produce the chemicals. This approach requires that EPA demonstrate certain health or environmental risks before it can require companies to further test their chemicals. As a result, EPA has only limited information on the health and environmental risks posed by these chemicals. In previous reports on TSCA, we have identified for Congressional consideration statutory changes to strengthen EPA's authority to obtain information from the chemical industry. In our view, these changes remain viable options for improving the effectiveness of TSCA and thereby enhancing EPA's ability to protect public health and the environment.

While TSCA authorizes EPA to issue regulations that may, among other things, ban existing toxic chemicals or place limits on their production or use, the statutory requirements EPA must meet to do so present a legal threshold that has proven difficult for EPA and discouraged agency action. For example, EPA has long concluded that asbestos is a known human carcinogen that can cause lung cancer and other diseases. Although EPA spent 10 years developing a rule to phase out the use of nearly all products containing asbestos under its TSCA authority, a federal appeals court largely vacated the rule because it was not based on "substantial evidence." In contrast to the United States, the European Union and a number of other countries have essentially banned asbestos and asbestos-containing products. Since EPA's asbestos rule was rejected in 1991, the agency has not completed any actions to ban or limit toxic chemicals under section 6. The options for enhancing the effectiveness of TSCA that we have identified in prior reports include amendments to reduce the

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evidentiary burden that EPA must meet to enable EPA to better protect the public health and the environment.

EPA's ability to provide the public with information on chemical production and risk has been hindered by strict confidential business information provisions of TSCA, which generally prohibits the disclosure of confidential business information. State environmental agencies and others have expressed interest in obtaining information claimed as confidential business information for use in various activities, such as developing contingency plans to alert emergency response personnel to the presence of highly toxic substances at manufacturing facilities. In previous reports, we have identified options for statutory changes to improve EPA's ability to make more chemical information publicly available.

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## Background

The Toxic Substances Control Act was enacted in 1976 to provide EPA with the authority, upon making certain determinations, to collect information about the hazards posed by chemical substances and to take action to control unreasonable risks by either preventing dangerous chemicals from making their way into use or placing restrictions on those already in commerce. TSCA authorizes EPA to review chemicals already in commerce (existing chemicals) and chemicals yet to enter commerce (new chemicals). EPA lists chemicals in commerce in the TSCA inventory. Of the over 83,000 chemicals currently in the TSCA inventory, about 62,000 were already in commerce when EPA began reviewing chemicals in 1979. Since then, over 21,000 new chemicals were added to the inventory and are now in use as existing chemicals. To assess risks, EPA examines a chemical's toxicity or potential adverse effects and the amount of human and environmental exposures. TSCA generally requires the industry to notify EPA at least 90 days before producing or importing a new chemical. These notices contain information, such as the chemical's molecular structure and intended uses that EPA uses to evaluate the chemical's potential risks. TSCA also authorizes EPA to promulgate rules to require manufacturers to perform tests on chemicals in certain circumstances or provide other data, such as production volumes, on existing chemicals. In addition, TSCA requires chemical companies to report to EPA any data that reasonably support a conclusion that a chemical presents a substantial risk. If EPA finds that a chemical's risks are unreasonable, it can prohibit or limit its production, processing, distribution, use, and disposal or take other action, such as requiring warning labels on the substance. While TSCA authorizes EPA to release chemical information obtained by the agency under the act, TSCA provides that certain

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information, such as data disclosing chemical processes, can be claimed as confidential business information by chemical manufacturers and processors. EPA generally must protect such information against public disclosure unless such disclosure is necessary to protect against an unreasonable risk of injury to health or the environment.

Like the United States, the European Union has laws and regulations governing the manufacturing and use of chemicals. However, the EU has recently revised its chemical control policy through legislation known as Registration, Evaluation and Authorization of Chemicals (REACH). REACH went into effect in June 2007, but full implementation of all the provisions of REACH will be phased in over an 11-year period. Under REACH, authority exists to establish restrictions for any chemical that poses unacceptable risks and to require authorization for the use of chemicals identified as being of very high concern. These restrictions could include banning uses in certain products, banning uses by consumers, or even completely banning the chemical. Authorization will be granted if a manufacturer can demonstrate that the risks from a use of the chemical can be adequately controlled or that the socioeconomic benefits outweigh the risks and that there are no suitable alternatives. In addition, a key aspect of REACH is that it places the burden on manufacturers, importers, and downstream users to ensure that they manufacture, place on the market, or use such substances that do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary principle. In general, the precautionary principle means that where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to reduce risks to human health and the environment.

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### EPA Lacks Adequate Information on Potential Health and Environmental Risks of Toxic Chemicals

While TSCA authorizes EPA to review existing chemicals, it generally provides no specific requirement, time frame, or methodology for doing so. Significantly, chemical companies are not required to develop and submit toxicity information to EPA on existing chemicals unless the agency finds that a chemical may present an unreasonable risk of injury to human health or the environment or is or will be produced in substantial quantities and that either (a) there is or may be significant or substantial human exposure to the chemical or (b) the chemical enters the environment in substantial quantities. EPA must also determine there are insufficient data to reasonably determine the effects on health or the environment and that testing is necessary to develop such data before it can require a company to test its chemicals for harmful effects. This

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structure places the burden on EPA to demonstrate a need for data on a chemical's toxicity rather than on a company to demonstrate that a chemical is safe. As a result, EPA does not routinely assess the risks of the roughly 80,000 industrial chemicals in use.

EPA has begun to rely on voluntary programs for data, such as the High Production Volume Challenge program, where companies voluntarily agree to provide EPA certain data on high-production volume chemicals. However, these programs may not provide EPA with complete data in a timely manner. For example, there are currently over 200 high-production-volume chemicals for which chemical companies have not voluntarily agreed to provide the minimal test data that EPA believes are needed to initially assess their risks. EPA officials told us that in cases where chemical companies do not voluntarily provide test data and health and safety studies in a complete and timely manner, requiring the testing of existing chemicals of concern—those chemicals for which some suspicion of harm exists—is the only practical way to ensure that the agency obtains the needed information. Furthermore, many additional chemicals are likely to become high production chemicals because the specific chemicals used in commerce are constantly changing, as are their production volumes.

However, EPA officials told us that it is time-consuming, costly, and inefficient for the agency to use TSCA's two-step process of (1) issuing rules under TSCA (which can take months or years to develop) to obtain exposure data or available test data that the chemical industry does not voluntarily provide to EPA and then (2) issuing additional rules requiring companies to perform specific tests necessary to ensure the safety of the chemicals tested. Officials also said that EPA's authority under TSCA to issue rules requiring chemical companies to conduct tests on existing chemicals has been difficult to use because the agency must first make certain findings before it can require testing. Specifically, TSCA requires EPA to find that current data is insufficient; testing is necessary; and that either (1) the chemical may present an unreasonable risk or (2) that the chemical is or will be produced in substantial quantities and that there is or may be substantial human or environmental exposure to the chemical.

Once EPA has made the required findings, the agency can issue a proposed rule for public comment, consider the comments it receives, and promulgate a final rule ordering chemical testing. EPA officials told us that finalizing rules can take from 2 to 10 years and require the expenditure of substantial resources. Given the time and resources required, the agency has issued rules requiring testing for only about 200 chemicals. Because



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EPA has used authority to issue rules to require testing so sparingly, it has not continued to maintain information on the cost of implementing these rules. However, in our October 1994 report on TSCA, we noted that EPA officials told us that issuing such a rule can cost hundreds of thousands of dollars. Given the difficulties involved in requiring testing, EPA officials do not believe that TSCA provides an effective means for testing a large number of existing chemicals. They believe that EPA could review substantially more chemicals in less time if they had the authority to require chemical companies to conduct testing and provide test data on chemicals once they reach a substantial production volume, assuming EPA had first determined that these data cannot be obtained without testing. We have long held a similar view based on our reviews involving TSCA. For example, in our June 2005 report,<sup>2</sup> we recommended that the Congress consider giving EPA the authority to require chemical manufacturers and processors to develop test data based on substantial production volume and the necessity for testing. We continue to believe that providing EPA with more authority to obtain test data from companies would enhance the effectiveness of TSCA.

In contrast with TSCA's provisions for obtaining information on chemicals, we found that REACH, the legislation through which the European Union has recently revised its chemical control policy, requires chemical companies to develop more information than TSCA on the effects of chemicals on human health and the environment. REACH generally requires that chemical companies provide to, and in some cases develop for, government regulators information on chemicals' effects on human health and the environment, while TSCA generally does not. For example, under REACH, chemical companies provide information on chemicals' properties and health and environmental effects for chemicals produced over specified volumes. REACH also provides regulators the general authority to require chemical companies to provide additional test data and other information when necessary to evaluate a chemical's risk to human health and the environment. In contrast, TSCA places the burden on EPA to demonstrate that data on health and environmental effects are needed.

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<sup>2</sup>GAO, *Chemical Regulation: Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program*. GAO-05-458. Washington, D.C.: June 13, 2005

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Regarding new chemicals, TSCA generally requires chemical companies to notify EPA of their intent to manufacture or import new chemicals and to provide any available test data. Yet EPA estimates that most premanufacture notices do not include test data of any type, and only about 15 percent include health or safety test data. Chemical companies do not have an incentive to conduct these tests because they may take over a year to complete, and some tests may cost hundreds of thousands of dollars. Because EPA generally does not have sufficient data on a chemical's properties and effects when reviewing a new chemical, EPA uses models to compare new chemicals with chemicals with similar molecular structures for which test data on health and environmental effects are available.

EPA bases its exposure estimates for new chemicals on information contained in premanufacture notices. However, the anticipated production volume, uses, exposure levels, and release estimates outlined in these notices generally do not have to be amended once manufacturing begins. That is, once EPA completes its review and production begins, chemical companies are not required under TSCA to limit the production of a chemical or its uses to those specified in the premanufacture notice or to submit another premanufacture notice if changes occur. However, the potential risk of injury to human health or the environment may increase when chemical companies increase production levels or expand the uses of a chemical. TSCA addresses expanded uses of chemicals by authorizing EPA to promulgate a rule specifying that a particular use of a chemical would be a significant new use. However, EPA has infrequently issued such rules, which require manufacturers, importers, and processors of the chemical for the new use to notify EPA at least 90 days before beginning manufacturing or processing the chemical for that use.

An option that could make TSCA more effective would be to revise the act to require companies to test their chemicals and submit the results to EPA with their premanufacture notices. Currently, such a step is required only if EPA makes the necessary findings and promulgates a testing rule. A major drawback to testing is its cost to chemical companies, possibly resulting in a reduced willingness to perform chemical research and innovation. To ameliorate such costs, or to delay them until the new chemicals are produced in large enough quantity to offset the cost of testing, requirements for testing could be based on production volume. For example, in Canada and the European Union, testing requirements for low-volume chemicals are less extensive and complex than for those for high-volume chemicals. Congress could give EPA, in addition to its current authorities under section 4 of TSCA, the authority to require chemical

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substance manufacturers and processors to develop test data based on, for example, substantial production volume and the necessity for testing.

Another option would be to provide EPA with greater authority to require testing targeted to those areas in which EPA's analysis models do not adequately predict toxicity. For example, EPA could be authorized to require such testing if it finds that it cannot be confident of the results of its analysis (e.g., when it does not have sufficient toxicity data on chemicals with molecular structures similar to those of the new chemicals submitted by chemical companies.) Under such an option, EPA could establish a minimal set of tests for new chemicals to be submitted at the time a chemical company submits a premanufacture notice for the chemical for EPA's review. Additional and more complex and costly testing could be required as the new chemical's potential risks increase, based on, for example, production or environmental release levels.

According to some chemical companies, the cost of initial testing could be reduced by amending TSCA to require EPA to review new chemicals before they are marketed, rather than before they are manufactured. In this regard, according to EPA, about half of the premanufacture notices the agency receives from chemical companies are for new chemicals that, for various reasons, never enter the marketplace. Thus, requiring companies to conduct tests and submit the resulting test data only for chemicals that are actually marketed would be substantially less expensive than requiring them to test all new chemicals submitted for EPA's review.

Likewise, TSCA's chemical review provisions could be strengthened by requiring the systematic review of existing chemicals. In requiring that EPA review premanufacture notices within 90 days, TSCA established a firm requirement for reviewing new chemicals, but the act contains no similar requirement for existing chemicals unless EPA determines by rule that they are being put to a significant new use. TSCA could be amended to establish a time frame for the review of existing chemicals, putting existing chemicals on a more equal footing with new chemicals. However, because of the large number of existing chemicals, EPA would need the flexibility to identify which chemicals should be given priority. TSCA could be amended to require individual chemical companies or the industry as a whole to compile and submit chemical data, such as that included in EPA's High Production Volume (HPV) Challenge Program, for example, as a condition of manufacture or import above some specified volume.

### TSCA's Regulatory Framework Impedes EPA's Efforts to Control Toxic Chemicals

While TSCA authorizes EPA to issue regulations that may, among other things, ban existing toxic chemicals or place limits on their production or use, the statutory requirements EPA must meet to do so present a legal threshold that has proven to be difficult for EPA. Specifically, in order to regulate an existing chemical under section 6 of TSCA, EPA must find that there is a reasonable basis to conclude that the chemical presents or will present an unreasonable risk of injury to health or the environment. EPA officials believe that demonstrating an unreasonable risk is a more stringent requirement than demonstrating, for example, a significant risk, and that a finding of unreasonable risk requires an extensive cost-benefit analysis. In addition, before regulating a chemical under section 6, the EPA Administrator must consider and publish a statement regarding

- the effects of the chemical on human health and the magnitude of human exposure to the chemical;
- the effects of the chemical on the environment and the magnitude of the environment's exposure to the chemical;
- the benefits of the chemical for various uses and the availability of substitutes for those uses; and
- the reasonably ascertainable economic consequences of the rule, after consideration of the effect on the national economy, small business, technological innovation, the environment, and public health.

Moreover, while TSCA offers EPA a range of control options when regulating existing chemicals—ban or restrict a chemical's production, processing, distribution in commerce, or disposal or use, or require warning labels on the chemicals—EPA is required to choose the least burdensome requirement that will be adequately protective. For example, if EPA finds that it can adequately manage the unreasonable risk of a chemical by requiring chemical companies to place warning labels on the chemical, EPA may not ban or otherwise restrict the use of that chemical. EPA must also develop substantial evidence in the rulemaking record in order to withstand judicial review. Under TSCA, a court reviewing a TSCA rule "shall hold [it] unlawful and set [it] aside...if the court finds that the rule is not supported by substantial evidence in the rulemaking record." As several courts have noted, the substantial evidence standard is more rigorous than the arbitrary and capricious standard normally applied to rulemaking under the Administrative Procedure Act. Further, according to EPA officials, the economic costs of regulating a chemical are usually more easily documented than the risks of the chemical or the benefits associated with controlling those risks, and it is difficult to show

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substantial evidence that EPA is promulgating the least burdensome requirement.

EPA has had difficulty demonstrating that harmful chemicals pose an unreasonable risk and consequently should be banned or have limits placed on their production or use. In fact, since Congress passed TSCA nearly 33 years ago, EPA has issued regulations under the act to ban or limit or restrict the production or use of only five existing chemicals or chemical classes.<sup>3</sup> Significantly, in 1991, EPA's 1989 regulation broadly banning asbestos was largely vacated by a federal appeals court decision that cited EPA's failure to meet statutory requirements.<sup>4</sup> In contrast to the United States, the European Union, as well as a number of other countries, has banned all, or almost all, asbestos and asbestos-containing products.

Asbestos, which refers to several minerals that typically separate into very tiny fibers, is a known human carcinogen that can cause lung cancer and other diseases if inhaled. Asbestos has been used widely in products such as fireproofing, thermal insulation, and friction products, including brake linings. EPA invested 10 years in exploring the need for the asbestos ban and in developing the regulation. Based on its review of over 100 studies of the health risks of asbestos as well as public comments on the proposed rule, EPA determined that asbestos is a potential carcinogen at all levels of exposure—that is, that it had no known safe exposure level. EPA's 1989 rule under TSCA section 6 prohibited the future manufacture, importation, processing, and distribution of asbestos in almost all products. In response, some manufacturers of asbestos products filed suit against EPA arguing, in part, that the rule was not promulgated on the basis of substantial evidence regarding unreasonable risk. In October 1991, the U.S. Court of Appeals for the Fifth Circuit agreed with the chemical companies, concluding that EPA had failed to muster substantial evidence to justify its asbestos ban and returning parts of the rule to EPA for reconsideration.

Specifically, the court concluded that EPA did not present sufficient evidence to justify the ban on asbestos because it did not consider all necessary evidence and failed to show that the control action it chose was the least burdensome regulation required to adequately protect human

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<sup>3</sup>EPA has placed controls on four new chemicals under section 5(f).

<sup>4</sup>The court vacated most of the rule but continued the rule's ban on asbestos products no longer in commerce.

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health or the environment. EPA had not calculated the risk levels for intermediate levels of regulation because it believed there was no asbestos exposure level for which the risk of injury or death was zero. As articulated by the court, the proper course of action for EPA, after an initial showing of product danger, would have been to consider each regulatory option listed in TSCA, beginning with the least burdensome, and the costs and benefits of each option. The court further criticized EPA's ban of products for which no substitutes were currently available stating that, in such cases, EPA "bears a tough burden" to demonstrate, as TSCA requires, that a ban is the least burdensome alternative. In addition, the court stated that in evaluating what risks are unreasonable, EPA must consider the costs of any proposed actions; moreover, the court noted that TSCA's requirement that EPA impose the least burdensome regulation reinforces the view that EPA must balance the costs of its regulations against their benefits. After completing the 1989 asbestos rule, EPA has completed only one regulation to ban or limit the production or use of an existing chemical (for hexavalent chromium in 1990). Further, EPA has not completed any actions to ban or limit toxic chemicals under section 6 since the court rejected its asbestos rule in 1991.

With EPA's limited actions to control toxic chemicals under TSCA, state and federal actions have established controls for some toxic chemicals. For example, a California statute enacted in 2007 prohibits the manufacture, sale, or distribution of certain toys and child care articles after January 1, 2009, if the products contain concentrations of phthalates exceeding 0.1 percent.<sup>3</sup> In 2008, Congress took similar action. California has also enacted limits on formaldehyde in pressed wood. In response to a petition asking EPA to use section 6 of TSCA to adopt the California formaldehyde regulation, EPA recently issued an advance notice of proposed rulemaking suggesting several regulatory options the agency could pursue under its TSCA section 6 authority to limit exposure to formaldehyde. However, because of the legal hurdles the agency would face in regulating formaldehyde under TSCA, some stakeholders have recommended that EPA pursue legislation to control formaldehyde.

In our previous reports on TSCA, we identified a number of options that could strengthen EPA's ability to regulate harmful chemicals under TSCA

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<sup>3</sup>This statute, as well as restrictions in place by the European Union, covers several phthalates, including dibutyl phthalate. In 2000, the Department of Health and Human Services' National Toxicology Program concluded that dibutyl phthalate may adversely affect human reproduction or development if exposures are sufficiently high.

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and enhance EPA's ability to protect public health and the environment. Potential changes to TSCA include reducing the evidentiary burden that EPA must meet to take regulatory action under the act by amending the (1) unreasonable risk standard that EPA must meet to regulate existing chemicals under section 6 of TSCA, (2) standard for judicial review that currently requires a court to hold a TSCA rule unlawful and set it aside unless it is supported by substantial evidence in the rulemaking record, and (3) requirement that EPA choose the least burdensome regulatory requirement. We have previously recommended that the Congress amend TSCA to reduce the evidentiary burden that EPA must meet.<sup>6</sup>

Alternatively, the European Union's recently enacted chemical control legislation, REACH, represents a regulatory model that differs from the TSCA framework in key ways. For example, REACH is based on the principle that chemical companies have the responsibility to demonstrate that the chemicals they place in the market, distribute, or use do not adversely affect human health or the environment, while TSCA generally requires EPA to demonstrate that chemicals pose risks to human health or the environment prior to controlling risks related to their production, distribution, or use. In addition, under REACH, chemical companies must obtain authorization to continue to use a chemical of very high concern, such as a chemical for which there is scientific evidence of probable serious health or environmental effects. Generally, to obtain such authorization, the chemical company needs to demonstrate that it can adequately control risks posed by the chemical, such as by requiring that workers wear safety equipment when working with the chemical or otherwise ensuring that the chemical is produced under safe conditions. If the chemical company cannot provide evidence of adequate control, authorization would be granted only if the socioeconomic advantages of a specific use of the chemical are greater than its potential risks, and if there are no suitable alternatives or technologies. This process substantially differs from TSCA's section 6 requirements as discussed above.

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<sup>6</sup>GAO, *Toxic Substances Control Act: Legislative Changes Could Make the Act More Effective*. GAO/RCED-94-103. Washington, D.C.: September 26, 1994.

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### EPA's Ability to Share Information Under TSCA's Confidential Business Information Provisions Are Limited

EPA's ability to make publicly available the information that it collects under TSCA is limited. Chemical companies may claim some of the information they provide to EPA under TSCA as confidential business information. EPA is required under the act to protect trade secrets and privileged or confidential commercial or financial information against unauthorized disclosures, and this information generally cannot be shared with others, including state health and environmental officials and foreign governments. However, some state officials believe this information would be useful for informing and managing their environmental risk programs. Furthermore, while EPA believes that some claims of confidential business information may be unwarranted, challenging the claims is resource-intensive.

EPA has not performed any recent studies of the appropriateness of confidentiality claims, but a 1992 EPA study indicated that problems with inappropriate claims were extensive. This study examined the extent to which companies made confidential business information claims, the validity of the claims, and the impact of inappropriate claims on the usefulness of TSCA data to the public. While EPA may suspect that some chemical companies' confidentiality claims are unwarranted, the agency does not have data on the number of inappropriate claims. According to EPA, about 95 percent of premanufacture notices contain some information that chemical companies claim as confidential. EPA officials also told us that the agency does not have the resources that would be needed to investigate and, as appropriate, challenge claims to determine the number that are inappropriate. Consequently, EPA focuses on investigating primarily those claims that it believes may be both inappropriate and among the most potentially important—that is, claims relating to health and safety studies performed by the chemical companies involving chemicals currently used in commerce. The EPA official responsible for initiating challenges to confidentiality claims told us that EPA challenges about 14 such claims each year and that the chemical companies withdraw nearly all of the claims challenged.

Officials who have various responsibilities for protecting public health and the environment from the dangers posed by chemicals believe that having access to confidential TSCA information would allow them to examine information on chemical properties and processes that they currently do not possess and could enable them to better control the risks of potentially harmful chemicals. Likewise, the general public may also find information provided under TSCA useful. 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,



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neighborhood organizations can use such information to engage in dialogue with chemical companies about reducing chemical risks, preventing accidents, and limiting chemical exposures.

While both TSCA and REACH have provisions to protect information claimed by chemical companies as confidential, REACH requires greater public disclosure of certain information, such as basic chemical properties. Furthermore, REACH places greater restrictions on the kinds of information chemical companies may claim as confidential. For example, REACH includes a provision for public access to basic chemical information, including brief profiles of hazardous properties and authorized uses. The European Union's approach to public's access to information combines a variety of ways that the interests of the public's right to know is balanced with the need to keep certain information confidential. As such, nonconfidential information will be published on the chemical agency's Web site. REACH also includes a provision under which confidential information can generally be shared with government authorities of other countries or international organizations under an agreement between the parties provided that certain conditions are met.

In previous reports, we recommended that the Congress consider providing EPA additional authorities under TSCA to improve its ability to make more chemical information publicly available. For example, in our June 2005 report,<sup>7</sup> we recommended that the Congress consider amending TSCA to authorize EPA to share with the states and foreign governments the confidential business information that chemical companies provide to EPA, subject to regulations to be established by EPA in consultation with the chemical industry and other interested parties that would set forth the procedures to be followed by all recipients of the information in order to protect the information from unauthorized disclosures. In our September 1994 report,<sup>8</sup> we recommended that the Congress consider limiting the length of time for which information may be claimed as confidential without resubstantiation of the need for confidentiality.

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<sup>7</sup>GAO, *Chemical Regulation: Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program*. GAO-05-458. Washington, D.C.: June 13, 2005.

<sup>8</sup>GAO, *Toxic Substances Control Act: Legislative Changes Could Make the Act More Effective*. GAO/RCED-94-103. Washington, D.C.: September 26, 1994.

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Mr. Chairman, this concludes my prepared statement. I would be happy to respond to any questions that you or Members of the Subcommittee may have.

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### Contacts and Acknowledgments

For further information about this testimony, please contact John Stephenson at (202) 512-3841 or [stephensonj@gao.gov](mailto:stephensonj@gao.gov). Key contributors to this testimony were David Bennett, Antoinette Capaccio, Nancy Crothers, Christine Fishkin, Richard Johnson, and Ed Kratzer.

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## Related GAO Products

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*High-Risk Series: An Update.* GAO-09-271. Washington, D.C.: January 22, 2009.

*Chemical Regulation: Comparison of U.S. and Recently Enacted European Union Approaches to Protect against the Risks of Toxic Chemicals.* GAO-07-825. Washington, D.C.: August 17 2007.

*Chemical Regulation: Actions are Needed to Improve the Effectiveness of EPA's Chemical Review Program.* GAO-06-1032T. Washington, D.C.: August 2, 2006.

*Chemical Regulation: Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program.* GAO-05-458. Washington, D.C.: June 13, 2005.

*Toxic Substances Control Act: Legislative Changes Could Make the Act More Effective.* GAO/RCED-94-103. Washington, D.C.: September 26, 1994.



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Mr. RUSH. Thank you very much.

The chair now recognizes Mr. Davies for the purpose of 5 minutes of opening statements.

#### TESTIMONY OF J. CLARENCE DAVIES

Mr. DAVIES. Thank you, Mr. Chairman. My name is J. Clarence Davies. I am a senior advisor to the Project on Emerging Nanotechnologies at the Woodrow Wilson International Center for Scholars and a senior fellow at Resources for the Future. The opinions expressed here are my personal opinions and do not represent the views of those organizations or their funders.

I commend the subcommittee for holding this hearing. The committee's focus on TSCA is timely because of changes taking place both at the State level and internationally. States are increasingly taking the initiative to deal with toxics. Internationally, the European Union's launch of the REACH directive has radically changed the requirements for marketing chemicals in Europe. The huge impact of technologies that were unknown when TSCA was enacted adds to the importance of reviewing TSCA now.

I have followed TSCA from its inception. In 1969 I wrote a book which called for a law regulating new chemicals and in 1970 I wrote the original version of what became TSCA. In the past several years I have written three reports on oversight of nanotechnology. Each of them is relevant to the subject of this hearing and I would like permission to submit them for the record.

Mr. RUSH. So granted.

Mr. DAVIES. Thank you.

Before dealing with TSCA's weaknesses, let me note some of its strengths. First is the broadness and potential flexibility of the law. Its coverage is not limited to any one part of the environment, a definite asset, because most chemicals are not limited to air or water or land. TSCA also allows EPA to choose among a broad range of measures to control chemical risks. Another strength is TSCA's reporting mechanism. Section 8(e), which requires manufacturers to immediately notify EPA of new risk information, is particularly important. I believe that the general cost-benefit framework of TSCA needs to be preserved. The law deals with products, not with pollutants. Commercial products by definition have benefits so limiting their use or banning them to prevent adverse effects almost always has costs. This fact makes an absolute safety standard unwise because the government would be forced to ban chemicals that do more good than harm.

Many of the good things in TSCA are undermined by the procedural landmines in the Act. The Act contains difficult, perhaps impossible requirements that must be met before a chemical can be regulated. For example, EPA must show that the regulation is less burdensome than any alternative. All the requirements must be supported by substantial evidence in the rulemaking record, an extraordinarily high legal criterion. These provisions make it practically impossible for EPA to regulate existing chemicals. Equally damaging is TSCA's implicit assumption that no knowledge or no data is equivalent to no risk. Most of the new chemical notices contain no testing information. However, as the chairman mentioned, if EPA lacks the information to evaluate the risk of the chemical,

the agency cannot get the information without showing that the chemical may present an unreasonable risk. It is a classic catch-22 and badly needs to be changed.

Confidential business information is a third problem area. A very large portion of information submitted under the Act is classified as confidential. The Act prohibits sharing of confidential information with States or with foreign governments. The result is that TSCA is less conducive to State, federal and international cooperation than any other environmental statute.

EPA estimates that it received notice of about 50 nanomaterials under TSCA's new chemical provisions because TSCA defines a chemical only by its molecular structure and does not consider size. Many, perhaps most, nanomaterials are considered existing chemicals, not new ones. This is important because the TSCA provisions relating to existing chemicals have mostly been rendered inoperative. Also, because size is a defining factor for nanomaterials, EPA cannot be sure which new chemicals are nonmaterials, even though the risks of nanomaterials may be quite distinct from both materials. There is a general issue of the capability of the existing regulatory systems to deal with the new technologies that are emerging at an accelerating pace. Nanotechnology is one example. Another is synthetic biology, which TSCA also has jurisdiction over in part. A particular challenge for EPA will be its ability to assess the risks of future complex synthetic organisms that have no counterpart in nature and TSCA does not provide adequate authority or tools to address those kinds of risks.

I urge this committee to devote some time and effort to consider what new oversight and regulatory approaches are needed to deal with 21st century science and technology. Considering TSCA's effectiveness is a step in the right direction but over the long run we are going to need whole new approaches to deal with the new technologies. Thank you.

[The prepared statement of Mr. Davies follows:]

TESTIMONY OF  
J. CLARENCE (TERRY) DAVIES  
before the  
SUBCOMMITTEE ON COMMERCE, TRADE, and CONSUMER PROTECTION  
of the  
COMMITTEE ON ENERGY and COMMERCE  
U.S. HOUSE OF REPRESENTATIVES  
Feb. 26, 2009

My name is J. Clarence Davies. I am a Senior Advisor to the Project on Emerging Nanotechnologies at the Woodrow Wilson International Center for Scholars and a Senior Fellow at Resources for the Future. Neither the Wilson Center nor RFF take institutional positions on public policy matters, so the opinions expressed in my testimony are my personal opinions and do not represent the views of those organizations or their funders.

Let me start by commending the subcommittee for holding this hearing. The committee's focus on the Toxic Substances Control Act (TSCA) is timely because of changes taking place both at the state level and internationally. At the state level there have been a variety of new initiatives dealing with toxics. Internationally, the European Union's launch of the REACH directive has radically changed the requirements for any company wanting to market chemicals in Europe.

I believe this hearing could represent a turning point in the history of TSCA. For many years the chemical industry and EPA have agreed that TSCA is adequate to protect the public from the risks of chemicals despite much evidence to the contrary. That agreement, I think, no longer holds, and this hearing will provide solid evidence that TSCA is not functioning adequately and that changes are necessary.

I have followed TSCA from its inception. In 1969 I wrote a book which called for a law regulating new chemicals. In 1970, as a staff member with the newly formed Council on Environmental Quality, I wrote the original version of what became TSCA. I was not completely happy with the bill that emerged from the administration, and the intervening years have only strengthened my concerns about TSCA's flaws.

In the past several years, working with the Wilson Center, I have focused my attention on nanotechnology. I have written three reports on oversight of nanotechnology. Each of them is relevant to the subject of this hearing and I would like permission to



submit them for the record. Nanotechnology reveals many of TSCA's longstanding flaws and poses some new challenges. TSCA is the only existing law that can deal with nanotechnology generally. I will today discuss how shortcomings of TSCA that apply to all chemicals also apply to nano, and I will describe how trying to regulate nano has shown some TSCA problems that are unique to nano.

Before dealing with TSCA's weaknesses, let me note some good things about TSCA, things that should be preserved in any efforts to revise the law. First is the broadness and potential flexibility of the law. Its coverage is not limited to any one part of the environment and this is a definite asset because most chemicals are not limited to air or water or land but can travel from one part of the environment to another. TSCA also allows EPA to take a broad range of measures to deal with potential chemical problems. In theory, it gives the agency the flexibility to cope with new problems and unanticipated situations, although in practice this has not been the case.

The reporting mechanisms in TSCA also are valuable. Section 8(e), which requires manufacturers to immediately notify EPA of new information that supports the conclusion that a chemical may be a substantial risk, is particularly important. It allows EPA to adapt to new threats and to remedy problems caused by adverse effects that were overlooked in previous reviews of a chemical. Other sections of the act also contain useful reporting tools.

I would argue that the general cost-benefit framework of TSCA needs to be preserved. The law deals with useful products, not with pollutants. Because of this, decisions about regulating chemicals involve making trade-offs. Products, by definition, have benefits, so limiting their use or banning them to prevent adverse health or environmental effects almost always has some costs. This fact makes an absolute safety standard unwise because the government would be forced to ban chemicals that do more good than harm.

Many of the good things in TSCA are undermined by the procedural land mines scattered throughout the act. The act contains a number of very difficult, perhaps impossible, requirements that must be met before a chemical can be regulated. For example, EPA must show that the proposed regulation is less burdensome than any alternative and that the risk could not be sufficiently reduced under some other law. All

the requirements must be “supported by substantial evidence in the rulemaking record,” an extraordinarily high legal hurdle. Court decisions have demonstrated that the combination of the difficult requirements and the high legal hurdle make it practically impossible for EPA to regulate existing chemicals under TSCA (*Corrosion Proof Fittings v. EPA*). Only if a chemical is considered a new chemical is EPA able to review its risk and perhaps impose limits on it.

Just as damaging as the procedural traps is TSCA’s implicit assumption that no knowledge or no data is equivalent to no risk. This is epitomized in the “Catch 22” contained in TSCA section 5(e). It states that if EPA does not have enough information “to permit a reasoned evaluation of the health and environmental effects of a chemical,” the agency can delay or prohibit manufacture of the chemical only if it can show that the chemical “may present an unreasonable risk” – which is precisely the thing the agency cannot show. There is another criterion that in theory can be used for EPA action. This is that the chemical will be produced in “substantial quantities” and that there will be significant environmental or human exposure. In practice, this criterion only rarely can be used, because most new chemicals initially are produced in small volumes, and because the likelihood of significant exposure is difficult to establish. The problem is even greater for nanomaterials because quantity or volume may not be a relevant indicator of potential risk.

In the long list of TSCA problems, a third area that needs to be noted is confidential business information (CBI). The act makes it very easy for manufacturers to classify information as CBI. As a result, a very large portion of all information submitted under the act is classified as confidential. The act then prohibits sharing of confidential information with states or with foreign governments. The result is that TSCA is less conducive to state-federal cooperation than any other environmental statute. The CBI provisions also are a major impediment to cooperating with other nations or international organizations. There is, I think, widespread agreement that TSCA’s CBI provisions need to be changed.

Turning specifically to nanotechnology, nanomaterials are chemicals, so TSCA covers nanomaterials to the extent that they are not covered by other laws (such as the Food, Drug and Cosmetic Act or the federal pesticide law). Nanotechnology is the

science and application of manipulating matter at the scale of individual atoms and molecules. All natural processes, from the growth of human embryos to plant photosynthesis, operate in this way, but only recently have we developed the tools that allow us to build and analyze things at the molecular level. Nanotechnology's potential applications are boundless in scope and promise, and it is already being applied in hundreds of ways ranging from drugs to chemical catalysts to sports equipment.

As with most significant technologies, nano has potential costs as well as benefits. To date, there have been no documented cases of adverse health or environmental effects from nanotechnology. However, everything we know about nanomaterials leads to the conclusion that there is the potential for such adverse effects to occur. Nanomaterials generally are more biologically and chemically active than their bulk counterparts and can reach places in the environment and the human body that larger materials cannot. Very few resources have been devoted to investigating the health and environmental effects of nanomaterials, but the studies that have been done support the need to be concerned about nano's potential adverse effects. For example, a recent study on rats has shown that some kinds of carbon nanotubes (one of the most widely used nanomaterials) produce the same kind of pre-cancerous lung irritation that asbestos causes in humans.

EPA estimates that it has received notice of about 50 nanomaterials under TSCA's new chemicals provisions. The agency cannot be sure of this because its interpretation of TSCA's definition of a chemical excludes size. Because size is a defining factor in what is a nanomaterial, the agency cannot be sure what new chemicals are or are not nanomaterials.

Even more importantly, because TSCA defines a chemical only by its molecular structure, many, perhaps most, nanomaterials are considered existing chemicals, not new ones. This is because many nanomaterials have the same molecular structure as existing bulk chemicals. Gold nanoparticles, for example, have the same molecular structure as a bar of gold, even though they may have radically different chemical and physical properties. This is important because, as noted above, the TSCA provisions relating to existing chemicals have mostly been rendered inoperative. The "significant new use" provisions of TSCA may provide a partial way around this obstacle, but EPA has not chosen to use these provisions. In sum, TSCA, at least as currently interpreted by EPA,

cannot regulate most nanomaterials as new chemicals and it cannot regulate any chemicals if they are not defined as new.

The definitional problem is reinforced by a volume exemption that EPA has applied to TSCA. Basically, chemicals manufactured in volumes less than 10,000 kilograms (about 11 tons) are excluded from most of TSCA's provisions. The 10,000 kilo figure is ridiculously large when applied to nanomaterials, where one kilo is a fairly large amount. However, this exemption is not in the law itself, so EPA could and should modify it administratively.

Another TSCA problem raised by nanotechnology, as well as by other new technologies such as synthetic biology, is created by TSCA's limited ability to require information on the new chemical notices it receives. Most of the new chemical notices contain no testing information. The only information they contain is the chemical structure of the substance. Given this situation, EPA has resorted to using what is called "structure-activity relationship" or SAR analysis. SAR compares the molecular structure of the new chemical to the molecular structure of similar existing chemicals and uses the risks of the similar existing chemicals to predict the risks of the new chemical. Under the best of circumstances this approach has limitations, but it is useless when there are no similar chemicals with known risks, as is the case with nanomaterials..

The issues raised by TSCA's application to nanotechnology raise the more general issue of the capability of existing regulatory systems to deal with the new technologies that are emerging at an accelerating pace. Nanotechnology is one example. Another is the rapidly developing field of synthetic biology, which gives scientists the ability to design genetic sequences from scratch and use the sequences to create new custom microbes, such as those that could be used to make biofuels. A particular challenge for EPA will be its ability to assess the risks of future complex synthetic organisms that have no counterpart in nature, and TSCA does not provide adequate authority or tools to address these risks.

There is a large mismatch between the current regulatory system and the characteristics of 21st century science and technology. This mismatch will grow rapidly. I urge this committee to devote some time and effort to considering what new oversight and regulatory approaches are needed. Considering TSCA's effectiveness is a step in the

right direction, but over the long run we are going to need whole new approaches to deal with the new technologies.

TSCA is not serving us well now and it will not in the future. The committee deserves praise for giving its attention to TSCA, and I hope that your efforts result in constructive changes to the law.

Mr. RUSH. The chair thanks the gentleman. And now I have been told by the subcommittee staff of a new procedure especially at it relates to the oversight aspects of these hearings, and that is I am supposed to swear in all the witnesses, so I am going to ask the witnesses to please stand to be sworn in, and I am going to ask those that testified whether or not you want to keep your testimony consistent pre-swearing in the same as post swearing in, so if you didn't like before, then—excuse me for saying that. I shouldn't have said that. We just want you to be consistent in your testimony both prior to the swearing in and after the swearing in.

[Witnesses sworn.]

Mr. RUSH. Please let the record reflect that all the witnesses have answered in the affirmative, and now our next witness will be Ms. Swanson for the purposes of opening statement.

#### TESTIMONY OF MAUREEN SWANSON

Ms. SWANSON. Thank you, Mr. Chairman and Ranking Member Radanovich. My name is Maureen Swanson and I direct the Healthy Children Project for the Learning Disabilities Association of America. I also am here on behalf of the organizations of the Learning and Developmental Disabilities Initiative, which I have described my written testimony.

I would like to explain the connection between neurodevelopmental disabilities and the need to reform TSCA. Certain diseases and disorders including neurodevelopmental disorders are increasing among American children. This is particularly true of autism and attention deficit hyperactivity disorder, or ADHD. On average it costs twice as much to educate a child with a neurodevelopmental disability as it does to educate a child who does not have these disabilities. A growing body of scientific evidence shows that some of this increase is due to exposure to toxic chemicals. Most recently, a study by researchers at the University of California found that a large portion of the increase in the State's autism cases is most likely due to toxic chemical exposures.

Children are especially vulnerable to toxic chemicals. Relative to adults, children eat more, drink more and breathe more. They spend a lot of time on the ground and they put things in their mouths. From conception to early childhood is a time of rapid brain development, a time when even a tiny dose of a toxic chemical can cause neurological problems that last a lifetime. Of the 80,000 chemicals registered under TSCA, about 3,000 are produced at more than 1 million pounds a year. Of these 3,000 chemicals, we know for certain that 10 are neurotoxins. They affect brain development. We have good evidence that another 200 are neurotoxins but we don't have better information or more information because there is no requirement under TSCA to test chemicals for effects on brain development. Isn't it right for parents to assume that the government will protect their children from toxic chemical exposures?

When I talk to people and they find out that the vast majority of chemicals used in products are not tested for health effects, first they are dumbfounded and then they are outraged. I share that outrage. As the mother of a 2-year-old and a 4-year-old, I know how hard it is to figure out which shampoos and sippy cups and

toys are safest for my kids. No parent should have to stand in front of a store shelf full of toys and guess which ones have toxic constituents and none of us should have to pay a premium for a specially made nontoxic product. No one should have to buy their way out of health risks to their children.

LDA began its focus on neurotoxins decades ago by supporting efforts to get lead out of gasoline. Once lead was removed from gasoline, blood lead levels in American children dropped dramatically. At the same time, IQ levels increased. Another LDA concern is chemicals that are endocrine disruptors, particularly those that affect the thyroid gland, which is essential for healthy brain development. These chemicals are often found in plastics and include phthalates, Bisphenol A, dioxins and brominated flame retardants.

I would like to thank Congress for its bipartisan support of the Consumer Products Safety Improvement Act, which will keep lead and phthalates out of children's products. This is a crucial step toward preventing toxic chemical exposures. TSCA, on the other hand, demands that the government prove beyond all reasonable doubt that a chemical is toxic after it has been put on the market, after it has infiltrated our homes and our bodies. We need legislation that requires manufacturers to prove that a chemical is safe before it can be used in products and before it can put our children at risk. We know that a preventive policy works. Lead is just one example. Chlorpyrifos is another. Chlorpyrifos is a widely used pesticide and a neurotoxin. Since EPA banned its residential use in 2001, a study in New York City showed that levels of chlorpyrifos in maternal and umbilical cord blood have decreased by a factor of 10 and the newborns in the study showed an increase in birth weight and length, which are measures of healthy development.

To stem the rising incidence of childhood diseases such as asthma, autism and cancer, we need a preventive approach to toxic chemical policy that requires manufacturers to test chemicals for health effects including neurodevelopmental effects and prohibits the use of toxic chemicals that can harm the developing fetus, infants and children. For more than 30 years, TSCA has enabled the chemical industry to take risks with our children's health that no parent would ever knowingly permit.

We urge Congress to reform TSCA without further delay and provide all our children the opportunity to lead healthier and fuller lives. Thank you.

[The prepared statement of Ms. Swanson follows:]



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**Statement Of**

**Maureen H. Swanson  
Healthy Children Project Coordinator  
Learning Disabilities Association of America**

**Before**

**The U.S. House of Representatives  
Committee on Energy and Commerce  
Subcommittee on Commerce, Trade, and Consumer Protection**

**At a Hearing On**

**Revisiting the Toxic Substances Control Act of 1976**

**February 26, 2009**



Thank you for this opportunity to address the House Subcommittee on Commerce, Trade and Consumer Protection regarding the need to revise the Toxic Substances Control Act.

My name is Maureen Swanson and I direct the Healthy Children Project for the Learning Disabilities Association of America (LDA). LDA is the oldest and largest national volunteer organization advocating for children and adults with learning disabilities, with headquarters in Pittsburgh and affiliates in 43 states. My work focuses on raising awareness of toxic chemicals that can harm brain development, and on finding ways to prevent exposures to toxic chemicals, especially among pregnant women and children.

I also am here today on behalf of the leading member organizations of the Learning and Developmental Disabilities Initiative (LDDI), a national working group of the Collaborative on Health and the Environment. In addition to LDA, these organizations include the American Association on Intellectual and Developmental Disabilities, the Autism Society of America and the National Association for the Dually Diagnosed (those with mental health issues and developmental disabilities). Together, our organizations and other LDDI members represent almost 500,000 people in the United States.

We believe there is an urgent need to reform the way our country regulates toxic chemicals. We need to test chemicals for health effects, and keep toxic chemicals out of consumer products, so that we better protect our children from increasing incidences of diseases and disorders linked to toxic chemical exposures.

Our particular concern is with neurotoxins: chemicals that interfere with brain development and function. LDA began its focus on neurotoxins decades ago by supporting efforts to get lead out of gasoline, and continues to advocate for research to better understand the effects of low levels of lead exposure on brain function and behavior.

LDA also has a long-standing interest in preventing exposures to chemicals that interfere with the hormonal system, particularly through effects on the thyroid gland. A healthy thyroid is essential for healthy brain development. These chemicals are called “endocrine disruptors” and include phthalates, PCBs, Bisphenol A, dioxins and brominated flame retardants (PBDEs).

On behalf of LDA and our partner organizations, I would like to thank Congress for its overwhelming bipartisan support of the Consumer Product Safety Improvement Act, which will keep lead and phthalates out of children’s products. This is a crucial step toward preventing toxic chemical exposures that can affect brain development.

As a mother, I know how difficult it is to figure out which toys, sippy cups, shampoos and foods are safest and healthiest for my young children. No parent should have to stand in front of a store shelf full of toys and guess which ones have toxic constituents. They most certainly should not be forced to pay a premium for a specially made non-toxic product. None of us should have to buy our way out of health risks to our children.

We focus our concerns on children because they are particularly vulnerable to toxic chemicals. The CDC's 2005 report on environmental exposure to chemicals shows that the youngest Americans sampled – ages 6 to 11 years old – often have higher levels of particular chemicals in their bodies than adolescents and adults.<sup>i</sup>

For their body weight, children consume more food, drink more water and breathe more air than adults. Children spend a lot of time on the ground and put things in their mouths. Most importantly, the time from conception into early childhood is a period of rapid brain development. We know that exposure to chemicals that are neurotoxins during early fetal development can harm the brain at doses much lower than those affecting adult brain function."<sup>ii</sup>

The incidence of neurological problems in children is increasing, especially for autism and attention deficit hyperactivity disorder (ADHD)."<sup>iii</sup> Some physicians now talk about autism and asthma as epidemics, based on the exponential increase in the numbers of children suffering from them. Today, 1 in 150 American children are diagnosed with autism spectrum disorder."<sup>iv</sup>

Dr. Joel Forman, a professor of pediatrics at Mt. Sinai School of Medicine and practicing pediatrician, describes, "the new pediatric morbidity: a range of chronic, disabling and sometimes life threatening conditions...that affect increasing numbers of American children today."<sup>v</sup> These conditions include asthma, obesity, endocrine and sexual development disorders, cancers and neurodevelopmental disorders.<sup>v</sup>

Ask any teacher in any school district in any state, and they will confirm this trend. Many of the teachers in LDA tell me how many more special education students they have in their schools compared to a decade or two ago. Doctors and nurses report seeing more and more children with behavior disorders and neurological problems in their practices.

A growing body of evidence shows that some of this increase in neurological problems is associated with toxic chemical exposures. In January, scientists at the University of California studied all factors that might be contributing to the state's huge increase in autism cases, and found that a potentially large portion of the increase is linked to environmental exposures. They have called for a national focus on toxic chemical exposures and links to autism, with an initial emphasis on fetal and infant exposures to pesticides and toxic chemicals in products."<sup>vi</sup>

The costs associated with the increasing incidence of these childhood diseases are enormous. On average, it costs twice as much to educate a child who has learning or developmental disabilities than it does to educate a child who does not. A 2006 Harvard study estimated that the costs of autism to the U.S. exceed \$35 billion annually."<sup>vii</sup>

A 2002 study by Dr. Philip Landrigan assessed the contribution of environmental pollutants to the incidence and costs of four categories of illness in American children: lead poisoning, asthma, cancer, and neurobehavioral disorders. The total annual costs

attributable to the environmentally related portion of these diseases are estimated at \$54.9 billion – which is the middle of the cost range estimate in the study results.<sup>viii</sup>

There are more than 80,000 chemicals on the TSCA Inventory, and many tens of thousands in active commerce. Approximately 3000 chemicals are produced at more than one million pounds per year.<sup>ix</sup> More than half of these high volume chemicals lack even a basic set of toxicity information. This data gap includes a lack of information on developmental toxicity. This appalling lack of information under TSCA has persisted for more than 30 years, despite EPA's efforts over the past decade to get chemical producers to voluntarily develop such data.<sup>x</sup> Even fewer data are available for lower volume chemicals despite the fact that many of them are used in consumer products or can otherwise result in human exposure.

Of these 3000 high volume chemicals, we know for certain that 10 are neurotoxins that can cause learning and developmental disabilities. There is good evidence that another 200 of these chemicals are also neurotoxins. We don't have better information because there is no requirement under TSCA to test chemicals for effects on brain development.<sup>xi</sup>

Isn't it right for parents to assume that the government will protect their children from exposure to toxic chemicals? When people find out that the vast majority of chemicals used in products and services are not tested for health effects, they are aghast and outraged. American consumers should have the assurance that if a product is on a store shelf, then its ingredients have been tested and found to be safe.

But TSCA demands that the government prove beyond all reasonable doubt that a chemical is toxic after it has already been put on the market, after it has already infiltrated our homes and our bodies. According to a 2006 Lancet article by Drs. Grandjean and Landrigan, the two main impediments to prevention of neurodevelopmental deficits of chemical origin are the great gaps in testing chemicals for developmental neurotoxicity and the high level of proof required for regulation.<sup>xii</sup>

We need legislation that requires manufacturers to prove that a chemical is safe and nontoxic before it can be used in products – before it puts our children at risk.

We know that a preventive policy works. When lead, one of the most potent and well-researched neurotoxins, was finally removed from gasoline, blood lead levels in American children plummeted from an average of 15.5 micrograms per deciliter in 1975 to about 2 micrograms per deciliter in 1990, which is the current average blood lead level. During the same time period, children's IQ levels increased.<sup>xiii</sup>

Chlorpyrifos is a widely used pesticide and a neurotoxin. CDC data collected for 1999-2002 showed that young children have greater levels of chlorpyrifos in their bodies than adolescents and adults.<sup>xiv</sup> Since EPA banned the residential use of chlorpyrifos in 2001, a New York City study showed that levels of this potent neurotoxin in maternal and umbilical cord blood have decreased by a factor of 10, with a corresponding increase in newborn weight and length, which are measures of healthy development.<sup>xv</sup>

Brominated flame retardants, or PBDEs, provide another example. PBDEs are used in electronics, carpet, furniture and clothing, and accumulate in household dust. They have a chemical structure similar to PCBs and are a known neurotoxin. A 2008 study showed that toddlers had levels of PBDEs in their bodies three times higher than adults in the same households.<sup>xvi</sup>

Since Sweden began an accelerated phase-out of PBDEs in the late '90s, PBDE levels in breast milk have plummeted. In the same time period, levels of PBDEs in North American breast milk have skyrocketed, exposing our tiniest and most vulnerable citizens to a known neurotoxin in the very first hours of their lives.<sup>xvii</sup>

In the absence of federal action on these neurotoxins, which are linked to other serious health effects as well, Maine and Washington banned the use of PBDEs in 2007. We applaud these and other states that are seeking to protect children's health and development, but we need a national solution.

To stem the rising incidence of childhood diseases such as asthma, autism and cancer, we need a preventive approach to toxic chemical policy at the federal level. The government must require manufacturers to test chemicals for health effects, including neurodevelopmental effects, and prohibit the use of toxic chemicals that can harm the developing fetus, infants and children.

For more than 30 years, TSCA has enabled the chemical industry to take risks with our children's health that no parent would ever knowingly permit. We urge Congress to reform TSCA without further delay, and provide all children the opportunity to lead healthier, fuller lives.

Thank You.

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<sup>x</sup> Third National Report on Environmental Exposures to Chemicals. Centers for Disease Control and Prevention National Center for Health Statistics; 2005.  
[www.cdc.gov/exposurereport](http://www.cdc.gov/exposurereport).

<sup>xi</sup> Grandjean, P, Landrigan, PJ. Developmental neurotoxicity of industrial chemicals. *Lancet* 2006; 368(9553):2167-78.

<sup>xii</sup> Forman, J. Pediatric Environmental Health: Evidence and Public Policy. Presentation, February 4, 2009.

<sup>xiii</sup> Marguerite Kirst Colson, Director of Communications, Autism Society of America. Personal communication, 2009.

<sup>xiv</sup> Forman, J. Pediatric Environmental Health: Evidence and Public Policy. Presentation, February 4, 2009.

<sup>xv</sup> Cone, Marla. "New Study: Autism Linked to Environment," *Scientific American*, January 9, 2009.

<sup>vii</sup> Ganz, Michael. "The Costs of Autism" chapter in *Understanding Autism: From Basic Neuroscience to Treatment*. CRC Press, 2006.

<sup>viii</sup> Landrigan, P et al. Environmental Pollutants and Disease in American Children: Estimates of Morbidity, Mortality and Costs for Lead Poisoning, Asthma, Cancer and Developmental Disabilities. *Environmental Health Perspectives*, 110(7), July 2002.

<sup>ix</sup> EPA Inventory Update Reporting from 2006, [www.epa.gov/oppt/iur](http://www.epa.gov/oppt/iur).

<sup>x</sup> U.S. EPA HPV Challenge, [www.epa.gov/HPV](http://www.epa.gov/HPV); Environmental Defense Fund, HPVTracker ([www.cdf.org/HPVTracker](http://www.cdf.org/HPVTracker)), and personal communication, Dr. Richard Denison, February 2009.

<sup>xi</sup> Grandjean, P, Landrigan, PJ. Developmental neurotoxicity of industrial chemicals. *Lancet* 2006; 368(9553):2167-78.

<sup>xii</sup> Grandjean, P, Landrigan, PJ. Developmental neurotoxicity of industrial chemicals. *Lancet* 2006; 368(9553):2167-78.

<sup>xiii</sup> Needleman, H., Landrigan, P. "What level of lead in blood is toxic for children?" *American Journal of Public Health*, 94(11), 2004.

<sup>xiv</sup> "Third National Report on Environmental Exposures to Chemicals," Centers for Disease Control and Prevention National Center for Health Statistics; 2005. [www.cdc.gov/exposurereport](http://www.cdc.gov/exposurereport)

<sup>xv</sup> Whyatt, RM et al. Prenatal Insecticide Exposure and Birth Weight and Length Among an Urban Minority Cohort. Columbia Center for Children's Environmental Health, 2004.

<sup>xvi</sup> Environmental Working Group. "Young Children in U.S. Among World's Most Polluted with Fire Retardants." September, 2008. [www.ewg.org](http://www.ewg.org)

<sup>xvii</sup> Forman, J. Pediatric Environmental Health: Evidence and Public Policy. Presentation, February 4, 2009.

Mr. RUSH. Thank you.

Our next witness is Mr. Cecil Corbin-Mark. Mr. Mark, you are recognized for 5 minutes.

#### **TESTIMONY OF CECIL CORBIN-MARK**

Mr. CORBIN-MARK. Good morning. I want to thank Chairman Rush for his leadership on this committee and in bringing this issue to the forefront. I also want to recognize and thank Mr. Radanovich and likewise to all the other distinguished members who are present and here today. And lastly, I want to thank the committee staff for their dedication and professionalism.

So why is a guy from Harlem here to talk to you about Toxic Substances Control Act? Quite simply because I have been impacted by chemicals and my family has and some of my neighbors have. Two quick stories. I can remember a long time ago when my mother brought home a chemical curtain, that I later found out was a chemical curtain, but a curtain filled with superheroes imprinted on it, and I couldn't wait to actually take a shower with that chemical curtain. I wanted to be in that shower because I thought the superheroes would transfer their powers to me and I could join their ranks. Instead, what happened was, I came out dizzy, unsure of what was happening and filled with a really piercing headache.

The next story is about my son, the pride and joy of my life. I am a doting dad, and my son is in school in New York City and is playing on a basketball team. I am across the country at a conference in San Francisco and his mom calls to say that they have had to rush him to the hospital for an asthma attack at a visiting school. In talking to him later that day, I asked him what do you remember, what happened, how did this happen, and after pressing him he realized one thing that he did remember was the smell of pesticides in the visiting locker room of his team's locker room.

I want to share with you that I think that in places like the community that I live and work in Harlem, New York, many people are exposed to toxics. I live in, as I said, Harlem and it is a community of 7.4 square miles and is home to more than 650,000 mostly low- and middle-income African-Americans and Latinos. It is known for its richly diverse population and cultural history but the area also bears disproportionate rates of disease, air pollution and toxic exposures. Northern Manhattan leads the Nation in asthma hospitalizations, low birth weight and lead poisoning, to name a few, and diabetes and obesity are also raging epidemics in our communities. High levels of public assistance in our neighborhoods are a part of the fabric and residents often don't have health insurance. And while downtown Manhattan may be known for Broadway, the Empire State Building, the Statue of Liberty and other iconic landmarks, uptown our neighborhoods have auto body shops, dry cleaners co-located with residential apartments, diesel bus depots across the street from parks and bedroom windows, and likewise nail salons and dollar stores with many products that contain ingredients capable of disrupting a woman's or a man's reproductive system abound in northern Manhattan.

While I am describing my hometown, I could be talking about any place in Texas, Michigan, Louisiana, Ohio, Georgia, you name

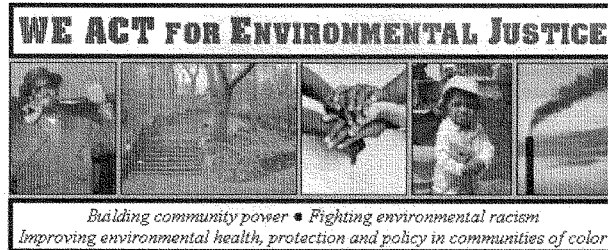
the State, and you might conclude that because these facilities or stores are located in our neighborhoods, that doesn't necessarily mean that we might be impacted by chemicals, but I assure you, you could be wrong.

I want to just point out a couple of studies, one of them from the New York Research Public Interest Group done a couple of years ago that documented while upstate is the major agricultural production area for New York State, it is in New York City that the greatest tons of poundage of pesticides are actually used and they are applied to public buildings like schools or hospitals. Another one, the New York State Department of Health conducted a study in East Harlem and found high levels of PERC in apartments where dry cleaners were collated. PERC is a volatile organic compound with many health effects that moves easily through walls and easily enters the bloodstream. The Columbia Mailman School of Children's Environmental Health Center that we co-partner with conducted studies that looked at 700 mother-children pairs and examined dust samples in their homes and found high levels of pesticides like chlorpyrifos and diazinon, which transfer readily to the fetus, and these were found to reduce birth weight by an average of 6.6 ounces. Furthermore, high prenatal exposure to pesticides like chlorpyrifos was found to be associated with psychomotor cognitive delay and attentional disorders at age 3. Early findings from another study projected that the same cohort is indicating dibutyl phthalate, which is commonly found in perfumes, is staying in mothers' bodies longer than thought.

Toxic chemicals don't belong in people, and while researchers don't have all the answers to what the health effects are, environmental justice advocates are mobilizing to fix what we see as a flawed chemical system.

What are the problems in this system? I mean, there are many and I have submitted them in my testimony. I urge you to read them, but we need a comprehensive regulatory reform for toxic chemicals and I ask you to help us in making that possible. Thank you.

[The prepared statement of Mr. Corbin-Mark follows:]



STATEMENT OF

CECIL D. CORBIN-MARK  
DEPUTY DIRECTOR/DIRECTOR OF POLICY INITIATIVES  
WE ACT FOR ENVIRONMENTAL JUSTICE

BEFORE THE HOUSE OF REPRESENTATIVES  
COMMITTEE ON ENERGY AND COMMERCE  
SUBCOMMITTEE ON COMMERCE, TRADE AND CONSUMER PROTECTION

AT A HEARING TO  
REVISIT THE TOXIC SUBSTANCES CONTROL ACT OF 1976





Good morning I want to thank Chairmen Waxman and Rush for the opportunity to present testimony and their leadership. Likewise, my thanks to the other distinguished members of the committee for their time and attention. I also want to thank the committee staff, in particular Dr. Frandsen and Robin Appleberry, for their dedication and professionalism.

I am here today to testify about how chemicals have impacted me personally, to talk some about the health disparities in the community that I live and work in and why that makes my community and many like it across the country particularly vulnerable to the harmful effects of toxic chemicals. In addition, I want to share with you what several EJ communities and advocates across the country are currently doing to address the broken chemical policy system that is unable to protect our families from harm. I will close by highlighting that transitioning to safer alternatives to the toxic stew of chemicals currently in commerce is a pathway to creating new green jobs, and I will offer a few recommendations for a better chemical policy framework.

So why is a guy from Harlem, New York before you today to talk about the Toxic Substances Control Act? The answer is simple. Chemicals have impacted my health, the health of my family members and some of my neighbors.

I want to share with two personal stories of how chemicals have directly impacted my life.

My first story is about the shower curtain smell. I am one of the many Americans who experienced headaches triggered as a result of the smell of my shower curtain, which I later learned were the chemicals off gassing. I remember one year when I was still a kid my mom purchased a clear plastic curtain with superheroes imprinted on it and a liner. I was so excited to take a shower with the super heroes. I believed that I would emerge from that shower with super powers. Instead the smell triggered one of the worst headaches I ever had. To this day I can still remember the tears, the pain and that smell. As I grew older, I recognized that the smell was a problem, but prior to being engaged in this work I did not know that there were alternatives. I suffered with debilitating headaches for a long-time thinking that there was something wrong with me instead of the curtain in my bathroom.

My second story is about my son, Nigel. He attends La Salle Academy in New York City. Last year while I was attending a conference in San Francisco, Nigel suffered an asthma attack at a school basketball game. His mom called to let me know that the school officials had rushed him to the hospital. Thank God everything turned out for the best. While Nigel's asthma is not really that bad, that day was a very scary one for him and his mother and I. When I asked my son about what could have brought on the attack he was baffled. He said the day had been a good day and that he was not in anyway really exerting himself. I asked him to replay the moments leading up to the attack in his mind only then did he remember a strong smell of pesticide in the boys locker room that triggered him to sneeze when he first got there. Obviously I cannot say with absolute certainty that the lingering pesticide residue was what caused his attack, but I also know that no can say beyond the shadow of a doubt that it was not the culprit.

I live and work in Harlem, New York and my family has lived in the same neighborhood for about eight decades. The communities that I work in West, Central and East Harlem and Washington Heights covers an area of 7.4 square miles and is home to 650,000 mostly low to mid-income African-Americans and Latinos. Known for its richly diverse population and cultural history, the area also bears disproportionate rates of disease, air pollution and toxic exposures. Northern Manhattan leads the nation in asthma hospitalizations, low birth weight and lead poisoning to name a few. Diabetes and obesity are also raging epidemics in our communities.

There are high rates of public assistance in our neighborhoods and many of the residents that we organize do not have health insurance. Studies conducted by the New York City Planning Department document that many of our neighborhoods have limited to no access to fresh fruits and vegetables. And the availability of access to regular quality medical care is also a significant challenge.

Downtown Manhattan may be known for Broadway, the Empire State Building, the Statue of Liberty and several other iconic landmarks, but uptown our neighborhoods have auto body shops and dry cleaners collocated with residential apartments, diesel bus depots across the street from parks and bedroom windows. Likewise, nail salons and drug stores with many products that contain ingredients capable of disrupting a woman or man's reproductive system abound in Northern Manhattan.

When I am describing my hometown, I could in many ways be talking about places in Michigan, Illinois, Ohio, Georgia, Maryland, Texas, Tennessee, Pennsylvania, Florida or Louisiana. The combination of poor health outcomes and negative socio-economic factors make Harlem and Washington Heights, and the many places like it across this great nation, ill equipped to handle the toxic chemical exposures they face because our chemical regulatory system is broken.

You might conclude that just because the dry-cleaning store, nail salons and auto body shops abound and are co-located with residential buildings in my community doesn't mean that we are exposed to toxic chemicals. You would be wrong. I draw your attention to the following studies and reports.

Despite the fact that New York State is a major agricultural state, a study released by the New York Public Interest Research Group (NYPIRG) a few years ago documented that the highest use of pesticides in the state occurred in New York City. The report noted that schools and other public buildings had a greater number of pounds of pesticides applied than the fields and farms upstate.

New York State Department of Health conducted a study in East Harlem and it found high levels of PERC in the apartments where dry cleaners were co-located. PERC is a volatile organic compound that can move through walls and easily enter the blood stream. In many studies PERC has been found in mothers breast milk.

The Columbia University Mailman School of Public Health Children's Environmental Health Center and my organization, WE ACT for Environmental Justice, collaborate on two community-based research projects looking at mothers and children in Northern Manhattan. In one research project following a cohort of 700 mother child pairs and examining dust samples in the homes of the mothers prenatal exposure to two household pesticides, chlorpyrifos and diazinon, which transfer readily to the fetus, were found to reduce birth weight by an average of 6.6 ounces (Whyatt, et al, *EHP* 2004). Furthermore, high prenatal exposure to pesticide chlorpyrifos was found to be associated with psychomotor and cognitive delay and attentional disorders at age 3 (Rauh et al, *Pediatrics* in press).

Early findings from another research project with the same cohort is indicating that Dibutyl Phthalate, a phthalate commonly found in perfumes is staying in the mothers body longer than first thought and researchers are concerned that the Dibutyl Phthalate may be passed on to the fetus. I want to emphasize that these findings are very early.

Toxic chemicals don't belong in people. Yet all the studies that I have just rehearsed all indicate that these chemicals are present in the bodies of some 700 mothers and children in Northern Manhattan. Chemicals are entering our bodies in our homes and in the places where we work.

While researchers have not yet come up with all the answers to what these exposures mean, advocates in the environmental justice communities have begun to mobilize and are calling on government to fix our broken chemical policy system. Just this past weekend EJ advocates met in Atlanta, GA with our colleagues in the chemical policy reform movement to join forces.

We see the current regulatory system as flawed and badly in need of reform. Specifically, we are calling for comprehensive and inclusive approach to chemicals policy. All chemicals need to be subject to the same regulatory system.

What would a comprehensive chemical regulatory system look like? It would:

- Require chemical manufacturers to provide data on the chemicals they make and their potential public health impacts before they can get to the market
- Eliminate the most highly hazardous chemicals from the market
- It would work with manufacturers to find safer substitutes for the most hazardous substances
- It would require labeling that communicates effective information to the consumer in a culturally appropriate manner and in multiple languages
- Provide the regulatory agency with the power to protect the health of the public and the environment
- It would employ a hazard rather than exposure-based risk system
- It would work in cooperation with international chemical treaties

We are at a crossroads in the history of our nation. Each of you has before you the opportunity to redesign our chemical policy based on new understanding about the impacts of chemicals in the lives of every American. You have the chance to make sure that there are no more stories of communities like Sunrise, Reveilletown, Morrisonville, Bel Air or Diamond Louisiana, which today no longer exist because of chemical toxic pollution and exposures. You have the opportunity to protect future generations of Americans like my son from lives riddled by contamination. And you have the opportunity to set us on an economic path that will lead to prosperity and health for those working in the chemical industry by propelling us to be the leaders in the development of safer substitutes.

Will you take us to that better America?

Thank you.

Mr. RUSH. Thank you very much.

Our final witness for purposes of opening statements is Mr. Wright. Mr. Wright, you are recognized for 5 minutes.

#### TESTIMONY OF MICHAEL J. WRIGHT

Mr. WRIGHT. Thank you, Chairman Rush, and thank you, Ranking Member Radanovich, for the opportunity to testify before you this morning.

My name is Mike Wright. I am the director of health, safety and the environment for the United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union, and I promise not to use the full name again. We are the USW for short. We represent 850,000 workers in the sectors I just mentioned and many others including a majority of unionized workers in the chemical industry and hundreds of thousands of workers who use industrial chemicals on the job.

My written statement details my background. Let me just say I have been dealing with chemical issues for more than 30 years, both within my union and internationally, primarily through several United Nations organizations.

I will talk this morning about one mission that affected me the most and it still haunts me to this day. I was a member of an international team which traveled to Bhopal, India, to investigate the December 1984 methyl isocyanate release from a Union Carbide plant that took several thousand lives, nobody knows how many, in the first few hours, and many more in subsequent weeks and continues to claim victims at a rate of one or two a week even a quarter century later. In my sleep I still see the faces of parents whose children died. I still see children left without parents. I can still hear the constant coughing of victims who survived but with most of their lungs burned away. Two members of that team were from the United States, and one thing we quickly realized was, had the Bhopal plant existed in the United States, none of the underlying causes of the accident, none of them, would have violated any OSHA or EPA or any other regulation and that includes the Toxic Substances Control Act, even though TSCA was then in force. Think about that for a minute. The Toxic Substances Control Act wouldn't have controlled the causes, much less prevented, the worst toxic substance accident in human history. Much has changed since then. We have a lot of laws and regulations which chip at the edges but the basic chemical safety law in this country, TSCA, the cornerstone on which everything else rests, remains unchanged.

Let me turn to the impact of TSCA or rather the lack of impact in the workplace. I am wearing a little lapel pin this morning. It is a tiny birdcage with a canary. Thousands of our members and many of our supporters wear them. It symbolizes what workers have become in relation to toxic chemicals. Before the invention of modern testing equipment, miners used to bring canaries underground. If the bird died, you knew something in the air was toxic and you got out. Today we are the canaries in those cages. Others might testify as time goes on in these activities about things like Bisphenol A, phthalates, carbon nanotubes. All of them may pose serious risk to consumers and communities but we are the first to

be exposed and we are usually the highest exposed. Most epidemiology regarding toxic substances uses cohorts of workers. In other words, it is our bodies that get counted in these retrospective human experiments.

My colleagues and I in the USW's health, safety and environment department visit several hundred workplaces a year in all manner of industries. Collectively, we have a lot of experience with chemicals and chemical hazards so our members depend on us to say whether what they are working with is safe. Too often we don't have a clue. OSHA requires labels and written information sheets for workplace chemicals but they frequently contain almost no useful information beyond acute toxicity because the chemicals have never been tested for any other effects. Too often we learn the consequences of that ignorance only by chance and only too late. My written testimony includes several examples of chemicals found to be dangerous only because the men and women using them on the job died or became critically ill and they are only the very small tip of a very large iceberg. The dangers of these chemicals were discovered only through unusual circumstances like rare medical conditions, an overwhelming number of deaths or a chance discussion by workers. We have no idea how many more untested chemicals are causing unrecognized illness among workers and consumers. In short, the way we now evaluate many potentially toxic chemicals is by counting bodies and measuring human misery long after those chemicals have been introduced. That has to change.

Let me turn for a minute to economics. Of course, the main reason for reforming TSCA is for human health but there are also good economic reasons. There will be many who say that we can't afford to reform chemical policy, especially not in the current economic climate. In truth, we can't afford not to. First, there is the economic burden of occupational disease and environment disease, which I discuss in my written statement. It saps our productivity, destroys the earning potential of our families, increases healthcare costs. Then there is the issue of competitiveness. Europe has adopted a strong new system called REACH and it has been mentioned earlier this morning, designed to ensure that chemicals and products made with chemicals are safe to manufacture and use. Unless the United States follows suit, consumers will ultimately come to trust European products more than they trust American products. I believe it was the great consumer advocate Esther Peterson who said, "Made in USA should be a guarantee, not a warning."

I have great faith in the chemical industry. Our members work in the chemical industry. I actually believe all those Sunday morning commercials about the human element and the innovative potential of American chemistry. I believe we can produce chemical products that are safe to manufacture and safe to use. Thousands of our members work in the industry. They want to make things that are safe for them, safe for their kids, safe for the planet. They know that in the long run their jobs depend on that as well. The critical first step is the reform of our basic chemical safety law, TSCA.

Mr. Chairman, you, your committee and this Congress can make that happen. We urge you to do so, and I want to thank you again for the opportunity to testify this morning.

[The prepared statement of Mr. Wright follows:]

**Testimony of  
Michael J. Wright  
Director of Health, Safety and Environment  
United Steelworkers  
before the  
House Subcommittee on Commerce, Trade, and Consumer Protection  
on  
Revisiting the Toxic Substances Control Act of 1976  
February 25, 2009  
Washington, DC**

Chairman Rush, Ranking Member Radanovich and members of the Committee, thank you for the opportunity to testify this morning on the important issue of chemical safety. My name is Mike Wright; I'm the Director of Health, Safety and Environment for the United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union – USW for short. We represent 850,000 workers in the sectors I just mentioned and many others, including the majority of unionized workers in the chemical industry and hundreds of thousands of workers who use industrial chemicals on the job.

A little about my own background: I have an engineering degree from Cornell and a degree in Environmental Health Sciences from the Harvard School of Public Health. I joined the USW's safety and health staff in 1977. I've also served as a member of federal National Advisory Committee on Occupational Safety and Health; the Program Advisory Committee of the International Program on Chemical Safety, which is a collaborative effort of several United Nations agencies; and on the industry side, the Public Advisory Panel for the Responsible Care Program of the American Chemistry Council. I was the leader and chief negotiator for the Workers Group in the tripartite negotiations that led to the International Convention on Safety in the Use of Chemicals at Work, which is binding international law on those countries which have ratified it (not including, I'm sorry to say, the United States). Most recently, I was a member of the Steering Committee and several subcommittees of the international group which wrote the Globally Harmonized System of Classification and Labeling of Chemicals.

But the mission which affected me the most, and which haunts me to this day, was as a member of an international team which traveled to Bhopal, India to investigate the December 1984 methyl isocyanate release from a

Union Carbide plant that took several thousand lives – no one knows the true number – in the first few hours, many more in subsequent weeks, and continues to claim victims even a quarter century later from the injuries suffered that night and perhaps from the chronic toxicity of the chemicals released. In my sleep I still see the faces of the parents whose children died, of the children left without parents; I can still hear the constant coughing of the victims who survived, but with most of their lungs burned away.

Two members of our team were from the United States. And one thing we quickly realized was that, had the Bhopal plant existed in the United States, none of the underlying causes of the accident – the lack of any risk assessment of the potential for harm under the conditions of use, the storage of large amounts of highly toxic chemicals, the inoperability or undersizing of safety systems – none of it would have violated any existing EPA or OSHA or any other regulation. That includes the Toxic Substances Control Act, although TSCA was then in force. Think about that for a moment: the Toxic Substances Control Act wouldn't have controlled the causes, much less prevented, the worst toxic substance accident in human history.

Of course, much has changed since then. We have the OSHA Process Safety Standard, the EPA Risk Management Program, the Toxic Release Inventory, the Chemical Safety Board, and in the private sector, industry's Responsible Care Program and a whole variety of citizen groups and labor organizations organizing for better chemical safety. But the basic chemical safety law in this country, TSCA – the cornerstone on which everything else rests – remains unchanged.

Let me turn to the impact of TSCA – or rather the lack of impact – in the workplace. I'm wearing a little lapel pin this morning. It's a tiny birdcage, with a canary. Thousands of our members and many of our supporters wear them. It symbolizes what workers have become in relation to toxic chemicals. Before the invention of modern testing equipment, miners used to bring canaries underground. If the bird died, you knew something in the air was toxic and you got out. Today, we are the canaries in those cages. Others may testify this morning about bisphenol-A, phthalates, or carbon nanotubes. All of them may pose serious risks to consumers and communities, but the first to be exposed, and usually the highest exposed, are the workers who produce them and incorporate them into products. Most epidemiology regarding toxic substances uses cohorts of workers – in other words, it's our bodies that get counted in these retrospective human experiments.



My colleagues and I in the USW's Health, Safety and Environment Department visit several hundred workplaces a year in all manner of industries. Sometimes it's a full-blown inspection or audit; sometimes it's an accident investigation; sometimes it's to help solve a specific safety or health problem. Collectively we have a lot of experience with chemicals and chemical hazards, so our members depend on us to say whether what they're working with is safe. But all too often, we don't have a clue. OSHA requires labels and written information sheets for workplace chemicals, but they frequently contain almost no useful information beyond acute toxicity – nothing at all about long-term effects, because those chemicals have never been tested.

I've often seen information sheets which say: "This product contains no hazardous ingredients as defined by the OSHA Hazard Communication Standard," and then goes on to say: "Avoid breathing vapors; use only with adequate ventilation; use appropriate personal protective equipment; if overexposed [and of course overexposure is never defined] seek immediate medical attention." That kind of mismatch makes people question whether they are really being protected from long-term chemical poisoning. And the simple answer is, we just don't know.

Too often we learn the consequences of that ignorance only by chance and only too late. Vinyl chloride was found to be a potent carcinogen only after a physician diagnosed two cases of a very rare cancer – angiosarcoma of the liver – in workers from a single plant. Had it been a more common cancer, the effect would have been overlooked. It took the lung cancer deaths of 54 workers in a plant making ion-exchange resins to identify bis-chloromethyl ether as a carcinogen. Dibromochloropropane (DBCP) is a pesticide now banned in the United States, although it regularly turns up in groundwater from past use. DBCP causes sterility in men. We first learned of that when a group of men in a California chemical plant realized that their inability to father children – which each of them thought was his problem alone – in fact afflicted all of them. Dimethylaminopropionitrile, a chemical formerly used as a catalyst in polyurethane plastics, causes severe bladder paralysis, a condition discovered in exposed workers shortly after the chemical was introduced.

The most recent example is diacetyl, the main component in artificial butter flavoring. When inhaled, diacetyl causes a rare lung disease called bronchiolitis obliterans – and it's as bad as it sounds, always devastating, sometimes fatal. In May 2000, eight workers in a microwave popcorn plant were diagnosed with the condition, and although it took some time, diacetyl was recognized as the cause. You would think that a food additive would

have been extensively tested before it was approved by the FDA. But it was never tested for toxicity by inhalation. Many additional workers have now contracted bronchiolitis obliterans, and we have seen at least one case in a consumer.

In fairness, let me say that the first two of my examples predated TSCA, but TSCA would not have made any difference. The other three came after TSCA was in place, and TSCA provided no help. And these are only the very small tip of a very large iceberg. The dangers of these chemicals were discovered only through unusual circumstances – rare medical conditions in three cases, an overwhelming number of deaths in one, a chance discussion by a group of workers in another. We have no idea how many more untested chemicals are causing unrecognized illness among workers and consumers.

Nor do we know the ultimate burden of occupational disease. Paul Schulte of the National Institute for Occupational Safety and Health, in a 2005 review of 38 studies, conservatively puts it at approximately 50,000 deaths a year, and at a cost of between \$128 billion and \$155 billion.<sup>1</sup> But since many of the studies Shulte relied on were of known causes, the true impact may be much higher. And unless we change how we evaluate new chemicals and other materials, that impact and the impact on consumers can only grow as new technologies, like nanotechnology and synthetic biology come into play.

In short, the way we now evaluate many potentially toxic chemicals is by counting bodies and measuring human misery long after those chemicals have been introduced. That has to change.

Let me turn for a moment to economics. Of course, the main reason for reforming TSCA is to protect human health, but there are also good economic reasons. There will be many who say that we can't afford to reform chemical policy, especially not in the current economic climate. But in truth, we can't afford not to. First, there is the economic burden of occupational disease and environmental disease I mentioned. It saps our productivity, destroys the earnings potential of families, increases health care costs.

Then there is the issue of competitiveness. 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

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<sup>1</sup> Shulte, "Characterizing the Burden of Occupational Injury and Disease," *Journal of Occupational and Environmental Medicine*, Vol. 47, No. 6, pp. 607-622, 2005.

States follows suit, consumers will ultimately come to trust European products more than they trust American products. I believe it was the great consumer advocate Esther Peterson who said: "Made in USA should be a guarantee, not a warning."

Three weeks ago our union joined many other organizations in sponsoring a conference here in Washington called "Good Jobs – Green Jobs." Twenty-six hundred people attended, and we had to turn hundreds more away. The conference was dedicated to the idea that we can remake our economy to be far more environmentally sustainable while creating millions of good jobs in the process. Green chemistry will be an important part of that green economy.

I have great faith in the chemical industry. I actually believe all those Sunday morning commercials about the "human element" and the innovative potential of American chemistry. I believe we can produce chemical products that are safe to manufacture and safe to use. 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.

The critical first step is the reform of our basic chemical safety law – the Toxic Substances Control Act. Mr. Chairman, you, your committee and this Congress can make that happen. We urge you to do so.

Thank you again for the opportunity to testify this morning.

Mr. RUSH. Thank you very much, and we thank all the witnesses. I have been informed by staff that around 11:20 there will be three votes on the Floor, and these will be the only votes of the day. However, the chair would like to proceed with its questions and we will get as far as we can before we have to go for a vote, but I would also like to ask the witnesses if they can possibly remain until we come back from the Floor where we will be voting.

The chairman recognizes himself for 5 minutes. I would like to get each of you on the record on a very basic question. Do you believe that TSCA needs to be reformed? And please answer with a yes or no, starting with my guest and my friend, Mr. Stephenson.

Mr. STEPHENSON. Yes.

Mr. RUSH. Mr. Davies.

Mr. DAVIES. Yes.

Mr. RUSH. Ms. Swanson.

Ms. SWANSON. Yes, Mr. Chairman.

Mr. RUSH. Mr. Corbin-Mark.

Mr. CORBIN-MARK. Yes.

Mr. RUSH. Mr. Wright.

Mr. WRIGHT. Yes.

Mr. RUSH. All right. I have heard some suggestion the problem here is not really the statute, but the problem is EPA's interpretation of the statute. It seems to me that after 30 years of failed efforts to carry out the law through many different Administrations of different political stripes, it is fair to say that there are some serious problems with the statute itself. Do you agree with this conclusion?

Mr. STEPHENSON. That it is EPA's interpretation and not the law itself? Was that the question?

Mr. RUSH. No, that we have some serious problems with the statute itself.

Mr. STEPHENSON. Yes.

Mr. RUSH. Mr. Davies.

Mr. DAVIES. Yes, I do agree.

Mr. RUSH. Ms. Swanson.

Ms. SWANSON. Yes, I agree.

Mr. RUSH. Mr. Corbin-Mark.

Mr. CORBIN-MARK. Absolutely, I agree.

Mr. RUSH. Mr. Wright.

Mr. WRIGHT. Yes.

Mr. RUSH. Let me ask you another question and answer as briefly as you possibly can. What are the top two or three areas of TSCA that you think are in most need of reform? Please follow with your reasoning and be as brief as you possibly can. Did you hear my question?

Mr. STEPHENSON. I think the evidentiary standard that we talked about is too high and I think there is room for better hearing of information to the public and I think that the burden of proof for safe chemicals is tipped entirely on the government right now and should be moved more to industry. We are not here to endorse REACH. We are only using that as an example where the chemical industry is required to provide information to show that the chemicals are safe. We think it can be risk based. We think it can be production volume based but nevertheless the way TSCA

works right now, in 30 years it has just proven so burdensome that it doesn't serve its purpose.

Mr. RUSH. Mr. Davies, would you care to respond?

Mr. DAVIES. I agree with Mr. Stephenson. Let me make two quick comments. One, in terms of the evidentiary burden, it is different from what it is in almost all of the other environmental statutes. I mean, arbitrary and capricious is the standard used in almost all the environmental statutes, and in TSCA it is substantial evidence on the record, which is an incredibly high burden, and when you combine that with the other requirements in the Act, that is enough to undermine everything. The other thing is, again I would just urge the committee to pay some attention to things like nanotechnology and synthetic biology, which are coming down the track very fast. The regulatory system is not equipped to address those kinds of problems and we have to try to think through what changes are needed to address those things.

Mr. RUSH. Thank you very much.

Ms. Swanson?

Ms. SWANSON. I would agree that a major area for reform is to shift the burden of proof from government and proving that a chemical is toxic after it is on the market, shift that to industry proving that a chemical is safe before it goes on the market. That is just a key element that needs to be reformed. Also, we would like to see neurodevelopmental testing specifically included as part of the toxicity testing that is required by the statute.

Mr. CORBIN-MARK. I think that the one-by-one review approach of chemicals that is under TSCA sorely needs to be reformed. Many low-income communities and communities of color are not impacted by chemicals on a one-by-one basis but through their multiple and synergistic effects. I also think that the fragmentation that TSCA provides for chemical policy is really bad. The fact that some chemicals are regulated in the workplace and some chemicals are regulated in food and some chemicals are regulated in cosmetics and they are all regulated differently is a problem. A chemical is a chemical is a chemical. And then lastly, the whole notion of sort of the risk-based approach with which our chemicals are dealt with under TSCA is a problem. From our standpoint, risk models do not often include people of color, they don't include women and they often don't include children, some of the most vulnerable populations, given some of the things that I have talked about in terms of the communities that I work and organize in.

Mr. RUSH. Thank you very much.

Mr. Wright?

Mr. WRIGHT. Well, I agree with all of the above, but let me add to the list the great trade secrecy burdens that really prevent people from getting much information about the chemicals to which they are exposed. I also think that a new statute should require a lot more testing. Most chemicals are tested really only for their acute toxicity and not for chronic, long-term effects, and I think we need a combination of a risk-based and a hazard-based approach. That is to say the reporting should be the reporting by a company of the intrinsic hazards of a chemical that they produce whether it is acutely toxic, whether it is a neurotoxin, whether it causes cancer, and after that is done, after we have that information which

we need to evaluate the risk, that is when you look at risk and that is when you look at how you actually deal with that chemical.

Mr. RUSH. Thank you very much.

The chair now recognizes for 5 minutes the ranking member.

Mr. RADANOVICH. Thank you, Mr. Chairman, and again I appreciate the testimony of the panel. Let me start off by saying I know firsthand on the issue of chronic disease and diseases for which you cannot take a pill to get an immediate cure. I deal with that in my family as we speak, so I understand fully, Ms. Swanson and Mr. Corbin-Mark. I am empathetic with your issues and I care about the same things that you care about. However, I just want to make sure that whatever is done in something like this has to be based on good science and it has to be done in such a way that doesn't cripple a good industry, and I think those are the points that I think I would like to leave you with to make sure that whatever is done in a law that is generally accepted the fact that it needs to be updated and reformed, that we don't do it in such a way that we cripple an entire industry that is legitimate out there.

So I guess, Mr. Stephenson, if I could ask you a question. There were either 80,000 or 82,000 chemicals registered—

Mr. STEPHENSON. Eighty thousand on the existing chemical—

Mr. RADANOVICH. It is 80,000?

Mr. STEPHENSON. Yes.

Mr. RADANOVICH. In your view, do you think that the industry, the chemical industry should be on the hook to prove that every one of those by good science is a safe material? Do you believe that under the law that the industry should take on every one of them and then come back with—

Mr. STEPHENSON. I don't think you can apply a one size fits all to everything. That has been the complaints of the European approach under REACH, that they require too much information on some chemicals that are known to be safe. I am not a chemistry expert but I think there are ways to segment that family of chemicals into those where the chemical industry should be required to provide information and those that should not. I think EPA has even offered to scrub the list in some way. They haven't done that but they could do that.

Mr. RADANOVICH. And also in your testimony, was it the number 200 that were—200 chemicals that were—

Mr. STEPHENSON. Where they actually required additional information from industry, and there is a burden of proof on EPA and a case that it has to go through and years that it takes even to get that. So in 30 years of TSCA, there has been 200 times where the law has worked to require additional information.

Mr. RADANOVICH. In your view, knowing what you know about the industry, can you give me a sense of—you know, because we are looking at 200 to 80,000, somewhere in between there a sense of the chemicals that are out there that need to be looked at further?

Mr. STEPHENSON. The catch-22 that Mr. Davies pointed to is the biggest problem. EPA is required to prove the chemical is dangerous and it needs information to do that. Well, who has the information? The person who produced it does so they can't meet that burden without information from the industry so there has to be

more of a collaboration here for EPA to get the information that it needs to do its job more easily than it can right now.

Mr. RADANOVICH. Thank you.

Ms. Swanson, you mentioned a list of chemicals, the same 80,000 that are registered, of course, that is common, 3,000, and then 10 that were proven. Can you go over that list and give me an idea of what you are talking about in the overall chemical world of all those registered on TSCA how many things we are looking at here?

Ms. SWANSON. Yes, I mentioned of the 80,000 that are registered, about 3,000 are produced at more than 1 million pounds annually so these high-volume chemicals, there are 3,000 of those which might be one good starting point for requiring information, and of those 3,000 we know that 10 are neurotoxins and there is good evidence to suggest that another 200 are neurotoxins.

Mr. RADANOVICH. Are those 10 neurotoxins that you know of for sure backed by good science and still in products today, being manufactured into products today?

Ms. SWANSON. It is backed by a very good body of science that in many cases stretches over decades. Some of them are not—well, lead is one of the main and most potent neurotoxins that we know about and so lead has been gotten out of a lot of products certainly, but then some of the others are still being used in products today such as the chemicals that come from combustion. Those are used in products today. A lot of the solvents are known neurotoxins so compounds that are used in products like lighter fluid and oils and paint strippers and thinners, a lot of those chemicals are known neurotoxins and are still being used. So it varies. PCBs are a known neurotoxin that has been banned so some of them we have gotten rid of and some of them are still being used.

Mr. RADANOVICH. My time is expiring but I look forward to further questioning after we get done here, but I would like to go into a little bit more about a good idea, that the devil usually comes in the detail and when you do these regulations how they can have an unintended consequence on an industry that drives up the cost of purchased goods and such. So there is another side of this thing that I would like to continue discussing when we get back.

Thank you, Mr. Chairman.

Mr. RUSH. The chair now recognizes Mr. Sarbanes for 5 minutes of questioning.

Mr. SARBANES. Thank you, Mr. Chair.

Ms. Swanson, you said in your testimony that many people, particularly parents, would be, I think you said, dumbfounded and then outraged to learn that there isn't more oversight and data available with respect to these chemicals, and I am frankly becoming dumbfounded as I learn more about what hasn't happened as a result of what the expectations were of TSCA, and I would be very interested to hear from anyone that wants to comment on it briefly, because TSCA was hailed in the day when it was passed as this huge step. What happened? In other words, what expectations for what it was going to do were not met and how different is the oversight environment now as a result of the passage of TSCA, given the interpretations of it compared to the way things were before it was passed?

Mr. STEPHENSON. I will take a stab at part of it, the evidentiary standard we talked about. Just the use of the term “unreasonable risk” in a legal sense bears a high evidentiary burden, one that EPA can seldom meet, and that is why the asbestos case is important. They finally spent the 2 to 10 years that it took to make the case that it needed more information only to have it thrown out by the courts by not meeting that high evidentiary standard that is spelled out in the rule. That is why as a minimum we think that kind of language needs to be modified.

Mr. DAVIES. Just in terms of the history of the Act, basically the sort of fundamental tradeoff made when the Act was formulated under the Nixon Administration was a set of very broad and sweeping authorities in exchange for a bunch of very high procedural hurdles, and the court decisions since then, particularly corrosion-proof fittings, which is the 1991 decisions, made it very clear that in effect those broad and fairly sweeping authorities to take action were undetermined and negated by the procedural hurdles.

Mr. SARBANES. So basically it sounds like a lot of it has to do with judicial interpretation subsequent to the passage of the Act, which is not an unusual thing to happen. You have expectations of what will be changed, and then once it gets into the court system, things get more nuanced.

Let me move on real quick because I got 2 minutes here. I was curious, what other—are there analogies on this issue of the burden of proof, which now resides heavily on EPA to prove that something is unsafe, versus on the manufacturers and so forth to prove that it is? Are there analogies to other statutes administered by the EPA where you see that sort of what I would call imbalance at work or is this one of the more egregious instances of where you have got the burdens flipped in the wrong direction? That is my view of it.

Mr. DAVIES. The two more egregious examples in my mind in addition to TSCA are cosmetics and dietary supplements. In both cases, the burden of proof is entirely on the agency, in that case Food and Drug Administration, and furthermore, the statute in effect prohibits any kind of adequate oversight, which is even further than TSCA goes, but TSCA is definitely if not the most important definitely one of the most important examples where the burden of proof problems interfere with the effectiveness of the statute.

Mr. SARBANES. Thank you. I yield back.

Mr. RUSH. The chair thanks the gentleman.

I think that we will stand in recess until we return from the votes, and we again ask the witness if they will remain for the conclusion of this first panel. Thank you. The committee is in recess.

[Recess.]

Mr. RUSH. The committee is called to order. I want to thank the panelists and our guests for their patience. I think that right now we will recognize Ms. Castor, the gentlelady from Florida, for 5 minutes of questioning to the panel.

Ms. CASTOR. Thank you very much, Mr. Chairman.

Thank you to the panel very much for attending today. The evidentiary standard obviously is very problematic and you made your points very well on that. I would like to move on and have a better understanding of the statute, how it forbids EPA from sharing in-



formation that it obtains, the sharing of scientific data that it obtains with the public. Could you all comment on that, please?

Mr. STEPHENSON. I will take the first shot at it. When a new chemical is introduced, the industry has to submit what is called a pre-manufacturer notice, and as part of that there is actually a box on the form that you check that claims competitive business information and we have been told often that that is the default and we think if there was more guidance or definition as to when that claim could legitimately be made or if there was a certification that the industry would make to certify the fact that is indeed CBI would be better than the way it works now.

Mr. DAVIES. That is a key part of the problem but also it is made worse because unlike most of the other environmental statutes, TSCA doesn't allow EPA to share confidential business information with either States or with other national governments. In most of the statutes, it says if the State or the other national government can provide equivalent protection for that trade secret information, then you can share it with them. TSCA doesn't have any provision like that. It has a flat prohibition on sharing any confidential business information. So that combined with the ease with which you can classifying something as confidential, that is what contributes to the problem.

Mr. WRIGHT. If I can add kind of another model, the OSHA hazard communication standard also has a provision for trade secrecy but it has two important provisions. One is that if chemical in question, the chemical mixture usually is obtainable on the open market and can be essentially, it is called reverse engineered, analyzed in a lab to figure out what it is, then it is really not much of a trade secret because any competitor can do that. So the standard excludes things that can be reverse engineered. And second, it provides a provision that people with a legitimate need to know that information, for example, in our case, a worker representative, a worker himself or herself, somebody providing medical treatment can also get what would otherwise be confidential business information. And those would be good things to include.

Ms. CASTOR. Yes, I think it is fairly obvious that we can modernize the statute to better serve the public, especially when it comes to information that families need to understand. It is true that since TSCA was adopted in 1976 that it has only led to one group of chemicals that have been subjected to a ban because of its properties?

Mr. STEPHENSON. The example we use, there has only been five in total, and I don't know what chemical classes those were in but even of those, the corrosion fitting case that dealt with asbestos, the courts threw that out because it couldn't meet the high evidentiary standard within the law. The courts didn't address whether the asbestos was safe or not. Like courts often do, they just showed that it didn't meet the standards in TSCA.

Ms. CASTOR. Mr. Stephenson, in your written testimony, you gave an example of formaldehyde, and I think it would be very helpful to take just a minute and explain that circumstance of the formaldehyde in wood coming from China that now cannot go to other countries but continues to be marketed in the United States.

Mr. STEPHENSON. Well, you are getting even beyond TSCA into assessing the toxicity of chemicals as well and there are many ways you can do that. It doesn't fall under TSCA. That process is also broken at EPA, the integrated risk information system process, and formaldehyde is a case where the research is compelling but not compelling enough for EPA to regulate, so that is sort of related but a little bit different issue.

Ms. CASTOR. My time is running out. I recommend that you all review this case of the wood now that other countries are able to regulate and keep out of their countries because of the toxic chemicals contained therein but it is still coming to the United States including some of the trailers that were provided to Katrina victims.

Mr. STEPHENSON. Absolutely. That is true of asbestos too. Nearly every other country in the world has banned it. We have not.

Ms. CASTOR. Thank you, Mr. Chairman.

Mr. RUSH. Seeing that there are no more members, I want just to thank this panel. This will conclude your testimony, and I want you to understand that all witnesses should be prepared to respond to written follow-up questions submitted by members of the subcommittee. I again want to thank you so much for your patience and you really helped us along. You provide a real service to the American people by your presence here today. Thank you, and may God bless you in your travels.

As the first panel departs, I would ask that the second panel be prepared now to come and join us at the witness table. I want to advise the second panel that they will be testifying under oath, and as a result of that, would you please rise to be sworn in?

[Witnesses sworn.]

Mr. RUSH. Please let the record reflect that all witnesses have responded in the affirmative. Please take your seats.

I want to introduce the witnesses beginning at my left, your right. Mr. Richard Denison is the senior scientist for the Environmental Defense Fund. Ms. Kathy Gerwig is the vice president of Workplace Safety and Environment. She is the stewardship officer at Kaiser Permanente. An ex-Member of the House is with us here, Mr. Cal Dooley. Mr. Dooley is now the president and CEO of the American Chemistry Council. He served in the House from 1991 to 2005, representing the 17th and 20th districts of California. He didn't represent them all at the time. Mr. V.M., Jim, DeLisi is the president of Fanwood Chemical Incorporated. He is the chairman of the International Affairs Committee for the Synthetic Organic Chemical Manufacturers Association. Mr. Charles T. Drevna is the president of the National Petrochemical & Refiners Association.

I would ask that the panelists now provide a maximum of 5 minutes of opening statements beginning with Mr. Denison.

**TESTIMONY OF RICHARD DENISON, SENIOR SCIENTIST, ENVIRONMENTAL DEFENSE FUND; KATHY GERWIG, VICE PRESIDENT, WORKPLACE SAFETY AND ENVIRONMENTAL STEWARDSHIP OFFICER, KAISER PERMANENTE; CAL DOOLEY, PRESIDENT AND CEO, AMERICAN CHEMISTRY COUNCIL; V.M. (JIM) DELISI, PRESIDENT, FANWOOD CHEMICAL INC., AND CHAIRMAN, INTERNATIONAL AFFAIRS COMMITTEE, SYNTHETIC ORGANIC CHEMICAL MANUFACTURERS ASSOCIATION; AND CHARLES T. DREVNA, PRESIDENT, NATIONAL PETROCHEMICAL & REFINERS ASSOCIATION**

**TESTIMONY OF RICHARD DENISON**

Mr. DENISON. Thank you, Chairman Rush and Ranking Member Radanovich for holding this hearing today.

I would like to do three brief things in my testimony today. I want to start with a story about one chemical. In fact, it is the chemical that Congresswoman Castor was just speaking about that illustrates why reform of TSCA is so urgent. I then want to briefly describe several structural problems with TSCA that help to explain why EPA has been unable to act effectively to ensure chemical safety. And finally I want to describe how U.S. policies are falling behind those of the rest of the world, putting U.S. companies at risk of losing access to global markets and putting all of us at risk of becoming a dumping ground for unsafe products made elsewhere in the world.

That brings me to the story about that one chemical. The United States imports vast amounts of plywood from China that is made using formaldehyde-based adhesives, a chemical known to cause cancer, to exacerbate asthma and to cause numerous other respiratory ailments. Some of that plywood ended up in the infamous FEMA trailers to which so many people were forced to flee in the wake of Hurricane Katrina. That toxic exposure turned what was already a national scandal into a true debacle. The plywood China sells to the United States cannot legally be sold to Japan or the European Union nor can it be sold even for domestic use in China, and that is because all of those countries have enacted strong regulations that restrict the release of formaldehyde. As of January of this year, California also enacted such regulations.

Now, China exports a low-formaldehyde version of this plywood to Japan and the European Union but it continues to enjoy a market for its more toxic product here in the United States. Domestic makers of low- or even formaldehyde-free plywood can't compete with those cheap imports from China so we are hurting American businesses that have found safer alternatives to this use. Last year EPA was petitioned by 5,000 citizens to take the California regulations and adopt them nationally. EPA promptly denied that petition. It said that the information available on formaldehyde, one of the best-studied chemicals in all of commerce, was insufficient. As bad as that sounds, what is worse is that EPA is likely right. EPA must show that a chemical presents an unreasonable risk as defined under TSCA and interpreted by the courts, and I think many other witnesses have already alluded to the fact that that burden is so high that it essentially is impossible to meet. Over the history of TSCA, EPA has banned only one group of chemicals, PCBs, and

that was because Congress legislated the ban. It has partially restricted four other sets of chemicals in the 33-year history. In the 1980s EPA tried to ban asbestos, as we have heard, and it was immediately challenged by industry and the courts overturned that decision.

A lot has been said about that already but I want to add two other things. First, EPA took over 10 years to develop that regulation and they amassed a 45,000-page documentary record of the risks of asbestos. Despite that, the courts found EPA had not met its burden under TSCA. Now, it has become fashionable in some circles to argue that the problem with TSCA is that EPA hasn't been trying hard enough or hasn't been doing a good enough job. I ask you, if 45,000 pages of documentation and 10 years of regulatory development is not enough to ban a chemical like asbestos, what is? Something is badly broken. TSCA has never been significantly amended in the 33-year life it has lived despite enormous changes in our chemicals economy and our state of knowledge about chemicals. One example. We now know that all Americans including newborn infants carry hundreds of synthetic chemicals in their bodies, some at levels that we already know are high enough to cause harm in laboratory animals. The more chemicals we look for in people, the more we find, and yet government nor industry can tell us how those chemicals got there nor can they adequately explain what their impact will be on our health. TSCA fails to provide EPA with the authority it needs to develop information to identify not only unsafe chemicals but safe chemicals that could be substitutes for the risky ones and TSCA forbids EPA from sharing that information even with other levels of government, as we have already heard. Companies are largely free to claim the information that they deem confidential. Those claims are rarely, if ever, reviewed or even required to be justified up front, and even the name and identity of a chemical that is being submitted because of a study that shows high risk, the identity of that chemical can be hidden from the public.

EPA had to resort to voluntary programs, given these constraints that it has to operate under. The most notable of these is the High Production Volume Challenge program. Now, we supported that when it was launched a decade ago.

Mr. RUSH. Will you please bring your testimony to a close? You are over the 5 minutes. Please bring it to a close.

Mr. DENISON. But that program—I will wrap up very quickly here. That program has failed to deliver the data because it is a voluntary program. I want to just end by saying that lest you think that what we are looking for with TSCA reform is a heavier hand of government, the largest failing of TSCA is the dysfunctional market it perpetuates, one that is ill informed and does not allow anyone who needs to make good decisions about chemicals access to the information to make those good decisions. Thank you very much.

[The prepared statement of Mr. Denison follows:]

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ENVIRONMENTAL DEFENSE FUND  
finding the ways that work

STATEMENT OF

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

BEFORE

THE U.S HOUSE OF REPRESENTATIVES  
COMMITTEE ON ENERGY AND COMMERCE  
SUBCOMMITTEE ON COMMERCE, TRADE, AND CONSUMER PROTECTION

AT A HEARING ON

REVISITING THE TOXIC SUBSTANCES CONTROL ACT OF 1976

26 FEBRUARY 2009

I will start my testimony today with a story about one chemical that vividly illustrates why reform of the Toxic Substances Control Act (TSCA) is essential and urgent. I will then briefly touch on some of the key *structural* flaws in TSCA and describe why EPA's efforts, given the constraints it must operate under, are failing to get the job done. Finally, I'll describe how U.S. policies have fallen far behind those of the rest of the developed world, and why acting promptly to modernize TSCA is essential if U.S. companies are to retain access to global markets for their products, and if we are to avoid becoming the dumping ground for unsafe products made elsewhere in the world.

First, a story about one chemical and, in fact, one use of that chemical. This story speaks directly to our nation's ability to ensure the safety of the tens of thousands of chemicals we produce and use every day, and to protect the health of the most vulnerable among us. The U.S. imports vast amounts of plywood and other composite wood products from China.<sup>1</sup> Many of these products are made using adhesives that contain formaldehyde, a chemical known to cause cancer<sup>2</sup> and to exacerbate asthma and other respiratory ailments. Formaldehyde is also suspected to be toxic to the neurological and immune systems.<sup>3</sup>

The plywood we import from China releases high levels of formaldehyde into the air, a major concern when it is used in the construction of places where people live and work. The plywood China sells to us cannot legally be sold to Japan or the European Union or even for domestic use in China. That is because all of these countries have enacted strong restrictions on formaldehyde release.

Some of this plywood ended up in the infamous FEMA trailers to which so many people were forced to flee in the wake of Hurricane Katrina. The resulting toxic exposures greatly compounded what was already a national scandal and disgrace.<sup>4</sup>

Now, it turns out that China makes low-formaldehyde plywood for export to Japan and the EU, but continues to have a market for its more toxic product here in the U.S. And U.S. companies that make low- or even formaldehyde-free plywood are having a hard time competing against these imports.

California has been the first in the U.S. to tackle this problem. As of January 1 of this year, emission limits on formaldehyde comparable to those in Japan and the EU apply to all composite wood products sold in California, and those limits will be further ratcheted down over the next few years.<sup>5</sup> The new regulations don't actually ban formaldehyde in these products; they only limit its release into the air. But the hope is they will drive replacement of formaldehyde with safer alternatives.

After California adopted its regulation, 25 organizations and 5,000 citizens petitioned the U.S. Environmental Protection Agency (EPA) to adopt the California regulations nationally under TSCA.<sup>6</sup> EPA promptly denied the request, saying the available information on formaldehyde – one of the most studied toxic chemicals in all of commerce – was insufficient for EPA to meet its

burden of proof under TSCA.<sup>7</sup> Instead, EPA said it will gather more information and further study the issue.<sup>8</sup>

As bad as this sounds, what's worse is that EPA is likely right about its inability to act under TSCA. To regulate a chemical, TSCA requires EPA to prove that it presents an *unreasonable risk*. In practice, and as defined through a series of court cases, this onus placed on the Agency has proven essentially impossible to meet.<sup>9</sup> Over the history of TSCA, EPA has managed to ban only one group of chemicals, PCBs, which was legislated into TSCA by Congress in 1976. And for only four other chemicals has it been able to impose even partial restrictions.<sup>10</sup>

The final nail in the coffin of EPA's authority under TSCA to regulate chemicals came in 1991, when the Fifth Circuit Court of Appeals threw out EPA's entire regulation to ban asbestos.<sup>11</sup> EPA had spent well over a decade to develop that rule, amassing a 45,000-page record of documentation of the risks of asbestos. But the Court still ruled that EPA had failed to show that asbestos posed an *unreasonable risk* as defined by TSCA. Since that decision 18 years ago, EPA has never tried again, and its denial of the formaldehyde petition is but the latest in a series of such denials.

Clearly, something is badly broken.

TSCA was passed 33 years ago. Its basic provisions have never been amended, despite enormous changes both in chemical production and use and in our understanding of human and environmental exposures and biological effects of chemicals. Just one example: We now know that virtually every American – including newborn infants – carry in their bodies hundreds of synthetic chemicals, some at levels known to cause harm in studies involving laboratory animals.<sup>12</sup> And the more chemicals we look for, the more we find. Neither the producers of these chemicals nor our government can adequately explain how they got there or what the cumulative health effects might be from our exposures to this cocktail of chemicals.

Foremost among its core *structural* flaws, TSCA:

- fails to provide EPA the authority to deliver the information needed to identify unsafe – as well as safer – chemicals;
- forbids EPA from sharing much of the limited information it does obtain;
- imposes an essentially unmeetable burden on EPA to prove actual harm in order to control or replace a dangerous chemical; and
- thereby perpetuates the chemicals industry's failure to innovate toward inherently safer chemical and product design.

For drugs and pesticides (which are regulated under different laws) to enter or stay on the market, their producers have the burden of providing to the government information sufficient to demonstrate their safety. Yet for chemicals subject to TSCA, the opposite is true: When it grandfathered in the tens of thousands of chemicals that were on the market at the time it was passed – and which still today constitute the vast majority of chemicals in use – TSCA granted

each of them a strong “presumption of innocence” by not requiring them to be tested or shown to be safe. Under TSCA, EPA – and, hence, the public – shoulders the burden of proof.

In what amounts to a classic *Catch-22*, EPA must already have information sufficient to document potential risk or extensive exposure in order to require a company to test its chemical to determine whether there is actual risk. This burden is so high that EPA has been able to require testing for only about 200 chemicals under TSCA.<sup>13</sup>

As a result, EPA has been forced to rely on voluntary efforts to obtain more information on existing chemicals. The most notable of these is the U.S. High Production Volume (HPV) Chemicals Challenge, which EDF helped EPA to launch in 1998.<sup>14</sup> Because it was voluntary, it sidestepped the “unreasonable risk” and other findings EPA must make to compel testing. But for the same reason, EPA has had essentially no regulatory backstop. It has been unable to compel full and timely industry participation, and the program has fallen far behind schedule. Worse, the Challenge has delivered data sets that are all too often incomplete or of poor quality, and it has never reached hundreds of high-volume chemicals.<sup>15</sup>

Under its so-called ChAMP initiative,<sup>16</sup> EPA is now trying to use these limited hazard data, coupled with even more questionable and incomplete information on chemical use and exposure collected sporadically from manufacturers, to make pronouncements about these chemicals’ risks to the public, workers, consumers and children, as well as the environment.

The failings of these EPA initiatives, which we have detailed in a series of reports and comments submitted to EPA,<sup>17</sup> directly reflect the constraints under which EPA must operate under TSCA:

- EPA faces a high bar to require testing under TSCA, so it must rely on existing data, no matter how poor or incomplete, or propose voluntary programs to try to fill the gaps.
- EPA’s authority to regulate chemicals is even more constrained, so even for the few high-concern chemicals it has identified, EPA merely “encourages companies to provide available information on a voluntary and non-confidential basis.”
- EPA is reluctant to acknowledge the limits of its authority, so it obscures rather than highlights the deficiencies in the available data and the assessments based on them.
- EPA faces onerous requirements under TSCA to protect any information claimed by submitters to be confidential, and lacks the resources to challenge the large number of questionable claims, further exacerbating the lack of transparency and accountability of its assessments.

There is a better way. Dramatic changes have taken place during this decade in Europe, in Canada and in several U.S. states, which have set in motion the process of bringing their chemical policies into the 21<sup>st</sup> century.<sup>18</sup> These policies share several hallmarks:

- They aim to be comprehensive in scope, seeking to identify and control all chemicals of concern.
- They shift the burden of proof from government to show harm, to industry to demonstrate safety.



- They seek to regulate hazardous chemicals so as to protect the most vulnerable among us.
- They are acting to redress our current state of "toxic ignorance," by greatly expanding the amount of information on chemicals, and driving that information into the public domain – with the express intent of better informing and empowering the many thousands of market participants who make daily decisions about which chemicals are produced and how they are used to make better decisions.

Without prompt federal action, the U.S. risks falling well behind the rest of the developed world in ensuring the safety of the chemicals and chemical products we make and use every day – just as we risk becoming a dumping ground for unsafe products like the formaldehyde-laced plywood I described at the outset of my testimony.

Lest you come away thinking this is all too much of the heavy hand of government, let me say the greatest failing of TSCA is that it perpetuates a very dysfunctional market in chemicals and chemical products. The market is ill-informed because we haven't required companies to develop even basic safety data for their chemicals. And because of government's failure to effectively identify and act to control toxic chemicals, companies, institutions and individuals making or selecting chemicals or chemical products can't tell a safer one from a less safe one.<sup>19</sup>

I have attached to my written testimony a paper I recently published that sets forth ten essential elements of TSCA reform.<sup>20</sup> The reforms we seek are driven by the need to shape a market that functions correctly – one that is driven by knowledge rather than ignorance and uncertainty, and that rewards innovation toward safer chemicals and products.

Thank you.

## Endnotes

- <sup>1</sup> See Cone, Marla, "U.S. rules allow the sale of products others ban; Chemical-laden goods outlawed in Europe and Japan are permitted in the American market," *Los Angeles Times*, October 8, 2006, p. A1, at [coch.berkeley.edu/docs/news/2006-10-8\\_latimes.pdf](http://coch.berkeley.edu/docs/news/2006-10-8_latimes.pdf).
- <sup>2</sup> See International Agency for Research on Cancer, at [www.iarc.fr/en/Media-Centre/IARC-Press-Releases/Archives-2006-2004/2004/IARC-classifies-formaldehyde-as-carcinogenic-to-humans](http://www.iarc.fr/en/Media-Centre/IARC-Press-Releases/Archives-2006-2004/2004/IARC-classifies-formaldehyde-as-carcinogenic-to-humans); State of California Proposition 65 list, at [www.oehha.ca.gov/prop65/prop65\\_list/files/P65single121908.pdf](http://www.oehha.ca.gov/prop65/prop65_list/files/P65single121908.pdf); U.S. National Toxicology Program, at [ntp.niehs.nih.gov/index.cfm?objectid=7BE524E1-F1F6-975E-76B0ABD6CC9076A](http://ntp.niehs.nih.gov/index.cfm?objectid=7BE524E1-F1F6-975E-76B0ABD6CC9076A).
- <sup>3</sup> See [www.scorecard.org/chemical-profiles/summary.tcl?edf\\_substance\\_id=50%2d00%2d0](http://www.scorecard.org/chemical-profiles/summary.tcl?edf_substance_id=50%2d00%2d0).
- <sup>4</sup> See, for example, U.S. House of Representatives, Committee on Oversight and Government Reform, at [oversight.house.gov/story.asp?ID=1751](http://oversight.house.gov/story.asp?ID=1751); U.S. House of Representatives, Committee on Science and Technology, Subcommittee on Investigations and Oversight, September 22, 2008 Staff Report, "Toxic Trailers - Toxic Lethargy: How the Centers for Disease Control and Prevention Has Failed to Protect the Public Health," at [science.house.gov/publications/caucus\\_detail.aspx?NewsID=2313](http://science.house.gov/publications/caucus_detail.aspx?NewsID=2313); and CBS News, "FEMA Protecting Itself, But Not Evacuees," November 7, 2007, at [www.cbsnews.com/stories/2007/11/07/cbsnews\\_investigates/main3469283.shtml](http://www.cbsnews.com/stories/2007/11/07/cbsnews_investigates/main3469283.shtml).
- <sup>5</sup> See California Air Resources Board, "Information on California's Formaldehyde Air Toxic Control Measure", at [www.carb.ca.gov/](http://www.carb.ca.gov/).
- <sup>6</sup> See [www.epa.gov/oppt/chemtest/pubs/petition3.pdf](http://www.epa.gov/oppt/chemtest/pubs/petition3.pdf). This petition was filed under Section 21 of TSCA.
- <sup>7</sup> See [www.epa.gov/EPA-TOX/2008/June/Day-27/t14618.htm](http://www.epa.gov/EPA-TOX/2008/June/Day-27/t14618.htm). EPA stated "Notwithstanding the substantial amount of information submitted by reference with the petition or otherwise available to the Agency, EPA has determined that this information is not sufficient to support an evaluation of whether formaldehyde emitted from composite wood products presents or will present an unreasonable risk to human health (including cancer and non-cancer endpoints) under TSCA section 6."
- <sup>8</sup> See [www.epa.gov/fedrgstr/EPA-TOX/2008/December/Day-03/t28585.htm](http://www.epa.gov/fedrgstr/EPA-TOX/2008/December/Day-03/t28585.htm).
- <sup>9</sup> See, for example, Heinzerling, Lisa, Testimony before the Subcommittee on Environment and Hazardous Materials of the Committee on Energy and Commerce, U.S. House of Representatives, July 13, 2004, at [www.law.georgetown.edu/faculty/Heinzerling/Testimony/POPs\\_Testimony\\_July\\_2004.pdf](http://www.law.georgetown.edu/faculty/Heinzerling/Testimony/POPs_Testimony_July_2004.pdf), and 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, at [www.gao.gov/cgi-bin/getrpt?GAO-05-458](http://www.gao.gov/cgi-bin/getrpt?GAO-05-458).
- <sup>10</sup> The four are: fully halogenated chlorofluoroalkanes used as aerosol propellants, dioxin in certain wastes; asbestos (limited to products no longer in commerce, because the initial rule was vacated by U.S. courts after legal challenge); and hexavalent chromium used in water treatment chemicals in comfort cooling towers. 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. 58, at [www.gao.gov/cgi-bin/getrpt?GAO-05-458](http://www.gao.gov/cgi-bin/getrpt?GAO-05-458).
- <sup>11</sup> See *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (5th Cir. 1991), at [www.ultlaw.org/v1/cases/514839](http://www.ultlaw.org/v1/cases/514839).
- <sup>12</sup> See Centers for Disease Control and Prevention, *Third National Report on Human Exposure to Environmental Chemicals* (2005), at [www.cdc.gov/exposurereport/report.htm](http://www.cdc.gov/exposurereport/report.htm). This study was published in 2005 and tested samples collected in 2001 and 2002 for 148 chemicals. Also see Environmental Working Group (2005) "Body Burden. The Pollution in Newborns," at [archive.ewg.org/reports/bodyburden2/execsumm.php](http://archive.ewg.org/reports/bodyburden2/execsumm.php).
- <sup>13</sup> See Office of Pollution Prevention and Toxics, U.S. EPA, *Overview: Office of Pollution Prevention and Toxics Programs*, pp. 4, 15 (Jan. 2007), at [www.epa.gov/oppt/pubs/oppt101c2.pdf](http://www.epa.gov/oppt/pubs/oppt101c2.pdf).
- <sup>14</sup> See U.S. EPA, High Production Volume Challenge, at [www.epa.gov/chemrtk/index.htm](http://www.epa.gov/chemrtk/index.htm).
- <sup>15</sup> For a full description of the HPV Challenge and what it has and has not accomplished, 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](http://www.edf.org/documents/6653_HighHopesLowMarks.pdf).
- <sup>16</sup> See *Chemical Assessment and Management Program*, see [www.epa.gov/champ](http://www.epa.gov/champ).
- <sup>17</sup> See series of EDF reports on the HPV Challenge at [www.environmentaldefense.org/hpvreportcard](http://www.environmentaldefense.org/hpvreportcard); and EDF's Comments on ChAMP, submitted to EPA on May 2, 2008, at [www.edf.org/documents/7871\\_Comments\\_ChAMP\\_May08.pdf](http://www.edf.org/documents/7871_Comments_ChAMP_May08.pdf).
- <sup>18</sup> For a detailed comparison of TSCA with the chemicals policies in Canada and the European Union, see Richard A. Denison, *Not That Innocent: A Comparative Analysis of Canadian, European Union and United States Policies on Industrial Chemicals* (2007), at [www.edf.org/chempolicyreport](http://www.edf.org/chempolicyreport).
- <sup>19</sup> See Joseph H. Guth, Richard A. Denison and Jennifer Sass, "Require Comprehensive Safety Data for all Chemicals," in *New Solutions J. of Envtl. & Occupational Health Policy*, Vol. 17, pp. 233-258, at [www.louisvillecharter.org/paper/safetydata.shtml](http://www.louisvillecharter.org/paper/safetydata.shtml).
- <sup>20</sup> See Denison, Richard A. (2009) "Ten Essential Elements in TSCA Reform," *Environmental Law Reporter*, 39 ELR 10020 (Environmental Law Institute, Washington, D.C.), at [www.edf.org/documents/9279\\_Denison\\_10\\_Elements\\_TSCA\\_Reform.pdf](http://www.edf.org/documents/9279_Denison_10_Elements_TSCA_Reform.pdf).

## Ten Essential Elements in TSCA Reform

by Richard A. Denison

Richard Denison is a Senior Scientist with Environmental Defense Fund in Washington, D.C.

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### Editors' Summary:

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Congress enacted TSCA in 1976 to control risks from chemicals in commerce. It requires the government to review most new chemicals while they are being developed and it gives government the power to regulate chemicals already in or entering commerce if they create an "unreasonable risk" to health or to the environment. Yet current policy hinders government's ability to generate information and to act on such information when it indicates significant risk. This Article identifies 10 elements that can facilitate a shift toward knowledge-driven policies that motivate and reward, rather than impede and penalize, the development of information sufficient to provide a reasonable assurance of chemical safety. Adopting a more comprehensive approach that seeks to develop good information on most or all chemicals would allow us to select safer chemicals with confidence.

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For the last several decades, government policy has granted the tens of thousands of industrial chemicals already in commerce a strong "presumption of innocence." In the absence of clear evidence of harm, companies have largely been free to produce and use such chemicals as they've seen fit. This policy contrasts sharply with the "presumed guilty until proven innocent" approach adopted for pharmaceuticals and pesticides. For these substances, producers have the burden of providing to the government information demonstrating their safety, at least when used as intended.

Yet for industrial chemicals, the opposite is true: Government—and, hence, the public—shoulders the burden of proof. In what amounts to a classic Catch-22, *government must already have information sufficient to document potential risk, or at the very least, extensive exposure, in order to require the development of information sufficient to determine whether there is actual risk.* This burden is so high that in the 32 years since the Toxic Substances Control Act (TSCA)<sup>1</sup> was enacted, the U.S. Environmental Protection Agency (EPA) has required testing for only about 200 chemicals.<sup>2</sup>

Current policy essentially says: "We'll consider developing a better understanding only of those chemicals that we already have good reason to believe pose a risk." This is rather like the old adage about looking for lost car keys at night only under the streetlight because the light is better there. So when it comes to choosing among several available options to provide a desired chemical function, or to replacing a problematic chemical, we are often in the dark and run the risk of simply "replacing the devil we know with the devil we don't." Society remains largely ignorant about the risks of the great majority of chemicals because we only investigate those about which we already know something. That means we fail to learn not only which chemicals pose risks, but also which chemicals pose little or no risk. Adopting a more comprehensive approach that seeks to develop good information on most or all chemicals would allow us to select safer chemicals with confidence.

TSCA places an even higher—some would say impossibly high—burden on EPA before it can act to control a chemical. Government must effectively prove beyond all reasonable doubt that a chemical poses a risk in order to take any regulatory action to restrict its production or use. Since adoption of

1. 15 U.S.C. §§2601-2692, ELR STAT. TSCA §§2-412.

2. Since 1979, EPA has used its test rule authority under TSCA §4, 15 U.S.C. §2603, to require testing of about 200 chemicals. For about 60 of these chemicals, the data were obtained through §4 Enforceable Consent Agreements (ECAs), which EPA uses as an alternative to test rules in cases where there is agreement with industry on the need and scope of testing. OFFICE OF POLLUTION PREVENTION & TOXICS (OPPT), U.S. EPA, OVERVIEW: OFFICE OF POLLUTION PREVENTION AND TOXICS PROGRAMS 4, 15 (2007), available at <http://www.epa.gov/oppt/pubs/oppt101c2.pdf> [hereinafter OPPT OVERVIEW, 2007].

TSCA in 1976, EPA has succeeded in mandating restrictions on the production or use of only five substances.<sup>3</sup>

By allowing action only once there is clear evidence of harm, current policy does not reward, and may well provide a sizeable disincentive against, the gathering of better information about chemicals. A company is likely to view undertaking this activity as only increasing the likelihood that evidence of harm will be uncovered. And where the default in the face of any uncertainty is no action, industry has an incentive to seek to perpetuate rather than resolve the uncertainty.

As recognition of these problems has increased, calls for reforming TSCA have become more urgent. This Article lays out 10 essential elements in any such reform.

## I. Establish a Policy and Develop and Apply Criteria to Identify and Act to Control All Chemicals of Concern

Outside the vague and undefined concept of “unreasonable risk,” TSCA provides no basis on which to identify what attributes of chemicals should trigger action. Establishing such a policy framework is critical to direct and drive further needed efforts: developing information about chemicals focused on those attributes; efficiently prioritizing and assessing chemicals against the relevant criteria; and undertaking appropriate actions to reduce production, use, and release of chemicals of concern and to replace them with alternatives known to be of lesser or no concern.

Attributes and their associated criteria can be hazard-based or exposure-based. Such criteria-driven policies have become core elements and drivers in other countries’ recent reforms of chemicals policies. For example, the Canadian Environmental Protection Act (CEPA), as amended in 1999, required health and environmental agencies to use available information to categorize each of the roughly 23,000 previously unassessed chemicals on its domestic substances list to identify chemicals that are persistent, bioaccumulative, inherently toxic to humans or nonhuman organisms, or of greatest potential for exposure to humans.<sup>4</sup>

REACH (Registration, Evaluation, Authorisation, and Restriction of Chemicals),<sup>5</sup> the European Union’s recently adopted chemicals regulation, is also attribute- and criteria-driven. It uses hazard-based criteria, surrogates for exposure and use attributes, to drive the processes it puts in motion of

registering, evaluating, and authorizing use of an estimated 30,000 chemicals.<sup>7</sup>

In the United States, some states have adopted policies that focus on particular chemical classes or uses to identify and drive action on chemicals of concern. Maine, for example, has prioritized the elimination of mercury-containing products.<sup>8</sup> In Washington, priority has been placed on identifying and restricting use of PBT chemicals, focusing initially on mercury and brominated flame retardants.<sup>9</sup> More recently, both states as well as California have passed broader bills that establish policies and set in motion processes to identify and act to control chemicals of concern.<sup>10</sup>

*Recommendation:* TSCA should rest on clear policy objectives and criteria for identifying and acting to control chemicals of concern. These criteria should be used to determine information requirements, prioritize chemicals for assessment, and decide whether and what risk management is needed.

The policy should allow chemicals of concern to be identified based on their hazard or exposure characteristics, not just on risk; hence, hazard- and exposure-specific, as well as risk-based, criteria should be articulated. EPA should be authorized and required to assess and impose risk management measures on chemicals that meet such criteria.

## II. Separate Scientific Decisions as to Whether a Chemical Is of Significant Concern From Policy Decisions as to How Best to Address Such Concerns

TSCA’s only articulation of a safety standard, that of “unreasonable risk,” demands that EPA answer much more than the scientific question of whether a chemical may or will harm people or the environment. It must also consider the economic and social costs of imposing controls on the chemical, including the benefits of the chemical, the availability of alternatives, and the impact of regulation on the economy, small businesses, and innovation.<sup>11</sup> EPA must also demonstrate that any proposed control is the least burdensome it could have

7. See *id.* art. 57.

8. See Maine Department of Environmental Protection, *Mercury Products*, <http://www.maine.gov/dep/mercury/products.htm>.

9. See Washington Department of Ecology, *PBT Initiative*, <http://www.ecy.wa.gov/programs/wfa/pbt/>.

10. In 2008, Maine adopted the Act to Protect Children’s Health and the Environment from Toxic Chemicals in Toys and Children’s Products, which calls for the state eventually to identify 100 chemicals of high priority and for producers or manufacturers of such chemicals to register their use with the state. See [janus.state.me.us/legis/LawMakerWeb/externalsiteframe.asp?ID=280027552&LD=2048&Type=1&SessionID=7](http://janus.state.me.us/legis/LawMakerWeb/externalsiteframe.asp?ID=280027552&LD=2048&Type=1&SessionID=7). Also in 2008, Washington passed the Children’s Safe Products Act of 2008, which calls for the virtual elimination of phthalates, lead, and cadmium in children’s products and requires the state to develop an inventory of potentially harmful chemicals. See [apps.leg.wa.gov/documents/bills/docs/2007/08/Pdf/Amerndments/Senate/2647-S2-E%20MS%20NCR%20-S5756-E.pdf](http://apps.leg.wa.gov/documents/bills/docs/2007/08/Pdf/Amerndments/Senate/2647-S2-E%20MS%20NCR%20-S5756-E.pdf). In September 2008, California passed AB 1879, which calls for the development of regulations to establish processes to identify, prioritize, and evaluate chemicals of concern and their potential alternatives. See [http://www.leginfo.ca.gov/pub/07-08/bills/asmn/ab\\_1851-1900/ab\\_1879\\_bill\\_20080929\\_chaptered.html](http://www.leginfo.ca.gov/pub/07-08/bills/asmn/ab_1851-1900/ab_1879_bill_20080929_chaptered.html).

11. 15 U.S.C. §2605(c)(1).

3. The five substances are: polychlorinated biphenyls (PCBs), by virtue of a mandate from Congress; fully halogenated chlorofluorocarbons used as aerosol propellants; dioxin in certain wastes; asbestos (limited to products no longer in commerce); and hexavalent chromium used in water treatment chemicals in comfort cooling towers. See U.S. GOVERNMENT ACCOUNTABILITY OFFICE, CHEMICAL REGULATION—OPTIONS EXIST TO IMPROVE EPA’S ABILITY TO ASSESS HEALTH RISKS AND MANAGE ITS CHEMICALS REVIEW PROGRAM 58 (2005) (GAO-05-458), available at <http://www.gao.gov/new.items/d05458.pdf> [hereinafter GAO, 2005].

4. 15 U.S.C. §§2601(b)(2) & 2604(a).

5. See Canadian Environmental Protection Act, 1999, R.S.C. ch. 33, §73 (1999) (Can.), available at [http://www.ec.gc.ca/CEPARRegistry/the\\_act/Contents.cfm](http://www.ec.gc.ca/CEPARRegistry/the_act/Contents.cfm) [hereinafter CEPA].

6. Regulation (EC) 1907/2006, 30.12.2006 J.O. (396) I, available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:396:0001:0849:EN:PDF> [hereinafter REACH].

proposed.<sup>12</sup> Finally, it must demonstrate that no other statute could address the concern.<sup>13</sup>

The result is a blurring together of what should be two distinct questions: Does a chemical pose a significant risk? If so, what should be done about it? In effect, TSCA precludes EPA from identifying a chemical that poses a significant risk unless it can also demonstrate that the risk could be or is *unreasonable*. While both questions are appropriate for government to answer, precluding government from providing a clear answer to the first question effectively denies both the public (citizens and consumers) and private entities their right to act on their own to reduce risks even in the absence of government action.

This policy again stands in contrast to those of Canada and the EU. Under CEPA, the determination of whether a chemical is “CEPA-toxic” and requires some type of regulatory or other risk management action is separate from the determination of how risk should be managed.<sup>14</sup> The former decision does not entail consideration of economic and social factors, the benefits of the chemical, or the availability of alternatives, although these types of factors do influence the subsequent decision about what risk management measures to impose.

Similarly, under REACH, the activity of identifying “substances of very high concern” based on application of objective criteria is wholly separate from both industry’s and government’s subsequent decisions relating to managing and regulating such chemicals. Economic and social factors, the costs and benefits of the chemical, and the availability alternatives are all considered in determining whether to “grant such substances use-specific authorizations”<sup>15</sup> (although the burden of analyzing these factors as well as the burden of proof rest with the industry applicant for authorization rather than with government).

**Recommendation:** The determination as to whether an existing chemical is of sufficient concern to require the imposition of controls should be based *solely* on its hazard, exposure, or risk characteristics. Socioeconomic factors may play a role in determining what measures should be mandated, but they should not influence the decision about whether a chemical warrants control.

### III. Eliminate the All-or-Nothing Approach to Regulation Under TSCA

The range of regulatory measures that EPA can impose on a chemical under TSCA §6 is very broad. On one end of the spectrum, EPA can merely require recordkeeping or monitoring, or communication or labeling of potential risks. On the other end, it can ban all production and use of a chemical. Yet to exercise any of these authorities, EPA must meet the same standard of proof: It must demonstrate that the chemical “presents or will present an unreasonable risk.” If EPA can-

not meet its burden, it cannot impose even the most innocuous of measures, even those such as monitoring for releases or exposures that could help to clarify both the certainty and magnitude of risk.

In contrast, CEPA §64 allows designation of a chemical as CEPA-toxic—and hence eligible for regulation<sup>16</sup>—based on a showing of *potential* harm. This showing can be based on evidence of significant hazard or exposure, not necessarily both, and applies to substances that enter or *may* enter the environment.<sup>17</sup> A substance may be “suspected” of being toxic if either its hazards or exposure potential are of concern.<sup>18</sup>

REACH is underpinned by the precautionary principle, which the European Commission indicates applies “where scientific evidence is insufficient, inconclusive or uncertain and there are indications through preliminary objective scientific evaluation that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the chosen level of protection.”<sup>19</sup>

While the principle’s implied allowance for government to act even in the face of scientific uncertainty is typically highlighted (and often criticized by U.S. government and industry representatives), another of its core elements is far less frequently acknowledged or understood: its reliance on the so-called proportionality principle.<sup>20</sup> Measures taken to address potential or uncertain risk are to be in proportion to the appropriate level of protection to be achieved and should reflect the associated uncertainty and magnitude, e.g., severity, reversibility, etc., of the potential harm.

**Recommendation:** Reforms to TSCA should provide a calibrated approach that would provide for application of specific risk management measures in proportion to the strength of evidence of risk as well as the magnitude of risk. Further, EPA should be allowed to initiate action in response to less than absolute evidence of harm. And the Agency should be able to impose controls that address potential harm as well as uncertain, but potentially significant, harm.

### IV. Shift the Burden of Proof From Government to Demonstrate Harm to Industry to Demonstrate Safety

Under TSCA, the government must demonstrate that a chemical is or could be harmful before any action can be taken. Those who produce and use chemicals bear no burden of

12. *Id.* §2605(a).

13. *Id.* §§2605(c) & 2608.

14. See U.S. GENERAL ACCOUNTING OFFICE, TOXIC SUBSTANCES CONTROL ACT—LEGISLATIVE CHANGES COULD MAKE THE ACT MORE EFFECTIVE 26 (1994) (GAO/RCE-94-103), available at <http://archive.gao.gov/h2pbat2/152799.pdf>.

15. See REACH, *supra* note 6, tit. VII.

16. Once a substance is found to be CEPA toxic and placed on the List of Toxic Substances, the government has two years to develop and propose a management strategy and an additional 18 months to finalize the strategy. See *A Guide to Understanding the Canadian Environmental Protection Act, 1999* 11-13 (Dec. 10, 2004), available at [http://www.ec.gc.ca/CEPARegistry/the\\_act/guide04/toc.cfm](http://www.ec.gc.ca/CEPARegistry/the_act/guide04/toc.cfm).

17. CEPA, *supra* note 5, §64.

18. GUIDELINES FOR THE NOTIFICATION AND TESTING OF NEW SUBSTANCES: CHEMICALS AND POLYMERS 97-98 (Environment Canada & Health Canada 2005), available at <http://www.ec.gc.ca/substances/nrtb/pdf/guidenot68.pdf>.

19. See COMMISSION OF THE EUROPEAN COMMUNITIES, COMMUNICATION FROM THE COMMISSION ON THE PRECAUTIONARY PRINCIPLE 8 (2000), available at [http://ec.europa.eu/dgs/health\\_consumer/library/pub/pub07\\_en.pdf](http://ec.europa.eu/dgs/health_consumer/library/pub/pub07_en.pdf).

20. See *id.* at 18.

demonstrating, or even being routinely required to provide the information necessary to determine whether, their chemicals are safe.

This policy stands in marked contrast to those affecting other classes of chemicals, most notably pharmaceuticals and pesticides, which are regulated under other statutes. Producers must generate extensive data demonstrating the safety of these chemicals, and government review and approval are required as conditions for their entering or remaining on the market. For example, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), pesticides are subject to extensive testing and government approval processes before they can be registered<sup>21</sup>:

EPA must first ensure that the pesticide, when used according to label directions, can be used with a reasonable certainty of no harm to human health and without posing unreasonable risks to the environment. To make such determinations, EPA requires more than 100 different scientific studies and tests from applicants.<sup>22</sup>

FIFRA also requires pesticides already in use to be reregistered and reassessed for safety.<sup>23</sup>

It may have been reasonable not to expect most industrial chemicals to pose health or environmental risk based on the science available at the time TSCA was enacted, given that many or most of them were not intentionally designed to be biologically active. But recent advances have deepened our understanding of the myriad ways by which chemicals can enter and accumulate in the environment, lead to exposure of people or other organisms, and exert adverse effects.

Chemicals widely used in consumer products—including phthalates used as plasticizers, polybrominated diphenyl ethers (PBDEs) used as flame retardants, and several families of perfluorinated chemicals used in coatings for textiles, cookware, and food packaging—were thought to be safely embedded in polymers or other matrices and, hence, to pose no risk of exposure. Yet they are present in the bodies of virtually all people on earth.

**Recommendation:** Chemical manufacturers should be required to demonstrate the safety of their products as a condition for entering or remaining on the market, using a standard that establishes a reasonable certainty of no harm. Where government bears the burden of demonstrating harm in order to act, the default in the face of inadequate data or high uncertainty is to implicitly assume safety and take no action. Shifting the burden of proof to industry would help create incentives to expedite information development and assessment and to reach closure and agreement, rather than perpetuate uncertainty.

Manufacturers should also be responsible for developing information sufficient to demonstrate safety. They are best able to maximize the efficiency of producing the information and to allocate those costs to all users of the chemicals. They

are also best able to internalize such costs and information and use them to minimize risk from their products.

EPA should be required to determine whether manufacturers have met their burden of proof of safety.

## V. Require Comprehensive Hazard Information as a Condition for Existing Chemicals to Remain On, and for New Chemicals to Enter, the Market

TSCA's Preamble states:

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.<sup>24</sup>

This statement applies to all chemicals and places the burden of data generation squarely on chemical producers and processors. Yet the reality under TSCA has been far different.

For the great majority of chemicals already in commerce, few data are available to the public or to EPA to characterize their hazards. EPA's authority to require testing of chemicals is highly constrained. First, it must have enough information about a chemical to demonstrate that it "may present an unreasonable risk" or that it is produced in large quantities a results in significant environmental releases or human exposures. EPA must also demonstrate that insufficient information exists to determine the effects of the chemical on health or the environment, and that testing is necessary to develop such information.<sup>25</sup> Finally, EPA must, on a case-by-case basis, promulgate a regulation, which typically takes many years and substantial agency resources.<sup>26</sup> In contrast, Canadian officials need only promulgate a Ministerial notice to require testing,<sup>27</sup> while REACH mandates that a minimum data set be developed for all chemicals produced annually above one metric ton per producer (applicable immediately for new chemicals and phased in over time for chemicals already in commerce).<sup>28</sup>

Large data gaps and limited regulatory authority to fill them have led EPA to rely on voluntary efforts to obtain more information on existing chemicals. The most notable of them is the U.S. High Production Volume (HPV) Chemicals Challenge<sup>29</sup> under which producers of HPV chemicals were asked voluntarily to develop and make public a "base set" of screening-level hazard information on their chemicals.<sup>30</sup> Because it

24. 15 U.S.C. §2601(b)(1).

25. 15 U.S.C. §2603(a)(1)(A)(ii) and (iii). ELR STAT. TSCA, §4(a)(1)(A)(ii) and (iii).

26. A TSCA §4 rule can take between 2-10 years to promulgate and requires significant resources. GAO, 2005, *supra* note 3, at 26.

27. See CEPA, *supra* note 5, §71(e).

28. REACH, *supra* note 6, art. 23.

29. See U.S. EPA, *High Production Volume Challenge*, at <http://www.epa.gov/chemrisk/index.htm>.

30. The base set is based on the Screening Information Data Set developed by the Chemicals Committee of the Organization for Economic Cooperation and Development. For a list of the data elements, see U.S. EPA, *Determining the Adequacy of Existing Data*, app. A, <http://www.epa.gov/chemrisk/pubs/general/data/final.htm>.

21. 7 U.S.C. §§136-136y, ELR STAT. FIFRA §§2-34.

22. See Office of Pesticides, U.S. EPA, *Regulating Pesticides*, <http://www.epa.gov/pesticides/regulating/index.htm#eval>.

23. See Office of Pesticides, U.S. EPA, *Pesticide Reregistration Facts*, [http://www.epa.gov/oppssdrl/reregistration/reregistration\\_facts.htm](http://www.epa.gov/oppssdrl/reregistration/reregistration_facts.htm).

is voluntary, it sidesteps the “unreasonable risk” and other findings EPA must make to compel data development and submission. However, for the same reason, EPA has had limited recourse to ensure full participation by manufacturers or the timely submission of complete and high-quality hazard data sets for HPV chemicals, and the program has fallen well short of its goals.<sup>31</sup>

For new chemicals, TSCA provides EPA with premanufacturing review authority. Two major constraints apply, however. First, TSCA precludes EPA from requiring upfront development and submission of a minimum set of data on a chemical's hazards.<sup>32</sup> As a result, the majority of new chemical notifications EPA receives actually contain no hazard data.<sup>33</sup> Second, TSCA grants EPA typically only one bite at the apple—a one-time, 90-day review opportunity. Once that review is completed and manufacture commences, the chemical is placed on the TSCA Inventory, becomes an “existing” chemical, and any company can manufacture and use it without even having to notify EPA it is doing so. Any conditions EPA imposes apply only to the original notifier, unless EPA also promulgates a significant new use rule (SNUR) specific to that chemical.<sup>34</sup>

These limitations—little if any hazard data and one-time review at the premanufacturing stage, well before the full picture of the actual production, use and exposure, and lifecycle impacts of a chemical has emerged—are in contrast to prac-

tices in Canada and the EU. Both of those systems employ multi-tiered notification and assessment systems, and both mandate submission of minimum data sets, the scope of which increases as production and use expand.<sup>35</sup>

**Recommendation:** Reform of TSCA needs to provide EPA with broad authority, without having to demonstrate potential or actual risk, to require industry to generate and submit any data or other information necessary to gain a thorough understanding of the potential risks of any chemical of interest or concern. Submission of minimum data sets should be required of all chemicals, both new and existing.

Companies should be required to notify EPA whenever significant changes occur in a chemical's production volume or use pattern. Government should be authorized and required to request any additional information needed for a re-review of such chemicals to assess the effects of such changes.

For new chemicals, a tiered scheme should be used, with increasing information required as production increases and the extent or diversity of uses expands. While there is merit in retaining the first notification at the premanufacturing stage, even in the absence of a significant data requirement, such an approach needs to be coupled with subsequent notifications accompanied by sufficient data.

## VI. Require Robust Data on Chemical Uses and Exposures

For industrial chemicals already in commerce, EPA requires reporting of only limited information on how chemicals are used and the extent to which environmental releases or exposures to workers, consumers, or the environment may occur, and it does so infrequently. TSCA requires such reporting only from chemical manufacturers (and in some cases, processors), but not from the companies that use the chemicals, whether directly or as ingredients in products.

Because of recent amendments, EPA's Inventory Update Rule (IUR) now requires limited reporting on use and exposure.<sup>36</sup> Beginning in the 2006 reporting cycle, all manufacturers of non-exempt<sup>37</sup> chemicals in amounts of 25,000 pounds or more per year per site must report “known or reasonably ascertainable” information pertaining to:

- the number of workers reasonably likely to be exposed to the chemical substance at the site;
- physical form(s) of the chemical substance as it leaves the submitter's possession, along with the associated percent of total production volume; and

<sup>31</sup>For a full description of the HPV Challenge and what it has and has not accomplished, see RICHARD A. DENISON, HIGH HOPES, LOW MARKS: A FINAL REPORT CARD ON THE HIGH PRODUCTION VOLUME CHEMICAL CHALLENGE (Environmental Defense Fund 2007), available at [http://www.eli.org/documents/6653\\_High-HopesLowMarks.pdf](http://www.eli.org/documents/6653_High-HopesLowMarks.pdf).

<sup>32</sup>Any requirement for submitting hazard data for a new chemical under TSCA §5 is limited to existing test data already “in the possession and control” of the notifier of the new chemical (§5(d)(1)(B)) and to descriptions of any other relevant information that is already known or “reasonably ascertainable” to the notifier (§5(d)(1)(C)). The lack of an upfront minimum data requirement may in part reflect the fact that notification takes place premanufacture, when it may not be realistic to expect a company to have conducted much testing. EPA's intervention at this stage has the advantage of flagging potential concerns before manufacturing has commenced and before significant financial investment has been made by the producer. It also may allow redesign of the manufacturing process or the chemical itself to eliminate or reduce any concern in advance of commercialization. However, the lack of data on a chemical's hazards and other properties, and the more speculative nature of information on its potential uses, releases, and exposures can severely limit the robustness of any risk evaluation conducted at this stage. See GAO, 2005, *supra* note 3, at 10-16.

<sup>33</sup>According to EPA, 67% of PMNs contain no test data and 85% of PMNs contain no health data. OPPT OVERVIEW, 2007, *supra* note 2, at 8. More than 95% of PMNs contain no ecotoxicity data. OPPT, U.S. EPA, DRAFT Q&A FOR THE NEW CHEMICALS PROGRAM 1-55 (answer to question 11B-5) (undated), <http://www.epa.gov/opptintr/newchemicals/pubs/qanda-newchemicals.pdf>. EPA can, and, for a small fraction of new chemicals, does, require some testing or data development on a case-by-case basis where it is able to meet the statutory burdens for requiring testing. A requirement for such data may be included in a TSCA §4 Enforceable Consent Agreements (ECAs), which EPA uses as an alternative to test rules in cases where there is agreement with industry on the need and scope of testing. EPA has issued such orders for about 60 chemicals. See OPPT OVERVIEW, 2007, *supra* note 2, at 15. Alternatively, EPA may negotiate with the notifier a voluntary agreement to conduct testing, which is known as a Voluntary Testing Action. Through the end of September 2005, EPA had negotiated about 300 Voluntary Testing Actions. See OPPT OVERVIEW, 2007, *supra* note 2, at 11.

<sup>34</sup>SNURs, which EPA has issued for about 7% of new chemicals, typically extend the same conditions imposed on the original notifier to any other manufacturer and require that anyone else who begins producing or using the chemical outside of such conditions first notify EPA. See OPPT OVERVIEW, 2007, *supra* note 2, 9-11.

<sup>35</sup>See RICHARD A. DENISON, NOT THAT INNOCENT: A COMPARATIVE ANALYSIS OF CANADIAN, EUROPEAN UNION AND UNITED STATES POLICIES ON INDUSTRIAL CHEMICALS III-4 to III-6 (2007), available at <http://www.eli.org/chempolicyreport>.

<sup>36</sup>See U.S. EPA, TSCA Inventory Update Rule Amendments, 68 Fed. Reg. 847 (Jan. 7, 2003), available at <http://www.epa.gov/tcdrgstr/EPA-TOX/2003/January/Day-07/832909.htm>.

<sup>37</sup>Certain chemicals on the TSCA Inventory are fully or partially exempted from IUR reporting. See OPPT, U.S. EPA, QUESTIONS AND ANSWERS FOR REPORTING FOR THE 2006 PARTIAL UPDATING OF THE TSCA CHEMICAL INVENTORY DATABASE 7-10 (2006), available at [http://www.epa.gov/opptintr/fair/pubs/guidance\\_qanda.pdf](http://www.epa.gov/opptintr/fair/pubs/guidance_qanda.pdf) (answers to questions 30-37).

- the maximum concentration of the chemical substance as it leaves the submitter's possession.

For chemicals manufactured in amounts of 300,000 pounds or more per year per site, additional information is required, including the number of downstream processing and use sites, the number of workers reasonably likely to be exposed, and the types of commercial and consumer uses. Manufacturers, however, only need to report this additional information to the extent it is "readily obtainable." While EPA has yet to release any data from the 2006 IUR reporting cycle, early indications are that significant amounts of the requested information were not submitted because they were deemed by submitters to be "not readily obtainable."<sup>38</sup> This result is not surprising, as manufacturers frequently have only limited access to information about downstream uses.<sup>39</sup>

Reporting requirements now cover fewer than 8,000 chemicals. At most, a few thousand of these are subject to the more extensive reporting that extends to downstream processing and use information. Reporting is required only once every five years and then only for a single reporting year. Infrequent reporting yields a highly inaccurate picture of actual manufacturing levels and use patterns over time,<sup>40</sup> and this inaccuracy is likely to extend to the use and exposure information EPA is now beginning to collect.

EPA may require manufacturers and processors of specified chemicals to report basic manufacture and use information under TSCA §8(a).<sup>41</sup> But each request requires a case-by-case rulemaking and provides for only one-time reporting, although a single rule can cover multiple chemicals. EPA has standardized this type of regulation in the form of a Preliminary Assessment Information Reporting rule, a few dozen of which have been issued for about 1,200 chemicals.<sup>42</sup>

For new chemicals, Premanufacture Notifications (PMNs) must include basic information on anticipated use, production volume, exposure, and release—but only to the extent it is known or reasonably foreseeable by the submitter at the pre-manufacture stage. The only other circumstances under TSCA requiring reporting of changes in manufacture or use are the rare cases where a new chemical is subject to such a condition during PMN review or when a chemical is subject to a SNUR that includes such a requirement (called a "volume SNUR"<sup>43</sup>).

REACH offers two major innovations in this regard. First, REACH compels the bidirectional flow of information along the chain that links chemical producers, processors, distributors and users.<sup>44</sup> Suppliers typically have limited knowledge of how or by whom their chemicals are used, and users have limited knowledge of the characteristics of the substances they receive or appropriate risk management measures recommended by the producers. REACH requires suppliers to inform their customers about the hazards and risks of their chemicals and about risk management measures that need to be applied. In turn, it requires downstream users to give their suppliers sufficient information on their use(s) of a substance so the supplier can evaluate exposure and identify risk management measures that are then communicated back to the users.<sup>45</sup>

Second, while REACH has no direct counterpart to the TSCA IUR periodic reporting requirement, information is updated as new and existing chemicals move along the program's multi-tiered registration scheme. In addition, REACH requires registrants to update and resubmit "without undue delay" their registrations whenever there is any significant change in status, including any new use, as well as any new knowledge of risks.<sup>46</sup>

In addition to chemical usage, directly measuring chemicals in human (or other organisms') tissues or fluids can be a powerful means of gauging the actual extent of exposure, and has the further advantage of effectively integrating all exposure sources. Since 1999, the Centers for Disease Control's National Health and Nutrition Examination Survey<sup>47</sup> measured the levels of a limited number of chemicals and their metabolites in samples of human blood and urine every two years.<sup>48</sup> Biomonitoring to date has focused on chemicals already known to be hazardous and on chemicals that are known to bioaccumulate, which are only a subset of chemicals of potential health concern. Government has yet to conduct broader, more exploratory biomonitoring—aimed at identifying the full range of xenobiotics to which humans are exposed, as one means of identifying chemicals that are priorities for further scrutiny with respect to both hazard and exposure. In addition, the extent of sampling conducted to date is too limited to provide the degree of geospatial "resolution" that

38. Such cases are so common that EPA has coined an acronym for use as shorthand: "NRO." See Richard A. Denison, *Environmental Defense Fund's Comments on ChAMP: EPA's Recent Commitments and Possible New Initiatives for Existing Chemicals*, May 2, 2008, available at [http://www.edf.org/documents/7871\\_Comments\\_ChAMP\\_May08.pdf](http://www.edf.org/documents/7871_Comments_ChAMP_May08.pdf).

39. See references in note 44, *infra*.

40. See U.S. EPA, NATIONAL POLLUTION PREVENTION AND TOXICS ADVISORY COMMITTEE (NPPATAC), BROADER ISSUES WORK GROUP, INITIAL THOUGHT-STARTER: HOW CAN EPA MORE EFFICIENTLY IDENTIFY POTENTIAL RISKS AND FACILITATE RISK REDUCTION DECISIONS FOR NON-HPV EXISTING CHEMICALS? 3-4 (Draft Oct. 6, 2005), available at <http://www.epa.gov/oppt/nppat/pubs/finaldraftnonhpvpaper051006.pdf>. See also Comments on Proposed Rule, TSCA Inventory Update Reporting Revisions (Feb. 18, 2005), available at <http://www.regulations.gov/fdmspublic/ContentViewer?objectId=09000064800ac9de&disposition=attachment&contentType=pdf>.

41. See U.S. EPA, EPA AUTHORITIES UNDER TSCA 23 (2005), available at <http://www.epa.gov/oppt/nppat/pubs/tscauthorities71105.pdf>.

42. OPPT OVERVIEW, 2007, *supra* note 2, at 16.

43. U.S. EPA, *supra* note 41, at 16.

44. For more discussion of information flow in the context of improved chemicals assessment and management, see Richard A. Denison, *Improving Information Flows—In Supply Chains and Beyond*, paper presented at the North American Dialog on "Framing a Future Chemicals Policy," Boston, Mass., Apr. 2005, available at <http://www.chemicalspolicy.org/downloads/W3-InformationFlow.doc>; and Rachel Massey, *Sharing Knowledge about Chemicals: Policy Options for Facilitating Information Flow in Options for State Chemicals Policy Reform: A RESOURCE GUIDE 69-96* (Lowell Center for Sustainable Production, University of Massachusetts at Lowell 2008), available at <http://www.chemicalspolicy.org/downloads/OptionsforStateChemicalsPolicyReform.pdf>.

45. Two entire titles of REACH are devoted to these tasks: Title IV covers Information in the Supply Chain and Title V covers Downstream Users.

46. REACH, *supra* note 6, art. 22.

47. The latest survey was published in 2005 and tested samples collected in 2001 and 2002 for 148 chemicals. While many of the chemicals included are either "historical" or unintentionally produced substances, human biomonitoring of substances still in commerce has increased in the more recent survey. See CENTERS FOR DISEASE CONTROL & PREVENTION, THIRD NATIONAL REPORT ON HUMAN EXPOSURE TO ENVIRONMENTAL CHEMICALS (2005), available at <http://www.cdc.gov/exposurereport/report.htm>.



is needed to begin to elucidate exposure routes for chemicals found in human tissues.

*Recommendation:* As with hazard data, EPA should have broad authority to require industry—both chemical manufacturers and downstream users of chemicals—to generate and submit any use, release, or exposure data or other information necessary to gain a thorough understanding of the potential risks of any chemical of interest or concern. Submission of minimum sets of such data should be required of all chemicals, both new and existing.

Companies should be required to notify EPA whenever significant changes occur in a chemical's production volume or use pattern. Government should have authority and be required to request any additional information needed for a review of such chemicals to assess the effects of such changes.

In addition, biomonitoring should be required for any chemical for which there is any reason to suspect human exposure. To avoid conflicts of interest, the government should conduct biomonitoring at manufacturers' expense.

## VII. Improve Integrity and Credibility of Industry-Generated Data

Essentially all policies affecting chemicals worldwide—whether industrial chemicals or drugs, cosmetics ingredients, pesticides, or food additives—rely on data chemical manufacturers generate. It is critical, therefore, that every effort be made to ensure that industry-generated data used to formulate and support public policy are—and are seen as—credible. This need is even more pronounced when one considers the obvious financial incentives industry has in minimizing testing costs and being able to state that its products are safe.

*Recommendation:* To ensure a high degree of public trust in the government's assessment and management of chemicals, sound policy should<sup>48</sup>:

- Establish a registry of health- and safety-related studies to ensure that all study results, along with details of the method used in each study, are reported and made available to the public. This is similar to what already occurs in pharmaceuticals regulation.
- Provide government access to all records of privately sponsored research used in setting or implementing public policy. Such a requirement already exists for publicly funded research.
- Require privately funded researchers whose research is used in public policy settings to disclose the source of their funding and the extent of sponsor review or approval, as well as potential financial conflicts of interest. A growing number of scientific journals and organizations require such disclosures.

48. Many of these proposals are liberally adapted from RENA STEINZOR ET AL., *SAVING SCIENCE FROM POLITICS: NINE ESSENTIAL REFORMS OF THE LEGAL SYSTEM* (Center for Progressive Reform 2008), summary available at <http://www.progressivereform.org/scienceRescue.cfm>.

- Require independent peer review or certification of studies submitted for use in public policy contexts, along with transparency safeguards to ensure disclosure of the identity of reviewers and any potential conflicts of interest, as well as balanced representation of the scientific community among reviewers.

- Provide unfettered authority and requirements for government to conduct random inspections of laboratories used to develop data submitted by industry and audits of the data submissions.

## VIII. Broaden Public Access to Chemical Data

Independent of the extent to which government itself acts on chemical information to identify and reduce or manage risks, providing broad public access to such information can empower a host of other actors to make better decisions about the chemicals. Such actors include companies and institutions that make, purchase, or sell chemicals or chemical products, as well as citizens and end consumers.

Better access to information may also drive markets to demand more information and to migrate away from chemicals known or suspected of being risky. Indeed, a field of specialization within economics known as information economics has demonstrated that access to information is a critical need if markets are to operate properly, and, conversely, that the lack of robust information can adversely affect market economies.<sup>49</sup>

One of REACH's main strengths is the extent to which the government intends to make public a large amount of the information it receives, including the identification of substances of very high concern that are to be subject to authorization and information about potential substitutes. In contrast to TSCA, REACH includes numerous provisions calling for public access to non-confidential information—including government decisions and the basis for them—and it mandates that most such information be made available on the internet, free of charge.

*Recommendation:* Chemical policy reform should include explicit requirements that government make readily and publicly available, in a timely manner, as much information as possible about chemicals as well as documentation of government decisions and the basis for them.

49. See, e.g., Joseph E. Stiglitz, *Information and the Change in the Paradigm in Economics*, Part 1, 47 AM. ECON. 6-26 (2003); Joseph E. Stiglitz, *Information and the Change in the Paradigm in Economics*, Part 2, 48 AM. ECON. 17-49 (2004) and JOSEPH E. STIGLITZ, *GLOBALIZATION AND ITS DISCONTENTS* 73-74, 261 n.2 (W.W. Norton & Co. 2005), all cited in Joseph H. Guth et al., *Require Comprehensive Safety Data for all Chemicals*, 17 NEW SOLUTIONS: J. ENVTL. & OCCUPATIONAL HEALTH POL'Y 233-38 (2005), available at <http://www.louisvillecharter.org/paper.safetydata.shtml>.

## IX. Tighten Conditions Under Which Industry Can Claim Its Submissions as Confidential Business Information

TSCA §14 provides that “manufacturers, processors or distributors” submitting information may designate any such information as confidential and submit it separately. It further states that, with limited exceptions, information considered to be “trade secrets and commercial or financial information obtained from a person and privileged or confidential” that is reported to or otherwise obtained by EPA “shall not be disclosed” except to federal government employees or their designated contractors, or to law enforcement officials.<sup>50</sup> This prohibits EPA from disclosing any information designated by a submitter as confidential business information (CBI) not only to the general public but also to foreign governments, U.S. states, tribes, and local governments.<sup>51</sup>

Although health and safety studies and associated data are not eligible for CBI protection, chemical and company identity can be eligible.<sup>52</sup> This allowance can lead to perverse outcomes, such as that a chemical’s adverse effects on mammalian reproduction must be disclosed, but identification of which chemical causes the effect may be kept a secret.<sup>53</sup>

CBI designations are common; for example, about 95% of PMNs for new chemicals contain information, including chemical identity, designated by the submitter as CBI.<sup>54</sup> There is typically no requirement to reassert such claims even after these chemicals enter commerce.<sup>55</sup> A 1992 EPA study identified extensive problems with respect to the extent of inappropriate CBI claims.<sup>56</sup>

EPA does not always require submitters to provide a justification for such designations at the time they are made.<sup>57</sup> Nor does it require that these claims be reviewed and approved in order to be retained. In addition, such designations are generally not time-limited and, hence, do not expire unless the submitter so designates. EPA may challenge CBI designations on a case-by-case basis, but it rarely does so because of the extensive resources required.<sup>58</sup> In the absence of a successful challenge by EPA, the information must be held as confidential.

The net result of all of these provisions and practices is a system that effectively denies access by the public and even other levels of government to much more chemical information than is legitimately to be claimed CBI.

**Recommendations:** Submitters advancing CBI claims should be required to: specify precisely what information is requested to be kept confidential; make such a request at the time of submission and provide a full justification and documentation in writing; and specify and justify a time period for which the request is made.

EPA should be required to: specify acceptable and unacceptable justifications for, and documentation that must accompany, any confidentiality request; review, in a timely manner, all confidentiality requests and determine whether to accept or deny the requests; and where a request is accepted, set a time period after which disclosure may occur unless a new request is submitted and accepted.

EPA should be able to disclose submitted information which it has rejected a confidentiality request, after providing a reasonable opportunity for the submitter to rectify the request.

Health and safety information should never be eligible for CBI protection. As a rule, the identity of the associated chemical and of the submitter of the information should also be ineligible; government should explicitly state the basis for any exceptions.

Workers should have access to all available information, whether or not CBI protected, concerning chemical identity, properties, hazards and workplace exposures for any substance with which they work or to which they could be exposed during work.

Other governments, whether those of domestic states, provinces, municipalities, tribes or foreign countries, should be given access to CBI for the purpose of administration or enforcement of a law, under appropriate agreements and where the recipient takes appropriate steps to keep the information confidential.

50. 15 U.S.C. §2613 (citing 5 U.S.C. §552(b)(4) of the Administrative Procedure Act).

51. See OPPT OVERVIEW, 2007, *supra* note 2, at 21.

52. See, for example, such allowance in EPA’s PMN regulations, 40 CFR §720.85(a). Elsewhere, EPA regulations state that EPA considers chemical identity to be part of the underlying data to a health and safety study. See, e.g., 40 CFR §§716.3 and 720.3(k).

53. An example of where this frequently occurs is in EPA’s public listings of submissions received under TSCA §8(e), which requires the submission of information indicative of substantial risk. Whereas a generic name for the substance must be supplied, its specific name and other identifiers such as Chemical Abstract Service (CAS) number are often listed as “confidential”—as are the names of the submitters themselves. For a recent example, see EPA’s compilation of §8(e) submissions received in July 2003, at <http://www.epa.gov/oppt/intr/tscabel/pubs/bcmonrthyreports/200009ejul2000.htm>. Oddly, EPA’s guidance for §8(e) submissions states that “EPA considers chemical identity to be part of the underlying data to, a health and safety study,” citing 40 CFR §§716.3 and 720.3(k). EPA goes on to state: “Consequently, the confidential identity of a chemical substance will not be protected by EPA unless otherwise provided for under section 14 of TSCA and the interpreting regulations in 40 CFR part 2.” See <http://www.epa.gov/edrgsta/EPA-TOX/2003/June/Day-03/13888.htm>. Either EPA has not been able or willing to challenge such claims made in §8(e) submissions or the claims have been found to comport with TSCA §14 and the interpreting regulations in 40 CFR pt. 2.

54. CAO, 2005, *supra* note 3, at 5, 32; OPPT OVERVIEW, 2007, *supra* note 2, at 10. The fraction of submitters making CBI claims for chemical identity drops to about 65% for chemicals actually entering commerce, those chemicals for which Notices of Commencement (of manufacture) are filed.

55. An exception is that a claim to keep chemical identity—but not other information—in a PMN confidential expires once manufacture of the chemical commences, unless in filing the required Notice of Commencement the modifier again asserts that the chemical identity is CBI. In this latter case, in contrast to the case when filing a PMN, a justification for the CBI claim must be provided. See 40 CFR §720.85(b).

56. Cited in CAO, 2005, *supra* note 3, at 32-33.

57. Examples of cases where an up-front justification is explicitly required include CBI claims for chemical identity and facility identification under EPCRA TSCA Inventory Update Rule (see <http://www.epa.gov/oppt/intr/pubs/guidance/confidentiality.htm>) and for “substantial risk” information required to be submitted under TSCA §8(e) (see <http://www.epa.gov/oppt/intr/pubs/confidentialbusinessinformation.htm>).

58. CAO, 2005, *supra* note 3, at 5, 33.

## X. Allow State Governments to Undertake More Protective Actions

Given the very limited level of activity at the federal level in advancing policy reforms to better identify and address chemicals of concern, many states have stepped in to fill the void.<sup>59</sup> States have a critical role to play in chemicals policy development and implementation, not only in affecting practice within their borders, but also in innovating new policy approaches and driving national policy forward.

A chemical's use pattern and human or environmental exposure to it is often specific to a geographic region and may change over time. For this reason, such information may be more appropriately developed at the state level. It is reasonable for states to take steps to understand the flow of chemicals within and across their boundaries. States can and do differ with respect to their policy priorities, both from each other and from national priorities. These priorities may be of cultural or historic origins, signify economic conditions, or reflect geospatial distinctions, such as the extent of reliance on groundwater, features of the natural landscape, or the presence of subpopulations dependent on subsistence lifestyles. Given these distinctions, it makes sense that states will pursue approaches that may differ from and in some cases go beyond those of the federal government or other states.

*Recommendation:* While some measures needed to establish effective chemicals policies are best undertaken at the federal level, maintaining a vibrant level of state activity is important both in its own right and in driving the evolution of federal policy. Federal policy reform should establish floors, not ceilings, for state government action and should only preclude state actions that are less protective of health or the environment.

## XI. Conclusion

Implementation of the elements identified in this Article can facilitate a shift toward *knowledge-driven* policies that motivate and reward, rather than impede and penalize, the development of information sufficient to provide a reasonable assurance of safety for chemicals. Such policies would also place more of the burden of providing and acting on that information on those who stand to profit financially from the production and use of chemicals, as they are arguably in the best position to internalize such information and use it to design out risk from their products from the outset.

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59. See Massey, *supra* note 44.

Mr. RUSH. Thank you very much.  
 Ms. Gerwig, please, 5 minutes.

#### TESTIMONY OF KATHY GERWIG

Ms. GERWIG. Mr. Chairman and distinguished members of the subcommittee, thank you very much for inviting me to testify today. I am Kathy Gerwig. I am vice president and environmental stewardship officer for Kaiser Permanente. That is the Nation's largest integrated healthcare delivery system. We provide comprehensive health services to 8.7 million people in nine States and the District of Columbia.

At Kaiser Permanente, we recognize that a healthy environment is critical to the health and wellness of every person. We are dedicated to environmental sustainability as we believe it has direct positive effects on individual and community health. We lead and support innovative efforts to decrease pollutants and enhance the environment. This year we will spend about \$13 billion on purchased products and services. We lease or own more than 65 million square feet of real estate. We have a 10-year capital plan of more than \$30 billion.

Despite this leverage, we have experienced limitations in achieving our goal of using products and materials that are environmentally sustainable. We have developed our own chemicals disclosure document that is required for all of our large purchasing contracts. This disclosure asks suppliers for information on the categories of persistent bioaccumulative toxic compounds, carcinogens, mutagens, reproductive toxins and specific chemicals of concern such as mercury, polyvinyl chloride, phthalates, Bisphenol A and halogenated flame retardants. When the information is provided by suppliers, there are many times that it is not meaningful due to the vendor's lack of knowledge, trade secret caveats or the absence of safety information for thousands of chemicals in commerce today.

We are also challenged by suppliers' claims that a product is green when it doesn't meet our environmental criteria. For example, a product that saves energy, which is good, might be made of vinyl, which creates dioxin pollution. Starting in 1997, Kaiser Permanente spent 10 years virtually eliminating mercury, a neurotoxin, from our operations. We now use digital thermometers and blood pressure devices. The mercury in esophageal dilators was replaced with tungsten by that industry. Now there is emerging evidence that tungsten is related to leukemia in towns near tungsten mining operations. This is an example of a large effort across the healthcare sector to replace a known hazardous material which may be resulting in the unintentional use of potentially hazardous material.

Another example includes the replacement of products containing di(2-ethylhexyl) phthalate, or DEHP, which is used as a plasticizer in flexible medical devices such as intravenous tubing and bags. DEHP can leach from the plastic, posing health risks. Our project began in 2001 when evidence was available to show that DEHP is a potential reproductive toxicant to neonatal males. We identified alternatives, conducted clinical trials before we were able to begin using products free of DEHP.

For more than 10 years, Kaiser Permanente has been working to reduce our use of vinyl products because vinyl creates dioxin pollution when it is manufactured or incinerated. In 2004 we were instrumental in driving the creation of a vinyl-free carpet suitable for healthcare settings. It was a multi-year effort that took considerable time and resources on our part. We now contract exclusively with a vendor that created that product and we have installed approximately 10 million square feet of this carpet in our facilities.

When we were testing alternatives to hard surface flooring made from vinyl, we had to actually invent our own testing protocol and use in-house certified industrial hygienists to perform tests to understand the health impacts of the alternatives. As we strive to use products that are not harmful, we invest significant time and resources. That degree of investment is simply not feasible for most products and materials we buy nor is it possible for smaller organizations that don't have the resources and skills that Kaiser Permanente has developed over the decades. Mechanisms are needed to support downstream users such as us in procuring safer products and materials for our needs.

Mr. Chairman and members of the committee, thank you for this opportunity and I look forward to answering any questions.

[The prepared statement of Ms. Gerwig follows:]



## KAISER PERMANENTE

**Testimony of Kathy Gerwig, Kaiser Permanente**

**House Committee on Energy and Commerce  
Subcommittee on Commerce, Trade, and Consumer Protection**

**Hearing on  
Revisiting the Toxic Substances Control Act of 1976**

**February 26, 2009**

I would very much like to thank the Chairman, Ranking Member and Members of the Subcommittee for inviting me to testify before you today. My name is Kathy Gerwig. I am Vice President for Workplace Safety and Environmental Stewardship Officer for Kaiser Permanente, which is comprised of the Kaiser Foundation Health Plan, Kaiser Foundation Hospitals and the Permanente Medical Groups. I am testifying today on behalf of the national Kaiser Permanente Medical Care Program. We are the nation's largest integrated health care delivery system, providing comprehensive health care services to more than 8.7 million members in nine states (California, Colorado, Georgia, Hawaii, Maryland, Ohio, Oregon, Virginia, Washington) and the District of Columbia.

Kaiser Permanente's environmental roots can be traced to the beginning of the modern environmental movement. In 1963, the author and environmental crusader Rachel Carson was invited to speak to Kaiser Permanente doctors in one of her last speeches. Carson warned us about the dangers of certain chemicals to human health and to the environment. We were concerned about the environment then, and we're concerned now. Forty-five years later, we are working to curb our overall impact on the environment by using safe chemicals, building greener hospitals, reducing waste and looking at new ways to use less energy. We are a non-profit organization, with the clearly-stated mission to improve the health of the communities we serve. Our commitment to the issues the Subcommittee is exploring today is an important and integral part of this overall mission.

### KP Values

#### *Linking the environment to the health of our communities:*

At Kaiser Permanente, we recognize that healthy communities and a healthy environment are critical to the health and wellness of every person. We are dedicated to environmental sustainability and social equity, as we believe these have direct, positive effects on individual and community health. We invest in and promote "green" solutions. To encourage healthy environments, we lead or support innovative efforts to decrease pollutants and enhance the environment.

#### *Preventive medicine:*

KP is committed to preventive medicine both through our physicians' and clinical staff's emphasis on these kinds of services as well as plan coverage including annual physicals and health screenings. This commitment extends to the work we do to ensure that our business practices are in alignment with public health and sound environmental policies. Purchasing materials that do not contain persistent, bioaccumulative toxins as well as those that are not known to be carcinogenic, mutagenic or reproductive toxins is a key part of this challenge.

*Community health:*

We are dedicated to improving the health of people living and working in the communities we serve. In 2007, Kaiser Permanente invested more than \$1 billion to ensure access to health care and promote healthier lives. To accomplish our goals, we pay for medical coverage for the uninsured, fund local community health centers and train doctors and nurses.

*Proceed with caution:*

We've taken a cautious approach to materials, meaning that where there is credible evidence that a material we're using may result in environmental or public health harm, we should strive to replace it with safer alternatives. For example, there is enough evidence about the hazards of vinyl that the responsible course of action for Kaiser Permanente is to replace it with healthier, commercially available alternatives that meet our performance criteria.

Kaiser Permanente's Internal Guideline Regarding Chemicals:

To advance an economy where the production and use of chemicals are not harmful for humans as well as for our global environment and all of its inhabitants, Kaiser Permanente has adopted the following five guiding principles for chemicals:

1. Understand product chemistry. To increase the transparency of the chemical constituents in products we buy, we request product chemistry data from suppliers.
2. Assess and avoid hazards. We have and will continue to encourage suppliers to use chemicals with inherently low hazard potential, eliminate chemicals of high concern, minimize exposure when hazards cannot be prevented and redesign products and processes to avoid the use and/or generation of hazardous chemicals.
3. Commit to continuous improvement. We have created a framework for the review of product and process chemistry, and are promoting the use of chemicals, processes and products with inherently lower hazard potential.
4. Support industry standards that, in Kaiser Permanente's opinion, eliminate or reduce known hazards and promote a greener economy, including support for green chemistry research and education.
5. Inform public policies and be part of the public dialogue that advances the implementation of the above principles.

Our Experiences and Challenges:

Our annual spending for purchased products is approximately \$13 billion. Kaiser Permanente leases or owns more than 65 million square feet of real estate, and has a ten year capital plan of more than \$30 billion. Despite this leverage, we have experienced limitations in achieving our goal of using products and materials that are environmentally sustainable.

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

At Kaiser Permanente, we have developed our own chemicals disclosure document that is required for all large national purchasing contracts. The disclosure asks for information on the categories of: persistent bioaccumulative toxic compounds and carcinogens, mutagens and reproductive toxins in addition to specific existing and emerging chemicals of concern such as mercury, polyvinyl chloride, phthalates, Bisphenol-A and halogenated flame retardants.

Many of the ingredients on the disclosure document are not present on the Occupational Safety and Health Administration's (OSHA's) required Material Safety Data Sheets due to trade secret caveats and the exemption of small concentrations from reporting even though the chemicals may cause harm in low doses. In many cases, even with the purchasing power represented by Kaiser Permanente it is difficult to get the information we request. The process requires comprehensive vendor education and aggressive demands for safety and ingredient information. When the information is provided, it is often useless due to the vendor's lack of knowledge, trade secret caveats or the absence of safety information for thousands of chemicals in commerce today.

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

Another experience includes the replacement of products containing di(2-ethylhexyl) phthalate (DEHP), a substance often used as a plasticizer in flexible medical devices made of polyvinyl chloride (PVC) such as intravenous tubing and bags. DEHP can leach from the plastic, posing health risks. The project began in 2001 when evidence was available to show that DEHP is a potential reproductive toxicant to neonatal males. It included thorough investigations into products already in use in Kaiser Permanente's neonatal intensive care units (NICUs) and field evaluations of identified non-DEHP products. After comprehensive efficacy trials at two NICUs, a labor intensive materials management contracting process and implementation project ensured the approved alternatives were in place in all of our NICUs.

Starting in 1997, Kaiser Permanente spent ten years virtually eliminating mercury, a neurotoxin, from its operations. We purged almost 1,400 pounds of mercury from our facilities. This included creating a market demand for non-mercury blood pressure devices and esophageal dilators that meet our performance needs. The mercury in esophageal dilators was replaced with tungsten by that industry. Now there is emerging science that tungsten is related to leukemia in towns near tungsten mining operations. This is an example of large efforts to replace a known hazardous material resulting in the possible use of an unknown potentially hazardous material.

In 2004, Kaiser Permanente was instrumental in driving the creation of a vinyl-free carpet that is completely recyclable and made from post-consumer recycled content that meets demanding health care performance specifications. We now contract exclusively with the vendor that created the product, and we have installed approximately 10 million square feet of this carpet in our facilities. The creation of a greener carpet is one of several ways in which KP's green focus and buying power have helped foster a greener health care economy.

As we strive to advance an economy where the production and use of chemicals are not harmful for humans or the environment around us, we invest significant time and resources. When we were testing alternatives to vinyl flooring, we had to invent our own testing protocol and use in-house certified industrial hygienists to perform tests to understand the health impacts of the alternatives. That degree of investment is simply not feasible for most products and materials we buy, nor is it possible for smaller organizations that do not have the resources and organizational skills that Kaiser Permanente has developed over decades. Mechanisms are needed to support downstream users in procuring the safest products and materials for our needs.

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



Ms. SUTTON [presiding]. Thank you, Ms. Gerwig.  
Mr. Dooley.

#### TESTIMONY OF CAL DOOLEY

Mr. DOOLEY. Thank you, members of the subcommittee. My name is Cal Dooley and I am president and CEO of the American Chemistry Council, and our council represents about 140 member companies that produce almost 85 percent of the chemicals manufactured in this country.

I would just ask you to briefly consider the role that chemicals played in your lives today. Chemical products are fundamental to the clothes you wear, the way you got to work this morning, the electronic products that you communicate with, the chair you are sitting on, the protective finish on the dais and the desk. Chemicals are the medicines that help save lives, the safety equipment that protect our children and our military forces, and the insulation in the lightweight vehicles that reduce greenhouse gas emissions and save energy.

ACC and its members share your goal of protecting human health and the environment from risks associated with some chemicals. In the vast majority of cases, however, chemicals can be and are used safely. While ACC believes that TSCA has been protective of health and the environment, there are good reasons why Congress should consider modernizing the statute.

First, it is clear that the public for a variety of reasons does not have confidence that the regulatory system is adequately ensuring the safety of the products they use. Second, science and technology of testing and detecting chemicals has advanced considerably since TSCA was enacted and we can more effectively incorporate these new capabilities into a modernized regulatory system. And third, modernizing TSCA will make the best use of emerging developments in science and technology and protect our Nation's interests in an innovative, competitive chemical industry.

My simple message to the subcommittee this morning is that ACC and its member companies are prepared to work with you in modernizing TSCA. I would like to quickly address a few of the areas where Congress should focus its attention in considering changes to TSCA. We are committed to having the appropriate hazard, use and exposure information necessary to make decisions about safe use and we think the approach should be reflected in law. In general, we think it is appropriate to have more information about those uses where there are or may be exposures to humans or the environment. Information requirements should be driven by use and exposure patterns. We support new detection methodologies like biomonitoring. We think the federal chemical management system should be robust enough to apply that data and other relevant information in a prioritization process that allows a focus on key health and safety concerns like potential exposures to children. EPA should use hazard, use and exposure information to determine the safety of priority chemicals for their intended uses.

Safety assessments conducted by EPA should not simply rely, however, on hazard as a sole determinant of the outcome. As an example, consider a single chemical that might be used in many

different applications, maybe from bullet-resistant vests and goods that are used in the retail marketplace to a chemical input in an industrial process. While the hazard characteristics are clearly the same regardless of the application, the exposure and risk considerations will vary significantly. This simple example helps illustrate the questions that a federal chemical management system must be capable of addressing. For example, what additional information is needed to ensure that the chemical can be used safely for its intended purpose? On what basis should EPA make a decision that it is safe? How should EPA weight the relative hazards and risks of the alternatives? And how can we ensure that the decisions are made in a timely manner and that they protect health and the environment and the national interests and technological innovation?

In ACC's view, a robust federal chemical management system must be capable of providing chemical manufacturers, users, the public and the government with the answers to those questions. Those are the questions that we are committed to addressing and we are also committed to working with you toward the goal of modernizing TSCA. Thank you.

[The prepared statement of Mr. Dooley follows:]

**TESTIMONY OF CAL DOOLEY  
ON BEHALF OF THE AMERICAN CHEMISTRY COUNCIL  
BEFORE THE SUBCOMMITTEE ON COMMERCE, TRADE AND  
CONSUMER PROTECTION**

February 26, 2009

Good morning Mr. Chairman and members of the Subcommittee.

My name is Cal Dooley. I am the President of the American Chemistry Council, a national trade association representing 140 member companies and 850,000 Americans employed in our industry.

ACC and its member companies welcome the Subcommittee's inquiry into revisiting the Toxic Substances Control Act (TSCA), the fundamental statutory construct for industrial chemicals.

- Although TSCA has been protective of health and the environment, and confers significant regulatory authority on the U.S. Environmental Protection Agency, there are several reasons why Congress should begin the effort to modernize TSCA.
- The public's confidence in the federal chemical management system has been challenged. ACC believes that appropriate modifications to federal law will help enhance public confidence that health and the environment are protected.
- The science of testing chemicals and understanding their health or environmental effects has evolved considerably since TSCA was enacted. The federal chemical management system should be updated to better leverage new science and technology, where there is scientific consensus on both the methods and how to interpret results. This will lead to more intelligent evaluations of chemicals and regulatory decisions about their use.
- TSCA has helped foster innovation and competition in the chemical industry. Modernizing TSCA can help assure that we protect the nation's interest in a strong American business of chemistry – and assure that we can continue to innovate, manufacture and bring to market the products that save lives, protect our children, make our economy more energy efficient, and reduce greenhouse gas emissions.

These are important considerations that should guide the Subcommittee as it considers modifications to TSCA. We think it appropriate to focus attention on a few key elements:

- TSCA does not require EPA to prioritize its activities on the chemicals that warrant regulatory scrutiny. With a process and criteria clearly established by law, a prioritization system could provide a means to more efficiently address important policy concerns such as children's health.

- The federal system should assure that manufacturers and users have appropriate hazard, use and exposure information necessary to make decisions about safe use. It does not mean that an identical set of information must be available on all chemicals. Rather, exposure considerations should drive information requirements. This approach would in general require more information about chemicals where there are exposures to humans or the environment, compared to those used solely to manufacture other chemicals or in enclosed processes.
- EPA should have the authority to determine the safety of priority chemicals for their intended uses by using hazard, use and exposure information to assure an understanding of the risks being considered. A safety assessment is a review of the likelihood of harm, based on an understanding of both hazard characteristic and exposure considerations. Chemical safety assessments and decisions that are based only on hazard characteristic(s) overlook important information and are bad public policy.
- EPA should have the authority to share appropriate confidential business information with state, local and select foreign governments when it is relevant to a decision on chemical safety and when there are appropriate safeguards against inappropriate disclosure.
- EPA should have the resources consistent with a modernized chemical management system. Current staff and funding levels at EPA are not adequate to do this work.
- The federal chemical management system should promote coordination and cooperation among scientists in the federal government, industry and academia to help interpret the data emerging from new scientific techniques and understand the consequences, if any, for health and environmental protection.
- All chemical research and testing should be held to the highest standards, regardless of who conducts it. The federal chemical management system should help establish clear principles and protocols that help assess the quality of scientific data.
- There are important elements of TSCA that should be preserved, notably EPA's broad information collection authority.
- Appropriate enhancements to the U.S. federal chemical management system should be cost and resource efficient, and should promote innovation. To be clear, ACC is NOT advocating the adoption of the European Union's REACH system. We have an opportunity to establish a chemical management system that provides greater confidence for health and environmental protection, in a more effective way.

In short, the American Chemistry Council and its members believe that modernization of the Toxic Substances Control Act can help promote and achieve key health, environmental and commercial policy objectives. We look forward to working with you as you begin this important work.

Ms. SUTTON. Thank you, Mr. Dooley.  
Mr. DeLisi.

#### TESTIMONY OF V.M. DELISI

Mr. DELISI. Good afternoon. It is a pleasure being before this distinguished subcommittee. My name is Jim DeLisi and I am president of Fanwood Chemical located in Fanwood, New Jersey. Fanwood Chemical is a member of SOCMA, the leading trade association representing the batch and custom chemical industry.

Our industry makes a \$60 billion annual contribution to the U.S. economy and contributes to the chemical industry's position as the Nation's leading exporter. SOCMA supports EPA's and Congress's fundamental goal of protecting health and the environment. SOCMA members are prepared to do our part in that effort. We are pleased to have this opportunity to share with you our perspective on revisiting the Toxic Substances Control Act. As I will explain today, SOCMA agrees with many that TSCA needs to be revisited and certain aspects of EPA's TSCA program could be improved but a sweeping overhaul like implementing Europe's REACH is unnecessary and would be unwise. Since its enactment, TSCA and its unreasonable-risk standard have generally stood the test of time as a flexible law that has protected human health and the environment without crippling innovation.

First, I would like to start by saying that any evaluation of TSCA should consider the contributions the chemical industry has made in providing the United States with one of the highest standards of living in the world, even as overall indices of public health and environmental quality have improved. Secondly, any evaluation should also take into account the vast amount of data that have been submitted by our industry to the EPA and to other agencies such as the FDA, DOT, OSHA, Consumer Products Safety Commission under other statutes that regulate our industry. Lastly, it should look at how this balance between protecting human health and the environment and preserving innovation has been achieved and how it can be maintained. SOCMA believe this balance has been and will continue to be achieved by a chemicals policy that is fundamentally guided by science in a careful assessment of risk. Data requirements have been driven by the intended and foreseeable use and disposal of a chemical. This fundamental approach should be maintained when considering a revised approach to chemical risk management.

One area of TSCA that has faced substantial criticism is the reporting requirements applicable to industry. In particular, many believe that EPA does not have sufficient authority under TSCA to request data. SOCMA disagrees with this claim but we do believe that data gathering is an area worthy of improvement and that we should reconsider what is the best approach to gathering data and information on chemicals. In order to do this, Congress should look at how EPA currently implements TSCA and consider how the program could be enhanced.

Before amending TSCA to create new obligations for EPA, Congress should also explore whether EPA can better leverage activities going on outside of the TSCA program, whether occurring under federal agencies like FDA or abroad. For example, companies

are embarking on a massive project to generate standardized test data for European REACH program. Through collaborative data-sharing efforts, EPA should be able to take advantage of the work done for that program just as other countries can leverage the work conducted here. Why should the United States want to duplicate testing that is already being conducted? A collaborative approach should be promoted by Congress.

This leads me to the Chemical Assessment and Management Program, better known as ChAMP, the voluntary program to which the United States committed in 2007 along with Canada and Mexico under the Security and Prosperity Partnership. Through this program, EPA is prioritizing chemicals by hazard and risk in order to systematically decide what further action may or may not be required. EPA is already well down the path of implementing this program. ChAMP is also addressing the TSCA inventory. EPA has initiated action to reset the TSCA inventory to more accurately identify chemicals in commerce. Many people do not realize that at any given time, significantly fewer than the roughly 80,000 chemicals currently on the inventory are likely to actually be in commerce. For example, the last inventory update reported only 6,200 chemicals in commerce during 2005. Admittedly, that does not include materials produced on a single site at less than 25,000 pounds a year. Nevertheless, this important fact is conveniently ignored by those who try to show that TSCA is inadequate, who claim that the inventory reflects the number of chemicals in commerce and then compare that number to the number of existing chemicals that have been studied by EPA under section 4.

In closing, SOCMA has pointed out several main areas of TSCA that are being enhanced and we would urge you to focus your current inquiry on how to better implement existing authorities and activities. SOCMA believe that TSCA will not require a complete overhaul but could be enhanced by new challenges. Thank you, and I look forward to taking questions.

[The prepared statement of Mr. DeLisi follows:]



Testimony  
of  
V.M. Jim DeLisi

President  
Fanwood Chemical, Inc.

*On behalf of the*

Synthetic Organic Chemical Manufacturers Association

*Before the*

U.S. House of Representatives  
Energy and Commerce Committee  
Subcommittee on Commerce, Trade, and Consumer Protection

*On*

Revisiting the Toxic Substances Control Act of 1976

**February 26, 2009**

**1850 M Street, NW • Suite 700 • Washington, DC 20036  
(202) 721- 4100 • Fax (202) 296 - 8548**

Good morning Chairman Rush, Ranking Member Radanovich, and Distinguished Members of the Subcommittee. My name is Jim DeLisi, and I am President of Fanwood Chemical, Inc., located in Fanwood, New Jersey. I have been employed by Fanwood Chemical for over 30 years, and during those years we have specialized in marketing organic chemical intermediates in North America as well as Europe and South America. Fanwood Chemical, Inc. is a member of the Synthetic Organic Chemical Manufacturers Association, or SOCMA, the leading trade association representing the batch and custom chemical industry. Our industry makes a \$60 billion annual contribution to the U.S. economy and contributes to the chemical industry's position as the nation's leading exporter. SOCMA has over 300 member companies, which are typically small to medium businesses with fewer than 100 employees and less than \$100 million in annual sales.

SOCMA supports EPA's – and Congress's – fundamental goal of protecting human health and the environment from harmful exposures to chemicals. SOCMA members are prepared to do our part in that effort. We are pleased to have this opportunity to share with you our unique perspective on revisiting the Toxic Substances Control Act (TSCA). As I will explain today, SOCMA agrees with many that TSCA needs to be revisited, and that certain aspects of EPA's TSCA program could be improved. But a sweeping overhaul like implementing Europe's REACH is unnecessary and would be unwise. It would not produce major changes in our ability to protect human health and the environment. But it probably would result in many unintended consequences, such as delaying the development of new products and hastening the move to offshore manufacturing, with disproportional impacts on small businesses, such as SOCMA members. Since its enactment, TSCA and its "unreasonable risk" standard have generally stood the test of time as a flexible law that has protected human health and the environment without crippling innovation.

First, I would like to start by saying that any evaluation of TSCA should consider the contributions the chemical industry has made in providing the United States with one of the highest standards of living in the world, even as overall indices of public health and environmental quality have improved. Secondly, any evaluation should also take into account the vast amounts of data that have been submitted by the industry to EPA and to other agencies, like the FDA, OSHA and the CPSC, under other statutes that regulate the chemical industry. Lastly, it should look at how this balance between protecting human health and the environment and preserving innovation has been achieved and how it can be maintained.

**SOCMA believes this balance has been and will continue to be achieved by a chemicals policy that is fundamentally guided by science and a careful assessment of risk.** That is, when assessing a chemical, EPA scientists historically have analyzed both the chemical's intrinsic hazard properties and the potential routes of exposure in order to make sound regulatory decisions on whether the chemical poses a risk. Data requirements have been driven by the intended and foreseeable use and disposal of a chemical. This fundamental approach should be maintained when considering a revised approach to chemical risk management.



One area of TSCA that has faced substantial criticism is the reporting requirements applicable to industry. In particular, many believe that the EPA does not have sufficient authority under TSCA to request data. SOCMA disagrees with this claim, but we do believe that data gathering is an area worthy of improvement, and that we should reconsider what is the best approach to gather data and information on chemicals.

**In order to do this, Congress should look at how EPA currently implements TSCA and consider how the program could be enhanced.** For example, under TSCA Section 4, EPA has broad authority to issue rules requiring testing of existing chemicals. SOCMA believes that EPA's use of this authority needs to be examined. We question whether it has been implemented to its full potential. EPA also may be able to collect more data on new chemicals – for example, on exposures to children – through the Section 5 Premanufacture (PMN) program as it has with existing chemicals under the amended Inventory Update Rule (IUR).

Before amending TSCA to create new obligations for EPA, Congress should also explore where EPA can better leverage activities going on outside of the TSCA program, whether occurring under other federal agencies like FDA, or abroad. For example, companies are embarking a massive project to generate standardized test data for the European REACH program. Through collaborative data sharing efforts, EPA should be able to take advantage of the work done for that program, just as other countries can leverage the work conducted here. Why would the United States want to duplicate testing that is already being conducted? **A collaborative approach should be promoted by Congress.**

This leads me to the Chemical Assessment and Management Program (ChAMP), the voluntary program to which the United States committed in 2007, along with Canada and Mexico, under the Security and Prosperity Partnership (SPP). Through this program, EPA is prioritizing chemicals by hazard and risk in order to systematically decide what further action may or may not be required. EPA is already well down the path of implementing this program. SOCMA believes that ChAMP is an especially worthy approach to collecting data and should be allowed to continue.

ChAMP is also addressing the TSCA Inventory. EPA has initiated action to reset the TSCA inventory to more accurately identify chemicals currently in commerce. Many people do not realize that, at any given time, significantly fewer than the roughly 80,000 chemicals currently on the inventory are likely to actually be in commerce in the United States. For example, the last Inventory Update Rule (IUR) reported 6,200 chemicals in commerce during 2005. We note that this excludes exemptions such as polymers, R & D chemicals and chemicals manufactured under 25,000 lbs/year. Nevertheless, this important fact is conveniently ignored by those who try to show that TSCA is inadequate, who claim that the inventory reflects the number of chemicals in commerce, and then compare that number to the number of existing chemicals that have been studied by EPA under Section 4, Section 8(d) or otherwise.

In closing, SOCMA has pointed out several main areas of TSCA that are being enhanced, and we would urge you to focus your current inquiry on how to better implement existing authorities and activities. SOCMA believes that TSCA will not require a complete overhaul, but could be enhanced to meet new challenges. A rigid approach like Europe's REACH is unnecessary and unwise. In order to tackle the chemical assessment challenges we face in an even more challenging economy, we should maintain a science based framework, fully implement existing authorities, and maximize programmatic and collaborative efforts like ChAMP. Lastly, the TSCA program will need to be adequately funded and provided with resources to accomplish its mission of protecting human health and the environment. Thank you, and I would be happy to answer any questions you have.

Mr. RUSH. Mr. Drevna.

**TESTIMONY OF CHARLES T. DREVNA**

Mr. DREVNA. Chairman Rush, Ranking Member Radanovich and the rest of the subcommittee, thanks for having us here. My name is Charlie Drevna. I am president of NPRA, the National Petrochemical & Refiners Association. Our member companies produce the basic chemicals that are the building blocks of the thousands of finished products that help make our lives simpler and safer. NPRA welcomes the opportunity to provide its perspective on the Toxic Substances Control Act, which is one of the key laws that can directly affect the marketplace, both for chemicals and for finished products.

Congress enacted TSCA in 1976 as an effort to categorize and evaluate the risk that chemicals may pose to humans and the environment. NPRA believes that the intent of Congress in crafting the statute was to construct a scientifically based chemical risk management program that was protective of human health and the environment while also allowing the development of products that will enhance health, safety and the environment. NPRA fully understands the committee's desire to examine TSCA's implementation and where necessary make the appropriate modifications to the statute to ensure that its goals and objectives are realized.

We live in an era where global competition and rapid technologic change now unfortunately coupled with a debilitating financial crisis are calling into question the business and political foundations upon which our prosperity has rested for decades. NPRA believes we must ensure the overarching goals of TSCA are achieved while at the same time promoting innovation in creating life-saving or -enhancing products, promoting economic growth and strengthening American competitiveness in the global marketplace. We are confident that these goals are complementary, not mutually exclusive, as some would say, and NPRA pledges to work with Congress and with all stakeholders to ensure the desired outcome.

Recently, several groups have called for a substantial overhaul of TSCA to make it more like the system recently adopted in Europe, otherwise known as REACH. While I agree that we could all benefit by first reviewing and then perhaps reforming TSCA and updating certain sections, I do not believe that a wholesale rewrite is necessary, especially given the fact that systems like REACH are largely new and untested. We have not yet begun to see what the impact of REACH will have on chemicals management in the E.U. or its effect on a European economy. My written testimony further elaborates on this point.

NPRA believes that a more pragmatic approach to TSCA reform will result in a better chemicals management system and still achieve the original intent of Congress. Key areas to explore while examining TSCA reform include information sharing, information collection and use, and a statutory recognition of EPA's own best practices and timelines for action. For example, EPA could share confidential business information with other types of government officials, both domestic and foreign, as long as that information is afforded the same level of protection required of EPA. NPRA would

not object to changes in the statute that would allow for better information sharing.

Another area that could be updated is how EPA collects information and prioritizes future work. Under TSCA, EPA is given the authority to collect information on the hazards, potential exposures and risks of chemicals. However, the statute does not mandate that the information be collected in any particular order nor does it require EPA to collect and disseminate the information in a timely manner. In addition, test rules could be updated to reflect EPA's own best practices and specific timelines for action. Test rules could also institutionalize a tiered, targeted and risk-based approach, which has proven over time to be the most effective and efficient chemicals policy.

NPRA urges this subcommittee to consider the approaches used by Canada and the United States under the Security and Prosperity Management Program, otherwise known as ChAMP, and at EPA it is also undertaking and making significant progress. This innovative program should be afforded the opportunity to work and produce the desired results.

The last area I would like to address is EPA resources for TSCA implementation. While many say the statute is flawed or outdated, I contend that a lack of sufficient funding has been every bit as big a problem as any challenge imposed by statutory language. EPA must be given the resources to appropriately manage chemicals in commerce.

In conclusion, I believe that if we take a careful, thorough look at TSCA and the history of its implementation along with the funding requirements associated with this kind of complex and technical work, we will find a strong statutory framework. I think if we work together as stakeholders in a transparent process and give this effort the time and thought that it deserves, we will end up in this Nation with a chemicals management system that is unparalleled. I thank you for your attention and the opportunity to be here today and look forward to your questions.

[The prepared statement of Mr. Drevna follows:]



**Written Statement of**  
**Charles T. Drevna**  
**President**  
**National Petrochemical & Refiners Association**

**on**

**“Revisiting the Toxic Substance Control Act of 1976”**

**before the**

**Subcommittee on Commerce, Trade & Consumer Protection**  
**Committee on Energy & Commerce**  
**U.S. House of Representatives**

**February 26, 2009**

Chairman Rush, Ranking Member Radanovich, and members of the Commerce, Trade and Consumer Protection Subcommittee, NPRA, the National Petrochemical & Refiners Association, appreciates the opportunity to present its views on “Revisiting the Toxic Substances Control Act of 1976.” I am Charlie Drevna, NPRA’s President.

My testimony today will describe the unique role of the petrochemical manufacturing sector in our nation’s economy. In addition, I will share with you how three decades of science-based, chemical risk management regulation in the United States have resulted in the development, marketing and use of hundreds of millions of consumer products derived from petrochemicals in a manner that is safe for consumers, protective of public health, and good for the environment.

As you may know, NPRA is a national trade association with over 450 members, including those who own or operate virtually all U.S. refining capacity, as well as most of the nation’s petrochemical manufacturers with processes similar to those of refiners. The products of NPRA member companies are the building blocks for thousands of finished products that help make all of our lives simpler and safer.

#### **I. Introduction**

NPRA understands the Subcommittee’s desire to examine the implementation of the Toxic Substance Control Act (TSCA) and, where necessary, make the appropriate modifications to the statute to ensure that its important goals and objectives are realized. NPRA supports this desire and looks forward to working with the Subcommittee on this examination. We consider the current federal chemicals regulatory framework to be a solid “foundation” for protecting the health of our customers and the environment, while simultaneously allowing for the development of products to enhance health, safety and the environment. NPRA and our member companies

support responsibly updating our chemicals risk management regulatory framework to recognize marketplace and scientific developments over the last several years.

We believe that the above statements are complementary, not contradictory, and that by working together, sharing information, and appropriating the necessary resources, the task will be much less cumbersome and much more effective.

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

Petrochemicals and their first and second derivatives are the fundamental building blocks that have enabled the United States to continue its position as an economic world power.

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

## **III. The Science of Chemistry: Chemicals are Fundamental**

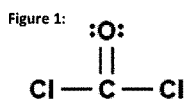
As previously stated, chemistry affects most, if not all, manufacturing in one form or another. Like all manufacturing processes, chemistry is bound by the laws of physics and nature. These physical laws place restrictions on what can and cannot be done when trying to make a chemical

compound. For instance, a molecule (i.e., a chemical) is made up of atoms (e.g., sodium, carbon, chlorine, etc.) that are in specific locations or positions on the molecule. In organic chemistry the goal is to take the atoms from one molecule and move them to locations on another, different molecule so that the target molecule takes on a specific function or behavior.

The laws of physics dictate if, how and when those atoms can be moved. To achieve certain critical structural changes, reactive chemicals must be used, and many are by their very nature hazardous, e.g., toxic, flammable, explosive, etc. In light of these constraints, scientists seeking to achieve certain chemical changes are left with few alternatives. Where hazardous chemicals are used, they are regulated by EPA, CPSC, OSHA, DOT and others, and appropriately managed by professional chemists in universities, government and industry.

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

For instance, common table salt consists of the sodium (Na) and chlorine (Cl) atoms, which make up the chemical sodium chloride (NaCl). The chlorine atom used to make medicine,





however, often comes from phosgene ( $\text{COCl}_2$ ) or phosphorous trichloride ( $\text{PCl}_3$ ). Phosgene, for example, has one carbon atom bonded to one oxygen atom and two chlorine atoms (see Figure 1), giving the chlorine atoms in phosgene very specific characteristics that are quite different from the chlorine found in table salt. The very specific nature of the chlorine atom in phosgene is critical to its fundamental role in pharmaceutical manufacturing, and minimizes the formation of unwanted, potentially toxic by-products that would otherwise contaminate the medicine. The complex chemistry associated with making medicine has well-defined physical boundaries and requires the use of reactive and toxic chemicals.

#### **IV. Chemical Risk Management is an Essential Part of Doing Business.**

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

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

To assure compliance with the wide range of environmental and occupational safety laws and regulations, many chemical manufacturing companies, including NPRA members, have created and maintained environmental, health and safety (EH&S) departments to help fulfill their

obligations under the law. EH&S departments of petrochemical manufacturers quickly concluded that, if approached in a well-organized, systematic manner, compliance with these statutory and regulatory requirements would be less difficult. The collective experience of EH&S professionals world-wide has led to the current evolution in industrial chemical risk management. This approach has gone beyond the petrochemical industry as the practice had been adopted by most other major manufacturing sectors, such as electronics, aerospace, automotive and consumer products.

**V. Chemical Risk Management Must Be Appropriate For The Situation and Based on Sound Science**

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

When Congress enacted TSCA, its intent was to provide EPA with broad authority to regulate chemicals in commerce. However, it was also the intent of Congress to provide a series of checks-and-balances so that regulatory decisions made under TSCA were scientifically and economically sound. TSCA charges EPA with the collection of existing health and hazard characterization information on all chemicals in commerce today, authorizes EPA to require chemical manufacturers to generate new information on these chemicals, requires manufacturers to report to EPA accounts of previously undetected hazards and risks, and requires both EPA and

the manufacturers to manage known risks posed by certain chemicals. The statute also provides the Agency with an opportunity to review new chemicals prior to their introduction into commerce.

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

When EPA does find that a chemical presents, or will present, an unreasonable risk, TSCA provides the Agency with very broad authority to take action to reduce the risk. EPA can require a company to communicate the risk in a specific manner, place restrictions on how a chemical is used, ban certain uses and even ban the chemical from the marketplace altogether. Because Congress gave the Agency such broad authority, it also felt the need to ensure that the Executive Branch fully understood the potential consequences of its actions. TSCA requires that EPA fully explore various options to manage the risk, from scientific, economic and social perspectives, because restrictions and bans can cause far-reaching disruption in the marketplace, including the availability of essential goods.

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

#### **VI. Regulatory Chemical Risk Management has Evolved in the United States**

To fully appreciate the evolution of regulatory chemical risk management in the United States, it is important to look at TSCA in its entirety and resist focusing on individual sections. The first question that could be asked is why a distinction was made between existing and new chemicals. (This distinction was not only made in the United States; in fact, it was made by all nations and regions that established chemical regulation laws in the 1970s.) As enacted, Section 8 of TSCA required EPA to establish an inventory of chemicals that already existed in commerce and promulgate regulations that required companies to update the health and safety information on those chemicals periodically. This was to provide a baseline of information that enabled the Agency to know what chemicals were in the marketplace and in what amounts. Requiring EPA to conduct risk assessments on the existing chemicals all at once was simply not feasible or cost-effective because many of the chemicals on the TSCA Inventory were industrial intermediates used only to make other chemicals in closed systems and under tightly controlled industrial environments (i.e., the public would never be exposed to those chemicals). Instead, Congress added provisions to Section 8 that required companies to keep records of alleged significant adverse reactions to any chemical and to report any known substantial risk immediately to the Agency. Congress provided EPA with additional authority under Section 8 to collect existing information related to hazards and exposures, even if the risks were not fully characterized.

If EPA determined that the existing hazard and exposure information was insufficient to adequately determine a chemical's risk, then Congress intended for the information collected

under Section 8 actions to be used by the Agency to justify requiring companies to conduct additional testing and submit the studies to EPA under TSCA Section 4. Section 4 of TSCA gives EPA authority to require companies to conduct specific laboratory tests to augment the Agency's risk assessment and risk management activities. Once EPA had sufficient information, if it determined that the chemical posed an unreasonable risk, the Agency could take action under TSCA Section 6, which gives EPA very broad authority to take risk management actions, such as restricting the use of a substance, requiring specific protective measures or even an outright ban of a material. The caveat, however, is that EPA would have to fully consider the consequences of its proposed actions, due to potential disruption in the marketplace.

This approach to chemical risk management is straight-forward and makes sense. However, the implementation phase has not always been so easy. Over the years, EPA has faced conflicting pressures -- from activists on the one hand, who have wanted EPA to quickly determine the risks of all chemicals in commerce and take immediate action on those that are found to present risks, and from the regulated community on the other, which has expressed concerns about the aggregate costs and cost-efficiency of an overzealous regulatory testing program. To find a balance between the two interests and maintain a workable and scientifically sound regulatory scheme, EPA has pursued a tiered, targeted and risk-based approach to chemicals management. Resources and testing are focused on those chemicals with the greatest potential to cause harm to the most people. The Agency first implemented this regulatory concept, in the late 1970s and early 1980s, in the area of new chemicals, which EPA is required to review before they enter into commerce.

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

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

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

reasonable and workable approach to ask for testing in a tiered and targeted manner, which used exposure information to help determine which tests would be appropriate.

EPA has been successful in obtaining hazard and exposure information for new chemicals. During the nearly three decades of chemical reviews, Agency technical staff noticed that the hazard information revealed patterns that could be associated with certain chemicals' molecular structures. Scientists in the field of chemistry already knew that certain physical and chemical properties could be ascertained according to a chemical's molecular structure. (This is really what chemistry is all about: predicting the way that molecules behave.) It was reasonable for Agency scientists to assume that structure-activity relationships (SAR) would hold true for chemical reactions taking place inside the body. However, even to this day, the chemical reactions taking place inside the body are not nearly as well-understood as reactions taking place in a test tube, where most variables can be recognized and controlled.

EPA technical reviewers understood that predicting chemical reactions inside the body -- the basis upon which the field of toxicology is based -- was in its infancy (and still is when compared to other natural sciences). The question then became: to achieve protection of consumers and the environment, how accurate does EPA have to be when characterizing the hazards of chemicals? If the Agency took a conservative approach sufficient to protect from unreasonable risks, then the need for scientific certainty would be diminished accordingly. Conservative approaches use default assumptions, which usually overestimate conditions and employ protective safety factors. This is why EPA began estimating ranges of toxicity, versus trying to characterize certain endpoints with exactitude.

Both a June 2005 and January 2009 GAO report to Congress on TSCA questioned the accuracy of the long-standing models used by EPA to review new chemicals. They failed to

note, however, that the protectiveness of the models is sufficient to achieve their risk assessment and risk management objectives. With an ever-increasing amount of data from testing programs and consent agreements under the new chemicals program and existing chemicals program, EPA has plenty of data to refine its models. Patience is needed, however, because this is not and should not be an overnight process.

The field of toxicology is still evolving and the discipline should be afforded the same time that it took other natural sciences to develop. The constant demand by some that EPA should do everything at an unreasonably rapid pace, like what will be done under the new European chemicals policy, is premature and may inhibit the natural evolution of toxicology as a science. It may also lead to some errant decision-making.

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

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

That is not to say NPRA believes that EPA has not been doing its job well; on the contrary, when TSCA was passed, chemical risk management was in its infancy, as were certain aspects of the fields of toxicology, exposure assessment and chemical risk assessment. NPRA believes that EPA has been able to successfully develop ways to achieve the objectives and goals of TSCA,



while allowing innovation to foster in the marketplace. In NPRA's opinion, the main factors contributing to EPA's difficulties in implementing TSCA are due more to its choices in the timing and sequence of Section 4 test rules, and over-reaching bans of uses in Section 6 risk management actions, versus challenges posed by the statute.

Many proponents of TSCA reform point to one specific case (*Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (5th Cir. 1991)) as proof that TSCA does not provide EPA sufficient authority to manage risks. EPA was challenged in court because there was a critical need for asbestos in this particular use (brake linings), no suitable alternatives for asbestos existed in this application and the Agency did not explore other ways to manage the risk. Just reading the opinion of the Court of Appeals for the Fifth Circuit, which is clearly written, shows where EPA could have maximized their chances for success in regulating certain uses of asbestos. If EPA had taken the appropriate approach towards the risk management of asbestos – concentrating resources first on those uses that could result in the highest concentrations of airborne particles and where alternatives could be used – they would have been in a significantly better position to win this case. Instead, the Agency tried to ban a critical use of the substance where there were no readily available substitutes. Further, EPA did not evaluate other risk management approaches short of a ban. NPRA is convinced that this is the major factor in why the rule was successfully challenged in court rather than being indicative of a TSCA shortcoming. NPRA believes that trying to ban most uses of a substance with readily demonstrable benefits, especially public health or life-saving benefits, is and should be laborious for the Agency.

The Agency's difficulties in promulgating test rules have been due less to TSCA statutory problems than to decisions made by EPA on timing and sequence. In most cases, if the Agency had chosen to collect use and exposure information under Section 8 first, then reviewed the

available information, especially pertaining to uses and potential exposures, the Agency would not have faced the challenges that it had faced early on when attempting to promulgate test rules. Since EPA will now be collecting use and exposure information as part of the Inventory updates from industry, in addition to its use of information collections under other parts of Section 8, issues surrounding the promulgation of Section 4 test rules should begin to diminish.

After these early experiences in court, EPA has been reluctant to attempt Section 6 and Section 4 actions. The Agency has stated that the findings for actions under these particular sections are difficult to make. EPA has recently used its Section 8 authority, however, to successfully collect the necessary use and exposure information to justify more Section 4 test rules on the remainder of the high production volume chemicals that have not been voluntarily tested by industry. The first Section 4 test rule was successfully promulgated several years ago and the Agency plans to finalize another test rule within the next several months.<sup>2</sup>

Regarding Section 6, EPA has used collaborative partnerships and stewardship programs to provide manufacturers along the supply chain with opportunities to voluntarily discontinue certain products. All cases where the Agency has taken the collaborative approach have resulted in demonstrable success (e.g., withdrawal of the substance from commerce or a specific timeframe for withdrawal). In addition, EPA typically follows up with a Section 5 Significant New Use Rule, which authorizes the Agency to require companies to submit notifications (similar to PMNs) when a company wants to reintroduce the existing chemical back into the marketplace. EPA considers Section 5 to be an effective risk management tool for existing chemicals as well as new chemicals.

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<sup>2</sup> The first HPV test rule was not challenged in court by any chemical company, primarily because EPA collaborated with industry and did its homework to make the appropriate exposure findings.

In addition to the authorities provided under TSCA, EPA has found that collaboration with multiple stakeholders is probably the most workable and efficient use of its resources when assessing and managing the risks of chemicals. The collaborative approach was put to the test in a dramatic way in the late 1990s, when the High Production Volume Chemical Challenge (HPV Challenge) was created. EPA asked chemical companies to voluntarily provide a base set of hazard and environmental fate information for all chemicals manufactured or imported at greater than 1 million pounds per year in aggregate. The chemical industry stepped up and sponsored over 2,150 chemicals, either in the U.S. HPV Challenge program or the Organization for Economic Cooperation and Development (OECD) HPV Programme. The HPV Challenge has resulted in more publicly available hazard data, in a timelier manner, than any other program in the world, regulatory or otherwise. For the remainder of chemicals, which were not sponsored, EPA has begun promulgating Section 8 data call-ins and Section 4 test rules and will continue to do so until all HPV chemicals are characterized for hazard, exposure and risk.

Building upon the success of the HPV Challenge and coordinating with its colleagues in Canada, EPA has committed to conducting hazard and risk characterizations on all HPVs and moderate volume chemicals (MPVs) in commerce as part of the U.S. government commitment to the Security & Prosperity Partnership of North America.<sup>3</sup> The name for this initiative is the Chemical Assessment and Management Program (ChAMP). Under ChAMP, EPA will be able to prioritize risk assessment and risk management activities for chemicals in a more transparent and expeditious manner than ever before.

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<sup>3</sup> MPVs are described as chemicals manufactured or imported at quantities between 25,000 pounds and 1,000,000 pounds per year in aggregate. Most chemicals below the 25,000 pound per year threshold are primarily research and development chemicals and certain fine chemicals, both of which are typically used in tightly controlled industrial environments.

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

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

Reality: REACH only increases the burden on industry. It does not reduce the burden on government. No government authority is going to receive a chemical dossier from industry and take it at face value. Rather, the government authority will conduct its own risk assessment, based on available information, and render its own decisions, risk-based or not. This will be just as time-consuming and resource-intensive under REACH as it is under TSCA. A careful reading of the REACH statute shows that the authorities must fully evaluate socio-economic considerations before proposing a restriction or ban, much like what EPA has to do under Section 6 of TSCA. It is only in the decision-making criteria that the two approaches diverge. Decisions in the U.S. must be based on sound science and full information, while decisions in the EU can be based on partial science and wherever the political winds are blowing at that time.

- Assertion: REACH will spur innovation in safer chemicals.

Reality: Innovation is a function of spending on research and development and ease of entry into the marketplace. Little more than a decade ago, the EU decided to require companies to conduct toxicity and environmental fate testing before a chemical could enter the marketplace, which has inhibited the development of products in Europe that could enhance health and the environment. This fact can be verified through the number of new, and usually safer, chemicals introduced into the European marketplace (around 2,000 over the past ten years), versus the number of new chemicals introduced in the U.S. (between 1,200 and 1,500 per year!). Another compounding factor is that in business, toxicity and other laboratory testing is considered part of research and development and typically comes out of the R&D budget. That leaves much less money for new, and often safer, product development.

- Assertion: REACH fully considers animal welfare.

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

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

Reality: REACH is a regulatory concept that has never been attempted anywhere in the world, at any time. It is entirely premature to draw any conclusions about REACH and it is equally untimely to attempt any comparison between REACH and regulatory programs that have been in effect for decades.

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

#### **VIII. Due to Current Economic Uncertainty, Care Must be Taken When Reforming Chemicals Policy**

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

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

#### **IX. Conclusion**

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

NPRA believes that current chemicals policy has allowed American businesses to survive in an increasingly competitive marketplace. NPRA also believes that reform of domestic chemicals policy will necessarily take time and careful deliberation. NPRA urges Congress to consider an inclusive, transparent process when crafting language to modernize TSCA.

Mr. RUSH. The Chair thanks all the witnesses. I recognize myself for 5 minutes for the purposes of questioning the panel.

I would like to ask each one of you on the record the same basic question that I asked the first panel. Do you believe that TSCA needs to be reformed? Please answer yes or no beginning with Mr. Denison.

Mr. DENISON. Yes, I do, Mr. Chairman.

Mr. RUSH. Ms. Gerwin.

Ms. GERWIN. Mr. Chairman, my organization has not taken a public policy position.

Mr. RUSH. Cal Dooley.

Mr. DOOLEY. We support modernization and reform, yes.

Mr. RUSH. Mr. DeLisi.

Mr. DELISI. We support revisiting the statute.

Mr. RUSH. Mr. Drevna.

Mr. DREVNA. Mr. Chairman, we support the revisiting, then if necessary the reform. I think it has to be a stepwise process.

Mr. RUSH. Mr. Denison, it sounds to me like there are a lot of problem with this statute. It looks that way to me. Furthermore, it sounds to me like these are generally problems that cannot be fixed by having EPA take a different approach to interpreting the statute or getting a few more staff. At the same time, others have suggested that the problem here is not really the statute, that the problem is EPA's interpretation of the statute. Now, what do you believe? Do you believe that the statute really needs to be rewritten or do you think that changes at the EPA will address all these problems and concerns?

Mr. DENISON. Mr. Chairman, I believe that the problems with TSCA are fundamentally structural and inherent to the language with the addition that legal interpretation of those standards has made matters even worse and has confounded the Congressional intent, as evidenced in the original statute. But the problems are structural in that they require such heavy burdens on the agency in terms of both resources and evidence that they effectively take provisions that would work if those burdens were not so high and make them unworkable. For example, the requirement that EPA must face to require a company to test a chemical is so onerous in terms of having to first have evidence that that chemical may pose a risk in order to require information, the catch-22 that was alluded to earlier is in operation. Even if that were not there, the fact that a rule to require testing has to go through full notice and comment rulemaking and takes many hundreds of thousands of dollars to develop and 2 to 10 years to develop means that when we are dealing with tens of thousands of chemicals, we simply can't rely on a system that has that level of burden placed on the agency and that level of resource required.

Mr. RUSH. Ms. Gerwin, you mentioned in your testimony about the difficulties that your company is facing trying to move toward using safer chemicals, and I applaud your company's efforts. You describe tremendous costs that Kaiser Permanente has taken on in this effort including hiring your own industrial hygienist and coming up with the testing protocols to test the safety of products and chemicals that you use. This sounds to me like it is a very large burden that you have assumed. Are you aware of any other compa-

nies that are doing similar things? Do you think that a smaller company would be able to do what you have done?

Ms. GERWIN. It is a significant use of our time and resources to do the kind of testing that we have done, and I think there are other organizations that take on some similar tasks. I don't know of any that actually go to the lengths that we have gone to for so long. As I had mentioned in my testimony, we have been doing this for more than a decade, and I think smaller organizations would find it to be an extreme burden on their resources to try to do the kind of work that we are doing. So it is an investment on our part that we are making in order to achieve the goals that we want to achieve and it represents an organizational burden of time and resources.

Mr. RUSH. Are you aware of any other companies besides Kaiser, your company, that are doing similar things?

Ms. GERWIN. I am not aware of any organization that is doing the amount of testing that we are doing but I know that there are other organizations and some healthcare organizations that are focusing on single chemicals or single products.

Mr. RUSH. The Chair now recognizes the ranking member for 5 minutes of questioning.

Mr. RADANOVICH. Thank you, Mr. Chairman.

I want to welcome the panel and thank you for being here. I want to preface the discussion that we have by quoting a New York Times article that was printed on June 30, 2008, and it is regarding the hyperbole of taking on difficult subjects like this. It starts out by saying "Need press, repeat, green, sex, toxic, cancer, secret and fat." Those are the things that get attention on the press, and the reason I am saying that is because when you start talking about, a previous witness mentioned the idea of the shower curtains that were a problem emitting odors and it was later on debunked in total because after they went into and found out that there was nothing behind the accusation that it could be releasing as many as 108 volatile chemicals, and this is the scary part about getting into changes like this. Most people here agree that TSCA needs to be looked at, but what I don't want to see is a repeat of the Consumer Products Safety Act where you end up putting an incredible burden on industry, raising their costs in association with this. So again, you know, this is the red flag that needs to go up when the consideration of the revision of something like TSCA needs to happen.

I do have a couple of questions. Mr. Denison, when you mentioned on the issue of asbestos, was it TSCA that prevented asbestos from—as I understand the regulations that were being sought after had failed in court. Wasn't it shoddy workmanship on the part of EPA that brought that case to the court that ended up preventing the listing of asbestos?

Mr. DENISON. Congressman, it absolutely was not. EPA spent more than a decade and millions of dollars developing that regulation. It amassed, as I said, a 45,000-page record of documentation. What the court found was on several levels that the agency had not examined every possible alternative to asbestos in every possible use of asbestos on the market, and if you read that court decision and the analyses that have been done of it, you find very quickly



that the amount of work that the agency would have had to have done to have met the statutory requirements as interpreted by the courts was simply impossible to reach.

Mr. RADANOVICH. Let me read the court decision. It says, "We note that of all the asbestos bans, the EPA did the most impressive job in this area both in conducting its studies and in supporting its contention that banning asbestos products would save over 102 lives. Were the petitions only questioning the EPA's decision to ban friction products like brake pads, we would be tempted to uphold the EPA."

Mr. DENISON. Well, in that particular case, I am not familiar with that particular passage but I think what they were saying was that the standard of evidence that was required under the statute was only met according to the court in that one area. That doesn't mean that that is the only area that EPA looked at the risks or looked at the benefits but that is how high the bar was.

Mr. RADANOVICH. Thank you, Mr. Denison.

One of the other questions, I want to repeat this throughout this hearing because I think it needs to be a mantra, the previous witness had mentioned the awful accident in Bhopal, India. I fail to see any part of TSCA that had anything to do with that accident or where that law came into it but you bring up these sexy things that get press and you alarm people and it opens the door to regulations that can be not really done surgically to make a law better but it brings it in with a meat cleaver and makes a mess out of it. So that is the caution that I want to make, that is, if we move forward in regulation that it works for everybody and it keeps a legitimate, good industry and allows them to continue to thrive.

So with that, Mr. DeLisi, I would like to ask you a question. I come from the point of view that managing risk is not as simple as removing risk but rather gets into the business of risk-risk tradeoffs. Could you please tell me if you agree with this risk-risk tradeoff concept as it relates to the regulation of chemicals, for example, maybe formaldehyde?

Mr. DELISI. Absolutely. Frankly, I would not want to be a regulator that had to try to make some of these decisions, but when you replace a chemical, you need to understand completely what the tradeoffs are and some of the things that have been suggested for replacement, things like benzene, I mean, if you don't have benzene you don't have Tylenol. So there needs to be a careful study of the tradeoffs that are being made, things like tires. We all understand the risks. Tires can explode. I was on the New Jersey Turnpike yesterday and a truck lost a tire that exploded. We face that every day. So we all face risk tradeoffs in our lives every day and also involved in the chemical industry too.

Mr. RADANOVICH. Thank you, sir.

Mr. Chairman, I see that I am over time so I would request one more round of questioning.

Mr. RUSH. The chairman is committed to a second round of questions for those members who can't complete their line of questioning in the 5-minute time.

Mr. RADANOVICH. Thank you so much, Mr. Chairman.

Mr. RUSH. The Chair now recognizes Ms. Schakowsky of Illinois.

Ms. SCHAKOWSKY. Thank you, Mr. Chairman.

First let me apologize to the panel for not being in the room for your testimony. I think as Mr. Dooley is well aware, that won't prevent me from asking questions, even if it should.

Mr. Denison, this is directed to you. Actually, they all are. As we have heard from several members today, everybody supports the use of good science I think it is instructive to the committee to be aware of the recent observations of a committee of the National Research Council. In a 2006 report entitled "Toxicity Testing for the Assessment of Environmental Agents," the committee stated, "TSCA authorizing EPA to review existing chemicals for toxicity and exposure information on them is typically so incomplete that it does not support the review process. The basis for establishing priorities and requiring testing for industrial chemicals in the United States has not progressed much over the last 20 years." I am wondering if you agree with this assessment of the scientific experts.

Mr. DENISON. Congresswoman, I do very much. I believe the National Academy was one of the first to sound the alarm about the lack of data way back in the mid-1980s and pointed out that TSCA was failing even then to generate the information needed to base good scientific decisions about chemicals on and that report that you alluded to just 2 years ago simply says that we have not made much progress in the intervening 2 decades in terms of tackling that basic problem. The Academy has also issued a set of reports over the last few months on risk assessment as managed by the Environmental Protection Agency and it has found that there are major problems with the assumptions that EPA uses and with the lack of ability for EPA to recognize that people are exposed to multiple chemicals at the same time, not just one chemical at a time.

So I think the good science mantra that we hear here is absolutely a need that requires TSCA reform because TSCA is not using the best science, and I think that we have an opportunity here to bring our chemicals management program into the 21st century in terms of using the best science out there to drive these decisions. So the notion that good science is only practiced by industry somehow or that this is a one-sided issue is not the case.

Ms. SCHAKOWSKY. This all may have come up already in testimony, so were we to do in a perfect world the kind of review that is necessary, it wouldn't just be chemical-by-chemical review, we would also be looking at the cumulative effect and the interactions as well?

Mr. DENISON. That is right. We are exposed to multiple chemicals from multiple sources all at the same time and yet our assessment methods and our way of going about getting data on chemicals one at a time does not lend itself to elucidating the question, what is the impact of all of that cumulative and aggregate exposure? So there is a lot of new science going on here that could begin to answer that question. We need to incorporate that best science into the way EPA assesses chemicals.

Ms. SCHAKOWSKY. We worked a lot in this subcommittee and committee on the Consumer Products Safety Commission Improvement Act, and I have heard some suggest that we shouldn't worry about levels of a particular chemical in a particular product such

as phthalates in rubber duckies because it is far too low to have any impact. How are we to respond to that kind of charge?

Mr. DENISON. Well, it is a very good question. I think the emphasis that the associations at this table just made on the need to look at use of chemicals and making decisions about them I hardly endorse. The problem has been that we have done a very lousy job as a Nation in understanding what we can be exposed to and how. The phthalates in plastics, the brominated flame retardants used in our furniture are all chemicals that for decades we were told there would be no human exposure to those chemicals. They absolutely would stay put and we would never be exposed to them. We have found out how wrong those assumptions were. So I think part of the reason why I call for much more comprehensive information about chemicals including the use of chemicals, because I agree that is very important, is because without that information, we make wrong assumptions that prove wrong only decades later when essentially the entire human population has been exposed to those chemicals and we still don't know what the risks are.

Ms. SCHAKOWSKY. Well, this is a new area of jurisdiction for our subcommittee that we look very much forward to working on. I thank all of you for your input and testimony.

Mr. RUSH. The Chair now recognizes Mr. Sarbanes.

Mr. SARBANES. Thank you, Mr. Chairman.

Thank you all for your testimony. I am trying to understand how TSCA is viewed from sort of different quarters, and I imagine there are some people who would say that it is a joke. If you were just at lunch with somebody, Mr. Denison, and they said oh, yeah, TSCA, you know, that regulates chemical safety, would you, well, that is really kind of a joke or would you say it is an open secret that it doesn't really do much, or do you say well, that is a reasonably good statute that just needs some upgrading and overhauling? Just kind of put it in a vernacular for me.

Mr. DENISON. Congressman, I think I would probably aim toward the middle of the three statements that you made. I think it is largely an open secret that this policy has not been sufficiently protected, that EPA has not been able to get the information it needs and has not been able to act on that information when it does happen to obtain it. So I don't know that it is a joke. I think the intent at the time and the policy statements in TSCA are very solid. The problem has been that it simply has not delivered on the promises it made, and I think that is inherent in the statute that has not been looked at for essentially 3 decades. So we have to go back and figure out why it didn't work and fix those structural defects.

Mr. SARBANES. Let me ask you about REACH because a couple people have alluded to that, some with a sense of alarm, and I would ask anyone on the panel to speak to this. Is REACH too far, is that overreaching to go to REACH? I mean, how much of a burden would that really represent? Describe that burden in terms of there might be an initial period of assimilating the new standards but presumably over time you can make the gathering of information, the presentation of safety data and other things part of the course of your operations such that it would not be so burdensome. And I don't know that REACH is the answer. It just that it has

been invoked a couple of times as a standard either to be concerned about or to reach for. So again, anybody can speak to that.

Mr. DELISI. I would like to make a couple of comments on that. First, many of the things that have been discussed this morning and this afternoon are not regulated by TSCA. There was a lot of discussion this morning about exposure to biocides and insecticides and things like that, which are regulated under FIFRA, not under TSCA, and my understanding from my friends in the ag chemical industry is, there are broad reviews being undertaken on a whole swath of ag chemicals under the FIFRA statute. There was some reference this morning to some cleaning products and some consumer goods. I don't think TSCA was ever envisioned to be involved in that. That is the Consumer Products Safety Commission and other places where things are reasonably well regulated.

REACH is a significant overreach because of the deadlines and the way things are put together under REACH and the so-called substance information exchange forums. When the E.U. proposed REACH, they expected to have somewhere around 30,000 products and 300,000 pre-registrations. What they ended up with is 2.5 million pre-registrations of 150,000 products. Until the world gets a chance to see if REACH can work, 3 or 4 years from now we may all be sitting here saying REACH is an outstandingly good way to regulate chemicals and be recommending it to Congress and EPA to look at it, but I think the E.U. needs a chance to test it and see if it works. There are many of us that believe it is going to have a substantial detrimental effect on the E.U. economy all the way up the line.

Mr. DOOLEY. Congressman Sarbanes, I would just encourage the committee—Stu Eisenstadt has submitted a statement for the record that deals with REACH and I encourage you to read it. It includes some of the information that Mr. DeLisi also addressed, but I would also encourage the committee to look not only at REACH but look at the Canadian system that they are currently putting in place because they are somewhat different, and I think they are instructive in terms of how we think we can be most effective in modernizing our TSCA system.

One of our concerns about REACH is, is that it doesn't really embrace a prioritization system. You know, we always are going to have to recognize that, you know, a regulatory agency such as EPA is going to have limited resources. We ought to be targeting those resources and focusing our greatest concern on those chemicals that are chemicals of concern, that might be those that are persistent, that are biocumulative and that we ought to also then have a prioritization where you are going to require more information from my member companies when you have these high chemicals of concern, which REACH doesn't address effectively. The Canadian system takes a much different approach where they have analyzed about 23,000 different chemicals. They identified 4,000 or so that we ought to be focusing most of our attention on. When we are talking about modernizing TSCA, we think that has to be one of the fundamental components of it. You know, let us set up a system where we are providing more information and data out there. Let us identify those chemicals which we should be most concerned with in terms of the health risks. Let us ensure that EPA has the

resources and the ability to make a safety assessment of those chemicals that are going into the marketplace because ultimately, you know, my manufacturers, my companies want to ensure that Kaiser has the confidence in the products that they are using and they are going to have the confidence when they are assuring that the private sector is providing the right information and EPA and the regulatory process is doing the appropriate science-based assessment of the safety of those products.

Mr. SARBANES. Thank you.

Mr. DENISON. Could I briefly address that, Congressman?

Ms. SCHAKOWSKY [Presiding]. Yes.

Mr. DENISON. REACH is a reality. It is in place and it changes the dynamic of many of the issues we are talking about as we look at TSCA reform. So most of the chemical industry is global in nature and many of the companies represented by the associations at this table do business in Europe. They are already going to have to comply with REACH. They are going to have to develop the data that it requires. That makes our lift that much easier. You know, we don't have to reinvent the wheel, and I totally agree with Mr. Dooley, we shouldn't be out there testing chemicals that have already been tested in Europe. So I think REACH, regardless of how good or bad a model people think it is, it changes the entire chemical global economy in a way that has to be recognized and has to be taken into account in terms of how we think about TSCA reform. The idea of getting to all of the chemicals in commerce which REACH is trying to do I think is fundamentally where we need to go. How fast we can get there and how we do it and how we prioritize that, those are all great areas for discussion. But we have to get to that point.

Ms. SCHAKOWSKY. My friend, Mr. Stearns from Florida.

Mr. STEARNS. Thank you, Madam Chair.

Mr. DeLisi, is it unfair to say that since the World Trade Organization will make it very tough to ban articles in commerce, if we ban chemicals in the United States, the manufacturers of those chemicals in the United States will go somewhere else, but the products for which the chemicals were made will still wind up being sold in the United States, and if so, why?

Mr. DELISI. Basically the United States consumer will look for the best value they can get, and if you take a chemical out of commerce in the United States that produces a product that the consumer wants to buy and they can get the same finished product, the same finished article from India, China or Korea or anyplace else, that material will find its way to the United States market and the United States will have lost the ability to produce that product and the WTO would make it very difficult to ban the importation of that article as long as there was no exposure to that particular product.

Mr. STEARNS. Do you want to add to that, Mr. Drevna?

Mr. DREVNA. I would like to add one thing to that and maybe augment it a bit, and again, you know, I think we are all sitting at the table, and the first panel, I think we don't disagree on a lot. It is how we get there that is the important thing and do it the right way. But in follow-up to Mr. DeLisi's comment, if you don't make the finished product, if you don't have the chemical here, you

are not going to make the finished product here, and if you start going down the food chain, so to speak, you are not going to have the building blocks made here either, my members, the petrochemical producers. So if we don't do this right, we will be ceding our entire manufacturing base to foreign suppliers. So these are the kinds of things I think that Ranking Member Mr. Radanovich was speaking about, that whatever we do, let us do it right. From the industry side here, we are not sitting here saying don't do anything to TSCA, leave us alone, you have beaten us up over the last 30 years. No, we are not saying that at all. We all have the same objective, I hope, because if not, we shouldn't even be here. But let us make sure we do it right so from Mr. Denison's side of the table, and I don't want to put sides on this thing, that we get to where he and his group want to go but we still maintain a strong manufacturing base and employment in this country. And again, they are not mutually exclusive.

Mr. STEARNS. Mr. DeLisi, small- and medium-sized companies, can they do the REACH themselves?

Mr. DELISI. It is almost impossible. The setup under REACH, all the testing work has to be done in so-called substance information exchange forums, many of which have more than 4,000 or 5,000 members, and so what is happening is that consortia are being formed to do some of the testing and in many instances the consortia are being controlled by very large European companies and sometimes they are not allowing U.S. and other producers equal access to the data. It is going to be very, very difficult to figure out how small- and medium-sized companies can survive under REACH-like requirements.

Mr. STEARNS. Maybe we can talk about, I guess REACH is just starting in Europe. Can you tell me the laboratory capacity in Europe maybe after REACH went into effect? Has this allowed the European chemical manufacturers to innovate with better or safer chemicals or more carbon emission-friendly efforts like alternative energy or green energy? What is the status here?

Mr. DELISI. Well, it has been widely published that most, if not all, the laboratory capacity in Europe is being diverted to REACH testing requirements, and in fact a lot of the laboratory capacity all over the world is being diverted to that and so it is not doing other kinds of things that may or may not have a better result.

Mr. STEARNS. So you are saying basically they are not innovating and they are not necessarily providing safer chemicals, they are just complying with all the regulations?

Mr. DELISI. There is only a limited amount of resource to put into R&D activities and a lot of it right now is being diverted into REACH.

Mr. STEARNS. So if that happened in the United States, do you expect the same thing to happen here that is happening in Europe?

Mr. DELISI. Undoubtedly.

Mr. STEARNS. Is your contention that the main difference between REACH and TSCA is not section 6(c) requirements to consider other factors but rather whether sound, high-quality and repeatable science underpins the regulation rather than unsubstantiated research or gaps in the data? A very contorted question. The main difference between REACH and TSCA.

Mr. DELISI. The main difference between REACH and TSCA is, there is no grandfathering under REACH and so it requires complete testing data sets to be done on everything that is going to continue to be in commerce regardless of the inherent hazards or known on the products. So it is requiring the redoing of an awful lot of effort that is reasonably well known by industry.

Mr. STEARNS. Mr. Drevna, do you want to comment on that too?

Mr. DREVNA. Well, you know, I only go to say that, you know, and I will agree with Mr. Denison, if it is already done, why duplicate it, and to force that on every manufacturer in the United States will cause paralysis.

Mr. STEARNS. Thank you, Madam Chair.

Ms. SCHAKOWSKY. My friend, Ms. Sutton, the Representative from Ohio, is next.

Ms. SUTTON. Thank you, Chairwoman Schakowsky.

Mr. Denison and all of you, it has been alluded to here today, and I think that most Americans would be shocked that asbestos is not currently banned. I think that they would be surprised to learn that. A week or so ago we had a hearing in another area but I am noticing a pattern here, and it dealt with the tainted peanut butter that has resulted in a salmonella outbreak across this country killing people where I live, and we learned then, or I know because I knew it because we introduced a bill last year to give the FDA mandatory recall authority, which people were likewise shocked to understand that our government didn't have the authority to recall things when they know that there is a problem, that it is voluntary, that we expect companies to just do what is in the best interest of the American public and perhaps sometimes they live up to that more than others. Certainly some do, some obviously do not.

And then you come and tell us about the issue of formaldehyde in plywood, and I just have to get more information about this. You made a reference to the United States becoming a dumping ground for unsafe products and you used the example of the plywood coming in from China, plywood that does not even reach standards that allow it to be utilized in China or Japan or other parts of the world, but it is coming to the United States. And I guess my first question is this. It is coming to the United States because it is cheaper?

Mr. DENISON. Yes, that is the primary reason. Those adhesives are less expensive than the safer alternatives and they reduce cost and there are other reasons that have to do with why it is being made in China in the first place that make it cheaper as well.

Ms. SUTTON. And I would love in another venue to talk about those other reasons because, you know, I am a person that thinks frankly our international trading system isn't living up to the promise that perhaps it could but another day and another time.

Okay. So it is coming in because of its cost, lower cost, it is being imported. I assume that it has been banned for use in these other countries because of data that exists that shows it is dangerous, correct, so we know it? And what is the liability for a company that is choosing because it is cheaper to import this which we know is toxic for the American people? Can you give us an idea about what potential consequence that company has when, you know, years

from now people suffer and die because we are allowing it to come into the country?

Mr. DENISON. Well, I do think that the contrast between asbestos and an example like formaldehyde is an important one. Part of the reason that asbestos despite the fact that it was not banned is actually largely off the market, it is creeping back in in a few places but it is largely off the market, is because of liability that the companies that made it and used it face. But that is a very special case because asbestos causes a signature disease that can be linked directly to asbestos exposure. Most chemicals are far more complex than that and the ability to go to court and say this chemical caused that person to get that disease is very limited. That is part of the new science that we have to incorporate into the way we think about chemicals because we can't wait until we can have absolute proof that chemical X is the sole cause of disease Y in order to regulate. Formaldehyde is in that case where we know it is linked to many different diseases, and in fact actually there the evidence of its ability to cause cancer is established firmly. But I think we have to adapt our model and the way we think about chemicals and this burden of proof to reflect the reality of the science that we now know about chemical exposures and effects.

Ms. SUTTON. Well, I appreciate that and I would love to follow up with you after the hearing. Thank you.

Mr. DENISON. I would be happy to.

Ms. SCHAKOWSKY. Now a new member to this Congress and to this committee, Mr. Scalise.

Mr. SCALISE. Thank you, Madam Chair.

Mr. Dooley, we have had some testimony in other subcommittees where the effects of energy regulation is being considered, what effects that would have on various industries, and there were a few industry members of your organization that had talked about the various problems they have had as energy costs went up but also as some of these changes are being anticipated and what that meant to jobs in the United States and in some case layoffs here and other cases people making decisions to move operations overseas so as not to be regulated in an overly burdensome way, and I think as we look at TSCA and revisit the changes that might be made and we realize the importance of being cautious that we address problems without being over-regulatory in a way that actually creates jobs that are safe jobs in this country. How is your industry looking at this and what things have you seen already or what concerns do you have about how that may impact jobs for businesses that are playing by the rules, doing things right but concerned about over-regulation?

Mr. DOOLEY. I think what our industry is supportive of is a modernization of our chemical management system that is done in a manner which enhances the public confidence that consumers and users of our products have, that also ensures we are enacting a system that is science based and is efficient and also embraces a risk-based approach, and we think we can do that through this modernization that would accomplish a lot of the objectives of all parties that have testified today. But there are some areas which we think are critical in order to maintain the investment in the United States in the development of these innovative and technological ad-



vances that are contributing to the U.S. chemical industry being at the leading edge of, you know, a lot of the energy efficiency technologies that are being developed.

And if I can just touch a little bit of where we at, which is again, as I have stated before, is that, you know, we are committed to providing the appropriate data. You know, there needs to be some improvements in what we have seen in the past. We need, though, to ensure that we are prioritizing when we are providing all that data, unlike what REACH does where you have, you know, millions of these applications that are coming in, is that you need to be, you know, targeting those chemicals that should be the greatest concern, and then when you have those chemicals that are the greatest concern, it might be formaldehyde, it might be asbestos, it might be something else, is it doesn't mean that those chemicals or products are going to be dangerous in all applications because some applications might not have an exposure to humans and so then you are going to have to have a system that will allow you to go down and to identify where those chemicals are at risk, those exposures which we should be concerned with so that we can also incorporate that data that can help us manage that. And the one thing that also brings into play is, is like REACH is taking more of what we refer to as a hazard-based approach, that if you have a chemical that is identified as a chemical of concern, is that you could ban it for all applications versus just those applications which result in an exposure that could result in a problem. And that is a system that we think if you put in place will ensure that our industry can continue to be competitive internationally.

Mr. SCALISE. And I think there are some—ethanol is an example where used at a high level it is very dangerous but it is actually very prevalent in a number of products that are used across the board at a low level and it causes no problem, so obviously the dosage, the amount is something that has really go to be focused on.

Mr. DOOLEY. And that is a great example. We had Ms. Swanson with the Learning Disabilities Association which talked about, you know, some of their concerns with neurological impacts of various chemicals. Ethanol is in fact a chemical that has been demonstrated if used in excess to cause fetal alcohol syndrome, a neurological disease, and something nobody wants to, you know, see occur. But ethanol is also a naturally occurring product in apple juice. If you took it to the extreme and took a hazard-based approach because ethanol created a neurological response, you would end up then again in the extreme banning apple juice and a lot of other, you know, natural products which actually have no risk or pose no risk to consumption. And so that is the challenge we face here is, you know, how do we put together a system where we provide the adequate information, we have those exposures which create a risk and a problem and ensure that we are providing that level of safety.

Mr. SCALISE. And I think that is a concern, that we take a responsible approach that encompasses all those variables

I will yield back. Thank you.

Ms. SCHAKOWSKY. Representative Castor of Florida.

Ms. CASTOR. Thank you, Madam Chair.

I would like each of you on the panel to just state very briefly whether or not you support as part of the modernization of TSCA the shifting of the burden of proof to the chemical manufacturer rather than forcing EPA to assume complete responsibility for determining risk.

Mr. DREVNA. Ms. Castor, I think a lot of that is already being done. There has been talk that a REACH-like approach would take all the burden off the government and put all the burden on the industry. The industry is more than willing to give the appropriate data and to do what is right but that is not going to relieve government, the EPA, whatever authority you deem necessary to handle these myriad of laws, that they can't get data from other sources, and they do, and I think there is either a miscommunication or a misunderstanding with how much data EPA has and what they have done with it. They have got tons of data.

Ms. CASTOR. So is that a yes or a no?

Mr. DREVNA. I am sorry. Yes, we think that the industry has and will step up more to the plate.

Ms. CASTOR. And you would support a statutory change?

Mr. DREVNA. If it is done—again, as I said before, if it gets to the end, the result without extra burdens, without making it non-competitive vis-&-vis international and keeping the American economy strong and growing or hopefully get back to that.

Mr. DELISI. I agree basically with what has been said and I think at the end of the day that burden is going to need to be shared.

Mr. DOOLEY. I would just echo that. It is an inevitably going to be a shared responsibility. Our board at the American Chemistry Council has adopted a position where EPA needs to be in a position of assessing the safety of the products that we put into the marketplace. So, you know, we are willing to accept a much greater responsibility than is currently required under statute but it will inevitably have to be a shared responsibility.

Ms. GERWIG. And I think where the burden of proof should not exist is at the end-user level, which is the experience that I have been describing at Kaiser Permanente. So I think the discussion that others on the panel have been having about perhaps a shared collaborative approach would be a good one.

Mr. DENISON. I do think in a legal basis, the industry needs to have the burden of proof, but I absolutely agree, EPA needs to play an oversight role of that that is very careful.

I do want to say, there have been, with all due respect, a number of major inaccuracies stated about REACH. It does prioritize. It does not require the same data for all chemicals. It has some aspects that are driven by hazard but its fundamental framework is risk based, not hazard based, and it does consider uses of chemicals in deciding whether or not to restrict a particular use.

Ms. CASTOR. Thank you, and I have one other question. I would ask you to submit your answers for the record because I think it is going to be a more involved answer. I would ask you all to explain why since the adoption of TSCA in 1976 only one group of chemicals has been barred.

With that, I will yield back my time.

Ms. SCHAKOWSKY. Thank you.

At this point let me ask unanimous consent to submit a number of documents including those from Mr. Radanovich and others into the record.

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

Ms. SCHAKOWSKY. Mr. Radanovich has asked to have one more question, and you may.

Mr. RADANOVICH. Thank you, Madam Chair.

Mr. Dooley, welcome to the panel and back to Congress. Cal and I shared a district in California, a big ag producing district, so I have got a FIFRA question. But I wanted a real quick once, since we are running out of time and going to vote, on the change-o-meter if zero is no change to TSCA and 10 is change like the Consumer Products Safety Act, where would you be in the zero to 10 range?

Mr. DOOLEY. That is tough because that is always going to be relative, and, you know, I could say that 50 percent but Mr. Denison might think my 50 percent is only 25 percent. But, you know, I would contend that TSCA is not broken but is in dire need of modernization and we think that it provides a good foundation to move forward, and so I will go with a 50 percent change-o-meter.

Mr. RADANOVICH. Real quickly, Mr. Dooley, if FIFRA—there is a lot of people that feel that the FIFRA, which deals with pesticides, agriculture stuff, that the rules of FIFRA ought to just be flipped into TSCA and that be done. Can you state whether or not that would be a great idea or not?

Mr. DOOLEY. Well, we would be very, very cautious about going down that path, again because of the—it wouldn't in many cases be effective at enhancing the public safety of our products, but I would say again that when you go through a process of prioritization and you do find a chemical that is of great concern because it might be an endocrine disruptor, it might be biocumulative, is that we are going to have to have a different standard in terms of the amount of data that the industry is going to have to provide and the scientific research and assessment of those products. We don't contend it would be FIFRA necessarily but it will be a higher standard than what is currently being provided under TSCA.

Mr. RADANOVICH. All right. Thank you, Mr. Dooley, and Madam Chair, I yield back.

Ms. SCHAKOWSKY. Thank you. At this point let me thank our panel for their testimony, we appreciate it very much, and the hearing is adjourned.

[Whereupon, at 1:46 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]



STATE OF MAINE  
DEPARTMENT OF ENVIRONMENTAL PROTECTION

JOHN ELIAS BALDACC  
GOVERNOR

DAVID P. LITTELL  
COMMISSIONER

February 26, 2009

Written Testimony of David P. Littell  
Commissioner, Maine Department of Environmental Protection  
17 State House Station  
Augusta, Maine 04333-0017

House Committee on Energy and Commerce  
Subcommittee on Commerce, Trade, and Consumer Protection  
Revisiting the Toxic Substances Control Act

Chairman Rush and Ranking Minority member Radanovich I am David P. Littell, Commissioner of the Maine Department of Environmental Protection. I also note for the record that I currently serve as Chair of the Environmental Council of States, Cross Media Committee.

The State of Maine supports Congressional discussion on TSCA reform to improve the chemical safety of consumer products and protect public health and the environment. Maine's legislature has passed and Governor Baldacci signed a statute to address comprehensive chemicals policy reform due to lack of TSCA reform and we are actively engaged in ongoing discussions with other states who are also interested in comprehensive chemicals policy reform.

The State of Maine legislative and executive branches have each enacted and implemented consumer product bans to protect public health and the environment from toxic chemicals in consumer products for several decades and through multiple administrations. Bans on consumer products containing mercury began with specific items such as fever thermometers and broadened to categories of products such as switches, relays and measuring devices containing mercury. Brominated flame retardant bans have been enacted for pentabromodiphenyl ether, octabromodiphenyl ether, and decabromodiphenyl ether (in TV and computer housings and mattresses, mattress pads and upholstered home furniture).

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The statute created further authority for the Commissioner of Environmental Protection to ban any flame retardant that is harmful to public health and the environment in those consumer products specified in the statute.<sup>1</sup>

The time and resources invested by Maine's environmental and health agencies, the Maine legislature and concerned citizens and Maine businesses to improve the health and environmental safety of consumer products has been considerable. My state is frustrated with the lack of an effective and comprehensive national regulatory framework that could greatly assist us in these state efforts and reduce the burden on our limited resources.

In 2006 Maine's Governor John E. Baldacci established a Task Force to Promote Safer Chemicals in Consumer Products. The 2007 Final Report of the Task Force<sup>2</sup> agreed with the U.S. Government Accountability Office and others that TSCA does not provide sufficient chemical safety data for public use by consumers, businesses and workers; is inadequate to ensure the safety of chemicals in commerce in the United States; and fails to create incentives to develop safer alternatives. The report recommended the following principles of comprehensive chemicals policy reform that we would like to see considered in federal TSCA reform:

- Shift the burden of proof away from government to prove harm and onto manufacturers to prove the relative safety of chemicals they produce;
- Shift the standard of proof away from having to demonstrate unreasonable risk to acting with foresight to avoid harm to people and the environment;
- Ensure that chemical policies protect the most vulnerable populations among us;
- Require safer alternatives to hazardous chemicals when available, while phasing out high hazard chemicals such as persistent, bioaccumulative and toxic chemicals (PBTs);
- Honor the public's right-to-know about chemicals hazards, by ensuring that data gaps on chemical safety are closed;
- Consider the best of the work of other governments that are developing chemical policies, such as Canada and the European Union, to inform our own work.

The Task Force further recognized that the federal government and the states share responsibility for developing and implementing effective chemical policies that fully protect public health and the

<sup>1</sup> <http://www.mainelegislature.org/legis/Statutes/38/title38sec1609.html>

<sup>2</sup> [http://www.maine.gov/dep/oc/safechem/me-safer\\_chem\\_rpt.pdf](http://www.maine.gov/dep/oc/safechem/me-safer_chem_rpt.pdf)

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environment and further promote green economic development. Governor Baldacci's Task Force recommended unique state and federal roles that are complementary and build on the strengths and capabilities of each level of government.

Policy Action	State Role	Federal Role
General Leadership	Cooperate with other states to establish a model state policy framework and share resources.	Reauthorize and strengthen the federal Toxic Substances Control Act, while funding state programs.
Close the Safety Gap	Identify chemicals of high concern based on existing lists and select priority chemicals for early action. Restrict specific uses of priority chemicals in products when safer alternatives are available, effective and affordable.	Categorize all existing chemicals by level of concern based on their inherent properties; update regularly with latest science. Restrict use or production of chemicals of concern when safer alternatives are available or when unsafe exposures exist.
Close the Data Gap	Use and publicize existing data and published lists of chemicals. Require reporting on uses of priority chemicals in products by product manufacturers.	Fund research and analysis of all potential inherent properties of concern for existing chemicals. Require reporting on chemicals' inherent properties of concern by chemical manufacturers.
Close the Technology Gap	Develop capacity to assess and promote safer alternatives to priority chemicals in products. Invest R&D funds in green economic development, e.g. sustainable biobased plastics.	Fund research and development of green chemistry, safer chemicals and clean technology. Award grants to state-based R&D and demonstration projects that promote safer alternatives.

Many of these principles were subsequently included in state legislation introduced by Representative Hannah Pingree, then majority leader of the Maine House of Representatives and now Speaker of the House. This legislation *An Act to Protect Children's health and the Environment from Toxic Chemicals in Toys and Children's Products*<sup>3</sup> was enacted with overwhelming support in our legislature and within a few weeks of the passage of similar legislation in Washington State<sup>4</sup>. Maine agency staff are fielding ongoing requests from other states and jurisdictions about our new comprehensive chemicals policy

<sup>3</sup> <http://www.mainelegislature.org/legis/Statutes/38/title38sec1691.html>

<sup>4</sup> <http://apps.leg.wa.gov/documents/billdocs/2007-08/Pdf/Bills/Session%20Law%202008/2647-S2.SL.pdf>

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statute. In concert with Washington State, Maine staff have provided in-depth information on our respective statutes at the request of a legislative task force in Vermont, and state agency staff in California, Minnesota and Oregon.

With increasingly limited resources the states must and will share information to reduce duplication, enhance efficiency and effectiveness, facilitate collaboration, and build state capacity to identify and promote safer chemicals and products and increase access to high quality and authoritative data, information and assessment methods. For example, recently enacted statutes in both Maine and Connecticut include explicit authorization for those states to participate in an interstate chemicals clearinghouse.

A thoughtful national discussion on TSCA reform is long overdue. We are encouraged by the recent message from Administrator-designate Jackson to EPA employees "More than 30 years after Congress enacted the Toxic Substances Control Act, it is clear that we are not doing an adequate job of assessing and managing the risks of chemicals in consumer products, the workplace and the environment. It is now time to revise and strengthen EPA's chemicals management and risk assessment programs." Maine welcomes robust Congressional discussion on TSCA reform and the opportunity to be a partner in that discussion. We look forward to effective and practical national solutions that will restore confidence in the chemical safety of consumer products, begin to rebuild the U.S. reputation as an international leader in chemicals policy and provide assistance to the states in fulfilling their mandate to protect public health and the environment.



Commissioner David P. Littell

Attachments:  
Maine 2007 Public Law Chapter 643  
Executive Summary Final Report Task Force Safer Chemicals

MAINE GOVERNOR JOHN E. BALDACCIO'S

## Task Force to Promote Safer Chemicals in Consumer Products

### EXECUTIVE SUMMARY: KEY CONCLUSIONS



**There is inadequate federal regulation to assure that consumer products are safe.**

The 1976 federal Toxic Substances and Control Act (ToSCA) was intended to provide a framework for federal regulation of chemicals found to present an unreasonable risk of injury to health or the environment. It was meant to encourage industry to develop adequate data with respect to the effect of chemical substances and mixtures on health and the environment.

The Task Force to Promote Safer Chemicals in Consumer Products agrees with the U.S. Government Accountability Office (GAO) and others that ToSCA does not provide sufficient chemical safety data for public use by consumers, businesses and workers; is inadequate to ensure the safety of chemicals in commerce in the United States; and fails to create incentives to develop safer alternatives. Even consid-

ering ToSCA combined with the federal Occupational Safety and Health Act (OSHA), federal regulation fails to provide health and ecotoxicity information regarding the safety of chemicals that have the potential to harm workers and the public at large.

**There are real concerns regarding pesticides found in consumer products.**

Pesticide products are registered by the EPA for use in the U.S. under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) of 1972, and there are additional requirements for pesticide safety testing and risk assessment under the 1996 Food Quality Protection Act. Nonetheless, shortcomings in the pesticide regulatory process still remain. There are flaws in the testing process for pesticide approval, and not all pesticide-related consumer products are regulated under FIFRA. Furthermore, pesticides must be used exactly as di-

rected on the label in order to prevent unintended human and environmental exposure. Instructions for use, storage and disposal on many product labels are difficult to read and understand, and they are printed in very small type. Improvements in pesticide label requirements are needed.

**The health costs of toxic chemicals in consumer products are significant.**

Toxic chemicals in consumer products present significant risk of adverse health consequences ranging from subtle cognitive development to chronic disease and premature death. The Task Force concludes that substantial human and societal costs of disability, birth defects and disease, including health care, educational and employment-related costs, may be attributable to increasing exposures to toxic chemicals. Reducing or eliminating exposures to these chemicals by shifting to use of



safer alternatives may significantly reduce these costs.

**Businesses want and need better information on the health impacts of chemicals in their workplace and in their products to help them create more sustainable workplaces and safer products.**

Lack of comprehensive and standardized information on the toxicity and ecotoxicity of most chemicals has presented challenges for companies that have developed profitable lines of safer consumer products. Material Safety Data Sheets (MSDS) are the most common available source of chemical information. The primary purpose of an MSDS is to communicate hazards and protective measures to workers, but, in the absence of alternative resources, an MSDS also serves as a major source of information for businesses wishing to produce safer products and institute safer processes. For consumers, an MSDS can provide information on products. Efforts to improve MSDS would benefit many sectors.

**The State of Maine leads by example: "environmentally preferable" is also proving effective and affordable.**

Maine's government agencies are playing a leadership role through purchasing and using safer chemicals in product areas that are commonly used by consumers. These practices have produced cost savings and improved performance. The State should continue to purchase additional environmentally preferable products.

**Growing markets for safer products will encourage innovation and provide economic opportunity for Maine.**

Technological innovation is one of the keys to both the development of safer alternatives to toxic chemicals and to

allowing our companies to maximize the value of Maine's rich natural resource base. Green Chemistry, including the development of bio-based products from Maine agricultural and forest resources, offers the potential for substantial economic growth and job expansion in this state. This innovative

technology will supply a demand that already exists on the part of successful Maine businesses committed to sustainable materials, processes, and products. Becoming preeminent in the field of Green Chemistry is a natural for this state and its businesses.

## Key Recommendations

### Comprehensive Chemicals Policy

- Adopt and publicize a list of chemicals of high and moderate concern, based on inherent properties of concern (such as toxicity, persistence or bioaccumulation), identified on previously published lists by authoritative government or scientific bodies;
- Establish the authority to require consumer product manufacturers to report which chemicals of high and moderate concern are present in their products, in what amounts and for what purpose;
- Develop a publicly accessible (web-based) database of readily available information that informs consumers about the chemicals of high concern identified by the state; which products contain such chemicals; and actions consumers can take to purchase safer alternatives or reduce exposure; and
- Establish the authority to restrict the use of chemicals of high concern in consumer products when safer alternatives are available, effective and affordable.

### Expanded Consumer and Retailer Education

- Secure adequate funding for Board of Pesticides Control for education and outreach, pesticide use tracking, and compliance visits (with mandated IPM requirements) to educational, governmental, commercial and institutional operations
- Expand the amount of information available on MSDS that are provided to state, county, and municipal organizations under the existing authority of the Board of Occupational Safety & Health.

### Maine Innovation Economy Advisory Board

With the State, consider supporting expanded efforts of the University of Maine System and private industry to become leaders in the field of Green Chemistry and the emerging potential of bio-based products.



For Additional information contact the  
Maine Department of Environmental Protection:  
Phone 207-287-7688 • Toll-free 800-452-1942  
Web [www.maine.gov/dep](http://www.maine.gov/dep)



**Public Law**  
123rd Legislature  
Second Regular Session  
**Chapter 643**  
**H.P. 1432 - L.D. 2048**

**An Act To Protect Children's Health and the Environment from Toxic  
Chemicals in Toys and Children's Products**

**Be it enacted by the People of the State of Maine as follows:**

**Sec. 1. 38 MRSA §1609, sub-§10,** as enacted by PL 2007, c. 296, §1, is repealed.

**Sec. 2. 38 MRSA c. 16-D** is enacted to read:

**CHAPTER 16-D**  
**TOXIC CHEMICALS IN CHILDREN'S PRODUCTS**

**§ 1691. Definitions**

As used in this chapter, unless the context otherwise indicates, the following terms have the following meanings.

**1. Alternative.** "Alternative" means a substitute process, product, material, chemical, strategy or combination of these that serves a functionally equivalent purpose to a chemical in a children's product.

**2. Chemical.** "Chemical" means a substance with a distinct molecular composition or a group of structurally related substances and includes the breakdown products of the substance or substances that form through decomposition, degradation or metabolism.

**3. Chemical of high concern.** "Chemical of high concern" means a chemical identified by the department pursuant to section 1693.

**4. Chemical of low concern.** "Chemical of low concern" means a chemical for which adequate toxicity and environmental data are available to determine that it is not a chemical of high concern, a chemical of moderate concern or a chemical of unknown concern.

**5. Chemical of moderate concern.** "Chemical of moderate concern" means a chemical identified by an authoritative governmental entity on the basis of credible scientific evidence as being suspected of causing an adverse health or environmental effect listed in section 1693, subsection 1.

**6. Chemical of unknown concern.** "Chemical of unknown concern" means a chemical for which insufficient data are available to classify it as a chemical of high concern, a chemical of moderate concern or a chemical of low concern.

**7. Children's product.** "Children's product" means a consumer product intended for use by children, such as baby products, toys, car seats, personal care products and clothing, and any consumer product containing a chemical of high concern that when used or disposed of will likely

result in a child's or a fetus's being exposed to that chemical.

**8. Consumer product.** "Consumer product" means any item sold for residential or commercial use, including any component parts and packaging. "Consumer product" does not include a food or beverage or an additive to a food or beverage, a tobacco product or paper or forest products or a pesticide regulated by the federal Environmental Protection Agency. "Consumer product" also does not include a drug or biologic regulated by the federal Food and Drug Administration or the packaging of a drug or biologic regulated by the federal Food and Drug Administration if the packaging is regulated by the federal Food and Drug Administration.

**9. Distributor.** "Distributor" means a person who sells consumer products to retail establishments on a wholesale basis.

**10. Manufacturer.** "Manufacturer" means any person who manufactured a final consumer product or whose brand name is affixed to the consumer product. In the case of a consumer product that was imported into the United States, "manufacturer" includes the importer or first domestic distributor of the consumer product if the person who manufactured or assembled the consumer product or whose brand name is affixed to the consumer product does not have a presence in the United States.

**11. Priority chemical.** "Priority chemical" means a chemical identified as such by the commissioner pursuant to section 1694, subsection 1.

**12. Safer alternative.** "Safer alternative" means an alternative that, when compared to a priority chemical that it could replace, would reduce the potential for harm to human health or the environment or that has not been shown to pose the same or greater potential for harm to human health or the environment as that priority chemical.

#### **§ 1692. Declaration of policy**

It is the policy of the State, consistent with its duty to protect the health, safety and welfare of its citizens, to reduce exposure of children and other vulnerable populations to chemicals of high concern by substituting safer alternatives when feasible. By enactment of this chapter, the Legislature confers upon the department the regulatory power to collect information on chemical use and prohibit the sale of children's products containing priority chemicals when safer alternatives are available. The policy represented in this chapter is in furtherance of the toxics use reduction policies under chapter 26.

#### **§ 1693. Identification of chemicals of high concern**

**1. Criteria.** By January 1, 2010, the department, in concurrence with the Department of Health and Human Services, Maine Center for Disease Control and Prevention, shall publish a list of chemicals of high concern. A chemical may be included on the list only if it has been identified by an authoritative governmental entity on the basis of credible scientific evidence as being known as:

- A. A carcinogen, a reproductive or developmental toxicant or an endocrine disruptor;
- B. Persistent, bioaccumulative and toxic; or
- C. Very persistent and very bioaccumulative.

**2. Revisions.** The department may periodically review and revise the list of chemicals of high concern. The department may add chemicals to the list if, in the judgment of the Department of

Health and Human Services, Maine Center for Disease Control and Prevention, the chemical meets one or more of the criteria in subsection 1. The department may remove a chemical from the list of chemicals of high concern based on evidence that the chemical is not present in a children's product or otherwise would not be subject to the requirements of this chapter.

#### **§ 1694. Identification of priority chemicals**

**1. Designation.** The commissioner may designate a chemical of high concern as a priority chemical if the commissioner finds, in concurrence with the Department of Health and Human Services, Maine Center for Disease Control and Prevention:

- A. The chemical has been found through biomonitoring to be present in human blood, including umbilical cord blood, breast milk, urine or other bodily tissues or fluids;
- B. The chemical has been found through sampling and analysis to be present in household dust, indoor air, drinking water or elsewhere in the home environment;
- C. The chemical has been found through monitoring to be present in fish, wildlife or the natural environment;
- D. The chemical is present in a consumer product used or present in the home;
- E. The chemical has been identified as a high production volume chemical by the federal Environmental Protection Agency; or
- F. The sale or use of the chemical or a product containing the chemical has been banned in another state within the United States.

The commissioner shall designate at least 2 priority chemicals by January 1, 2011.

**2. Updates.** The commissioner shall review the list of chemicals of high concern at least every 3 years and may designate additional priority chemicals if the commissioner finds that the chemicals meet one of the criteria listed in subsection 1.

The commissioner shall adopt rules to implement the provisions of this section. Rules adopted pursuant to this section are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.

#### **§ 1695. Disclosure of information on priority chemicals**

**1. Reporting of chemical use.** Not later than 180 days after a priority chemical is identified pursuant to section 1694, a person who is a manufacturer or distributor of a children's product for sale in the State that contains a priority chemical shall notify the department in writing unless waived by the commissioner pursuant to this section or exempt from this chapter pursuant to section 1697. This written notice must identify the children's product, the number of units sold or distributed for sale in the State or nationally, the priority chemical or chemicals contained in the children's product, the amount of such chemicals in each unit of children's product and the intended purpose of the chemicals in the children's product.

**2. Supplemental information.** The manufacturer or distributor of a children's product that contains a priority chemical shall provide the following additional information if requested by the department:

A. Information on the likelihood that the chemical will be released from the children's product to the environment during the children's product's life cycle and the extent to which users of the children's product are likely to be exposed to the chemical;

B. Information on the extent to which the chemical is present in the environment or human body; and

C. An assessment of the availability, cost, feasibility and performance, including potential for harm to human health and the environment, of alternatives to the priority chemical and the reason the priority chemical is used in the manufacture of the children's product in lieu of identified alternatives. If an assessment acceptable to the department is not timely submitted, the department may assess a fee on the manufacturer or distributor to cover the costs to prepare an independent report on the availability of safer alternatives by a contractor of the department's choice.

The manufacturer or distributor of a children's product that contains a priority chemical may provide additional information to the department regarding the potential for harm to human health and the environment from specific uses of the priority chemical.

**3. Waiver of reporting; fee; extension of deadline.** The commissioner may waive all or part of the notification requirement under subsection 1 for one or more specified uses of a priority chemical if the commissioner determines that substantially equivalent information is already publicly available, that the information is not needed for the purposes of this chapter or that the specified use or uses are minor in volume. The department may assess a fee payable by the manufacturer or distributor upon submission of the notification to cover the department's reasonable costs in managing the information collected. The department may extend the deadline for submission of the information required under subsection 1 for one or more specified uses of a priority chemical in a children's product if it determines that more time is needed by the manufacturer or distributor to comply with the submission requirement or if the information is not needed at that time.

**4. Rulemaking to determine fees.** If the department assesses a fee pursuant to subsection 2, paragraph C or subsection 3, the department shall determine the appropriate fee through major substantive rulemaking, as defined in Title 5, chapter 375, subchapter 2-A.

## **§ 1696. Sales prohibition; rules; safer alternatives to priority chemicals**

**1. Authority.** The board may adopt rules prohibiting the manufacture, sale or distribution in the State of a children's product containing a priority chemical if the board finds, after consideration of information filed under section 1695 and other relevant information submitted to or obtained by the board, that:

A. Distribution of the children's product directly or indirectly exposes children and vulnerable populations to the priority chemical; and

B. One or more safer alternatives to the priority chemical are available at a comparable cost.

If there are several available safer alternatives to a priority chemical, the board may prohibit the sale of children's products that do not contain the safer alternative that is least toxic to human health or least harmful to the environment.

A rule established pursuant to this subsection must specify the effective date of the prohibition, which may not be sooner than 12 months after notice of the proposed rule is published as required under Title

5, section 8053, subsection 5. Rules adopted pursuant to this subsection are major substantive rules as defined in Title 5, chapter 375, subchapter 2-A.

**2. Alternatives assessment; presumptions.** For the purpose of determining whether a safer alternative is available under subsection 1, paragraph B, the board may, in the absence of persuasive evidence to the contrary:

- A. Presume that an alternative is a safer alternative if the alternative is not a chemical of high concern;
- B. Presume that a safer alternative is available if the sale of the children's product containing the priority chemical has been banned by another state within the United States;
- C. Presume that a safer alternative is available if the children's product containing the priority chemical is an item of apparel or a novelty; and
- D. Presume that a safer alternative is available if the alternative is sold in the United States.

**3. Implementation.** No later than 180 days prior to the effective date of a prohibition adopted under subsection 1, the manufacturer or distributor of a children's product that contains the priority chemical and that is subject to the prohibition at the time of adoption shall file a compliance plan with the commissioner or seek a waiver under subsection 5. A compliance plan must:

- A. Identify the children's product that contains the priority chemical;
- B. Specify whether compliance will be achieved by discontinuing the sale of the children's product in the State or by substituting a safer alternative in the product; and
- C. If compliance is achieved by substitution of a safer alternative in the product, identify the safer alternative and the timetable for substitution.

**4. Responsibility.** A manufacturer or distributor of a children's product containing a priority chemical shall notify persons that offer the product for sale or distribution in the State of the requirements of this chapter.

**5. Waiver for specific uses.** The manufacturer or distributor of a children's product that contains a priority chemical and that is subject to a prohibition adopted pursuant to subsection 1 may apply to the commissioner for a waiver for one or more specific uses of the priority chemical. The waiver application must, at a minimum:

- A. Identify the specific children's product use or uses for which the waiver is sought;
- B. Identify the alternatives considered for substitution of the priority chemical;
- C. Explain the basis for concluding that the use of an alternative is not feasible; and
- D. Identify the steps that have and will be taken to minimize the use of the priority chemical.

The commissioner may grant a waiver with or without conditions upon finding that there is a need for the children's product in which the priority chemical is used and there are no technically or economically feasible alternatives for the use of the priority chemical in the children's product. Waivers may be granted for a term not to exceed 5 years and may be renewed for one or more additional 5-year terms upon written application demonstrating that technically or economically

feasible alternatives remain unavailable. The commissioner shall deny or grant waiver requests within 60 days after receipt of a completed waiver application.

**6. Petitions.** If rulemaking to prohibit the sale of a children's product containing a priority chemical is initiated by petition under Title 5, section 8055, the department shall consider the information submitted in support of the petition but is not obligated to conduct a search of other sources of information on the chemical or its uses. The petitioner bears the burden of demonstrating that the criteria under subsection 1 for adoption of rules are met.

#### **§ 1697. Applicability**

**1. Used products.** This chapter does not apply to chemicals in used products.

**2. Industry.** The requirements of this chapter do not apply to priority chemicals used in or for industry or manufacturing, including chemicals processed or otherwise used in or for industrial or manufacturing processes.

**3. Transportation.** The requirements of this chapter do not apply to motor vehicles as defined in Title 29-A, section 101, subsection 42 or watercraft as defined in Title 12, section 13001, subsection 28 or their component parts, except that the use of priority chemicals in detachable car seats is not exempt.

**4. Combustion.** The requirements of this chapter do not apply to priority chemicals generated solely as combustion by-products or that are present in combustible fuels.

**5. Retailers.** A retailer is exempt from the requirements of this chapter unless that retailer knowingly sells a children's product containing a priority chemical after the effective date of its prohibition for which that retailer has received prior notification from a manufacturer, distributor or the State.

**6. Mercury-added products.** The commissioner may designate mercury or a mercury compound as a priority chemical for the purpose of adopting rules under section 1696 to prohibit the manufacture, sale or distribution of a mercury-added product that is not regulated under section 1661-C or 1667 prior to the effective date of this section. The disclosure requirements of section 1695 do not apply to the manufacturer or distributor of a children's product that contains the designated mercury or mercury compound if the manufacturer has complied with the notification requirement under section 1661-A.

**7. Telecommunications.** The disclosure requirements of section 1695 do not apply to a service provider whose name appears on a telecommunications device unless the service provider is the actual manufacturer of the device. As used in this subsection, "service provider" has the meaning set out in Title 35-A, section 7107, subsection 1, paragraph C.

**8. Food and beverage packaging.** A container or packaging for a food or beverage product is exempt from the requirements of this chapter, unless that product is intentionally marketed or intended for the use of children under 3 years of age.

#### **§ 1698. Interstate clearinghouse to promote safer chemicals**

The department is authorized to participate in an interstate clearinghouse to promote safer chemicals in consumer products in cooperation with other states and governmental entities. The

department may cooperate with the interstate clearinghouse to classify existing chemicals in commerce into one of 4 categories: chemicals of high concern, chemicals of moderate concern, chemicals of unknown concern and chemicals of low concern.

The department may also cooperate with the interstate clearinghouse in order to organize and manage available data on chemicals, including information on uses, hazards and environmental concerns; to produce and inventory information on safer alternatives to specific uses of chemicals of concern and on model policies and programs; to provide technical assistance to businesses and consumers related to safer chemicals; and to undertake other activities in support of state programs to promote safer chemicals.

#### **§ 1699. Education and assistance**

As resources allow, the department shall develop a program to educate and assist consumers and retailers in identifying children's products that may contain priority chemicals.

#### **§ 1699-A. Enforcement and implementation**

**1. Failure to provide notice.** A children's product containing a priority chemical may not be sold, offered for sale or distributed for sale in this State if the manufacturer or distributor has failed to provide information required under section 1695 by the date required in that section. The commissioner shall exempt a children's product from this prohibition if, in the commissioner's judgment, the lack of availability of the children's product could pose an unreasonable risk to public health, safety or welfare.

**2. Certificate of compliance.** If there are grounds to suspect that a children's product is being offered for sale in violation of this chapter, the department may request the manufacturer or distributor of the product to provide a certificate of compliance with the provisions of this chapter. Within 10 days of receipt of a request under this subsection, the manufacturer or distributor shall:

- A. Provide the department with the certificate attesting that the children's product does not contain the priority chemical; or
- B. Notify persons who sell the product in this State that the sale of the children's product is prohibited and provide the department with a list of the names and addresses of those notified.

#### **§ 1699-B. Donations to the State**

The department, through the Governor, may accept donations, grants and other funds to carry out the purposes of this chapter.

**Sec. 3. Initial list of chemicals of high concern.** By January 1, 2010, the Department of Environmental Protection, in consultation with the Department of Health and Human Services, Maine Center for Disease Control and Prevention, shall identify an initial list of chemicals of high concern in accordance with the Maine Revised Statutes, Title 38, section 1693. In developing the list, the departments may consider:

- 1. Chemicals identified as "Group 1 carcinogens" or "Group 2A carcinogens" by the World Health Organization, International Agency for Research on Cancer;
- 2. Chemicals identified as "known to be a human carcinogen" and "reasonably anticipated to be a human carcinogen" by the Secretary of the United States Department of Health and Human Services pursuant to the Public Health Service Act, 42 United States Code, Section 241(b)(4), as amended;



3. Chemicals identified as “Group A carcinogens” or “Group B carcinogens” by the United States Environmental Protection Agency;
4. Chemicals identified as reproductive or developmental toxicants by:
  - A. The United States Department of Health and Human Services, National Toxicology Program, Center for the Evaluation of Risks to Human Reproduction; and
  - B. The California Environmental Protection Agency, Office of Environmental Health Hazard Assessment pursuant to the California Health and Safety Code, Safe Drinking Water and Toxic Enforcement Act of 1986, Chapter 6.6, Section 25249.8;
5. Chemicals identified as known or likely endocrine disruptors through screening or testing conducted in accordance with protocols developed by the United States Environmental Protection Agency pursuant to the Federal Food, Drug and Cosmetic Act, 21 United States Code, 346a(p), as amended by the federal Food Quality Protection Act (Public Law 104-170) or the federal Safe Drinking Water Act, 42 United States Code, Section 300j-17;
6. Chemicals listed on the basis of endocrine-disrupting properties in Annex XIV, List of Substances Subject to Authorisation, Regulation (EC) No 1907/2006 of the European Parliament concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals;
7. Persistent, bioaccumulative and toxic chemicals identified by:
  - A. The State of Washington Department of Ecology in Washington Administrative Code, Chapter 173-333; or
  - B. The United States Environmental Protection Agency in 40 Code of Federal Regulations, Part 372; and
8. A very persistent, very bioaccumulative chemical listed in Annex XIV, List of Substances Subject to Authorisation, Regulation (EC) No 1907/2006 of the European Parliament concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals.

**Sec. 4. Stakeholder group convened.** Prior to designation of a priority chemical pursuant to the Maine Revised Statutes, Title 38, section 1694, subsection 1, the Commissioner of Environmental Protection shall convene a stakeholder group that includes representatives of consumer product manufacturers, chemical manufacturers, retailers, trade associations, nonprofit health organizations, business and environmental groups and other affected parties and shall invite the participation of independent experts with relevant experience with chemicals. The commissioner shall seek recommendations from the group on:

1. Development of a protocol to be utilized for the designation of priority chemicals;
2. The responsibilities, activities and proposed rules necessary to implement Title 38, chapter 16-D; and
3. Stakeholder issues of concern.



# European-American Business Council

*"Investment ~ Innovation ~ Integration"*

Testimony of Stuart E. Eizenstat  
Co-Chairman, European American Business Council

Submitted for the Record

Committee on Energy & Commerce,  
Subcommittee on Commerce, Trade, and Consumer Protection

Revisiting the Toxic Substances Control Act of 1976

February 26, 2009

Chairman Rush, Ranking Member Radanovich, and Members of the Subcommittee, I am pleased to submit this testimony for the record in the Subcommittee's hearing examining potential changes to the Toxic Substances Control Act of 1976. I submit this testimony in my capacity as Co-Chairman of the European American Business Council ("EABC"), a private sector group that was created nearly twenty years ago to support unrestricted trade and investment between the United States and the European Community. The European and American companies of the EABC promote robust governmental, regulatory, and policy cooperation across the Atlantic. I served as the U.S. Ambassador to the European Union and held a number of other senior positions in the Clinton Administration, which brought me into close contact with the European Union's regulatory approach. I have continued to follow these regulatory issues since leaving the Administration, including by serving as Co-Chairman of EABC.

As Congress considers changes to the Toxic Substances Control Act and more general reform of the United States' policy on chemical substance regulation, I urge you to consider the lessons I learned – both positive and negative – from the EU's adoption of Regulation (EC) 1907/2006 on the Registration, Evaluation, Authorization, and Restriction of Chemicals, known simply as "REACH." REACH is perhaps the most ambitious and sweeping attempt to modernize a government's evaluation and control of chemicals. The REACH regulation was the product of more than eight years of debate, consultations, and legislative process.

Although the goal was to construct a regulatory framework that responds to public concerns about human health and environment, and simultaneously improve the competitiveness of the European chemicals industry, the implementation of REACH has left many business leaders, government regulators, and public interest organizations wondering about the

Brussels & Washington DC  
[www.eabc.org](http://www.eabc.org)

workability of the EU's ambitious project. I would like to highlight for Congress some of the more salient lessons to emerge from the REACH process.

**Scope.** REACH applies to virtually all goods that are manufactured or imported for sale into Europe and contain or include chemicals. Although this broad scale and general applicability was touted as a fair and unbiased way to ensure consistent regulation, it has already produced some unintended consequences. For example, the financial industry was surprised to learn that it was covered by REACH merely because it trades in gold. Even life-critical medical and humanitarian products providers have found that certain substances in human blood products may trigger REACH applicability. The inclusion of some monomers of imported polymers and of virtually all substances in imported mixtures has resulted in regulatory challenges for importers and has ended up before the EU courts.

Likewise, REACH's broad application to all entities in the production chain – from manufacturers of raw chemicals to retailers of finished goods – has led to confusion about which entities are required to register with the European Chemicals Agency. Although the agency expected about 30,000 registrations, there are currently more than 2.7 million pre-registrations on file, covering 65,000 companies and 145,000 chemical substances. It is highly likely that many of these companies will have little role in the REACH process other than to pass information through the supply chain. The mass pre-registration will also make it very difficult for companies to complete their registration dossiers and for regulators to target those companies with a truly important role to play in REACH.

**Authorization.** The authorization process was expected to be one of the key innovations of REACH. The process essentially requires chemical producers to prove that the risk from a particular substance is adequately controlled, or that it cannot be substituted by use of another product. The early phases of implementation of the authorization process, however, have revealed significant problems. First, the listing of candidate chemicals in the authorization process can have very negative market effects if the listing is mischaracterized, as it has been by some, as a scientific conclusion about the safety of a product. Second, the implementation of the substitution criteria may be very problematic because it places regulators in the position of picking winners and losers in the marketplace, opening the possibility for pressure from economic and political interests without regard for scientific conclusions. This threatens to take the EU into endless litigation and international disputes concerning the relative weight or strength of scientific conclusions reached for similarly situated chemicals. Third, assessing whether the risk of a particular substance is adequately controlled and whether it can be substituted by use of another product is extremely costly for both industry and regulators. These anticipated costs are likely to result in unjustified market withdrawals and in effect preventing regulators from targeting priority substances.

**Consistency.** REACH applies "horizontally" across all industries that use chemical substances. Yet the EU still has in place legacy regulations that operate "vertically" within individual industries – be it toys, cosmetics, or electronic equipment. The Directive on the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (RoHS) is one example of many such vertical regulations that overlap REACH. Both REACH and the legacy programs can be used to restrict chemical products, but the differences in process and standards between REACH and legacy regulations like RoHS can often lead to

divergent results, where a chemical may be restricted in electronic products but not in applications of the chemical in other industries. Of even greater concern, the standards may vary across different regulatory regimes, leaving the EU open to criticism for arbitrary decision making, inconsistent with its own scientific conclusions.

We have also already seen inconsistency between legacy cosmetic regulation in the EU and the new regime under REACH threatening terrible market disruption and discriminatory treatment against cosmetic importers, as compared to domestic European manufacturers. There are other examples.

**Science.** United States policy on chemical regulation has at its core the fundamental principle of adherence to sound scientific conclusions, free from political or other outside influences. In contrast, the EU has often been criticized for resorting to a broad application of the precautionary principle, under which incomplete data identifying potential risks can trigger a ban or restriction in response to strong political pressure. It is critically important that the United States not replicate this approach. Companies should not fear that their products risk being banned to satisfy politically driven precautionary conclusions. In the lead up to REACH, we have unfortunately seen instances in which the EU has ignored the conclusions of its own scientific experts or implemented restrictions in advance of conducting a scientific review. It is essential that the United States maintain its policy of following sound scientific conclusions.

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I applaud Congress for reviewing these important issues. Without action, the United States risks becoming a secondary player with antiquated laws for chemical substance regulation. We risk ceding our leadership role in this area to those who have proposed new and comprehensive measures, such as Europe, even if some aspects of these measures are flawed. I urge Congress to reclaim the leadership role and help promote fair and science-based regulatory decision making around the world.

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**TESTIMONY OF THE  
PHYSICIANS COMMITTEE FOR RESPONSIBLE MEDICINE  
AND  
PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS**

**BEFORE THE  
HOUSE COMMITTEE ON ENERGY AND COMMERCE  
SUBCOMMITTEE ON COMMERCE, TRADE AND CONSUMER PROTECTION**

**ON THE  
TOXIC SUBSTANCES CONTROL ACT**

**FEBRUARY 26, 2009**

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## I. Introduction

The current legislation authorizing the EPA to regulate chemicals, the Toxic Substances Control Act (TSCA), enacted in 1976, has many shortcomings that have been extensively documented and have lead to a chorus of calls for TSCA reform. We must, however, also be sure to reform the science that underlies these regulations—namely, the way in which toxicity testing is conducted. Done right, TSCA reform can leave the US with a strong program of chemical assessment and management consistent with the National Academy of Sciences recent landmark report detailing a vision and strategy for toxicity testing in the 21st Century (NRC, 2007). Pursued unwisely, TSCA reform could be the latest in a string of disastrous and ineffective chemical regulation programs that wastes time, money, and hundreds of thousands of animals while leaving human health and the environment unprotected.<sup>1</sup> Our testimony focuses on a critical aspect of this reform: updating the science behind toxicity data used to make regulatory decisions.

Under TSCA, the marketing, sale and distribution of a chemical do not require prior safety testing. Only if there is an after-market indication that a chemical may be toxic does the EPA become involved and request information regarding potential toxicity. One of the major issues driving TSCA reform is the desire to reverse this process and shift the burden of proof of reasonable safety to the manufacturer prior to marketing. While this is a desirable goal, it presents a significant logistical and scientific challenge. Not only will specific safety testing be required for all chemicals under development, but a back-log of tens of thousands of chemicals will also require testing. To review all of the chemicals in the TSCA Inventory over 10 years, the EPA would have to review approximately 6,000 – 8,000 chemicals each year (approximately 20 each day), at heavy expense to the taxpayer. Currently, the EPA's Office of Pollution, Prevention, and Toxics—the office that would be charged with implementing this legislation—reviews about 1000 pre-manufacture notices<sup>2</sup> each year.

The current toxicity testing paradigm used by the EPA and other regulatory agencies is largely based on experiments in animals, particularly rodents, and uses methods that were developed as long ago as the 1930's and 40's. These tests are time-consuming, expensive and use thousands of animals. For example, a single two-generation reproductive toxicity study takes a minimum of two years, \$380,000, and 2,600 rats to perform. Generation of data for all of the existing chemicals using current toxicology tests is not feasible within a reasonable time-frame (it is more likely to take several decades); there are simply not enough laboratories in the world to conduct all the testing required. In addition, the current testing paradigm has a

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<sup>1</sup> See, for example, the June 17, 1999 proceeding of the Hearing Before the Subcommittee on Energy and the Environment of the House Committee on Science (106<sup>th</sup> Congress, Serial No. 106-18) on the EPA's High Production Volume (HPV) Chemical Testing Program at which the authors' organizations, PETA and PCRM, testified.

<sup>2</sup> <http://www.epa.gov/oppt/ar/2007-2008/reviewnewchem/index.htm>

poor record in predicting effects in humans (Knight and Bailey 2006a & b; Ennever and Lave 2003) and an even poorer record in leading to actual regulation of dangerous chemicals (PETA 2006).

Many scientific and practical factors contribute to the poor predictivity and performance of animal testing, including the fact that, in order to see an effect, animals are usually given extremely high doses of chemicals, and results are often complicated by side-effects from the large doses. In addition, and perhaps most significantly, results from non-human animals are often misleading due to biochemical and metabolic differences between humans and other animals. Consequently, regulators are often challenged to determine the real relevance of test results to humans—and this uncertainty leads to more testing and further delays in taking regulatory action.

Toxicity assessment needs are increasingly outpacing the capacity of toxicity testing laboratories. Animal experiments take anywhere from months to years and tens of thousands to millions of dollars to perform. It is simply not possible to test all the chemicals, ingredients, products, mixtures, and environmental contaminants to which humans are exposed using animal-based methods—the time, money, and laboratory space do not exist.

In light of these concerns, the Environmental Protection Agency (EPA) realized that the current toxicity testing paradigm is in urgent need of overhaul and contracted the National Academy of Sciences' National Research Council to assess the current system and recommend actions to improve it. The NRC Committee on Toxicity Testing and Assessment of Environmental Agents (NRC Committee)<sup>3</sup> found that the current system is not predictive or practical—in terms of time, cost, animals, or testing needs—and set out to create a vision for the future of toxicity testing and a strategy that, once implemented, would improve the depth and breadth of toxicology and its usefulness as a predictive science (Edwards and Preston 2008). *Toxicity Testing in the 21<sup>st</sup> Century: A Vision and Strategy* outlines that vision and how to implement it (NRC 2007). The NRC Committee envisions an iterative process of chemical characterization, toxicity testing, and dose-response and extrapolation modeling informed by population-based data and human exposure information. The report calls for the development of a suite of human-based *in vitro*<sup>4</sup> cell and tissue assays instead of whole-animal tests for hazard assessment and regulatory decision-making.

Such a biology-based approach could also address currently intractable problems such as toxic effects of chemical mixtures and nanoparticles, synergistic effects of chemicals, susceptibility of sensitive sub-populations, sensitivity at different life stages, gene-environment interactions, the need to test the effects of chemicals over wider dose ranges, and the effects of chemicals at very low, environmentally relevant concentrations (Gibb 2008). The conclusion of the report is that a

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

<sup>4</sup> *In vitro* refers to assays that take place in a culture dish or test tube.

reduced reliance on whole-animal testing leads to a more predictive and efficient toxicity testing paradigm, leading to increased protections for people and the environment.

## II. The Foundation for a Paradigm Shift is Underway

While much of the necessary technology is in use today (Anderson 2009), accomplishing the NRC vision in a timely fashion will take a concerted effort and an influx of resources. Spurred in part by the NRC report, work is underway at several different government agencies and private research centers to create the knowledge base necessary. Work under way at the National Institutes of Health's Chemical Genomics Center (NCGC), the National Toxicology Program, and the EPA's Office of Research and Development (ToxCast Program) has been formalized into a working partnership to share funds and resources.<sup>5</sup> High-throughput systems capable of running hundreds of chemicals at many different doses through suites of different cell-based and biochemical assays are being used to generate information predictive of the modes of action of test chemicals, to create clusters of chemicals with similar mechanisms of action, and to prioritize chemicals for immediate investigation or regulation.<sup>6</sup>

Currently, these methods are being used to prioritize chemicals for further study or as a first "tier" in order to characterize the potential mechanisms of action of test chemicals—as has been done at Harvard with 50 different nanomaterials (Shaw et al. 2008). *In vivo* testing need not be conducted on those agents that do not show the potential to perturb a toxicity pathway and initiate the chain of events leading to an apical<sup>7</sup> effect. These analyses are also being used to elucidate the major pathways by which environmental agents cause toxic effects. A refined suite of assays that detect perturbations of these pathways will form the basis of the new toxicity testing paradigm.

Stakeholders from various backgrounds, including industry, government, and non-governmental organizations (NGOs), have formed partnerships to conduct research projects and other activities with the aim of making toxicity testing more efficient and reducing animal use, mainly through the use of tiered (Becker et al. 2007; Sullivan et al. 2007) or integrated (Hoffmann et al. 2008) testing strategies. For example, in November of 2007, the EPA, through the Organisation for

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<sup>5</sup> Memorandum of Understanding on High Throughput Screening, Toxicity Pathway Profiling, and Biological Interpretation of Findings between the US DHHS NIH NIEHS/NTP and the US DHHS NIH NHGRI NCGS and the US EPA ORD. Signed 30 January 2008. Available at: <http://www.epa.gov/comptox/articles/files/ntpncgcecpamou.pdf>. Accessed 12 December 2008.

<sup>6</sup> This year scientists at the NCGC published results of a mechanism-of-action study that used 26 assays in 13 different cell types to cluster 1,408 compounds given at 14 different concentrations according to mechanism of action. The results compared favorably with current information about the chemicals toxic profiles, and provide support for such approaches. Huang, R et al. 2008. Characterization of diversity in toxicity mechanism using in vitro cytotoxicity assays in quantitative high throughput screening. *Chem Res Toxicol* 21:659-667.

<sup>7</sup> In this context, an apical effect is a toxic effect that is the final, visible result of a chemical exposure, such as a tumor, lesion, or neurological symptom. Current animal tests look for apical endpoints, but the NRC vision would shift this emphasis to the identification of chemical-mediated precursor events, such as gene induction or cytokine regulation, that will eventually result in a toxic effect. The NRC vision calls these events perturbations.



Economic Co-operation and Development (OECD), hosted a workshop on Integrated Approaches to Testing and Assessment, which sought to establish recommendations on how to use nontraditional test data, data from similar chemicals, *in vitro* data, and simulation data from QSAR modeling<sup>8</sup> to prioritize and characterize the hazards of pesticides and industrial chemicals.<sup>9</sup>

A workshop sponsored by the International Life Sciences Institute Health and Environmental Sciences Institute in 2002 to streamline the testing process for pesticides (Carmichael et al. 2006) resulted in a series of publications outlining a comprehensive, tiered approach that integrates key studies with existing knowledge on the chemistry, toxicology, and actual human exposure scenarios of a chemical. Complicated or lengthy animal studies are only conducted if triggered by results of initial studies (Doe et al. 2006). When implemented, such a tiered approach will reduce the number of animals killed per registered pesticide by 2,500 or more (Cooper et al. 2006). The EPA's Office of Pesticide Programs and the OECD are both currently working to implement these recommendations.<sup>10</sup>

Some simple strategies for increasing the efficiency of testing programs, and thereby reducing the number of animals killed, were put into the EPA's High Production Volume Challenge program in 1999 as a result of input from animal protection organizations. During the program, the EPA and NGOs codified further principles that minimized the testing conducted (Sandusky et al. 2006). The major principles include: 1) combining protocols that assess the same endpoints; 2) identifying chemical categories that allows extrapolation of results from related chemicals; 3) eliminating testing requirements for classes of chemicals with known toxicity (e.g. acids, corrosives); 4) identifying chemicals for which certain testing is not feasible (i.e. highly reactive or insoluble materials), and 5) applying of weight-of-evidence approaches.

Outside the United States, the development of alternatives has progressed at a quicker pace, primarily due to legislative deadlines set by the European Union Cosmetics Directive and the impending European Registration, Evaluation, Authorization and Restriction of Chemical Substances (REACH) legislation (EC 2006). Amendments to the Cosmetics directives prohibit the use of animals for cosmetics testing beginning in 2009 (EC 2003). Consequently *in vitro* methods have been developed for most of the required endpoints for cosmetics. REACH is an overarching program that will require the toxicity characterization of all chemicals manufactured or sold in the European Union. The amount of testing a chemical undergoes is proportional to its annual production or import amount. Because of the sheer magnitude of this program, as it will be with any revision of TSCA that contains the pre-emptive elements of REACH, it is physically impossible to carry out complete batteries of animal tests for every chemical; therefore, REACH incorporates several alternative strategies for risk assessment. In addition to the incorporation of

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<sup>8</sup> Structure-Activity Relationship, or SAR, modeling refers to computer models built to correlate chemical structure to some resulting activity, such as receptor binding. Quantitative SAR, or QSAR, does this quantitatively.

<sup>9</sup> [http://www.epa.gov/NHEERL/ontheroad/washington\\_dc.html#6](http://www.epa.gov/NHEERL/ontheroad/washington_dc.html#6)

<sup>10</sup> See <http://www.epa.gov/pesticides/ppdc/testing/index.html>

non-animal testing methods, REACH includes:

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

To facilitate regulatory application of these new methods, the European Union has funded a facility whose sole purpose is the validation of alternative methods, the European Center for the Validation of Alternative Methods (ECVAM). ECVAM receives approximately 25 million € per year from the E.U. Directorate General on Research (ICCVAM 2006). ECVAM is a division of the EC's Joint Research Council's Institute for Health and Consumer Protection (IHCP) and is housed in IHCP facilities in Ispra, Italy. It has 60 staff members, roughly half of whom work directly in laboratories. ECVAM is currently involved in the evaluation of 170 methods (Hartung 2007).

There is no equivalent effort in the United States. The only entity dealing with the validation of alternative methods in the United States is a voluntary committee, the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM). ICCVAM does not receive major funding, lacks a scientific staff or facilities, and has been repeatedly documented as obstructing the implementation of non-animal testing methods (Gaul 2008, PETA 2007). The European Commission also funds directives for special applications of alternative methods to specific areas of toxicity. These are interdisciplinary projects involving the government, academia and industry, with focused goals. For example the ACuteTox and ReProTect projects are developing non-animal methods for acute toxicity and reproductive toxicity, respectively.

### III. Any Effective Revision of TSCA Must Include this Paradigm Shift

The strategies outlined above all lead to a decreased reliance on animal testing and collectively help move toxicity testing into the future. However, as the NRC report describes, a bird's-eye-view is needed to create a comprehensive program, coupled with a substantial commitment of resources, along with the support of lawmakers, regulators, industry, environmental groups, and the general public. An Integrated Toxicology Program, along with the underpinning experimental approach, has been proposed by two EPA scientists this year (Edwards and Preston, 2008). Interpretive tools and policy mechanisms to deal with new kinds of hazard data are required and must be developed along with the science. All of this requires the support and investment of all stakeholders and Congress.

The fact that implementation of this science-based approach will take some time and effort should not be used as a rationale to postpone its development. Is it worth the effort to achieve? Why not just go ahead with the approach we have been using since we need protection now? Enacting legislation based on the current approach to toxicity testing will only maintain the status quo, leading to the expenditure of vast resources and years of testing new and existing chemicals that will continue to , generate data of dubious value for protecting humans or the

environment. If long-term protection of human and environmental health is the goal, then the NRC approach is the only option.

#### **IV. Recommendations for TSCA Reform**

For any legislative reform of TSCA to be effective in generating data that could be used for the protection of human health or the environment in general, or any vulnerable sub-population in particular, that legislation would have to include the paradigm shift described in the NRC report. For example, application of the technology outlined in the NRC report will also allow for the assessment of low-doses and mixtures (Anderson 2009), which is not currently possible under the existing paradigm. Outlined below are some suggested changes to the existing KSCA that would align the Act with this goal.

##### **A. Mandate the release and use of existing data**

1. Require public availability of all existing information on TSCA Inventory chemicals, as well as information from any other chemical testing programs (i.e., the High Production Volume Challenge Program, the Voluntary Children's Chemical Evaluation Program, various NTP programs such as the Center for the Evaluation of Risks to Human Reproduction and the Rodent Carcinogenicity Bioassay program).
2. Mandate relevant data-sharing between companies (with fair compensation). This is a stipulation of the REACH legislation, and the KSCA should be consistent with REACH where appropriate.
3. Require coordination between the U.S. EPA and the regulatory agencies of other regions (e.g. Health Canada, which is currently reviewing the safety of 23,000 chemicals on its Domestic Substance List; the EU's REACH program, which aims to generate a wide array of toxicity data for approximately 30,000 chemicals; the Danish EPA's database of QSAR evaluations of toxicity for approximately 47,000 chemicals).
4. These data should be collected in a comprehensive, publicly available database prior to the initiation of any further testing.

##### **B. Explicit incorporation of the toxicity testing paradigm outlined by the NRC**

1. Expressly prohibit the duplication of animal studies or further testing on animals if another scientifically satisfactory method is reasonably and practicably available and stipulate manufacturer and regulator education on available alternatives. New legislation should also embrace the REACH maxim of animal testing as a last resort for the collection of hazard data.
2. As in REACH, encourage grouping of similar chemicals into scientifically appropriate categories to enable data gaps to be filled by read-across and to limit new testing to representative chemicals.
3. As in REACH, require that companies form consortia for the purposes of data sharing and the coordination of any new testing.
4. A significant amount of funding should be stipulated for alternative methods development, translation, and validation. An estimate of the investment required to achieve the NRC vision in 10 – 15 years is \$100 – \$200 million per year, much of which is already being invested by relevant industry and the U.S. and European governments, albeit in a non-coordinated fashion (NRC 2007; Rowan 2008; Collins et al. 2008).

Revised TSCA legislation should therefore stipulate a minimum of \$50 million per year additional to be invested in alternative methods development.

5. The revised TSCA should provide for a public review process before new animal testing takes place.

#### **C. Incorporation of intelligent testing strategies**

1. Hazard data should be collected as part of a chemical-specific design strategy that takes into account physiochemical properties, existing *in vitro*, *in vivo*, and *in silico* data, and real or potential exposure information for each chemical—a minimum list of initial tests or hazard data to be generated should not be prescribed in legislation. This is consistent with national and international chemical policies that emphasize intelligent toxicology.
2. Chemical testing should be performed in a stepwise fashion; data requirements should be tiered to allow the most expeditious application of test methods to a given chemical.
3. The EPA should be given flexibility to determine quantitative risk estimates, toxic effects and/or endpoints of concern, and necessary evaluations should be conducted on a case-by-case basis. Hazard and risk assessments should be made based on any relevant data using a weight-of-evidence approach; hence, specific references to animal-based risk measures (BMD1, LD50, etc) should be removed. This would also allow for greater test method flexibility.
4. Language requesting “reasonable certainty of no harm” is scientifically unsupportable. Suggested alternative language: “weight of evidence suggests that the chemical poses no significant risk to human health (or the environment) under reasonably anticipated conditions of use.”

#### **Summary and Conclusion**

Protecting human health and the environment is the critical goal of effective chemical regulation. In order to achieve this goal, it is necessary to reform chemical testing methods along with policy. The current toxicity testing paradigm relies on animal testing and is slow, inaccurate, open to uncertainty and manipulation, and does not adequately protect human health. Reform of TSCA should not only modernize policy, but modernize the science that supports that policy. The approach mentioned above, and described in detail in the NRC report, will “produce more relevant data on which to base risk management decisions about chemical hazards and greatly expand the numbers of chemicals that can be tested. These improvements can fulfill the vision of better protecting people from the risks posed by chemicals in our environment” (Krewski 2008).

This approach has only benefits: an increased ability to regulate unsafe chemicals, resulting in improved human and environmental health, and a decreased reliance on the use of animals in the process of safety testing. Many of the necessary tools already exist, and the NRC has provided a roadmap for achieving the rest of what remains to be accomplished in order to create an effective and protective toxicity program. The time to move forward is now.

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## Summary Comparison of Existing Chemical Policy Laws

	<b>TSCA</b>	<b>REACH</b>	<b>the States</b>
<b>The Statutes (Government, Year Passed)</b>	Toxic Substances Control Act (United States, 1976)	Registration, Evaluation, Authorisation, and Restriction of Chemicals (European Union, 2006)	New state laws create a chemical policy frame- work (California, Maine, and Washington, 2008)
<b>Addresses many EXISTING CHEMICALS</b>	<b>NO</b> – 62,000 chemicals grand- fathered in without testing or restrictions	<b>YES</b> – more than 30,000 chemicals must be registered, potentially subject to further action	<b>NO</b> – <i>but</i> focuses on priority hazardous chemicals in products (ME, WA, CA authority)
<b>PRECAUTIONARY PRINCIPLE in play</b>	<b>NO</b>	<b>YES</b>	<b>YES</b> (all 3 states)
<b>BURDEN of PROOF</b>	on government	on industry	on government (all 3) <i>and</i> industry (ME, WA)
<b>HAZARD DATA required for most chemicals</b>	<b>NO</b> – first requires substantial evidence re: potential risk	<b>YES</b> – industry must submit information on > 30,000 chemicals	<b>NO</b> – <i>but</i> California law requires a database on chemical hazards
<b>USE DATA and EXPOSURE DATA on chemicals</b>	<b>LIMITED</b> information reported for some every 5 years	<b>EXTENSIVE</b> information must flow up & down supply chain	<b>DISCLOSURE</b> of priority chemicals in products (ME, WA)
<b>PUBLIC ACCESS &amp; CONFIDENTIALITY</b>	Very restrictive - poor public right to know	Good public access to data <i>and</i> protection	Public access to data, <i>but</i> could be improved
<b>Identification of priority chemicals: HAZARD-BASED &amp;</b>	<b>NO</b>  <i>not applicable</i>	<b>YES</b> – substances of very high concern, i.e. CMRs, PBTs, vPvBs & EDCs	<b>YES</b> – based on hazard traits similar to REACH (ME, WA, CA authority)
<b>EXPOSURE-BASED factors applied</b>		Wide dispersive use and/or high volume use	In people, products, high volume use (all 3)
<b>ALTERNATIVES ASSESSMENT &amp; Substitution Plan</b>	<b>NO</b>	<b>YES</b> – may be required for priority substances of very high concern	<b>YES</b> – may be required for priority chemicals (CA, ME, WA for PBTs)

by Mike Belliveau, Environmental Health Strategy Center, [www.preventharm.org](http://www.preventharm.org), Feb. 2009

## Summary Comparison of Existing Chemical Policy Laws – page 2

Risk Management Pathways	TSCA	REACH	the States
<b>1. Prohibit use of chemicals <i>unless</i> industry shows SUBSTITUTION is not feasible</b>	<b>NO</b> – but the production of highly hazardous PCBs was banned by statute and uses were restricted	<b>YES</b> – for priority substances of very high concern that are <b>PBTs</b> , <b>vPvBs</b> or have <b>no safe exposure threshold</b>	<b>YES</b> – for same priority chemicals of high concern in products (ME, WA for PBTs)
<b><i>What has to be shown to avoid or trigger prohibition</i></b>	<i>not applicable</i>	To continue chemical use, industry must show socio-economic benefits outweigh risks <i>and</i> there are no suitable alternative substances or technologies	To trigger restriction, state must show there's exposure <i>and</i> safer alternatives available at comparable cost (ME, WA through PBTs rule)
<b>2. Prohibit use of chemicals <i>unless</i> industry controls RISKS or substitution is not feasible</b>	<b>NO</b>	<b>YES</b> – for <i>other</i> priority substances of very high concern, e.g. <b>CMRs</b> , where a safe threshold can be determined	<b>YES</b> – for same priority chemicals of high concern in products ( <i>without regard to risk</i> ) (ME)
<b><i>What has to be shown to avoid or trigger prohibition</i></b>	<i>not applicable</i>	Industry shows risks are adequately controlled, <b>or</b> socio-economic benefits outweigh risks <i>and</i> there are no suitable alternative substances or technologies	To trigger restriction, state must show there's exposure <i>and</i> safer alternatives available at comparable cost (ME)
<b>3. Restrict specific uses of chemicals</b>	<b>YES</b> – may restrict chemical production, use or disposal by rule	<b>YES</b> – for <i>other</i> toxic chemicals not subject to authorization above	<b>YES</b> – broad authority to restrict or prohibit chemical use (CA)
<b><i>What has to be shown to restrict chemical uses</i></b>	Agency must show unreasonable risk <i>and</i> restrictions are least burdensome after cost-benefit analyses of all alternatives	Agency must show unacceptable risk to health or environment considering socio-economic impact and available alternatives	Not yet specified in rules under development, <i>but</i> must consider hazards, exposure pathways and alternatives (CA)
NOTES: <b>CMRs</b> = Carcinogens, Mutagens, Reproductive toxicants; <b>PBTs</b> = Persistent, Bioaccumulative and Toxic chemicals; <b>vPvBs</b> = very Persistent, very Bioaccumulative chemicals; <b>EDCs</b> = Endocrine Disrupting Chemicals			





February 25, 2009

The Honorable Bobby Rush  
Chairman  
Subcommittee on Commerce, Trade and Consumer Protection  
House Committee on Energy and Commerce  
Washington, D.C. 20515

The Honorable George Radanovich  
Ranking Member  
Subcommittee on Commerce, Trade and Consumer Protection  
House Committee on Energy and Commerce  
Washington, D.C. 20515

Dear Chairman Rush and Ranking Member Radanovich:

Ensuring the safety of our products – while maintaining the confidence of consumers – is the single most important goal of the consumer products industry. Product safety is the foundation of consumer trust, and our industry devotes enormous resources to ensure the safe use of our products.

Consumer products companies recognize that steps must be taken to improve confidence in the safety of chemicals used to manufacture consumer products and packaging and to promote even greater innovation. To that end, we support legislative enhancements to the Toxic Substances Control Act of 1976 and urge you to create and endorse a stakeholder process that recognizes the critical role played by the consumer products industry.

Improvements to TSCA should recognize changes in science and technology, establish deadlines for review of priority chemicals, ensure that EPA has timely and adequate information on use and exposure, leverage ingredient or chemical management programs undertaken by other nations, promote innovation, and integrate the patchwork quilt of laws governing product safety.

In particular, we look forward to working with you to address the following policy challenges:

· **Setting Priorities.** Congress should consider ways to identify “priority” substances that should be reviewed, including chemicals that may pose health risks to sensitive populations. In particular, Congress should examine how industry studies that meet EPA standards for protocols and procedures should be used to support government efforts.

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

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

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

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

As you consider enhancements to TSCA, our organizations strongly urge you to create a stakeholder process that will reflect the critical role played by the consumer products industry. By setting priorities, ensuring that use and exposure data is provided, providing deadlines and resources, and by clarifying risk management options, Congress can foster innovation and enhance consumer confidence.

Sincerely,

D. Christopher Cathcart  
President & CEO  
CSPA

Pamela G. Bailey  
President & CEO  
GMA

Ernie Rosenberg  
President & CEO  
SDA

## New York Times

### Need Press? Repeat: 'Green,' 'Sex,' 'Cancer,' 'Secret,' 'Fat'

By JOANNE KAUFMAN  
Published: June 30, 2008

The original pitch landed in the inbox with a whiff of medical authenticity overlaid with a snicker-inducing headline: "Toxic Ties to 'New Shower Curtain Smell' Evident, According to Latest Laboratory Testing."

There was a news conference, this release said, at New York University Medical Center. It was led by a doctor representing an obscure if official-sounding group that few people have heard of, the Center for Health, Environment and Justice. There were revelations about how shower curtains that are "routinely sold at multiple retail outlets" and can "release as many as 108 volatile chemicals into the air."

Thus, the Toxic Shower Curtain Story was born.

ABCNews.com picked up on it, only to debunk it. With varying amounts of credulousness, other outlets ran with it as well, including U.S. News & World Report, The Daily News in New York, MSNBC.com and The Los Angeles Times. The gist of some of the coverage was that it was all a tempest in a bathtub, though other reports took the information at face value.

How do stories of this ilk get such bounce from major news organizations?

Those who make their living composing news releases say there is an art to this easily dismissed craft. Strategic word selection can catapult an announcement about a study, a product or a "breakthrough" onto the evening news instead of to its usual destination — the spam folder or circular file.

"P.R. people want to invest time in things that are going to get picked up, so they try to put something to the 'who cares?' and 'so what?' test," said Kate Robins, a longtime public relations consultant. "If you say something is first, most, fastest, tallest — that's likely to get attention. If you can use the words like 'money,' 'fat,' 'cancer' or 'sex,' you're likely to get some ink in the general audience media."

David Seaman, a P.R. stunt planner and the author of a book to be published in October, "Dirty Little Secrets of Buzz," is a proponent of "safe," "easy" "secret," "trick" and "breaking" because they suggest that something is new and fresh, he said.

Anyone who read or heard the Toxic Shower Curtain Story can probably relax: the unsettling findings about possible respiratory, liver and reproductive damage were dismissed by the Consumer Product Safety Commission. "Our staff scientist found many problems with the testing methodology, which called into question the credibility of the science," said Julie Vallese, a spokeswoman for the commission.

The Center for Health, Environment and Justice stands by its study and says that it was trying to issue an earnest public warning about an environmental hazard. "It's so important to let people know all the evidence out there when making decisions about which products to bring into their homes," said Dianna S. Wentz, a spokeswoman for the group.

The center was founded by Lois Gibbs, who in the '70s fought successfully against the toxic waste dump at Love Canal.

But if the organization's testing methodology drew skepticism, its P.R. methodology was spot on.

"Anytime you have 'toxic' next to an item everyone has in their house and has always been assumed to be the last thing that would harm them, you can be sure it will get picked up on the news, and the Web will spread it like wildfire," said Allen P. Adamson, managing director of Landor, a corporate branding firm, and the author of "BrandSimple."

The words that attract media attention change with the times. "Anything that speaks to long-term health risks is good these days, because there is a belief that there's a lot of stuff out there harming us, from the cellphone on down," Mr. Adamson said.

David B. Armon, the president of PR Newswire, a distribution service for public relations professionals, likens writing a news release to writing a headline for the front page of a newspaper: every word has to do heavy lifting.

“It’s a lot more scientific than it used to be,” Mr. Armon said, “because you’re not just trying to get media pickup, but to get search engine attention.”

To aid in this endeavor, PR Newswire offers its members a so-called keyword density tool. “It lets you know the words someone would have to type into a search engine for your particular press release to be found, and helps put your release at the top of the search engine,” Mr. Armon said.

“Green” and “environment” are huge right now, he said, as is “foreclosure.” “We’ve done 412 press releases that incorporate that word so far in ’08, up from 261 last year.” For the record, Mr. Armon added, the use of the word “toxic” in news releases is up 5 percent.

The words that may help get a news release picked up vary from region to region. Brenda Baumgartner, the news director and anchor at KPVI, the NBC affiliate in Pocatello, Idaho, for example, looks for words like “fishing,” “hunting,” “Mormon” and “polygamy,” she said, “because they fit the culture we live around.” KPVI also went with the toxic curtain story. “Everybody takes showers,” Ms. Baumgartner said, by way of explanation.

Words that help elevate a news release also vary from industry to industry. For instance, Tom Gable, the head of a San Diego public relations firm, said a news release about video games could benefit from a phrase like “faster graphics.” When talking about technology, he said, it would be “‘cost breakthrough,’ like the \$200 computer.”

In the entertainment industry, on the other hand, the most basic of nouns will do — baby, breakup, marriage, divorce — according to Cindi Berger, co-chief executive of the public relations firm PMK/HBH. “Now attach names like Madonna or Jessica Simpson,” Ms. Berger said, “and of course the assignment editor is going to pay attention.”

Perhaps because many people in public relations are former journalists, they know what grates on the Fourth Estate. Mr. Gable, who was once the business editor of The San Diego Union, has compiled a list of words that will do a news release no good whatsoever, like “solutions,” “leading edge,” “cutting edge,” “state of the art,” “mission critical,” and “turnkey.”

Mr. Gable said that his company once did a weeklong survey of the releases that came out of PR Newswire and Business Wire, a commercial news distribution service, “and most of the releases identified their company as ‘a leader’ and described their research as ‘cutting edge.’”

“They were empty, unsubstantiated and had no news value,” he said.

Ken Sunshine, the head of a P.R. firm in Manhattan, said he thought the media had an institutional bias against “hype-y terms” like “world renowned” and “once in a lifetime,” which he studiously avoids putting in his news releases. “But ‘unique’ is fine,” he said, “if something really is unique.”

Ultimately, perhaps, the whole thing is less about terms than timing.

“Was it really the issue of toxic shower curtains that fired up assignment editors?” asked Mr. Armon of PR Newswire. “Or was it just a slow news day?”

Championing solutions to protect public health  
and communities from toxic chemicals



February 25, 2009

Honorable Bobby L. Rush, Chairman  
**Subcommittee on Commerce, Trade and Consumer Protection**  
Committee on Energy and Commerce, U.S. House of Representatives  
2125 Rayburn House Office Building, Washington, D.C. 20515

Dear Chairman Rush and Members of the Subcommittee,

Thank you so much for scheduling a hearing on "Revisiting the Toxic Substances Control Act of 1976" on February 26. As your investigation will reveal, our consumer safety system for industrial chemicals in commerce is badly broken.

At the state level, we have experienced TSCA's failure first hand. SAFER is a national alliance of state-based coalitions and allied organizations working to protect human health from unnecessary toxic chemicals and to promote economic opportunity through safer consumer products. Several hundred organizations have joined our efforts. Together we represent hundreds of thousands of parents, health professionals, people whose health has been affected, consumers, and workers in more than a dozen states.

Toxic chemicals are widely found in our environment, homes and workplaces. They are found in everyday products, the air we breathe, the food we eat and the water we drink. They are found in our bodies, breast milk and even in the most vulnerable – fetuses, newborns, infants and toddlers. The growing rates of cancer, developmental disorders, asthma and other health effects is caused in part by these toxic chemicals, and the substantial costs of these diseases related to environmentally attributable factors are well documented.

Because TSCA does not work, the states are stepping forward to protect public health and the environment from industrial chemicals in commerce. With broad support from coalitions of health, business, labor, environmental and consumer groups, policy and market solutions are being created.

Through the efforts of proactive state legislators and governors, chemical policies are under development all across the country. In 2008, three states adopted comprehensive chemical policy reforms into law:

- In Washington state, the Children's Safe Products Act requires identification of chemicals posing the greatest threat to children and disclosure of toxic chemicals by manufacturers of children's products;
- In Maine, the Kid Safe Products Act requires adoption of a list of priority chemicals of high concern and disclosure of priority chemicals in consumer products, and authorizes their replacement with safer alternatives;

- In California, two laws require the state to identify and prioritize chemicals of concern, create a toxic chemical database, evaluate alternatives and specify a range of regulatory responses.

However, states can not solve the toxic chemical threat alone. In fact the states and businesses are sorely burdened by the lack of data on chemical hazards, use and exposure. We need Congressional leadership to make TSCA reform a priority.

Please consider the policy experience of the states in developing a new federal chemical policy. We ask that you consider the following key policy principles among those that will guide your deliberations on federal chemical policy reform:

**Protect the Most Vulnerable.** Toxic chemicals that build up in people's bodies and get passed onto children in the womb should be phased out in order to ensure that the most vulnerable, including workers and low-income communities of color, are protected. Such chemicals are the 'worst of the worst' and are known as PBTs or persistent, bioaccumulative and toxic chemicals;

**Address Cumulative Impacts.** Our regulatory framework should move beyond the existing silo approach that looks at only one chemical exposure at a time. We should consider multiple exposures from all sources in any standards to protect public health and the environment;

**Ensure Safer Alternatives.** An effective chemical management system should force companies to find the safest alternative substance or technology to replace inherently dangerous chemicals and to make continuous improvements. Otherwise, we will continue to see a series of harmful chemicals being used in everyday consumer products; and

**Support the States.** Federal law should support implementation of state chemical policy programs. States should be allowed to adopt more stringent requirements to regulate manufacturing and sale of safer chemicals in consumer products. Any new federal policy should *not* include state preemption.

We look forward to supporting your leadership to modernize and update our federal chemicals management system. Your public policy success will protect environmental public health today and for many generations to come. Please don't hesitate to contact the SAFER policy coordinators, Laurie Valeriano at (206) 632-1545 or Mike Belliveau at (207) 827-6331, if we can provide you with further information or assistance. Thank you for your consideration.

Respectfully submitted on behalf of SAFER,



**CALIFORNIA**

Jeanne Rizzo, RN, CEO & President  
Breast Cancer Fund

Martha Dina Arguello, Executive Dir.  
Physicians for Social Responsibility – LA

Joe Guth, JD, PhD, Legal Director  
Science & Environmental Health  
Network

Ansje Miller, Policy Director \*  
Center for Environmental Health

Jose Bravo, Executive Director \*  
Just Transition Alliance

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**MARYLAND**

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**MASSACHUSETTS**

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\* Member of SAFER's Steering Committee



STATE OF WASHINGTON  
DEPARTMENT OF ECOLOGY

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February 25 2009

The Honorable Bobby L. Rush, Chairman  
The Honorable George Radanovich  
Subcommittee on Commerce, Trade, and Consumer Protection  
2416 Rayburn HOB  
Washington, DC 20515

**RE: Toxics Substances Control Act**

Dear Congressmen:

The State of Washington strongly supports the reform of the Toxics Substances Control Act (TSCA). It has been 33 years since its passage, but the act's promise has yet to be realized. In 1976, Congress expressed its intent: "the most effective and efficient time to prevent unreasonable risks to public health or the environment is prior to first manufacture... it is at this point that the costs of regulation in terms of human suffering, jobs lost, wasted capital expenditures, and other costs are lowest." This principle is just as true today – the only sensible approach to protecting citizens from toxic threats is one based on prevention. Unfortunately, TSCA has not yet achieved these laudable and still relevant goals.

Citizens expect that if a product is on the shelf, that it is safe to use. As TSCA has been unable to deliver this basic guarantee, states have stepped forward to protect citizens from a wide array of toxic threats. We believe robust protection at the federal level is far preferable to a patchwork of state-level regulations. However, until that federal protection is assured, states will be left with little choice but to take steps on their own.

Washington State has pioneered legislation to address toxic chemicals in children's products, developed the first strategic approach to persistent, bioaccumulative toxics, and passed the first ban on the toxic flame retardant Deca-BDE. In recent years, states such as Washington, Maine, and California, have served as a laboratory for chemical policy reform. We look forward to partnering with you, and offer both our support and experience as you undertake much needed federal reform.



The Honorable Bobby L. Rush  
The Honorable George Radanovich  
February 25, 2009  
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The Washington State Department of Ecology encourages Congress to undertake fundamental reform of TSCA without further delay. TSCA reform should include the following:

- Place the burden of proof on manufacturers to prove safety before widespread use, rather than relying on EPA to demonstrate harm after exposures are ubiquitous and irreversible.
- Eliminate the “grandfather” assumption that chemicals in use prior to the passage of TSCA are safe.
- Provide transparency. People should be able to make informed decisions about products they bring into their homes and environment. The current system allows far too much data to be classified as confidential business information.
- Require the use of safer alternatives when they are available and promote the phase out of those substances that pose the biggest risks such as persistent, bioaccumulative and persistent, toxic chemicals.
- Develop methods for assessing safer alternatives that incorporate the principles of green chemistry.
- Build on the work of the states, as well as Canada and the European Union.

We look forward to working with you to establish a safe, fair, and predictable regulatory framework for chemicals across the country, and to finally provide the level of protection for families and our environment that our citizens demand and deserve.

Sincerely,



Jay J. Manning,  
Director

cc: The Honorable Jay Inslee

The Honorable Bobby L. Rush  
The Honorable George Radanovich  
February 25, 2009  
Page No. 3

bcc: Janice Adair  
Laurie Davies  
Rob Duff  
Carol Kraege  
Jim Pendowski  
Keith Phillips  
Mark Rupp  
K. Seiler  
Mary Selecky  
Ted Sturdevant



G A O

Accountability • Integrity • Reliability

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United States Government Accountability Office  
Washington, DC 20548

March 30, 2009

The Honorable Henry A. Waxman  
Chairman  
The Honorable Joe Barton  
Ranking Member  
Committee on Energy and Commerce  
House of Representatives

We appreciate the opportunity to respond to the committee's questions for the record as a follow-up to the hearing before the Subcommittee on Commerce, Trade and Consumer Protection hearing on February 26, entitled "Revisiting the Toxic Substances Control Act of 1976." We also appreciated the opportunity to testify at that hearing and hope that the Subcommittee found our testimony useful in its deliberations. This letter responds to your request that I provide answers to questions for the record. The questions, along with my responses, follow. It is worth noting that, in some cases, we do not have a basis to respond to some of the questions because we do not have ongoing or completed work in those areas. To the extent that the Subcommittee has a continuing interest in areas where we are not able to provide complete responses, we are available to meet with you or your staff to discuss your interests and assist in developing a request for GAO to do additional work that would enable us to respond to these and other questions about the regulation of chemicals. Please do not hesitate to contact me or my staff should you have additional questions.

Sincerely yours,

John B. Stephenson  
Director, Natural Resources  
and Environment

Enclosure

cc: Earley Green

Enclosure**GAO Response to Questions from the Honorable Joe Barton****1. How many chemical substances or mixtures has EPA studied or reviewed under Sections 4 and 5 of TSCA that have never made it to market?**

EPA officials estimate that about half of the approximately 40,000 premanufacture notices the agency has received from chemical companies are for new chemicals that, for various reasons, never enter the marketplace. EPA adds a new chemical to the TSCA Inventory after the premanufacture notice review period has expired and the submitter has provided a notice of commencement within 30 calendar days of the date the substance is first manufactured or imported. The chemical substance is considered to be on the TSCA Inventory and an existing chemical as soon as a complete notice of commencement is received by EPA.

**2. How many chemicals has EPA studied under TSCA, but yet no regulations resulted?**

We have not requested data from EPA on how many chemicals it has studied, and it is not clear whether the agency has such data. However, some data from our previous work provides a partial answer. Since the enactment of TSCA, EPA has reviewed premanufacture notices for approximately 40,000 new chemicals and has taken no action for about 36,000 of these. But we have not requested data from EPA on how many of these 36,000 it has studied, or to what extent. EPA officials have told us that not all premanufacture notices receive the same level of review. For existing chemicals, EPA has required chemical companies to test about 200, but has issued regulations under TSCA to ban or limit the production or restrict the use of only five chemicals. To more completely answer your question, we would need to more clearly define what extent of a review

would qualify as a 'study'.

**3. Won't the initiatives EPA is advancing through ChAMP address some of the concerns your report raises?**

We have not assessed the effectiveness of EPA's implementation of its Chemical Assessment and Management Program (ChAMP), which EPA initiated in 2007. Under ChAMP, EPA plans by 2012 to conduct a basic screening level assessment of the potential risks of more than 6,000 chemicals. EPA plans on using these screening level assessments to prioritize the chemicals for possible future action. While laudable, this effort would be hampered by limitations on the availability of data on chemical toxicity or potential for exposure, and by EPA's limited ability to obtain such information from chemical companies. Furthermore, risk management efforts EPA could take would be hampered by EPA's limited ability to place controls on chemicals. As of December 2008, EPA reported it has developed and posted risk-based prioritizations for 151 chemicals.

**4. How does a TSCA inventory reset, accompanied with appropriate funding for EPA to conduct such a reset, address your stated concerns about data collection and assessment?**

We have not assessed the implications of EPA's proposed TSCA Inventory Reset. There are currently almost 84,000 chemicals on the Inventory. However, EPA officials say it is unclear which chemicals are actually being used in commerce at a given point in time. According to EPA, a key benefit of the Inventory Reset is that it would provide EPA with a better understanding of the chemicals that are actually being used in commerce, and would provide it with the opportunity to review under TSCA section 5 any chemical substances removed from the TSCA Inventory, but for which a chemical company subsequently intended to commence manufacture or import. This would allow EPA to take action (for example, restrict manufacture and/or require the development of certain toxicity data), where appropriate, under TSCA's authority for new chemicals prior to that



chemical being manufactured or imported for commercial purposes again.

**5. Your report focuses on a lack of health and safety data in pre-manufacturing notices. If that's the case, then shouldn't the pre-manufacturing notice requirements be beefed up? Does this have to be done by revising the legislation?**

In our testimony, GAO suggested revising TSCA to require companies to test their chemicals and submit the results to EPA with their premanufacture notices. EPA estimates that only 15% of premanufacture notices submitted under the authority of section 5 of TSCA contain health and safety test data. This is because section 5 of TSCA only requires companies to submit test data they already have on hand and companies are unlikely to have such data on hand for new chemicals, which represent the bulk of the chemicals for which premanufacture notices are submitted. While a notice under Section 5 may include test data required to be developed under a Section 4 test rule, GAO has noted the difficulties that EPA has in using its authorities under Section 4. The process is difficult, expensive, and time consuming. In addition, EPA must meet certain thresholds for demonstrating hazard or exposure before it can require testing of chemicals. These thresholds are difficult for EPA to meet without having access to the test data it seeks under the rule.

**6. Your report mentions that EPA often does not use its existing TSCA authority to obtain more information. Is this an area in which Congress needs to alter the law or should this be something that EPA tackles on its own?**

GAO observed that EPA does not often use its authority to obtain more information with respect to the 85 percent of premanufacture notices it receives that lack any health or safety test data. As noted above, EPA follow-up under Section 4 or 5 as currently written is unlikely to yield more results because the needed data often does not yet exist and EPA is often unable to require that it be developed.

7. In your written testimony, you state a 1991 Federal appeals court vacated the EPA's asbestos ruling because it was not based on "substantial evidence;" that the EU and several other countries have found asbestos to be a known carcinogen; and then you recommend TSCA be amended to reduce the evidentiary burden. The way your testimony is written, you appear to imply that because the evidentiary burden is so high, the EPA failed to prove what the EU and other countries have determined: that asbestos causes cancer. How do you square this position with the following excerpt from the Corrosion Proof decision?

"We note that of all the asbestos bans, the EPA did the most impressive job in this area, both in conducting its studies and in supporting its contention that banning asbestos products would save over 102... lives ... Were the petitions only questioning the EPA's decision to ban friction products ...we would be tempted to uphold the EPA[.]"

This question concerning the friction products portion of the Corrosion Proof Fittings decision confuses two similar but distinct problems that we identified with TSCA: the difficulty EPA has in demonstrating that a given chemical poses an "unreasonable risk" in order to *justify taking some action* under sections 4 or 6 of TSCA, and the difficulty that it has in meeting the "substantial evidence" standard required to *support the specific action taken* (in this case a ban). With respect to friction products, the Corrosion Proof Fittings court admitted that EPA "may have presented substantial evidence to underpin the danger of asbestos brakes."<sup>1</sup> Corrosion Proof Fittings v. EPA, 947 F.2d 1201, 1226 (5th Cir. 1991). The court nevertheless held that despite ten years of EPA investigation and review of over 100 health and safety studies, EPA had not presented "substantial evidence" to justify an asbestos ban, as other countries have been able to do. Under the court's interpretation of TSCA, the American public may continue to be exposed indefinitely to "unreasonable risks" from a chemical even *after* EPA establishes that such

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<sup>1</sup> Note the court's phrasing: EPA "may have" established the dangers of asbestos brakes, clearly implying the EPA may also have failed to establish that these products presented an unreasonable risk.

risks exist. This is why we believe the substantial evidence standard of TSCA warrants reexamination.

**8. You testified GAO recommends Congress "shift more of the burden to chemical companies for demonstrating the safety of their chemicals." How much quality control or involvement does the EU exhibit over industry risk assessments once they have begun? Does EPA have the legal authority under TSCA to handle this matter differently?**

We have not assessed the effectiveness of the European Chemicals Agency's review over industry risk assessments. The provisions of REACH will be phased in over an 11- year period, and at the time of our review, the European Chemicals Agency was not yet organized and staffed.

EPA does not have the legal authority under TSCA to handle this matter differently. As GAO has reported previously, TSCA places the burden squarely on EPA to demonstrate the safety of chemicals. While EPA can require companies to develop health and safety data under certain circumstances, EPA must first establish that certain hazard or exposure thresholds are met before it can do so, thus placing EPA in the difficult position of having to demonstrate risk before it has the data necessary that may be necessary to demonstrate risk.

**9. In the Corrosion Proof decision, the court cited the EPA's lack of consideration of each rung in the increasing step-ladder of regulatory actions, the failure to consider the availability of alternatives, its failure to present scientific evidence while the review and comment period was open, and most disturbingly, the failure to consider the "comparative toxic cost" of available alternatives? Why shouldn't we expect a regulatory agency to layout its argument in full, including a complete understanding of the ramifications of its actions, before deciding to permanently remove any product from interstate commerce?**

We referred to the Corrosion Proof Fittings decision simply as an illustration of the difficulty EPA has in regulating toxic substances under TSCA. In the wake of that decision it became clear that EPA would need to amass much more data and analysis in support of a regulation issued under TSCA than one issued under many other environmental laws. EPA should of course be expected to take complete and thoughtful regulatory actions. The question is not whether a regulatory agency should have a basis for acting, an assertion no one disputes, but rather why regulation of chemicals in the United States should be substantially more difficult than regulation of other environmental hazards, and as explained in response to question 11 below, who should bear the burden of demonstrating a chemical's safety.

**10. Isn't it true the REACH system is the subject of much criticism already even though it isn't fully implemented yet? Should we adopt a model that hasn't demonstrated its purported benefits?**

We have not assessed the effectiveness of the EU's implementation of REACH. As noted in our response above, the provisions of REACH will be phased in over an 11-year period. We have not taken a position on whether or not REACH is the best model for chemical regulation reform. Other nations, such as Canada, have also revised their chemical control legislation.

**11. In your written testimony, you state, "In general, the precautionary principle means that where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to reduce risks to human health and the environment." How do you know what is a cost-effective measure if the regulatory agency does not examine and compare each of its regulatory options - and a limited number of options at that? This was one of the chief criticisms of the Corrosion Proof court - that the EPA did not complete its review of each option as required under TSCA.**

The question is not whether an agency should assess regulatory options, an assertion no one disputes, but rather who should bear the burden of assessing a chemical's safety (the chemical company or the taxpayer) and who should bear the risk in the absence of substantial health and safety data (again, the company or the public). GAO cited the precautionary principle as the underpinning of the REACH program provisions that shift to manufacturers, importers, and downstream users the burden to ensure that they do not manufacture, place on the market, or use substances that adversely affect human health or the environment. The EU believes that it is cost-effective for industry to conduct such tests at the outset in an attempt to avoid costly health problems down the road. Similarly, the Corrosion Proof Fittings court believed that EPA should evaluate the cost-effectiveness of the regulatory options available to it. In keeping with both of these approaches, GAO has asked Congress to consider streamlining what is an expensive and difficult task for EPA by shifting some of the burden to industry to demonstrate that its own chemicals are safe before marketing those chemicals.

**12. How do you define what "serious or irreversible damage" is if you do not have evidence to demonstrate the claim?**

The phrase "serious or irreversible damage" comes from our background section describing the general approach of the EU's REACH legislation. We noted that "Its [REACH's] provisions are underpinned by the precautionary principle. In general, the precautionary principle means that where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to reduce risks to human health and the environment." We did not further define or elaborate on the precautionary principal.

**13. Your 2007 report claims that TSCA's information provisions are insufficient based upon critics' claim that information is not public about the safety of chemicals which could be used for emergency response purposes. While it is technically true that TSCA does not provide this kind of information, isn't it**

**also true that Sections 311, 312, and 313 of the Superfund Amendments and Reauthorization do (42 USC 1102111023) -- including material safety data sheets and toxic release inventory reporting requirements? Was TSCA drafted to fill in other Federal legal gaps or create a single repository for all chemical laws? Is it fair to criticize TSCA as specifically deficient in this area when other Federal environmental law clearly requires this information of the chemical companies and make it publicly available?**

No, the information supplied in material safety data sheets and in toxic release inventory reporting is not a substitute for the detailed health, safety, and exposure information EPA must assemble in order to adequately defend a regulation under section 4 of TSCA. Moreover, the toxic chemicals covered by those provisions are limited and do not include all the chemicals in the TSCA inventory. If the information under these other laws provided a sufficient basis for EPA to take action under section 6 of TSCA, it is reasonable to surmise EPA would have done so at least once in the last 17 years.

**14. Your 2007 report makes several claims about company misuse of privileges for confidential business information even though EPA was the final arbiter of the privilege. In fact you suggest that all of the reports EPA found lacking, or 22 percent of them, were amended to make them publicly available. Was this 22 percent uncovered as a random sample? If not, then why is this important?**

The question does not accurately summarize our discussion about confidential business information. EPA has not performed any recent studies of the appropriateness of confidentiality claims, although EPA told us that their 1992 study indicated that problems with inappropriate claims were extensive. Thus, while EPA may suspect that some chemical companies' confidentiality claims are unwarranted, they have no data on the number of inappropriate claims. We reported the figure of 22 percent as an indication of the possible scope of the problem. The more salient point is that when EPA asks companies to remove CBI claims, in this case, companies did so. However, EPA says it rarely does ask because of resource constraints.

**15. You testify the EPA does not routinely assess the risks of roughly 80,000 industrial chemicals in use. Is it GAO's position that all these chemicals should be assessed? And if so, how often?**

We have not taken a position on how often these chemicals should be assessed. While TSCA authorizes the review of existing chemicals, it generally provides no specific requirement, time frame, or methodology for doing so. Furthermore, TSCA does not require chemical companies to develop hazard information for these chemicals, absent EPA rule making. Partly because of the resources and difficulties the agency faces in order to require testing to develop information on existing chemicals, EPA has moved towards using voluntary programs as an alternative means of gathering information from chemical companies in order to assess chemicals. While these programs are noteworthy, data collection has been slow in some cases and it is unclear if the programs will provide EPA with enough information to identify chemical risks.

**16. Please put in perspective the magnitude of the task of assessing the risks for 80,000 industrial chemical substances and mixtures: what would it take in man hours, time, and money to assess 80,000 chemicals routinely -- even if performed by industry? And how much safer would we be and is this the best way to accomplish this goal?**

We have not assessed how much time or money would be needed to assess 80,000 chemicals routinely. The amount of time or resources required would vary based on the extent of the risk assessments conducted, and availability of data on the chemical's hazards and the potential for exposure. EPA officials have told us that they prefer using a tiered assessment process. Under such a tiered assessment process, not all chemicals would receive the same level of review. For example, under the ChAMP program, EPA plans to conduct a screening-level assessment of over 6,000 chemicals by 2012. As an initial effort under ChAMP, EPA began, in 2007, posting screening-level hazard characterizations and expanded this effort in 2008 by posting risk-based prioritizations.

(RBPs). The RBPs summarize basic hazard and exposure information on high production volume chemicals, identify potential risks, note scientific issues and uncertainties, and indicate the initial priority being assigned by the agency for potential future appropriate action.

**17. You cite EPA's failure to meet the legal hurdles to ban asbestos needing substantial evidence, and cite Europe's more lenient rule which has allowed it to ban asbestos. Here's one of the legal hurdles that stopped EPA's ban, and I quote the Fifth Circuit Court of Appeals decision that vacated EPA's ban:**  
**a. " ...the EPA failed to study the effect of non-asbestos brakes on automotive safety, despite credible evidence that non-asbestos brakes could increase significantly the number of highway fatalities, and that the EPA failed to evaluate the toxicity of likely brake substitutes..." b. The EPA spent ten years developing a rule to ban asbestos and it didn't fully evaluate that substitutes could cause more fatalities? Why do we want to remove that common sense legal hurdle?**

As we explained in response to question 9, the issue is not whether a regulatory agency should have a basis for acting, an assertion no one disputes, but rather why regulation of chemicals in the United States should be substantially more difficult than regulation of other environmental hazards. It is GAO's position that the evidentiary burden under TSCA could be amended to adopt the arbitrary and capricious standard normally applied to rulemaking under the Administrative Procedures Act. The Congress could amend the standard for judicial review to instead reflect a rational basis test to prevent arbitrary and capricious administrative decisions. In considering such actions, Congress should take into account EPA's position that the social and economic costs of regulating a chemical are usually more easily documented than the risks of the chemical or the benefits associated with controlling those risks and it is thus difficult for EPA to show by substantial evidence that EPA is promulgating the least burdensome requirement.

**18. You recommend that business confidential information be made more**



**publicly available. What are the risks of releasing confidential business information to the public? Are you concerned about piracy?**

We did not recommend that confidential business information be made more publicly available. Legitimate confidential business information should be protected from inappropriate disclosure. We note that EPA has limited ability to publicly share the information it receives under TSCA. TSCA authorizes chemical companies to claim data as confidential business information, and, according to EPA officials, a large portion of information provided to EPA contains information flagged by companies as confidential. While EPA has the authority to evaluate the appropriateness of confidentiality claims and can deny companies' claims of confidentiality if they are found to be illegitimate, these efforts are time and resource-intensive, and the agency does not challenge a significant large number of claims

**19. Has GAO evaluated the ability of EPA and the states to maintain adequate controls over confidential business information?**

We have not assessed either EPA's or the state's ability to maintain adequate control over confidential business information. Confidential business information should be protected from inappropriate disclosure. However, chemical industry representatives told us that the policies and procedures EPA currently uses to protect confidential information are appropriate. Accordingly, they said that the chemical industry would not object to TSCA revisions allowing EPA to share confidential information with states provided that such revisions contain specific reference to safeguards that EPA would establish and enforce to ensure that those receiving the information have stringent policies and procedures to protect it.

**20. How does EPA assess the reliability of chemical information from foreign firms? Does it have a system like the Food and Drug Administration's system of registration and foreign inspections? Has GAO evaluated FDA's management of confidential information or the quality of that information? What did it find?**

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We have not reviewed the extent to which EPA determines the reliability of data provided by chemical companies, either foreign or domestic or how EPA's reliability assessments compare with the FDA's. Furthermore, we have not evaluated FDA's management of confidential business information.

**RESPONSE OF J. CLARENCE DAVIES to QUESTIONS from****HON. JOE BARTON**

1. Q. You state support for the cost benefit analysis required by TSCA and recommend preserving it. You also state that an absolute safety standard is unwise because the government would be forced to ban chemicals that do more good than harm. Please Explain.

A. In my opinion, good decision making requires taking into account all factors relevant to the decision – goods and bads, pluses and minuses, costs and benefits. An absolute safety standard mandates that, in many circumstances, a whole set of relevant factors be ignored. When regulating products, as TSCA does, the value of the product should not be ignored. Many chemical products (e.g. cleaning products, insulating fluids, braking materials) are valuable in terms of lives saved, injuries avoided, or other benefits. If an absolute safety standard is set, it may result in prohibiting manufacture of a chemical that saves more lives than would be saved by the prohibition.

Another problem, which I did not discuss in my testimony, is that almost any absolute safety standard is subject to political manipulation. Thus, for example, a one in a million additional cancer cases standard is almost never empirically verifiable and incorporates many assumptions that are more policy than science (e.g. the shape of the dose-response curve, methods of extrapolation, exposure assumptions).

2. Q. If the EPA regulates a chemical because the risk is not sufficiently reduced under some other law, the EPA is then enacting a regulation that mitigates that risk. As long as EPA's rule mitigates the risk enough to meet that legal protection, why shouldn't the regulation be the least burdensome? Wouldn't it be gratuitous "piling-on" if the rules mitigating harm were more than the least burdensome?

A. The least burdensome requirement in TSCA, especially when combined with the substantial evidence test, is simply a requirement that cannot be met. It requires taking all other reasonable alternative rules, of which there are dozens if not hundreds, and doing a complete cost-benefit analysis of each one. As the Corrosion Proof case showed, ten years of analysis (on asbestos) was not sufficient to meet the standard. Because the standard cannot be met, no rules that are subject to the standard can be promulgated, which is exactly what has happened with respect to TSCA and existing chemicals. No other law of which I am aware contains this kind of requirement and yet I don't believe that there has been a lot of "gratuitous piling-on."

3. Q. You believe CBI needs to be changed, while many of the regulated entities believe they need that protection. What type of information is classified as CBI?

A. Nothing in my testimony was intended to question the need for CBI. Confidentiality is an important protection in any regulatory scheme. What I think needs to be changed are the specific CBI provisions in TSCA. A number of regulated entities have told me that the TSCA CBI provisions could be amended without any loss of necessary protection.

4. Q. Shouldn't CBI be protected as long as the EPA receives it and can review it? How do you substantiate that there exists information that should be disclosed that has otherwise been protected as CBI? Isn't EPA required to remove the CBI protections if it finds information indicating it should not be protected?

A. My basis for thinking the TSCA CBI provisions are a problem include statements by state government officials that TSCA data would be useful in their efforts to regulate chemicals but the data are unavailable to them because of the TSCA CBI sharing prohibitions; and looking at listings of PMN notices and other information issued by EPA where important information relevant to health and safety, such as the name of the chemical, are classified as CBI.

5. Q. Do you believe the problem with the CBI restrictions in TSCA is a problem with the restriction on sharing CBI with state and foreign governments, or is your concern that too much information is classified as CBI?

A. Both. My recommendations for changing the TSCA CBI provisions are described in detail on p. 28 of my report "Nanotechnology Oversight: An Agenda for the New Administration," which I submitted for the hearing record.

5a. Q. Doesn't section 14 prevent the protection of CBI for health and safety reasons – unless the information would reveal a protected process or formula?

A. The health and safety provisions of section 14 have, in my view, been narrowly interpreted by EPA. Thus, information that is relevant to health and safety, such as the name of the chemical, its use, its location of manufacture, etc. are not considered to fall under the provisions. Determining how much of this is a problem of interpretation and how much is due to the language of the act would require a legal analysis which I have not seen done.

5b. Q. Does section 14(a)(3) require the EPA to disclose information if it finds it necessary to protect health or environment? What other information are you seeking to have disclosed that is protected?

A. Section 14(a)(3) requires a finding of unreasonable risk which usually cannot be made because of the other restrictions in the act. With respect to other information, see above.

5c. Q. Are Material Safety Data Sheets (MSDS) and Toxic Release Information (TRI) sheets already available? What further information does the EPA have in its possession that it withholds that needs to be made public or shared?

A. MSDSs and TRI do not help much with respect to new chemicals. With respect to other information, see above.

6. Q. We have had spies infiltrate some of our most sensitive regulatory agencies and government facilities – including nuclear research – for foreign governments. Most western governments have seen fit to embrace the need for strong IP protections that are a source of our productivity. Shouldn't we be worried about what other countries will do with sensitive proprietary information if we share it when it is not of relevance to safety?

A. Yes. I would have no problems limiting data sharing with foreign governments to safety data provided that safety data was adequately defined.

7. Is there a consistent record of information that would help increase public health or safety that has been withheld from state or foreign governments because it is CBI?

A. I believe that there is, but I would suggest that the committee pose this question to state or foreign governments.

8. Q. You indicate many nano-materials may be considered "existing" chemicals but may be more effectively addressed through the significant new uses provisions of TSCA. Is TSCA the right regulatory regime for this technology given the applications and regulatory regime it is under for health (FFDCA) and pesticides? Would a specific stand-alone law better accomplish this mission rather than changes to TSCA?

A. Regulation of nanomaterials should be done under FFDCA and FIFRA, but these laws cover only a small portion of the uses of nanomaterials and thus are not a substitute for TSCA regulation. The question of a stand-alone law has been debated, and I have discussed what such a law might contain in my report "Managing the Effects of Nanotechnology" (pp. 18-23) which I also have submitted for the record. I think that in the short run coverage of nanomaterials should continue to be under TSCA, but that in the longer run (5-15 years) we will need a new law to deal with nano and other new technologies.

9. Q. You state there is some reason to examine potential adverse effects of carbon nanotubes because of some observed reactions in rats. Is that study based on sound, repeatable science? Is the study relevant given pathway exposure difference between humans and rats?

A. I am not a toxicologist, but my understanding is that the answer to both questions is yes. More generally, I do not know of any reputable toxicologist who thinks that it is likely that there are no potential adverse effects from nanomaterials.

10. Q. Recognizing your concerns, nanotechnology advocates point out that this is an area that produces great promises. If we worry about regulating nanotechnology because we don't know enough about its safety, yet because of its infancy there isn't a ton to know, how do we allow it to get off the ground to realize its promise without stifling interest in it?

A. I think nanotechnology has tremendous promise, and it is because I want it to get off the ground that I think we need to worry about regulating it. Nothing would stifle its promise more quickly than some kind of adverse event or than the public getting the impression that this invisible and mysterious technology is totally devoid of adequate oversight. The responsible nanotechnology advocates that I talk to agree with this perspective.

11. Q. Several government agencies are working to understand nanotechnology, including the EPA. Is your concern that these agencies are going too slowly and that's why we need TSCA amended to cover this area or that we know enough to decide that TSCA needs to cover this area?

A. Both. With respect to going too slowly, I would refer you to the recent Congressional hearings on reauthorization of the National Nanotechnology Initiative, where there was nearly unanimous opinion that funding for research on nano health and safety was very inadequate. With respect to knowing enough, everything we know about the chemistry and physics of nanomaterials indicates that they are likely to pose more problems than chemicals of ordinary size, and we know that chemicals of ordinary size pose enough problems to warrant TSCA oversight.

12. Q. This is simply a yes or no question. Yes or NO, if Congress is going to move legislation to change TSCA, do you think we should convene a broad stakeholder process to try to work through these issues? Again, Yes or NO, would you be willing to serve in the process?

A. If forced to answer yes or no, the answer to both questions would be yes. However, in reality the answers depend on how the process is structured. I have had a good deal of experience with stakeholder processes, and they are not easy to do correctly. If structured incorrectly, a stakeholder process might waste a lot of time and resources and could delay reaching agreement on TSCA amendments. Obviously, if I thought the process would be counterproductive I would not agree to participate.

**Maureen Swanson  
Healthy Children Project Coordinator  
Learning Disabilities Association of America**

**Responses to Hearing Follow-Up Questions From Congressman Joe Barton  
Committee on Energy & Commerce  
Subcommittee on Commerce, Trade & Consumer Protection  
“Revisiting the Toxic Substances Control Act of 1976”  
February 26, 2009**

**Question #1**

Would you agree that we need focus on the actual exposure to dangerous chemicals and not simply their uses? In other words, if the substance in question is not absorbed into our systems in a significant or otherwise harmful way, shouldn't the use be deemed appropriate?

**Answer:**

Determining the threats posed by toxic chemicals – the process of risk assessment – depends on both hazard and exposure information. Unfortunately, the Toxic Substances Control Act (TSCA) has failed to generate sufficient information on both hazards and exposures for most chemicals.

In terms of “significant” exposure, we know from new studies of toxicity that some chemicals are associated with adverse health effects at extremely low doses, and that the developing fetus, infants and young children are especially vulnerable to harm from tiny doses of toxic chemicals. This is particularly true of chemicals that disrupt the endocrine system. LDA believes that policy makers should take the same approach to dose-response assessments for all health effects, cancer and non-cancer, including neurodevelopmental effects, with the assumption that there is no “safe level” of chemical exposure – that even the smallest exposure may cause or contribute to human health effects.

To prioritize chemicals for assessment and possible restrictions or bans, the Learning Disabilities Association of America (LDA) believes that federal policy on chemicals should first focus on chemicals which are highly hazardous; chemicals that persist in the environment and accumulate up the food chain; and chemicals to which the developing fetus and infants are exposed, as evidenced through detection in pregnant women and umbilical cord blood. LDA also believes that chemical manufacturers should have an obligation to provide necessary information to EPA and other relevant agencies on all chemicals intended for commerce.

**Question #2**

In enacting the Consumer Product Safety Improvement Act and its restrictions on the use of some phthalates, Congress made a strong statement about the use of strong, repeatable science in decision-making related to chemical restrictions. Do you agree that any science used to justify chemical restrictions should be of high quality, peer-reviewed, have results that can be repeated, and include data that correlates to the studies findings?

**Answer:**

LDA applauds the Obama Administration's swift and ongoing actions to restore the integrity and role of sound, reputable science in federal policy-making. Policy decisions should be informed by scientific studies with replicable results and data that correlate to the study findings. There should also be careful attention to the scientists' affiliations and funding sources, to avoid conflicts of interest and further ensure the validity of results.

**Question #3**

You mentioned in your testimony that there is a "growing body of evidence that some" of the increase in neurological problems is associated with toxic chemical exposures. Is there any way to determine what percentage of this increase is attributable to chemical exposures?

**Answer:**

Estimate of Environmental Contributors to Learning & Developmental Disabilities (LDD):

In 2000, an expert committee convened by the National Academy of Sciences estimated that environmental contaminants cause or contribute to at least 28 percent of all neurobehavioral disorders in children. These environmental contaminants do *not* include alcohol, tobacco or drugs of abuse.<sup>i</sup>

Planned Research on Environmental Contributors to Autism

A 2008 study by scientists at the University of California-Irvine's M.I.N.D. Institute found that the enormous increase in the incidence of autism in children in California cannot be explained by changes in how the condition is diagnosed or counted. The study results suggest that research needs to focus on "the host of chemicals and infectious microbes in the environment that are likely at the root of changes in the neurodevelopment of California's children."<sup>ii</sup>

In March 2009, the National Institutes of Health (NIH) announced that it will commit roughly \$60 million from the American Recovery and Reinvestment Act (ARRA) to support a range of autism research projects over the next two years. The NIH has specified autism research that "assesses risk from prenatal or early life exposures" as one of the funding priorities.<sup>iii</sup>



Planned Research on Environmental Contributors to LDD: National Children's Study

The National Children's Study, (NCS), a nationwide longitudinal study authorized by Congress in the Children's Health Act of 2000, will follow 100,000 children from the prenatal period to adulthood (age 21), to define the actual risks associated with broad environmental exposures.

The Research Plan for the National Children's Study notes that the major illnesses and disorders that impair children's health, growth and development today are chronic conditions stemming from the complex interaction of environmental exposures and inherent genetic factors. One of the NCS's priorities is neurodevelopmental disorders, including learning disabilities, mental retardation, attention deficit hyperactivity disorder and autism. The NCS is designed to determine the role of specific environmental contaminants in neurodevelopmental disorders.<sup>iv</sup>

Much as the national, longitudinal Framingham Heart Study begun in 1948 defined key contributors to heart disease in adults, we anticipate that the National Children's Study will provide enormous scientific insight into the environmental contaminants affecting children's health and development.

**Question #4**

The 2002 study by Dr. Landrigan you mentioned attempted to assess environmental pollutants' contributions to the incidence of some children's illnesses. Yet, some other studies, including one from the Erik Willcutt at the University of Colorado state: *"available data suggest that ADHD and virtually all other psychological traits and disorders are caused by the combination of many genetic and environmental risk factors, none of which is necessary or sufficient to cause the development of ADHD by itself"*. Given the many factors, environmental and otherwise, that can cause these problems, is there any reliable way to pinpoint their origins across large populations?

**Answer:**

Scientists and doctors are able to pinpoint the exact origin of neurodevelopmental problems caused by lead poisoning. However, even with lead, there are other factors that can interact to influence the degree of harm, including diet, poverty and obesity.

In most cases, there is a complex interaction of environmental, genetic and social factors that can determine threats to children's health and development. A large body of peer-reviewed scientific evidence has identified 10 chemicals or categories of chemicals as known neurotoxins and another 200 industrial chemicals as likely neurotoxins.<sup>v</sup> Policy makers should have absolutely no trouble in identifying at least 200 scientifically valid starting points for taking steps to reduce chemical-related risks of neurodevelopmental harm that will benefit children across large populations.

Also, as described in my answer to Question #3, the National Children's Study is the largest prospective birth cohort study ever undertaken in the United States that is

explicitly designed to seek information on the environmental causes of pediatric disease, including neurodevelopmental disorders. The NCS is specifically designed to use and generate “robust science and the ability to generalize the data to the U.S. population.”<sup>vi</sup>

#### **Question #5**

You call for more testing to be done relating to the neurotoxicity in children. How do you propose such testing to be carried out? Since we cannot test on humans, animal testing can be done. Yet rats have significantly different brain structures and functions than humans? How can we effectively assess neurotoxicity on brain development?

#### **Answer:**

The United States leads the world in developing an extensively validated testing protocol for assessing the developmental neurotoxicity (DNT) of chemicals. The U.S. Environmental Protection Agency (EPA) developed and implemented the first DNT guideline in 1991, with modifications in 1998. This testing protocol has been subjected to many validation studies and rigorous peer reviews over the years, all concluding that the DNT test method is “relevant, reliable and sensitive” in screening chemicals for adverse effects of pre- and postnatal exposure on the development and function of the nervous system, and in providing dose-response characterizations of those outcomes.

This spring, the Organization of Economic Cooperation and Development (OECD) is in the process of finalizing and implementing its DNT guideline, modeled on the U.S. DNT guideline. In 2008, an international team of experts led by the U.S. National Center for Environmental Assessment and the U.S. EPA, and including a scientist from Bayer CropScience LP in Kansas, as well as scientists from the UK, Canada, Denmark, Italy and France, conducted a review of the history and performance of DNT testing. They concluded that the DNT guideline “represents the best available science for assessing the potential for DNT in human health risk assessment, and data generated with this protocol are relevant and reliable for the assessment of these end points.”

Their review further finds that “ultimately, the result of more than 30 years of work in this area is a consensus opinion of neurotoxicologists that proper use and interpretation of the data derived from these test methods provide unique insight into the impact of xenobiotics on the developing and adult nervous system.”

Neurotoxicologists also agree on the need for ongoing evaluation and refinement of the test method, as new scientific knowledge becomes available. People are exposed on a daily basis to many mixtures of chemicals, with very little known about the chemicals’ interactions or cumulative effects. The DNT review team states, “A pressing goal of future research is to develop a validated true first-tier screening paradigm that can rapidly screen large numbers of chemicals for their potential to cause developmental neurotoxicity.”<sup>vii</sup>

As described above, this extremely well validated testing methodology is not only available but also being adopted throughout the European Union. The problem seems to lie in making good use of the DNT protocol, as thousands of chemicals lack any toxicological data at all, including data on DNT. The EPA has used the DNT protocol to screen 73 pesticides, but has tested only eight industrial chemicals and seven solvents for DNT since adopting the protocol in 1991.<sup>viii</sup>

**Question #6**

In relation to your points about obesity, a 1990 study among Navajos on diabetes from Arizona shows that the primary cause of obesity is diet. How do reconcile your link to environmental chemical exposure with the Navaho study?

**Answer:**

The National Children's Study has identified obesity as a key focus, and will be studying the origins of obesity from preconception through late adolescence, considering factors ranging from genetic inheritance to individual behaviors to the social, built and natural environments and chemical exposures. The NCS will examine interactions among these multiple influences, with the intent of identifying risk factors for childhood obesity and ways to eliminate those factors through prevention.

Obviously, diet and lifestyle play major roles in obesity, as does the metabolic system. Chemicals that are endocrine disruptors can affect the metabolic system. Recent peer-reviewed scientific studies raise the possibility that endocrine disrupting chemicals including Bisphenol A and phthalates may be risk factors for the development of obesity.<sup>ix</sup>

The NCS will be representative of American children. For example, the NCS seeks to enroll more than 20,000 Hispanic children – a subgroup disproportionately affected by obesity. The study also will enroll Native American children, with several of the study centers based in or near American Indian reservations.

**Question#7**

This is simply a yes or no question. Yes or NO, if Congress is going to move legislation to change TSCA, do you think we should convene a broad stakeholder process to try to work through these issues? Again, Yes or NO, would you be willing to serve in the process?

**Answer:**

I am unable to answer yes or no to commit to a process on behalf of LDA without knowing the process's purpose, direction, participants and the time frame. Perhaps once legislation is passed to reform the Toxic Substances Control Act, there would be

value in a stakeholder process focused on the most effective and expedient ways to start implementing the new legislation.

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<sup>i</sup> *Scientific Frontiers in Developmental Toxicology and Risk Assessment*, Committee on Developmental Toxicology, Board on Environmental Studies and Toxicology, National Research Council, Committee on Life Sciences. National Academies Press, 2000.

<sup>ii</sup> Hertz-Picciotto, Irva, Delwiche, Lora. "The Rise in Autism and the Role of Age at . . . Diagnosis" *Epidemiology*, Vol. 20(1), January 2009, pp.84-90.

<sup>iii</sup> "Recovery Act Funding for Research to Address the Heterogeneity of Autism Spectrum Disorders." Website Announcement, National Institute of Mental Health, March 2009. Website: <http://www.nimh.nih.gov/recovery/index.shtml#autism-spectrum-disorders>

<sup>iv</sup> National Children's Study Research Plan, September 17, 2007.

<sup>v</sup> Gilbert, Steven G. "Scientific Consensus Statement on Environmental Agents Associated with Neurodevelopmental Disorders" Issued by the Learning and Developmental Disabilities Initiative, November 7, 2007.

<sup>vi</sup> National Children's Study Research Plan, September 17, 2007.

<sup>vii</sup> Makris, Susan L., et al. "A Retrospective Performance Assessment of the Developmental Neurotoxicity Study in Support of OECD Test Guideline 426", *Environmental Health Perspectives*, Vol. 117(1), January 2009.

<sup>viii</sup> Ibid.

<sup>ix</sup> Trasande, Leonardo, et al. "Environment and Obesity in the National Children's Study," *Environmental Health Perspectives*, Vol. 117(2), February 2009.



ENVIRONMENTAL DEFENSE FUND

*finding the ways that work*

March 24, 2009

The Honorable Henry A. Waxman  
Chairman  
Committee on Energy and Commerce  
U.S. House of Representatives  
2125 Rayburn House Office Building  
Washington, DC 20515-6115

Dear Chairman Waxman:

Attached please find my responses to the written questions for the record I received in follow-up to the February 26, 2009 hearing held by the Subcommittee on Commerce, Trade & Consumer Protection, titled "Revisiting the Toxic Substances Control Act of 1976."

I received two sets of questions, one from you and Subcommittee Chairman Bobby Rush, and a second from Congressman Joe Barton. Responses to each are attached.

I greatly appreciate the opportunity to have testified before the Subcommittee on this very important subject, and applaud your leadership in enhancing the nation's ability to ensure the safety of industrial chemicals under the Toxic Substances Control Act.

Best regards,

Richard A. Denison, Ph.D.  
Senior Scientist  
Environmental Defense Fund  
1875 Connecticut Avenue, NW #600  
Washington, DC 20009

cc: Earley Green, Chief Clerk

Responses of Dr. Richard A. Denison  
Senior Scientist  
Environmental Defense Fund

to Follow-Up Questions from  
Congressmen Henry Waxman and Bobby Rush  
Committee on Energy & Commerce  
Subcommittee on Commerce, Trade & Consumer Protection  
for the Hearing on “Revisiting the Toxic Substances Control Act of 1976”  
held on February 26, 2009

1. *Several industry witnesses characterized REACH as hazard-based, lacking prioritization and requiring the same data for all chemicals. In response, you briefly indicated these were mischaracterizations of how REACH actually works. Can you elaborate on this point?*

There has been a great deal of mischaracterization of how REACH works by those who object to its broad aims. I have studied REACH for many years, including in the context of developing a detailed comparison of REACH, the Canadian Environmental Protection Act and TSCA. This work, funded by the Canadian government, culminated in an extensive report I published in 2007.<sup>1</sup> That report fully documents the points made below.

REACH essentially requires that most chemicals in commerce be *registered*; their safety be assessed using data developed about their hazards, uses and exposures; and needed risk management measures be identified and applied. These tasks are conducted by the companies that make and use the chemicals. Government has authority to *evaluate* the adequacy of the data, the assessments and the risk management measures used. For certain chemicals that meet specific criteria defining substances of very high concern (SVHCs), government can require that only those uses of a chemical it specifically *authorizes* be allowed in commerce.

Virtually all aspects of REACH are driven by prioritization. For example:

- REACH prioritizes some types of substances over others, based on risk considerations; some substances (e.g., R&D chemicals) are exempted entirely, while others (e.g., certain polymers) have reduced requirements.
- REACH establishes thresholds below which its provisions do not apply or are reduced in scope. Only chemicals produced above one metric ton per year and only chemicals used in formulations above 0.1% are covered, for example.
- REACH prioritizes chemicals based on their use. For example, chemical intermediates and products containing chemicals are either entirely exempt or face reduced requirements under REACH.
- REACH establishes a tiered approach to both the scope and timing of the registration process of chemicals. Chemicals are prioritized based on their production volumes and

existing data indicating that they are hazardous. These prioritization factors determine how soon a chemical must be registered, and how much information is required to be submitted.

- Certain data requirements can be waived in cases where registrants can demonstrate that exposure is low.
- Chemicals found to possess certain dangerous properties are prioritized for government evaluation of their risks.
- Such chemicals produced in large volumes or in wide or dispersive uses are prioritized in the authorization process.

In sum, under REACH, prioritization factors are used in every facet of its implementation and application to specific chemicals. **And far from being one-size-fits-all, the amount of data required of chemicals varies significantly based on such factors.**

While REACH uses both hazard and exposure criteria to prioritize chemicals, its core decision-making process for regulating chemicals is risk-based:

- For the vast majority of chemicals under REACH, companies are required to demonstrate that their chemicals are adequately controlled, based on a risk assessment.
- Even for chemicals subject to authorization, for most of them their use *must* be authorized if adequate control is demonstrated.
- The most dangerous of SVHCs – those for which no safe level of exposure can be established and hence adequate control cannot be demonstrated – can only be authorized if a company establishes that no safer alternatives exist and that the socio-economic benefits of continued use of the chemical outweigh the risk to human health or the environment. But even this is a decision informed by risk: Essentially, these are chemicals deemed so hazardous that no safe level of exposure can be established.

In sum, while aspects of REACH are driven by hazard or exposure factors, it is fundamentally a risk-based regulatory program.

2. *Mr. DeLisi, testifying on behalf of the Synthetic Organic Chemical Manufacturers Association, cited the much larger than expected number of pre-registrations received under REACH as a reason to be critical of the REACH approach. Could you respond and indicate why more pre-registrations were received than expected? What are the implications?*

A major unknown under both the pre-REACH European chemicals regulatory system and that of the U.S. is how many chemicals are actually in commerce. That is because neither system has provided for comprehensive and timely collection of such information. REACH's registration process will change that for the European Union. But in preparing for REACH, European Union authorities had to estimate how many chemicals might fall under REACH based on incomplete and dated information. They estimated that about 30,000 such substances would be registered. As explained below, *registration is not the same as pre-registration.*

The EU's counterpart to our TSCA Inventory contains 105,000 chemical substances. The European Chemicals Agency (ECHA) reported receiving about pre-registrations for about 150,000 substances.<sup>1</sup> It noted that these pre-registrations covered all 105,000 inventoried substances and about 45,000 apparently additional substances. ECHA is now in the process of screening the "extra" chemicals, but notes several reasons why the pre-registration numbers are higher than expected:

- Not all pre-registered chemicals may actually fall under REACH. For example, chemicals exempted from REACH may have been pre-registered.
- Chemicals not produced above the one-metric ton-per-year threshold for REACH coverage may have been pre-registered.
- Chemicals have many names/synonyms, and it is likely that there are many cases where the same substance has been pre-registered using different ones.

The fact that all inventoried chemicals in the EU are covered by pre-registrations suggests that one or more companies is either actively producing each of them or is interested in retaining the option to do so in the future. Failing to pre-register a substance under REACH has significant consequences: Only pre-registered substances are eligible to be registered on a phased schedule, either 3.5, 6 or 11 years after REACH's effective date, depending on production volume or other factors. Otherwise, registration is due immediately. So companies have a major incentive to pre-register substances even if they later need not register them, so as to keep their options open. Pre-registration merely required electronic submission of the company's and chemical's names, so it imposed virtually no burden or cost. In contrast, registration is much more involved and may require generation of new data and assessments. Hence it is not at all unexpected that many more substances would be pre-registered than are likely ultimately to be registered.

For all of these reasons, therefore, it remains to be seen both what the actual number of unique pre-registered chemicals is, and whether the number of chemicals actually registered under REACH will approach the number pre-registered.

But even assuming that many more than 30,000 chemicals end up being registered, what that means is basically that the prior system for tracking chemicals in the EU – not much different than that in place in the U.S. – had significantly underestimated the number of chemicals in commerce above one metric ton per year. All the more reason to institute a comprehensive program that ensures government has a complete picture of the chemical universe – and to set in motion the processes needed to develop safety information on these chemicals and determine and impose the conditions needed to ensure their safe use.

[end]

## Endnotes

<sup>1</sup> See Denison, R.A. (2007) *Not That Innocent: A Comparative Analysis of Canadian, European Union and United States Policies on Industrial Chemicals* Appendix B, (Environmental Defense Fund, Washington, DC), at [www.edf.org/chempolicyreport](http://www.edf.org/chempolicyreport).

<sup>2</sup> See [http://echa.europa.eu/doc/press/pr\\_08\\_59\\_publication\\_pre-registered\\_substances\\_list\\_20081219.pdf](http://echa.europa.eu/doc/press/pr_08_59_publication_pre-registered_substances_list_20081219.pdf).



Responses of Dr. Richard A. Denison  
Senior Scientist  
Environmental Defense Fund

to Follow-Up Questions from  
Congressman Joe Barton  
Committee on Energy & Commerce  
Subcommittee on Commerce, Trade & Consumer Protection  
for the Hearing on "Revisiting the Toxic Substances Control Act of 1976"  
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1. *In your paper, Ten Essential Elements in TSCA Reform, you maintain that TSCA requires the "government to prove beyond all reasonable doubt that a chemical poses a risk in order to take any regulatory action to restrict its production or use." Is that really accurate? Is the standard really beyond all reasonable doubt?*

While I was speaking somewhat figuratively and I am not a lawyer, the answer is effectively yes. This is the combined effect of the burdens imposed by numerous provisions of TSCA itself and judicial interpretations that define the magnitude of these burdens:

- For EPA to take regulatory action to control any chemical in commerce, it must first find that the chemical "*presents or will present* an unreasonable risk of injury to health or the environment."<sup>3</sup> This does not allow action to be initiated for potential or uncertain risks.
- Before initiating any regulatory action, EPA must consider more than whether the chemical is harmful and if there are significant exposures to it. EPA must:
  - consider and document the economic and social costs of imposing controls on the chemical, including the benefits of the chemical,
  - consider and document the availability of alternatives,
  - consider and document the impact of regulation on the economy, small businesses and innovation.<sup>4</sup>
  - demonstrate that the proposed control is the least burdensome it could have proposed.<sup>5</sup>
  - demonstrate that no other statute could address the concern.<sup>6</sup>
- In addition to all this, the standard under TSCA for judicial review of EPA decisions is not the typical requirement for federal agencies under the Administrative Procedures Act to demonstrate a regulation is not an "abuse of discretion" or "arbitrary and capricious," but the far higher burden of showing that its decision is "supported by substantial evidence."<sup>7</sup> As a result, EPA decisions are granted little deference when legally challenged. In these regards, TSCA differs not only from virtually all other federal environmental statutes, but most other federal laws as well.

2. *Further, your paper is critical of TSCA because EPA has only mandated restrictions on the production or use of only five substances since 1976. I don't understand the correlation between the number and your point? What do you maintain would be the correct number and why?*

First, only a single class of substances – PCBs – has been banned by EPA under TSCA, and that was mandated by Congress. The other four examples involve only highly selective restrictions on specific uses or occurrences of those chemicals.

Of course there is no magic number, and because of massive data gaps and the lack of any requirement for EPA to review existing chemicals, it is difficult to say how many chemicals warrant restrictions. But there are several barometers that indicate the number of such chemicals should be far higher. For example:

- EPA has placed conditions on about 10% of new chemicals it has reviewed.<sup>8</sup> Assuming existing chemicals are neither more nor less risky than new ones, extrapolation to existing chemicals would suggest at least 6,200 chemicals on the TSCA Inventory<sup>9</sup> might warrant conditions on their use.
  - The European Union found that about 70% of all new substances assessed under its pre-REACH legislation possess at least one dangerous property. It concluded that “[a]n unknown but potentially significant proportion of all chemical substances will enter the environment and reach sufficiently high concentrations to induce adverse effects.”<sup>10</sup>
  - The recently completed Domestic Substances List (DSL) Categorization process mandated under the Canadian Environmental Protection Act (CEPA), which examined all 23,000 previously unassessed existing chemicals on the DSL, identified more than 4,300 substances possessing hazard or exposure characteristics sufficient to warrant further assessment.<sup>11</sup>
  - Both the EU and Canada have acted on a much larger number of chemicals than has the U.S. That is because both countries have actually assessed many more chemicals, utilize clear criteria for identifying chemicals of concern, and have greater authority to impose restrictions where needed.
3. *Your paper advocates a policy that “undertakes appropriate actions to reduce production, use, and release of chemicals of concern and to replace them with alternatives known to be of lesser or no concern.”*

*What chemical—even seemingly innocuous ones—aren't of concern at a particular dose?*

I agree that potency has to be considered. That is why I advocate for policies that establish *criteria* for what constitute chemicals of concern. Such criteria provide the ability to assess the significance of an adverse effect. Many such criteria have been developed through an international consensus process coordinated by the Organization for Economic Cooperation and Development (OECD), in the form of the Globally Harmonized System for the Classification and Labeling of Chemical Substances.<sup>12</sup> The other examples of criteria-driven policies I cited in my testimony – REACH, CEPA, emerging state policies – all are criteria-based and establish quantitative (where possible) or qualitative measures of potency.

*Are you suggesting there aren't reasonable risk management controls that can be established?*

Not at all. Acting appropriately to address chemicals of concern means exactly that: identifying needed measures to adequately control a chemical's potential risks. Such measures cover a broad range, extending from imposing monitoring or labeling requirements, to restrictions on storage or disposal, to restrictions on some uses of a chemical while allowing others, to a full ban on all production and use of a chemical.

4. *Do you really believe that all so called "data gaps" are "data needs?" Haven't animal welfare groups criticized your organization for demanding excessive testing using laboratory animals?*

I have worked for over a decade in OECD and EPA programs that seek to develop a base set of chemical hazard data called the Screening Information Data Set (SIDS). This data set was developed through an international consensus process to constitute the *minimum amount* of data needed to conduct even a screening-level hazard assessment for a chemical.<sup>13</sup> These programs were spurred by findings that the great majority of even the highest-volume and most widely used chemicals in commerce lacked such data. For example, in 1998 EPA found that 43% of high production volume (HPV) chemicals had no publicly available SIDS data, and only 7% had a complete SIDS base set.<sup>14</sup>

While that situation has improved somewhat due to these programs, many HPV chemicals still lack a SIDS data set.<sup>15</sup> Of the first 300 HPV chemicals assessed by EPA using the Challenge data, EPA found gaps remaining in the final data sets submitted for at least 35% of them.<sup>16</sup> Sponsors of many hundreds of HPV chemicals under the Challenge have yet to submit complete final data sets. Several hundred HPV chemicals were never sponsored and hence lack SIDS data sets. Meanwhile many hundreds of additional chemicals have reached HPV levels of production yet have not been sponsored. And finally, there is the much larger number of chemicals produced below HPV levels, for which even less data are available.

Remember: The SIDS constitutes the *minimum amount* of data needed to conduct even a screening-level hazard assessment for a chemical. For many chemicals, more data will be needed to fully assess their hazards and risks. So yes, *these data gaps are data needs*. As the National Research Council (NRC) of the National Academies of Sciences concluded in 2006:

TSCA authorizes EPA to review existing chemicals, but toxicity and exposure information on them is typically so incomplete that it does not support the review process.<sup>17</sup>

5. *Isn't a tiered testing approach the most appropriate path forward? Why should we require extensive toxicity studies for all substances when we can characterize substances with existing information on their structural similarity to other chemicals and characterize the risk with a reasonable degree of scientific certainty?*

I don't advocate a one-size-fits-all approach and agree that there is a role for tiering. I also agree with and have supported appropriate use of alternative methods to direct toxicity testing – where they yield information of comparable scientific validity. These methods include the use of

validated predictive structure-activity relationship (SAR) models, "read-across" from closely related chemicals, and validated *in vitro* tests.<sup>18</sup>

6. *What is your opinion of the National Academy of Sciences' recommendation for a risk assessment approach for evaluating threats to health from both natural and synthetic substances—a risk-based approach that integrates both hazard information and exposures?*

I don't know to which specific NAS recommendation you refer, but I agree that natural sources of exposure to a substance are important to consider, and I also believe that both hazard and exposure information is important to consider in deciding how to regulate a chemical. In general, I also support a risk-based approach to regulating chemicals – with the significant caveat that the practice of risk assessment requires significant improvement (as recommended in a series of recent NAS reports), and that a full-blown risk assessment is not always needed to make sound decisions: We don't need to conduct a risk assessment to know that using lead in children's lunch boxes should not be done.

7. *You state TSCA forbids the EPA from sharing the information it receives. Doesn't EPA share MSDS and TRI information, pursuant to the Sections 311-313 of the Superfund Amendments and Reauthorization Act (42 USC 11021-11023), as well as any information required under the health and safety requirements of the law?*

My statement was that "TSCA forbids EPA from sharing much of the limited information it does obtain," referring to that information which is claimed by submitters to be confidential business information (CBI).

My statement refers to EPA's authority under TSCA, whereas your question refers to EPA's broader authorities *under other laws*. You are quite right that EPA has far better authority and even requirements to disclose information under other laws. Indeed, the Toxics Release Inventory – which requires public reporting of chemical *emissions* data -- was established under the Superfund Amendments and Reauthorization Act (SARA), the very purpose of which is revealed in its common title, the Community Right-to-Know Act. It is precisely the type of reform in chemical information disclosure for which I advocate under TSCA, the primary chemicals law applicable to *production, processing and use*.

8. *Do you believe we should follow zero risk tolerance? If so, what are the implications to our standard of living and the products we rely upon? Can you say with certainty that safe chemicals will not disappear if we abandon a risk-based system to evaluate chemicals?*

No, I do not. This is not about achieving "zero risk" or getting rid of chemicals. It's about creating policy that rewards innovation towards the development and use of safer chemicals and chemical products. As my testimony and the references provided in it document, TSCA does the opposite.

9. *Doesn't the evolution and development of the EPA's testing regime, more precise modeling techniques to measure exposure, and information gathering through the pre-manufacture*

*notification process provide the EPA authority to require more testing or halt production of the chemical provide a sound regulatory model to mitigate risks?*

Because of the high burdens TSCA places on EPA to show evidence of risk or high exposure in order to require testing, EPA has rarely been able to use that authority. There has been no evolution of that testing regime; GAO has repeatedly described this concern in a series of reports dating back to 1991.

I support the improvement of exposure modeling, and EDF has worked in a number of EPA and OECD programs that aim to do so. But we have along way to go, as evidenced by the detection of chemicals through biomonitoring at levels much higher than had been predicted by experts and their models. 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. Biomonitoring of phthalates by the Centers for Disease Control (CDC) 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.<sup>19</sup> 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.<sup>20</sup>
- Polybrominated diphenyl ethers (PBDEs) are widely used flame retardants. Different 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, exposure modeling assumed that they would more or less stay in place in products, and they 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 reported in the United States.<sup>21</sup>

The reference in your question to the "premanufacture notification process" applies to new, not existing, chemicals. While TSCA grants EPA somewhat greater authority to require testing of and to regulate new chemicals, several major constraints apply:

- EPA is precluded under TSCA from requiring up-front development and submission of a minimum set of data on a chemical's hazards.<sup>22</sup> This oddity of TSCA stands in contrast to the policies of virtually every other developed country in the world. As a result, the majority of new chemical notifications EPA receives actually contain no hazard data.<sup>23</sup>
- EPA can, and, for a small fraction of new chemicals, does, require some testing or data development on a case-by-case basis. These are cases where EPA can meet the statutory burdens to require testing.<sup>24</sup> First, it must already have substantial information about a chemical—enough to demonstrate that it "may present an unreasonable risk" or that it will be

produced in large quantities and result in significant environmental releases or human exposures. EPA must also demonstrate that insufficient information exists to determine the effects of the chemical on health or the environment,<sup>25</sup> and that testing is necessary to develop such information.<sup>26</sup>

- TSCA grants EPA typically only one bite at the apple for new chemicals—a one-time, 90-day review opportunity at the premanufacture stage, well before the full picture of the actual production, use and exposure, and lifecycle impacts of a chemical has emerged. Once that review is completed and manufacture commences, the chemical is placed on the TSCA Inventory, becomes an "existing" chemical, and any company can manufacture and use it without even having to notify EPA it is doing so. Any conditions EPA imposes apply only to the original notifier, unless EPA also promulgates a Significant New Use Rule (SNUR) specific to that chemical. SNURs, which EPA has issued for about 7% of new chemicals,<sup>27</sup> typically extend the same conditions imposed on the original notifier to any other manufacturer and require that anyone else who begins producing or using the chemical outside of such conditions first notify EPA. However, SNURs only require notification of EPA so that EPA can review the new use, and do not themselves impose new regulatory controls.
- Any prohibition or limitation on a new chemical issued by EPA only applies pending submission of the specified information;<sup>28</sup> any permanent regulation of a new chemical still requires EPA to find that it "presents or will present an unreasonable risk,"<sup>29</sup> the same near-impossible burden that applies to existing chemicals under Section 6 of TSCA.

The concern over data gaps clearly extends to new as well as existing chemicals. In 2006, the National Academy of Sciences noted:

In 1984, an NRC committee providing advice to the National Toxicology Program on testing priorities noted that there are far more chemicals in the human environment than can be evaluated for potential toxicity with available resources and methods (NRC 1984). That committee bemoaned the fragmentary information available with which to set priorities. The same holds true today. For the roughly 700 new industrial chemicals introduced into commerce each year, EPA essentially relies on its own structure-activity models to assess potential hazards and on information on use and estimated production volume contained in PMNs [pre-manufacture notifications] to characterize potential exposure.<sup>30</sup>

10. *Even though the ruling of the D.C. Circuit in Chemical Manufacturers of America v. EPA gave EPA greater deference in defining "unreasonable risk" for section 4 materials, you state that the current government burden of "no unreasonable risk" is ill defined and you recommend shifting to a "reasonable certainty of no harm" standard. Even if there is some previous basis, how many chemicals would meet the "reasonable certainty of no harm" standard?*

This question mixes up two distinct authorities under TSCA:

- Authority to issue a test rule under Section 4 – which requires EPA to demonstrate either that the chemical "*may present* an unreasonable risk" or that it is produced in large quantities and results in significant environmental releases or human exposures.

- Authority to impose restrictions on production, use or disposal of a chemical under Section 6 – which requires EPA to demonstrate that the chemical “*presents or will present an unreasonable risk.*”

The former (which does not entail controlling a chemical) imposes a lesser, but still substantial, burden on EPA than does the latter, as clearly stated in my testimony and as affirmed in the D.C. Circuit decision you cite.<sup>31</sup> That decision also affirmed that EPA test rules issued under Section 4 must satisfy the “substantial evidence” standard for judicial review (see my response to Question 1 above).

I support replacement of TSCA’s “presents or will present an unreasonable risk” standard with a standard of “reasonable certainty of no harm” for purposes of regulating chemicals. Use of this standard has a long and successful history, first as applied to food additives and similar substances for many decades under the Federal Food, Drug and Cosmetics Act, and more recently under the Food Quality Protection Act as applied to pesticides with food uses (as an amendment to section 408 of the FFDCA).

Through the Food Quality Protection Act, Congress directed EPA to review the safety of all existing food tolerances for pesticides that were in effect as of August 1996 using the “reasonable certainty of no harm” standard. These reviews served as a basis for deciding whether, and if so under what conditions, to re-register such pesticides for food uses. According to EPA, the Agency completed reviews of more than 99% of the nearly 10,000 existing tolerances (food-pesticide combinations) within the 10 years Congress mandated for these reviews, and completed re-registration actions or eligibility decisions for nearly 99% of the 566 affected food-use pesticides.<sup>32</sup>

These reviews led EPA to:

- recommend the revocation of 3,200 tolerances;
- recommend the modification of 1,200 tolerances; and
- maintain the safety of 5,237 tolerances.

While most pesticides and tolerances were approved as meeting the “reasonable certainty of no harm” standard, for about a quarter of the pesticide end-use product registrations, the chemical company registrants voluntarily withdrew their registrations – whether because they knew they would not pass the standard, because EPA had recommended revocation, because the pesticides were no longer in use or because they were deemed no longer worth supporting. The great majority of this limited number of cancelled end-use products was voluntary withdrawn from the market by the registrants without EPA issuing cancellation orders or taking enforcement action.

While this FQPA experience is useful, in the context of TSCA, it is simply not possible to say how many chemicals will meet this standard – which points precisely to a key problem with the statute: It has failed to generate needed safety data for the vast majority of chemicals in commerce, and has failed to require that safety assessments be conducted. The result is a wholly justified lack of confidence among the American public that our government knows about and is

prepared to take necessary action to protect people and the environment from the harmful effects of chemicals.

*11. This is simply a yes or no question. Yes or NO, if Congress is going to move legislation to change TSCA, do you think we should convene a broad stakeholder process to try to work through these issues? Again, Yes or NO, would you be willing to serve in the process?*

I cannot provide a simple yes/no answer. Whether I think Congress should convene such a process and whether I would participate depends on when and how it was to take place. I believe such a process would only have value if it was:

- a) driven by fully informed and engaged legislative staff, with a clear set of objectives set in advance intended to resolve key legislative issues,
- b) used an existing legislative vehicle as a starting point (I would suggest the Kid-Safe Chemicals Act), rather than start from scratch;
- c) did not involve trade associations,
- d) included a full range of participants from various non-industry stakeholder groups, and
- e) included not only companies that make chemicals, but companies and institutions that purchase, use, and make or sell products containing chemicals.

[end]



## Endnotes

- <sup>3</sup> TSCA, §6(a). Emphasis added.
- <sup>4</sup> TSCA, §6(c)(1).
- <sup>5</sup> TSCA, §6(a).
- <sup>6</sup> TSCA, §§6(c) and 9.
- <sup>7</sup> TSCA, §19(c)(1)(B).
- <sup>8</sup> U.S. Environmental Protection Agency, *Overview: Office of Pollution Prevention and Toxics Programs*, January 2007, prepared by OPPT ("OPPT Overview, 2007"), p. 11, available at [www.epa.gov/oppt/pubs/oppt101c2.pdf](http://www.epa.gov/oppt/pubs/oppt101c2.pdf).
- <sup>9</sup> At the time it was established, the TSCA Inventory contained about 62,000 chemicals.
- <sup>10</sup> European Commission, *Extended Impact Assessment*, COM(2003)644 final, SEC(2003)1171/3, 29 October 2003, p. 27, available at [http://ec.europa.eu/enterprise/reach/eia\\_en.htm](http://ec.europa.eu/enterprise/reach/eia_en.htm).
- <sup>11</sup> See "Summary of Government of Canada Categorization Decisions for Substances on the DSL," available at [www.ec.gc.ca/substances/csc/eng/dsl/cat\\_gc\\_decisions.cfm](http://www.ec.gc.ca/substances/csc/eng/dsl/cat_gc_decisions.cfm). As noted by Environment Canada: "The purpose of categorization is not to establish the risks to the environment or human health. Any such risk must be additionally investigated through a screening assessment of the substance." See [www.ec.gc.ca/substances/csc/eng/dsl/cat\\_background.cfm](http://www.ec.gc.ca/substances/csc/eng/dsl/cat_background.cfm). Nonetheless, sufficient evidence of potential risk based on available information has been found for these chemicals to warrant their further investigation, including development of more and better information about them.
- <sup>12</sup> Organization for Economic Cooperation and Development (OECD), Series on Testing and Assessment, Number 33, 14 August 2001. *Harmonised Integrated Classification System for Human Health and Environmental Hazards of Chemical Substances and Mixtures*, available at [www.oecd.org/LongAbstract/0,2546,en\\_2649\\_34365\\_2671862\\_1\\_1\\_1\\_1,00.html](http://www.oecd.org/LongAbstract/0,2546,en_2649_34365_2671862_1_1_1_1,00.html).
- <sup>13</sup> According to OECD: "The SIDS is regarded as the minimum information needed to assess an HPV chemical to determine whether any further work should be carried out or not." See [www.oecd.org/document/21/0,3343,en\\_2649\\_34379\\_1939669\\_1\\_1\\_1\\_1,00.html](http://www.oecd.org/document/21/0,3343,en_2649_34379_1939669_1_1_1_1,00.html).
- <sup>14</sup> EPA's 1998 Data Availability Study is available at [www.epa.gov/chemrtk/pubs/general/hazchem.htm](http://www.epa.gov/chemrtk/pubs/general/hazchem.htm). The undertaking of that study and the launch of the HPV Challenge were spurred by a 1997 report, *Toxic Ignorance*, published by Environmental Defense Fund, which examined 100 HPV chemicals and found that more than 70% of them lacked publicly available data sufficient to conduct even a screening-level hazard assessment. *Toxic Ignorance* and other Environmental Defense reports and information on the HPV Challenge are available at [www.environmentaldefense.org/subissue.cfm?subissue=14](http://www.environmentaldefense.org/subissue.cfm?subissue=14).
- <sup>15</sup> See EDF's *HPVTracker*, at [www.environmentaldefense.org/documents/2734\\_WelcomeTracker.htm](http://www.environmentaldefense.org/documents/2734_WelcomeTracker.htm); and Denison, R.A., *High Hopes, Low Marks: A final report card on the High Production Volume Chemical Challenge*, July 2007, at [www.environmentaldefense.org/hpvreportcard](http://www.environmentaldefense.org/hpvreportcard).
- <sup>16</sup> Source: Environmental Defense Fund analysis of EPA's hazard characterizations of HPV Challenge chemicals posted through September 2008 at [iaspub.epa.gov/opthpv/hpv\\_hc\\_characterization.get\\_report?doctype=2](http://iaspub.epa.gov/opthpv/hpv_hc_characterization.get_report?doctype=2).
- <sup>17</sup> National Research Council (2006) *Toxicity Testing for Assessment of Environmental Agents*, Board on Environmental Studies and Toxicology, National Academy of Sciences, p. 112, at [http://books.nap.edu/openbook.php?record\\_id=11523&page=112](http://books.nap.edu/openbook.php?record_id=11523&page=112).
- <sup>18</sup> See Denison, R.A. (2007) *Not That Innocent: A Comparative Analysis of Canadian, European Union and United States Policies on Industrial Chemicals* Appendix B, (Environmental Defense Fund, Washington, DC), at [www.edf.org/chempolicyreport](http://www.edf.org/chempolicyreport).
- <sup>19</sup> National Toxicology Program Center for the Evaluation of Risk to Human Reproduction (CERHR). (2000) NTP-CERHR Expert Panel Report on Di-n-Butyl Phthalate, at [cerhr.niehs.nih.gov/chemicals/phthalates/dbp/dbp-final-inprog.pdf](http://cerhr.niehs.nih.gov/chemicals/phthalates/dbp/dbp-final-inprog.pdf); David RM. (2000) Exposure to phthalate esters. *Environ. Health Perspect.* 108(10):979-982; and Kohn MC, Parham F, Masten SA, et al. (2000) Human exposure estimates for phthalates. *Environ. Health Perspect.* 108(11):A495.
- <sup>20</sup> Agency for Toxic Substances and Disease Registry. "ATSDR's Substance-Specific Priority Data Needs (PDNs)." Available at [www.atsdr.cdc.gov/pdns/unfilled.html](http://www.atsdr.cdc.gov/pdns/unfilled.html).
- <sup>21</sup> 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.

<sup>23</sup> §5(d) of TSCA limits any requirement to submit hazard data for a new chemical, as specified in §5(b)(2), to test data that already exist and are "in the possession and control" of the notifier of the new chemical (§5(d)(1)(B)), and a description of any other relevant information that is already known to the notifier or "reasonably ascertainable" (§5(d)(1)(C)).

<sup>23</sup> According to EPA: 67% of PMNs contain no test data; 85% of PMNs contain no health data; and more than 95% of PMNs contain no ecotoxicity data. The first two statistics are from EPA, OPPT Overview, 2007, *op. cit.*, p. 8. The third statistic is from EPA, OPPT, Draft Q&A for the New Chemicals Program, undated, answer to Question 118-5, at [www.epa.gov/opptintr/newchemicals/pubs/qanda-newchemicals.pdf](http://www.epa.gov/opptintr/newchemicals/pubs/qanda-newchemicals.pdf).

<sup>24</sup> Where EPA determines that additional data are needed to assess a new chemical, a requirement for such data may be included in a TSCA §4 Enforceable Consent Agreements (ECAs), which it uses as an alternative to test rules in cases where there is agreement with industry on the need and scope of testing. EPA has issued such orders for about 60 chemicals; see EPA, OPPT Overview, 2007, *op. cit.*, p. 15. Alternatively EPA may negotiate with the notifier a voluntary agreement to conduct testing, which is known as a Voluntary Testing Action. Through the end of September 2005, EPA had negotiated about 300 Voluntary Testing Actions; see EPA, OPPT Overview, 2007, *op. cit.*, p. 11.

<sup>25</sup> In practice, this requirement can be extremely onerous and consume substantial resources, as it compels an extensive search for information. It can also be viewed as effectively having to prove the nonexistence of sufficient information.

<sup>26</sup> TSCA, §4(a)(1)(A)(ii) and (iii).

<sup>27</sup> See EPA, OPPT Overview, 2007, *op. cit.*, pp. 9-11.

<sup>28</sup> TSCA, §5(c).

<sup>29</sup> TSCA, §5(f).

<sup>30</sup> National Research Council (2006) *Toxicity Testing for Assessment of Environmental Agents*, Board on Environmental Studies and Toxicology, National Academy of Sciences, p. 112, at [http://books.nap.edu/openbook.php?record\\_id=11523&page=112](http://books.nap.edu/openbook.php?record_id=11523&page=112).

<sup>31</sup> "... section 4's 'may present' language demands even less [than section 6's 'presents or will present' language]."

Paragraph 39 of 859 F.2d 977, *Chemical Manufacturers Association, et al. v. EPA*, at <http://bulk.resource.org/courts.gov/c/F2/859/859.F2d.977.86-1718.html>.

<sup>32</sup> See [www.epa.gov/pesticides/regulating/laws/fupa/fupa\\_accomplishments.htm](http://www.epa.gov/pesticides/regulating/laws/fupa/fupa_accomplishments.htm).



March 20, 2009

The Honorable Joe Barton  
Ranking Member  
Committee on Energy and Commerce  
2125 Rayburn House Office Building  
U.S. House of Representatives  
Washington, DC 20515-6115

Dear Mr. Barton,

In response to my testimony before the Subcommittee on Commerce, Trade, and Consumer Protection on February 26, 2009 at the hearing entitled "Revisiting the Toxic Substances Control Act of 1976," you sent the following question:

"Kaiser Permanente has been gracious with its time and resources to look at alternatives to current products and do so with in-house certified industrial hygienists that explore the health impacts of the alternatives. How are these hygienists certified and do you disclose your findings?"

Following is my response:

Industrial hygienists who achieve certification through the American Board of Industrial Hygiene have passed the Certified Industrial Hygienist (CIH) examination and meet all of the rigorous requirements associated with obtaining and maintaining their certifications. Kaiser Permanente has several Certified Industrial Hygienists on staff.

Information gathered during our internal testing is disclosed in some cases. We conduct our tests to make internal purchasing decisions, and at times we are bound by confidentiality agreements with prospective suppliers. Additionally, we do not conduct the tests for the purpose of public disclosure as that would add to the time and cost of our testing. But, we can at times make the broad results available (e.g., the rubber-based resilient flooring we tested did not pose air quality hazards based on our tests). And our CIH staff speak at national conferences on a variety of topics to share learnings.

Thank you very much for your interest in this topic.

Sincerely,

Kathy Gerwig  
Vice President, Workplace Safety and  
Environmental Stewardship Officer  
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ONE HUNDRED ELEVENTH CONGRESS

## Congress of the United States

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March 16, 2009

Cal Dooley  
President and CEO  
American Chemistry Council  
1300 Wilson Blvd.  
Arlington, VA 22209

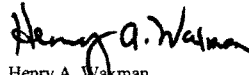
Dear Mr. Dooley:

Thank you for appearing before the Subcommittee on Commerce, Trade, and Consumer Protection on February 26, 2009, at the hearing entitled "Revisiting the Toxic Substances Control Act of 1976".

Pursuant to the Committee's Rules, attached are written questions for the record directed to you from certain Members of the Committee. In preparing your answers, please address your response to the Member who submitted the questions and include the text of the question with your response, using separate pages for responses to each Member.

Please provide your responses by March 30, 2009, to Earley Green, Chief Clerk, in Room 2125 of the Rayburn House Office Building and via e-mail to [Earley.Green@mail.house.gov](mailto:Earley.Green@mail.house.gov). Please contact Earley Green or Jennifer Berenholz at (202) 225-2927 if you have any questions.

Sincerely,



Henry A. Waxman  
Chairman

Attachment

**The Honorable Henry Waxman and the Honorable Bobby Rush**

1. In the debate last year over a proposed ban on phthalates in children's toys—ultimately enacted as part of HR 4040—the American Chemistry Council expressed serious concern over the safety of whatever chemicals would replace the banned substances. Yet ACC appears to oppose proposals that TSCA require at least a base set of information to be developed for most or all chemicals in commerce. Please explain your position on this issue and how it would be possible to identify safer alternatives to chemicals of concern without developing basic information on all chemicals.
2. Many of your member companies are preparing to meet the requirements of the European regulation for the Registration, Evaluation and Authorization of Chemicals ("REACH"). In your opinion, should manufacturers and importers of chemicals in the United States, whether foreign or domestic, be allowed to claim information as "confidential business information" under TSCA if they provide comparable information for public disclosure under REACH?

**Follow-up Questions for Written Submission from the House Energy and Commerce  
Committee, Subcommittee on Commerce, Trade, and Consumer Protection Hearing  
February 26, 2009**

WAXMAN AND RUSH QUESTIONS:

**1. *In the debate last year over a proposed ban on phthalates in children's toys – ultimately enacted as part of HR 4040 – the American Chemistry Council expressed serious concern over the safety of whatever chemicals would replace the banned substances. Yet ACC appears to oppose proposals that TSCA require at least a base set of information to be developed for most or all chemicals in commerce. Please explain your position on this issue and how it would be possible to identify safer alternatives to chemicals of concern without developing basic information on all chemicals.***

Answer:

In ACC's view, the federal chemical management system under TSCA should assure that manufacturers and users have not only appropriate hazard data (which is, in most instances, already available), but also appropriate use and exposure information necessary to make decisions about safe use of chemicals. This does not mean that an identical set of hazard information (sometimes referred to as a "base set" of information) must be available on all chemicals. Rather, exposure and use considerations should drive hazard information requirements about chemicals.

Under such an approach, manufacturers and chemical users would provide more information about chemicals where there are exposures to humans or the environment, compared to, for example, chemicals with uses in enclosed processes or where potential health and environmental exposures are minimized. By itself, a "base set" approach of information on the hazards of chemicals provides an insufficient basis to evaluate the potential risks of chemicals and their "safer" alternatives. That is why in our support for modernizing TSCA, ACC supports: 1) information requirements that also include basic use and exposure information; 2) a system by which EPA can prioritize its review of chemicals based on hazard, use and exposure information; and 3) authority for EPA to determine the safety of priority chemicals for their intended use(s). This approach would assure that priority chemicals are reviewed for their likelihood to cause harm in the expected use or exposure pattern.

Chemical safety assessments and decisions that are based only on hazard characteristic(s) overlook important information and are bad public policy.

**2. *Many of your member companies are preparing to meet the requirements of the European regulation for the Registration, Evaluation and Authorization of Chemicals ("REACH"). In your opinion, should manufacturers and importers of chemicals in the United States, whether foreign or domestic, be allowed to claim information as "confidential***

*business information” under TSCA if they provide comparable information for public disclosure under REACH?*

Answer:

Once information is publicly available, be it in the U.S., Europe, or Asia, it is public and cannot be claimed confidential. ACC has never suggested, and is not suggesting, that information publicly available in another region should be able to be claimed confidential in the United States.

It should be noted, however, that even the European REACH system permits claims of confidentiality – not all information submitted to the European Chemicals Agency will be publicly available. In ACC’s view, this is appropriate. Provisions for protection of appropriate confidential business information are included in TSCA today and must be included in any modernized US chemical management system under TSCA. That said, the fact is that TSCA currently prohibits EPA from receiving or sharing confidential business information with other governments. In ACC’s view, EPA should have the authority under TSCA to share appropriate confidential business information with state, local and select foreign governments when it is relevant to a decision on chemical safety and when there are appropriate safeguards against inappropriate disclosure. In this context, appropriate safeguards would include requirements similar to those applied under U.S. law for requests to disclose confidential business information.

## BARTON QUESTIONS

**1. Because TSCA is focused on interstate commerce, it has a pretty strong version of conflict pre-emption in it. Recognizing the balkanizing effect of disparate state standards, it makes sense that ACC would support a Federal pre-emption provision that prevents states and localities from enacting laws that conflict with, hinder, frustrate the purpose of or pose obstacles to the Federal law. Is that correct?**

Answer:

ACC believes that the existing pre-emption provisions of TSCA provide a workable approach to conflict pre-emption, while retaining State authority to pursue any necessary regulatory requirements that do not conflict with the federal approach.

**2. Would ACC support a hazard-only based approach in any form of a TSCA rewrite?**

Answer:

No. ACC supports a risk-based approach to chemicals management and regulation under TSCA. In our view, a hazard-only based approach ignores important use and exposure information that is critical to understanding the risks posed by a chemical. A hazard-only based approach could result in decisions that imperil, rather than protect, public health and the environment.

**3. Does ACC support the requirement that TSCA assessed science show the weight of the evidence, be conducted under good laboratory conditions, be of high quality, have findings correlate to data generated, and the experiments repeatable from start to finish?**

Answer:

Yes. ACC believes there is considerable value in having agreed upon, science-based criteria and approaches to support federal decision-making about chemicals under TSCA. These should include promotion and use of scientific weight of evidence processes within government risk assessment activities. ACC believes that weight of the evidence processes must include good laboratory conditions, findings correlated to generate data and fully repeatable experiments. All science, whether conducted by academics, non-governmental organizations, government or industry, should adhere to such criteria and approaches to promote the credibility, reliability and high quality of data that support decisionmaking about chemicals under TSCA. ACC believes such criteria and approaches will appropriately move the debate from the quality of science to the implications of the science for decisions.

**4. Your testimony states that ACC would support some sharing of CBI only with other governmental bodies. Are you confident that these bodies will be able to protect your trade secrets, especially the international bodies? Should any public disclosures of this information be allowed?**



Answer:

ACC believes that EPA should have the authority under TSCA to receive and share confidential business information (CBI) with other governments, where there are assurances that the information will be protected to the same level as the U.S. government protects the information. We believe the Executive Branch should have the ability to negotiate appropriate agreements to share such information, with the condition that legal recourse exists for information that has been wrongfully disclosed. There are, however, governments and legal systems in various parts of the world where ACC and its members would not have confidence that CBI would be appropriately protected. Therefore, ACC would urge the U.S. government to not enter into such agreements where such critical protection cannot be assured.

**5. This is simply a yes or no question. Yes or NO, if Congress is going to move legislation to change TSCA, do you think we should convene a broad stakeholder process to try to work through these issues? Again, Yes or NO, would you be willing to serve in the process?**

Answer:

Yes, Congress should consider convening a broad stakeholder process to work through chemical management issues under TSCA. Yes, ACC would be willing to participate in the process, and indeed would look forward to the opportunity to engage in a detailed discussion of TSCA and the future of the U.S. chemical management system. Additionally, chemical users (downstream value chain) must be represented in such a stakeholder process.



March 30, 2009

The Honorable Joe Barton  
Ranking Member  
Committee on Energy and Commerce  
U.S. House of Representatives  
2125 Rayburn House Office Building  
Washington, DC 20510-6115

Dear Ranking Member Barton:

On behalf of the Synthetic Organic Chemical Manufacturers Association (SOCMA), I am writing in response to a letter from Chairman Henry A. Waxman dated March 16, 2009. The letter attached a list of written questions from you that I was asked to answer for the record.

Enclosed are my responses to your questions. We would appreciate an opportunity to discuss them with your staff in detail. Please ask the appropriate person to contact Dan Newton, Government Relations Manager, of SOCMA's staff at (202) 721-4158 or [newtond@socma.com](mailto:newtond@socma.com), or me at 908-322-8440 [idelisi@fanwoodchemical.com](mailto:idelisi@fanwoodchemical.com).

Sincerely yours,

V.M. (Jim) DeLisi  
President, Fanwood Chemical, Inc.

Enclosures (2)

cc Henry A. Waxman



**Follow-up Questions for Written Submission from Commerce, Trade, and Consumer Protection  
Subcommittee Hearing  
February 26, 2009**

**Questions:**

1. You testified that "TSCA and its 'unreasonable risk' standard have generally stood the test of time as a flexible law that has protected human health and the environment." What do you say to those individuals that now argue, particularly after the *Corrosion Proof Fittings* case of 1991 that EPA's authority under TSCA to regulate individual chemicals is really no useful authority at all?

I would say to those individuals that they should further examine the approach the EPA took to achieve its goal in this case and the intent of the statute. EPA has issued a number of Section 6 rules banning specific uses of various products. The asbestos ban addressed in *Corrosion Proof Fittings* is the only Section 6 rule that has ever been challenged successfully. EPA lost in that case not because Section 6 is inadequate, but because EPA did not follow the statute's requirements or engage in reasoned decisionmaking.

Section 6 contains a hierarchy of regulatory measures and requires EPA to "us[e] the least burdensome requirements." 15 U.S.C. § 2605(a). EPA attempted to ban almost all asbestos-containing products and in doing so chose the most burdensome approach. The court found that EPA did not adequately consider the intermediate options, primarily because it was trying to achieve "zero risk," rather than to eliminate "unreasonable risks." *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1217 (5<sup>th</sup> Cir. 1991).

The reason the statute uses the "unreasonable risk" standard is because Congress recognized that we do not live in a risk-free world. Additionally, while the "primary purpose" of TSCA is "to assure that . . . chemical[s] do not present an unreasonable risk," Congress also recognized the importance of looking at the societal and commercial benefits a chemical may have when used as intended and the importance of balancing costs and benefits when regulating. *Id.* §§ 2601(b)(3); 2605(c). An example highlighted in the case involved the life-saving use of asbestos in brakes. EPA's own studies indicated that replacing asbestos in brakes with something else presented as much risk, if not more, than the status quo, both because other fibrous substitutes also posed cancer risks and because performance shortcomings with the substitutes would increase automobile accidents. The court also faulted EPA for a number of procedural failings in the rulemaking process that EPA could easily have avoided. 947 F.2d at 1211-13

To the extent the statute makes it difficult to ban substances, Congress did so intentionally not only because of the potential risks associated with substituted chemicals, which oftentimes lack toxicity data, but also because of the commercial disruptions and lost benefits that product bans can have. If EPA had not tried to ban critical uses of a substance that did not have readily available substitutes, it likely would have prevailed. Indeed, given the deference that agencies routinely get when interpreting statutes they are charged with administering, EPA might have won if it simply had fairly addressed the substance of critical comments, rather than ignoring them or giving them short shrift.

Many TSCA critics point to this case as evidence of TSCA being an inadequate statute. This is an effective lobbying and PR approach, given all the adverse publicity asbestos has gotten. It is not a valid approach on the merits, however, since the decision was a reasonable resolution in light of Congress's

intent in enacting TSCA and the flawed approaches that EPA chose. SOCMA believes the approach laid out in the statute is reasonable and encourages you to read the opinion of the Court of Appeals, which is attached.

2. Some of our panelists today are arguing that Congress should enact a hazard-based standard. What would be the effect of a hazard-based standard for small and medium sized chemical manufacturers in the United States? Do these facilities have the ability to relocate like many of the larger companies?

The effect of a hazard-based standard for small and medium companies, as most SOCMA members are, would be substantially negative. For that matter, it would be substantially negative for most large companies. I am certain that some of our members would lose market access, which has obvious bad consequences such as job loss and less tax revenue.

The inherent flaw in the hazard-based approach was recognized 500 years ago by Paracelsus, a great physician who is considered by some the father of toxicology, and who said: "All things are poison and nothing is without poison, only the dose permits something not to be poisonous."<sup>1</sup> A hazard-based standard does not factor in use and resulting exposures, which should always be weighed when making policy decisions on chemicals. By leaving out half the risk equation (i.e., hazard x exposure = risk), unsound conclusions can be reached, creating unnecessary public angst and adversely affecting the chemical industry and its many vital customer markets.

Plant relocations can and do occur, even for small and medium sized companies, for a myriad of reasons. Excessive regulation that impacts on the costs of operations is one of them. Some of our smallest members have already moved some of their processing to China and India. In some instances, they do this by investing in facilities in these lands. In other instances, it is done by taking their technology to existing factories and allowing them to produce chemicals under a tolling arrangement. In other cases, our members have been driven out of businesses when less expensive comparable products have been offered to their customers from overseas sources.

In addition, many of our members are being hurt by the fact that the production of Active Pharmaceutical Intermediates (APIs) is moving to India and China at an alarming rate. It is expected that more than 80% of such substances will be sourced from these two countries by 2014. This type of manufacturing often requires the type of chemical processing that our members provide. Many of our members that provide services to the Pharmaceuticals Industry have been severely impacted by the relocation of this type of chemical processing from the USA and the EU, some of which is related to the regulatory burden.

Another way that our members lose business is when the next processing step is moved by their customer outside of North America. A REACH like rule in the USA is very likely to have a profound impact on our "downstream" users in every sector that we service. Since REACH does not cover finished articles, unless they are designed to release a substance, it is very likely that articles such as tires will move to non-EU overseas locations, costing our members further business in the future.

<sup>1</sup> <http://en.wikipedia.org/wiki/Paracelsus>.



Finally, I would like to note that when the toy industry moved overseas, we lost not only the manufacturers of toys, with the tremendous quantities of plastics, paints, etc., that are entailed in their manufacture, but also all of the ancillary components such as packaging, which consumed large quantities of colorants and paper processing chemicals, many of which are made by our members.

3. You testified EPA has broad authority to issue rules requiring testing of chemicals in existing use, and you questioned whether EPA currently uses its authority to the fullest extent. Can you please expand what on authority you believe EPA has but is not using in this arena?

The primary authority that EPA could use more to address existing chemicals is TSCA Section 4. EPA could have used this avenue much more aggressively for high production volume (HPV) chemicals that were not sponsored under the HPV Challenge program, a voluntary program intended to encourage companies to generate data on their chemicals. EPA has only issued one Section 4 test rule regarding such "orphan" chemicals, even though the HPV Challenge was initiated in 1998. On March 31, EPA will hold a public meeting on a second such rule, which was proposed last July but still has not been issued.

TSCA Section 4 has a risk trigger, TSCA 4(a)(1)(A), and an exposure trigger, TSCA 4(a)(1)(B). To elaborate on TSCA 4(a)(1)(B), which I feel is of particular significance to the question at hand, the EPA can mandate testing on chemicals with substantial production volumes and exposures even without making a risk finding. This is broad authority. Many of the chemicals in commerce by volume are high production volume chemicals.

4. We've run into issues before on this Subcommittee with cross-border information sharing. Are there any problems of which you are aware that would prevent EPA from working with EU to obtain the information submitted for the REACH program?

I am not aware of any problems that would prevent EPA from obtaining information submitted for the REACH program. Since almost everything submitted under REACH is to be in the public domain, and the testing guidelines are the same as they are here, there should not be problems with EPA accessing the data. It is important to note in this connection that, since the EU has a larger chemical industry than the US, there are very few chemicals in commerce in the US that will not be subject to REACH. For this reason, it is truly in our best interest to let the process that the EU has begun play out for several years, and then re-examine this issue with the goal of filling in any "holes" that are found. Also, where companies conducting or sponsoring REACH testing conclude that such testing reveals that a chemical presents a substantial risk of injury to health or the environment, and that company manufactures, processes or distributes that chemical within the U.S. (as should generally be the case; see above), that company would be required to file a Section 8(e) substantial risk notice with EPA. While REACH is being implemented, therefore, TSCA gives EPA all the authority it needs to fill any gaps that it perceives, as well as to respond to issues that may come to light in the EU.

5. You testified that as of 2005, less than 6,500 of the chemicals of the EPA's 80,000+ inventory were in use in commerce. That's a significantly smaller world of chemicals. While we know the EPA has only regulated a handful of chemicals under TSCA, do you know how many have been studied by EPA under TSCA? In other words, are there a significant number of chemicals the EPA has studied but declined to regulate?

First, I would like to qualify what I said in my testimony by noting that this number excludes exemptions for polymers, R&D chemicals and chemicals manufactured under 25,000 lbs/year. We know that the



EPA has studied many chemicals and that most chemicals are not regulated because they can be used safely. Again, when looking at hazard and exposure, oftentimes the exposure part of the equation can be controlled, by protective equipment, warnings, etc., therefore mitigating risk.

Second, I would note that every chemical that has been manufactured in the United States since 1979 that does not fall into an exemption has been reviewed by EPA under its new chemical program. As of 2004, "premanufacture notices" (PMNs) had been submitted for over 32,000 chemicals. Some 22,000 of these chemicals ultimately commenced manufacture, but most of these are no longer in commerce according to the EPA's last Inventory Update Rule (IUR).

In the new chemical review process, EPA uses data the submitter provides in PMNs, additional data that may be available from other sources, structural activity relationships (SARs), and "read-across," where chemicals being considered are analogous to chemicals that EPA has previously assessed. EPA is also able to compel PMN submitters to provide it with additional data, either voluntarily or via administrative orders. EPA's new chemical decision making fundamentally involves looking at hazard, use and exposures to make a risk determination. Most chemicals are approved because the EPA is able to determine that the potential risks a chemical poses can be mitigated via some control measure. But EPA has the power to limit or prohibit the manufacture, processing or use of new chemicals, and over 3,800 of the 32,000+ PMN chemicals were regulated in some way or had their PMNs withdrawn in the face of impending EPA action.

As to existing chemicals, EPA can issue rules or enter into enforceable consent agreements to require chemical testing. Perhaps more important, under the High Production Volume (HPV) Challenge program, data on over a thousand substances have been submitted voluntarily. The HPV program has provided the EPA with a foundation to work from in its prioritization efforts under the new ChAMP program. EPA is continuing the study of existing chemicals via this program, which encompasses moderate production volume organic chemicals (i.e., those manufactured between 25,000 and 1,000,000 lbs/yr) and high production inorganic chemicals.

6. What do you see as the benefits of ChAMP? Should, as some argue, ChAMP be abolished in favor of a European-style approach?

The benefits of ChAMP are clear. It is underway, and should continue. The program in essence is being used as a mechanism to collect data and increase public confidence. ChAMP will reset the TSCA inventory of 80,000+ chemicals -- which TSCA critics like to point to for shock value and to belittle EPA's work thus far -- to reflect the significantly lower number of chemicals that are actually in commerce. I expect the reset will indeed enhance public confidence.

As noted earlier, ChAMP is addressing existing chemicals, working with clusters of similar chemicals in a prioritized fashion. The prioritizations that EPA has already begun developing under the ChAMP program build on the HPV Challenge program. This is a success often overlooked by many critics who assert the HPV program's shortcomings. Data will also be leveraged from other countries, especially Canada. In addition, data generated in Europe will be made public and can be used by EPA in these evaluations. After this step of prioritizing and assessing, the EPA can decide whether regulation is warranted.



ChAMP will accomplish a lot and will do so faster than REACH and with much less burden. ChAMP should be regarded as a viable approach to chemicals policy and should certainly not be abolished in favor of a European-style approach. The European approach is experimental and, in our view, unduly burdensome because it requires creation of a uniform data set for chemicals without regard to risk. The Europeans are developing data on many of the same chemicals that exist in the US. Why would we want to duplicate this?

7. This is simply a yes or no question. Yes or NO, if Congress is going to move legislation to change TSCA, do you think we should convene a broad stakeholder process to try to work through these issues? Again, Yes or NO, would you be willing to serve in the process?

YES.



April 16, 2009

The Honorable Kathy Castor  
U.S. House of Representatives Committee on Energy and Commerce  
2125 Rayburn House Office Building  
Washington, DC 20510-6115

Dear Representative Castor:

On behalf of the Synthetic Organic Chemical Manufacturers Association (SOCMA) I am writing in response to an oral question you posed at the February 26, 2009 Subcommittee Hearing entitled *Revisiting the Toxic Substances Control Act of 1976*. At the end of the hearing, you asked, for the record, why only one group of chemicals has been barred since the enactment of TSCA in 1976. I would like to provide you with an answer from the unique perspective of a SOCMA member.

Enclosed is my response to your question. We would be happy to discuss this with you in more detail. If you would like to schedule a meeting or have any further questions, please contact Dan Newton, Government Relations Manager, of SOCMA's staff at (202) 721-4158 or [newtond@socma.com](mailto:newtond@socma.com), or me at 908-322-8440 [idelisi@fanwoodchemical.com](mailto:idelisi@fanwoodchemical.com).

Sincerely yours,

V.M. (Jim) DeLisi  
President, Fanwood Chemical, Inc.

Enclosures (1)





Follow-up Oral Question from Commerce, Trade, and Consumer Protection Subcommittee Hearing  
February 26, 2009

**Question:**

1. Why has only one group of chemicals been barred since the adoption of TSCA in 1976?

I believe your question is a reference to the polychlorinated biphenyls (PCBs) prohibition established by Congress under TSCA Section 6(e). With that said, I would like to note that since the enactment of TSCA, EPA has restricted the following existing chemicals (or certain uses of them) under its TSCA Section 6(a) authority:

1. Nonessential uses of chlorofluorocarbons;
2. Wastes containing dioxin;
3. Asbestos flooring felt, commercial paper, corrugated cardboard, rollboard, and specialty paper, as well as any new (post-1990) uses of asbestos<sup>1</sup>;
4. Three chemicals when used in metalworking fluids<sup>2</sup>; and
5. Hexavalent chromium-based water treatment chemicals when used in comfort cooling towers<sup>3</sup>.

The regulation of dioxin and chlorofluorocarbons was eventually superseded by regulations under other statutes, the Resource Conservation and Recovery Act and the Clean Air Act, respectively.

One may understandably wonder why such a relatively low number of chemicals has been regulated or banned under this authority, especially given the vast number of chemicals on the TSCA inventory.

However, before drawing adverse conclusions about the adequacy of current law, one should consider: 1) how the concept of risk ties into your question, 2) the successes of the new chemicals program, 3) EPA's jurisdiction under TSCA, and finally 4) the intent of TSCA Section 6. I shall go through each below.

**TSCA's Risk Orientation**

I would like to emphasize the importance of using a risk-based approach when considering chemical policy and explain how this ties into your question. TSCA is fundamentally a risk-based statute, and its provisions generally turn on whether a chemical presents an "unreasonable risk" to health or the environment. The statute uses this "unreasonable risk" standard because Congress recognized that we do not live in a risk-free world. Additionally, while the "primary purpose" of TSCA is "to assure that . . . chemical[s] do not present an unreasonable risk," Congress also recognized the importance of looking at the societal and commercial benefits a chemical may have when used as intended and the importance of balancing costs and benefits when regulating.<sup>4</sup>

A risk-based approach factors the inherent hazards a chemical may have with the potential exposures (i.e., hazard x exposure = risk) in order to make a sound risk-based policy decision. **Under this approach, the great majority of chemicals can be used safely.** The risks associated with a chemical can typically be mitigated to the point that they are no longer "unreasonable" by controlling the exposure side of the

<sup>1</sup> 40 C.F.R. Part 763, Subpart I.

<sup>2</sup> Id. Part 747.

<sup>3</sup> Id. Part 749.

<sup>4</sup> 15 U.S.C. §§ 2601(b)(3); 2605(c).



risk equation. The EPA can restrict certain activities encompassed within the manufacture, processing, distribution, use or disposal of a chemical in order to accomplish this.

#### The New Chemicals Program

Many TSCA critics overlook the successes of the new chemicals program. Every chemical that has been proposed for manufacture since 1979 – over 32,000 in all – has been reviewed by EPA under this program. As of 2004, approximately 3,200 chemicals that have gone through the new chemical review process have faced regulatory action under TSCA Section 5, such as the issuance of consent orders or significant new use rules (SNURs). This regulatory action averted the need for an after-the-fact ban. Indeed, some 1,600 of those chemicals had been withdrawn in the face of Section 5(e) regulatory action – in effect, the manufacturers banned them themselves. Additionally, there are many chemicals still in review, as submitters have agreed to suspend the 90 day review period mandated for PMNs under TSCA in order to conduct testing. Finally, lower volume chemicals, like Low Volume Exemptions (LVEs) that are not intended to be manufactured over 10,000 kg/yr, have been issued denials. These denials are in essence the low volume equivalent of a ban.

#### EPA's Jurisdiction Under TSCA

Another factor that should be considered when answering your question is EPA's jurisdiction under TSCA and the types of substances and uses the statute covers. TSCA covers industrial chemicals. This is important because many people do not realize that the statute does not address the management of the entire world of chemicals and all of their possible uses. Rather, it only covers a piece. Substances intended to be used as pesticides, for example, fall under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA). Radioactive source material does not fall under TSCA, neither do explosives. Substances intended to be ingested, like food additives and drugs, also do not fall under TSCA. Different statutes cover different uses of chemicals, and have risk management options in place.

#### The Intent of Section 6

Section 6 contains a hierarchy of regulatory measures and requires EPA to “us[e] the least burdensome requirements.” This requirement flows from the statutory provisions noted earlier that restrict EPA to regulating “unreasonable risks” and that require EPA to balance the societal and commercial benefits of a chemical against its risks.

To the extent the statute makes it difficult to ban substances, Congress did so intentionally, not only because of the potential risks associated with the chemicals that may be substituted for banned chemicals, for which there may be less knowledge about the chemical's properties, but also because of the commercial disruptions and lost benefits that product bans can have. In the *Corrosion Proof Fittings v. EPA* case, EPA tried to ban critical uses of asbestos that did not have readily available substitutes that were equally or more safe or effective.<sup>5</sup> In doing so, EPA failed to accomplish TSCA's goal. Also, many of EPA's failures in that case were unnecessary, and given the deference that agencies routinely get when interpreting statutes they are charged with administering, EPA might have won the case if it simply had fairly addressed the substance of critical comments, rather than ignoring them or giving them short shrift.

<sup>5</sup> See 947 F.2d 1201, 1211-1213 (5<sup>th</sup> Cir. 1991).



Many TSCA critics point to this case as evidence of TSCA being an inadequate statute. This may be an effective lobbying or PR approach, given all the adverse publicity asbestos has gotten. It is not a valid approach on the merits, however, since the decision was a reasonable resolution in light of Congress's intent in enacting TSCA and the flawed approaches that EPA chose. SOCMA believes the approach laid out in the statute is reasonable



National Petrochemical & Refiners Association

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March 30, 2009

Representative Bobby Rush  
Chairman, Subcommittee on Commerce,  
Trade & Consumer Protection  
2125 Rayburn House Office Building  
Washington, DC 20515

Representative George Radanovich  
Ranking Member, Subcommittee on  
Commerce, Trade & Consumer Protection  
2125 Rayburn House Office Building  
Washington, DC 20515

Dear Representatives Rush and Radanovich,

I testified before the House Subcommittee on Commerce, Trade and Consumer Protection  
February 26, 2009 on the Toxic Substance Control Act of 1976.

I am pleased to respond to the questions sent on March 16, 2009. Please see the enclosed  
document.

NPRA and its members look forward to working further with the Subcommittee on this issue.

Sincerely,

A handwritten signature in cursive script, appearing to read "C. Drevna".

Charlie T. Drevna  
President



National Petrochemical &amp; Refiners Association

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**Post Hearing Questions  
Subcommittee on Commerce, Trade & Consumer Protection  
March 16, 2009**

**Responses to the Honorable Joe Barton**

- 1. Your testimony talks about how Congress tried to set up a series of checks-and-balances on regulatory systems under TSCA. Could you please expand more for me on that point?**

The checks-and-balances to which our testimony refers have to do with the scientific findings that EPA must make before requiring potentially burdensome actions from the regulated community. For example, under TSCA Section 4, EPA must find that a substantial number of people may be exposed before requiring companies to conduct laboratory testing, which can be quite costly and a significant burden on animal welfare. Under TSCA Section 6, the Agency must find that a substance will present an unreasonable risk before taking action to control uses or banning the substance outright. These provisions were incorporated to prevent the Executive Branch from making arbitrary or politically-motivated decisions on matters that could disrupt the flow of interstate commerce.

The checks-and-balances under TSCA are consistent with other statutes giving broad authority to the Executive Branch. Other environmental statutes require EPA to base its decisions on sound science and risk. Even the recent authority granted to the U.S. Department of Homeland Security requires that the Department base its regulatory decisions on sound science and risk. There are also statutes that affect all regulatory actions by the Executive Branch, such as the American Procedures Act, the Regulatory Fairness Act and the Small Business Regulatory Enforcement Fairness Act, most of which have historically received strong bipartisan support. It would be unfortunate and counter-productive if Congress were to move in a direction that minimized the checks and balances that have been part of the Congressional tradition.

- 2. Your testimony focuses on making chemical management policies that are appropriate for the situation. Does this mean you would reject a hazard-based system as inappropriate? Why? Could you please provide greater detail as to why this is important as well as give us some examples?**

The key to chemical safety lies in how, where and under what conditions a chemical is produced, how it is used and its ultimate disposition. In other words, the potential for exposure is as important in the determination of safety as is the chemical's inherent

Responses from Charlie T. Drevna, President  
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properties. A hazard-based system only analyzes a portion of the safety picture. Fully informed decisions that are based on science require a look at the complete picture.

Appropriate chemical management must consider both hazard and exposure or we risk uninformed decision-making due to an incomplete information set. For instance, phosgene is known to be a highly toxic gas and is used in the pharmaceutical industry to make medicine. Industry has extensively studied the potential to which people could be exposed to phosgene and found that under tight industrial controls, it can be used safely. Without the use of phosgene, many chemical side-reactions could occur when making pharmaceuticals. Some of these could produce toxic by-products that would be found in the medicine, thereby rendering them unusable.

Another example is sodium hydroxide, also called lye, which is known to cause tissue damage and blindness when spilled onto the skin or into the eyes. However, it has been used in households as a degreasing agent for well over a century, if not longer. Sodium hydroxide is used safely because its properties are well-known and users are educated through appropriate labeling. There is a willingness to accept the risk associated with use of a caustic agent because of its effectiveness and benefits to household hygiene. The same holds true for chlorine bleach, acid-based toilet bowl cleaners, solvent-based cleaners and many other household items.

If we were to base our system on hazard only, one could conclude that the appropriate agencies would be required to control substances that cause the greatest number of injuries. Water, alcohol, penicillin and a multitude of other common substances would be the first under such control, because these chemical compounds cause more injury and death each year than most any industrial chemical.

**3. Notwithstanding the criticism of TSCA Section 6 because of the Corrosion Proof Fittings case, have the other parts of TSCA performed well, including Sections 4, 5, and 8?**

NPRA believes that Sections 4, 5 and 8 have worked reasonably well. However, some stakeholders argue that the findings EPA must make under Sections 4 and 5 are an impediment to success. We disagree. The statute uses the phrase "may present an unreasonable risk" as the regulatory hurdle. Through this language, Congress made the process quite workable for the Agency.

The problems with early TSCA implementation were due largely in part to rushed decision-making by EPA because of outside pressures. Under Section 8, EPA can use its authority to collect information to make the finding that the production, use or disposal of a substance may result in significant exposures, which is all the Agency must find to

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issue a test rule under Section 4. The early difficulties EPA had in implementing Section 4 were because the Agency issued test rules without solid evidence of exposure or issued the rules before collecting the information under Section 8. The Agency failed to employ its Section 4 authority for quite some time after being challenged and losing in court for issuing a final test rule without the requisite exposure finding.

EPA's initial approach after the court challenge was to enter into enforceable consent orders with companies, under the threat of a Section 4 action. Issuing consent orders has proven to be an efficient and successful approach for the Agency. Those insisting that TSCA has failed, however, do not include the results of consent orders when discussing the number of actions taken by EPA under Section 4.

Another important thing to note is that the Interagency Testing Committee and National Pollution Prevention and Toxics Advisory Committee advised EPA years ago to use its Section 8 authority to collect the necessary information to make its Section 4 findings. The Office of Pollution Prevention and Toxics (OPPT) followed that advice. EPA issued a test rule for 17 high production volume (HPV) chemicals that were not sponsored under the HPV Challenge and, after much time, finalized the rule with no challenge from industry. The Agency issued another Section 4 test rule on HPV chemicals several years ago after using its Section 8 authorities; however, the final rule still sits at EPA.

4. **Many people argue that EPA should not be forced to examine the consequences of its actions when regulating. You think this is a good thing. What is your response to those who want to see this requirement stricken from the law? What is the risk trade-off we might encounter?**

It is an anathema to disregard or ignore either unintended consequences of regulatory actions or programs, or ill-conceived efforts that are unnecessarily burdensome or even counter-productive. It always has, and should be, the intent of Congress to provide a series of checks-and-balances in its approach to law-making. Indeed, authorizing committees of Congress have as integral to their makeup "oversight" committees whose function is to investigate and ensure not only compliance with various statutes, but also problems or the unintended consequences of that very legislation. Any regulatory framework authorized by Congress (including TSCA) needs to employ a similar approach. This has been consistent ever since Congress expanded the powers of the Executive Branch, beginning with the Administrative Procedures Act, continuing through the Regulatory Flexibility Act, Small Business Regulatory Enforcement Fairness Act and many other bipartisan statutes. The corrosion-proof fittings case is a good example of potential risk trade-off. If EPA had succeeded in banning the use of asbestos in automotive brake systems, it would have significantly increased the likelihood of automobile accidents.

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- 5. Your testimony has a footnote on page 10 respecting the association between pre-market testing and the lack of new chemicals. Can you give me some examples? If we are trying to get safer chemicals on the market, does a pre-market testing requirement kill the very thing we are trying to incentivize?**

The association to which our testimony refers is the link between the introduction of new and often safer chemicals and the cost of entry into the marketplace. Fundamental economics dictates that for products, as the cost of entry into a particular regional marketplace rises, firms will tend to find other markets for their products. This can be seen by contrasting the number of new chemicals entered into Europe after it instituted a “no data, no market” policy approximately ten years ago. This policy substantially raised the cost of entry into European markets, while a number of new substances entered the U.S. marketplace. Over ten years, Europe saw a total of approximately 2,000 chemicals entering commerce, while in the U.S. an average range of 1,200 to 1,500 new chemicals *per year* were reviewed by EPA for entry into the marketplace. If the U.S. adopts a “no data, no market” approach, we can expect innovation to shift overseas to areas that do not require up-front testing. Those business decisions have become easier to make as our industry has become more and more globalized. The question then becomes: Does the United States want to be a leader in chemistry innovation?

- 6. You mention that EPA’s software allows conservative modeling of information gleaned from pre-manufacturing notices. How conservative are these assumptions and how much margin for safety is included?**

There are two components that EPA looks at when reviewing new chemicals: hazard and exposure. Toxicology testing approaches are inherently conservative because laboratories try to dose animals until an adverse response is seen, even if this means in quantities that would never realistically be ingested. The interpretive part of toxicology requires scientists to distinguish toxic effects from the physical effects associated with massive dosing, which is a difficult exercise.

For exposure, EPA uses models that assume a substantial amount of substance remains in manufacturing equipment and is flushed down the drain during cleaning, which is contrary to any company’s economic self-interest. The models also assume a substantial amount of residue left in containers, which when cleaned allow the remaining product to go down the drain, again, not in a company’s self-interest. The models also assume total inefficiency with respect to water treatment facilities. Therefore, it is reasonable to conclude that EPA will assume a substantial amount of the product will result in environmental and drinking water exposures, unless a company can prove otherwise. EPA’s overly cautious assumptions that significant quantities of substances will make





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their way into the environment are extremely precautionary. Such an approach results in very conservative conclusions that lead to regulation that is extremely protective.

After characterizing the hazards and exposures of new chemicals, the Agency conducts a screening-level risk assessment, which includes a ten-fold safety factor for animal-to-human toxicity extrapolation, and another 10-fold factor to address sensitive sub-populations. This equates to a hundred-fold safety factor, on top of all the other conservative methods and assumptions employed by the Agency.

- 7. In your opinion, have the periodic table or chemistry fundamentals changed in the last 30 years? How much different are test-tube results as opposed to body reactions to chemical exposures?**

The principles of chemistry follow the fundamental laws of physics and have remained consistent over time. Any changes in the periodic table over the past 30 years can be attributed to additional elements created in physics laboratories, which exist for fractions of a second.

Variables are much easier to control in test tube reactions than in reactions that take place within our bodies. As a science, toxicology is still in its infancy when compared to the physical sciences. Toxicology is still very interpretive, as much an art as it is a science. Unfortunately, we cannot yet account for many chemical reactions that take place inside the body, such as free-radical and enzymatic reactions. It is difficult to observe those reactions without harming the subject to the extent that it affects the reactions we are trying to observe. One thing we do know, however, is that the body is capable of detoxifying itself and we can measure the rate of detoxification compared to the rate of exposure, also known as time-weighted dosage. The drawback, though, is that these types of experiments are very time-consuming and animal intensive.

- 8. Why do you think the EPA TSCA models are protective enough to assure that its decisions will protect the public from risks?**

The same reasoning from the answer to Question 6 applies here. There is so much conservatism built into the TSCA models and EPA's risk assessment approaches that one can conclude a high degree of protectiveness. In addition, the scientists at the Office of Pollution Prevention and Toxics take their mission very seriously. If there is any doubt at all during a review process, EPA will ask for more information, usually under the threat of regulatory action.

- 9. Should Congress junk the risk and cost-benefit provisions of TSCA because EPA would not see if there were efficacious alternatives to asbestos brake pads?**

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The risk and cost-benefit provisions under TSCA are consistent with the history of Congressional intent when crafting statutes that provide additional authority to the Executive Branch. Most statutes contain provisions that maintain a system of checks and balances that ensure continuing improvement or adjustment of programs and procedures. The asbestos case proves that the intent of Congress was most appropriate. The Agency was about to make a pre-mature and arbitrary decision to ban most uses of the substance, without any respect to other regulatory options or the availability of alternatives. Had Congress allowed EPA to act in such a manner, the number of automobile accidents would have sky-rocketed, causing more injuries and deaths than any exposure to asbestos through its use in automotive brake systems. Instead of pursuing a ban, the Agency should have focused on specific uses and functions that asbestos served at that time. It is called a "functional-use approach," which was also recommended by the National Pollution Prevention and Toxics Advisory Committee to EPA a few years ago.

If EPA had focused on uses that had high levels of inhalation exposures, or uses where there were viable and functionally effective alternatives, then the Agency would have been successful in its application of Section 6. Further, if EPA's action resulted in a court challenge, the court would have been hard-pressed not to find in favor of EPA.

Certain stakeholders continually point to asbestos and the fact that it took EPA ten years to build its case as evidence that TSCA doesn't work. The fact is EPA spent too much time and effort gathering information already established about asbestos. It was known to be toxic by inhalation when the asbestos particles were of a certain size and that the safety precautions during manufacture had been lacking and people could be exposed. On the other hand, it was also known that not all uses of asbestos resulted in inhalation exposures and that asbestos provided very well-defined benefits in the areas of heat and fire safety. EPA would have been better served spending its time focusing on the few uses and situations that could result in more than negligible inhalation exposures. Instead, the Agency chose what can be described as an outright ban of most uses, whether people were being exposed or not.

**10. Are your points about timing and sequencing of EPA actions something that can be helped by legislative action? If not, what recommendations do you have to correct the matter?**

Timing and sequencing in the past were EPA decisions and not a Congressional requirement. Congress gave the Agency broad authority and discretion. Because chemicals management was new 30 years ago, EPA went through some growing pains with respect to early decisions on when and how to regulate chemicals in commerce. This is certainly not the case today.

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EPA's approach for chemicals management has evolved from a command-and-control to one of collaboration that includes multiple stakeholders and is more transparent than most other approaches used around the world. Over the past 10 years the Agency has accomplished a great deal through a combination of collaborative and regulatory efforts. In fact, EPA has made more information on chemicals available to the public than any other country to date. Only recently has Canada approached EPA's accomplishments through their Chemical Management Plan, which, interestingly, is an approach that EPA is partially replicating under the Chemical Assessment and Management Program (ChAMP).

EPA has also adjusted its approach for Section 4 actions quite effectively. For the most recently proposed test rule on HPV chemicals the Agency first issued an information collection under Section 8 to obtain use and exposure information on those substances. In light of the fact that the last finalized test rule went unchallenged, it is reasonable to assume that this action, when final, will also go unchallenged. Most of the challenges EPA has had with Section 4 are things of the past. Not only have their test rules become more effective, OPPT has also shown a great deal of creative thinking in their implementation of enforceable consent orders. Unfortunately, proponents of a major TSCA overhaul do not credit the Agency for the good work they have done over the past 10 years. Rather, they point to challenges from years ago that EPA has readily overcome. Therefore, I think it is safe to say that legislative action may not be necessary with respect to information collection and test rules.

Congress should encourage EPA to continue its collaborative approaches, admonish the Agency when it delays actions such as test rules, and provide OPPT with the funding necessary to fulfill its critical mission. In addition, Congress should urge EPA to reinstate the National Pollution Prevention and Toxics Advisory Committee, the mission of which was to advise EPA on TSCA implementation. It could have been an effective group but, unfortunately, certain stakeholders walked away because they thought the focus should have been expanded to include TSCA reform.

**11. Your testimony suggests your support for ChAMP. What do you say to critics that want to scrap it in favor of a mandatory, statutory program with enforceable provisions?**

Although there may be skeptics, considering the lack of funding at OPPT, it would be surprising if certain stakeholders disagreed with the conceptual approach of ChAMP, which is a tiered, targeted and science-based approach to chemicals management. This approach is a logical evolution in chemicals management; one that will produce tangible results and allows EPA to prioritize its work. EPA already has the authority to move forward with ChAMP and can use all of the appropriate TSCA sections, which are fully

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enforceable, at any time. Interestingly, Richard Denison of the Environmental Defense Fund suggested that EPA evaluate moderate production volume (MPV) chemicals using the same methods the Agency uses to evaluate new chemicals. Dr. Denison presented this option for chemicals management at a meeting of the National Pollution Prevention and Toxics Advisory Committee several years ago. Under ChAMP, EPA is using its new chemicals methods and models to evaluate MPVs, so I am not sure why the initiative is being criticized. If Congress were to codify the ChAMP process, NPRA would not be opposed, as long as it remains true to a tiered, targeted and science-based approach.

- 12. Is your contention that the main difference between REACH and TSCA is not Section 6(c) requirements to consider other factors, but rather whether sound, high-quality, and repeatable science underpins the regulation rather than unsubstantiated research or gaps in data?**

NPRA believes that the European version of precaution is not the same as the Precautionary Principle that the United States and other countries agreed to as part of Article 21 of the Rio Declaration at the World Summit on Sustainable Development. Sound science underpins the Rio version of the Precautionary Principle. The European version of precaution ignores part of the risk equation (i.e., the potential for exposure) and focuses too much on hazard. The findings and requirements for risk management under Section 6 are very similar to the restriction provisions found in REACH. In both systems the authorities must weigh costs and benefits, evaluate viable alternatives and search for the least burdensome approach to risk management. The main difference between the two systems is the Authorization component under REACH, which is primarily a hazard-based approach to chemicals management. A hazard-based approach only captures a portion of the safety picture. For fully informed risk management decisions, the potential for exposure plays an equally important role. Under the Authorization scheme of REACH decisions will be made considering only part of the science.

- 13. This is simply a yes or no question. Yes or no, if Congress is going to move legislation to change TSCA, do you think we should convene a broad stakeholder process to try to work through these issues? Again, yes or no, would you be willing to serve in the process?**

The answer to the first question is yes. The answer to the second question is also yes, NPRA would be willing to serve in that process and provide whatever expertise is needed.

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