

**PRIORITIZING CHEMICALS FOR SAFETY  
DETERMINATION**

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**HEARING**  
BEFORE THE  
SUBCOMMITTEE ON COMMERCE, TRADE,  
AND CONSUMER PROTECTION  
OF THE  
COMMITTEE ON ENERGY AND  
COMMERCE  
HOUSE OF REPRESENTATIVES  
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## **PRIORITIZING CHEMICALS FOR SAFETY DETERMINATION**

**TUESDAY, NOVEMBER 17, 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 11:07 a.m., in Room 2123 of the Rayburn House Office Building, Hon. Bobby L. Rush [Chairman of the Subcommittee] presiding.

Members present: Representatives Rush, Schakowsky, Sarbanes, Sutton, Green, Matheson, Butterfield, Barrow, Castor, Space, DeGette, Dingell, Markey, Radanovich, Pitts, Murphy, Gingrey and Scalise.

Staff present: Michelle Ash, Chief Counsel; Rebecca Brown, Fellow; Timothy Robinson, Counsel; Angelle Kwemo, Counsel; Aaron Ampaw, CBC Fellow; Will Cusey, Special Assistant; Lindsay Vidal, Press Assistant; Matt Eisenberg, Special Assistant; Theresa Cederoth, Intern; Shannon Weinberg, Minority Counsel; Will Carty, Minority Professional Staff; Brian McCullough, Minority Senior Professional Staff; Sam Costello, Minority Legislative Assistant; and Jerry Couri, Minority Senior Professional Staff.

### **OPENING STATEMENT OF HON. BOBBY L. RUSH, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS**

Mr. RUSH. The subcommittee will come to order.

This is the Subcommittee on Commerce, Trade, and Consumer Protection, and the purpose of today's hearing is to hear from various witnesses on the subject of prioritizing chemicals for safety determination, and the Chair wants to acknowledge and welcome everybody, all the participants and the audience, to this very important and timely hearing.

The Chair now recognizes himself for 5 minutes for the purposes of an opening statement.

The troubling alert that the GAO issued in January 2009 regarding the Environmental Protection Agency should still echo through the 111th Congress. Upon adding EPA oversight of toxic chemicals and mixtures to its high-risk series, the GAO stated, and I quote, "EPA's inadequate progress in assessing toxic chemicals significantly limits the agency's ability to fulfill its mission of protecting human health and the environment." Given the long-term and adverse impacts that a poor effort to reform the TSCA would have on

our economy, public health and environment, we cannot pretend to have not heard the alarm.

There is growing evidence that some of these toxic agents are linked to serious and chronic health problems as well as to environmental pollution and contamination of our food sources, our air quality and our waterways.

I stated at our last TSCA subcommittee hearing in February of this year that I intended to conduct and conclude a deliberative process that reverses past Congressional inaction of reauthorizing TSCA and conducting meaningful oversight of the statute's effectiveness. By coming together this morning to review the EPA's prioritization practices, we are approaching another significant milestone in the above-stated process.

When TSCA was enacted in 1976, Congress failed to employ adequate authority upon the EPA to restrict or ban the use of unsafe toxics. Before engaging its enforcement authority under Title I, Sections 6 and 9, of TSCA, the EPA would have to meet what now appears to have been an insurmountable burden of proof for meeting the unreasonable risk to public safety standard.

Indeed, the courts have construed the EPA's power under TSCA so narrowly that it has not acted effectively to ban not a one, not a single chemical since 1991, nor has the EPA issued testing rules for more than 5 percent of those chemicals that appear on the EPA's current Priority Testing List, many of which currently lack sufficient safety testing information.

Even though the EPA has been reluctant to invoke its enforcement authority under TSCA, around 22,000 new chemical substances have been added since 1979 to the EPA's inventory of individual chemicals, which currently totals more than 84,000 chemicals. As a result, the safety of the vast majority of chemical substances which have been placed into the stream of commerce has never been adequately reviewed under TSCA.

One of our tasks today is to consider options for ranking chemicals from the most unsafe to human health and the environment to the least unsafe to human and to the environment. In listening to and questioning the witnesses, we should also discuss which parties should bear the obligation of providing sufficient data about the properties of chemicals and testing those chemicals, how these chemicals and the products containing them are used, and when the data that is on hand is inadequate and should trigger further testing and assessment.

Let me extend my deepest thanks to the witnesses who are present here. They have come unselfishly give their time, expertise and candid viewpoints on this central theme of prioritization as it relates to the comprehensive reform of TSCA, and I look forward to hearing your testimony.

And with that, I yield back the balance of my time.

The Chair now recognizes the ranking member, Mr. Radanovich, for the purposes of an opening statement for 5 minutes.

**OPENING STATEMENT OF HON. GEORGE RADANOVICH, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA**

Mr. RADANOVICH. Thank you, Mr. Chairman.

I want to welcome everybody to the committee. I appreciate you being here with your input and do appreciate the chairman and this deliberative process with a subject that hopefully recognizes the complexity of the law, the persons impacted by it and the overall impact any reform might have on our Nation's manufacturing sector. Based on my experiences with enormous negative ramifications from enactment of some well-meaning provisions in the toy bill and my continuing concerns about the benefits of some of the environmental legislation coming out of my home State of California, I remain quite concerned about the direction any effort on TSCA might take in the name of reform. I am especially concerned that a course of diverse interests might be seen to be calling for TSCA reform when in reality these stakeholders might be only looking for modest or cosmetic changes. We all know that TSCA is a very complex statute and that making radical changes to this law could have drastic effects on Americans' standard of living. Further, we also know that TSCA does not operate in a legal vacuum when it comes to regulating chemicals. There are other federal chemical laws that deal with specific segments of the American economy, be it pharmaceuticals, pesticides, household consumer products and workplace safety. Because these and other authorities, Section 6 of TSCA suggests that its authority should only be used to fill other gaps in the law rather than have it gratuitously pile on duplicative regulations for its own sake.

I think our discussion this morning is a helpful one. While EPA's Web site claims 83,000 chemicals that have been in commerce at some point, there is also broad agreement that the number currently in commerce in the United States is significantly less than the 83,000 figure. In light of the fiscal and resource realities facing the country and the agency, prioritization of the highest-risk chemicals first not only makes sense but I think it is essential. In prioritizing chemicals, though, I think that we should be enormously careful not to create overly expansive lists that will be used to arbitrarily scare the public without full information about actual occurrences, true exposures, possible mitigation strategies and how these chemicals fit into the overall risk management or reduction strategy.

While I think prioritization is important, I also want to voice my interest in trying to understand the second half of the hearing title, which calls for safety determination. The Majority's hearing memo calls the existing standard under TSCA Section 6 a safety standard, as does EPA's written testimony. If that is what to consider it, then it is helpful in putting testimony in context since we would be asking questions about the existing regulatory standard in TSCA. If the Majority considers the safety standard to be something else, we should know that too. Without full knowledge of what EPA might be prioritizing to or for, our questions will be mostly conjecture in search of a mythical legal standard which may or may not exist.

I want to welcome our witnesses and say how much I appreciate your being here to give us your perspective. I especially want to welcome Mr. Owens from the EPA. I have several questions for him about the size and scope of this issue and want to make sure that the EPA is neither over- nor underestimating the issues at

hand as they relate to prioritization. Further, I notice that the current EPA is scraping the programs of the previous Administration, which is something the Bush Administration did not do concerning the high productive volume challenge program and I hope solid reasons and a deliberative process, not simple politics, were at the core of these plans. As President Obama has said before, we have to use good ideas regardless of who the author is.

Mr. Chairman, I want to express my support for protecting people from unhealthy exposures to chemicals based on their intended use and based on and with sound objective scientific research. At the same time, we need to be cognizant that a poorly written bill will drive these chemical makers overseas quickly, leaving our high standards for worker safety and environment protection in the rearview mirror and compromising any serious effect to police quality control. With 10.2 percent national unemployment, 11.9 percent unemployment in the domestic manufacturing sector and the U.S. Bureau of Labor Statistics projecting a 16 percent decrease in wages and employment in the United States chemical manufacturing sector, we can't be cavalier about what this bill means and what it can do simply because it sounds like a good idea.

Thank you again, Mr. Chairman, and I look forward to working on this matter with you.

[The prepared statement of Mr. Radanovich follows:]

**Statement of the Honorable George Radanovich**  
**Ranking Member, Subcommittee on Commerce, Trade, and Consumer Protection**  
**Hearing Entitled: "Prioritizing Chemicals for Safety Determination"**  
**November 17, 2009**

Thank you, Mr. Chairman, for recognizing me for my opening statement. I appreciate that you have decided to be somewhat deliberative with this subject recognizing the complexity of the law, the persons impacted by it, and the overall impact any reform might have for our nation's manufacturing sector.

Based upon my experiences with the enormous, negative ramifications from enactment of some well meaning provisions in the Toy Bill and my continuing concerns about the benefits of some of the environmental legislation coming out of my home State of California, I remain quite concerned about the direction any effort on TSCA (*pronounce Toss-ka*) might take in the name of "reform". I am especially concerned that a chorus of diverse interests might be seen to be calling for TSCA reform –when in reality these stakeholders might be only looking for modest or cosmetic changes.

We all know that TSCA is a very complex statute and that making radical changes to this law could have drastic affects on Americans' standard of living. Further, we also know that TSCA does not operate in a legal vacuum when it comes to regulating chemicals. There are other federal chemical laws that deal with specific segments of the American economy – be it pharmaceuticals, pesticides, household consumer products, and workplace safety. Because there are these other authorities, Section 6 of TSCA suggests that its authority should only be used to fill other gaps in the law

rather than have it gratuitously pile on duplicate regulations for their own sake.

I think our discussion this morning is a helpful one. While EPA's website claims 83,000 chemicals that have been in commerce at some point, there is also broad agreement that the number currently in commerce in the United States is significantly less than the 83,000 figure. In light of the fiscal and resource realities facing the country and the Agency, prioritization of the highest risk chemicals first not only makes sense, I think it is essential. In prioritizing chemicals, though, I think we should be enormously careful not to create overly expansive lists that will be used to arbitrarily scare the public without full information about actual occurrences, true exposures, possible mitigation strategies, and how these chemicals fit into an overall risk management or reduction strategy.

While I think prioritization is important, I also want to voice my interest in trying to understand the second half of the hearing title, which calls for a safety determination. The Majority's hearing memo calls the existing standard under TSCA Section 6 a safety standard, as does EPA's written testimony. If that is what they consider it, then that is helpful in putting testimony in context since we would be asking questions about the existing regulatory standard in TSCA. If the Majority considers a safety standard to be something else, we should know that too. Without full knowledge of what EPA might be prioritizing to or for, our questions will be mostly conjecture in search of a mythical legal standard, which may or may not exist.

I want to welcome our witnesses and say how much I appreciate their being here to give us their perspective. I especially want to welcome Mr. Owens from EPA. I have several questions for him about the size and scope of this issue and want to make sure EPA is neither over nor underestimating the issues at hand as they relate to prioritization. Further, I noticed that the current EPA is scrapping the programs of the predecessor Administration, which is something the Bush Administration did not do concerning the High Production Volume Challenge Program. I hope solid reasons and deliberative processes -- not simple politics -- were at the core of these plans. As President Obama has said before, we have to use good ideas regardless of who the author is.

Mr. Chairman, I want to express my support for protecting people from unhealthy exposures to chemicals based on their intended use and on and with sound, objective scientific research. At the same time, we need to be cognizant that a poorly written bill will drive these chemical makers overseas quickly -- leaving our high standards for worker safety and environmental protection -- in the rear view mirror and compromising any serious effort to police quality control. With 10.2 percent national unemployment, 11.9 percent unemployment in the domestic manufacturing sector, and the U.S. Bureau of Labor Statistics projecting a 16 percent decrease in wages and employment in the U.S. chemical manufacturing sector, we cannot be cavalier about what this bill means and what it can do simply because it sounds like a good idea.

I thank you again for this time and look forward to our work today on this matter.

Mr. RUSH. The Chair thanks the gentleman.

The Chair now recognizes the gentleman from Texas for 2 minutes, Mr. Green, for the purposes of opening statement.

**OPENING STATEMENT OF HON. GENE GREEN, A  
REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS**

Mr. GREEN. Thank you, Mr. Chairman, for holding today's hearing to take another look at updating chemical regulations under the Toxic Substance Control Act. I want to welcome today's witnesses as we look at more defined issue in TSCA reform than our previous hearing. I look forward to hearing their thoughts on how to best move forward with prioritizing existing chemicals for review and assessment.

I would like to ask unanimous consent to enter into the record this letter, Mr. Chairman, from our former colleague and now president and CEO of the American Chemistry Council, Cal Dooley. Can I have unanimous consent to place this into the record, Mr. Chairman?

[The information follows:]



November 16, 2009

The Honorable Bobby L. Rush  
Chairman, Subcommittee on Commerce, Trade, and Consumer Protection  
Committee on Energy and Commerce  
United States House of Representatives  
2125 Rayburn House Office Building  
Washington, D.C. 20515

The Honorable George P. Radanovich  
Ranking Member, Subcommittee on Commerce, Trade, and Consumer Protection  
Committee on Energy and Commerce  
United States House of Representatives  
2125 Rayburn House Office Building  
Washington, D.C. 20515

Dear Chairman Rush and Ranking Member Radanovich:

The House Subcommittee on Commerce, Trade, and Consumer Protection is scheduled to hear testimony on November 17, 2009 concerning prioritization tools that support a robust federal chemical regulatory management system. The American Chemistry Council, a national trade association representing 140 member companies and 800,000 workers wants to take this opportunity to share our thoughts in advance of the Subcommittee's hearing.

As I testified before the Subcommittee in February 2009, ACC and its members welcome the Subcommittee's inquiry into revisiting the Toxic Substances Control Act (TSCA). In our view, Congress should have several objectives in modernizing TSCA:

- Protecting the public's health as the top priority;
- Restoring the public's confidence in the current federal chemical regulatory system and ensuring the safe beneficial use of chemicals;
- Reflecting the scientific and technological advances that have been made since TSCA was enacted; and
- Assuring continued innovation from the U.S. chemical industry – so we can keep making the products that save lives, make our economy more energy efficient, and reduce greenhouse gas emissions.



The Honorable Bobby L. Rush and the Honorable George P. Radanovich  
November 16, 2009  
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An effective prioritization system is the linchpin to a TSCA program that achieves these objectives. There are currently some 7,000 chemicals in U.S. commerce in volumes greater than 25,000 pounds. Without a prioritization system, the capacity of both the Environmental Protection Agency (EPA) and the private sector to identify and address those substances deserving additional product stewardship and regulatory control will be compromised.

ACC and its members believe that EPA should prioritize existing chemicals in commerce to guide subsequent safety reviews of high priority chemicals. The Agency also needs a range of regulatory tools to assure the safety of the chemicals for their intended use. Today, TSCA does not require this. It should. Prioritization is not just a matter of "which chemical goes first," but rather focuses the government's and the private sector's resources on those chemicals and chemical uses of greatest potential concern.

Prioritization is neither a theoretical exercise nor is it the end game. It is the first critical step in a process aimed at providing for the safe beneficial use of chemicals and enhancing the public's confidence in the system. To prioritize all chemicals in commerce, EPA needs adequate information about those chemicals. In ACC's view, EPA could normally prioritize chemicals based on available hazard, use and exposure information that manufacturers, processors and users would provide the Agency. In the majority of cases, we anticipate that existing information should be adequate to reach a screening level prioritization decision. As much as possible, EPA should leverage data from other regulatory programs, e.g. REACH. In those cases where the existing information is not adequate, EPA should be authorized to quickly solicit additional information from companies.

Congress should include in legislation hazard, use and exposure based criteria that would form the basis for EPA's prioritization. To get the safety review process moving quickly, Congress should also include criteria that EPA can use to create an initial "jump start" list of chemicals to be reviewed for safety.

Prioritization should be an iterative process that incorporates new information about a chemical's hazards, uses and exposures as it is developed. We think that such a process should also allow for the re-examination of priorities as new information becomes available and as new chemicals are approved for manufacturing. For example, chemicals initially identified as low priority could be moved to higher priority, or vice versa, depending on new information the Agency receives. Chemicals that lack adequate hazard and exposure information should be bumped higher up in prioritization (until relevant information is provided that suggests otherwise). While ACC envisions a prioritization process that focuses initially on existing chemicals, the process should be dynamic enough to allow EPA to revisit even new chemicals approved for manufacturing.



The Honorable Bobby L. Rush and the Honorable George P. Radanovich  
November 16, 2009  
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EPA clearly has existing authority under TSCA to implement a prioritization process even today. In fact, EPA had begun to do so under the recently halted Chemical Management and Assessment Program (ChAMP), which focused on high and medium production volume chemicals. ACC believes EPA should institute a prioritization process within EPA's recently announced Enhanced Chemical Management Program, as this new program does not contain an explicit prioritization step and includes no process by which industry could share existing information with EPA relevant to a prioritization decision. Indeed, EPA's new Chemical Action Plan (CAP) process appears to be focused on approximately 12 chemicals a year, and it is not clear how EPA is determining that the identified chemicals are those that should receive Agency attention. In short, a prioritization process can work hand-in-hand with CAP to determine which chemicals require action plans, and would inform EPA's subsequent implementation of a prioritization system under a modernized TSCA law.

Some have suggested that ACC's position on prioritization would have the Agency making a prioritization decision solely on the basis of exposure information. Those statements mischaracterize ACC's position. My February testimony to the Subcommittee clearly addressed ACC's interest in a prioritization process that relies on appropriate hazard, use and exposure information. More to the point: ACC believes that a prioritization system is an appropriate means to assure that a higher priority is given to substances that have highly hazardous traits (e.g. adverse effects on reproductive and developmental endpoints), and an indication of significant potential for exposure (e.g. found in human biomonitoring).

In short, the American Chemistry Council and its members believe that prioritization of chemicals in commerce is the critical first step in a systematic process by which EPA can determine the safety of chemicals for their intended uses. We think such a systematic process should be a centerpiece of a modernized Toxic Substances Control Act.

ACC looks forward to continuing to work with the Subcommittee to modernize TSCA. If we can provide any additional information, please contact me.

Sincerely,



Cal Dooley  
President and CEO

cc: Subcommittee on Commerce, Trade, and Consumer Protection



Mr. RUSH. So ordered.

Mr. GREEN. There is broad consensus expressed in the letter, from testimony today and given in testimony during our previous hearing in February that TSCA needs to be updated to give the EPA necessary authority to oversee and regulate chemicals that are hazardous to human health and the environment. As we are looking specifically at the prioritization process of chemicals currently in commerce today, I look forward to hearing what EPA plans to do under their existing authority to be in the prioritization process. I know EPA Administrator Jackson has made this a priority and I hope to hear how current steps taken under the Chemical Action Plan could be carried over to feed any subsequent prioritization process when there is Congressional action.

As we move forward on developing and legislating changes to TSCA to establish a process of prioritizing existing chemicals, we must look to the hazards to human health and the environmental exposure and use of chemicals as well as the impact on sensitive populations, and children specifically. Our chemicals warrant assessment and reevaluation if additional information is discovered, but to begin with, the chemicals that pose the biggest risk should be regulated or banned. If progress is not made in this area, we are going to continue to see attempts to do this piecemeal by Members of Congress, introduce bans to ban specific chemicals. We need an efficient way to protect human health by giving EPA the authority to prioritize and regulate hazardous chemicals.

Again, I want to thank the witnesses for being here today and educate our members on this issue and discuss the consequences of action by Congress as well as the potential impacts as we move forward the policy does not take into consideration the significance chemicals play in commerce and our everyday lives, and again, I thank you, Mr. Chairman. This is an important issue and we need to look at all aspects of legislating this area and the effect it will have, and I yield back my time.

Mr. RUSH. The gentleman from Pennsylvania, Mr. Pitts, is recognized.

**OPENING STATEMENT OF HON. JOSEPH R. PITTS, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF PENNSYLVANIA**

Mr. PITTS. Thank you, Mr. Chairman. Thank you for holding this important hearing on chemical prioritization and standard setting.

As we know, the Toxic Substance Chemicals Act signed by President Ford in 1976 is responsible for identifying and regulating toxic substances in United States commerce. TSCA currently regulates potential risk based on three policies. First, chemical manufacturers are responsible for testing chemicals to determine their potential effects on health and the environment. Second, the EPA should regulate chemicals that present an unreasonable risk to health or the environment, and third, EPA's implementation of the law should not create unnecessary economic barriers to technological innovation.

In the event that this committee moves to amend this law, it is prudent to keep in mind that a majority of stakeholders believe that overhauling TSCA will involve prioritizing tens of thousands

of chemicals. Most industry supports a method that requires the EPA to update its inventory to include only those chemicals in commerce and focus on the highest-priority chemicals. In addition, it is prudent that we start with existing data rather than requesting new data sets and disregarding the existing data. In addition, if reform moves forward, the issue of safety determination must be carefully evaluated. Currently, Section 6 defines a risk-based approach that requires the EPA to find that an unreasonable risk of injury must exist and that the EPA must use the least burdensome alternative to restrict the chemicals used in such cases. We must carefully evaluate the risk including hazards and exposures and intended uses and let these factors inform and guide any regulatory action. We do not want to jeopardize innovation.

I appreciate the witnesses being here today. I look forward to listening to their testimony and I thank you and yield back.

Mr. RUSH. The Chair now recognizes the gentleman from Georgia, Mr. Barrow, for 2 minutes.

Mr. BARROW. I thank the chairman. I waive.

Mr. RUSH. The Chair recognizes the gentlelady from Colorado, Ms. DeGette, for 2 minutes.

**OPENING STATEMENT OF HON. DIANA DEGETTE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF COLORADO**

Ms. DEGETTE. Thank you very much, Mr. Chairman. I want to thank you for holding this hearing, and I also want to greet our witnesses, especially my friend, Assistant Administrator Owens, for being here today.

I ran into our former colleague, Secretary Solis, yesterday. She was in my district of Denver with the First Lady and I was thinking about her years of courageous advocacy on the part of TSCA reform when she was a member of this subcommittee, and so we are pleased to carry on her tradition here today.

There is general agreement that TSCA needs to be updated to keep pace with modern technology and to increase the EPA's resources and authority. TSCA is over 30 years old now and it is the only major environmental law that has not been reauthorized. In those 30 years, the EPA has inventoried roughly 82,000 chemicals used in commerce in the United States. How to prioritize those chemicals that are most harmful to the public is a daunting challenge, particularly given the lack of solid information that the EPA faces for many of those chemicals. Today I am interested in hearing about how the EPA can expand its knowledge to focus its attention on the most harmful chemicals of those 82,000 and I am also interested in hearing how we can make use of the knowledge base that we currently have to take swift action to protect the public from high-priority chemicals like lead, mercury and PCBs. While prioritization is an important part of assuring that the EPA directs its resources most effectively, it should not be used as an excuse for excessive delay when frankly we have had an ineffective toxic statute for over 30 years.

Mr. Chairman, I look forward to working with you and the rest of the committee to strengthen TSCA, and I yield back the balance of my time.

Mr. RUSH. The Chair recognizes the gentleman from Georgia, Dr. Gingrey, for 2 minutes.

**OPENING STATEMENT OF HON. PHIL GINGREY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF GEORGIA**

Dr. GINGREY. Mr. Chairman, I want to thank you for calling this hearing on the prioritization of chemical study under the Toxic Substance Control Act. Even though it has been a number of months since we last held a hearing on TSCA, I am happy that we have once again delved into the complex issue.

TSCA directs the Environmental Protection Agency to regulate all phases of the manufacturing of chemicals and to identify unreasonable risk of injury from new or existing chemicals. In regulating these chemicals, TSCA directs the EPA to use the least burdensome option to reduce the risk of harm while balancing the benefits provided by the chemical. As a risk-based law, TSCA relies on the presence of sound science by both chemical producers and the EPA in order to properly implement the law.

Mr. Chairman, while there are many laudable elements of TSCA, that does not mean this law is anywhere close to perfect. Since its enactment, chemical manufacturing processes have advanced as has technology. Accordingly, TSCA needs to best reflect the science that is currently being utilized. As we heard during our first hearing on this matter back in February, TSCA reform is needed because we need to ensure the safety of chemicals used in all products. However, while there is that consensus, the way to accomplish that reform is subject to debate and, yes, disagreement. Ultimately, I believe that we should use this hearing to learn what the appropriate safety standards should be on the prioritization of chemical regulations through TSCA. Like a number of my colleagues, I fear that if we use this hearing as a vehicle to fundamentally overhaul TSCA, we will jeopardize the long-term viability of the chemical industry which will have lingering ramifications for other industries and subsequently this stressed economy of ours.

Mr. Chairman, I would suggest that as we hear from our distinguished panel of witnesses today, let us keep in mind the underlying risk-based principles that guide the current implementation of TSCA. I certainly look forward to their testimony and I yield back the balance of my time.

Mr. RUSH. The Chair now recognizes the chairman emeritus of the full committee, my friend from Michigan, Mr. Dingell, for 5 minutes for the purposes of opening statement.

**OPENING STATEMENT OF HON. JOHN D. DINGELL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN**

Mr. DINGELL. Mr. Chairman, first, thank you for holding this hearing today, and second of all, I want to commend you for the fine way in which you are chairing this committee. We owe you a debt for that.

Since our last hearing back in February, I have heard from various stakeholders about the need for reauthorization and revamping the Toxic Substances Control Act, TSCA. After 33 years, it has become quite clear that the law needs a thorough examination and

reauthorization. We have heard this from industry, environmental groups and consumer advocacy organizations. Now, EPA has not banned a single chemical under TSCA in nearly 20 years. Despite our best intentions back in 1976, it would appear that TSCA is not working as we hoped it would when it was enacted. We need to address our attention to whether the 84,000 chemicals in EPA's inventory growing by 700 new chemicals introduced each year tells us that something has to be done and it may be that the choice before this committee is going to be between coming to a judgment that the EPA is doing a superb job, that EPA is not doing the job that it should, that all these chemicals are safe or that there is not enough money or enough attention given or that historic bad leadership has made it impossible for the EPA to do the job. So we need to have a careful look at this.

Now, the nearly universal agreement that TSCA needs reauthorization is the easy part. The difficulty, as we all know, is in how and what we do. Frankly, the committee does look forward to hearing from our witnesses today, and I expect that we will have some very valuable differing points of view on the matter to look at and to frame our judgments as to how matters are going and what is to be done. Today the EPA has only been able to require testing on 200 of the 84,000 chemicals in the inventory. Figuring a way to prioritize how these chemicals are to be addressed in a timely manner based on sound science and the broad public interest in a way that protects the public health promises to be challenging, but indeed, it must be done.

Furthermore, I want to thank the witnesses here today for bringing up the important factor that often gets neglected, and that is funding. We need to reauthorize and to revise TSCA. We must work to have adequate and consistent funding for the program. Without this proper funding, we will not get the results that we want and it will lead to a constant source of frustration on the part of everybody including industry, which needs certainty in order to compete in a global marketplace, and we are finding that funding of programs of this kind is a continuing and ongoing problem. Certainly we have a similar situation with regard to Superfund, and I am sure that this committee is going to want to look at that at some early future time.

Again, Mr. Chairman, thank you for the deliberate and thoughtful approach that the subcommittee is taking in this matter. It is important that we do this right, not only to get the desirable result of a more workable law that protects human health but we also need to ensure that we do not needlessly inflict financial burdens on industry and producers in a very difficult economic climate. I thank you for your courtesy to me, Mr. Chairman, and I yield back the balance of my time.

Mr. RUSH. The Chair thanks the gentleman. The Chair now recognizes the gentleman from Pennsylvania, Mr. Murphy, for 2 minutes.

**OPENING STATEMENT OF HON. CHRISTOPHER S. MURPHY, A  
REPRESENTATIVE IN CONGRESS FROM THE STATE OF CON-  
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Mr. MURPHY. Thank you, Mr. Chairman, for holding this hearing on the Toxic Substances Control Act. I look forward to hearing all the testimony on this important issue.

Two of my top priorities in Congress are to protect the health and safety of our families and to protect and grow American jobs. These are not mutually exclusive and I believe that with proper regulation we can do both.

My district is home to chemical companies that directly employ 8,300 people, companies like Bayer, LANXESS, NOVA, PPG and Eastman, just to name a few.

As we examine this Act, it is important to realize that chemical manufacturers play a central role in America's manufacturing base and America's safety. We have already lost 120,000 chemical industry jobs this past decade due to volatile natural gas prices. As we deal with chemical regulation legislation, we should be careful not to drive more good jobs overseas but to find ways of preserving them and preserving public health. As America continues in this recession, these are the kind of jobs America needs now more than ever.

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

As this committee looks at potential reforms to TSCA and how to prioritize chemicals, it is extremely important we focus on those chemicals and their use that are currently in commerce and their effect on potential health risk. We do not need to reinvent the wheel with each chemical as there is plenty of existing data and models in the EU and in Canada that we can look upon as we research new data.

I look forward to hearing the testimony on the Toxic Substance Control Act, and I yield back, Mr. Chairman.

Mr. RUSH. The Chair thanks the gentleman.

The gentleman from Ohio, Mr. Space, is recognized for 2 minutes.

**OPENING STATEMENT OF HON. ZACHARY T. SPACE, A  
REPRESENTATIVE IN CONGRESS FROM THE STATE OF OHIO**

Mr. SPACE. Thank you, Mr. Chairman and Ranking Member Radanovich for convening today's hearing and thank you to our witnesses for taking the time to be here.

The overarching consensus seems to me that the Toxic Substances Control Act is badly in need of reform. In this day and age, it would be shocking if something 33 years old did not require updating as technology, industry and science progress. Specifically, we appear to all agree that changes to TSCA should call for the prioritization of certain chemicals for fast-track evaluation. Mr. Chairman, I applaud your efforts to continue this dialog. I truly believe that through bringing all stakeholders together we can develop a legislative product that represents an acceptable roadmap

for progress. Such process will sure that the EPA has the authority it needs to protect the public, in many cases young children and other vulnerable populations, and the producers and downstream users are provided with the regulatory framework within each market so that they can properly prepare their goods. Ultimately, consumers have a right to know that the products they purchase and use are safe and those reassurances benefit all involved.

I look forward to today's testimony. I look forward to continuing to work on TSCA reform with my colleagues. I yield back. Thank you, Mr. Chairman.

Mr. RUSH. The gentlelady from Illinois, the vice chair of the subcommittee, Ms. Schakowsky, is recognized for 2 minutes.

**OPENING STATEMENT OF HON. JANICE D. SCHAKOWSKY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS**

Ms. SCHAKOWSKY. Thank you, Mr. Chairman, for yielding and holding this hearing.

I want to publicly convey my thanks to EPA Administrator Lisa Jackson, who actually invited all the members of our subcommittee to breakfast. We enjoyed the conversation very much, which did involve TSCA. I want to thank Mr. Murphy for representing his side of the aisle at that breakfast, so I hope you will convey that to her, Mr. Owens.

The Toxic Substances Control Act has many deficiencies that endanger the public's health. One of the most striking is that when it was enacted, TSCA grandfathered in without conducting any assessment all chemicals that existed in 1976. This problem was further exacerbated by the fact that the statute never provided adequate authority for EPA to reevaluate existing chemicals as new concerns arose or science was updated. Consequently, in the 3 decades since TSCA became law, EPA has only been able to test 200 of the 80,000-plus chemicals produced and used in the United States. There is no question that this has placed every American but especially our Nation's poorest and most vulnerable at risk of being exposed to potentially lethal levels of harmful chemicals that have no place being in our stores and in our homes and in our environment.

Today's hearing will provide important insight into how TSCA can be amended so that the EPA does have the authority to immediately restrict or ban the use of chemicals like asbestos that we already know poses substantial risk to the public safety. I think a lot of people are surprised that it isn't banned already. I look forward to hearing from today's witnesses and yield back the balance of my time.

Mr. RUSH. The gentleman from Maryland, Mr. Sarbanes, for 2 minutes.

Mr. SARBANES. Thank you very much, Chairman Rush, for holding this hearing.

I have to say I continue to marvel at how ineffectual the Toxic Substances Control Act is, almost really to the point of making a mockery of its name. What it does is, it gives the EPA a front-row seat on chemical use in this country but really just is a kind of toothless observer, not as any kind of enforcer in any kind of active

way, and I think most Americans would not believe how unregulated this arena is. They really couldn't fathom it. I confess, I couldn't fathom it when we had the first hearing on the matter. So that is why we have got to reauthorize TSCA in a much more aggressive way going forward, and these hearings are sort of part of the due diligence that we are conducting as we anticipate doing that.

Because we are going to have to make up for so much lost time, it is critical that we do have a way of prioritizing the way the safety reviews are done, and that is what the testimony today is going to help us understand better, so I thank you for holding the hearing and I look forward to the witnesses' testimony. I yield back.

Mr. RUSH. The Chair now recognizes the gentlelady from Ohio, Ms. Sutton, for 2 minutes.

**OPENING STATEMENT OF HON. BETTY SUTTON, A  
REPRESENTATIVE IN CONGRESS FROM THE STATE OF OHIO**

Ms. SUTTON. Thank you, Chairman Rush, and thank you for holding this important hearing on prioritizing chemicals for safety determination.

At the hearings over the last few months, we have heard about the need for tremendous reform to the U.S. chemical safety laws. Industry and a variety of environmental, animal welfare, health and safety groups share the goal of modernizing the Toxic Substances Control Act and these stakeholders have agreed that prioritizing chemicals should be part of this effort. Currently there are approximately 84,000 chemicals in the EPA inventory. This volume with more chemicals being introduced every year poses a daunting task and prioritizing is of course an important first step in tackling the challenge. So as we proceed we must be pragmatic and make decisions based on sound science. It would be irresponsible to set the EPA, the industries or consumers up to fail. Our health, the environment and the public's confidence are all at risk and we need to know that the chemicals we use are safe. We need to know that the chemicals that touch over 96 percent of manufactured goods are safe. We need to know, and until we do know, until we have a framework that allows the public to know, people will not feel safe, and frankly, they may not be safe. So an effective, pragmatic, science-based prioritization system is key to public confidence and ensuring that the chemical industry is producing safe products.

In Ohio, the chemical industry directly employs over 46,000 people with over 2,000 in my district alone, and these are good-paying jobs that indirectly contribute to an additional 157,000 jobs in Ohio's economy. These jobs are clearly important, and as we move forward, we must forward together to ensure the public's trust, to protect the public and the future generations from the health and environmental harm and to provide industry with a clear direction to ensure that our workers keep working. These are multiple goals and multiple outcomes that we have to achieve, and I am confident that we can achieve.

So I am grateful for the panel being here. I look forward to hearing your ideas about how we get there together. I yield back.

Mr. RUSH. The gentlelady from Florida is recognized for 2 minutes, Ms. Castor.

Ms. CASTOR. Thank you, Chairman Rush, very much, for calling this very important hearing.

The oversight of these thousands and thousands of chemicals throughout America is vitally important to American families and to our public health. The Toxic Substances Control Act has had laudable goals but frankly it is broken. It has been very ineffectual. We can do a lot better.

I would like to salute EPA Administrator Lisa Jackson for her leadership. She is putting protection back into Environmental Protection Agency where it belongs. She is rightfully focused on the chemicals of concern and the chemicals that have the highest risk to the public health.

This is an area where American families and citizens everywhere rely on their government. The average person on the street doesn't have the expertise to determine what chemicals in our environment have the highest risk to our public health and the safety of our kids. So we have got to live up to our responsibility. It is our job to get this done and to ensure that TSCA is working for our families and citizens.

Thank you. I yield back.

Mr. RUSH. The Chair recognizes now the gentleman from North Carolina, Mr. Butterfield, for 2 minutes.

Mr. BUTTERFIELD. Thank you, Mr. Chairman. I am going to submit my statement for the record.

[The prepared statement of Mr. Butterfield follows:]

Opening Statement  
Congressman G. K. Butterfield  
House Committee on Energy and Commerce  
Subcommittee on Commerce, Trade and Consumer Protection  
Hearing: "Prioritizing Chemicals for Safety Determination"  
November 17, 2009

Chairman Rush, thank you for holding this hearing on prioritizing chemicals for safety determination. Confronted by lead-tainted children's toys and BPA-tainted baby bottles baby bottles, this subcommittee debated concerns over toxic substances during consideration of the Consumer Product Safety Improvement Act (CPSIA) last year. With CPSIA signed into law, children are better protected from many of the well-known chemical toxins. However, the EPA has little to no information on the 84,000 other chemicals currently in EPA's inventory.

When Congress passed the Toxic Substances Control Act (TSCA) in 1976, the intent of the legislation was to protect the public from harmful chemicals. TSCA grandfathered in most existing chemicals – exempting those chemicals from testing. The law put the burden of proving toxic dangers squarely on EPA, making it difficult to pull a chemical from the market. Consequently, TSCA has severely limited EPA's ability to fulfill its mission of protecting our people and environment.

When this Subcommittee considers changes to TSCA, we must first consider shifting the burden of responsibility. Currently, EPA must prove that a chemical is harmful or toxic once it already in use in commerce. We can better protect consumers by requiring manufacturers to test and demonstrate the safety of chemicals before they can enter the marketplace.

The larger question is how best to assess the 84,000 untested chemicals currently in EPA's inventory. Clearly some chemicals are more potentially dangerous than others, so EPA

must establish testing priorities based on potential hazards and exposures. The chemicals most potentially harmful to people must be given the highest priority for testing.

I appreciate the witnesses being here today to deliver their testimony. As the debate on chemical prioritization moves forward, I look forward to working with the witnesses, other stakeholders, and my colleagues on these needed reforms.

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

Mr. RUSH. The Chair thanks the gentleman and now the Chair recognizes the gentleman from Utah, Mr. Matheson, for 2 minutes.

Mr. MATHESON. Mr. Chair, I will waive my opening statement.

Mr. RUSH. Thank you very much.

Now it comes to the point where we are delighted frankly to hear from our witnesses, but before our witnesses are recognized, it is the practice of this subcommittee to swear in the witnesses. So I would ask that you please stand and raise your right hand.

[Witnesses sworn.]

Mr. RUSH. Let the record reflect that the witnesses have responded affirmatively. And now it is my privilege and honor to introduce the witnesses to you. On my left is the Hon. Steve Owens. Mr. Owens is the assistant administrator for the Office of Prevention Pesticides and Toxic Substances for the U.S. Environmental Protection Agency. Sitting next to Mr. Owens is Dr. Eric Sampson. Dr. Sampson is the director of the Division of Laboratory Sciences at the National Center for Environmental Health, the Centers for Disease Control and Prevention at the Department of the Health and Human Services. Next to Dr. Sampson is Dr. Daryl Ditz. He is the senior policy advisor for the Center for International Environmental Law. Next to Dr. Ditz is Mr. Bill Greggs. He is a consultant for the Consumer Specialty Products Association, for the Grocery Manufacturers Association and for the Soap and Detergent Association. And next to Mr. Greggs is Ms. Beth Bosley. She is a consultant also for the Society of Chemical Manufacturing and Affiliates.

Again, the Chair welcomes you and the Chair now recognizes the Hon. Steve Owens for 5 minutes for the purposes of an opening statement.

**TESTIMONY OF STEVE OWENS, ASSISTANT ADMINISTRATOR, OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES, U.S. ENVIRONMENTAL PROTECTION AGENCY; ERIC SAMPSON, DIRECTOR, DIVISION OF LABORATORY SCIENCES, NATIONAL CENTER FOR ENVIRONMENTAL HEALTH, CENTERS FOR DISEASE CONTROL AND PREVENTION; DARYL DITZ, SENIOR POLICY ADVISOR, CENTER FOR INTERNATIONAL ENVIRONMENTAL LAW; BILL GREGGS, CONSULTANT, CONSUMER SPECIALTY PRODUCTS ASSOCIATION, GROCERY MANUFACTURERS ASSOCIATION AND SOAP AND DETERGENT ASSOCIATION; AND BETH BOSLEY, CONSULTANT, SOCIETY OF CHEMICAL MANUFACTURERS AND AFFILIATES**

#### **TESTIMONY OF STEVE OWENS**

Mr. OWENS. Thank you, Mr. Chairman, and good morning to you and good morning to Vice Chair Schakowsky and Ranking Member Radanovich and members of the subcommittee. I thank you for the opportunity to address you today and I thank all of you for your leadership on this very important issue.

I have been on the job as the assistant administrator for the Office of Prevention, Pesticides and Toxic Substances for roughly 4 months now, so I am trying to get up to speed and working hard on this and other critical issues that are facing the EPA, but I do

want to say at the outset, as many of you know, I was a former Congressional committee staffer. It is a little different being on this side of the microphone than it was back then in those days, but again, I appreciate the opportunity to be here. It is also a privilege to be here with Dr. Eric Sampson, my colleague from the Centers for Disease Control. We work very closely with CDC on biomonitoring and a host of other very important issues.

As many of you have noted this morning, EPA has jurisdiction over chemicals pursuant to the 1976 Toxic Substances Control Act, which is called TSCA. TSCA is the only major environmental statute that has not been reauthorized since its passage and there are over 80,000 existing chemicals currently on the TSCA inventory, a few of which have actually been studied for their risk to children and families. Unlike the laws applicable to drugs and pesticides, TSCA does not have a mandatory program by which EPA must review the safety of existing chemicals, and in addition, TSCA places legal and procedural requirements on EPA's ability to request the generation and submission of health and environmental data on existing chemicals.

TSCA was an important step at the time it was enacted 33 years ago but over the years not only has TSCA fallen behind the industry it is supposed to regulate, it has also proven inadequate for providing the protection against chemical risk that the public rightfully expects. As noted by Vice Chair Schakowsky, when TSCA was enacted it grandfathered in without any evaluation more than 60,000 chemicals that were in existence in 1976. And further, TSCA never provided adequate authority for EPA to reevaluate existing chemicals as new concerns arose or as science was updated, and it failed to grant EPA full authority to compel companies to provide toxicity data on those chemicals. As a result, in the 33 years since TSCA was enacted, EPA has been able to require testing on only around 200 of the more than 80,000 chemicals now produced and used in the United States.

It has also been difficult for EPA to take action to limit or ban chemicals that have actually been found to cause unreasonable risk to human health or the environment. Even if the EPA has substantial data and wants to protect the public against known risk, the law creates obstacles to quick and effective regulatory action. For example, as was noted, after years of study and nearly unanimous scientific opinion, EPA issued a rule phasing out most uses of asbestos in products. Yet a federal court overturned most of this action because the rule failed to comply with the complicated requirements of TSCA. In fact, since 1976, only five chemicals have been successfully regulated under TSCA's authority to ban chemicals.

The problems with TSCA are so significant that the GAO has put TSCA on its high-risk list of items needing attention.

Today, advances in toxicology and analytical chemistry are revealing new pathways of exposure. There are subtle and troubling effects of many chemicals on hormone systems, human reproduction, intellectual development and cognition, particularly in young children. It is clear that TSCA must be updated and strengthened for EPA to properly do our job of protecting public health and the environment.

As noted, Administrator Lisa Jackson recently announced a set of principles on behalf of the Obama Administration to help inform the drafting of a new law to fix TSCA. These principles are: First, chemicals should be reviewed against safety standards that are based on sound science and reflect risk-based criteria protective of human health and the environment. Second, the responsibility for providing adequate health and safety information should rest on industry and EPA should have the necessary tools to quickly and efficiently require testing or obtain other information from manufacturers relevant to determining the safety of chemicals. Third, EPA should have clear authority to take risk management actions when chemicals do not meet the safety standards with the flexibility to take into account a range of considerations including children's health, economic costs, social benefits and equity concerns. Fourth, EPA should have clear authority to set priorities for conducting safety reviews. Fifth, we must encourage innovation in green chemistry and support strategies that will lead to safer and more substantially sustainable chemicals and processes. And finally, implementation of the law should be adequately and consistently funded in order to meet the goal of assuring the safety of chemicals and to maintain public confidence that EPA is meeting that goal. Manufacturers of chemicals should support the cost of agency implementation including the review of information provided by manufacturers.

We know that legislative reform may take time. Consequently, Administrator Jackson has directed my office in the interim to utilize our current authority under TSCA to the fullest extent possible to protect the American people from dangerous chemicals. We are currently evaluating an initial set of chemicals based on available hazard, exposure and use information for potential action. The factors we are using to determine this initial set include the use of the chemicals in consumer products, their persistence in human blood, the persist bioaccumulative and toxic characteristics of the chemicals, or otherwise known as the PBT characteristics, the toxicity of the chemicals and the volume of production of the chemicals in commerce. We will produce what we are calling actions plans that will outline the risks that these chemicals may present and establish that we may take to address those concerns. And following the initial list of chemicals that we address and the initial set of action plans that we produce, we will engage with stakeholders on prioritizing additional chemicals for evaluation and we aim to complete a group of action plans every 4 months going forward. EPA intends to engage stakeholders, federal partners and the public in the discussion of prioritizing chemicals for future risk management actions.

Mr. Chairman, the time has come to bring TSCA into the 21st century, and Administrator Jackson and I very much look forward to working with Congress and you and members of the subcommittee on this very important issue. I appreciate again the opportunity to be here.

[The prepared statement of Mr. Owens follows:]

**Testimony of Steve Owens  
Assistant Administrator  
Office of Prevention, Pesticides and Toxic Substances  
U.S. Environmental Protection Agency  
before the  
Subcommittee on Commerce, Trade and Consumer Protection  
Committee on Energy & Commerce  
U.S. House of Representatives**

**November 17, 2009**

Good morning, Chairman Rush, Vice Chair Schakowsky, Ranking Member Radanovich, and Members of the Subcommittee. Thank you for the opportunity to address the Subcommittee today on the reform of chemicals management in the United States. Ensuring chemical safety in a rapidly changing world, restoring public confidence that EPA is protecting the American people, and promoting our global leadership in chemicals management are top priorities for Administrator Jackson and the EPA. I am pleased to be here today with my colleague, Dr. Eric Sampson, at CDC. We are actively working with CDC on a range of issues, including biomonitoring efforts on priority chemicals.

Chemicals are increasingly found in everything in our country – from this table, to this microphone, to the lights around us. And the truth is, there are still significant scientific gaps in our knowledge regarding many chemicals. That's why, increasingly, the public is demanding that the government provide an assurance about the long term safety of these chemicals.

Mr. Chairman, EPA has jurisdiction over the safety of chemicals produced and used in the United States and this authority was given to the Agency through the 1976 Toxic Substances Control Act (TSCA). TSCA is the only major environmental statute that has not been reauthorized. The TSCA Inventory currently contains over 80,000 existing chemicals, few of which have been studied for their risks to children. Unlike the laws applicable to drugs and pesticides, TSCA does not have a mandatory program where EPA must conduct a review to

determine the safety of existing chemicals. In addition, TSCA places legal and procedural requirements on EPA before the Agency can request the generation and submission of health and environmental effects data on existing chemicals.

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

When TSCA was enacted, it grandfathered in, without any evaluation, all chemicals that existed in 1976. Further compounding this problem, the statute never provided adequate authority for EPA to reevaluate existing chemicals as new concerns arose or science was updated, and failed to grant EPA full and complete authority to compel companies to provide toxicity data. As a result, in the 33 years since TSCA was passed, EPA has only been able to require testing on around 200 of the 80,000 chemicals produced and used in the United States.

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

These requirements have limited EPA's ability to issue regulations to control existing chemicals that have been determined to present an unreasonable risk. To date, only five of these existing chemicals have been regulated under TSCA's ban authority.

Today, advances in toxicology and analytical chemistry are revealing new pathways of exposure. There are subtle and troubling effects of many chemicals on hormone systems, human reproduction, intellectual development and cognition, particularly in young children. Mr. Chairman, it is clear that in order to properly do our job of protecting public health and the environment, TSCA must be updated and strengthened. EPA needs the tools to do the job the public expects.

Administrator Jackson recently announced a set of clear Administration principles to help inform drafting of a new chemical risk management law that will fix the weaknesses in TSCA. Let me highlight the Obama Administration's principles:

First, chemicals should be reviewed against safety standards that are based on sound science and reflect risk-based criteria protective of human health and the environment. EPA should have the clear authority to establish safety standards based on risk assessments, while recognizing the need to assess and manage risk in the face of uncertainty.

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

Third, EPA should have clear authority to take risk management actions when chemicals do not meet the safety standard, with flexibility to take into account a range of considerations, including children's health, economic costs, social benefits, and equity concerns. Both EPA and industry must include special consideration for exposures and effects on groups with higher

vulnerabilities – particularly children. For example, children ingest chemicals at a higher ratio to their body weight than adults, and are more susceptible to long-term damage and developmental problems. Our new principles offer them much stronger protections.}

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

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

Finally, implementation of the law should be adequately and consistently funded, in order to meet the goal of assuring the safety of chemicals, and to maintain public confidence that EPA is meeting that goal. To that end, manufacturers of chemicals should support the costs of Agency implementation, including the review of information provided by manufacturers.

We know that legislative reform may take time. Consequently, Administrator Jackson has directed my office in the interim to utilize our current authority under TSCA to the fullest extent possible, including Section 6 authority to label, restrict, or ban a chemical, to ensure that we do everything we can to protect the American people from dangerous chemicals.

We will be taking a number of steps over the coming months to put in place a multi-pronged approach to strengthen EPA's efforts to manage industrial chemicals.

Upon her arrival at EPA, Administrator Jackson made strengthening the Agency's chemicals management effort a top priority. She asked my office to review ongoing programs such as ChAMP – the Chemical Assessment and Management Program – a multi-year program, which utilized data gathered under the HPV Challenge program and the Inventory Update Rule. ChAMP was designed to develop screening-level assessments and risk prioritizations for thousands of chemicals produced or imported in quantities of 25,000 pounds or greater a year. After careful review and consideration, EPA concluded that the program was too focused on categorizing thousands of chemicals, which would take years. This review also highlighted that the categorizations were often based on limited and incomplete test and exposure data. EPA's new approach seeks to more quickly identify chemicals that pose the greatest risk and initiate action now – including new regulations or other approaches – to address those risks. As part of EPA's enhanced chemical management program, the Agency will also require that companies submit information to fill the remaining gaps in basic health and safety data on HPV chemicals. EPA also intends to make the reporting of chemical use information more transparent, more current, more useful, and more useable by the public. EPA believes this new targeted approach will prove more protective of human health and the environment.

EPA is currently evaluating an initial set of chemicals, based on available hazard, exposure, and use information, for potential action. Factors used to determine this initial set include use in consumer products; presence in human blood; persistent, bioaccumulative and toxic characteristics; toxicity; and production volume. We will complete and make public "action plans" for the chemicals which will outline the risks that the use of these chemicals may present and what steps we may take to address those concerns. Following this, we will engage with stakeholders on prioritizing additional chemicals for evaluation, and we aim to complete and make publicly available a group of chemical action plans every four months. EPA intends to engage stakeholders and dialogue with other federal partners, as well as the public, in the discussion about prioritizing chemicals for future risk management action over the coming months through public notices and public meetings.

The time has come to bring TSCA into the 21<sup>st</sup> Century. Administrator Jackson and I look forward working with Congress and this Subcommittee on this very important issue.

Mr. RUSH. Thank you very much.  
The Chair now recognizes Dr. Sampson for 5 minutes.

#### TESTIMONY OF ERIC SAMPSON

Mr. SAMPSON. Good morning, Mr. Chairman and members of the subcommittee. My name is Eric Sampson. Thank you for this opportunity to testify concerning our experiences with biomonitoring and setting public health-related priorities for chemical exposures. It has been my pleasure to serve as the director of the Division of Laboratory Sciences at CDC for 25 years during which time our biomonitoring program has grown from a very small activity into a mature scientific discipline.

Biomonitoring as we define is the science of directly measuring chemicals and samples from people, typically blood and urine samples. We are aware that biomonitoring data personalizes exposure to chemicals and can lead to a high level of interest and concern. As such, we go to great care to ensure that we are providing the highest quality measurements that can be performed.

One thing we do in setting priorities is to take a snapshot of chemical exposures in the U.S. population and to identify subgroups with higher levels of exposure. To accomplish that, we perform biomonitoring measurements in samples from participants in the National Health and Nutrition Examination Survey, which is a nationally representative sample of the U.S. population. Survey participants receive a physical examination, complete a detailed questionnaire that collects more than 1,000 pieces of information, and donate blood and urine samples.

Our biomonitoring data from this survey are made publicly available by the National Center for Health Statistics. In addition, our staff and other scientists publish the findings in peer-reviewed journals and periodically we publish a National Report on Human Exposure to Environmental Chemicals. Our Fourth Report is due out by the end of this year.

A second way we try to establish priorities is to partner with States, other federal agencies, academic institutions and international organizations on 50 to 70 studies each year to examine vulnerable populations or populations likely to have higher exposure to chemicals. In that regard, I would like to highlight a recent partnership with NIH's National Children's Study, which will follow 100,000 children from before birth to age 21. Our laboratory is collaborating on a pilot study of the first 520 women in which we will be measuring chemicals in pregnant women's blood and urine and then after delivery the newborn's cord blood and mother's breast milk.

Finally, we help States set their own priorities by transferring our biomonitoring technology to their State laboratories. In fiscal year 2009 with new Congressional funds, CDC awarded a total of \$5 million to California, New York and Washington for State-based biomonitoring programs.

At CDC, we use biomonitoring to establish reference ranges in the U.S. population and to identify groups of people with higher levels of exposure. In addition, by tracking exposures in the U.S. population, we can detect trends in people over time and assess whether a chemical is present in a large number of people or is dis-

proportionately present in vulnerable subgroups such as children. This information is used by scientists and policymakers as one consideration in setting priorities for health impacts of chemicals.

In conclusion, biomonitoring offers a strong scientific basis for helping to prioritize chemicals for public health. We are fully committed to working with other federal agencies and partners in expanding the uses and benefits of biomonitoring.

Thank you, Chairman Rush, and members of the subcommittee. I look forward to answering any questions.

[The prepared statement of Mr. Sampson follows.]

	<p><b>Testimony</b> <b>Before the Committee on Energy and Commerce</b> <b>Subcommittee on Commerce, Trade and Consumer Protection</b> <b>United States House of Representatives</b></p>
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**Prioritizing Chemicals for Safety Determination**

*Statement of*  
**Eric Sampson, Ph.D.**  
*Director, Division of Laboratory Sciences,*  
*National Center for Environmental Health*  
*Centers for Disease Control and Prevention*  
*U.S. Department of Health and Human Services*



For Release on Delivery  
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Good morning Mr. Chairman and Members of the Subcommittee.

My name is Dr. Eric Sampson. Thank you for the opportunity to testify concerning uses of biomonitoring in setting public health priorities related to chemical exposure. It has been my pleasure to serve for the last 25 years as the Director of the Division of Laboratory Sciences of the National Center for Environmental Health at the Centers for Disease Control and Prevention (CDC). During that time, our biomonitoring program has grown into the mature discipline of science that I will discuss today. My testimony will focus on the biomonitoring program at CDC, and public health uses of biomonitoring.

#### CDC's Biomonitoring Program

Biomonitoring, as we define it, is the science of directly measuring chemicals in samples from people. Although the samples can be any tissue, we mostly use blood and urine. It is important to clearly differentiate biomonitoring from other important measurements conducted in environmental samples, such as air, soil, water, and food, and consumer products. Biomonitoring measurements have the advantage of indicating the amount of a chemical that actually gets into people, rather than extrapolating from measurements of environmental media. In addition, biomonitoring data tell us the amount of a chemical from all sources combined (e.g., air, soil, water, dust, food). Although biomonitoring is far ahead of the science of interpreting what exposures mean for health, biomonitoring data is valuable for a variety of public health purposes, such as identifying relative

levels of exposure in the population, particularly in children or other vulnerable groups, and setting priorities for research into the health impacts of chemicals.

Because CDC analyzes samples from people, we must deal with a host of considerations that may not arise in analysis of environmental samples. For example, we adhere to a human subjects review of all data collection protocols, as well as adherence to strict, statutorily required commitments to protect the subject confidentiality, as well as the good laboratory practice standards under the Clinical Laboratory Improvement Act (CLIA). CDC has highly-trained scientists who can assist on everything from sample collection and analysis to the interpretation of results. Almost all of our analytic measurements are conducted using an advanced technology, known as isotope dilution/mass spectrometry, which we consider the definitive, state-of-the-art method of measuring any chemical in blood and urine specimens.

We work hard to produce accurate and precise laboratory measurements. We study the best way to measure a chemical of interest, such as how the chemical is metabolized in the body, and how to avoid environmental contamination, which might affect our results. We are aware that biomonitoring "personalizes" exposure to chemicals and can lead to a high level of interest and concern regarding exposures. I will address three aspects of CDC's biomonitoring program: how we assess the U.S. population's exposure to chemicals; targeted

studies to examine vulnerable populations; and support of state biomonitoring programs.

How we assess the U.S. population's exposure to chemicals: Our laboratory measures chemicals or their metabolites in blood and urine samples from participants in the National Health and Nutrition Examination Survey (NHANES). NHANES, which is conducted by CDC's National Center for Health Statistics, involves a complete physical exam, a detailed questionnaire that collects more than 1,000 pieces of information, and the collection of blood and urine samples. The survey has been conducted multiple times since the 1970s and became a continuous survey in 1999 with two-year survey cycles. Although NHANES is nationally representative of the U.S. population, it offers limited exposure information on young children, mostly due to the difficulty in obtaining a large enough blood and urine sample from young children. Currently lead, cadmium, and mercury are measured in children aged 1 year and older, and cotinine, which is a marker for environmental tobacco smoke exposure, is measured in children aged 3 years and older.

Biomonitoring data from NHANES are included in the data files made publicly available in a form that does not permit the identification of individuals or their communities. In addition, CDC staff publishes findings in peer-reviewed publications, and then periodically publishes a summary report, the National Report on Human Exposure to Environmental Chemicals. The NHANES results,

as reported in each National Exposure Report, provide a snapshot of the U.S. population, identifying the amounts of selected chemicals that get into Americans' bodies. We plan to publish the Fourth Report by the end of 2009. Chemicals analyzed from the NHANES samples and reported in the Fourth Report were selected based on known or hypothesized exposure in the U.S. population; scientific data on the health effects known or thought to result from some levels of exposure; the need to assess the efficacy of public health actions to reduce exposure to a chemical with known health effects; the availability of an analytical method that is accurate, precise, sensitive, and specific; the availability of adequate blood or urine samples from the NHANES survey; and the analytical cost to perform the analysis. The choice of chemical analyses performed is also a function of requests or suggestions from other government agencies, who sometimes pay for those analyses. The Fourth Report will include data on 212 chemicals measured, including industrial chemicals, pesticides, flame retardants, a chemical related to tobacco use, combustion and disinfection by-products, and plasticizers.

Targeted studies: Each year we partner with states, other federal agencies, academic institutions and international organizations on 50-70 studies that examine vulnerable populations, particularly newborns, children, pregnant women and population groups or communities known or likely to have higher exposures. For example, one important current partnership is with the Eunice Kennedy Shriver National Institute of Child Health and Human Development at

the National Institutes of Health. This partnership involves the National Children's Study, which is designed to follow 100,000 children from conception to age 21. Our laboratory is collaborating on a pilot study of 525 pregnant women. We will measure chemicals in pregnant women's blood and urine and, after delivery, in the newborn's cord blood and mother's breast milk. Cord blood is a promising way to assess prenatal exposure to certain chemicals. However, cord blood is not the best way to measure exposures to chemicals that pass through the body more quickly; these generally are best measured in urine.

Support of state biomonitoring programs: State public health officials recognize the value of biomonitoring and of CDC's analysis of the samples from NHANES that are presented in the National Exposure Report. Many states are interested in conducting biomonitoring among residents within their own jurisdictions, and comparing their results with the national data published by CDC. In fiscal year 2009, CDC awarded a total of \$5 million to three states -- California, New York and Washington -- for state-based biomonitoring programs. In addition, many states already have some capacity for biomonitoring because the same technology is used in emergency preparedness and response for chemical terrorism, which CDC funds through the Public Health Emergency Preparedness cooperative agreement. Forty-seven states received funding for instrumentation as well as training for detecting a limited number of chemicals in people. Finally, CDC's Environmental Public Health Tracking Program funds some state targeted

biomonitoring activities through their state tracking cooperative agreement program.

#### Public Health Uses of Biomonitoring

Biomonitoring offers a strong basis for prioritizing public health attention to certain chemicals. We use it to establish reference ranges in the population and to identify groups of people with higher levels of exposure than those typical for the U.S. population. In addition, by tracking exposures in the U.S. population we can detect trends in people over time, and assess whether a chemical is present in large numbers of people, or is disproportionately present in vulnerable subgroups, such as children. This information can be used by scientists and policy makers as one of the considerations in setting priorities for evaluating health impacts of chemicals.

A National Research Council review of biomonitoring noted that it has been a key tool in some landmark public health actions (NRC, 2006). One example is lead. Our laboratory has been measuring lead in the NHANES blood samples since 1976. Lead poisoning can affect nearly every system in the body. It can cause learning disabilities, behavioral problems, and at very high levels, seizures, coma and even death. Our laboratory analysis of the NHANES samples, which showed that the American population's blood lead levels were declining in parallel with declining levels of lead in gasoline, provided an impetus for the Environmental Protection Agency (EPA) regulations that reduced lead in gasoline

(GAO, 2000). CDC and EPA have used this decline in blood lead levels over time to demonstrate that the removal of lead from gasoline had a dramatic impact on the levels of lead in the U.S. population. Today, the most common source of children's exposure to lead is dust from older homes that contain lead-based paint. In the late 1970s, CDC used the NHANES data to document that 88 percent of children had blood lead levels above the current level of concern. We collaborate with CDC's Lead Poisoning Prevention Program, and our data demonstrate that public health efforts are working to reduce children's exposure to lead. The most recent NHANES data, from 1999-2004, show that 1.4% of children aged 1 to 5 years have elevated blood lead levels.

Biomonitoring also can be used to monitor the effectiveness of interventions designed to reduce exposures. In the early 1990s, our laboratory analysis of data from NHANES showed that 88 percent of the nonsmoking population was exposed to tobacco smoke. This finding was used by State and local areas as a justification for restricting smoking in public places. Over the past 15 years we have collaborated with CDC's Office on Smoking and Health, and NHANES data have shown that exposure to secondhand smoke in nonsmokers has decreased about 70 percent, indicating that public health interventions to reduce exposure have been successful.

And finally, another benefit of biomonitoring data is transparency. When used as a decision tool, it provides the public with valuable information about exposures.

It also provides policy makers and regulators with accurate human exposure information on which to base their decisions.

#### Conclusion

CDC recognizes that biomonitoring is one important tool for helping to prioritize chemicals of concern. Biomonitoring fills a major gap in human exposure information that allows us to better identify and prevent health problems. Better exposure information means that we can make better decisions to protect our health. We are fully committed to working with other federal agencies and partners to improve the uses and benefits of biomonitoring.

Thank you Chairman Rush and members of the Subcommittee. I look forward to answering any questions you might have.

#### References

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United States General Accounting Office (2000). Toxic Chemicals: Long-Term Coordinated Strategy Needed to Measure Exposures in Humans. Washington, D.C.

Mr. RUSH. Thank you. The Chair now recognizes Dr. Ditz for 5 minutes.

#### TESTIMONY OF DARYL DITZ

Mr. DITZ. Thank you, Chairman Rush, Ranking Member Radanovich and members of the subcommittee for the opportunity to testify today.

The public is rightly concerned about the long-term effects of chemicals on health including increasing incidence of asthma, autism, birth defects, infertility and certain types of cancer. It is especially troubling in light of the growing evidence that industrial chemicals are building up in our bodies and in our children's. The Toxic Substances Control Act has failed to assess, let alone guarantee, safety of the overwhelming majority of chemicals on the market. TSCA stymies action by EPA, as you just heard, and other agencies. It perpetuates the reliance on dangerous chemicals. It leaves businesses in the dark and it undermines U.S. competitiveness. So I am grateful for this opportunity to discuss practical improvements to TSCA that can bring it into the 21st century.

I strongly agree that the United States must set priorities in order to manage chemicals safely but beware of any proposal that would give thousands of chemicals a free pass. More on that in a second.

Today I would like to discuss three critical fixes to TSCA. First, EPA needs authority to promptly regulate the worst of the worst chemicals. Second, EPA should evaluate all chemicals against a health-based standard. Third, Congress should require chemical manufacturers to provide all necessary information. Together, these can result in a stronger, more effective TSCA that restores public confidence while protecting the health of American workers, consumers and communities.

Let me briefly elaborate on these three points. First, EPA needs authority to regulate the worst of the worst chemicals. A new, reinvigorated TSCA can pinpoint high chemicals even now despite large data gaps. Chemicals that persist in the environment, that bioaccumulate in our bodies and threaten public health by their toxicity are especially high priorities for action. Such chemicals, called PBTs for short, defy traditional risk assessment techniques. For these substances, a slow, methodical process for evaluating safety is not necessary and it is not appropriate. The United States has already acknowledged the need to act on PBTs but EPA, as you have heard, is severely constrained by the statute. More than a decade ago, the United States and Canada targeted such pollutants for phase-out based on their buildup in the Great Lakes. Frustrated by the slow pace of federal progress, States from Maine to Hawaii are taking decisive action to tackle these chemicals.

Eliminating PBTs is also the goal of the Stockholm Convention on Persistent Organic Pollutants. This international treaty signed under President George W. Bush has been ratified by 168 countries but not the United States. Meanwhile, PBT levels are rising in the U.S. population, and sadly, Native Americans in Alaska, quite counterintuitively, are among the highest exposed people in the world.

In addition to PBTs, chemicals like formaldehyde, asbestos, phthalates, mercury and bisphenol A also warrant immediate action. The EPA administrator recently announced plans to address these and other notorious substances but the agency's ability to act depends on TSCA's unreasonable-risk standard, which is the Achilles heel that has prevented effective action for more than 2 decades.

Second, the EPA should evaluate all chemicals against a health-based standard. Because it will take years to complete this task, the EPA should prioritize the order in which chemicals are evaluated. The proposed 2008 Kid-Safe Chemicals Act charged the EPA with deciding which substances should be evaluated first based on a set of multiple criteria: high production volume, known hazards, presence in air, water and food, or human exposure. These are all reasonable factors to consider in managing an orderly process. But here is a critical point. Prioritization should be applied to organize the review but not to circumvent a full safety evaluation. It would be a serious mistake if in the guise of priority setting many or most chemicals escape the needed scrutiny. The American Chemistry Council's new principles for modernizing TSCA appear to favor this shortsighted approach.

Third, Congress should require chemical manufacturers to provide up-to-date, comprehensive safety information. This is vital if we are going to identify chemicals that pose little or no concern as well as high-risk chemicals. There is a role for prioritization here too. Chemicals that are first in line for the safety determination should be required to submit their data first. It just makes sense. Eventually all chemicals on the market should be required to submit and periodically update this information. That is basically how we regulate pesticides and pharmaceuticals today and it is suitable for industrial chemicals too. Safety data should also be supplemented by the kind of biomonitoring data we just heard about from CDC which provides a good reality check on the actual exposures of people in the real world.

Finally, in filling the existing data gaps, a revitalized TSCA can benefit from REACH, which is the European Union's attempt to update their own chemical law. This initiative is already generating valuable information that we can use to protect the health and safety of Americans and bolster our own international competitiveness. Thank you.

[The prepared statement of Mr. Ditz follows:]



CENTER FOR INTERNATIONAL ENVIRONMENTAL LAW

**Statement of Daryl W. Ditz  
On Behalf of the Center for International Environmental Law  
Before the U.S House of Representatives  
Subcommittee on Commerce, Trade and Consumer Protection  
At a Hearing on Prioritizing Chemicals for Safety Determination  
November 17, 2009**

Thank you, Chairman Rush, Ranking Member Radanovich, and members of the subcommittee for the opportunity to testify today. My name is Daryl Ditz and I am a Senior Policy Advisor at the Center for International Environmental Law (CIEL). CIEL is a nonprofit organization founded in 1989 and dedicated to protecting the environment, promoting human health, and ensuring a just and sustainable society through international and domestic law and institutions. CIEL is also a member of the Safer Chemicals, Healthy Families Coalition, a broad-based network of more than 100 health, environmental and justice organizations working to protect Americans from dangerous chemicals.

I appreciate your concern about the effectiveness of our national system for ensuring chemical safety. The public is concerned about the long-term effects of chemicals on health, including increasing incidence of asthma, autism, birth defects, infertility, and certain types of cancer. These problems are especially troubling in light of the growing evidence that industrial chemicals are building up in our bodies and in the environment.

Despite its aspirational title, the Toxic Substances Control Act (TSCA) has failed to assess, let alone guarantee, the safety of the great majority of chemicals in use today. TSCA stymies action by EPA and other agencies, perpetuates a reliance on dangerous substances, leaves businesses in the dark, and undermines U.S. competitiveness. Adopted by Congress over 30 years ago, TSCA today is failing to protect the health of Americans, our children, and their children. So I am especially grateful for this opportunity to discuss with you today practical improvements that can bring TSCA into the 21st Century.

In the current debate over TSCA reform, there is broad agreement that the United States must set priorities if we are to succeed in safely managing chemicals. I would like to offer three recommendations.

First, to expedite action, Congress should authorize EPA to promptly identify and phase out non-essential uses of a set of high-priority chemicals. A phase out of high-priority chemicals will jump start the process of protecting public health and inform decisions by other federal agencies, the States, businesses, and consumers. A slow, cumbersome safety determination process for these high-priority chemicals is neither necessary nor appropriate.

Second, Congress should authorize EPA to prioritize the order in which *all* chemicals, new as well as existing, are assessed against a health-based standard. Systematic review of all chemicals is not only possible, but necessary to identify dangerous as well as safer chemicals.

Third, Congress should ensure that up-to-date, comprehensive information is available on all chemicals, to protect the health and safety of Americans and foster confidence in the market.

These three reforms, already familiar to U.S. policy makers and businesses, should form the core of a new federal policy on chemicals that improves our international competitiveness while protecting the health of American workers, consumers, and communities.

Prioritization should play an important part in a new U.S. policy on chemicals. Setting priorities will help us to get started. But setting priorities is no substitute for a comprehensive system to identify, assess and control chemicals of concern. This is especially important because the United States must overcome an enormous backlog – tens of thousands of chemicals lack the basic information needed for preliminary screening. So it makes sense to focus public and private resources where they can do the most good.

#### **1) Prioritizing chemicals for action**

Despite major data gaps about chemical hazards and uses, we are not starting from scratch. A reinvigorated TSCA should recognize that sufficient and reliable information is already available for some chemicals to support prompt action by EPA and businesses.

One set of chemicals should be a top U.S. priority for action. Sometimes called the “worst of the worst,” these chemicals persist in the environment, bioaccumulate in the food chain and in our bodies, and pose serious threats due to their toxicity. These three properties -- persistence, bioaccumulation and toxicity, or “PBT” for short – defy

traditional risk assessment, because human exposure can continue to rise long after production has ceased.

But with the exception of PCBs, chemicals which Congress identified by name in the 1976 statute, TSCA has proven virtually powerless to eliminate such long-lasting threats to health and the environment. A reauthorized TSCA should prioritize PBTs for phase-out, subject to narrow exemptions for critical uses.

Targeting PBT chemicals for priority action is a pragmatic way to accelerate action on toxic chemicals. This is not a new concept for the United States. The U.S.-Canada Binational Toxics Strategy, for instance, was launched in 1997 with the goal of reducing or eliminating PBT chemicals in the fragile Great Lakes ecosystem. Several states (including Washington, Maine, California, and Minnesota), frustrated by the slow pace of federal progress, have taken decisive action on PBTs. EPA's Toxic Release Inventory already includes 20 PBT chemicals and chemical groups.

Eliminating PBTs is also the central objective of the Stockholm Convention on Persistent Organic Pollutants. This international treaty was signed under President George W. Bush and has since been ratified by at least 168 countries. PBTs are accumulating fastest in the Arctic, resulting in dire contamination of traditional foods of Native Americans and Indigenous people in Alaska. Just last week the National Congress of American Indians called on Congress to ratify this agreement and to enact comprehensive reform to ensure its implementation.<sup>1</sup>

PBTs are not the only chemicals that deserve priority action. Other notorious substances have been extensively studied, often for years, but remain on the market due to EPA's weak authority under TSCA. The recent example of high formaldehyde in imported plywood used in trailers after hurricane Katrina is especially tragic. But EPA has also found it nearly impossible to regulate asbestos, vinyl chloride, and other chemicals with well-known hazards and widespread human exposure.

The Environmental Protection Agency, under the leadership of Administrator Lisa Jackson, recently announced its plans to initiate risk management actions on formaldehyde, PCBs and several other chemicals. The agency is also developing action plans to target risk management efforts on other chemicals of concern, including bisphenol A (BPA), brominated flame retardants, phthalates.<sup>2</sup>

While EPA's goals are warranted and welcome, these actions hinge on TSCA's "unreasonable risk" standard, the Achilles' heel that has prevented EPA action since the Agency's asbestos rules were overturned by the courts nearly two decades ago.

Congress should provide EPA a stronger footing by granting it clear authority to reduce use of and exposures to these and other high-priority chemicals and to promote their replacement with safer alternatives.

Taking action on PBTs and other high hazard chemicals is good for public health and good for U.S. business. These chemicals, which represent a small fraction of the full set of chemicals to which Americans are exposed, deserve action without delay.

## **2) Prioritizing chemicals for safety determination**

A second important role for prioritization is found in establishing an orderly process for safety determination. We support the concept of applying a health-based standard to all chemicals under a revised TSCA. Chemical manufacturers should shoulder the burden of proof for demonstrating the safety of their products. These companies have the resources and technical expertise to undertake this analysis, and a commercial incentive to win approval. There is a corresponding responsibility for EPA to determine whether companies have met this burden. In short, chemical producers should make the case; but EPA should make the call.

Determining the safety of all chemicals is a big job that will require years to complete. So where should EPA begin? The proposed 2008 Kid-Safe Chemicals Act would have had EPA prioritize chemicals by considering a variety of criteria: high production volume; known hazards; presence in air, water or food; and, evidence of human exposure.<sup>3</sup> It is impossible to know which chemicals pose the greatest risks before this process begins. But these are reasonable considerations to inform EPA's decisions on which chemicals should be assessed first.

But here is an essential point. Prioritization should not be used to exclude chemicals from review, only to determine the order in which they are reviewed. As Administrator Jackson stated, "we need to review all chemicals" against a safety standard. It would be a serious mistake if chemicals escape scrutiny in the name of prioritization. Not only would we fail to catch dangerous chemicals, we would never learn which chemicals pose little or no concern. That would also deprive U.S. companies that invest in the developing with safer alternatives of the competitive advantage that should rightly reward their efforts.

Escaping scrutiny was an unfortunate result of EPA's misguided ChAMP initiative under the previous administration. In an attempt to speed up review of existing chemicals, the Agency pledged to sort some 6,750 chemicals into categories of high, medium and low risk. The fatal flaw of this approach is that many chemicals were wrongly labeled "low risk" on the basis of spotty and unreliable information. Indeed, EPA designated such

chemicals as requiring no further action – not even action to develop better information that could determine their true risk. The American Chemistry Council's new principles for TSCA modernization would repeat this mistake by subjecting only a fraction of existing chemicals, selected on the basis of whatever information can be cobbled together, to a safety determination and letting the majority of chemicals sidestep credible evaluation.<sup>4</sup>

### **3) Prioritizing chemicals to fill data gaps**

Here's a third way that prioritization should be incorporated into federal law. Prioritization decisions are only as good as the data on which they are based. Therefore, U.S. policy should require chemical manufacturers to develop, submit and periodically update data on the potential hazards, exposures, and uses of the chemicals they manufacture or import. This should be an ongoing process, reflecting new information, emerging science and evolving patterns of chemical use. It should continue even while EPA works through the inventory of chemicals in commerce.

Major data gaps frustrate efforts to set priorities. For example, the U.S. chemical industry spent much of the past ten years compiling hazard data under a voluntary program for a few thousand of the largest volume chemicals. Even now, however, hundreds of these chemicals still lack the bare minimum data needed even for initial screening purposes, and data quality problems abound. Obviously, we can't solve this problem overnight. That is why Congress should establish priorities to remedy these knowledge gaps.

Mandatory minimum data requirements for all chemicals are a necessary ingredient for effective prioritization. Chemical manufacturers should be responsible for developing and providing information on the physical and biological properties of their products, including persistence, bioaccumulation and toxicity, and exposures to workers or the environment from their operations. Providing reliable information on *uses* of chemicals is more challenging, because manufacturers often have limited information on how their own chemicals are used. Downstream companies that process and formulate chemicals often have an interest in concealing how they use a chemical to avoid being scooped by their suppliers.

Safety determinations also depend on understanding exposures to chemicals, but such information might not be readily available to manufacturers or even downstream users. Biomonitoring, as exemplified by the valuable work of the Centers for Disease Control and Prevention (CDC), helps to fill this data gap by indicating aggregate chemical exposures, providing an important check on human exposures in the real world.

Finally, the United States, and U.S. chemical companies, can benefit from the European Union's efforts to revise its own law on chemicals. REACH, the regulation on Registration, Evaluation and Authorization of Chemicals, is already resulting in the generation of new data that can be useful here. For example, under REACH data on roughly 3,000 high volume chemicals is due by December 1, 2010, just a year from now. Additional information will be available on many more chemicals in 2013 and 2018. At each milestone, data on chemical hazards will be publicly available. The U.S. government can also gain access to confidential business information submitted under REACH.

#### Conclusions

In conclusion, prioritization should play an important role in a reauthorized, revitalized TSCA. However, whether prioritizing chemicals for early action, expedited review, or other risk management measures, Congress should ensure that *all* chemical receive adequate scrutiny. Anything less would leave millions of Americans at risk from dangerous chemicals and would undercut U.S. companies that are bringing safer products to market.

Thank you.

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<sup>1</sup> National Congress of American Indians, Resolution PSP-21-2009, "Protection of the Health and Human Rights of Present and Future Generations through Ratification and Implementation by the United States of the Stockholm Convention on Persistent Organic Pollutants, November 12-16, 2009.  
[http://www.ncai.org/fileadmin/resolutions/PSP-09-021\\_final.pdf](http://www.ncai.org/fileadmin/resolutions/PSP-09-021_final.pdf)

<sup>2</sup> Enhancing EPA's Chemical Management Program,  
<http://www.epa.gov/oppt/existingchemicals/pubs/enhanchems.html>

<sup>3</sup> Introduced as S. 3040 and H.R. 6100 in 110th Congress, 2nd Sess., May 20, 2008.

<sup>4</sup> American Chemistry Council, 10 Principles for Modernizing TSCA, August 4, 2009.

Mr. RUSH. The Chair now recognizes Mr. Greggs for 5 minutes.

**TESTIMONY OF BILL GREGGS**

Mr. GREGGS. Thank you, Chairman Rush, Ranking Member Radanovich and members of the subcommittee for asking me to testify. I am Bill Greggs, a chemical engineer. My field of expertise is in global chemical management policy supporting the development of safe and sustainable products.

I am testifying on behalf of the Consumer Specialty Products Association, the Grocery Manufacturers Association and the Soap and Detergent Association. Now, these groups represent users of chemicals that are formulated into a broad array of consumer and commercial products. Our members are committed to manufacturing safe and innovative products that provide essential benefits to consumers while protecting public health and the environment.

Now, product safety is the foundation of consumer trust and confidence and our industry devotes substantial resources to achieving that goal. We support the modernization of TSCA and we continue to urge Congress to establish a stakeholder process to identify and work on the complex issues that are involved in this legislation. Prioritizing chemicals for review and assessment is key to TSCA's modernization. It provides the means to efficiently address important policy concerns such as children's health and chemical exposures that are identified through biomonitoring.

Now, you have my written testimony. I really want to briefly summarize three main points. The first is setting priorities based on hazard and exposure, the second is a quick-start concept and the third is stakeholder involvement.

Now, the priority-setting process developed by Congress must be risk based, that is, it ought to consider both hazards and potential exposures of a chemical in setting priorities. Our associations have collaborated with others in industry to develop an efficient risk-based matrix tool that EPA can use to set priorities in a timely manner. EPA can employ this tool to select the highest hazard and the highest potential exposure chemicals as the highest priority for further assessment. Chemicals with low hazard and potential exposure would be the lowest priority.

Now, this tool produces a numerical ranking, which is a lot better than kind of a yes-no type of approach. The matrix is illustrated in this illustration on my right. It shows increasing levels of hazard along the vertical access, and EPA would consider in this human environmental toxicology information such as whether a chemical has been identified as causing cancer, reproductive or developmental toxicity or is persistent, bioaccumulative and toxic. Indicators of increasing exposure are shown on the horizontal access. EPA would consider in this the use pattern of a chemical such as its use in closed systems, use in consumer and commercial products, and products intended for use by children. Also, EPA should consider CDC's biomonitoring findings as well as information from industrial releases and from environmental monitoring.

To reiterate, hazards and potential exposures must both be considered. A single factor, just hazard or just exposure, really isn't sufficient. If everything is a priority, then nothing is a priority. This process is relatively straightforward and EPA can conduct it

in a reasonable time frame, ranking all chemicals from high to low. Where information is not available, the agency, we believe, should have the authority that it doesn't have today to require timely submission of information after which a chemical can then be ranked. Additionally, this tool is dynamic as well. It allows EPA to update priority when new information does become available.

Now, the second idea that we have for Congress is to develop an additional mechanism, kind of a quick-start approach. It has been discussed today about the anxiety and the interest in moving quickly. We think EPA through this mechanism can identify the very highest-priority chemicals for immediate assessment. To do this, EPA would select chemicals that have the very highest hazards such as known carcinogens, reproductive or developmental toxicants, or PBTs, and the highest potential exposure, for instance, chemicals measured in CDC's biomonitoring program or used in chemicals intended for children. This would be identified 50 to 100 chemicals that could quickly move into EPA's safety assessment process while the agency completes priority setting for the remaining chemicals.

The third point is stakeholder involvement. The priority-setting process we believe should involve review and comment by stakeholders to allow them to provide additional data to EPA and allow more-informed decisions by EPA. CSPA, GMA and SDA believe this priority-setting approach is straightforward and efficient. We have discussed it with many industry and non-governmental groups and with many of your offices. We think it can provide EPA with a good way to identify the highest-priority chemicals for further assessment.

Our associations look forward to working with you to modernize TSCA. Thank you very much.

[The prepared statement of Mr. Greggs follows:]



**TESTIMONY OF BILL GREGGS  
ON BEHALF OF THE  
CONSUMER SPECIALTY PRODUCTS ASSOCIATION,  
GROCERY MANUFACTURERS ASSOCIATION,  
AND THE SOAP AND DETERGENT ASSOCIATION  
BEFORE THE SUBCOMMITTEE ON COMMERCE, TRADE AND CONSUMER  
PROTECTION**

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 Bill Greggs and I am a chemical engineer whose field of expertise over the last several decades has been global chemical policy supporting the development and production of safe and sustainable consumer products. I am testifying on behalf of the Consumer Specialty Products Association (CSPA), Grocery Manufacturers Association (GMA), and The Soap and Detergent Association (SDA). These three organizations primarily represent the processors and users of chemical substances, which they formulate into a broad array of consumer products.

The members of CSPA, GMA, and SDA are committed to manufacturing and marketing safe and innovative products that provide essential benefits, including important public health benefits, to consumers while protecting human health and the environment. Product safety is the foundation of consumer trust and the consumer products industry devotes substantial resources to achieving this goal. To that end, we support modernization of the Toxic Substances Control Act (TSCA) and continue to urge Congress to establish a stakeholder process to develop the most comprehensive chemicals management policy in the world. All stakeholders - Congress, regulators, downstream users, raw material suppliers, retailers, environmental, consumer and animal welfare and labor groups - should work together to develop sound public policy on this complex issue.

Among the issues that these three organizations believe should be addressed as part of any effort to modernize TSCA is the development of a mechanism by which EPA will prioritize existing chemicals for review and assessment – the focus of today’s hearing. A prioritization process clearly established by Congress can provide the means to more efficiently address important policy concerns such as children’s health and chemical exposures revealed through biomonitoring and begin the process of restoring public confidence in the U.S. chemicals management system.

A priority setting process developed by Congress *must* be risk-based, taking into consideration both a chemical's hazards and potential exposures. Chemicals identified as the high priorities should be those substances with *both* the highest hazards and the highest potential exposures. Although additional chemicals will warrant assessment and possible control, a program that is workable by EPA requires a selection of those chemicals that initially warrant further assessment to ensure meaningful protection of human health and the environment. Therefore, a chemical with high hazards and low potential exposures would be a lower priority, as would be a chemical with high potential exposures and low hazards.

CSPA, GMA, and SDA have collaborated with various industry representatives on the development of a risk-based and efficient tool that EPA can use to prioritize chemical substances in a timely manner under a modernized TSCA. As such, we recommend the use of a framework which accounts for increasing levels of hazard on one axis and increasing levels of potential exposure on the other axis. The displayed exhibit, illustrates conceptually how hazard and exposure information can be integrated for priority setting. The highest hazard and highest potential exposure chemicals (identified in the lower right corner) would be the highest priority for further assessment; while the lowest hazard and lowest potential exposure chemicals (identified in the upper left corner) would be the lowest priority for further review by EPA. Chemicals would be given numerical rankings providing better granularity than a "Yes" or "No" approach as to whether a chemical is a "priority" substance.

As represented in this illustration, increasing levels of hazards are on the vertical axis. We suggest that the appropriate hazard characteristics that EPA consider in this priority setting process should be human and environmental toxicology information, such as whether or not a chemical has been identified as a carcinogen, reproductive or developmental toxin or as a persistent, bioaccumulative, and toxic chemical (PBT) by programs such as those developed by EPA, the National Toxicology Program, the International Agency for Research on Cancer, or by the European Chemical Substances Information System.

Appropriate exposure indicators on the horizontal axis should include: the use pattern of a chemical (i.e., whether a chemical is used in a closed system, in transport or industrial use, in a consumer or commercial product, or in a product intended for use by children); its biomonitoring findings according to the Centers for Disease Control and Prevention (CDC); industrial releases as reported through the Toxics Release Inventory (TRI); and environmental monitoring information, such as whether the chemical is found in water or air.

To reiterate, the hazards and potential exposures must both be taken into consideration in this process. One single factor, whether it is based on hazards or potential exposures, is not sufficient for a chemical to be deemed as a high "priority" chemical. Selecting chemicals with either hazard or exposure will result in everything being a priority. If everything is a priority, then nothing is a priority.

This approach is easy to adopt for the Agency and able to be done in a reasonable timeframe when the hazard and exposure information is readily available to EPA. In the instances where this information is unavailable to EPA, the Agency should have the authority to require its submission from the appropriate industry representatives in a timely manner, allowing for the chemical to then be ranked.

Additionally, the priority setting process must allow for stakeholders to review and comment. There must be an opportunity for interested parties to provide information enabling a more informed decision or to remedy erroneous results of the priority setting process. This is a critical component Congress must include that will significantly improve the results of this very important exercise.

Done properly, this priority setting process would rank all chemicals from highest to lowest in a relatively short period of time, considering both human and environmental health impacts and the potential for exposure. Additionally, it is a dynamic tool, allowing EPA to update a chemical's priority, rather than only as a one-time assessment. This is especially valuable when new information becomes available regarding the hazard or exposure pattern of a chemical substance, which may force it into a higher prioritization status.

With no comprehensive priority setting mechanism in TSCA for over thirty years, there is an understandably high interest in EPA identifying those chemicals of highest concern and beginning their assessments immediately. While the complete priority setting process will take EPA some time to accomplish, we encourage Congress to develop an additional mechanism that will enable EPA to identify the chemicals of highest priority for immediate assessment.

As such, we recommend a process that would require EPA to screen the data from the most recent Inventory Update Rule (IUR) submissions to identify chemicals that have the highest hazards (i.e., carcinogen, reproductive or developmental toxin or PBTs) *and* highest potential exposures (i.e., chemicals that have been measured in the CDC's biomonitoring program or chemicals in products intended for use by children). Our analysis indicates that this process would identify approximately 50 to 100 chemicals that could quickly move into EPA's safety assessment process while the Agency works on prioritizing the remaining chemicals in commerce through the tool I have previously described.

CSPA, GMA, and SDA believe that the approach that I have discussed today represents a relatively simple, straightforward, and efficient process for prioritizing chemical substances. We have discussed this approach with many industry representatives, as well as several nongovernmental organizations, and feel that this process can provide EPA with an appropriate approach to identify the highest priority chemicals for in depth assessment to ensure the protection of human health and the environment.

Mr. Chairman and distinguished members of the Subcommittee, thank you again for the invitation to testify here today. CSPA, GMA, and SDA and their members look forward to working with you all on this very important issue. In the meantime, I look forward to answering any questions you may have.

**About CSPA**

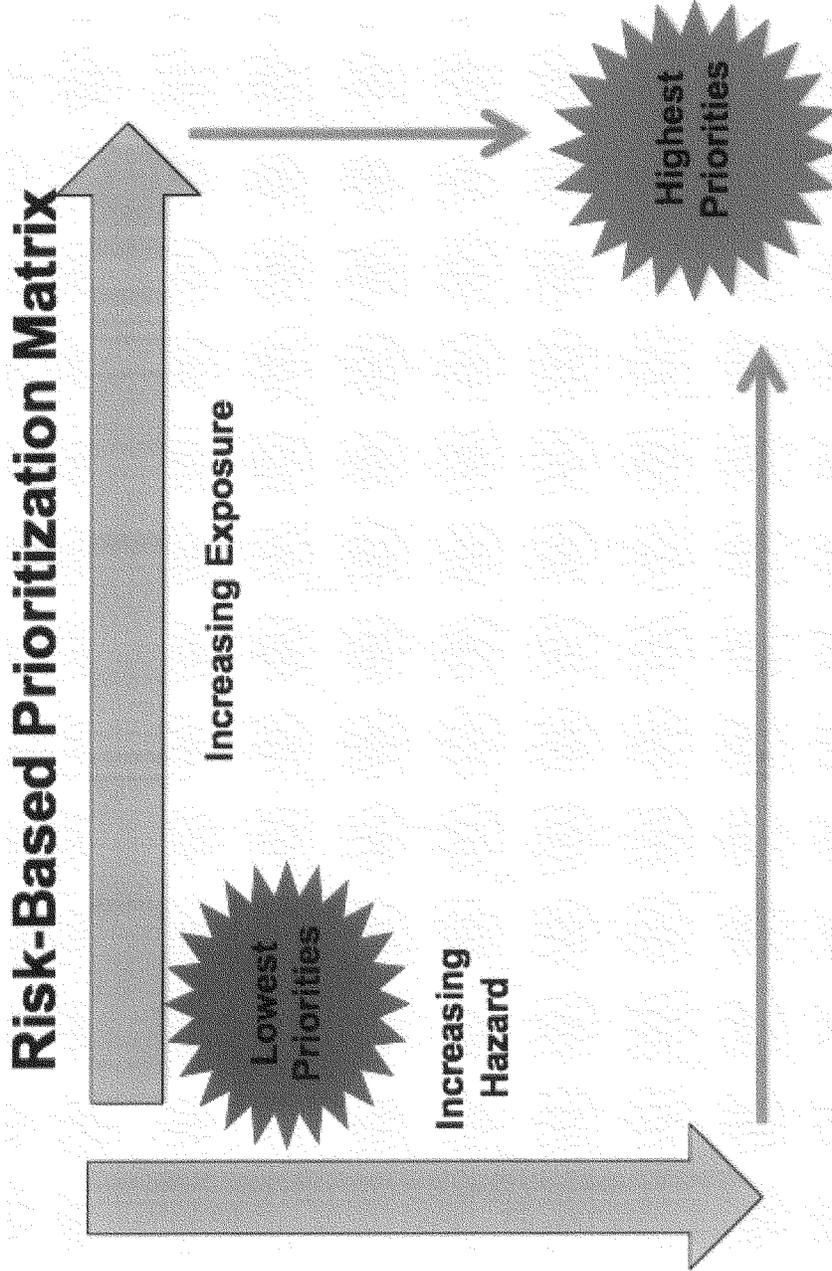
The Consumer Specialty Products Association (CSPA) is the premier trade association representing the interests of approximately 240 companies engaged in the manufacture, formulation, distribution and sale of approximately \$80 billion annually in the U.S. of hundreds of familiar consumer products that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

**About GMA**

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

**About SDA**

The Soap and Detergent Association, the Home of the U.S. Cleaning Products Industry®, represents the \$30 billion U.S. cleaning products market. SDA members include the formulators of soaps, detergents, and general cleaning products used in household, commercial, industrial and institutional settings; companies that supply ingredients and finished packaging for these products; and oleochemical producers. SDA and its members are dedicated to improving health and the quality of life through sustainable cleaning products and practices. SDA's mission is to support the sustainability of the cleaning products industry through research, education, outreach and science-based advocacy. For more information visit [www.cleaning101.com](http://www.cleaning101.com).



Mr. RUSH. The Chair thanks the gentleman, and now the Chair recognizes Ms. Bosley for 5 minutes.

#### TESTIMONY OF BETH BOSLEY

Ms. BOSLEY. Good afternoon, Chairman Rush, Ranking Member Radanovich and members of the subcommittee. I am pleased to testify before you today on behalf of the Society of Chemical Manufacturers and Affiliates, or SOCMA. SOCMA has served the batch and specialty chemical industry since 1921. We have 300 members, usually small-to medium-sized companies. Our members make a \$60 billion annual impact to the national economy and we contribute to the chemical industry's position as one of the Nation's largest exporters.

As we testified before the subcommittee last February, SOCMA supports EPA's and Congress's fundamental goal of protecting human health and the environment from hazardous chemical exposure. SOCMA members are prepared to continue doing our part in this effort. We are pleased to have this opportunity to share with you our perspective on revising TSCA. SOCMA agrees that TSCA can be modernized and that policy goals can be accomplished in a way that doesn't devastate a strategic American industry already fighting recession and foreign competition. As I will discuss, two principles are essential to sustainable chemical management law that won't eliminate jobs, economic growth or critical products. First, TSCA priorities should be established based on risk, as you have heard from some other witnesses this morning, and second, proven regulatory mechanisms should be used as the basis for this modernization.

Prioritization of risk must remain a fundamental principle of TSCA. This means basing priorities and regulatory criteria on scientific evaluation of toxicological response and exposure factors. For instance, if a chemical is highly toxic but used only in strictly controlled industrial environments or in small quantities, then the risk to public health is fairly small.

The second important principle for TSCA reform is leveraging regulatory mechanisms that already work. We agree with EPA that the existing regulatory framework is better suited to American health, environmental and economic interests than Europe's monolithic regime known as REACH. Applying an approach like REACH in the United States could devastate small- and medium-sized companies and do so unnecessarily since a more practical approach is available. Industry certainly does not oppose the potential for new regulation. We acknowledge the success of current environmental laws and programs and these mechanisms show promise in being able to achieve new policy objectives without sacrificing hundreds of businesses and thousands of jobs. For example, the Canadian approach to chemicals management has systematically prioritized that nation's inventory and is therefore much further ahead of EU with respect to evaluation of chemicals in commerce.

Another mechanism supported by SOCMA was the inventory reset, which was part of EPA's recently discontinued ChAMP program. This would have provided an accurate measurement of the chemicals now in commerce, which we believe is the only realistic starting point. Of the over 80,000 chemicals now listed on the in-

ventory, data suggests that only about one-third of these are presently in commerce. The program also identified categories of well-characterized chemicals, prioritized them and systematically targeted them for further review. Even the TSCA critics did not challenge the groupings identified by EPA at that time and supported this notion of prioritization. The program then went into an evaluation of the risks associated with the exposures to these chemicals. For these reasons, we believe that ChAMP should not have been abandoned because it will simply have to be reinstated under another name.

We should also embrace the TSCA mechanisms that have worked well like the New Chemicals Program, where EPA has successfully reviewed roughly 40,000 new chemicals since 1979 without impeding the innovation that is crucial to American competitiveness. Through this EPA program known as the PMN process, over 1,000 chemicals undergo a review every year. This successful model should also be applied to existing chemicals. We should recognize the massive amount of data that was generated during HPV, or High Production Volume program, and leverage that data in making initial determinations of risk. With reasonable amendments, TSCA should provide an easier mechanism for EPA to poll manufacturers and users for data on volume, health effects, and by health effects, I mean all health effects. Right now EPA gathers data only on adverse health effects. And we also need to know exposure characteristics both to the environment and to human health. Section of Canada's Environmental Protection Act effectively enables this sort of data collection.

SOCMA members have a deep commitment to the safe use of our chemicals and we are proud of our collective track record in protecting our workers and in our communities. SOCMA favors a formulation whereby EPA would make a safety determination and that safety determination should be based first on risk. We also believe that EPA should not be burdened with the determination that each chemical is safe for its intended use. Specific chemicals and specific uses may be approached this way when dealing with a short list of chemicals and narrow uses such as pesticides under FIFRA and drugs under the FDA. But with 55 categories of chemicals, a requirement that all new uses of any chemical be specifically approved would be burdensome and delay our transition to a lower carbon future. Instead, under an improved TSCA, EPA should provide goals, prioritization and oversight but implementation should be based on proven and practical regulatory mechanisms.

Finally, regardless of what approach Congress adopts, EPA will need to be adequately funded. The biggest shortcoming of the TSCA program today is a lack of resource and not the lack of the authority.

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

[The prepared statement of Ms. Bosley follows:]



Society of Chemical Manufacturers & Affiliates

Testimony  
of  
Beth D. Bosley

Managing Director  
Boron Specialties

*On behalf of the*

Society of Chemical Manufacturers & Affiliates

*Before the*

U.S. House of Representatives

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

*On*

“Prioritizing Chemicals for Safety Determination”

November 17, 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 members of the Subcommittee. My name is Beth Bosley, and I am the Managing Director for my company, Boron Specialties in Pittsburgh, Pennsylvania. I am pleased to testify before you today on behalf of the Society of Chemical Manufacturers and Affiliates (SOCMA) regarding the Toxic Substances Control Act (TSCA).

Since 1921 SOCMA has served as the leading trade association representing the batch and custom chemical industry. SOCMA has over 300 member companies, which are typically small to medium-sized businesses, each with up to \$100 million in annual sales. Our members make a \$60 billion annual impact on the U.S. economy and contribute to the chemical industry's position as one of the nation's largest exporters.

As we testified before this Subcommittee last February, SOCMA supports EPA's – and Congress's – fundamental goal of protecting human health and the environment from harmful chemical exposure. SOCMA members are prepared to continue doing our part in that effort. We are pleased to have this opportunity to share with you our perspective on revisiting the Toxic Substances Control Act. SOCMA agrees that TSCA can be modernized, and that policy goals can be accomplished in a way that doesn't devastate a strategic American industry that is already fighting recession and foreign competition. As I will discuss, two principles are essential to a sustainable chemical management law that won't eliminate jobs, economic growth, or products. First, TSCA priorities should be established based on risk. Second, proven regulatory mechanisms should be the basis for modernization.

Prioritization of risk must remain a fundamental principle of TSCA. This means basing priorities and regulatory criteria on the scientific evaluation of toxicological response and exposure factors. For instance, if a chemical is highly toxic, but used only in strictly controlled industrial environments, or in small quantities, then the risk to public health is fairly small.

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





This is not to say that industry opposes the potential for new regulation. We acknowledge the success of current environmental laws and programs. Moreover, these mechanisms show promise in being able to achieve new policy objectives without sacrificing hundreds of businesses and thousands of jobs. For example, the Canadian approach to chemicals management has systematically prioritized that nation's inventory and is, therefore, much further ahead of the EU with respect to evaluation of chemicals in commerce.

Another mechanism supported by SOCMA was the "inventory reset", which was part of EPA's recently discontinued Chemical Assessment and Management Program (ChAMP). This would have provided an accurate measure of the chemicals now in commerce, which we believe is the only realistic starting point. Of the over 80,000 chemicals now listed on the inventory, data suggest that only about 1/3 of these are presently in commerce. The program also identified categories of well-characterized chemicals, prioritized them, and systematically targeted them for further review. Even TSCA critics did not challenge the groupings identified by EPA and supported the notion of prioritization. The program then went into an evaluation of the risks associated with the exposures to these chemicals. We need to prioritize and categorize the universe of chemicals. ChAMP should not have been abandoned, because it will just have to be reinstated under another name.

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

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

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





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

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

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



Mr. RUSH. The Chair thanks all their witnesses for their testimony. Now it comes to the time where members of the committee will query the witnesses, and the Chair now recognizes himself for 5 minutes for the questioning of the witnesses.

One of the biggest problems that has been stated previously, one of the biggest problems today with TSCA is a lack of information on which EPA can base its decisions. A lack of information does not mean that there is not a problem. Also without information, it is hard to make informed decisions on prioritization. It seems to me that the EPA should require the submission of crucial information needed to determine how a chemical should be prioritized. The chemical industry is not currently required under TSCA to develop data on toxicity or exposure of the chemicals for chemicals that existed in commerce when TSCA was passed. My question is focused on the testimony of Mr. Owens. Mr. Owens, certain voluntary programs that offer a menu for industry to produce and submit data to EPA, have they been successful? And I have two related questions. You can answer all three of them at the same time. Do you believe there is existing data that has not been provided to EPA because submission is not mandatory? And the last part of the question is, if there were a mandatory submission of existing data to EPA, I would think that this requirement would be required not only for chemicals currently in commerce but for any chemical for which data may be available. Wouldn't a comprehensive data collection process assist the agency in other areas such as environmental cleanup, et cetera? Would you care to answer those questions, please?

Mr. OWENS. Thank you, Mr. Chairman. I will actually take them a little bit out of order, if I may, your last question first. I think absolutely a comprehensive data collection system would benefit not just the TSCA program but the agency as a whole. That is one of the biggest challenges that we face in implementing TSCA as well as some other programs but especially TSCA, that we don't have the data we need to make the kinds of safety determinations that we feel to be making in order to protect the health and safety of the American people and the children and families in this country.

With regard to your first question about voluntary programs, I think you asked whether they were successful. I would I think overall have to say no but maybe to qualify it by saying kind of sort of. The so-called ChAMP program that was started under the previous Administration was only modestly beneficial at best. It collected some data from some companies. It was an effort designed to develop screening-level assessments and to prioritize thousands of chemicals. It was over 6,000 chemicals that the agency was looking at at the time and it seems that some folks outside the agency have a much higher opinion of ChAMP than the people who are actually implementing it inside the agency. And a decision was made before I came on board in July by Administrator Jackson to take a look at ChAMP to see how it was working, and based on the review that was conducted by the staff at OPPTS, it was determined that that program, ChAMP, was too focused on categorizing chemicals and it would take years and years in order to get around to categorizing all those chemicals, and those categorizations were

having to be made on the basis of incomplete and inadequate information because it was a voluntary program. So being a westerner, I think one way that I have always tried to describe the ChAMP program since I have been there is, especially folks from Texas might say but in Arizona we would say as well it was all hat and no cattle, that is looked good on the outside but in terms of actually achieving what we needed to have it achieve and the agency just didn't do the job.

But lastly, you asked the question about is there existing data that is out there that hasn't yet been provided. TSCA does require companies if they have data in their possession of adverse health and environmental effects, they are required to provide that, and so it was actually a perverse disincentive in the statute for the generation of that kind of data because if they have it, they have to turn it over. There is no requirement now that they actually provide it up front either, especially for an existing chemical because of the way that new chemicals are treated vis-&-vis existing chemicals. But even with a new chemical, the burden is still on EPA to show that we think that there may be a problem from a health and environmental perspective in order to request data from the manufacturers or producers of those chemicals before it actually has to be provided to us.

Mr. RUSH. Thank you.

The Chair now recognizes the ranking member for 5 minutes.

Mr. RADANOVICH. Thank you, Mr. Chairman, and again welcome everybody to the subcommittee.

Mr. Owens, I would like to ask a few questions. Although I appreciate the testimony of everybody who is here, I really kind of want to get into this 80,000 figure because it was mentioned in some previous testimony but a third of that is stuff that is not in commerce anymore. There is some talk of worst-of-worst chemicals but I have not heard an amount of what is, you know, the numbers that entails. Here is what concerns me: 10 percent unemployment. I live in a part of California where the misapplication of the Endangered Species Act has driven the timber industry out of the State of California. In my area there used to be a number of them, now there is none because of overregulation. My concern is that when you are here talking about 80,000 chemicals without differentiating between the two of them, you are talking about canceling ChAMP, which is a cooperative effort, I think, between the government and the industry to base some risk assessment on these chemicals and you are looking at beefing up the Administration to me looks like treating those 80,000 chemicals the same. You are going to be driving the chemical production industry out of the United States much the way that the timber industry has been driven out by the Endangered Species Act. Is that what you want to do at the Administration, Mr. Owens? Do you want the chemical production industry to leave the United States?

Mr. OWENS. Is that a yes-or-no question?

Mr. RADANOVICH. Sure. Please. I don't have a lot of time.

Mr. OWENS. Representative Radanovich, I think the best way to answer that is obviously no, sir.

Mr. RADANOVICH. Is the Administration aware that the unemployment right now is over 10 percent? It is a fair question. This is my time and it is a fair question.

Mr. OWENS. I believe they are, Mr. Radanovich.

Mr. RADANOVICH. Thank you. Can you tell me, what is the worst of the worst? I will ask you, Mr. Owens or Mr. Ditz, what is the worst of—how many are there worst-of-worst chemicals on the list of 80,000?

Mr. OWENS. Congressman, if I may, I will go back a little bit to your question about the 80,000 because I think that was an important point you did make in that regard, that it isn't clear exactly how many of those 80,000 are still in commerce. There is a general belief that obviously the overwhelming majority of those chemicals are still in commerce. There are some questions out there certainly by industry and also by our agency that the existing inventory may not actually reflect what is going on out there. There is an effort—

Mr. RADANOVICH. Would you agree with the statement that there was about one-third that is not in commerce now?

Mr. OWENS. No, sir, I couldn't agree with that now because we just don't know. That assertion has been made by some industry groups but we just don't know, and one of the things that we do intend to move forward with over time is looking at updating the inventory, what is called the inventory reset. We would have to move forward with that in some point in the future after we get the other things in a row here. That was a long-term goal of the agency as part of the ChAMP program and some of the other efforts that were underway, and I think that is a valuable thing that we need to do in the future. The challenge is that we have to get that information from the industry groups. You have to have a mechanism for getting that and we have to have reliable data on what really is being used out there and what is being produced in commerce.

Mr. RADANOVICH. Thank you, Mr. Owens.

Mr. Ditz, how many are the worst of worst? How many?

Mr. DITZ. Of course, when we have the giant question marks about what—

Mr. RADANOVICH. Mr. Ditz, if you could just say how many worst of worst chemicals are out there.

Mr. DITZ. Thank you. I will try to give you a straight answer.

Mr. RADANOVICH. Well, it would be a number. Since you are the expert, you can tell me how worst-of-worst chemicals are out there.

Mr. DITZ. I can tell you roughly how many chemicals are known to be in this group. For example, for PBT chemicals—

Mr. RADANOVICH. Just tell me—

Mr. DITZ [continuing]. We are talking about dozens.

Mr. RADANOVICH. Mr. Ditz, if you could—dozens, so there is 12, 24?

Mr. DITZ. No, that would be a dozen, but there are 21, for example, on the international treaty, which the rest of the world is moving on with. There are—

Mr. RADANOVICH. OK. So there are 80,000 chemicals out there and you have got probably say less than 50 that are on the worst of worst.

Mr. DITZ. There is no way to know, and this is exactly the point that this hearing is so helpful for. We will never know unless they look at the——

Mr. RADANOVICH. All right. I appreciate the fact. I am just trying to get things in perspective because I don't want the chemical production industry to go offshore. Pretty much that it is. Thank you very much.

Now, Mr. Owens, you mentioned, ChAMP and how there was careful consideration under my, the information that I have, it was a rather hasty move. Can you tell me how you went through the deliberative process? And I would also like to know how that effects the Montebello Agreement where ChAMP was a significant part in the cooperation between Mexico and Canada in getting a handle on these chemicals and regulating them.

Mr. OWENS. Congressman, the review that took place, as I said, did place before I got there but what the staff did was take a look at the timelines involved for review of the over 6,000 chemicals that were being looked at under ChAMP, the types of data, the information that were being provided and it was fairly spotty, kind of hit-or-miss data that was coming in, some companies providing a fair amount, others providing none at all. Some chemicals had what they were calling sponsors where a particular company or group of companies would provide data on that. Other chemicals were completely orphaned and there was no data at all on those chemicals, so it really was a hit-or-miss, very spotty process going forward with ChAMP, and with the length of time it was going to take under the existing regulatory regime to cajole that data out of the people who had it, if it existed at all out there among industry groups, then to put it into these bins, as they were being called, three different categories that the agency was going to use, and then somewhere down the line to get around to actually deciding which were the worst of the worst and to do something about it, we were looking at years and years and years down the road.

With the focus of Administrator Jackson on the need to make chemical management a top priority for our agency and to do the kinds of things we need to do to protect the health and safety of children and families in this country, it was felt that we needed to take a more proactive approach to trying to identify what might be the worst-of-the-worst chemicals, in the immediate sense to take action on them, and that is why we have been developing these action plans, as I mentioned. We are hoping to unveil some of them in December and then every 4 months or so thereafter to have another smallish group of roughly four or so chemicals. You know, it is a pretty modest approach that we will be undertaking because of the limitations we have under TSCA and the limited amount of information but we are taking the data that we received under ChAMP and that we otherwise have at the agency, applying it to chemicals as we know we have, looking at data that CDC and other folks have developed through the biomonitoring processes that they have and the studies that have been done out there to do that kind of work.

Mr. RADANOVICH. Thank you, Mr. Owens. I appreciate your testimony.

Mr. RUSH. The gentlelady from Illinois is recognized for 2 minutes.

Ms. SCHAKOWSKY. Two minutes?

Mr. RUSH. For 5 minutes.

Ms. SCHAKOWSKY. Thank you, Mr. Chairman.

Dr. Sampson, you talked about three States getting additional funds for biomonitoring, and you mentioned—and I am concerned. I live in Chicago and we are sitting on 20 percent of the world's surface water in the Great Lakes. My understanding is that every fish that is caught in Illinois has excessive levels of mercury. I just wanted to know if there is any opportunity for a Midwestern city on the Great Lakes could be part of that or if you are doing that in other ways?

Mr. SAMPSON. In the awards that we mentioned for California, New York and the State of Washington, there were actually 33 States that turned in applications. They turned in very good proposals on how they would use their money locally and so—

Ms. SCHAKOWSKY. Well, you know, Dr. Ditz mentioned the Great Lakes. I just think that is really important that we look at that as well.

Mr. Owens, you said you are going to release action plans in December and then every 4 months, but Mr. Greggs mentioned, what did you call it quick-start approach, of 50 to 100 chemicals. I wonder what you think of that, you know, that there would be pretty universal agreement—I mean, correct me if I am wrong—of 50 to 100—I guess I am just talking about getting started and this quick-start approach as being one way to go.

Mr. OWENS. Well, Vice Chair Schakowsky, I think that that wouldn't necessarily be a bad place to start. I mean, we have actually been having a lot of conversations with the groups that Mr. Greggs represents here as well as with the American Chemistry Council and other industry groups and there are a lot of industry groups out there that do support reform of the Toxic Substances Control Act. Without having had a detailed conversation with them about it, I would say though that that should be a floor rather than a ceiling. It should be kind of the jumping-off point, not the be all and end all because you might have a situation in which you have low exposure because of a very narrow limited population. I think Alaska Natives were mentioned, maybe Native Americans, maybe a subset of children in a certain—

Ms. SCHAKOWSKY. No, I know. You talked about criteria. All I'm saying is that December we will have the action plan and then four months later some chemicals will be announced. It just seems to me if there is a consensus in regulators, the scientific community and the industry on some of the most toxic, the worst of the worst, that that would be a place to get going right away.

Mr. OWENS. Congresswoman, the only thing I would say on that, I don't think there actually has been an agreement on the actual list. I think that is what we are talking about with the criteria. But there would be substantial overlaps I think between what we would think would be the worst of the worst and what some industry groups would think and some advocacy groups as well and so that would be a good place to start, and we have identified six chemical groups that we are going to be looking at for the first ac-

tion plans. We will probably do four of those in December. Then the other ones will be carried over to early next year. We will have our public process where we will be getting information from NGOs and industry groups about what those worst-of-the-worst chemicals might be, to put them into our priority for action plans in the future.

Ms. SCHAKOWSKY. OK. I guess all I want to say is that while obviously we have to process, and it is refreshing to say that science is going to drive this, we also, I think, you know, need to move as quickly as possible.

Let me ask Mr. Greggs and Ms. Bosley, in terms of minimum data requirements, do you agree that the industry needs to be provide the information? Let me ask you that. But then also ask Mr. Owens if you think it ought to be mandatory to require that data.

Mr. GREGGS. Thank you, ma'am. We believe that EPA should have sufficient data not only just to make priority decisions but later as they do safety assessments and make decisions about risk and decisions about risk management, so we think that that is very important. As I testified today, the first thing to do is, let us identify the priority chemicals. We believe that there is substantial information, especially for this quick start using the criteria that I described where we could get started quickly. We believe that industry will have a significant role in that, unlike the action plan that EPA is starting now. Under our idea, the belief is that the development and assembly of that data, really the burden of that would be transferred to industry, industry putting that together and then providing it to the EPA to make the safety decision.

Ms. BOSLEY. I might add that industry isn't really sure what data EPA would like for a priority one, two, three, four or five chemistry. If there was a base set identified, industry could certainly provide as much data as it can.

Ms. SCHAKOWSKY. Mr. Owens, do you need the authority to require industry to provide the data?

Mr. OWENS. Congresswoman, yes, we do. That has been one of the challenges with the ChAMP program, with the heralding it has received here this morning by Ms. Bosley, that not all companies participated and not all companies generated the data and not all companies provided it, and without a mandatory requirement that the data be produced in the first place and then be provided to EPA, we will never get where we need to be in that regard.

Ms. SCHAKOWSKY. Thank you. I appreciate everyone's testimony. Dr. Ditz, though I didn't ask you, I appreciate it.

Mr. RUSH. The Chair recognizes now Mr. Scalise for 5 minutes.

Mr. SCALISE. I thank the chairman.

Mr. Sampson, in the CDC Third Report from July 2005, it stated that for many environmental chemicals we need more research to assess health risks from different blood or urine levels. The results shown in the Third Report should help prioritize and foster research on human health risks that result from exposure to environmental chemicals but the presence of a chemical does not imply disease. The levels or concentrations of the chemical are more important determinates of the relation to disease when established in appropriate research studies than the detection or presence of a chemical. Does CDC still stand behind that statement?

Mr. SAMPSON. Yes, sir, that is a very good question. We do. Would you like me to just explain?

Mr. SCALISE. Sure.

Mr. SAMPSON. Typically what we do in our surveys are that we measure this cross-section of the U.S. population, several thousand samples, and that is in the Third Report that you are talking about, and what has happened since the beginning of these reports, when we identify a chemical in a large percentage of the population, that typically will spur a lot of research in that area but we are very careful not to say that this chemical by its presence is causing harm. In most cases we just need additional information, and it is very important to mention that our ability to detect the chemicals in our surveys and in populations is exceeding the ability to actually determine whether health effects are occurring, and we think that is a very big area of research that is needed.

Mr. SCALISE. Thank you.

Mr. Greggs, could you comment on the new REACH policy that is currently being implemented in Europe and if such a policy was implemented here in the United States, what would that mean for U.S. industry?

Mr. GREGGS. Sure. As you I am sure are aware, REACH is an extremely comprehensive policy that has been recently put into place in Europe, some would say overwhelming is a potential concern. I think our thought really is, is that others as well as those in Europe have looked at chemical policies as well, Canada, for instance, which was mentioned in some earlier comments. Our thought really is, is that we ought to take the best parts from REACH from Canada and look at what is appropriate in the United States, apply that in the United States so that we get the gold standard in the U.S. for the chemical management policy that we put in as part of TSCA modernization.

Mr. SCALISE. Thanks. And then some of the advocates of legislation recommended that we should have in the law some kind of list, an actual list of chemicals of concern. Now, some people suggest that rather than inform people, that list would end up being a blacklist and make it much more complicated for manufacturers and processors. Do you agree with having a list and what would be the impacts of that?

Mr. GREGGS. Thanks for that question. I testified today that in approaching this prioritization that it ought to have several key steps. It ought to be science based. It ought to take a risk kind of approach using hazard and exposure. The scientists at EPA should be involved in that and there ought to be public review and comment to make sure that EPA has all the relevant data to make the right decisions about what chemicals should go under further assessment. Our concern about a list of course is, is that, you know, sort of whose list, what criteria. And our thought really is, is that by providing EPA with direction on the criteria for which priorities ought to be selected, that that will result in the right selection of priorities and the efforts going into the highest-priority chemicals first.

Mr. SCALISE. Thanks.

And then Ms. Bosley, if I can get your thoughts on both questions, on REACH as well as on the list.

Ms. BOSLEY. I think REACH's main problem is, it is a comprehensive legislation but it does not prioritize. So a chemical that is being manufactured at 20 metric tons that is highly toxic will get the same data set and the same priority as a chemical that is being manufactured at 20 metric tons that has almost no hazard to it. So there was no risk prioritization with respect to REACH, and I think the impact of a worst-of-the-worst list, those chemicals are fairly small and I think you just have to look at critical, strategic, national interest uses for those lists. I don't think it would overburden the industry to come out with a list.

Mr. SCALISE. That is all I have. I yield back.

Mr. RUSH. The Chair now recognizes Mr. Sarbanes for 5 minutes.

Mr. SARBANES. Thank you, Mr. Chairman. On this issue of the data the industry has provided, Mr. Ditz, I am going to direct a number of questions to you. On a scale of one to ten, where would you peg the integrity and usefulness of the data that industry now is providing, I gather mostly on a voluntary basis, in terms of what would be useful for reviewing an agency in making decisions about safety and so forth?

Mr. DITZ. Let me try to make sure I am answering the right question. You are asking one to ten on the integrity of the data that industry is providing by voluntary means. Is that right?

Mr. SARBANES. Yes, and then on the integrity in terms of whether they are trying to hide the ball, I mean just sort of how useful it is to the process of being able to get to the right answer.

Mr. DITZ. Well, the voluntary programs have primarily asked industry for hazard data. That is data on the intrinsic property of a chemical, and that is part of what is needed for any kind of risk assessment. There isn't a corresponding information on the exposure of the chemical, so basically in terms of risk, it is a zero. We don't have the adequate information. EPA doesn't have it. Customers of the chemical industry don't have it. Investors don't have it. So it is not a fault of industry that they haven't given that. They didn't offer that. It wasn't asked of them in the voluntary program. But when I hear the comments in the hearing today about a risk-based system, I just have to stop and say we don't have the information. The EPA doesn't have it, nobody has it, and that is why we are not protecting Americans and we are not protecting our industry from countries who have higher standards than our own.

Mr. SARBANES. And I assume that the REACH program is pulling all of that kind of information as part of its process, or not?

Mr. DITZ. Well, REACH is trying. You know, there are shortcomings of the European approach, no doubt about it, but it is asking chemical producers to generate basic information on the nature of the chemical—does it cause cancer, does it accumulate in people, et cetera. And it is also asking companies how is that chemical used, is it put into consumer products, does it go into things which children are exposed to, what are the workplace exposures. Those two kinds of information have to come together before you can do any kind of a risk prioritization. So hats off to Europe for trying. The other say I would say about REACH is, no matter if you think it is, you know, misguided or overreaching or a lot of other descriptions have been attached to it, it will make our job in the United States a lot easier because the data on hazards will be on the

Internet and the companies like Dow and Dupont who operate in the United States will not be hiding that information. It will be available for EPA and for CDC and for consumers and others. So frankly, we will benefit even if we don't lift a finger.

Mr. SARBANES. Let me ask you another question before my time runs out. First of all, I can see how seductive the conversation can become around the worst of the worst, which when you step back and think about it is a heck of a standard to start using. I mean, if you think of a spectrum, you would have chemicals that would be oK, you would have ones that would be bad, you would then have a universe that would be considered the worst, and then inside of that we seem to be spend a lot of time talking about the worst of the worst, but the danger is it will distract us from other parts of the spectrum that deserve I think an equal amount of attention for various reasons. Speak for a moment, because, you know, that matrix as well is quite seductive in advancing this notion of risk-based perspective and you start thinking, well, that red ball there, that red fiery ball down there in the bottom right-hand corner is really what we should be worrying about, but can you, Mr. Ditz, maybe give an example of a situation where you might not get to that part of the matrix but the inherent hazards associated with a particular chemical without maybe the corresponding high use of it would still suggest and call for taking steps to restrict its use.

Mr. DITZ. Well, as I mentioned, when I refer to the worst of the worst, you are right, that is kind of the top of the pyramid of badness and it represents a very small number of the universe of chemicals but that is the place where we ought to be able to quickly reach agreement. That is not going to put workers out of jobs or put businesses to shut their doors. It does make sense to weed out dangerous things and that is exactly what a Toxic Substances Control Act should have been doing all these decades but it hasn't. So I really think is the kind of thing where there ought to be broad agreement. An example of a chemical where is it not broadly used, widely used but still has these properties, well, the POPs treaty that I mentioned, the Stockholm Convention on Persistent Organic Pollutants, is an international scientific process that leads to the identification and the naming of exactly those chemicals. They get on that list when more than 100 countries agree to put them there. So that is the kind of place where it shouldn't be hard for us to sign on and agree. It includes, for example, a couple of brominated flame retardants, chemicals which historically have been added to things like consumer products, computers, furniture, foam, that kind of thing, and actually even though TSCA didn't really allow EPA the legal muscle to do it, they still negotiated an agreement with the producers to stop making that stuff. So I guess you could say in some certain cases when the writing is on the wall, even the manufacturer will surrender and move on to a different product. Those are the kinds of things where reasonable people ought to be able to agree, and frankly, we have to give EPA that power if we are going to ratify the treaty so eventually we are going to come back to this question even for the narrow question of those worst-of-the-worst chemicals.

Mr. SARBANES. Thank you.

Mr. OWENS. Can I just offer just a quick additional factor, Congressman Sarbanes? One point that I didn't get a chance to bring up in my oral testimony is covered in my written submission is the issue of the confidentiality of data that is submitted. Under the current law, the burden is on EPA to dispute a claim of confidential business information, CBI, as it is called, and on many occasions when the data submitted to us is claimed as confidential, over the years in fact taking the 80,000 figure just as a point, roughly one-fifth, about 16,000 chemicals on that list have claimed the identity to be confidential. So of the 80,000 chemicals that are on the list, the names of them are claimed to be confidential, so you could actually see that the chemical might cause a hazard to people or risk to people or adverse health effects but you don't know what that chemical is by looking at the data that we actually might have in our database at EPA. And Administrator Jackson has directed us to do what we can do under existing TSCA to try to make more of that data available but we do need TSCA reform to address that issue as well so that the data can be made publicly available when it is provided.

Mr. SARBANES. That is like the opposite of a blacklist in a sense, right?

Mr. RUSH. The Chair now recognizes the gentlelady from Florida for 5 minutes.

Mr. CASTOR. Thank you, Mr. Chairman, and thank you all very much for your testimony. I would like all of your opinions. Everyone is fairly united in their opinion that TSCA adopted originally in 1976, never updated, never modernized, is in need of reform. Does anyone disagree with that? So we have industry, we have environmental health experts, we have agency folks and legal experts, and this is generally the consensus across all of your fields, correct, that TSCA just hasn't lived up to what it was supposed to do to protect the environmental health, that it is in need of reform. So I find it interesting that there is some criticism right off the bat that this could harm jobs because I think you both said representing industry groups that this could be done, reform could be done without harming jobs and industry. Is that correct? Did I misstate your testimony?

Ms. BOSLEY. No, that is true.

Ms. CASTOR. And I think we all acknowledge, I have heard Administrator Jackson state how important it is to have a stakeholder process, and Mr. Owens, is that what is going on now? How important are stakeholders to reform efforts?

Mr. OWENS. Congresswoman, as I mentioned, the administrator unveiled a set of principles on behalf of the Obama Administration and those principles were developed in part based on a lot of conversations that we had at EPA, the administrator herself had with representatives of industry and various NGO groups, and as I also mentioned in testimony, as we go forward and develop these action plans in the future, we will be having conversations, we will have public meetings, we will have input from industry and public health groups as well as States and others that are looking at this issue and have things to add to the conversation.

Ms. CASTOR. Is there any disagreement that you all know of over the initial approach to focus on the highest risk? Does anyone dis-

agree? And Mr. Owens, that is the EPA's initial approach is to focus on the highest-risk chemicals in our environment that have the greatest threat to the health of our families and children and our public? Is that the—

Mr. OWENS. That is correct.

Ms. CASTOR. So no one disagrees with that approach? How do we—

Mr. DITZ. Could I add to it, though?

Ms. CASTOR. Yes, sir.

Mr. DITZ. It is one question, what should EPA do now with the law we have got, and they might as well start kind of where the streetlight is on, you know, where they already have information about chemicals that are posing risk to humans, yes. On the legislative side, on fixing TSCA, it is also necessary that we fix the basic structure of this approach, which means information shouldn't be hidden under rocks or in the dark, it should be out in the open and that should be the responsibility of business. I think that is also necessary as well as starting with where we know the problems already lie.

Ms. CASTOR. And then Dr. Sampson, how do we ensure that all of the great medical research that the taxpayers are paying for is incorporated into such a legislative process, for example, the study that you mentioned, the very broad-based, comprehensive study of pregnant women and children and following the health data for many years?

Mr. SAMPSON. We actually think it could be used as a very good mechanism for both setting the priorities but also looking at priority chemicals in the population over time, and one of the advantages of seeing it in people, it actually is how you are exposed from all sources, be it food, water, air or whatever. So if it is getting into people and we are detecting it, we can basically look at priority chemicals if there are regulations that are enacted, we will see those levels drop, or if new chemicals are introduced, they could appear through biomonitoring.

Ms. CASTOR. Mr. Owens, you will be actively looking for ways through the modernization of TSCA to incorporate all of the terrific medical research that is available?

Mr. OWENS. Absolutely. As I mentioned, we are already working closely with CDC as well as other federal agencies in looking at different substances and making sure that we are coordinating our activities as well and we have our own internal research group at our Office of Research and Development that are working on these issues as well.

Ms. CASTOR. Thank you. I yield back.

Mr. RUSH. The Chair now recognizes the gentleman from Utah for 5 minutes.

Mr. MATHESON. Thank you, Mr. Chairman.

Mr. Greggs and Ms. Bosley, is TSCA is reauthorized and reformed, how can Congress best balance necessary changes to the current program while still providing for appropriate cost-benefit analysis so that various players can make good decisions regarding which chemicals to use and not use?

Ms. BOSLEY. I can say that a definition of their safety standard would be a good first place to start, also, prioritization of high-risk

chemicals. I think that establishing a data set for different priorities of chemicals is very important and that data set should include that cost-benefit analysis.

Mr. MATHESON. Do you have anything to add to that?

Mr. GREGGS. You are asking me, sir?

Mr. MATHESON. Do you have anything to add to that?

Mr. GREGGS. Yes, the one thought I have on this is that, you know, you asked about risk-benefit. In current TSCA, I think it has been described in previous hearings where the safety determination is combined with risk-benefit analysis, and I think going forward one of the things that we really think is, is that chemicals ought to be looked at and determined whether or not they are safe for their intended uses and then separately risk management decisions made about how and when those—what kind of actions should be taken to make sure that those have been shown not to be safe can be taken.

Mr. MATHESON. Another question I would ask, and Dr. Sampson, if you can answer this first but others can chime in too, CDC currently runs the national biomonitoring program. It has produced a number of reports. Does the EPA or does the private sector have access to the data from these reports?

Mr. SAMPSON. Absolutely. After we have finished our measurements, it goes back to the National Center for Health Statistics and they actually put it online so everybody has access to it, and then our scientists as well as other scientists can begin working on it. EPA as other agencies are using it actually incorporate our data very heavily into their report on the Nation in terms of chemical exposures. Other programs such as the Office of Smoking and Health use our data. We look for tobacco products in addition. But it is used quite extensively now in terms of—

Mr. MATHESON. Do you have suggestions for improvements that could take place with the program at the CDC?

Mr. SAMPSON. In terms of an expansion, from what I understand today, if there was to be a large expansion of our present activities, first of all, I think the science of biomonitoring would have to be improved and increased. During the last decade instrumentation has come out that has just revolutionized our ability to measure chemicals in people and I think that will continue so that more chemicals can be measured in smaller and smaller amounts of blood. The amount of sample you get from a person is a very big deal. Getting more than a Vacutainer tube is a fairly big deal, so we have to do all of our measurements in very small amounts of bodily fluids. And then the second area is, if you are interested in any type of infrastructure outside of the existing ones, and the best one is the National Health and Nutrition Examination Survey, that would require an infrastructure to do that, and since it is human samples you have to go through institutional review boards and very detailed approval, so just saying we want to start looking at a new matrix—cord blood has been proposed—actually will have some hurdles and challenges associated with that.

I think, as I mentioned a little while ago, our ability to measure chemicals is ahead of our ability to interpret those in terms of health effects so more research is needed, and finally, if it was to be greatly expanded, we have most of the scientists that are doing

this in our current laboratory, and there will be a very large workforce demand, I think if you expand it hundreds more and thousands of chemicals, it would be a challenge just in terms of training a slightly larger workforce.

Mr. MATHESON. Thanks, Mr. Chairman. I yield back.

Mr. RUSH. The Chair now has a request, and without objection, Mr. Markey, the chairman of the Subcommittee on Energy and the Environment is recognized for 5 minutes for the purpose of questioning the panel. Mr. Markey.

Mr. MARKEY. Thank you, Mr. Chairman, very much, and thank you for giving me this opportunity. Thank you for your leadership and focusing on these issues of risk posed by toxic substances in our environment.

I would like to ask Mr. Ditz, Mr. Greggs and Ms. Bosley this question. Are there chemicals that you would identify that are already known to be so dangerous that they should be phased out or subject to other action to reduce human exposure immediately? Mr. Ditz?

Mr. DITZ. Thank you, Congressman. It is possible that I partially answered this question earlier before you joined us, but the answer is yes, and the sort of colloquial phrase I use is the worst-of-the-worst chemicals, those which are by their very nature inclined to last in the environment for months or years.

Mr. MARKEY. Could you name some, please?

Mr. DITZ. OK. Well, for example, brominated diphenol ethers. It doesn't exactly—it is not a household name but these are constituents that are added to plastic so they don't burst into flames. That is a very useful property but there are safer substances out there, and when there are such safer substances, it makes sense that we would not allow something which is inherently unsafe.

Mr. MARKEY. Are there others that come to mind?

Mr. DITZ. Well, I think there are a family of fluorinated compounds which are also almost infinitely persistent that last for a very long time in the environment. It has been the focus of some Congressional attention already. There are of course uses, not necessarily the full ban of a chemical, but uses of a chemical which might deserve to be phased out. I am thinking, of course, 20 years ago the attempted and failed restriction on forms of asbestos in certain products.

Mr. MARKEY. Mr. Greggs, are there any that you would ban immediately, phase out immediately?

Mr. GREGGS. Thank you, Mr. Markey. I testified about prioritization. One of the things I talked about was a quick-start effort that we believe that EPA could quickly undertake to identify 50 to 100 chemicals that met certain criteria and that could quickly be moved into assessment and decisions where there are safety issues into risk management.

Mr. MARKEY. Are there any that you have already concluded from previous studies that should be phased out immediately?

Mr. GREGGS. Sir, there are a number of chemicals, you know, that have been phased out of a lot of uses—

Mr. MARKEY. No, I mean any right now that not have been phased out. Can you just name a few that you think should be phased out?

Mr. GREGGS. No, I don't have any I would name but I think these are decisions really that should be made by EPA scientists looking at the data that is supplied by industry and other stakeholders.

Mr. MARKEY. So you are saying there are not some that don't need additional study, that they all need additional study?

Mr. GREGGS. No, sir. You know, I think that there is substantial data that is available. We also understand through REACH, which Mr. Scalise asked about, there will be substantial additional data, as Dr. Ditz indicated.

Mr. MARKEY. Well, let me go to you, Ms. Bosley. Any that you would phase out or subject to—

Ms. BOSLEY. No, not at this point, not phase out. I would point to a chemical's use and its exposure criteria. For instance, if you were to take a chemical like phosgene, it is a pretty bad chemical that killed tens of thousands of people in World War I and II yet you couldn't make Crixivan, an AIDS drug, today or breast-cancer drugs today or frankly this tabletop without phosgene, and there has not been a phosgene death in the United States for 30 years.

Mr. MARKEY. So let me ask the three of you yes or no, do you believe that the EPA should look at the chemicals that are known to cause health problems and at the chemicals that are already known to be found in humans immediately, yes or no?

Mr. GREGGS. Yes, sir, I testified to that.

Mr. MARKEY. Ms. Bosley?

Ms. BOSLEY. I think that those chemicals should be prioritized and EPA should take a closer look at them, yes.

Mr. DITZ. Yes.

Mr. MARKEY. And unlike many chemicals where one studies acute health impacts associated with high-dose exposure, there are disruptors that impact health after exposures to low doses over sustained periods of time. Can these disruptors be categorized using the same risk assessment as other toxic chemicals even though their characterizations are very different? Mr. Owens, can you answer that, please?

Mr. OWENS. Congressman, let me answer it this way. I think there are some differences there because of the issue related to low dosage. I think that is a very important thing for our agency to be looking at because there will be some chemicals, there are some chemicals that can have harmful effects in low dosage either because of the effect themselves or because they do bioaccumulate and have a cumulative effect when compared with other chemicals or other chemicals of the same type of grouping you can see not just linear but sometimes exponentially increases and effects and studies based on cumulative exposures, so that is one of the issues that we really have to take a look at.

Mr. MARKEY. So do you believe that the EPA's endocrine disruptor screening program does need modernization like the rest of the EPA's toxic chemical safety authority does?

Mr. OWENS. Congressman, as you know, we finally got the first test orders issued and that program was mandated by Congress in 1996. Finally a few weeks ago in October we were able to get the first test orders. The assays were developed and released earlier this year. The first test orders went out in October. There is a lot of catching up to be done in that program and we are going to be

working as hard as we can. Certainly Administrator Jackson has made that a priority for my office to get the endocrine disruptor screening program on track and move forward. So we will be looking very closely at the data that we receive from those test orders. They are focused right now on pesticides. There is a list of 67 pesticides that were identified and we will be investigating and reviewing the data, as I said, that we get in from the test orders that we have issued and that we will be issuing going forward to address those 67.

Mr. MARKEY. Thank you very much. What about non-pesticides?

Mr. OWENS. Congressman, that is an issue that we are clearly looking very closely at as well. I know there is language in the health report from earlier this year talking about the need for us to look at non-pesticides. That is a topic of very serious conversation within the agency. We have to address what is on our screen first, which is the list of 67 pesticides, but clearly that is—there is a great deal of concern about the endocrine-disrupting impact of non-pesticide chemicals and we certainly want to work very closely with members of this committee and other groups that have expressed concern about those chemicals and talk about how we can go forward on it, so we are very much aware of the interest of the House in that.

Mr. MARKEY. Well, the chairman is moving forward on the overhaul of TSCA and I think this non-pesticide issue is something that you should stay close to us on so that we can assure that we include everything that needs to be—

Mr. RUSH. The Chair will ask the witnesses if they could possibly stay for a second round of questioning. We will give each member 2 minutes for questioning. And the Chair recognizes himself for 2 minutes.

The CDC has stated that, and I quote, “The measurement of an environmental chemical in a person’s blood or urine does not by itself mean the chemical caused the disease.” Dr. Sampson, the question is, can’t biomonitoring evaluations be used to show a higher likelihood than not that a potential chemical is the cause of a certain disease? For example, a recent AMA Journal study tied higher blood BPA levels to cardiovascular diseases, diabetes and liver enzyme conditions, so the question again to you is, can’t biomonitoring evaluations be used?

Mr. SAMPSON. Mr. Chairman, that is a very excellent question. What we do—that publication came out of using our data which is collected on the HANES participants as well as medical information. As I explained, when people go through the survey, they actually do a complete physical. They collect 1,000 pieces of questionnaire information and then they donate blood and urine. Some of the other tests have to do with cardiovascular disease and diabetes and so forth, so investigators do have the ability to link our exposure data with disease type of data. Now, our ability to detect chemicals has exceeded the current ability to interpret it in those of those health effects so we are trying to work with other federal agencies like the National Institutes for Environmental Health Sciences and so forth to look at that problem more closely. The chemical you’re referring to is bisphenol A and I believe NIEHS has just introduced some money from the stimulus package to look

at more health effect studies associated with exposure to bisphenol A.

Mr. RUSH. Thank you. The Chair recognizes the ranking member.

Mr. RADANOVICH. Thank you, Mr. Chairman.

A question for Mr. Owens, if I may. I want to go back to the Montebello agreement and how the Administration plans to carry out the Montebello agreement without ChAMP. If you could respond rather quickly. I am sorry, I have only got 2 minutes.

Mr. OWENS. Well, I think certainly if we get TSCA reform, we will be able to have a lot more data on those chemicals and to be able to address it, but in the interim we will be using the data we have. We will be asking continually for data from industry, but again, our ability to get that data is based on the willingness of industry to provide it, and some of them have not.

Mr. RADANOVICH. Thank you.

My last question is for Mr. Greggs and Ms. Bosley. Mr. Greggs, I appreciated your poster over there that advocated the risk-based prioritization matrix and having that risk-based approach in analyzing these 80,000 chemicals that are out there. Can you tell me—and Mr. Ditz had advocated three priorities: identifying the worst of the worst, going up against a specific standard and industry providing a lot of the research and information, if I got that right. But how would this type of requirement without making it a risk-based approach affect your industries, and, you know, specifically to the cost of the regulations potentially that could be imposed?

Mr. GREGGS. I think what I heard Dr. Ditz talk about, I heard him talk about the need to have hazard and exposure data and some concerns that he expressed about the unavailability of some of that data. I think, you know, sort of two thoughts on this very quickly. One is that under REACH, over 90 percent of the chemicals reported to EPA just a couple years ago as being in commerce in the United States are pre-registered under REACH and most of that data is going to be submitted next year as part of the REACH deadlines. So on the hazard data, I think that there is going to be a resource there and I think EPA and others ought to be looking for how can we make that data available in the United States.

The second part is on the use and exposure data. Again, EPA started a system for collecting use and exposure data in 2006. In doing that, they asked the chemical manufacturers about where were chemicals being used. Of course, some of that information is known to the manufacturers but not all of that information and so the information that EPA presently has is incomplete. What CSPA, GMA and SDA have talked about is an idea for users providing chemical use information as part of the periodic inventory update that EPA does. That way we will have more complete use and exposure data to be able to both do prioritization but as well to target the assessments that need to be done on chemicals.

Mr. RADANOVICH. Ms. Bosley?

Ms. BOSLEY. As I mentioned, I think that EPA's ability to ask for data from industry should be enhanced. The data that industry has isn't hidden under any rocks. It informs everything that industry does from their material safety data sheets to their safety and handling information to general public knowledge, and for EPA to

be able to ask for that data should be enhanced. I also agree that EPA has exposure data based on the 2005 inventory update and that exposure data should be made public. I don't think the IUR is yet public in 2005.

Mr. RADANOVICH. Thank you, and thank you, Mr. Chairman.

Mr. RUSH. By unanimous consent, the gentleman from Massachusetts is recognized for 2 minutes.

Mr. MARKEY. Thank you, Mr. Chairman, very much.

Ms. Bosley, your testimony stated that we should embrace TSCA mechanisms that have worked well like the New Chemicals Program where EPA has successfully reviewed some 35,000 new chemicals since 1979 without impeding innovation. But according to EPA, 67 percent of pre-manufacture notices received by EPA under this program contain no hazard data on health or the environment and 85 percent contain no health data at all. If the goal is to determine the health and environment impacts of a chemical, how can this program possibly be characterized as successful if the data isn't even provided to make that determination?

Ms. BOSLEY. I can say that EPA has methods they have pioneered, the notion of structure activity relationships such that if data is not provided, they look at the chemical and take the most conservative approach and they decide their regulation of that chemical based on that conservative approach along with the pre-manufacture notice process always is needed, process information, identification information—

Mr. MARKEY. But how do they make—

Ms. BOSLEY [continuing]. Exposure and use information.

Mr. MARKEY. How do they make a decision if there is no health data or environmental data? How do they make a decision?

Ms. BOSLEY. EPA has a tremendous amount of health and environmental information and they use that structure activity relationship—

Mr. MARKEY. But if it is not provided by the corporation to them, how can they possibly be flying blind? What is the empirical basis that is used to make a decision if it is not even part of their process?

Ms. BOSLEY. They look at similar chemicals that have health and safety data available and that is the structure activity program that EPA has pioneered.

Mr. MARKEY. But then it sounds like EPA becomes kind of a chemical Carnac where they hold up the envelope, you know, without knowing the answer. They are somehow supposed to know what the answer is inside without ever having reviewed it, then they give the answer, huh? So that can't be a process that really can work for the long term.

Ms. BOSLEY. Well, I think it has worked successfully over the last 30 years.

Mr. MARKEY. Well, I think that is debatable. If they didn't have the health and environment data, then—Mr. Owens, would you like to briefly respond to that?

Mr. OWENS. Yes. Thank you, Congressman. I may have said this when you were out of the room but one issue we do have is the issue of confidential business information and the claiming of certain types of data, not necessarily health and safety data. So we

get data that is claimed as CBI we have but we can't make public and there is a resource issue here in terms of our ability to review all the information that is coming in. We have a 90-day window when data comes in to EPA to make a determination under the new chemical program that we have and if the data isn't provided, we have to go back and show a reason why we think that data needs to be provided and even then there is no requirement that it actually be generated or created in the first instance and so there are a number of handicaps and obstacles that we faced, and I think while it feels nice sitting over here as a new person at EPA to hear the agency being praised by someone on the outside, you know, it just ain't so. That is really not what reality is in terms of what the agency has been able to do over the years.

Mr. MARKEY. I thank you, Mr. Owens. I wrote to OMB to express my concerns that their approval for your endocrine disruptor rules appear to be limiting your ability to require the testing needed to determine the health risks of endocrine disruptors. I just received a response to my letter from OMB Director Peter Orszag last night which indicated that OMB was not in any way seeking to limit EPA's ability to get the data it needed to determine the health effects of potential endocrine disruptors. Are you confident that EPA will have the ability to get the data needed in this area?

Mr. OWENS. Absolutely, Congressman. Administrator Cass Sunstein, who is the head of the Office of Information and Regulatory Affairs at OMB, and I have had a lot of conversations about this and it is certainly my understanding based on our conversations with Mr. Sunstein that OMB's terms of clearance for the EDSP information collection request in no way limits our discretion in any way through the program so it sounds as though the letter you received is consistent with that.

Mr. MARKEY. Thank you, Mr. Chairman.

Mr. RUSH. The Chair thanks the gentleman. The Chair thanks all of the witnesses for the time that you have so graciously shared with us and I want to commend you for your testimony. It has been very enlightening and illuminating for us, and again, the Chair thanks the witnesses for participating.

The Chair has a unanimous-consent request with respect to two items that were submitted to the subcommittee for entry into the record of today's hearing. One is the testimony from the Humane Society, the Physicians Committee for Responsible Medicine, and the People for the Ethical Treatment of Animals, and the second UC request is written testimony from the National Petrochemical and Refiners Association. Hearing no objection, the unanimous consent is approved.

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

Mr. RUSH. Now the Chair must bring this hearing to a conclusion. The Subcommittee is hereby adjourned.

[Whereupon, at 1:15 p.m., the Subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

**Statement of Rep. Henry A. Waxman  
Chairman, Committee on Energy and Commerce  
“Prioritizing Chemicals for Safety Determination”  
Subcommittee on Commerce, Trade, and Consumer Protection  
November 17, 2009**

I commend Chairman Rush for holding this hearing. Today, we begin to delve into the details of how best to reform the Toxic Substances Control Act, the nation’s primary law for ensuring the safety of industrial chemicals.

At the first hearing on this subject earlier this year, the Committee learned of the widespread agreement among industry, labor, and nongovernmental organizations that the Toxic Substances Control Act needs to be reformed. Unlike the Clean Air Act, the Safe Drinking Water Act, or so many other laws within our Committee’s jurisdiction, TSCA has never been modernized to fix the flaws we know it has.

Since our first hearing, major developments have begun to narrow and shape the debate. On September 29, 2009, EPA Administrator Lisa Jackson announced the Administration’s principles for TSCA reform. These common sense principles call for TSCA to be reauthorized in a way that reflects our best scientific understanding to protect public health and the environment.

Similarly, the American Chemistry Council, the Consumer Specialty Products Association, the Grocery Manufacturers Association, and the Soap and Detergents Association have released principles for reform.

A new coalition of environmental, consumer, health, and faith groups called “The Safer Chemicals, Healthy Families” coalition has announced their platform for reform as well.

And the dialogue we are having here is also happening outside the halls of Congress. For instance, the Environmental Working Group joined with the American Chemistry Council and others in hosting a conference last month on the future of U.S. chemicals policy. These dialogues are important as we move towards legislation.

There are thousands of industrial chemicals currently in commerce that have not been adequately reviewed for safety. Today's hearing focuses on the key question: where do we begin? How do we prioritize chemicals for a safety determination?

I thank all of the witnesses for being here today and look forward to hearing their testimony on this important issue.

Thank you.

**Statement of the Honorable Joe Barton  
Hearing on "Prioritizing Chemicals for Safety Determination"  
Subcommittee on Commerce, Trade, and Consumer Protection  
November 17, 2009**

Thank you, Mr. Chairman.

I want to let you know how much I appreciate your decision to hold several hearings to help members understand an issue as complex as reform of the Toxic Substances Control Act.

Regardless of what some of the stakeholders say about how easy this will be, almost nothing about this is going to be easy or simple. The law directly impacts 97 percent of raw chemicals that go into making everything from the clothes we put on this morning and the cars we drove to work, to this microphone in front of me.

I support making sure that products that contain these chemicals are safe for the people who use them. But put me down as skeptical about efforts that do more to massage esoteric notions of perfection than to bring objective science and credible engineering to bear in determining which chemicals should be available for commerce and which should not. I believe we need more evidence than ominous sounding names or the mere presence of a substance on the periodic table of elements as grounds for banishment.

Our hearing today deals with priorities. I believe that if we are going to assess and rank chemicals, we need to make an educated assessment of high quality hazard and exposure data the driving force force behind any

decision. And we should do it in a way that makes EPA able to use it in a meaningful way with the staff and resources it has.

I am suspicious of claims that we need to set the stage for paradigm shifting reform of TSCA (*pronounced: "Toss-ka"*) because EPA is, quote, "under-funded, understaffed, ineffective, and TSCA needs to be more muscular and precautionary." We've all seen this kind of effort before and I don't wish to go through a sequel because it was a disaster.

Being skeptical about efforts to turn TSCA on its head does not mean that any of us are willing to accept unsafe chemicals in this country. I consider it a false choice between the provisions of the Kid Safe Chemicals Act and existing TSCA. If the Majority wants to move Kid Safe, they should just say so and they can do it without me. It concerns me that we are having a hearing that suggests chemical prioritization based on a safety standard is an improvement, and yet there is no legal language to establish either the criteria for informing the ranking process or the goal of the process. I think we need to be as transparent here in Congress as we expect the EPA and the industry to be in their efforts.

My home state of Texas has as much, if not more, of a domestic chemical industry than any other state in the union. And, it is no secret in Texas that the chemical industry is leaving, migrating to countries like China and taking thousands of jobs with it. The U.S. Bureau of Labor Statistics projects that jobs and wages will continue disappearing from United States' chemical industry. With unemployment at 10.2 percent and manufacturing unemployment at 11.9 percent, it seems to me that we should not be doing

things that accelerate the exodus. When we regulate, our policy priority must be to protect Americans against unreasonable risks, and do it in a way that also respects what a job means to a working family. We must insist that rules have the weight of the scientific evidence instead of notional politics behind them.

Mr. Chairman, the input of all affected stakeholders in this process is essential and the record must be comprehensive, balanced, and accurate to support any action by our Committee.

I look forward to the testimony of the witnesses and yield back my time.

TESTIMONY OF

THE HUMANE SOCIETY OF THE UNITED STATES, HUMANE SOCIETY INTERNATIONAL, HUMANE  
SOCIETY LEGISLATIVE FUND

AND

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

PRIORITIZING CHEMICALS FOR SAFETY DETERMINATION

NOVEMBER 17, 2009

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## I. Introduction

While Estimates of the numbers and the amount of information available on particular chemicals of chemicals in commerce differ, there could be environmental exposure to anywhere between 10,000 and 100,000 chemicals. Understanding the potential health and environmental risks posed by chemicals currently in the environment, while ensuring new chemicals are safe for use, presents a monumental challenge.

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

The current TSCA Inventory contains approximately 80,000 chemicals; in order to review this number of chemicals over 10 years, the EPA would have to review approximately 6,000 – 8,000 chemicals each year (approximately 20 each day), at heavy expense to the taxpayer. Currently, the EPA's Office of Pollution, Prevention, and Toxics—the office that would be charged with implementing this legislation—reviews about 1000 pre-manufacture notices<sup>1</sup> each year – review of existing chemicals would be in addition to these PMN reviews.

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

In light of these concerns, the Environmental Protection Agency (EPA) realized that the current toxicity testing paradigm is in urgent need of overhaul and contracted the National Academy of Sciences' National Research Council (NRC) to assess the current system and recommend actions

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<sup>1</sup> <http://www.epa.gov/oppt/ar/2007-2008/reviewnewchem/index.htm>

to improve it. The NRC Committee on Toxicity Testing and Assessment of Environmental Agents (NRC Committee)<sup>2</sup> set out to create a vision for the future of toxicity testing and a strategy that, once implemented, would improve the depth and breadth of toxicology and its usefulness as a predictive--and protective--science (Edwards and Preston 2008). *Toxicity Testing in the 21st Century: A Vision and Strategy* outlines 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>3</sup> cell and tissue assays instead of whole-animal tests for hazard assessment and regulatory decision-making.

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

While the NRC, 2007 report describes a way forward that will take time to fully achieve available methods and technologies can be applied to the prioritization of chemicals today. For example, as a first "tier" in order to characterize the potential mechanisms of action of test chemicals (Andersen 2009). In another example, data from the EPA Office of Research and Development's ToxCast Program<sup>4</sup> has been used to create prioritization scheme for detecting chemicals with the potential to interact detrimentally with endocrine system.<sup>5</sup> Shaw et al. (2008) showed the feasibility of a similar process for prioritizing 50 different nanomaterials based on likely biological reactivity according to differences in material characteristics. Last year, scientists at the NCGC published results of a mechanism-of-action study that used 26 assays in 13 different cell types to cluster 1,408 compounds given at 14 different concentrations according to mechanism of action. The results compared favorably with current information about the chemicals toxic profiles, and provide support for such approaches (Huang et al. 2008).

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<sup>2</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>3</sup> *In vitro* refers to assays that take place in a culture dish or test tube.

<sup>4</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>5</sup> Kavlock, Robert. Nov. 11, 2009. Presentation given at Johns Hopkins University School of Public Health, Center for Alternatives to Animal Testing, Chemical Information Day.

Recent changes in legislation regulating toxic chemicals in Europe, the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), has presented a similar challenge of scale (EC 2006). In an attempt to ensure that REACH is successful, European, American, and multi-national bodies like the Organization for Economic Cooperation and Development are working to further develop strategies to improve streamlined toxicity testing and risk assessment. In addition to the incorporation of non-animal testing methods, REACH includes:

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

In addition to these strategies, international efforts are collaborating with the Organization for Economic Co-operation and Development (OECD) to develop and standardize computer algorithm-based models, known as Quantitative Structure Activity Relationship models (QSARs). These models can group and classify chemicals based on similar structure or activity profiles, help extend information about similar chemicals to chemicals with little data (known as bridging), and provide data for classification or risk assessment. Scientists and regulators influential to the REACH legislation are currently demonstrating how these models can be—and why they must be—used in order to quickly assess chemical hazards in the scientific literature (Schaafsma et al 2009; vanLeeuwen et al 2009).

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

### **III. Common-sense principles for chemical prioritization**

#### **1. Review of TSCA inventory**

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

#### **2. Tabulate and review all existing data**

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

#### **3. Make regulatory determinations where possible**

Using available data, make determinations of safe use or put necessary controls in place where possible and warranted. Here, special emphasis should be placed on

chemicals with known high exposure profiles or those with high potential to remain in the environment after an accidental release.

**4. Group chemicals according to common modes of action or structural class**

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

**5. Apply QSAR and high-throughput biological methods to prioritize chemicals and design integrated strategies for further testing, if warranted.**

For some chemicals, cellular and computation methods can be used to fill information needs; in other cases these methods can be used to detect priority chemicals and endpoints that require further study.

**6. Determine and fulfill information needs according to exposure**

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

**7. Prevent duplicative testing by providing incentives for data sharing**

Companies should be required to form consortia and share data where appropriate, in order to prevent duplicative testing on the same chemical or category of chemicals.

#### **IV. Summary and Conclusion**

As the National Research Council and the Environmental Protection Agency<sup>6</sup> both state, advances in computational and cellular technologies will allow more predictive and protective toxicological assessments of chemicals. Until this vision is in place, existing methods and approaches can be used in addition to exposure variables, physical-chemical information, and existing knowledge to prioritize chemicals for regulation or further study.

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.

<sup>6</sup> See The U.S. Environmental Protection Agency's Strategic Plan for Evaluating the Toxicity of Chemicals, located at: <http://www.epa.gov/spc/toxicitytesting/index.htm>.

Prioritization of chemicals and endpoints to be tested by potential for hazard and exposure is essential in order to avoid unmanageable bottlenecks that would further stymie environmental protections.

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**WRITTEN STATEMENT OF  
NATIONAL PETROCHEMICAL & REFINERS ASSOCIATION (NPRA)  
AS SUBMITTED TO THE  
SUBCOMMITTEE ON COMMERCE, TRADE & CONSUMER PROTECTION**

**Committee on Energy & Commerce  
U.S. House of Representatives**

**on**

**“Prioritizing Chemicals for Safety Determination”**

**November 17, 2009**

**Introduction**

NPRA, the National Petrochemical & Refiners Association, appreciates the opportunity to submit written testimony for today's hearing examining chemicals prioritization and the Toxic Substances Control Act (TSCA). Our association includes more than 450 member businesses, including virtually all U.S. refiners and petrochemical manufacturers, their suppliers, and vendors. NPRA members supply consumers with a wide variety of products used daily in their homes and businesses, including gasoline, diesel fuel, home heating oil, lubricants, and chemicals that serve as building blocks for everything from plastics to clothing, medicine, and computers.

**Background and Overview**

NPRA considers the existing federal chemicals regulatory framework to be a strong foundation for protecting the health of consumers and the environment, while simultaneously allowing for the development of products that enhance our standard of living and safeguard all aspects of health, safety and the environment. NPRA and its member businesses support responsibly updating our chemicals risk management regulatory framework to recognize marketplace and scientific developments that have occurred over the past several years. Within that context, we understand the Subcommittee's interest in examining the chemical prioritization process as part of ongoing considerations regarding possible modifications to the Toxic Substances Control Act.

NPRA supports a tiered, targeted and risk-based approach to prioritization and chemical safety determinations, using well-founded and traditional approaches to risk assessment. Further, we view the approach to prioritization taken by Canada under its Chemical Management Plan, and the approach previously taken by the United States under the Environmental Protection Agency's (EPA) Chemical Assessment & Management Plan (ChAMP), as models for a solid, scientific framework from which to build.

## **Prioritization**

The goal of EPA's chemical prioritization process should be the establishment of an effective, efficient risk-based framework for prioritizing all chemicals in commerce for assessment of potential risk to human health and the environment. NPRA strongly recommends the incorporation of a number of practices and principles in EPA's implementation of a chemical prioritization mechanism:

### **1. A "Quick Start List"**

The prioritization process should include criteria for a "Quick Start List" that enables EPA to proceed to safety reviews on high-priority chemicals while other prioritization decisions are being made. The Quick Start List should screen for chemicals from the 2006 Inventory Update Reporting (IUR) database that represent both highest potential for hazard and greatest potential for exposure, including:

- Carcinogens, Mutagens and Reproductive Toxins (CMRs), or Persistent, Bioaccumulative and Toxic Chemicals (PBTs), recognizing that specific methodologies to consider bioavailability need to be applied for metal and metal compounds; and
- Substances that are present in the Center for Disease Control's biomonitoring program, or that are found in products intended for children, as identified in the TSCA Inventory Update.

### **2. Transparency and Timeliness**

The prioritization process should be transparent and should allow ample opportunity for public review and comment at key points throughout the process, including the opportunity to provide additional, existing information in advance of prioritization decisions. All methods, assumptions and other relevant factors should be made publicly available and part of the review and comment process. Additionally, EPA actions throughout the evaluation process should be subject to appropriate deadlines.

### **3. Methodology**

Clear and transparent prioritization screening criteria must be established and applied to identify chemicals with the highest hazard and exposure concerns. Prioritization should be based on existing information, through a “batching” process that assures Agency attention to particular chemicals, and should be subject to deadlines. All evaluation processes utilized under the prioritization mechanism should be based on an assessment methodology that considers hazards, uses and exposures, and all test methods and modeling should be based on validated or peer-reviewed approaches and held to consistent scientific scrutiny. In addition, EPA should employ a weight-of-the-evidence approach for safety determinations; all data should be evaluated and assigned appropriate weights according to quality.

EPA should also pursue opportunities to consider hazard or risk assessments already conducted by other government agencies, both domestic and international, in its evaluation process.

### **4. Exposure and Related Standards**

While prioritization screening decisions should account for both anthropogenic and biogenic sources of potential exposures, care should be taken to distinguish between natural and manmade sources of exposure to certain chemical substances. Appropriate safety standards should apply to different exposure scenarios; industrial exposure scenarios and consumer exposure scenarios, for example, are inherently different, and thus should not be treated in a similar manner under the prioritization process.

#### **Biomonitoring**

Biomonitoring is an important and useful tool that should play a role in the chemical risk prioritization process. Several fundamental principles must be considered in its application, however. First, due to the limitations of its data in determining sources of exposure,

biomonitoring should not be considered indicative of, or the primary determinant of, a substance's potential to cause harm. Second, the Centers for Disease Control and Prevention (CDC) should be the focal point for selecting chemicals for biomonitoring, collecting biomonitoring information, and communicating results; chemicals of anthropogenic origin identified to be present in human tissues and fluids as part of the CDC's biomonitoring program should be considered as one factor in the prioritization process. Third, any requirement for biomonitoring should have measurable public health goals as its fundamental underpinning, and potential for human health risk should be the primary driver for requiring biomonitoring data. Finally, substances that may pose a high level of risk to human health should be priority candidates for biomonitoring.

### **Conclusion**

NPRA and its members are committed to protecting consumers and the environment, and, to that end, are supportive of sound and sensible modifications to existing chemicals risk management regulations. As modifications to TSCA are discussed, we urge policymakers to take into account the important considerations we have raised with regard to prioritization and the application of biomonitoring.

NPRA looks forward to working with Congress and EPA toward the establishment of an effective, efficient, transparent chemical prioritization process as part of the broader implementation of responsive, responsible changes to the Toxic Substances Control Act.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

MAY - 6 2010

OFFICE OF CONGRESSIONAL AND  
INTERGOVERNMENTAL RELATIONS

The Honorable Henry A. Waxman  
Chairman  
Committee on Energy and Commerce  
U.S. House of Representatives  
Washington, D.C. 20515

Dear Chairman Waxman:

Thank you for the opportunity to respond to questions for the record that followed the November 17, 2009, hearing on U.S. Chemical Management Reform. I hope this information will be useful to you and the members of the Committee.

If you have any further questions, please contact me or your staff may contact Christina J. Moody in my office at 202.564.0260.

Sincerely,

A handwritten signature in black ink, appearing to read "Arvin R. Ganesan".

Arvin R. Ganesan  
Deputy Associate Administrator

Attachment

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The Honorable George Radanovich

1. In your testimony you mentioned that ChAMP was canceled after a careful review of the program. I am concerned that the decision process might have been hasty. Could you please give me a detailed description of what and who was involved in the review of ChAMP?

Soon after her arrival at the Agency, EPA Administrator Lisa Jackson identified strengthening the agency's chemical management program as one of her top priorities. After careful review and consideration by senior Agency officials EPA concluded that the Chemical Assessment and Management Program was too focused on categorizing thousands of chemicals, which would take years. This review also highlighted that the categorizations were often based on limited and incomplete test and exposure data. On September 29, 2009, EPA Administrator Lisa Jackson outlined a comprehensive program to strengthen the Agency's chemical management program. This effort includes the development of chemical action plans which identify potential concerns with the chemical and actions that the Agency is considering address those concerns. The Agency identified the initial list of chemicals for action plan development based on one or more of the following factors: their presence in human blood; persistent, bioaccumulative, and toxic (PBT) characteristics; use in consumer products; production volume; and other similar factors. EPA is considering how best to engage stakeholders and the public on the selection of future action plan chemicals.

On December 30, 2009, EPA made public the first four action plans on phthalates, short-chain chlorinated paraffins, perfluorinated chemicals (PFCs), and Polybrominated diphenyl ethers (PBDEs). For this initial set of chemicals, the actions EPA intends to take include adding phthalates and PBDE chemicals to the Chemical of Concern list, under TSCA Section 5(b)(4) as chemicals that "may present an unreasonable risk of injury to health and the environment.". In addition, EPA is beginning a process that could lead to risk reduction actions under section 6 of TSCA for several phthalates, short-chain chlorinated paraffins, and perfluorinated chemicals; reinforcing the DecaBDE phaseout – which will take place over three years – with requirements to ensure that any new uses of PBDEs are reviewed by EPA prior to returning to the market; and a range of Design for the Environment efforts to reduce risks. ]On March 29, 2010, EPA made public the BPA Action Plan which indicated that the Agency, among other things, is considering adding BPA to the Chemical Concern list on the basis of potential environmental effects.

EPA is still working on the action plan for the remaining chemical from the initial list, benzidine dyes. On March 17, 2010, EPA posted an additional four chemicals for upcoming action plan development, Diisocyanates, Hexabromocyclododecane (HBCD), Nonylphenol and nonylphenol ethoxylates (NP/NPE), Siloxanes.

As part of this broader effort, EPA will also continue to require submission of data on High Production Volume chemicals where it has not already been provided, review provided data

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and post the results of those reviews, and seek to improve the quality and quantity of data submitted to the Agency on existing chemical uses and exposures.

EPA believes that this targeted approach will prove more protective of human health and the environment.

2. If EPA is in need of data on chemicals so desperately, as you and some of the other members of the witness panel suggested, why did EPA end the ChAMP program? Were you having successes under ChAMP?

The ChAMP program was not designed to produce additional test data on chemicals, but rather used data already available, as a result of the voluntary HPV Challenge program and required exposure and use information provided under Inventory Update Rule (IUR) reporting, to identify chemicals as high, medium or low concern. Separate regulatory action is required under TSCA to require the submission of data. As the Administrator announced on Sept 29, 2009, EPA is continuing work to do what is possible under TSCA to require submission of data by issuing test rules and modifying required reporting under the IUR.

3. Has the EPA fully utilized all the information from the HPV program? In light of this, how would the EPA handle mass quantities of information regarding thousands of different chemicals?

The HPV Challenge Program was designed to ensure that basic, screening-level health and environmental effects data on approximately 2,800 HPV chemicals is available to the public. To that end, EPA has made all of the submissions available to the public through the High Production Volume Information System (HPVIS) and through its website <http://www.epa.gov/hpv>. Additionally, EPA is reviewing and summarizing the hazard information submitted under the HPV Challenge Program, and making this information available to the public through the continued development of hazard characterizations that are posted on our website (<http://www.epa.gov/champ/pubs/hpv/hazard.html>). To date, EPA has completed and made publicly available hazard characterizations for 320 chemicals.

While a large amount of data was collected through voluntary chemical sponsorships of some chemicals, other chemicals remained unsponsored in the HPV Challenge Program. Therefore, EPA is collecting basic hazard data for these unsponsored chemicals through regulatory efforts. Toxic Substances Control Act (TSCA) section 4 test rules and section 8(a) and 8(d) information reporting rules have been issued by EPA to gather this much needed data.

4. In Daryl Ditz's testimony he refers to the data on nearly 3,000 chemicals that will be provided by the REACH program in 2010. Considering that at your current level of staff and resources you still have information from the HPV program that has yet to be utilized, what would you need in terms of staff capabilities and resources to be able to efficiently handle this amount of information?

While EPA will not be able to determine additional resource needs in the absence of a specific proposal, EPA recognizes that REACH may result in the production of a significant volume of information on chemicals in commerce in Europe, and intends to make use of those data to the extent possible in both its current activities as well as under any new system of chemical assessments resulting from potential legislation. Although EPA cannot make any estimates regarding additional resource needs under a revised statute, the Agency hopes to avoid unnecessary duplication to the extent possible by using appropriate data generated elsewhere, including in REACH, if it is mandated to determine the safety of existing chemicals. The Agency would anticipate that chemical producers would also be able to take advantage of such data in support of their claims of safety. As the Administration's Principles for Legislative Reform indicate, we believe EPA should be given a sustained source of funding for implementation, and that manufacturers of chemicals should support the costs of Agency implementation, including review of the information provided to EPA.

5. Do you believe an increase in animal testing will need to be done in order to obtain the type of data that EPA might use for prioritizing, including but not limited to minimum data sets for non-priority chemicals? If so, how much? How reliable is computer modeling?

EPA prioritizes chemicals for various purposes, and depending on the end purpose of the prioritization exercise, EPA may consider a variety of endpoints such as hazard, exposure, production volume and use, biomonitoring, etc. Many of these do not involve new animal testing. Whether under TSCA or new legislation, EPA will strive to avoid unnecessary testing, while doing what is necessary to protect human health and the environment.

To this end, EPA recognizes the need to develop and utilize new technologies for chemical assessment, and EPA's Office of Research and Development (ORD) is currently an international leader in developing and assessing the utility of these technologies in its Computational Toxicology Program (<http://www.epa.gov/NCCT/>). For example, ORD's ToxCast program is determining whether the non-animal based, high throughput screening tools used by the pharmaceutical industry to discover new drugs can be applied to prioritize chemicals for Agency review. This year they will begin extending this screening approach to a total of 1,000 chemicals and we expect to see if this approach will be effective within the next two years. Additionally, EPA has partnered with NIH researchers to begin a study of 10,000 chemicals using the high throughput capabilities of the NIH Chemical Genomics Center. Together these research efforts will help improve our modeling capabilities while we continue to use existing tools to help avoid unnecessary animal testing.

6. Since EPA is prohibited from using human data in regulating, would that mean that bio-monitoring would be off-limits to you?

We noticed this question states that EPA is prohibited from using human data to regulate. Just to clarify, EPA does place many ethical protections on using human studies, and certain studies involving pregnant or nursing women and children are banned. However, provided the studies meet ethical and scientific standards (as reviewed by Institutional Review Boards), EPA can consider certain human studies in the decision making process. Human observational studies, which can include biomonitoring studies, are appropriate to use in EPA's chemical assessments and provide valuable information about human exposures. For example, EPA will use data where appropriate from the National Health and Nutrition Examination Survey (NHANES), which is a program of studies designed to assess the health and nutritional status of adults and children in the United States. The survey is unique in that it combines interviews and physical examinations. Sources of biomonitoring data such as NHANES are based on observations and do not involve the intentional dosing of test subjects. EPA will ensure that the biomonitoring data it uses are based on the most up-to-date sound science and the highest ethical standards, including conformance with the requirements at 40 CFR 26 where applicable.

7. When President George W. Bush came into office in 2000 he did NOT pull the plug on the High Production Volume (HPV) Challenge Program which had been started under President Clinton. Instead, he chose to continue the efforts of his predecessor and rather than see it as political, chose not to pull the plug or force it to be renamed. Why is the Obama administration pulling the plug on ChAMP when its replacement program is proceeding in a manner that is not inconsistent with ChAMP?

Soon after her arrival at the Agency, EPA Administrator Lisa Jackson identified strengthening the agency's chemical management program as one of her top priorities. After careful review and consideration by senior Agency officials, EPA concluded that the Chemical Assessment and Management Program was too focused on categorizing thousands of chemicals, which would take years. This review also highlighted that the categorizations were often based on limited and incomplete test and exposure data. On September 29, 2009, EPA Administrator Lisa Jackson outlined a comprehensive program to strengthen the Agency's chemical management program. This effort includes the development of chemical action plans which identify potential concerns with the chemical and actions that the Agency intends to take to address those concerns. The Agency identified the initial list of chemicals for action plan development based on one or more of the following factors: their presence in human blood; persistent, bioaccumulative, and toxic (PBT) characteristics; use in consumer products; production volume; and other similar factors. EPA is considering how best to engage stakeholders and the public on the selection of future action plan chemicals.

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section 6 of TSCA for several phthalates, short-chain chlorinated paraffins, and perfluorinated chemicals; reinforcing the DecaBDE phaseout – which will take place over three years – with requirements to ensure that any new uses of PBDEs are reviewed by EPA prior to returning to the market; and a range of Design for the Environment efforts to reduce risks. On March 29, 2010, EPA made public the BPA Action Plan which indicated that the Agency, among other things, is considering adding BPA to the Chemical Concern list on the basis of potential environmental effects.

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As part of this broader effort, EPA will also continue to require submission of data on High Production Volume chemicals where it has not already been provided, review provided data and post the results of those reviews, and seek to improve the quality and quantity of data submitted to the Agency on existing chemical uses and exposures.

EPA believes that this targeted approach will prove more protective of human health and the environment.

8. You mention that EPA has only been able to require testing on 200 chemicals. Does this number include new chemicals subject to section 5(e) orders which require testing?

No. This number refers to TSCA Section 4 authority to issue test rules and enforceable consent agreements to generate test data on existing chemicals.

9. Your testimony states that “chemicals should be reviewed against safety standards that are based on sound science and reflect risk-based criteria protective of human health and the environment. EPA should have the clear authority to establish safety standards based on risk assessments, while recognizing the need to assess and manage risk in the face of uncertainty.” Does this mean that EPA supports a risk management strategy rather than one based on “safety?”

Chemicals should be assessed on the basis of risk, against whatever safety standard is established. Risk-based criteria means taking into account both hazard and exposure. The principles also state that EPA should have clear authority to take risk management actions when chemicals do not meet the safety standard, with flexibility to take into account a range of considerations, including children’s health, economic costs, social benefits, and equity concerns.

10. You mention in your testimony that EPA should be able to act in the “face of uncertainty.” Could you please explain what this means?

Uncertainty is a routine issue confronted in science, and particularly in risk assessment. Even the most thorough assessments can not answer every conceivable question that may arise in the course of conducting a risk assessment. As long as assessments are based on sound scientific principles and data, the Agency should be able to use those assessments to carry out its responsibilities.

11. I noticed in the electronic version of your testimony submitted to the Committee that the type face appears different in a sentence on page three stating: "EPA should have clear authority to take risk management actions when chemicals do not meet the safety standard, with flexibility to take into account a range of considerations, including children's health, economic costs, social benefits, and equity concerns." Was this the product of inter-agency review? Did EPA try to change this and OMB made the Agency go back at the end? Do you support this language that is in your full testimony as presented to the committee?

The language quoted comes directly from Principle No. 3 of the Administration's "Essential Principles for Reform of Chemicals Management Legislation," and I fully support that language and the Administration principles.

12. Does EPA intend to try and regulate any chemicals under Section 6 of TSCA before Congress enacts changes to it? If so, for what purpose?

It is clear that TSCA could be significantly strengthened to improve effectiveness, as indicated in my testimony and the Administration principles. Nonetheless, EPA has a responsibility to do all that it can under current authority to assess chemicals and take appropriate action to protect human health and the environment. EPA intends to utilize the array of regulatory tools under TSCA to address risks, including authority to label, restrict, or ban chemicals under Section 6 of TSCA.

13. Are there existing authorities under TSCA that you feel EPA is not using to the fullest extent? Are there other authorities that are being used fully?

Since enactment over thirty years ago, EPA has only successfully used its Section 6 authority five times, and was largely unsuccessful in its attempt to ban asbestos, a well-known human carcinogen. EPA has required testing for only 200 of the tens of thousands of existing chemicals in commerce. TSCA needs to be updated to provide EPA the mechanisms and authorities to expeditiously target chemicals of concern and promptly assess and regulate new and existing chemicals.

14. The ChAMP approach involved applying the results of the HPV Challenge Program, reporting of use and exposure information under the Inventory Update Rule, and other available information (e.g., available in EPA or other databases). One of the criticisms you had of ChAMP was that it was based on voluntary information. Is the Inventory Update Rule reporting voluntary? How will the information sources that you plan to use

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for identifying and documenting action plan chemicals differ from the information sources used in ChAMP?

The IUR reporting is not voluntary; however, the nature of the data provided under the current IUR limits EPA's ability to assess exposure, particularly from uses "downstream" of the manufacturer or importer.

For chemicals identified in action plans, we have expanded the set of information sources searched and added more detailed evaluation of uses. Where we identify a need to initiate regulatory action, we will conduct more quantitative and detailed assessments, as appropriate to the specific regulatory finding.

15. In your oral testimony you stated that 16,000 chemicals on the TSCA Inventory had confidential chemical identities. How many of these 16,000 chemicals are former new chemicals? How many are chemicals that were on the original Inventory? How many of these 16,000 chemicals were reported under the most recent IUR as being produced at high volume?

Of the 16,000 chemicals on the TSCA Inventory with confidential chemical identities, approximately 3,000 were on the original Inventory and approximately 13,000 were added through the New Chemicals Program. Fewer than 100 were reported in the 2006 IUR as high production volume.

16. In your oral testimony you stated that EPA will move forward on one of ChAMP's components, the inventory reset effort, "in the future." Given the critical importance to future legislative development efforts of understanding how many and what chemicals are actually in commerce in the US, why is this not seen as essential work to undertake now?

Clarifying the number of chemicals in commerce may be useful for planning purposes, but is not essential to completing TSCA reform. In deciding how best to use current resources – both EPA resources and those of the regulated community - to protect human health and the environment under TSCA, EPA will consider the risk reduction benefits of an Inventory reset as compared to other activities.

17. Some questions were raised in the hearing about EPA's use of structure activity relationships (SAR) tools in assessing new chemicals. Recognizing that these tools have been used over the past 30 years and across both Republican and Democratic Administrations, this seems like an important issue to understand. What instances are you aware of where EPA's new chemicals program has failed to identify problematic new chemicals? Has EPA done any studies or other analyses to try to understand the performance of its SAR methods and the extent of erroneous SAR calls? What have those studies shown? Please provide details on what EPA has done and any reviews or peer reviews that have been conducted.

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EPA has developed an extensive multi-disciplinary process to predict the potential risks from each new substance, including the use of known information and data, expert judgment, as well as an array of tools and models (including SAR tools/models) built on the extensive experience with the review of thousands of other chemicals in the PMN program, and available data and information on analogous chemicals. Our experience has shown that our SAR tools do a good job of initially assessing new chemicals. This statement is based on peer review/verification studies we have conducted on these tools and the general lack of substantial risk reports submitted under TSCA section 8(e) on chemicals that have been reviewed in the New Chemicals Program that would indicate errors in our assessments.

The models and SAR tools have a history of peer review by the EPA Science Advisory Board (SAB) and other bodies. For example:

- **2005-2006** – SAB Review of EPI Suite models. [EPI Suite is a suite of models that provide screening level estimations of physical/chemical properties and environmental fate properties. These properties are the building blocks of exposure assessment.]
- **2002** - Peer review of the PBT Profiler prior to public release in 2002. [PBT Profiler predicts Persistence, Bioaccumulation, and Toxicity of organic chemicals from their structure]
- **1993** – EPA/European Community Project to verify new chemical SAR predictions for ecological toxicity. [The study found our SAR methods to be accurate 60-90% of the time depending on the endpoint. Study & Report entitled, *U.S. EPA/European Community (EC) Joint Project on the Evaluation of (Quantitative) Structure Activity Relationships.*]
- **1992 and 1998-1999** - Peer review of the OncoLogic system by external cancer experts prior to public release. [OncoLogic is a computerized expert system that analyzes a chemical's structure to determine the likelihood that it will cause cancer]

The Government Performance and Results Act (GPRA) sets objectives for offices to conduct periodic assessments of their key programs and to work toward developing results-based and cost-efficiency performance measures. In FY 2006, EPA adopted (with a FY 2004 baseline) a Performance Assessment Rating Tool (PART) measure that EPA uses to assess the performance of the TSCA New Chemicals Program (NCP). The measure establishes a "zero tolerance" performance standard for the number of new chemicals introduced into commerce that pose an unreasonable risk to workers, consumers, or the environment. The measure involves a comparison of TSCA section 8(e) hazard data submitted to EPA in a given fiscal year with any related previously submitted TSCA section 5 pre-manufacture notices to determine whether EPA properly identified those hazards. The question asked during the assessment is 'What would the New Chemicals Program conclude about the hazards if it received the same chemical today?' The Agency has achieved the 100 percent goal in four of five years that the measure has been tracked (FY 2004 to FY 2008), and has a 99.6 percent success rate overall. The Agency recognizes that this measure does not involve systematic sampling and testing of all

PMN-reviewed chemicals that have entered U.S. commerce, but believes nonetheless that it represents an efficient approach for using available information to assess and improve the effectiveness of EPA's new chemicals risk screening tools and decision-making processes.

When new test data that meet our data quality standards are submitted with a new chemical, OPPT uses this data to evaluate that new chemical but also to evaluate our model predictions (a model validation measure) and expand the database on which our predictive models are based or to develop a new predictive model.

The hazard identification process in the New Chemicals Program also utilizes data on structurally analogous existing chemicals. The procedures used by OPPT to uncover pertinent toxicity information rely on a variety of readily available bibliographic systems, databases, studies submitted to EPA under 8(e) and 8(d), and knowledge from technical experts. As appropriate, such information causes the New Chemicals Program to alter its assessments of the hazards of categories of new chemicals.

For example, long-chain perfluorinated chemicals provide an example of a category of chemicals presenting issues that were not anticipated by SAR. In 1999, EPA became aware, based on testing conducted by manufacturers and submitted under TSCA section 8(e), that certain of these chemicals already in commerce (i.e., existing chemicals) bioaccumulate in wildlife and humans and can be toxic to laboratory animals and wildlife. Although these perfluorinated chemicals were understood to be persistent, their toxicity and bioaccumulative potential were not anticipated by SAR. EPA immediately took regulatory and voluntary actions to further investigate these chemicals as well as to reduce their emissions and use in products. These actions included Significant New Use Rules, the PFOA Stewardship Program, Enforceable Consent Agreements, and development/implementation of a specific regulatory strategy for reviewing substitutes for long-chain perfluorinated substances as part of the TSCA New Chemical review process.

In addition, previously in 1995, EPA had issued a final rule exempting certain unreactive halogen-containing polymers (including polymers that may contain such perfluoroalkyl moieties) from full TSCA section 5 pre-manufacture notification requirements. In 1995, the best available information indicated that such polymers were chemically and environmentally stable and would not present an unreasonable risk to human health and the environment. In fact, some of these chemicals were included in an exemption from new chemicals review by EPA, based on a belief that their polymeric structure precluded any hazard. In January 2010, EPA issued a final rule revoking the exemption from full reporting for these types of polymers.

18. Do any other countries or organizations such as the Organization for Economic Co-operation and Development (OECD) rely on SAR methods in their efforts to prioritize or assess the hazards or environmental fate properties of new or existing chemicals (for example, will SAR methods be used under REACH?) and, if so, identify those countries and organizations? Has EPA made its SAR tools publicly available for use by industry (for example, in designing and developing new chemicals, assessing existing chemicals, etc.)

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or foreign governments? How have they been made available and for what purposes have they been used?

It is EPA's understanding that SAR tools will likely be used for some purposes under REACH and are also used by some OECD countries. Over the last 10 years the OECD has been educating member countries on the use of SAR methods and has turned to the US EPA/OPPT to often lead the efforts, along with other countries currently employing SAR. To facilitate practical application of (Q)SAR approaches in regulatory contexts by governments and industry and to improve their regulatory acceptance, the OECD (Q)SAR project has developed various outcomes such as the principles for the validation of (Q)SAR models, guidance documents, as well as the (Q)SAR Application Toolbox. The OECD (Q)SAR Toolbox (first released in March 2008, and updated in December 2008) includes many of EPA's SAR tools. EPA has also made its SAR tools publicly available for download via its own website. Case studies from OECD member countries employing predictive tools are included in the following document: OECD's Report on the Regulatory Uses and Applications in OECD Member Countries of (Q)SAR Models in the Assessment of New and Existing Chemicals (OECD, 2006).

In addition, in 2002, EPA initiated the Sustainable Futures (SF) Initiative, a voluntary program that encourages chemical developers to use EPA's models and SAR methods to screen new chemicals for potential risks early in the development process. The goal is to produce safer chemicals more reliably and more quickly, saving time and money. This means getting safer chemicals into the market and in use. Companies that take requisite training and graduate from Sustainable Futures can earn expedited review by EPA for prescreened new chemical notices.

19. Several of the witnesses at the hearing, including Dr. Ditz and the industry witnesses, emphasized the importance of the data development work which is already in process under REACH in the EU and how this information could contribute to US efforts to prioritize and assess chemicals. While recognizing that accessing CBI data presents difficulties, what steps has EPA taken to work out arrangements to obtain access to the non-CBI hazard and exposure information which will be reported in the EU? What assurances can you provide that EPA will be able to access the information and on what timeline?

EPA has informal arrangements with the EU, Australia and Canada which allow environmental and public health data to be accessed by the Agency, including confidential business information. EPA is exploring how such processes might be expanded and made routine. Because of the provisions in TSCA, however, it is difficult for the U.S. to reciprocate in sharing confidential business information with foreign regulators where it might contribute to mutual public benefit. Chemicals management experience and information is also shared more broadly with EPA's participation in activities of the OECD Environment, Health and Safety program. In collaboration with the EU, EPA contributed to the development of the eChemPortal from which multiple chemical data sources can easily be accessed.

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20. What is the existing overlap between chemicals on the US inventory and the results of the preregistration reporting under REACH and, based on this information, how many US chemicals will potentially be registered at the December 2010 time point? Considering the reporting under the Inventory Update Rule for these chemicals, how many are high volume chemicals in the US? How many are moderate or low volume chemicals in the US?

There could be significant overlap between the TSCA Inventory and the REACH pre-registration list. According to the European Chemicals Agency (ECHA), the current REACH pre-registration list contains about 143,000 chemicals, pre-registered by upwards of 65,000 companies. Given the large number of chemicals on the pre-registration list and questions regarding the accuracy and validity of the data,, we have not conducted a comparison with the TSCA Inventory. Once the REACH registration list is established, EPA will be able to make a more valid comparison between this list and chemicals listed in the TSCA Inventory.

The Honorable Cliff Stearns

1. Do you believe the U.S. Should move toward a purely European approach to regulating chemicals, such as what the Europeans are doing with their REACH initiative?

The EU's REACH initiative is in its early stages and EPA hopes to learn from their experience. EPA is advocating for legislation which follows the Administration Principles and which meets the needs of the U.S. for chemicals management.

2. It is my understanding that under REACH, the EU is being inundated with information about chemicals and they may have to suspend the program in order to get caught up. Is that correct?

EPA is not aware of any plans to suspend REACH.

3. As the Republican Co-Chair of the Transatlantic Legislators Dialogue, I have had to press my European counterparts to ensure that U.S. Cosmetics – a \$2 billion industry – were not taken off shelves in Europe due to the overly burdensome REACH requirements. Is this the direction you would like to see the U.S. Go in?

EPA is advocating for legislation which follows the Administration Principles and which meets the needs of the U.S. for chemicals management.

HENRY A. WAXMAN, CALIFORNIA  
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December 10, 2009

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 Director, Division of Laboratory Sciences  
 National Center for Environmental Health  
 Centers for Disease Control and Prevention  
 4770 Buford Hwy NE MS F-20  
 Atlanta, GA 30341

Dear Dr. Sampson:

Thank you for appearing before the Subcommittee on Commerce, Trade, and Consumer Protection on November 17, 2009, at the hearing entitled "Prioritizing Chemicals for Safety Determination".

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 December 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

CDC Response to Questions for the Record:  
11/17/09 Hearing before House Committee on Energy and Commerce,  
Subcommittee on Commerce, Trade and Consumer Protection,  
Prioritizing Chemicals for Safety Determination

**The Honorable George Radanovich**

- 1. Your testimony mentions how CDC uses good laboratory practices and that doing so enhances your confidence in your findings. In addition, the National Research Council/National Academy of Sciences report on bio-monitoring from July 25, 2006 mentions that persons should not assume that all bio-monitoring studies are conducted with the same rigor as CDC, and therefore guidelines should be put in place to make sure that any study meets CDC's high standards of quality. In view of this, do you think that biomonitoring information being used by policymakers should be subject to good laboratory practice and data quality requirements like those used by CDC?**

Answer: High-quality measurements are essential to ensure that data and the resulting data interpretation are valid and can be relied on for informing policy, conducting research, or for other public health interventions. For this reason, CDC's Division of Laboratory Sciences is taking steps to help states and other laboratories by developing a quality assurance system for biomonitoring measurements. This quality assurance system is in the planning stages, but once implemented, participating laboratories will have a system that ensures that the laboratories are consistently providing accurate test results.

- 2. Do you know every chemical that is in blood or fat? Do we know every possible chemical in the environment? How much effort would it take to assess all these things?**

Answer: We do not know every chemical in the human body or every chemical in the environment. Naturally occurring chemicals exist in the environment, and there are thousands of chemicals that are commercially produced. CDC began measuring human exposure to chemicals approximately 25 years ago, periodically adding new chemicals as methods were developed for measuring them in human blood, urine or tissue. CDC's most recent report on human exposure to environmental chemicals (12/09) addresses 212 chemicals, a small fraction of all chemicals. Moreover, it is not clear that scientific or policy needs would necessitate assessment of every chemical in people, or that doing so would be possible or feasible. In any event, it clearly would require enormous effort and resources, orders of magnitude beyond CDC's current biomonitoring program, to measure every chemical in human blood, urine or tissue.

- 3. How much would it cost to do bio-monitoring studies on a chemical? What would it cost if biomonitoring were required for every chemical? How long would these tests take?**

Answer: The cost per test varies depending on the chemical. For example, costs range from \$68 per sample for blood lead testing to \$1,000 per sample for a panel including dioxins, furans, and dioxin-like polychlorinated biphenyls (PCBs). These costs are calculated based on a variety of factors including equipment, supplies, and personnel. The costs do not include development of biomonitoring technologies and methods, survey design, sample collection and statistical analysis. CDC has not calculated how much it would cost to conduct biomonitoring on every chemical in production, and questions the feasibility of doing so.

**The Honorable Cliff Stearns**

- 1. Do you believe the U.S. should move toward a purely European approach to regulating chemicals, such as what the Europeans are doing with their REACH initiative?**

Answer: CDC is not a regulatory agency; this question might be more appropriately posed to the Environmental Protection Agency. The focus of CDC's biomonitoring program is to determine the levels of certain chemicals in the blood or urine of a representative sample of the noninstitutionalized U.S. population, and for scientists (within and outside of CDC) to conduct studies using that data, to examine what it means for human health.

- 2. It is my understanding that under REACH, the EU is being inundated with information about chemicals and they may have to suspend the program in order to get caught up. Is that correct?**

Answer: This question requests information on matters that are beyond CDC's mission or expertise.

- 3. As the Republican Co-Chair of the Transatlantic Legislators Dialogue, I have had to press my European counterparts to ensure that U.S. Cosmetics – a \$2 billion industry – were not taken off shelves in Europe due to the overly burdensome REACH requirements. Is this the direction you would like to see the U.S. go in?**

Answer: This question requests information on matters that are beyond CDC's mission or expertise.



CENTER FOR INTERNATIONAL ENVIRONMENTAL LAW

December 30, 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 November 17, 2009 hearing held by the Subcommittee on Commerce, Trade & Consumer Protection, titled "Prioritizing Chemicals for Safety Determination."

I received two sets of questions, one from Congressman George Radanovich and another from Congressman Cliff Stearns. Responses to each are attached.

I greatly appreciate the opportunity to testify before the Subcommittee on this timely important matter, and applaud your leadership in advancing much-needed improvements to the Toxic Substances Control Act.

Best regards,

Daryl Ditz, Ph.D.  
Senior Policy Advisor  
Center for International Environmental Law  
1350 Connecticut Avenue, NW #1100  
Washington, DC 20036

cc: Earley Green, Chief Clerk



CENTER FOR INTERNATIONAL ENVIRONMENTAL LAW

December 30, 2009

The Honorable George Radanovich  
 United States House of Representatives  
 Washington, D.C. 20515

Dear Mr. Radanovich:

Thank you for the opportunity to address your questions for the record concerning the Subcommittee on Commerce, Trade and Consumer Protection's November 17, 2009 hearing entitled "Prioritizing Chemicals for Safety Determination." I have included your questions along with my responses below.

1. Mr. Ditz, you suggest the reason the Fifth Circuit overturned the Agency's asbestos rules was the allegedly unattainable "unreasonable risk" standard.
  - a. In fact, the Court explicitly stated the EPA did an "impressive job...both in conducting its studies and in supporting its contention that banning asbestos products would save over 102...lives."
  - b. The Court further said that had "the petitions only question[ed] the EPA's decision to ban friction products...[it] would [have been] tempted to uphold the EPA."
  - c. The primary reason the EPA's asbestos rules were struck down was "[t]he failure of the EPA to [show not only that its proposed action reduces the risk ...but also that the actions Congress identified as less burdensome also would not do the job] constitute[d] a failure to meet its burden of showing[.]"

Response: I did not comment on the Fifth Circuit's reasoning in *Corrosion Proof Fittings, et al. v. EPA*. Rather I called TSCA's unreasonable risk standard, an "Achilles' heel that has prevented EPA action since the Agency's asbestos rules were overturned by the courts nearly two decades ago."

2. Given that the most oft-quoted proof of a need to reduce the risk standard is a Federal Circuit decision based on simple mechanics – that the EPA didn't show its "homework" on the problem – rather than an inability to meet a safety standard, is there other evidence that supports the notion the "unreasonable risk" standard is too high a bar?

Response: The most compelling evidence that TSCA's regulatory standard is too high a bar is the simple fact that the U.S. Environmental Protection Agency (EPA) has been unable to regulate more than a small number of the thousands of existing chemicals under TSCA in nearly twenty years.

3. In your testimony, you say that to expedite action, Congress should authorize EPA to promptly identify and phase out non-essential uses of a set of high-priority chemicals. What do you consider to be "non-essential" and "essential" uses of priority chemicals? How would "non-essential uses" and "high-priority" be defined, and who would determine the "set" of those "high-priority" chemicals?

Response: Clearly, these are among many issues for Congress to address in revising the Toxic Substances Control Act. I believe that in regulating a chemical, EPA should have discretion to take into consideration the uses of the chemicals. It strikes me as reasonable that Congress would provide general direction to EPA and authorize it to establish specific criteria to be used to identify essential uses, which might take into account, for example, national security considerations. With respect to defining "high priority" chemicals, I would support the addition of clear definitions and criteria in the revised statute. Thus, Congress would establish the criteria for "high priority" chemicals. I believe that chemical manufacturers should then have a responsibility to determine whether their products meet such criteria.

4. In your testimony you state "The American Chemistry Council's new principles for TSCA modernization would repeat this mistake by subjecting only a fraction of existing chemicals, selected on the basis of whatever information can be cobbled together, to a safety determination and letting the majority of chemicals sidestep credible evaluation."

Response: This is not a question.

5. It makes sense that the chemicals we include in the initial round of prioritization be ones where there is already existing data to expedite the process. Why do you disagree with this commonsense approach?

Response: This question presumes an "initial round of prioritization," but neglects to explain what is being prioritized, on what basis, or to what end. Therefore, I cannot agree that you are proposing a "commonsense approach." As I testified, prioritization on the basis of existing information can be applied "to inform EPA's decisions on which chemicals should be assessed first." I disagree with proposals by the American Chemical Council that would allow many, or even most, TSCA chemicals to remain on the market indefinitely without ever undergoing a safety determination. This would guarantee continued exposure to potentially dangerous chemicals and undermine innovative U.S. companies that provide safer alternatives.

6. What chemicals, if any, do you think should be preserved from bans under Federal law?

Response: See below, where this question is repeated.

7. It was curious to find your reference to the Stockholm Convention and Persistent Organic Pollutants (POPs). Your group has vigorously opposed legislation actually moving in Congress to have the United States implement this treaty. In fact, a couple of Congresses ago, your organization opposed exemptions for chemical uses related to public health (i.e. lindane for lice control). Are there any chemical substances or mixtures that you think should be protected

from bans under Federal legislation? Do you believe the government should give safe-harbor protection for certain uses of certain chemicals (i.e. public health)? What chemicals, if any, do you think should be preserved from bans under Federal law?

Response: My organization has been among the most active proponents of responsible implementing legislation to allow the United States to ratify the Stockholm Convention on Persistent Organic Pollutants. On March 2, 2006, my colleague Glenn Wiser testified on behalf of the Center for International Environmental Law and several other organizations in *support* of H.R. 4800 (109<sup>th</sup> Congress), a bill to amend TSCA for this purpose. With respect to your question, I would favor EPA authority to grant limited exemptions for certain uses of chemicals. I believe that the EPA should have authority to identify and regulate chemicals that are persistent, bioaccumulative and toxic. This, together with other legislative changes, could enable the United States to not only join the 168 other Parties, but also to better protect the health and environmental quality of Americans. Compliance with the Stockholm POPs treaty does not require "safe-harbor" protection for any uses of POPs chemicals.

8. How many POPs are permitted unrestricted use or manufacture in the United States?

Response: Some complexities of this issue preclude providing a simple numeric answer. The Stockholm Convention on Persistent Organic Pollutants now lists 21 chemicals that meet the treaty's definition of "POPs." Another international agreement (the LRTAP POPs Protocol) lists 16 chemicals that meet a slightly different definition of POPs. Many of these POPs chemicals have agricultural uses that would fall under the jurisdiction of U.S. laws on pesticides. In addition to these chemicals which have been identified as POPs through rigorous international review processes, many more chemicals meet the same criteria and could reasonably be considered POPs.

9. You obviously agree with the proponents of prioritization and TSCA reform and urge the prioritization of, quote, "all chemicals" against a health-based standard. First, how would "health-based standard" be defined, or who would determine what that standard would be? Second, how does this differ from a risk-based approach? Finally, over what timeframe do you propose this review should be completed?

Response: The statement confuses the issue of "prioritization" with the issue of assessing chemicals against a safety standard. Under a reauthorized TSCA, Congress could choose to adopt the regulatory standard of "reasonable certainty of no harm," the health-based standard that was incorporated in the 1996 Food Quality Protection Act (FQPA). This is also a risk-based standard, in the sense that it depends on both hazardous properties of chemicals and potential exposure. Because TSCA provides very poor information about the numbers and uses of industrial chemicals, it is difficult to estimate how many years would be required for chemical manufacturers to demonstrate the safety of their products. As one indication, EPA's implementation of FQPA included the review of nearly 10,000 pesticide tolerances over the course of a decade.

10. You suggest the US can benefit in its efforts to revise chemical regulations from the EU's same efforts under REACH, such as relying upon data collected there under REACH. Would that be the extent of how the US can benefit from REACH, or do you propose the US should follow the EU's efforts in precisely the same way? Should the US refer to such data and undergo independent data analysis to reach conclusion, or should the US simply rely on the EU's regulatory decision-making?

Response: I do not believe that the United States "should follow the EU's efforts in precisely the same way." However, the United States can directly benefit from information collected under REACH, both publicly available data as well as confidential information that the U.S. government should be given authority to access. Also, it could be advantageous to U.S. companies if TSCA reform took into consideration the definitions, processes and timelines under REACH. U.S. regulators can also learn useful lessons to ease domestic implementation since the European Union (EU) approach is proceeding ahead of TSCA reform.

11. As I understand your analysis, any chemical that meets the hazard characteristics (e.g., PBTs) should be banned, regardless of the actual risk of the substance in that particular use or application. Why should US taxpayers undertake a specific process to develop more information for prioritization – that your testimony supports -- if by definition those substances are a high priority and ultimately destined for elimination?

Response: I did not testify that "any chemical that meets the hazard characteristics (e.g., PBTs) should be banned." Rather, I urged Congress to grant EPA "clear authority to reduce use of and exposures to these [PBTs] and other high-priority chemicals and to promote their replacement with safer alternatives." For chemicals that meet EPA's criteria of high concern, U.S. taxpayers should not bear the costs of a process for developing more information. For the remainder of TSCA chemicals, it seems to me reasonable that chemical manufacturers would shoulder the costs and the primary responsibility for demonstrating safety.

12. Are there existing authorities under TSCA that you feel EPA is not using to the fullest extent? Are there other authorities that are being used fully?

Response: Under the leadership of Administrator Jackson, EPA is now beginning to test the limits of TSCA's authority to regulate new and existing chemicals. While these efforts are welcome, in light of the very limited progress of EPA under previous administrations and the many thoughtful TSCA critiques by the Government Accountability Office, I firmly believe that Congress should overhaul this statute to achieve its original aims and reflect the considerable changes in scientific understanding and realities of the global market.



CENTER FOR INTERNATIONAL ENVIRONMENTAL LAW

December 30, 2009

The Honorable Cliff Stearns  
United States House of Representatives  
Washington, D.C. 20515

Dear Mr. Stearns:

Thank you for the opportunity to address your questions for the record concerning the Subcommittee on Commerce, Trade and Consumer Protection's November 17, 2009 hearing entitled "Prioritizing Chemicals for Safety Determination." I have included your questions along with my responses below.

1. Do you believe the U.S. Should move toward a purely European approach to regulating chemicals, such as what the Europeans are doing with their REACH initiative?

Response: No, I do not believe that the United States should move toward a purely European approach to regulating chemicals such as their REACH initiative. However, as Congress considers long overdue improvements to the Toxic Substances Control Act, it can be instructive to consider the approaches of our international allies and trading partners. Given that most U.S. chemical companies are preparing to comply with the EU law, it could be advantageous if TSCA reform took into consideration REACH's definitions, processes and timelines. U.S. regulators can also learn useful lessons to ease domestic implementation since the European approach is proceeding ahead of TSCA reform.

2. It is my understanding that under REACH, the EU is being inundated with information about chemicals and they may have to suspend the program in order to get caught up. Is that correct?

Response: I know of no plans to suspend REACH. It is true that the implementation of REACH is generating a wealth of information, such as data on the potential health and environmental effects of chemicals. In fact, the United States can directly benefit from information collected under REACH, both publicly available data as well as confidential information that the Congress should give EPA the authority to access. Such information is essential to federal and state agencies responsible for protecting environmental quality and the health of Americans; it is also valuable to American businesses that make and use chemicals, and to U.S. workers, investors, researchers, consumers and others.

3. As the Republican Co-Chair of the Transatlantic Legislators Dialogue, I have had to press my European counterparts to ensure that U.S. Cosmetics – a \$2 billion industry – were not taken off shelves in Europe due to the overly burdensome REACH requirements. Is this the direction you would like to see the U.S. Go in?

Response: Congress should not adopt laws that discriminate against products on the basis of national origin. At the same time, any company that wishes to compete for the U.S. market must comply with U.S. standards. By the same token, U.S. companies that wish to do business in the European Union have no choice but to comply with the EU law. In terms of reforming the Toxic Substances Control Act, it is important that Congress adopts world-class standards, so that Americans can be confident of the safety of chemicals used at home, and so that U.S. exporters can satisfy even the most demanding regulatory standards overseas.



December 18, 2009

Honorable Henry A. Waxman  
Chairman  
Committee on Energy and Commerce  
U.S. House of Representatives  
2125 Rayburn House Office Building  
Washington, DC 20515

Attention: Earley Green, Chief Clerk

Dear Chairman Waxman:

Thank you for the opportunity to appear before the Subcommittee on Commerce Trade and Consumer Protection on November 17, 2009 at the hearing entitled "Prioritizing Chemicals for Safety Determination."

Attached are written responses for the record to your letter dated December 10, 2009 on behalf of the Consumer Specialty Products Association (CSPA); Grocery Manufacturers Association (GMA) and The Soap and Detergent Association (SDA).

Please contact me at (513) 315-4155 or [bgreggs@gmail.com](mailto:bgreggs@gmail.com) or Douglas Troutman at (202) 662-2508 or [dtoutman@sdahq.org](mailto:dtoutman@sdahq.org) if we can be of further assistance.

Sincerely,

William J. Greggs

cc: Representative Rush  
Representative Radanovich  
Representative Stearns

Grocery Manufacturers Association  
 Consumer Specialty Products Association  
 The Soap and Detergent Association

December 18, 2009

**The Honorable George Radanovich**

**1. You state that you want to have the most comprehensive chemicals management policy in the world. Some advocates of reform point to the European Reach model as more comprehensive than our model. Do you think that is the model the US should follow?**

It is important to modernize chemical regulation with a focus on protecting the public and the environment while retaining U.S. leadership in chemical innovation. To that end, the key building blocks for modernization of the U.S. chemical management system would include:

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

The European REACH regulation is a nascent and expansive regulatory requirement that is brand new and unproven. It is our understanding that even the process of preparing registrations for a small subset of chemicals is facing significant administrative problems. Indeed, it may be particularly ill-suited to our legal and political system. A better approach would be to set priorities at the front end of the program based on practical, scientific approaches that consider hazards and exposures. Existing data and information from U.S. and other nations with modern product safety systems should be considered and leveraged to avoid duplicative and wasteful testing. The data generated for REACH will enhance chemicals management in the United States.

Grocery Manufacturers Association  
 Consumer Specialty Products Association  
 The Soap and Detergent Association

December 18, 2009

2. **Your testimony, like many of the others we have heard, suggests that you support modernization of TSCA. Yet what I've heard from you is quite different than what I heard from the other panelists, both in November and in our prior hearing. In your mind, does a simple statement of support for TSCA modernization bind you to the solutions offered by any other group that has offered a similar statement?**

Ensuring the safety of our products and 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.

There is broad agreement that TSCA needs modernization. As you consider modernization issues, our organizations strongly urge you to create a stakeholder process that will reflect the critical role played by the consumer products industry. Congress should ensure that improvements to TSCA promote – and do not stifle -- innovation and new product development. Maintaining the global competitiveness of the producers and users of chemicals is critical to our economy. Generally speaking, protecting confidential business information, clarifying the roles of the states, and promoting a level global playing field will foster greater innovation and enhance consumer confidence.

3. **Do you think a broad, bipartisan stakeholder agreement is necessary for Congress to make meaningful improvements to chemicals management policy? Why? Would you participate in such an effort if asked?**

Federal chemical management legislation should be drafted with consultation of all relevant stakeholders with the necessary expertise to develop a workable and successful federal chemical management system. Experience has shown that when legislation is not thoroughly considered by all affected interests, there can be detrimental impacts to consumers and unintended consequences. The formulated consumer products industry and American Chemistry Council have been advocating a stakeholder process. Indeed, “principle papers” issued by public and private entities indicate broad agreement, and a stakeholder process could greatly narrow the range of disagreements that Congress would have to resolve.

4. **Could you describe for us what you would consider to be a poorly crafted reform of TSCA and how that would affect your industry, particularly as it relates to innovation and jobs? Do you fear that without a stakeholder process that you would end up with legislation, which brings serious, negative unintended consequences?**

A properly facilitated and managed stakeholder process could achieve a robust and thoughtful modernized chemical management policy focused on protecting the public and the

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December 18, 2009

environment while retaining U.S. leadership in chemical innovation. Innovation is critical to the goal of continuous improvement in product safety and effectiveness. The consumer products industry supports a federal chemical management program that is based on sound scientific risk assessments. This allows a robust and dynamic environment for chemical management and introduction of more innovative consumer products through efforts such as green chemistry and sustainability programs that provide health and safety benefits to consumers.

**5. Would you be able discuss in further detail some of the alternatives to the prioritization approach based on exposure and hazard which you outlined in your testimony, and the advantages your recommended approach would have over those alternatives? Why do you think your approach would be preferable to having the statute mandate the actual chemicals to be addressed?**

The strengths of our approach –

- It establishes a priority system that focuses on hazard and exposure and allows EPA to review the information and make scientific decisions. It takes into account the criteria of the chemicals and their uses that will identify the chemicals that require further assessment and, where necessary, risk management.
- The approach is easy for the Agency to adopt and able to be done in a reasonable timeframe where the hazard and exposure information is readily available to EPA. The Agency should have the authority to require information from industry representatives if it is unavailable to EPA. Moreover, the priority setting process must allow a stakeholder comment period.
- The approach is dynamic in that it allows for EPA to update a chemical's priority rather than a one-time assessment. This is especially valuable when new information becomes available regarding the hazard or exposure pattern of a chemical substance, which may force it into a higher prioritization status. This is in contrast to a classic "listing" approach. A simple list provides inadequate assurance that public health and the environment are properly considered. Lists usually are hazard driven; however, unless there is exposure or release, high hazard alone does not present the likelihood of injury. Further, lists are static in nature and fail to accommodate new information that can arise in a chemical management program. Any list of chemicals would become an unwavering mandate to which EPA would direct resources, regardless of the information that arises on a substance during the implementation of a chemical management program. It could prevent the Agency from directing scarce resources to other chemicals that may warrant examination. Recognizing that resources are finite, Congress should not tie the hands of the Agency, but rather provide criteria for priority setting and put the responsibility for those decisions in the hands of Agency scientists.

Grocery Manufacturers Association  
 Consumer Specialty Products Association  
 The Soap and Detergent Association

December 18, 2009

**6. Could you please detail for me all the Federal statutes that affect the production and sale of the products made by the associations you are representing?**

The laws regulating consumer products made by members of CSPA, GMA, and SDA include HMTA (Hazardous Material Transportation Act); FIFRA (Federal Insecticide, Fungicide, Rodenticide Act); FDCA (Federal Food, Drug and Cosmetic Act); CAA (Clean Air Act); CWA (Clean Water Act); CERCLA (Comprehensive Environmental, Response and Liability Act); EPCRA (Emergency Planning and Community Right to Know Act); RCRA (Resource Conservation and Recovery Act); TSCA (Toxic Substances Control Act); FPLA (Fair Packaging and Labeling Act); OSHA (Occupational Safety and Health Act); CPSA (Consumer Product Safety Act); FHSA (Federal Hazardous Substances Act); and the PPPA (Poison Prevention Packaging Act).

**7. Do you believe that EPA, as opposed to the Consumer Product Safety Commission under the Federal Hazardous Substances Act, should be in the business of regulating consumer products and uses? What do you think requirements like these would do for innovation and our standard of living?**

CPSA, GMA and SDA and their members develop products that meet or exceed the relevant safety requirements of all federal and state agencies in the United States charged with regulating consumer products. Product safety is the foundation of consumer trust and the consumer products industry devotes substantial resources to this goal. The consumer products industry is extensively regulated by several statutes falling under the scope of various agencies such as the Consumer Product Safety Commission, Department of Transportation, Environmental Protection Agency, Food & Drug Administration, Federal Trade Commission, and Occupational Safety & Health Administration. These authorities regulate the entire life cycle of consumer products, including the manufacturing, transport, labeling, packaging, advertising and disposal. While EPA has resources and authorities that cover a wide range of the chemical supply chain, other agencies have significant expertise in the regulation of chemical products at the point of consumer use. EPA should work closely with CPSC to address uses of chemicals and their potential risks. When it comes to risk management in particular, CPSC should retain the review and risk management decision for individual products. This extensive infrastructure and network of agency and statutory authority in the U.S. system underscores this comprehensive approach to consumer product safety.

**8. Your testimony states that GMA/SDA/CSPA support a risk-based priority process that focuses on both hazard and exposure. Is it fair to say that you would want a risk-based regulatory standard as well? If so, does your coalition support the use of a “reasonable certainty of no harm” standard for regulating under TSCA as some have proposed?**

CSPA, GMA and SDA support a risk based regulatory system. It is the only practical way to protect public health and the environment while addressing the broad range of chemicals and

Grocery Manufacturers Association  
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The Soap and Detergent Association

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uses and preserving the benefits of a wide range of products. The “reasonable certainty of no harm” standard has been applied by EPA’s pesticide program only in the context of human health [e.g. narrow range of chemicals and a narrow range of uses]. It is not at all clear how such a standard could be applied for the entire universe of chemicals and an even wider range of uses, foreseeable and otherwise.

- 9. Your testimony suggests using a hard-and-fast number system to prioritize chemicals. Superfund uses a numerical ranking system as well to prioritize hazardous waste sites and the need for cleanup. Yet, this ranking system has led to vast amounts of litigation complicating actual cleanups. Do you think that Superfund experience is a good one to use for reform efforts of this law?**

CSPA, GMA, and SDA have collaborated on the development of a risk-based and efficient tool that EPA can use to prioritize chemical substances in a timely manner under a modernized chemical management system. The recommendation is the use of a framework, which accounts for increasing levels of hazard on one axis and increasing levels of potential exposure on the other axis. The testimony from November 17<sup>th</sup> more fully details the prioritization proposal. The Superfund program is not analogous. In the context of this question, the Superfund ranking is related the outcome of an assessment and the assignment of liability. The prioritization system we are advocating is related to a decision as to which chemicals should be assessed first and does not apply to outcome or liability. The proposal as outlined in the testimony enables EPA to focus on those chemicals that have a higher potential of risk. In sum, the prioritization program as proposed in the testimony is related to deciding which chemicals should be assessed first and is not, therefore, analogous to a Superfund liability comparison or analysis.

- 10. You suggest that appropriate hazard characteristics that EPA should consider in a priority setting process include human and environmental toxicology information. Do you think these studies should be underpinned by good laboratory practices and sound, objective scientific practices?**

Data of good quality and reliability should have precedence over other data. Studies to assess hazards and exposures should be reliable, relevant and reproducible. They should be designed and conducted according to internationally recognized scientific principles. Study conditions should be transparent and the results of a test on a given chemical should be reproducible in order to consider that a test yields “valid” data. In this context, validation is the process by which the reliability and the relevance of a procedure are established for a particular purpose. Compliance with good laboratory practices is one criterion for assessing data quality, but requiring prescriptive good laboratory practices, would be too restrictive and narrow. For instance, there many older pre-GLP studies that are reliable and should not be excluded from use in assessments.

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December 18, 2009

**11. What information gathering authorities under Section 8 of TSCA do you consider lacking? Are you concerned that a public process of information review could lead to confidential business information concerns, especially when coupled with citizen suit provisions in Section 20 of TSCA?**

For a variety of reasons, EPA has not made as much use of its authority as it might have to order the submission of existing data under Section 8(d). We have also said that the downstream users of chemicals represented by GMA, CSPA and SDA recognize that a robust risk-based system will require EPA to have authority to have better information on chemical uses and exposures. The protection of information that is properly claimed as confidential is absolutely essential. The incentive to invest in innovation would be greatly diminished if chemical identity, chemical use, chemical volume, manufacturing processes or other proprietary information is disclosed allowing a competitor to quickly take advantage of an innovator's intellectual property. Finally, allowing citizen suits to force CBI to be breached would go against the goal of driving innovation to improve product safety and sustainability.

**12. Are EPA's programs to regulate chemicals founded on the notion that companies, not EPA, must bear the burden of testing their chemicals and satisfying EPA's concerns, if any, about their safety? Have companies always supplied the data on which EPA relies to evaluate the effects of their chemicals? Does EPA have the wherewithal to perform these tests on its own?**

Chemical manufacturers and companies bear the burden of providing information. Companies have the legal obligation to do testing under TSCA as required by Section 4 rules, or Section 5 orders. The Associations have acknowledged that EPA needs more robust authority to obtain data on a timely basis. In giving EPA more authority to obtain data, care must be given to avoid collecting data when the available information is sufficient, where unnecessary animal testing would be required or where alternative data (e.g., on similar chemicals) can be used. EPA is widely respected on the use of such data. EPA is authorized to work with industry to obtain the best information possible.

**13. Are there existing authorities under TSCA that you feel EPA is not using to the fullest extent? Are there other authorities that are being used fully?**

EPA has not used its authorities under Sections 4 and 8 optimally. Section 6 was the subject of unfortunate judicial precedent that limited its utility. Given years of practice and precedent, changes to TSCA are needed to generate more effective use of these authorities.

On improving existing authorities, CSPA, GMA and SDA have advocated the following:

- 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. As noted in response to Question 1,

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Congress also should explore ways to leverage information developed 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.
- Provide Adequate Use, Exposure and Toxicity Information. EPA should work with chemical manufacturers and users to ensure that EPA has timely and adequate information of chemical hazards, exposures and uses, including uses in children's products.

**14. Some interests have argued that States should be free to do whatever they want on chemicals management laws? Do you believe that harmonization of state laws under one Federal law is essential to prevent a patchwork of state laws? Can you legitimately manufacture products for multiple state markets based on their disparate laws?**

A uniform federal standard for chemical management is preferable to a patchwork quilt of state laws and policies. A robust chemicals management law will provide state policymakers and consumers with a strengthened confidence in chemicals management. Provisions that directly regulate substances and products wherever they are marketed must allow industry to operate efficiently. The burdens are real and substantial if companies must meet differing, even sometimes conflicting, state law provisions. Policymakers should take steps to leverage information from the chemical management programs undertaken by other nations and to integrate the patchwork quilt of laws governing chemical management. If the pattern of individual state actions continues, in the future it may actually become easier to move products among the countries of Europe than among the U.S. states.

**The Honorable Cliff Stearns**

**1. Do you believe the U.S. should move toward a purely European approach to regulating chemicals, such as what the Europeans are doing with their REACH initiative?**

Please refer to the response provided in Question 1, *supra*.

**2. It is my understanding that under REACH, the EU is being inundated with information about chemicals and they may have to suspend the program in order to get caught up. Is that correct?**

We have heard European regulators publicly express concern about their ability to manage all of the registrations and about the ability of industry to meet the deadlines. It is the

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understanding of CSPA, GMA and SDA that European regulators will not suspend the program. The nature of the European system is such that if the system was to become overwhelmed, there is implied authority to defer enforcement.

- 3. As the Republican Co-Chair of the Transatlantic Legislators Dialogue, I have had to press my European counterparts to ensure that U.S. Cosmetics – a \$2 billion industry – were not taken off shelves in Europe due to the overly burdensome REACH requirements. Is this the direction you would like to see the U.S. go in?**

CSPA, GMA and SDA believe that chemical regulation should not create unjustified technical barriers to trade.



13 January 2010

Mr. Earley Green  
Chief Clerk  
Rayburn House Office Building Room 2125  
Washington, D.C. 20515

Dear Mr. Green:

On behalf of the Society of Chemical Manufacturers and Affiliates (SOCMA), I am writing in response to a letter from Chairman Henry A. Waxman regarding questions I was asked to answer for the record following the November 17, 2009 US House Energy & Commerce Subcommittee Hearing entitled "Prioritizing Chemicals for Safety Determination".

Enclosed are my responses to the questions. Should you or any Committee members have any questions, please contact either Dan Newton, Government Relations Manager at SOCMA, at (202) 721-4158 or [newtond@socma.com](mailto:newtond@socma.com), or me at (724) 612-5766 or [beth\\_bosley@chmx.com](mailto:beth_bosley@chmx.com).

Best regards,

A handwritten signature in cursive script, appearing to read "Beth Bosley".

Beth Bosley  
BORON SPECIALTIES, LLC  
Managing Director  
[beth\\_bosley@chmx.com](mailto:beth_bosley@chmx.com)

Enclosures (1)

**Enclosure: Answers to Written Questions for the Record Following the November 17, 2009 House Subcommittee Hearing Entitled "Prioritizing Chemicals for Safety Determination"**

**The Honorable George Radanovich**

1. Mr. Ditz believes that all chemicals need to be characterized. Your testimony, if I understand it correctly, is quite different. Why should some chemicals be given higher priority than others? Why shouldn't all chemicals be treated the same?

Before any characterization effort, I believe that establishing a correct and complete inventory of the chemicals in commerce is essential. EPA's estimate, based on its collection of Inventory Update data, is that approximately 20,000 chemicals are actually in commerce (rather than the 80,000 that are currently on the TSCA inventory). After such an inventory reset, the universe of chemicals will be more manageable. Chemical substances in commerce should then be prioritized based on risk. Those substances that present the highest risk (taking into account both hazard *and* exposure characteristics) should be given the highest priority for review, characterization, and evaluation. It would be a misallocation of EPA's and industry's limited resources to require them to develop and analyze data for chemicals where the risk to public health and the environment is low.

2. How does the innovation and competitiveness of the United States' chemical industry compare with other countries?

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

Additionally, chemical science innovation, as an enabling technology, benefits many US industries – aerospace, advanced materials, agriculture, pharmaceuticals, electronics, and telecommunications (among many others) – making these industries better able to compete in the increasingly global marketplace. Without such US-based innovations, advances such as light-weight transportation components (a major factor in increasing fuel economy), low-emission paint (resulting in a safer consumer environment), and detergents that work in cold water (resulting in lower energy usage) would not be available in the marketplace today.

However, the US chemical industry's competitiveness has decreased substantially in recent years due to competition from countries with a less burdensome regulatory environment and lower wage standards. Shifting production to these developing countries does not make US citizens safer – we need only read the headlines regarding lead in children's toys and sulfides in foreign manufactured drywall to find examples where offshore manufacturing has increased risk to US individuals and decreased public confidence. Of course we need protective chemical regulation, but it needs to be as smart as we can make it, so that we minimize damage to U.S. industry's competitiveness.



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3. Some of our colleagues would like to see a greater use of biomonitoring data in regulation. A July 25, 2006 report from the National Academy of Sciences (NAS) National Research Council (NRC) Committee on Human Biomonitoring for Environmental Toxicants entitled: "Human Biomonitoring for Environmental Chemicals", as well as the testimony of Dr. Sampson cautioned about the limitations in evaluating how a chemical measured in a population may cause a health risk, if it causes a health risk at all, or the very sources and pathways for exposure. If, as the NAS report stated, that all biomonitoring data are not equal, should Congress be concerned about an overreliance on biomonitoring to accomplish cogen chemicals regulation? How should TSCA, or an amended version of TSCA, look to biomonitoring to better understand exposures to chemicals? Do you believe that standardized guidelines supporting good laboratory practices are important to ensure high quality results?

Biomonitoring has become a useful tool in establishing the presence of chemical substances in human populations. As Dr. Sampson frankly recognized, however, "biomonitoring is far ahead of the science of interpreting what exposures mean for health." Coordinated sampling strategies and methods, as well as data interpretation guidelines, are missing at present. For these reasons, Congress should not place disproportionate weight on biomonitoring data. Developing standards and guidance addressing the sampling, reporting, and interpretative aspects of biomonitoring is an important prior step in developing a sound strategy to use the data generated.

Once guidelines are in place and well understood, biomonitoring data can be used as one element of the exposure question to inform the priority setting task.

4. How might EPA better fill data gaps? Does EPA need more authority to fill these gaps?

EPA currently has broad authority under TSCA Section 4 [specifically section 4(a)(1)(B)] that allows the agency to mandate testing on existing chemicals that present an exposure hazard. This section does not require that EPA make an "unreasonable risk" finding. Section 4(a)(1)(A) still allows EPA to mandate testing when they believe a chemical presents an unreasonable risk.

Additionally, voluntary programs are always an option for data collection. EPA gathered a massive amount of data through the voluntary HPV program. EPA has reviewed the data and knows what gaps remain. Many critics will state that voluntary programs have not been successful, pointing to the fact that there have been few test rules issued. Manufacturers fully expected test rules designed to fill the data gaps that EPA has identified. To date, we have seen one final and one proposed test rule. Since EPA has full authority to issue these test rules, I can only assume that lack of resources at EPA has prevented more timely action. The lack of test rules therefore, is not a failure of the voluntary program.

Currently, manufacturers, importers, and processors are required to update EPA with data on *adverse* health effects under TSCA section 8(e). This reporting requirement is comprehensive, with no exemption for research and development substances or polymers. EPA considers an 8(e) report to be an early warning mechanism for adverse effects. However, when a manufacturer receives information that indicates a substance presents a lower risk than previously thought, there is no mechanism to report this finding to EPA.

Reasonable amendments to TSCA would enable EPA to poll manufacturers, importers and users for data on volume, adverse and non-adverse health and environmental data, and exposure



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characteristics. But, as noted above, EPA should seek this data on chemicals that are higher priorities, based on risk.

5. Does SOCMA consider it a wise move for EPA to have dumped CHAMP? What are the repercussions of such a move?

We do not consider the abandonment of ChAMP (Chemical Assessment and Management Program) to have been a wise decision. ChAMP was designed to broaden EPA's ability to ensure the safety of existing chemicals. According to EPA's assessment, ChAMP would have placed the US far ahead of other countries with respect to chemical evaluation. During the GlobalChem Chemical Regulations Conference in 2008, EPA personnel explained the ChAMP timeline, which stated that by the year 2012, all organic chemicals would have undergone categorization and risk assessment; follow-up action would have been initiated on those chemicals for which data was inadequate. ChAMP's first step, the inventory reset, was to have begun in 2010.

Without ChAMP, and no other defined program to take its place, it is not clear how long a revised chemicals management program will take to implement. At this point, in the absence of ChAMP, there is no comprehensive or cohesive program in place with defined milestones or regulatory goals.

6. Some people have suggested that EPA needs specific data from industry. Your testimony suggests that EPA has plenty of information about chemicals, through structural data (similarities between chemicals). Could you please explain this point?

Through the new chemicals program, EPA reviews approximately 2000 new chemicals per year. Under TSCA Section 5, EPA has authority to compel Pre-manufacture Notice (PMN) submitters to provide additional data, either voluntarily or via administrative order. A PMN must be submitted very early in a product's life cycle (before the first commercial pound is manufactured). At that phase of product development, while the manufacturer hopes the product will be a commercial success, they have not produced material in commercial equipment, they don't have an established market, and the predicted total sales volume is only a rough estimate. Success of new products often relies upon the success of our customers or even their customers' products.

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

The fact that limited data is available during the PMN process does not mean that the manufacturer has stopped testing or that they are selling products with inadequate health and safety data.

EPA recognizes that, at the PMN stage, detailed information may not yet be available, and has therefore pioneered efforts using modeling software and structure-activity relationships (SARs)



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to help inform agency decisions. EPA's EPISuite™ software contains 17 individual models that estimate environmental fate, aquatic toxicity, biodegradability, and other attributes that predict the effect of chemicals on human health and the environment. One of these tools is ECOSAR™, which is a tool utilizing SARs to predict the behavior of chemicals with limited test data, based on chemicals with structural similarity for which detailed test data is available. The scientists and engineers at EPA are extremely knowledgeable and, in the absence of test data, make decisions on regulation of chemicals based on extremely conservative interpretations of the data from their models.

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

7. Are there existing authorities under TSCA that you feel EPA is not using to the fullest extent? Are there other authorities that are being used fully?

EPA's authority under TSCA sections 4 and 8 is not used to its fullest extent. These sections allow EPA to determine where data on specific chemicals is lacking (section 8(a)) and to issue test rules (section 4) to fill the data gaps.

TSCA section 8(a) authorizes EPA to require that industry report on a variety of information that EPA may reasonably require. Examples of information that may be gathered include data on volume manufactured or imported, use category, and health and environmental effects. The Inventory Update Rule (IUR) is an example of a TSCA 8(a) reporting requirement, but this section could be used to more fully identify perceived data gaps.

Through TSCA section 4, EPA has the authority to issue test rules on chemical substances. EPA has made limited use of its test rule authority, issuing roughly 50 final rules since 1984.

Also, EPA and critics of TSCA both underestimate the authority EPA has under section 6 to restrict uses of chemicals that pose unreasonable risks. EPA lost in the notorious *Corrosion Proof Fittings* case (*Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (5<sup>th</sup> Cir. 1991)) not because Section 6 is inadequate, but because EPA did not follow the statute's requirements or engage in reasoned decisionmaking.

8. Do you agree that creating a list of chemicals for which to establish action plans will unnecessarily create a blacklist on their manufacture and use simply by having them on such a list, even if they have safe uses?

Creating a list of chemicals will undoubtedly limit the use of such chemicals, and likely will create unnecessary disruption in the chain of commerce. Such an effort also discourages research on new applications of existing chemicals. Certain chemicals that might be considered for such action could have valuable, low or no-exposure uses, some of which, for example, may be vital to our national interest. Creating such a list without taking into account critical uses and the viability of substitutes may have substantial unforeseen consequences. For the US to continue to be a leader in innovation (and maintain this competitive edge), the creation of lists should be discouraged. However, if pursued, such lists should be established in a fashion that (i)



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is transparent, allowing for stakeholder input in their development; and (ii) uses a consistent, risk-based approach for listing decisions.

9. If you create a list of chemicals for action plans, don't you believe that it automatically will preclude any possible safe uses currently known?

Yes. Uses of chemicals must be taken into account before any such lists are created and disseminated. It is important to view an effort to create lists in the context of risk. While some uses of a chemical may present a risk, others may not. Some uses may be safe and others may not. The creation of a list in general discourages the use of existing chemicals. In addition, creation of lists tends to inhibit the development of new, possibly safe, uses that are not presently known. There are many competing lists, moreover. For a list to be considered credible, it should be developed transparently, through stakeholder dialogue, and be systematic and risk-based.

10. Are EPA's programs to regulate chemicals founded on the notion that companies, not EPA, must bear the burden of testing their chemicals and satisfying EPA's concerns, if any, about their safety? Have companies always supplied the data on which EPA relies to evaluate the effects of their chemicals? Does EPA have the wherewithal to perform these tests on its own?

EPA currently has the authority to regulate chemical substances based upon current or updated knowledge. This is clearly shown by EPA's having developed extensive modeling techniques that did not exist at the time TSCA was enacted. These models have been developed based upon new information, made known to the agency through PMN's, Section 8(e) notification filed by companies, collaborative efforts with academics, collaborative efforts with other governmental authorities (US and abroad), or through the use of publically available information in the scientific literature. When EPA requires more information for a risk assessment, it has the authority to require testing from industry.

EPA also engages in testing and evaluation of certain chemical substances on its own. A recent example is the testing EPA is undertaking on certain nanomaterials (titanium dioxide, carbon nanotubes, silver, and others).

#### **The Honorable Cliff Stearns**

1. Do you believe the U.S. should move toward a purely European approach to regulating chemicals, such as what the Europeans are doing with their REACH initiative?

No, the REACH system is an overly burdensome regulation that, by most estimations, will cost jobs within the EU. REACH is fundamentally flawed in that there was no risk prioritization prior to the commencement of the initiative. Therefore, a low risk chemical (for instance, one that may exhibit some hazard, but very low probably of exposure) that is produced or imported at a volume 25,000-lb-per-year will be screened with the same priority as a high risk chemical (for example, one that is used in consumer products) that is manufactured or imported at the same volume threshold.



In contrast to the approach adopted by the EU under REACH, Canada, through its use of a Categorization and Prioritization process, was able to demonstrate that over 80% of the chemicals in commerce in Canada did not present an unreasonable risk to human health and the environment. This approach allowed them to then systematically assign to the remaining chemical substances a priority for more in depth review by Environment Canada and Health Canada

2. It is my understanding that under REACH, the EU is being inundated with information about chemicals and they may have to suspend the program in order to get caught up. Is that correct?

The European Chemicals Agency (ECHA) received many more pre-registrations than it expected during the recent pre-registration period. The electronic reporting system lacked the capacity to process these pre-registrations, causing significant electronic data issues and delays. For a time, the electronic reporting pre-registration process was suspended. It is unclear at this time how the system will respond to the data that will be generated in the next phase.

3. As the Republican Co-Chair of the Transatlantic Legislators Dialogue, I have had to press my European counterparts to ensure that U.S. cosmetics – a \$2 billion industry – were not taken off shelves in Europe due to the overly burdensome REACH requirements. Is this the direction you would like to see the U.S. go in?

No, the chemical industry, which contributes 2% to the US GDP and is responsible for approximately 10% of all US exports has already shed roughly a quarter million jobs in the past twenty years. This decline in high-paying jobs, along with the decreased tax revenue that accompanies downsized operations, would only worsen if a REACH-type system were implemented in the US. While we support a sustainable chemicals management policy, an overly burdensome system of regulation will significantly impact the cost of operations and result in a further weakening of an industry that is vital to the national interest.

Through the efforts of NGO's, industry and other governments, the EU modified the requirements under REACH to largely exclude the ingredients in cosmetics from the onerous requirements of REACH. All of the ingredients in cosmetics are covered by the Cosmetic Regulation. These same chemical substances are still covered completely under REACH when used in non-cosmetic uses.



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