THE TOXIC SUBSTANCES CONTROL ACT AND PERSISTENT, BIOACCUMULATIVE, AND TOXIC CHEMICALS: EXAMINING DOMESTIC AND INTERNATIONAL ACTIONS

HEARING

BEFORE THE

SUBCOMMITTEE ON COMMERCE, TRADE, AND CONSUMER PROTECTION

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

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THE TOXIC SUBSTANCES CONTROL ACT AND PERSISTENT, BIOACCUMULATIVE, AND TOXIC CHEMICALS: EXAMINING DOMESTIC AND INTERNATIONAL ACTIONS

THURSDAY, MARCH 4, 2010

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

The Subcommittee met, pursuant to call, at 10:16 a.m., in Room 2322 of the Rayburn House Office Building, Hon. Bobby L. Rush [Chairman of the Subcommittee] presiding.

Members present: Representatives Rush, Schakowsky, Sarbanes, Sutton, Green, Barrow, DeGette, Dingell, Whitfield, Radanovich, Pitts, Gingrey, Scalise, and Barton (ex officio).

Staff present: Michelle Ash, Chief Counsel; Rebecca Brown, EPA Fellow; Will Cusey, Special Assistant; Daniel Hekier, Intern; Angelle Kwemo, Counsel; Timothy Robinson, Counsel; Lindsay Vidal, Special Assistant; Jerry Couri, Minority Senior Professional Staff; Sam Costello, Minority Legislative Analyst; Shannon Weinberg, Minority Counsel; Brian McCullough, Minority Senior Professional Staff; Robert Frisby, Minority FTC Detailee; and Will Carty, Minority Professional Staff.

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

Mr. RUSH. The hearing is called to order. This hearing is called for the purpose of discussing the matter of TSCA and the hearing is entitled the Toxic Substances Control Act and Persistent, Bio-Accumulative, and Toxic Chemicals: Examining Domestic and International Actions, and the chair recognizes himself for 5 minutes.

I want to welcome all of you who are here this morning to participate in today's hearing on the Toxic Substances Control Act and specific efforts that have been, or need to be, taken to protect public health, and the environment, from a diverse array of toxic substances.

Our focus today is on a special group of chemicals known as PBTs that pose unique risks to human health and environment safety. Even at a very low exposure and concentration levels in our communities, our homes, our workplaces and the environment, PBTs have been linked to adverse health effects in humans and in animals. Some of the effects include cancers, and some include ge-

netic mutations, and some include the disruption of normal biological, neurological and hormonal functions of our bodies.

Examples of commonly known PBTs include unwanted wastes like mercury and dioxins. The list also includes pesticides like DDT and HCB. DDT, as most of you know, is a well-known synthetic pesticide. Also included in this list of potential toxins is HCB or hexachlorobenzene and other industrial chemicals, such as PCBs and heavy metal including cadmium, and mercury and lead.

The way I understand PBTs is to think of them in the following way, and generally speaking the P, or persistence, relates to environmental safety. Persistent pollutants or toxins are not biodegradable. That means that these chemicals do not break down easily in the environment. You can think of them in the way you think of—I like to think of them as unwelcome house guests who don't know when it is time to leave.

The B stands for bioaccumulative or bioaccumulation and it relates to human health and to the environment. Following their release into the environment, some of these substances concentrate in rising proportions in soils, sediments, water and in the air. Over time, these concentration levels rise continually within, and to the top of, the human food chain.

And the T, which stands for toxic or toxins, relates to human health. Toxic substances lead to adverse health effects, such as the ones I described earlier.

What is also important to remember is that these are not mutually exclusive categories. While it can be presumed that a chemical substance which displays all three characteristics is especially harmful, a chemical substance or a mixture can display just one of the three characteristics, that is, it can be persistent, bioaccumulative or toxic to human health. These substances are capable of traveling great distances on air or in oceanic currents.

Last year, I had the honor of receiving a delegation of indigenous peoples from the Savoonga and Gambell nations. These representatives were from two member tribes of the National Congress of American Indians. They told my staff of serious public health issues they are experiencing as a result of pollutants, particularly legacy chemicals such as PBDEs [polybromodiphenyl ethers] and PFCs [perflourinated compounds], that have blown and crested onto St. John's Island.

At our last hearing on TSCA in November, 2009, we discussed the need for including a prioritizing scheme in our soon-to-be-introduced bill, which will make critical reforms to the existing 33-year-old statute. Under this scheme, the Environmental Protection Agency's chemical risk and safety assessment responsibilities would be radically streamlined. With this new authority, the EPA will be able to take much swifter action to reduce the volume of especially threatening substances that are already in the commercial stream, that are in our bodies, and that are in our food and water sources.

I am pleased to welcome all six of our witnesses to this subcommittee this morning. The common thread through all of their testimonies is, obviously, PBTs. Today, each one of them will talk about the PBT problem and how to go about addressing it from their perspectives as government regulators, policy makers, public

interest and health advocates, and from the perspective of the industry. Each of these witnesses is prepared to testify and answer questions about PTC regulation and remediation by assessing the regulatory lay of the land, and meaning that the State and Federal levels are of concern to them and, of course, the impact of these chemicals on our planet. We have got just this one planet here and we got to be concerned about it, and we got to protect it, and we got to make sure that it will be around for a long, long, long time. It is a gift to us and we have got our responsibility to be able to pass it on a healthy path to generations to come.

And I want to thank you and I yield back the balance of my time.

And now I will recognize the ranking member from this subcommittee, my friend, the gentleman from Kentucky, Mr. Whitfield, for 5 minutes.

OPENING STATEMENT OF HON. ED WHITFIELD, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF KENTUCKY

Mr. WHITFIELD. Chairman Rush, thank you very much for holding this hearing on the Toxic Substances Control Act.

Today we will explore what many believe are the most generous chemicals, PBTs. These are chemicals and substances that are long-lasting and can build up in the food chain to levels that present threats to humans and the environment. We must take steps, obviously, the ensure Americans and the environment are as safe from these hazardous chemicals as possible but I also firmly believe that high-quality science, that is science that is measurable, reliable, relevant and that can be reproduced should lead the way for whatever reforms this Congress makes to current law.

Mr. Chairman, I understand that at some point it is your intention to move legislation to reform TSCA. I am pleased that you are going to do that and I hope that we on this side of the aisle have an opportunity to work with you and your staff as you write this legislation.

With that said, it is my hope that any action we do take does not have adverse consequences similar to those that the toy bill has had. We need to recognize the nuances of the science and give importance to exposure and risk data, not just hazards.

When this committee applied a precautionary ethos to the Consumer Product Safety Improvement Act, we closed down many small businesses because they simply cannot meet the requirements that we insisted upon. And I might also mention that in an op-ed piece in the Wall Street Journal this past Christmas season, a former colleague of ours now a commissioner at the CPSC, Consumer Protection, said that the new law reduced the Consumer Product Safety Commission's longstanding discretion to act in response to genuine risks, substituting instead the rigid broad brush and unscientific judgment of Congress. As we have seen, good intentions do not always lead to good results and I will simply urge that we continue to heed the lessons learned from the particular law.

I do look forward to hearing today from our witnesses, all of who are experts in their field, as we try to delineate between organic and inorganic PBTs, as we look at how widespread and effective

are the States that are working in this area. And then, of course, I think it is imperative that we also explore our international leadership and the fact that a number of important treaties that we are signatories have not been affirmed or confirmed by the U.S. Senate.

Mr. Chairman, while it has been over 3 decades since this law has been reformed, I again would like to stress the importance that we examine the issues carefully before we make sweeping changes that could adversely impact commerce, innovation and, of course, public and environmental health. We approach this subject with the very best of intentions and particularly in today's economic downturn I think that it is particularly important that we be mindful of the impact that any actions we may take on the job market.

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

Mr. RUSH. The chair now recognizes my friend, my colleague from Illinois, the vice chairman of the subcommittee, Ms. Schakowsky for 2 minutes for the purposes of opening statements.

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

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

This is the third we have held in the 111th Congress on the Toxic Substances Control Act and I look forward to working with you and Chairman Waxman on reforming the law so that it protects our community from harmful products, from harmful pollutants. When Congress passed TSCA, it's intention was to give EPA the tools it needed to protect the public from exposure to toxic chemicals that cause serious harm, however, more than 30 years later, as has already been stated, the scientific evidence is overwhelming that chemicals continue to persist in our environment, are a significant contributor to the problems of many diseases. Leukemia, brain cancer, other childhood cancers have increased by 20 percent since TSCA became law. We know for certain that exposure to substances like asbestos and mercury and many others pose lethal or catastrophic results. What these startling facts tell us is that TSCA in its current form is completely incapable of protecting the public and that it is imperative for Congress to amend the law so that it can safeguard the American people from exposure to lethal chemicals.

Today we hear from our witnesses about a specific subset of chemicals that meet the criteria for being labeled as persistent, bioaccumulative and toxic, PBTs, and I appreciate them. I appreciate our witnesses for being here today to shed light on these especially devastating chemicals and, again, Mr. Chairman, I thank you for holding the hearing.

And I yield back the balance of my time.

Mr. RUSH. The chair now recognizes the ranking member of the full committee and the gentleman from Texas, Mr. Barton, for 5 minutes.

OPENING STATEMENT OF HON. JOE BARTON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. BARTON. We thank you, Chairman Rush.

Before I give my opening statement, I want to say some words about our newest ranking member of this subcommittee, my good friend from Kentucky, Mr. Whitfield. I specifically asked him to take over for Congressman Radanovich because of Mr. Radanovich's situation with the death of his wife and the requirements that he take care of his young son. He didn't have the capability or the time to give the ranking membership his full attention and I understand that.

I specifically asked Mr. Whitfield to take on the duties of this subcommittee's ranking membership because it is my expectation, Mr. Chairman, that at some point in time you and Chairman Waxman intend to move legislation reforming TSCA, and I wanted my very best, senior, experienced person at the helm and that is Ed Whitfield. He has worked in both the majority and the minority on this subcommittee and he knows the issues well. He knows also the personalities well and he has the confidence of both sides of the aisle so it was not serendipity that Ed Whitfield got asked to take this ranking membership and I think it speaks to his capabilities that he has already hit the ground running.

I might also say, Mr. Chairman, that this is an important hearing and I think if you just look out in the audience you see former general counsels for the committee, and chiefs of staff for the committee and they don't come cheap, Mr. Chairman. They are here because this is a big deal and it is an important deal and it speaks to your leadership that you are taking this complex subject.

On the issue at hand, we understand that PBTs are extremely toxic and can be hazardous. We understand that they need to be regulated closely and monitored continuously.

We do have a witness from the Pellston Working Group here that has done some groundbreaking research and if their research is correct, Mr. Chairman, there is a possibility that we can adopt a more flexible regulatory approach based on not only the definition of what is hazardous but what the risk is of that hazard. So I am looking forward to their testimony, plus obviously the testimony of the other witnesses here.

Congress does not normally do complex, technical issues well. As Mr. Whitfield has pointed out, in the Consumer Protection Act reauthorization last year, I don't think it was intentional but we adopted a regulatory approach for lead which is basically zero tolerance and because of that there are many products that are no longer on the marketplace today that really didn't have any potential harm to the population. So in this case, I hope that we do listen to our panels and we do work together in a bipartisan fashion to move a bill if that is the wish of the chairman and yourself, Mr. Chairman at the subcommittee level, that encompasses the latest science, the latest data and so that we get this one right.

And with that, Mr. Chairman, I yield back.

[The prepared statement of Mr. Barton follows:]

Statement of the Honorable Joe Barton
Hearing on "TSCA and Persistent, Bioaccumulative, and Toxic Chemicals"
Subcommittee on Commerce, Trade, and Consumer Protection
March 4, 2010

Mr. Chairman, thank you for calling today's hearing on the topic of Persistent, Bioaccumulative, and Toxic chemicals.

Before I get to my remarks on the subject of this hearing, and because this is the first hearing held exclusively by this subcommittee, I want to congratulate our newest Ranking Member to this subcommittee, Ed Whitfield of Kentucky. Mr. Whitfield is no stranger to the jurisdiction of this subcommittee as he previously served as our Ranking Member and he will do an outstanding job again.

Concerning the subject of the hearing, I look forward to the testimony of our witnesses today on this subject. We all know that PBTs are toxic, long-lasting chemical substances and mixtures that can build up in the food chain to levels that are harmful to human health and the ecosystem.. Some have associated exposure to PBTs with a range of adverse human health effects, including effects on the nervous system and reproductive system of those exposed entities.

Protecting the public from the real risks concerning PBTs should be our fundamental goal and we should rely on science that is measurable, repeatable, reliable, and relevant in order to do so. In this hearing, we should endeavor to clearly define what a PBT is, based upon sound screening and evaluations, rather than simplistic notions. We also need to know just how many PBTs are out there in commerce and whether new PBTs are being produced and, if so, whether they are occurring at high volumes.

I am aware that a distinguished panel of scientists, known as the Pellston workshop, recently concluded that an evolution of science has produced new insights into persistence, bioaccumulation, and toxicity of chemical substances, and provided an array of new methods to identify PBT chemicals. Importantly, Pellston workshop findings argue that the appearance of a PBT in the environmental is not enough to warrant regulation, but rather, body or tissue residues showing a direct causal link to adverse responses are necessary to justify regulatory management.

I agree with this assessment and that is why I have a hard time supporting a rigid, PBT criteria to all chemical substances. We need to recognize the nuances of the science and treat exposure and risk data importantly. This committee got itself into a lot of hot water in the last Congress when it applied an overly precautionary ethos to the Consumer Product Safety Improvement Act. We have small businesses that are shutting their doors based upon well-intentioned, but badly constructed law. As we heard at the endocrine hearing last week, decisions based on incomplete or low-quality science can have serious negative effects for everyone.

I also hope that we can have a robust discussion today about the difference between organic and inorganic PBTs. There is a clear difference in these substances, and even the Europeans have recognized this value.

I also understand states are taking actions and I want to know how a coordinated Federal effort is either helped or hurt by these actions – not

to mention what it means for international efforts by the Executive Branch.

Finally, I understand that some PBTs, because they are organic, have the ability to travel long distances. These PBT's, also called Persistent Organic Pollutants or POPs, are the subject of the Stockholm Convention and the Arhus Protocol on long range air pollution caused by POPs. The U.S. is a signatory to these agreements, but is not a full party. The EPA and the State Department may push for implementing legislation,, but I am curious whether the Obama Administration will push the U.S. Senate to ratify these agreements.

Mr. Chairman, again, I look forward to the testimony of our witnesses and appreciate your indulgence.

Mr. RUSH. The chair thanks the ranking member.

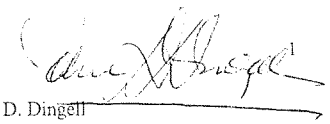
The chair is proud now to introduce the gentleman from Michigan, the chairman emeritus for the entire committee, who has provided leadership for this committee and on this particular issue for many years, and he should have been introduced earlier but somehow the chairman did not see him over there which is attributed to my bad eyesight. And so now the chair recognizes Mr. Dingell for 5 minutes for opening statements.

Mr. DINGELL. Thank you, Mr. Chairman.

First, I want to express my gratitude to you for your kind words and second, I would like to observe this meeting and this hearing as very, very important and useful. And I know under your leadership, we will begin a process of reviewing carefully TSCA of what it is doing, what it is not doing, how the changes of technology and other things over the past years, some 30 of which have passed since we have done this legislation in the first place, and how those things have changed the circumstances. We are also going to need to know what changes we have to make in the legislation and it is my hope that these things will be done carefully under your leadership, and I know that you will do this wisely and I think that the information to be achieved will be very valuable.

Mr. Chairman, with that I ask unanimous consent to revise and extend my remarks and I thank you for your courtesy.

[The prepared statement of Mr. Dingell follows:]



Statement of Representative John D. Dingell
Chairman Emeritus, House Committee on Energy and Commerce
Subcommittee on Commerce, Trade, and Consumer Protection
"TSCA and Persistent, Bioaccumulative, and Toxic Chemicals: Examining Domestic and International Actions"
March 4, 2010

Mr. Chairman – thank you for holding this hearing today. After 33 years, it has become blatantly clear TSCA needs a thorough examination and reauthorization. We have heard this from industry, environmental groups and consumer advocacy organizations. Indeed, EPA has not banned a single chemical under TSCA in nearly 20 years. Despite our best intentions back in 1976, TSCA is not working as we had hoped it would when it was enacted.

Today we are here to discuss Persistent Bioaccumulative and Toxic chemicals (PBTs) – chemicals with all three characteristics are considered particularly harmful. I have a particular interest in PBTs since I come from the Great Lakes state.

Because of their nature, PBTs have also been the subject of international agreements – the PIC Convention, the Convention on Long Range Transboundary Air Pollutants, and the 2001 Stockholm Convention.

It is clear that PBTs are a unique category of toxics and they require special consideration both internationally and domestically. I look forward to hearing from the witnesses on this point.

Again, Mr. Chairman, I want to thank you for the deliberate and thoughtful approach the Subcommittee is taking on this matter. It is important address TSCA the right way in order to not only get the desired result of a more workable law that protects human health, but also ensure that we do needlessly inflict financial burdens producers in this extremely difficult economic climate.

Mr. RUSH. The chair now recognizes the gentleman from Pennsylvania, Mr. Pitts, for 2 minutes.

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 the Toxic Substance Control Act and the subset of chemicals that meet the criteria for being labeled as persistent, bioaccumulative and toxic.

PBTs are considered to be particularly harmful because they are long-lasting chemical substances and mixtures that can build up in the food chain to levels that are harmful to human and ecosystem health. PBTs can transfer easily and linger for a long time in people and the environment, and they are associated with adverse human health effects.

We should take this subject very seriously. None of us want these substances negatively impacting humans or the environment however we must prudently go about regulating these chemicals. There are some that argue that the appearance of a PBT in the environment is not enough to warrant regulation but rather body or tissue residues showing a direct causal link to adverse responses are necessary to justify regulatory management.

Additionally, some experts make a case that regulatory action should be based on complete information in order to avoid negative, unintended consequences. For example, PBT screening criteria assesses only hazard and not risk. Something may be hazardous and not pose a risk if its exposure is controlled and hazard assessment only provides information on the properties of the substance not the likelihood of the facts. This is comparable to problems that have resulted from taking a similar approach to lead contents limits in the Consumer Product Safety Improvement Act which has led to the elimination of products that have not demonstrated a risk of lead poisoning.

Our committee should move forward with this example in mind. Yet I urge us to continue to place safety as the highest goal.

I appreciate the witnesses being here today. I look forward to listening to your testimony.

I thank you and I yield back.

Mr. RUSH. The chair now recognizes the gentleman from Georgia. He is no longer here.

The chair recognizes the gentlelady from Colorado, a leading voice on these and other matters, 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.

Mr. Chairman, ever since Rachel Carson's landmark book, Silent Spring, we have known the dangers of chemicals like DDT that persist in the environment, bioaccumulate and are highly toxic. When these chemicals move up the food chain, they increase in concentration and their effects can linger for decades. So as the species at the very top of the food chain, this should worry us. DDT

was banned in 1972 but its effects are felt today. Now, DDT is a pesticide covered under FIFRA that many harmful PBT chemicals are covered under the much weaker regime of TSCA.

One of those chemicals is mercury. In 2004, my State of Colorado initiated a 5-year study to assess the levels of mercury in fish in the State. Two lakes just outside of Denver were found to have fish with high levels of mercury and local residents are now advised not to eat fish from these lakes. Colorado's lakes are not unique, unfortunately and it just shows why TSCA reform is badly needed. TSCA was enacted over 30 years ago and it is our only major environmental law that has not been reauthorized.

Now, one of the most important considerations in TSCA reform as some of my colleagues on the other side of the aisle have mentioned this is how to characterize the risk posed by various chemicals. Focusing on those chemicals that persist in the environment and are highly toxic make sense and I want to point out also, I agree 100 percent with Mr. Whitfield and others who say that we should use science as the basis of our consideration as we look towards reauthorizing this bill. And I will also point out to our credit in this committee, when we reauthorized the Consumer Product Safety Act last year, we may have had some issues with lead and other substances but due to some very good conversations with me and others on this committee, we worked out what to do with phthalates in a bipartisan way and also in a bicameral way that is science-based and that we were all very pleased with. So, Mr. Chairman, I look forward to working with you and everyone on this committee to make sure that not just we are safe from these PBT chemicals but that our grandchildren are also safe as these chemicals move up the food chain.

Mr. RUSH. The chair recognizes the gentleman from Louisiana, Mr. Scalise, for 2 minutes.

OPENING STATEMENT OF HON. STEVE SCALISE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF LOUISIANA

Mr. SCALISE. Thank you, Mr. Chairman and Ranking Member Whitfield, for having this hearing today. I also want to thank our witnesses for taking the time to be with us.

I believe we can all agree that the issue of persistent, bioaccumulative and toxic chemicals, otherwise known as PBTs, is an important one that we must continue to examine. I am pleased that this subcommittee is once again taking up the issue of toxic substances and the laws governing their use in commerce.

The use and regulation of toxic substances and of chemicals in general is an issue that we all must take very seriously. First, because of the effects certain chemicals can have on our health and the environment. I know from hearing from the statements of my colleagues made today that they share these concerns but we also want to make sure that the chemicals that are produced, used and imported into our country are safe. But this issue is also important to be because of the chemical industry's presence in my home State of Louisiana and because of its importance to our national economy.

According to the American Chemistry Council, over 96 percent of all manufactured goods are directly touched by the business of chemistry, making this industry a vital part of every aspect of our economy. In Louisiana, the chemical industry directly employs over 22,000 people and for every chemistry industry job in Louisiana, an additional 4.5 jobs are created in our State, and one thing that must be pointed out is this chemical industry, these jobs are high-paying. The average wage of a chemistry industry employee in Louisiana is over $82,000, which is 53 percent higher than the average manufacturing wage in the State. During these tough economic times, these are the kind of jobs we need to be creating more of.

As this committee continues to consider legislation, we must make our decisions based on real science that is measurable, reliable and reproducible. We must also consider the unintended consequences of actions that might well be well-intentioned but don't fix the problems yet produce devastating consequences as was the case in the last Congress when changes to the Consumer Product Safety Improvement Act shut down small businesses in America.

Again, it is clear that there are harmful chemicals like PBTs out there that can have harmful effects if not used properly, and the proper safeguards need to be put in place, and we know that the EPA has been taking steps to ensure that is the case. I think the key finding is the appropriate balance between protecting our health and environment, and protecting a vital sector of our economy and the jobs in this industry. I believe these goals are not mutually exclusive.

I look forward to hearing from our panelists today on actions that have been taken in other States and other countries to put protections in place. And I am interested in our panelists' thoughts on the use of exposure and risk data, things that in my opinion should be based on sound science and should be used along with data on the hazards that chemicals may pose.

Thank you, Mr. Chairman, and I yield back.

Mr. RUSH. Mr. Barrow is recognized for 2 minutes. The chair thanks the gentleman.

Mr. Green is recognized for 2 minutes.

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

Mr. GREEN. Thank you, Mr. Chairman, for holding this hearing on continued looking at the modernization of the Toxic Substance Control Act. I also want to welcome and congratulate our new ranking member, Congressman Whitfield, and look forward to working with him as we move forward on TSCA modernization and other matters before the subcommittee.

The issue we are looking at today, persistent, bioaccumulative and toxic chemicals, or PBTs, are widely agreed to be a small but potentially dangerous class of chemicals. Their ability to build up in the food chain and persist over long periods of time pose a significant danger to human health and the environment, a fact that the EPA has recognized as they have taken action to implement more rigorous screenings for chemicals that display characters of PBTs. These actions include lower reporting thresholds for PBTs on the toxic release inventory, the development of prioritization of tool

for the waste streams containing PBTs and reviewing TSCA premanufacturing notices for substances that meet PBT-related criteria.

I look forward to our witnesses today and what further steps we can take to domestically further protect human health and environment but also the important international area. Transboundary migration of pollutants is an important issue and one this committee has worked on for some time through efforts to implement the Stockholm Convention on Persistent Organic Pollutants to Long-Range Transboundary Air Pollution, POPs protocol in the Rotterdam Convention on the Prior Informed Consent. Passing legislation of these treaties should be a priority in any TSCA modernization legislation this committee takes up.

Mr. Chairman, I know I am almost through with my time but I would like to ask unanimous consent to place a letter into the record from the American Chemistry Council in today's hearing. ACC has long supported implementing the international treaties and it sees U.S. leadership in this area as critical action in the international area, and I would encourage if we haven't started it to establish a working group of all the interested parties of such major legislation and I would hope we could pass it through this Congress.

Mr. RUSH. The chairman thanks the gentleman and without hearing no objection, the letter will be included into the record.

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

Mr. RUSH. We recognize Dr. Gingrey for 2 minutes for the purposes of opening statements.

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

Mr. GINGREY. Mr. Chairman, thank you for calling this third hearing on the Toxic Substance Control Act of 1976. I am happy that we have once again delved into this complex issue and I appreciate the diligence of Commerce, Trade, and Consumer Protection Subcommittee to continue to examine this important issue.

TSCA directs the Environmental Protection Agency to regulate all phases of manufacturing of chemicals and to identify unreasonable risk of injury from new or existing chemicals. When 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 promote the chemical produces and the EPA in order to properly implement the law.

Mr. Chairman, while there are many laudable elements of TSCA, that does not mean that this law is anywhere close to perfect. Since its enactment, chemical manufacturers and processes have advanced and so has technology. Accordingly, TSCA needs to best reflect the science that is currently being utilized. As we heard during our previous two hearings on this matter, 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 the reform is certainly subject to debate and, indeed, some disagreement.

Today's hearing looks at a different aspect of TSCA, and its domestic and international implications for health and environmental factors of persistent, bioaccumulative and toxic chemicals, PBT. Subsequently, today's panel of witnesses will discuss the efforts taken by TSCA to maintain the safe use of chemicals both at home and abroad, however, I hope that we do not use this hearing as a vehicle to fundamentally overhaul TSCA because if we do, my fear is that we will jeopardize the long term viability of the chemical industry which will have lingering ramifications for other industries and subsequently, of course, our economy.

Mr. Chairman, I would suggest that as we hear from our distinguished panel of witnesses today we keep in mind the underlying risk-based principles that guide the current implementation of TSCA for health and environment. I look forward to their testimonies.

And I yield back.

Mr. RUSH. The chair 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, for holding today's important hearing on TSCA and the persistent, bioaccumulative and toxic chemicals also known as PBTs.

This is a very serious issue. Our health, the environment and the public's confidence are at issue and chemicals that are considered to be persistent, bioaccumulative and toxic have been associated with severe health risks and results, and these types of chemicals have been found in human bodies and that they can build up in our food chain and last for long periods of time in our environment. In fact, PBTs accounted for 97 percent of all fish consumption advisories in 2008, and my congressional district includes part of Lake Erie's shoreline.

In 1997, the U.S. and Canada launched the Great Lakes Bi-National Toxics Strategy to eliminate PBTs and according to the state of the Great Lakes 2009 report produced jointly by the U.S. EPA and Environment Canada, releases of targeted bioaccumulative toxic chemicals have declined significantly from their peak period in past decades. The report continues to state that "For the most part, bioaccumulative toxic chemicals no longer limit the reproduction of fish, birds and mammals." And while this sounds like good news, there is still much work to be done. With funding from the Great Lakes Restoration Initiative, Ohio is investing $4.21 million in five projects to address toxic substances and reduce contamination.

I have met with health care professionals in my congressional district who have expressed concern about health consequences that they have seen from chemical exposure in patients, as well. And I am interested to hear from today's witnesses how the Toxic Substances Control Act can be modernized to more effectively address these very real health concerns. Industry and a variety of environmental, animal welfare, and health and safety groups have all stated that they support modernizing TSCA, and as we move forward, we need to ensure the public's trust, and protect the public

and future generations from health and environmental harm while providing industry with a clear direction to ensure that our workers keep working. It must not be a question of jobs versus the environment. We can and we must effectively tend to both.

And I yield back.

Mr. RUSH. The chair now recognizes the gentleman from Maryland, Mr. Sarbanes, for 2 minutes.

Mr. SARBANES. Thank you, Mr. Chairman. I appreciate your holding this third hearing on the Toxic Substances Control Act.

My continuing perspective on this is that few Americans would imagine how thin the protections are when it comes to some of these chemicals and so it is really incumbent on us to try to modernize this oversight. I am going to be particularly interested to hear about how we can sort of get a head start based on the fact that it has been 30-plus years since this was modernized and science has certainly advanced significantly. So even if we are now going to come armed with a stronger set of standards for how we judge the toxicity of these various chemicals, I imagine there is a whole set of them that we already know are sinister enough that they ought to be put in a category right at the outset so that we can sort of start on the 30-yardline or the 40-yardline instead of on the 10-yardline, and I am looking forward to the testimony of the panel in that respect and otherwise on this important issue.

And I yield back my time. Thanks.

Mr. RUSH. The chair thanks all of the members for their opening statements.

And it is now my pleasure and honor to introduce our witnesses. We have nine esteemed witnesses from both far and near and I want to really express to each and every one of you how grateful we are that you would take, you will take, the time out from your busy schedules to appear before this subcommittee and to give us your best in helping us and direct us as we travel down this path to modernizing and reauthorizing TSCA.

I want to introduce now Mr. James Jones who serves as the deputy assistant administrator for the Office of Prevention, Pesticides and Toxic Substances for the Environmental Protection Agency. And seated next to Mr. Jones is Dr. John Thompson and he is the division director for the Office of Environmental Policy, Bureau of Oceans, Environment and Science at the Department of State and next to Dr. Thompson is Mr. Ted Sturdevant. Mr. Sturdevant is the director of the Department of Ecology for the great State of Washington. And seated next to Mr. Sturdevant is Dr. Linda Greer who is director of the Health and Environmental Program for the Natural Resources Defense Council. And to her left is Dr. Christina Cowan-Ellsberry and she is from CE2 Consulting, former principal scientist of the Environmental Sciences Department at Procter and Gamble. And lastly, we have with us this morning Dr. William J. Adams who is the chairman of the North American Metals Council.

And I again want to welcome each and every one of you to this hearing. And it is the practice of this subcommittee to swear-in all of our witnesses, and so I want to ask that each one of you stand and raise your right hand and respond to this question. Do you solemnly swear to tell the truth, the whole truth and nothing but the

truth? Let the record reflect that the witnesses have all answered in the affirmative.

And before we hear the opening statements of the witnesses, I must inform each and every one of you who are present that there are votes occurring. I don't know how much time we have left on the votes right now. Less than 10 minutes so we will try to get to two or three and then we will have to see how many votes are there? Three? We have three votes so it will take us about a half-an-hour to get over there and get back so we ask that you just be patient with us while we go and vote.

Dr. Sturdevant, we are going to try to finish you up before we have to go over there. Is that okay? Yes, thank you very much.

Now, the chair recognizes Mr. Jones for 5 minutes.

STATEMENTS OF JIM JONES, DEPUTY ASSISTANT ADMINISTRATOR, OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES, ENVIRONMENTAL PROTECTION AGENCY; JOHN THOMPSON, DIVISION DIRECTOR, OFFICE OF ENVIRONMENTAL POLICY, BUREAU OF OCEANS, ENVIRONMENT AND SCIENCE, DEPARTMENT OF STATE; TED STURDEVANT, DIRECTOR, DEPARTMENT OF ECOLOGY, STATE OF WASHINGTON; LINDA GREER, DIRECTOR, HEALTH AND ENVIRONMENT PROGRAM, NATURAL RESOURCES DEFENSE COUNCIL; CHRISTINA COWAN-ELLSBERRY, CE2 CONSULTING, FORMER PRINCIPAL SCIENTIST, ENVIRONMENTAL SCIENCES DEPARTMENT, PROCTER AND GAMBLE; AND WILLIAM J. ADAMS, CHAIRMAN, NORTH AMERICAN METALS COUNCIL

STATEMENT OF JAMES J. JONES

Mr. JONES. Good morning, Chairman Rush and members of the subcommittee.

I am Jim Jones, Deputy Assistant Administrator for Prevention, Pesticides and Toxic Substances at EPA. I am here today to talk about chemicals that are persistent, bioaccumulative and toxic, otherwise known as PBTs, and EPA's domestic and international actions related to such chemicals. I appreciate the opportunity to be here today.

As this committee knows, EPA's mission is to protect public health and the environment. Ensuring that our citizens, and especially our children, are protected from exposure to unsafe levels of toxic chemicals and pollution by continually strengthening our chemical management regime is not only central to EPA's work but it is an area that EPA Administrator Jackson identified as one of her priorities for the agency.

You have asked me here today to talk about PBTs in particular. PBTs are long-lasting substances that build up in the food chain and at certain exposure levels may be harmful to human health and the environment. Their persistent property means that when they are released into the environment they remain essentially unaltered for months or years. With continued use and release, they build up in sediments and soil and their concentrations increase as they go up the food chain. It is this concentration in the food chain which, under certain circumstances, can cause adverse effects in humans or wildlife. Some PBTs are also susceptible to

long range transport such that adverse effects can be found far removed from their site of production or use. Combined, these properties are what make EPA concerned not only with historical PBT chemicals, such as DDT and PCBs, but also with chemicals with similar properties entering commerce today or in the future. And so I would like to take a few minutes to just touch on a few of the relevant domestic and international actions we have taken with respect to PBTs.

On September 29 of 2009, EPA Administrator Jackson announced that EPA is putting in place a comprehensive approach to enhance the agency's current chemicals management program under TSCA. On December 30 of 2009, EPA posted action plans on phthalates, perfluorinated chemicals, polybrominated diphenyl ethers and products, and short-chained chlorinated paraffins. The latter three are PBTs. These action plans summarize available hazard exposure and use information, outline the risks that each chemical may present and identify the specific steps the agency has taken to address those concerns.

The initial chemicals selected for action plan development were chosen on the basis of multiple factors including chemicals identified as persistent, bioaccumulative and toxic as well as other factors. But while we are moving forward to implement the actions in those plans, we know that the very nature of PBTs means that stand-alone action by any one country is not enough.

The global nature of many of these substances is why the Obama Administration identified the Stockholm Convention on Persistent Organic Pollutants, known as the POPs Convention, along with the Rotterdam Convention on Prior Informed Consent, known as the PIC Convention, as a priority treaty for U.S. ratification and why joining the POPs Protocol to the Convention on Long Range Transboundary Air Pollution, known as the LRTAP POPs Protocol, is in our interest. By joining with the rest of the world to phase out or reduce the use and release of these PBTs, we protect both human health and the environment, and not only for ourselves but for the rest of the world.

At EPA we take the risks posed by these substances to our environment and public health very seriously but we are hampered by our lack of implementing legislation. As your committee considers the issue of PBTs, I would stress the importance of implementing legislation that would allow the United States to join the Stockholm Convention, the Rotterdam Convention and the LRTAP POPs Protocol. The Obama Administration thinks it is time to become parties to these agreements.

Among our efforts to strengthen the agency's chemical management regime, we have released a set of administration principles to help guide legislative reform and outline a series of activities to enhance our programs. Much of that work will encompass PBT substances and could provide an opportunity for the consideration of implementing legislation for the POPs Convention, the PIC Convention and the LRTAP POPs Protocol. We look forward to working with Congress, our domestic stakeholders and the international community to strengthen both our domestic and international actions with respect to PBT substances.

Thank you for having me here today and I will be happy to respond to any questions that you may have.

[The prepared statement of Mr. Jones follows:]

TESTIMONY OF

JAMES J. JONES

DEPUTY ASSISTANT ADMINISTRATOR FOR

PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

BEFORE THE

SUBCOMMITTEE ON COMMERCE, TRADE, AND CONSUMER PROTECTION

COMMITTEE ON ENERGY AND COMMERCE

U.S. HOUSE OF REPRESENTATIVES

March 4, 2010

Good morning Chairman Rush and Members of the Subcommittee. I am James Jones, Deputy Assistant Administrator for Prevention, Pesticides and Toxic Substances at the United States Environmental Protection Agency. I am here today to talk about chemicals that are persistent, bioaccumulative, and toxic, otherwise known as PBTs, and EPA's domestic and international actions related to such chemicals. I appreciate the opportunity to be here today.

As this Committee knows, EPA's mission is to protect human health and the environment. Ensuring that our citizens, and especially our children, are protected from exposure to unsafe levels of toxic chemicals and pollution or other environmental threats in their homes, schools, or communities by continually strengthening our chemical management regime is not only central to EPA's work, but is an area that EPA Administrator Jackson identified as one of her priorities for the Agency. As she noted in her own testimony to Congress, the public expects the government to provide assurances that chemicals which are ubiquitous in our economy, our environment, and our bodies have been assessed, using the best available science, and that unacceptable risks have been eliminated.

You have asked me here today to talk about PBTs in particular. PBTs are long-lasting substances that build up in the food chain and, at certain exposure levels, may be harmful to human health and the environment. Their persistent property means that they do not break down, so when they are released to the environment they remain, essentially unaltered, for months or years. With continued use and release, they build up in sediments and soil. PBT's also bioaccumulate, such that their concentrations increase as they go up the food chain from sediment, to aquatic insects, to fish, for example. It is this concentration in the food chain which, under certain circumstances, can cause adverse effects in humans, including reproductive defects, or in wildlife. Some PBTs are also susceptible to long range transport such that adverse effects can be found far removed from their site of production or use. Combined, these properties are what make EPA concerned not only with historical PBT chemicals, such as DDT and PCBs, but also with chemicals with similar properties entering commerce today or in the future. And so I would like to take a few minutes to just touch on a few of the relevant domestic and international actions we have taken with respect to PBTs.

First, in terms of pesticides, the Agency has adapted its standard risk assessment methodologies to specifically address the particular needs of compounds that exhibit persistent, bioaccumulative, and toxic characteristics. These refined methods are designed to account for the unique attributes of PBT chemicals and are applied on the basis of internationally-recognized screening criteria. These unique attributes include the highly persistent nature of PBTs in the aquatic and terrestrial environment, their rapid partitioning onto soils and sediments, their accumulation in aquatic and terrestrial food webs, and their movement over exceptionally long distances away from their application. The Agency has begun using these methods to address the potential long-term build up of these chemicals in the environment, their potential biomagnification in aquatic food webs, and their potential transport to remote regions such as the Arctic.

Second, in terms of industrial chemicals, the Agency recently announced that our office completed and released an initial set of chemical action plans which outline potential steps to address chemical risks. The chemicals selected for action plan development were chosen on

the basis of multiple factors, including available hazard, exposure, and use information; potential concern for children's health; use in consumer products; presence in human blood; persistence, bioaccumulative, and toxic characteristics; and production volume. In fact, three of the first four chemical action plans, covering polybrominated diphenyl ethers (PBDEs), long-chained perfluorinated chemicals, and short-chained chlorinated paraffins, include chemicals that are known internationally for their PBT characteristics.

We are moving forward to implement the actions in those plans and are working to develop plans for other chemicals as well, which will be announced on a regular basis in the months ahead. Further, among an array of other activities that cover PBTs in our new chemicals program, EPA has developed a policy statement that provides guidance criteria for determining persistence, bioaccumulation, and toxicity, and advises the industry about our regulatory approach, including the evaluation criteria, review process, exposure/release controls, and testing strategy for potential new PBT chemicals. EPA has also developed a computerized tool, the PBT Profiler, to help evaluate whether chemical have characteristics of persistence, bioaccumulation, and toxicity and has made this PBT Profiler available on an EPA website at www.pbtprofiler.net. Our regional office in Chicago also has a significant PBT program and our TRI program takes into account the importance or significance of PBT characteristics through lower thresholds for reporting requirements. In addition, PBTs are a major regulatory focus in the Agency's Great Lakes Water Quality Initiative, finalized in 1995. All in all, the breadth of PBT actions throughout the Agency is indicative of the importance we place on protecting human health and the environment from exposure to such harmful substances.

But given the very nature of PBTs, stand-alone action by any one country is not enough. Depending on the exposure level, these substances can pose real health and environmental risks to U.S. citizens and to people around the world because they are used and released here and in other countries and many can travel long distances from their source.

The global nature of many of these substances is why the Obama Administration identified the Stockholm Convention on Persistent Organic Pollutants, along with the Rotterdam Convention

on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, as a priority treaty for U.S. ratification. The United States was instrumental in negotiating both the Stockholm Convention and the Rotterdam Convention, each of which contributes in its own way to a healthier global environment and to a healthier America. The Stockholm Convention on Persistent Organic Pollutants (POPs) prohibits or restricts the production, use, and release of chemicals that are toxic, persist in the environment for long periods of time, bioaccumulate as they move up through the food chain, and are transported long distances in the environment, often landing far from the sources where they are released. The reduction or elimination of these POPs sources will have significant benefit to the United States and other countries around the world by reducing exposures that adversely affect human health and the environment.

The Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade (PIC) was developed to promote information exchange and informed risk-based decision-making in the global movement of hazardous chemicals and pesticides. The Convention empowers governments to make their own domestic science- and risk-based decisions in an informed manner and, with regard to listed substances, obligates Parties to ensure that such substances are not exported to Parties that have not provided their consent. Additionally, for certain substances considered banned or severely restricted in the exporting country, the agreement requires the exporting government to provide export notification to the importing government. This prior informed consent regime is particularly helpful and important to developing countries that lack the capacity to enforce their own regulatory decisions.

The POPs Protocol to the Convention on Long Range Transboundary Air Pollution (the LRTAP POPs Protocol), which is similar to the Stockholm Convention, also addresses substances that are toxic, persistent, bioaccumulative, and susceptible to long range transport. However, this Protocol is regional in nature, covering the Member States of the United Nations Economic

Commission for Europe, which includes, among others, the United States, Canada, the EU, Russia, parts of the former Soviet Union, and Eastern Europe.

The United States has already taken some steps to address the risks posed by PBT substances generally, and specifically the risks posed by the PBT substances covered by the Stockholm Convention, the LRTAP POPs Protocol, and the Rotterdam Convention. But it is of utmost importance for the United States to take the final step and join these agreements. Full participation in these Conventions and this Protocol by the United States is of special importance, for example, for the people and environment of Alaska, which is impacted more than any other state by POPs transported by air and water from outside the United States. This is particularly true for Alaskan Natives, who, like many around the United States, rely heavily on traditional diets comprised of fish and wildlife.

By joining with the rest of the world to phase out or reduce the use and release of these PBTs, we protect both human health and the environment, not only for ourselves, but for the rest of the world. At EPA, we take the risks posed by these substances to our environment and public health very seriously. We are internationally recognized for our sound scientific risk assessments and regulatory decision making, and other countries look to the United States to provide strong leadership in the area of chemical safety. Our actions are respected and often replicated in other countries across the globe. But we are hampered by our lack of implementing legislation.

As your committee considers the issue of PBTs, I would stress the importance of implementing legislation that would allow the United States to join the Stockholm Convention, the Rotterdam Convention, and the LRTAP POPs Protocol. Over the past few decades, the United States has negotiated and signed international agreements that have the goal of protecting human health and the environment from toxic chemicals, but has been unable to join these agreements due to our lack of domestic legislation. The Obama Administration thinks it is time to pursue U.S. ratification of these agreements.

As part of our efforts to strengthen the Agency's chemical management regime, we have, among other actions, released a set of Administration principles to help guide legislative reform and outlined a series of ongoing and planned activities to enhance the Agency's chemical management efforts. Much of that work will encompass PBT substances and could provide an opportunity for the consideration of implementing legislation for the Rotterdam Convention, the Stockholm Convention, and the LRTAP POPs Protocol. We look forward to working with Congress, our domestic stakeholders, and the international community to strengthen both our domestic and our international actions with respect to PBT substances.

Thank you for having me here today and I'll be glad to respond to any questions you may have.

Mr. RUSH. The chair now recognizes Dr. Thompson for 5 minutes.

STATEMENT OF JOHN E. THOMPSON

Mr. THOMPSON. Thank you, Mr. Chairman, and my thanks to the members of the subcommittee for holding this hearing on domestic and international actions on PBTs.

I have a written statement I would like to submit for the record with your permission.

Mr. RUSH. Hearing no objection.

Mr. THOMPSON. Thank you.

The advances in the discovery and application of chemicals have led to many benefits enjoyed by society. At the same time, certain chemicals impose significant risks to human health and the environment. Production and use of such chemicals is increasing outside of the United States. That is important because of the potential for local harm and also because some chemicals are capable of having impacts far from where they are used and released.

Indigenous people in Alaska and elsewhere in the United States, though often remote from such sources, may be particularly at risk to exposure because of their reliance on a subsistence diet. Of particular interest, are those PBTs which are organic and capable of transporting over long distances, these chemicals are referred to persistent, organic pollutants or POPs. We focus on these chemicals internationally because they can pose risks far from their source of release. The role of the State Department is to facilitate international cooperation aimed at mitigating these risks and we do so working closely with our colleagues from the Environmental Protection Agency. In that regard, I would like to describe three key international agreements aimed at controlling these types of chemicals, the Stockholm Convention on POPs, the Protocol on POPs on the Convention on Long Range Transboundary Air Pollution and the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade.

The Stockholm Convention aims to protect human health and the environment from exposure to POPs. It has been ratified by 169 countries including nearly all of our major trading partners and allies. The Convention calls upon parties to prohibit or restrict production in use of POPs such PCBs, and to reduce byproduct emissions of substances such as dioxins and furans. It includes a science-based procedure to govern the addition of chemicals and allows a party to decide whether to join amendments adding a substance to the Convention.

The second agreement I would like to mention is the POPs Protocol to the Convention on Long Range Transboundary Air Pollution. This agreement is broadly similar to the global Stockholm Convention, but it is regional in nature, encompassing the United States, Canada, Europe and the former Soviet Republics.

A third important agreement is the Rotterdam Convention which promotes shared responsibility between exporting and importing countries in the trade of certain chemicals. For international shipments of such chemicals, it stipulates that consent of the importing country must be obtained before the chemical can be exported. The

Convention helps to ensure countries have information to make decisions on sound chemicals management which means less likelihood of health and environmental risks in those countries and in the United States.

These agreements have the support of this Administration and the business and environmental communities but we are a nonparty because we need legislation to fully implement their provisions. We are therefore unable as a nonparty to participate fully in their proceedings. Only by joining these agreements, can we use them effectively to pursue public health protection in the United States. What is of paramount interest to the Department of State is enabling full U.S. participation in the deliberation of these agreements as soon as possible so we can pursue U.S. interests, especially protecting public health and the environment.

I also note that EPA recently announced the development of action plans to address certain classes of chemicals as potential priorities. Some of these chemicals are under consideration or are already included in the agreements that I have described. The best way for the United States to lead internationally is to do so based on a strong domestic approach that is consistent with our international obligations. By taking action at home, we can use these agreements to ensure chemicals are managed more responsibly abroad.

In summary, Mr. Chairman, there are some chemicals whose use anywhere in the world may present a public health and environmental threat to the United States because they are persistent, bioaccumulative, toxic and are transported over long distances. We are most effective leading abroad when we have been diligent and effective in addressing chemicals management at home. We have the tools to promote better management of these chemicals on a global basis through these agreements but we need to join them to do that most effectively.

Thank you for having me here today and I would be pleased to answer any questions.

[The prepared statement of Mr. Thompson follows:]

WRITTEN TESTIMONY OF

DR. JOHN E. THOMPSON

DIVISION DIRECTOR

BUREAU OF OCEANS, ENVIRONMENT AND SCIENCE

U.S. DEPARTMENT OF STATE

BEFORE THE

SUBCOMMITTEE ON COMMERCE, TRADE, AND CONSUMER PROTECTION

COMMITTEE ON ENERGY AND COMMERCE

U.S. HOUSE OF REPRESENTATIVES

March 4, 2010

Thank you, Mr. Chairman, and my thanks also to the members of the Subcommittee for holding this hearing on domestic and international actions on persistent, bioaccumulative, and toxic chemicals.

Advances in the discovery, production, and application of chemicals have been responsible for many benefits enjoyed by society all over the world. But as scientific knowledge of these substances has increased, we have learned that certain chemicals impose significant risks to human health and the environment. We also see a trend of growing production and use of chemicals in developing countries, which may lack fully developed regulatory systems to ensure sound management practices. We care about how other countries manage and use chemicals for at least two reasons: because of the potential for local harm, and because some chemicals are capable of having significant impacts far from where they are released. For example, the elevated levels of persistent organic pollutants (POPs) measured in Alaska and the Arctic, far from where they are used or produced, make it clear that poor management abroad can lead to human health and environmental risks at home.

The set of chemicals we are talking about today – chemicals that persist in the environment, bioaccumulate in organisms, and are toxic - are being focused on because of their intrinsic characteristics. Of particular concern is a subset of these chemicals which are organic and

capable of transporting over long distances; these chemicals are often referred to as POPs. It is these chemicals in particular we are focusing on internationally because they can pose risks to public health and the environment in countries far from the source of production or use. While the United States and many developed countries stopped using these chemicals many years ago, they can still present a threat to the health of our population because of their continued use in other countries today. Indigenous people in Alaska and elsewhere in the United States may be particularly at risk to exposure because of their reliance on a subsistence diet. Through our global efforts of collaboration and cooperation, we can seek to improve standards for the management of chemicals and raise environmental protection in other countries to a level that will benefit their public health as well as ours. The role of the State Department is to work with other countries to facilitate this type of cooperation, working side by side with our colleagues from the Environmental Protection Agency.

For these reasons, international cooperation is not only desirable, but vitally necessary to protect public health and the environment in the United States. I would like to focus on three key international agreements aimed at controlling the types of chemicals that are the subject of this hearing. The three agreements are the Stockholm Convention on Persistent Organic Pollutants, the Protocol on Persistent Organic Pollutants of the Convention on Long Range Transboundary Air Pollution (LRTAP), and the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade (PIC).

The Stockholm Convention aims to protect human health and the environment from chemicals that are of particular concern because of four intrinsic characteristics: they are toxic, they bioaccumulate in humans and animals, they are resistant to natural breakdown, and they have the potential to be transported over long distances. The twelve POPs initially covered by the agreement are: aldrin, hexachlorobenzene, chlordane, mirex, DDT, toxaphene, dieldrin, polychlorinated biphenyls (PCBs), endrin, heptachlor, dioxins and furans. None of these twelve chemicals is now used or manufactured in the United States, but they are still used in some parts of the world. Sale and use of DDT, for example, has been banned domestically since 1973, but continues to be used in other countries as an antifoulant in paint when alternatives to that use already exist. Through international cooperation we can put an end to these unnecessary uses of POPs.

The Stockholm Convention entered into force on May 17, 2004, and has been ratified by 169 countries, including nearly all of our major trading partners and allies. It calls upon countries to prohibit or restrict production and use of POPs such as PCBs, and to reduce byproduct emissions of chemicals like dioxins and furans. It includes a science-based procedure to govern the addition of chemicals to the Convention. This procedure includes a review process which

considers criteria for inclusion of chemicals of global concern, as well as socio-economic aspects of the use of these chemicals. This is the procedure used to add nine new substances to the Convention in May, 2009: hexabromobiphenyl, hexa- and hepta-bromodiphenyl ether, lindane, pentachlorobenzene, perfluorooctane sulfonic acid, tetra- and penta-bromodiphenyl ether, chlordecone, and alpha and beta hexachlorocyclohexane. While the Parties continue to consider additional substances for inclusion in the Convention's scope, the Convention includes provisions that allow a party to affirmatively decide whether to join amendments adding new substances to the Convention. Therefore, should the United States join the Convention, we can utilize this provision to ensure that we only take on obligations to address further chemicals if we affirmatively agree to do so.

The second agreement I would like to describe is the POPs Protocol to LRTAP, which entered into force on October 23, 2003, and has 29 Parties. This agreement is broadly similar to the global Stockholm Convention, but it is regional in nature, encompassing the United States, Canada, Europe, and the former Soviet Republics. The POPs Protocol initially included sixteen substances, and in December 2009, it was amended to add 7 additional substances to its scope. Like the Stockholm Convention, the LRTAP POPs Protocol is structured to ensure the United States would only take on obligations to address further chemicals if we affirmatively agree to do so.

Another important agreement is the Rotterdam Convention on the Prior Informed Consent Procedure. The Rotterdam Convention promotes shared responsibility between exporting and importing countries in the trade of certain chemicals and pesticides. It entered into force on February 24, 2004 and has been ratified by 131 countries. The Convention currently lists 40 chemicals, many of which are the same chemicals considered to be POPs. For international shipments of the chemicals listed, the Convention stipulates that prior informed consent of the importing country must be obtained before the chemical can be exported to that country. Many countries simply lack the capacity to either control their borders, or lack a fully effective regulatory system that ensures their proper use. The Rotterdam Convention helps to ensure they have full information to make decisions on the sound use and management of chemicals within their own domestic environments. Better management of harmful chemicals in other countries means less likelihood of public health and environmental risks in those countries and in the United States due to their unnecessary release into commerce and the environment.

The United States participated actively in the negotiation of each of these agreements, and has supported them through multiple administrations. We have vital interests at stake in protecting public health and the environment in the United States, and the tools available to us in these agreements can be used to galvanize global efforts aimed at controlling their

production and use. While these agreements enjoy the support of this Administration, the business community, and environmental organizations, we are currently not a party to any of them. The United States has taken some domestic action related to most of the listed substances, but we would require legislation to fully implement the obligations of the agreements. Meanwhile, as a non-Party, the United States is unable to participate fully in the political or technical aspects of their proceedings and contribute to the process as the agreements evolve over time and add additional chemicals to their scope. By joining these agreements the United States will be able to take on the role befitting our status as a leader in environmental protection, and be able to use them effectively to pursue public health protection in the United States.

I would also like to emphasize the importance of the connection between the domestic and international aspects of the control of persistent, bioaccumulative and toxic chemicals. EPA has recently announced the development of chemical action plans to address certain classes of chemicals as potential priorities because they may present risks to human health and the environment. In some cases, the chemicals on which EPA is focusing are also the subject of international attention. Short-chain chlorinated paraffins (SCCPs) are an example of such a group of chemicals for which EPA has developed an action plan, and at the same time, has been proposed for listing in the Stockholm Convention and already been added as an amendment to the LRTAP POPs Protocol. And this isn't the only example. Several of the chemicals EPA is focusing on are included or are under consideration for inclusion under the Stockholm Convention. The best way for the United States to lead internationally, is to do so based on a strong approach at home that is risk-based and consistent with our international obligations. Development of action plans or other effective domestic approaches to address these chemicals allows us to promote sound, risk-based management approaches in other countries through these international agreements. When we have taken strong action at home, the United States has been very successful in mobilizing political will in other countries to ensure chemicals are managed in a more environmentally sound manner.

We are very pleased at the attention being paid in Congress to the need to undertake a comprehensive and thoughtful review of one of our domestic laws as a part of possible changes to the Toxic Substances Control Act (TSCA). The particular approaches and technical issues involved in this legislation are outside of my area of expertise so the Department of State will not express views on these matters. What is of paramount interest to the Department of State is enabling the full participation of our government in the deliberations that take place under the international Conventions I have described as soon as possible, because their evolution impacts vital U.S. interests, especially protecting public health and the environment for U.S. citizens. The sooner the United States takes a seat at these tables, the sooner we will be

ensured that we have a voice as further changes to the agreements are contemplated, for example the addition of chemicals to their scope. Our participation will significantly help international efforts to address the types of chemicals that are the subject of this hearing. For these reasons, it is vital that we move forward quickly to join these agreements.

In summary, Mr. Chairman, there are some chemicals whose use anywhere in the world may present a public health and environmental threat to the United States because they are persistent, bioaccumulative, toxic, and are transported over long distances. We have the tools to promote better management and safer alternatives to these chemicals on a global basis if we join these international agreements and utilize them to elevate other countries to our level of environmental protection. We are most effective leading abroad when we have been diligent and effective in addressing chemicals management at home first. This hearing is a sign of a renewed domestic interest in pursuing improved sound chemicals management at home, which I hope can facilitate our further efforts abroad aimed at the same goal of public health and environmental protection in the United States. We need to join these key Conventions to do that most effectively. I thank the Subcommittee for holding a hearing on this important issue, and I would be pleased to answer any questions the subcommittee might have.

Mr. RUSH. Thank you, Dr. Thompson.

Mr. Sturdevant, will you please hold your testimony until we return? The committee stands in recess until 11:30.

[Recess]

Mr. RUSH. Dr. Greer, are you prepared with your opening statement?

Ms. GREER. Yes, sir.

Mr. RUSH. All right, well, the chair recognizes Dr. Greer for 5 minutes for the purposes of an opening statement.

STATEMENT OF LINDA E. GREER

Ms. GREER. Thank you for the opportunity to testify today.

I am Linda Greer and I am the director of the Health Program at NRDC, the Natural Resources Defense Council. I have a Ph.D. in environmental toxicology and a masters degree in public health. Since 1981, I have worked on a wide range of environmental health issues, and have focused on numerous persistent, bioaccumulative and toxic chemicals including mercury, dioxin and PCBs, among others.

Commonsense tells us that chemicals with a PBT profile are bad actors and that laws designed to protect people from dangerous environmental contaminants should prioritize the phase-out of chemicals with this alarming profile. Society should rely upon safer chemicals that will degrade and be metabolized easily in the body back into harmless chemicals after use, not those that will take shelter in our bones, in our blood and in our fat for the rest of eternity.

Remarkably, however, PBTs are not a thing of the past. Despite the notoriety of this class and all that scientists have learned about them over the past 30 years, there are still many such chemicals that continue to be used in commerce today and sometimes in very large quantities. Three of EPA's four recently announced chemical action plans, for example, are from the PBT class.

The polybrominated diphenyl ethers, the PBDEs, are still used today as flame-retardants in plastics, polyurethane foams and textiles, even though safer alternatives are available. They remain in products in millions of homes. This, despite the evidence that their chemical structure is extraordinarily similar to the PCBs banned decades ago that they share structural characteristics of the dioxins.

Despite the toxicological evidence that shows that PBDEs are thyroid hormone disrupters, that they are neurotoxic to the developing brain, and that they have immunotoxic properties similar to PCBs; despite the doubling of their concentration milk samples every 5 years; despite their detection globally, including in the arctic where they have never been used, PBDEs are still in use in 2010. And other PBDEs are similarly still in the market and used in high volume despite all that we know about the hazards they pose, defying commonsense.

So how can this be? It is truly a tribute to the utter impotence of TSCA that chemicals with such notorious profiles remain on the market allowing the public to be endlessly exposed while analysis after analysis lumbers on. TSCA constraints make it very difficult for EPA to fully assess new chemicals or require the testing of

chemicals in use, and the hurdles for EPA to actually restrict use of an existing chemical are even higher. It is almost impossible for EPA to take regulatory action against PBTs and other dangerous chemicals, even those like asbestos that are well-known to cause cancer or other serious health effects. And although some in industry see the problems and agree that we need reform, many others are comfortable with the culture or study and delay that have kept EPA from taking action on chemicals they have marketed without safety data for more than a generation.

This head-in-the-sand mentality is not good for business in the long run. Europe is far ahead of us and will prohibit the export of these chemicals to their markets. Safety problems will plague these companies eventually as the latest story from Toyota shows us.

The consequence of such delay in getting PBTS and other dangerous chemicals off the market may well have had a personal impact on me. Three years ago as I continued my career to reduce toxic chemical pollution, I got a call from my doctor about an abnormality in my mammogram. Soon afterwards, I was struggling to come to terms with the diagnosis every woman dreads, breast cancer. Despite my Ph.D., I found myself thinking what everyone thinks in a situation like this, why did this happen to me, and not just why me but why so many colleagues and friends. The president of NRDC, Frances Beinecke, was diagnosed with breast cancer about 8 years ago. So was the executive assistant of John Adams, our former president. She died of that disease before the age of 45, a woman in our finance department, another in communications, one of our senior analysts, an office manager, a young temporary secretary, my sister-in-law. Most or all of these women did not have known risk factors and all of them contracted this disease when they were very young.

I suspect many of the members of this committee, and their staff, have had similar experiences. Friends, family and colleagues who have been diagnosed with cancer, or who have children with infertility issues, or grandchildren with development or learning disabilities, or elderly parents with Alzheimer's or Parkinson's disease.

I tell my story to inspire you, this committee, this Congress and this Administration to seriously consider what it will take to get action on hazardous chemicals still being used in commerce today, known PBTs and others. Not just testing. Not just information. Not more analysis, action. Well known PBTs, such as dioxin, DDT and PCBs have been associated with the risks of breast cancer for many, many years. A survey of peer review literature found more than 200 chemicals has been associated with mammary tumors in animals. Chlorinated solvents, polynuclear aromatics and others, yet EPA has taken action on only four of 80,000 chemicals in commerce in the 35 years of TSCA.

The public is rightfully alarmed and wants to see action and results not just more years of studies that lead nowhere. Many retailers have themselves taken action to remove products from shelves where they fear harm to their customers in light of government stagnation. Even certain segments of industry itself, the personal products manufacturers, for example, who manufacture our lotions and shampoos, have begun to speak out for the need for reform

fearing problems in the ingredients that they buy for their formulation.

For this reason, we recommend Congress and this committee, mandate the phase-out of at least the handful of best known PBTs and bad actors in a reauthorized TSCA and put our country on a path forward for the use of safer chemicals. We have spent literally decades quantifying the risks of these chemicals and exposed an entire generation in the meantime, unable to turn to the more practical questions of how these PBTs are used, how they can be reduced, how they can be phased out. It is time for EPA to parse the uses, identify the critical uses, identify the unnecessary uses, and move forward on these chemicals.

I was one of the lucky ones. My breast cancer has been caught early and I am doing well but as I do my work every day, I think of my daughter who was dosed with every contaminant in my breast milk four or more times a day for the first year of her life and of her generation. My efforts here today and back at the desk to reduce or eliminate toxic chemicals are for her, and you too should take action to protect your children and grandchildren.

Thank you very much for this opportunity to testify.

[The prepared statement of Ms. Greer follows:]

TESTIMONY OF

LINDA E. GREER, Ph.D

DIRECTOR, HEALTH AND ENVIRONMENT PROGRAM

ON BEHALF OF:

NATURAL RESOURCES DEFENSE COUNCIL

BEFORE THE U.S. CONGRESS

COMMITTEE ON ENERGY AND COMMERCE

SUBCOMMITTEE ON COMMERCE, TRADE AND CONSUMER PROTECTION

AT HEARING ENTITLED:

TSCA AND PERSISTENT, BIOACCUMULATIVE, AND TOXIC CHEMICALS: EXAMINING DOMESTIC AND INTERNATIONAL ACTIONS

MARCH 4, 2010

Thank you for the opportunity to testify today. My name is Linda Greer, and I am the Director of the Health Program at NRDC (the Natural Resources Defense Council). I have a Ph.D. in environmental toxicology and a masters degree in public health. Since 1981, I have worked on a wide range of environmental health issues, including Federal policies for assessing hazardous chemicals, pollution prevention opportunities in U.S. and Chinese manufacturing plants, and global mercury use reduction. My work and research has focused on numerous persistent, bioaccumulative and toxic chemicals, including mercury, dioxin, and PCBs, among many others. As I scientist, I know that PBT chemicals should be a high priority for use and exposure reduction because failure to act will result in ever-increasing contamination, not just of the environment, but also of our bodies.

PBTs are uniquely dangerous because once they are released into the environment (intentionally or accidentally), they don't go away. They linger for years or even decades, accumulating and increasing in concentration over time. PCBs, the only chemicals banned by Congress under the original TSCA, similarly continue to plague both our environment and our bodies. Although levels of PCBs have gradually declined over the past 3 decades, these chemicals can still be found lingering in the blood of nearly everyone in the U.S. Rachel Carson warned about the dangers of persistent chemicals, saying: "This pollution is for the most part irrecoverable; the chain of evil it initiates...is for the most part irreversible."[i]

As if persisting for more than 30 years were not enough, PBT chemicals also increase in concentration in living things over time as they move up the food chain – the "B" property of their PBT classification: bioaccumulation. This means that even low concentrations in environmental media (such as air, water, or soil) can lead to levels hundreds or thousands of times higher in living things. Bioaccumulation is the reason that 43% of the Nation's total lake acreage and 39% of the nation's total river miles in all 50 states now carry fish advisories warning against consumption due to contamination with persistent chemicals such as mercury, PCBs, and dioxin (Figure 1).[ii]

The combined properties of toxicity, persistence and bioaccumulation make quantifying the threat posed by these chemicals extremely challenging. It is not enough to look simply at existing concentrations in air, water, soil or sediment, to evaluate the harm they pose; one must consider that concentrations will continue to rise over time and only decrease very slowly, perhaps taking decades or longer. Similarly one must look beyond environmental concentrations to the concentrations at the top of the food chain for PBT chemicals in order to evaluate effects. Here again, existing concentrations are not necessarily at equilibrium; with or in some cases even without continued loading, they too will continue to rise over time and not go away. The tool that EPA and others use to quantify the harm that chemicals pose – risk assessment – is in fact an inadequate tool for evaluating the harm posed by PBTs for this reason. Because risk assessments require a quantification of exposure levels, and because the levels of PBTs will continue to rise for as long as the contaminant is released into the environment of the food chain, they cannot adequately evaluate the harm posed by this class of compounds.

The application of risk assessment to PBTs is further limited due to the complex movement of PBTs through multiple levels of the food web and the long distance transport of PBTs throughout the global environment. For these reasons, using risk assessment to determine which uses of PBTs should be reduced or eliminated, and to what extent, is fraught with difficulty. Many layers of added uncertainty result, severely limiting the predictive value of such judgments when risk assessment is applied to PBTs.

Common sense tells us that chemicals with a PBT profile are bad actors, and that a law or policy designed to protect people must phase out the use of PBTs and require the use of safer chemicals that degrade easily back into harmless chemicals when treated or discharged into the environment, rather than sequestered in our bones, blood or fat deposits because they cannot be degraded.

It is instructive to look historically at the evaluation of the toxic properties of PCBs to understand why risk assessment doesn't work well for this class of chemicals. Initial small studies of adult male workers done in the 1960s did not detect dramatic health effects, so the chemicals were initially touted as relatively nontoxic and the fact that they were persistent and accumulated in fat was not considered a problem.[iii] Over the decades, larger and more detailed studies on young children have shown that PCBs are neurotoxic, and have anti-thyroid and immunotoxic effects.[iv] These health effects occur at low doses – at levels that many people who consume fish from the Great Lakes and other areas today have in their bodies. But by the time the newer, much more complex and expensive scientific studies were done, it was too late – significant damage was already done because PCBs had persisted and accumulated in the environment, contaminating the entire food web.

PCBs were banned outright by Congress in 1976 (one of the few successes of the Toxic Substances Control Act). In 1978, the United States entered into the binational Great Lakes Water Quality Agreement with Canada, which called for the virtual elimination of persistent toxic chemicals to protect human health and the aquatic environment. Less than two years ago, Congress overwhelmingly voted to ban the export of mercury from the U.S. – an important step toward an international treaty to substantially reduce mercury in commerce and significantly curb emissions and thereby protect our food supply. Unfortunately it will take many more decades before the damage from these persistent chemicals begins to subside.

The history of persistent, bioaccumulative and toxic chemicals has created a compelling case for prevention. Many scientists have pointed out that waiting for clear evidence of harm from these chemicals is tantamount to closing the proverbial barn door long after the animals have scattered far and wide. If we fail to act to reduce or eliminate chemicals in use today that are likely to be the PCBs, dioxins, and mercury of the future, then future generations will be faced with the realization that the food they eat is tainted by health dangers.

Despite the notoriety of PBT chemicals, there are many such chemicals that continue to be used in commerce today —and sometimes in very large quantities. For example, some of the polybrominated diphenyl ethers (PBDEs) are still used as flame retardants in plastics, polyurethane foams, and textiles even though safer alternatives are available. While some PBDEs are no longer used, they remain in products in millions of homes. The chemical structure of the PBDEs is extraordinarily similar to the PCBs, and these chemicals also share structural characteristics of the dioxins. In fact, the toxicologic evidence shows that the PBDEs are thyroid hormone disruptors, that they are neurotoxic to the developing brain, and that they have immunotoxic properties similar to the PCBs.[v]

The PBDEs are environmentally persistent and bioaccumulate rapidly. Levels of the PBDEs doubled every five years in breast milk samples from Sweden, and residues of these chemicals have been detected globally including in the arctic, where they have never been used.[vi] Several U.S. states, including California, Illinois, Maryland, Michigan, Minnesota, Maine, New York, and Washington have restricted major uses of PBDEs based on their inherent properties as PBTs without attempting to apply ineffective risk assessment methods to the task.

EPA has announced plans to take more additional, although limited, action on these chemicals, and urgently requires additional Congressional authority to take immediate action on persistent chemicals such as the PBDEs. Meanwhile many other chemicals are also turning out to be persistent, bioaccumlative and toxic: the di-, tri-, tetra- and pentachlorobenzenes, hexachlorobutadiene, other flame

retardants such as tetrabromobisphenol A and HBCD, and PFOS, and the musk xylenes, to name only a few. All of these chemicals require decisive action, not years of additional study while the levels in the food supply creep upward.

Scientific and regulatory consensus definitions for persistent, bioaccumulative, and toxic chemicals already exist. These criteria are not particularly controversial, and it makes sense for Congress to simply state that, as a matter of U.S. policy, with narrow exceptions, new chemicals with these properties should not be introduced into commerce. Similarly, PBT chemicals that are currently in commerce should be phased out, allowing, of course, for exemptions for essential uses for which no alternatives yet exist.

Before I close, I would like to mention that the hazards posed by PBTs are very personal for me. Three years ago, when I was doing work to reduce global mercury use and pollution, I got a call from my doctor about an abnormality on my mammogram. Soon afterward, I was struggling to come to terms with the diagnosis every woman dreads – breast cancer. I have to tell you, it really threw me for a loop. I found myself thinking what everyone thinks in a situation like this – why did this happen to me? I don't have many of the conventional risk factors for breast cancer, but I'm not alone. Most of the women with this disease don't have known risk factors.

One difference between me and many other women with breast cancer is my familiarity with the science. I know that in the United States between the 1970's and 2000, breast cancer incidence rates increased by more than 40 percent. As of 2008 a woman's lifetime risk of breast cancer in the U.S. was one in eight.

I also know that the belief that breast cancer is mainly a genetic disease is unfounded. In July of 2000, a Scandinavian study of nearly 45,000 twins published in the New England Journal of Medicine tried to separate out genetic vs. environmental factors in cancer. The bottom line of this important study was that the vast majority of cancers are environmental rather than genetic. In the case of breast cancer, only about one-quarter of the risk is due to inherited factors; that leaves the remaining risk of breast cancer linked to environmental factors.

There are numerous known or suspected environmental toxicants that have been linked to breast cancer. In fact, a 2007 study identified 216 chemicals that have been shown to cause cancers of the mammary gland in animals.[vii] Worse still, after more than three decades since the establishment of EPA, only a small handful of the tens of thousands of chemicals on the market have been evaluated for their ability to cause this terrible disease.

Numerous chemicals that have been linked to breast cancers in animals and humans are PBTs, including now-banned pesticides such as dieldrin, aldrin, and heptachlor, as well as the PCBs and dioxins. It's no surprise to a toxicologist like myself that these chemicals might be linked to breast cancer -- since they accumulate in fat cells, and are known to concentrate in breast tissue and even breast milk. Just this fall, an updated study on women exposed to dioxin from a 1976 industrial accident in Italy reported a statistically significant increased risk of breast cancer (by more than 2.5-fold) in dioxin-exposed women.[viii] Meanwhile EPA began an assessment of the health risks of dioxin in 1985, and 25 years later has still not completed the work.

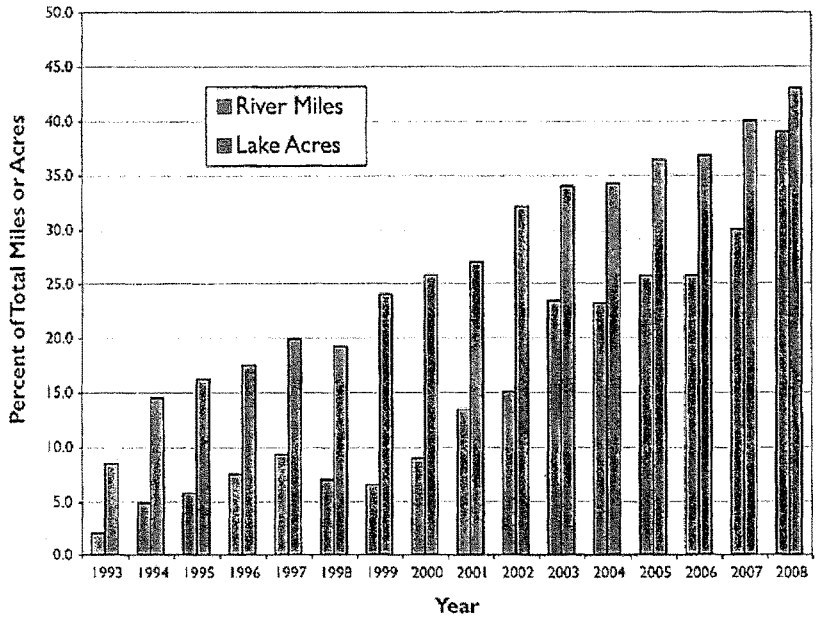
As great as the problems posed by these historical examples of persistent, bioaccumulative carcinogens are, this Committee, Congress, and the Administration, should be thinking seriously about how to address chemicals that are still being used in commerce today, that are known to have these same properties of persistence and bioaccumulation. These are chemicals that are not only used for industrial purposes like PCBs in transformers. We are talking about PBT chemicals used in everyday products that people have in their homes – in their furniture, in their computers, in their cookware. From there, PBT chemicals can easily make their way into our breast milk, our food, and our bodies. Congress must take responsible action to phase out the use of PBTs and put our country on a path toward use of safer chemicals. When

chemicals accumulate rapidly, and then linger on for generations, we don't have the luxury to engage in a lengthy research study or prolonged risk assessments. It should simply be a matter of common sense policy that manufacturers must, where feasible, switch to alternative chemicals that are not persistent and do not bioaccumulate.

I was one of the lucky ones. My breast cancer was caught early and I am doing well. But as I do my work every day, I think of my daughter – who received whatever contaminants I had in my breast milk when I nursed her -- and of her generation. My efforts to reduce or eliminate toxic chemicals are for her. We must protect the next generation by creating responsible and effective chemical policy today.

Thank you for this opportunity to testify.

Figure 1: Fish Advisories for PBT Contamination in the United States



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Mr. RUSH. The chair now recognizes Dr. Cowan-Ellsberry.

STATEMENT OF CHRISTINA COWAN-ELLSBERRY

Ms. COWAN-ELLSBERRY. First, I would like to thank the chairman and the ranking member and the members of the subcommittee for inviting me to testify before you today.

My name is Christina Cowan-Ellsberry and I have worked in the field of environmental and human safety and risk assessment of chemicals for over 30 years. I am here of my own volition and represent only myself. My testimony is based on my scientific training and expertise and my experience with the PBT issue. There are two reasons I decided to come on my own. First, as a consumer and citizen of the United States, I am as concerned as you are about chemicals that may be in commerce and that could cause adverse impacts on me, my family and the environment.

Secondly, I have worked since the 1990s, and actually earlier, on the development of the PBT criteria and methods for identifying and evaluating the safety of organic PBTs in several national and international fora, including the United States, Canada, Europe and the United Nations. I have seen how using the established criteria, and science and risk-based assessment process has resulted in effective PBT identification and assessment programs, and has resulted in prioritization of resources toward PBT management on national and global scales. As successful as these initiatives have been in illustrating it is possible to identify, assess and manage PBTs, these initiatives have also illustrated that the process can be scientifically challenging, and require the active involvement of the best scientists and the use of the most reliable and relevant data.

At the recent SETAC Pellston Workshop, one common frustration voiced by participants was that many of the current national and international regulations accept only a limited set of test data. While this may be appropriate for screening and prioritization, it fails to recognize the incredible evolution of the science which has produced new insights into PBT chemical and an array of new methods to identify and assess PBT chemicals. As a result, the scientists are frustrated when they bring forward these new data and insights only to find that they are rejected, not because of scientific reasons but rather because the regulatory framework does not allow for its consideration. Given the rapid improvement in these test methods and guidance, it is critically important for U.S. EPA scientists to contribute to and incorporate the most current science and scientific understanding into their assessments.

Through all my years of work on PBTs, I have greatly valued the scientific expertise and interaction with my colleagues in the U.S. EPA, and commend them for their role in promoting the risk-based and science-based underpinnings of the PBT identification and assessment process. My concern is, and as voiced by several here, is that although the U.S. publicly committed in the 1990s to working within the international community to address chemicals of international concern, the U.S. has not become a full party to either the LRTAP POPs Protocol or the Stockholm POPs Protocol. Unfortunately, the risk-based and science-based underpinning of these two conventions, which the United States promoted are being eroded without this active U.S. involvement. I strongly urge you to make

sure that the U.S. becomes a full party to these conventions so that the U.S. government scientists can once again bring their knowledge and expertise forward in leadership internationally.

Finally, I believe it is also important that EPA develop a stronger Federal PBT program so that the States do not have to take separate, and potentially conflicting, actions to identify and manage these substances. Many States don't have the depth in scientific expertise nor the number of staff to effectively conduct these scientifically challenging assessments on their own. To ensure a technically strong and coordinated process for identification, assessment and management of PBTs, this program should include a scientific, multi-stakeholder fora, that includes representatives from these States, as well as potentially other scientific advisory panel members. Ultimately, I believe that a reform of TSCA that contains a strong commitment to and adequate funding for this Federal program of PBT identification, assessment and management, and U.S. leadership internationally in PBT conventions, will benefit U.S. citizens as it will contribute to improving global public health and the environment through managing existing PBT chemicals, and provide assurance that new chemicals that have PBT properties will not enter commerce.

And once again, I thank you for this opportunity to testify today and I look forward to answering your questions.

[The prepared statement of Ms. Cowan-Ellsberry follows:]

WRITTEN TESTIMONY OF CHRISTINA COWAN-ELLSBERRY, PH.D.

To the Subcommittee on Commerce, Trade, and Consumer Protection Hearing on "TSCA and Persistent, Bioaccumulative, and Toxic Chemicals: Examining Domestic and International Actions"
March 4, 2010

I would very much like to thank the Chairman, Mr. Rush, Ranking Member, Mr. Whitfield and Members of the Subcommittee for inviting me to testify before you today. My name is Christina Cowan-Ellsberry. I have a Ph.D. in Civil Engineering with emphasis in Environmental Engineering. I have worked in the field of environmental and human safety and risk assessments for chemicals for over 30 years. Because I was invited as a technical witness to this hearing on Persistent, Bioaccumulative and Toxic Substances (PBTs) in TSCA, I thought it would be relevant for this committee to understand my background on this topic.

I have worked on the development of the technical criteria and process for identifying and evaluating the safety of PBTs since the 1990s. I was a technical contributor to the Canadian Toxic Substance Management Policy criteria and assessment approach, and to their technical guidance documents on how to determine if a substance under evaluation meets the Persistence, Bioaccumulation and/or Toxicity criteria. I contributed to the technical criteria and process for UN Economic Cooperation for Europe's (UNECE) Persistent Organic Pollutants (POPs) Protocol to the Long-Range Transboundary Air Pollution (LRTAP) Convention and the NAFTA Commission for Environmental Cooperation's Sound Management of Chemicals Initiative both of which contain PBT assessments. I served as a representative to the Criteria Expert Group for the UN's Stockholm Persistent Organic Pollutants Convention. I have also contributed technical comments to the REACH implementation approach for PBTs. On a detailed scientific level, I have organized and been a key contributor in several technical workshops and discussion groups both nationally and internationally on various aspects of the science and approaches to identifying and evaluating PBTs. This included the most recent Society of Environmental Toxicology and Chemistry's Pellston Workshop whose goal was to improve the process of identification and evaluation of chemicals against the PBT criteria. Furthermore, I am the chairperson for the International Life Sciences Institute's Health and Environmental Sciences Institute (HESI) Bioaccumulation Project Committee whose mission is to develop the tools needed for improving the assessment of the potential bioaccumulation of organic substances. In all of these activities, I have worked with staff from the US EPA. You can see from this brief summary of my background that I have both a comprehensive knowledge of the technical basis for the criteria, identification and assessment of Persistent, Bioaccumulative and Toxic (PBT) substances and the subcategory of organic PBTs called Persistent Organic Pollutants (POPs)s. In addition, I understand the goals of the various global PBT programs and how these lead to apparent differences in criteria and consequences.

INTERNATIONAL PROGRAMS HAVE BEEN ADDRESSING PBT'S FOR SEVERAL DECADES. PBT identification and assessment for new and existing chemicals has been a priority of governments including the United States since the early 1990s. The first national regulatory effort to establish criteria and a process to identify PBT substances was Environment

Canada's Toxic Substance Management Policy (TSMP), which was published in 1995[1]. An integral part of this policy was development and publication of the first set of screening criteria for identifying if a substance was persistent and/or bioaccumulative. The objective of the policy and its associated criteria was to provide a framework for making science-based decisions to identify and prioritize PBT substances for risk assessment and potential management. This scientific framework and criteria for Persistence and Bioaccumulation were also incorporated into the NAFTA CEC's Sound Management of Chemical's initiative (implemented in 1995)[2] and the UN ECE's Persistent Organic Pollutants protocol within their Long-Range Transport and Persistence (LRTAP) Convention (Entered into force 2003)[3]. Within the UN ECE POP's protocol, the persistence criteria for water and sediment were reduced slightly from those included in the TSMP. These final set of criteria for Persistence and Bioaccumulation were eventually incorporated into the UN Stockholm Convention on Persistent Organic Pollutants (entered into force 2004)[4]. Initially, in all these conventions, toxicity identification was determined by a risk based assessment called a risk profile but more recently a numeric criterion has also been incorporated in addition to the risk profile. Based on this vetting and discussion there is now international consensus that the UN Stockholm Convention and the Canadian TSMP criteria are scientifically-based and appropriate because these criteria are now incorporated into many national PBT regulatory programs. In Table 1, I illustrate the cross-section of Persistence and Bioaccumulation criteria used in several national and international programs. This table illustrates that although there are some differences in criteria, most regulatory programs have the same or very similar criteria. The differences in criteria typically reflect differences in regulatory objectives.

Using these criteria and assessment processes, very effective PBT screening identification and assessment processes have been on-going in Canada and Europe for approximately a decade. The Canadian Government in the Canadian Environmental Protection Act reauthorization in 1999 initiated a process to identify and prioritize PBT substances that are in commerce in Canada together with chemicals that have concerns for human health. This initial screening or categorization of the approximately 23,000 substances on the Domestic Substances List was completed in September 2006. Environment and Health Canada are now conducting screening assessments on the 200 highest priority substances (of which 77 were identified as potential PBT's) to determine whether the substance truly meets the criteria and if it is "toxic" or capable of becoming "toxic" as defined in CEPA 1999. This determination of toxic consists of conducting a risk assessment, which integrates the known or potential exposure of a substance with known or potential adverse effects on the environment and humans. A similar initiative was undertaken in Europe. Beginning in June 2001, the European Chemicals Bureau conducted a screening study to identify PBT substances among the 2682 high production volume chemicals[5]. They identified an initial list of 127 substances, which was finally reduced to 24 substances by incorporating data from manufacturers as part of a scientific review by regulators from across Europe. The next step in each of these programs after the initial PBT identification is to conduct

[1] http://www.ec.gc.ca/toxics/TSMP/EN/execsum.cfm
[2] http://www.cec.org/Page.asp?PageID=924&SiteNodeID=237
[3] http://www.unece.org/env/irtap/pops_h1.htm
[4] http://chm.pops.int/
[5] The approach and results are described at http://ecb.jrc.ec.europa.eu/esis/index.php?PGM=pbt

an evaluation of the sources, major emissions pathways to the environment in order to establish the most appropriate and effective measures to minimize risks to humans and the environment.

Since the 1990s, the US EPA has also been actively involved in developing a strategy for identifying PBTs and in assessing these priority substances for more detailed review of their persistence, bioaccumulation and toxicity properties, risk assessment and management within several TSCA programs. On November 4, 1999, EPA issued its final policy statement (64 FR 60194) on a category for PBT new chemicals which represented the first formal statement of national policy regarding new chemical "persistent organic pollutants" ("POPs"). The policy statement provided guidance criteria for persistence, bioaccumulation, and toxicity for new chemicals (Table 1) and advised the industry about EPAs regulatory approach for chemicals meeting the criteria. Using these criteria, the U.S. EPA initially developed a list of 53 chemicals, which was reduced to 28 organic chemicals and 3 metals based on comments and new information during public comment on the methodology. This list is used to help implement EPA's national RCRA waste minimization policy to reduce the generation of PBT chemicals found in RCRA hazardous waste. In 2004, EPA established a goal of a 10 percent reduction of these PBT priority chemicals by 2008 compared to a 2001 baseline. US EPA has complemented this waste minimization policy by adding many of these PBT chemicals to the Toxic Releases Inventory (TRI) reporting. For existing chemicals, PBT screening and the developed list of priority PBT substances has been used as one basis for choosing substances for development of EPA's chemical action plans. These National Action Plans for several of the chemicals included on the Priority Chemical list which include dioxins/furans, hexachlorobenzene, mercury, benzo(a)pyrene, and six additional polycyclic aromatic hydrocarbons (PAHs) are also used as part of the US's international commitments under NAFTA, the Canada-United States Binational Toxics Strategy, the United Nations Environment Programme's Persistent Organic Pollutants (POPs) effort, and the United Nations Economic Commission for Europe's Long Range Transport Air Pollutants (LRTAP) Persistent Organic Pollutants effort.

Since 1999, PBT screening has been an integral part of EPA's New Chemical PMN review under TSCA to avoid approving new PBTs. To provide transparency to stakeholders, EPA developed an evaluation tool called the PBT Profiler, which predicts PBT potential of chemicals. This assessment tool estimates the environmental persistence (P), bioconcentration potential (B), and aquatic toxicity (T) of discrete chemicals based on their molecular structure and compares the results to the PBT criteria The model compares results with the PBT criteria established for Premanufacture Notices (PMNs) submitted under section 5 of TSCA. This tool has been recognized as an extremely valuable contribution to the international community – regulators, industry and scientists - involved in PBT identification and assessments.

TSCA MUST BE FLEXIBLE TO INCORPORATE STATE OF THE SCIENCE. These initiatives in United States, Canada, and Europe have illustrated that it is possible to identify PBT substances and to conduct risk-based assessments; however, the process can be a scientifically challenging and requires the active involvement of manufacturers and scientists. Some of these challenges are related to the low water solubility, difficulty in measurement, and attachment to surfaces of these types of chemicals, which cause them to be classified as "difficult to test" substances. Thus, the scientific community has been working on developing guidance on how to evaluate chemicals with PB and T properties using readily available data. There has also

been an emphasis on developing improved test methods or modifying existing test methods so that the results are valid for "difficult to test" substances. For example, bioaccumulation tests have been modified to include new *in-vitro* metabolism methods. Because of the wide range of challenges and the importance of PBT assessments, many scientific groups are actively involved in research to improve assessment approaches and ensure greater confidence in the final PBT conclusions. For example, the Society of Environmental Toxicology and Chemistry conducted a Pellston Workshop whose goal was to improve the process of identification and evaluation of chemicals against the PBT criteria building on the most recent science[6]. Organization for Economic Co-operation and Development (OECD) and HESI's Bioaccumulation Committee are actively engaged in developing and validating alternative methods for Bioaccumulation assessments. European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC) has also developed guidance on how to conduct risk assessments for PBT substances[7]. Given the rapid improvement in the test methods and guidance it is critically important for US EPA to contribute to and incorporate the most current science and scientific understanding in their assessments, especially as these relate to reducing animal testing.

One recent example of the effort to improve the process and guidance for PBT identification and assessment was Society of Environmental Toxicology and Chemistry's (SETAC) Pellston Workshop. This workshop which was held in January of 2008 brought together experts from academia, government, and industry to review and discuss significance recent advancements in our understanding of the behavior and potential impact of PBTs in the environment as well as to develop recommendations for policy-makers on how to improve the science in the regulatory context. One concern raised by the workshop participants is that most of current national and international regulations define PBTs in terms of fairly strict pass or fail criteria. This is appropriate for early screening and prioritization but fails to recognize that the state of the science and our understanding of PBT which have vastly improved since these criteria were developed in the late 1970s and early 1980s. The incredible evolution in the state of the science since then has produced new insights into PBT substances and an array of new methods to identify PBT chemicals but the regulatory programs have not kept up with the rapid development in environmental chemistry and toxicology. As a result, scientists sometimes bring forward new data using the state-of-the-science test methods and evaluations, but find the data rejected because the regulatory framework does not allow for its consideration. With this background, any revision of existing frameworks for evaluating PBTs need to provide adequate flexibility to allow the introduction of additional, new, and emerging scientific evidence into the processes. One example is the application of bioconcentration factors to judge whether a substance is Bioaccumulative. Under most of the current regulatory schemes the only options are older models known as the OECD 305 tests which use a large number of fish and are very time consuming and costly. Providing flexibility to incorporate improved predictive models, in vitro metabolism test data, shorter less animal intensive screening BCF test data, and field data in the

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[6] **Integrated Environmental Assessment and Management** Volume 5 Issue 4 Nine papers on p. 535-711.

[7] ECETOC. TR 098 - Risk Assessment of PBT Chemicals. February 2006 http://www.ecetoc.org/index.php?mact=MCSoap,cntnt01,details,0&cntnt01by_category=5&cntnt01template=display_list_v2&cntnt01order_by=Reference%20Desc&cntnt01display_template=display_details_v2&cntnt01document_id=277&cntnt01returnid=89

evaluation would result in improved confidence in the PBT assessments while reducing cost, time and animals used in testing. The modernization of TSCA should be flexible to incorporate new, validated methods that used advanced state-of-the-science methods.

PBT'S MUST BE PRIORITIZED, ASSESSED FOR RISK AND, WHERE APPROPRIATE, MANAGED. For PBT screening identification, the chemical substances are evaluated as to whether they meet any of the three criteria, i.e., are they persistent or bioaccumulative or toxic. Depending on the objective of the particular regulatory framework within which the PBT identification is contained, the substances may be categorized into different groups by level of concern or priority depending on whether the substance meets a combination of these criteria. The highest priority for risk assessment and potential management are those substances that meet all three criteria - the combination of Persistence and Bioaccumulation and Toxicity. Canada's CEPA 1999 law took the focus beyond combined PBT to specify that chemicals which were persistent and toxic only (PiT) or bioaccumulative and toxic only (BiT) should also be prioritized, albeit with the very highest priority placed first on chemicals that meet all three criteria for P, B and T. The EU PBT strategy focused priority on those chemicals that are P, B and T and those that are very persistent and very bioaccumulative only (i.e., meet UN Stockholm Criteria P and B criteria) which are called vPvB. These options in how to prioritize substance for further scrutiny and risk-based assessment have some scientific basis, and can be incorporated into a priority setting approach based on PBT categorization. It is important to recognize that even if the same criteria are used to identify a PBT, the different regulations may designate them by different abbreviations (Table 1).

In all of these PBT identification programs, the initial prioritization of the substance is based on whether it meets the combination of PB and T criteria. The next step is to conduct a scientific risk-based assessment of potential for harm. This risk assessment process is separated from any final risk management decision although it can be used to inform potential risk management options. Furthermore, there is a range of management options available depending on uses of the substance. For example in the Stockholm protocol, management options range from 1) prohibition and legal or administrative action to eliminate the production and use of the chemical (Annex A) to 2) allowing production and specific exemptions for use by specific parties (Annex B). Environment Canada's PBT assessments also allow for range of management options from no-further action at this time to implementation of virtual elimination.

All of these programs, both nationally and internationally have illustrated that the use of PBT identification for existing chemicals would result in a relatively limited number of substances to assess and for which, if necessary, develop management strategies. It is not possible to predict the final number of PBT substances currently in commerce nationally and/or internationally that will require risk assessment and potential management; however, it would appear to be less than 100. For example, within the Stockholm POPs Protocol the initial number of high priority substances was 12 many of which were no longer manufactured. Currently an additional 9 substances have been recommended for listing in Annexes A, B and/or C with specific control measures. An additional three substance are under review. The EU review of their 2683 high volume chemicals resulted in identification of 24 PBT substances. The Canadian DSL categorization of 23,000 substances identified 77 PBT substances. The US EPA list of organic priority PBT substances is 30. There is a significant overlap of the substances across the lists. Some of the differences in numbers relates to the targeted objectives of the different national

programs, the actual value of the criteria and the way that these criteria are combined in the final identification (see Table 1).

RATIFICATION OF INTERNATIONAL CONVENTIONS SO THAT EPA CAN BRING SCIENTIFIC LEADERSHIP TO INTERNATIONAL FORA. My concern is that although the US and EPA scientists have publically committed to working with the international community to address chemicals of international concern and the EPA scientists were very active in the discussions on PBT screening criteria and assessment process on many of these international protocols including UNECE's POPs protocol and the Stockholm POPs convention, the US has not become a signatory to either of these critically important chemical management conventions. In fact, the October 5, 1998 notice that signaled the development of EPA's PBT strategy stated that part of the intent of this notice was to alert the parties involved in negotiation of the United Nations Environment Programme (UNEP) POPs Convention that the US was taking leadership on this issue. It was envisioned that this strategy could serve as a model for other countries in taking steps to discourage the introduction of chemicals with PBT properties as new chemicals and pesticides. In fact, the development of the PBT profiler has been a key contribution to this strategy and a tool that is used internationally as mentioned previously. However, the leadership position of the US in international chemical management has been weakened by not becoming a full signatory to these critically important conventions. I strongly urge the US to become a signatory to these Conventions so that U.S. government scientists can once again bring their knowledge and expertise forward in leadership internationally as full parties to these conventions. Within this role, the US and its scientists can also play an important role in leading first world nations to increase their participation in the global identification, risk-based assessment and management of PBTs which will improve the safety of US citizens from these international pollutants. Because, as mentioned previously, the process of identification, assessment and where necessary, risk management of PBTs is being continuously improved, EPA scientists should be in a position to provide leadership within these technical areas in the US as well as globally. Full US participation in these agreements is critical in maintaining, risk-based and science-based processes in PBT identification, assessment and management efforts globally. Thus, as you consider modernization of TSCA, in addition to becoming full signatories and parties to these conventions, it will be very important to provide adequate funding of EPA scientists to be integral members of national and international groups working on the continual improvement of methods and assessment approaches.

STRONG NATIONAL PBT PROGRAM. It is also important that the US EPA develop a stronger Federal PBT program to build confidence so that States do not have to take separate and potentially conflicting actions to identify and manage these types of substances. Most states don't have the depth of scientific expertise nor the number of staff to effectively conduct these scientifically challenging assessments. Thus, a role that EPA can play is to develop and promulgate methods for identification and assessment and provide assistance to states that are interested in investigating PBTs. To ensure acceptance and a technically strong, comprehensive process for identification and assessment of PBT's, these methods should be developed within a scientific multi-stakeholder process or through the use of a Scientific Advisory Panel. This will also require a commitment from Congress for full funding, staffing, and support of such a strong Federal PBT program.

Ultimately a reform of TSCA that contains a strong commitment and adequate funding to a Federal program for PBT identification, assessment and management and US leadership internationally in PBT conventions will encourage technical innovation of new chemicals and products that will improve the lives of US citizens and the international community. As a result, this modernized TSCA will benefit the US citizens as it will contribute to improving global public health and the environment for existing chemicals and provide assurance that new chemicals that have PBT properties will not enter commerce.

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

Table 1: Persistence and Bioaccumulation Criteria and their use in Various Regulations and Conventions.

Bioaccumulation Criteria Persistence Criteria (half-lives)	BCF/BAF* > 1000	BCF/BAF* > 2000	BCF/BAF* > 5000
Water = 180 days Soil = 180 days Sediment = 360 days			• US EPA New Chemicals Program (Ban)[2] • Canada TSMP [3] NAFTA SMOC [6]
Water = 60 days Soil = 180 days Sediment = 180 days		• EU TGD PBT [7]	• Stockholm POPs Protocol [4] • UNECE POPs Protocol [5] • EU vPvB [7]
Water = 60 days Soil = 60 days Sediment = 60 days	• US EPA New Chemicals Program (SNUR)[1]		

*Bioconcentration Factor (BCF)/Bioaccumulation Factor (BAF)

1. US EPA New Chemicals Program. 64 FR 60194 Category for Persistent, Bioaccumulative and Toxic New Chemicals Nov. 4 1999. TSCA 5e Action. Order Pending Testing/Significant New Use Rule (SNUR). Criteria also used in other TSCA regulatory programs.

2. US EPA New Chemicals Program. 64 FR 60194 Category for Persistent, Bioaccumulative and Toxic New Chemicals Nov. 4 1999. TSCA 5e Action. Ban Pending Testing. Criteria also used in other TSCA regulatory programs.

3. Canadian TSMP Criteria. http://www.ec.gc.ca/toxics/TSMP/ENG/assessment.cfm . These criteria were used in the Categorization of the DSL.

4. Stockholm Persistent Organic Pollutants Protocol. http://chm.pops.int Annex D contains the criteria

5. *1998 Aarhus Protocol on Persistent Organic Pollutants* http://www.unece.org/env/lrtap/pops_h1.htm

6.NAFTA Commission for Environmental Cooperation's Sound Management of Chemicals Initiative. http://www.cec.org/Storage/44/5963_CJS-2-e_EN.pdf

7. European Commission Joint Research Centre Institute for Health and Consumer Protection. for http://ecb.jrc.ec.europa.eu/csis/index.php?PGM=pbt

Mr. RUSH. The chair now recognizes Mr. Sturdevant for 5 minutes.

STATEMENT OF TED STURDEVANT

Mr. STURDEVANT. Thank you, Mr. Chair, members of the subcommittee for holding this hearing and for having me.

My name is Ted Sturdevant. I am the director of the Washington State Department of Ecology.

Citizens in Washington State, like elsewhere, I imagine, expect from government basic health protections from things like toxic exposures. In recent years, we in Washington were seeing rising levels of concern around toxic chemicals and so a few years ago we made an agency priority the reduction of toxic threats in our State, and we started with starting the nation's first PBT program. That seemed like a very logical place to start for reasons that you have heard. It is very clear that we should be very careful with PBTs and it is also very clear that we are not very careful with PBTs.

I had a real ah-ha moment when we were writing our PBT regulation. I was at home one morning, shaving, and I looked at the ingredients in the shaving cream and Nonylphenol was on there and the only reason that I knew what the heck that was is that we were considering inclusion of that chemical in our PBT list. It was right on the bubble and, you know, nothing on the can indicated it was anything I should be worried about and it just and, you know, I was rubbing this stuff on my face every day, and it just left me with this sense that no one was really watching and certainly not watching as closely as we should be.

I think that only prevention works with PBTs. Once you let the PBT genie out of the bottle, you can't get it back in. PCBs are a great example of that. They were banned 34 years ago but today PCBs are flowing into Puget Sound all the time. We are spending millions of dollars on cleanup and we are still seeing fish and wildlife impacts from PCBs.

A good and more recent example of both the challenge and I think the solution is found in the PBDE flame retardants you have heard about. They have been around since the '70s. In 2003, we were seeing rising levels of PBDEs in Washington's environment and citizens. We didn't really know much about them. They were appearing in women's breast milk, in house dust that babies crawl around in, in polar bears in the artic. So we decided to take a look at them as part of our PBT program. We spent 3 years working on a chemical action plan for those flame retardants and the more we looked, the more concerned we grew. Levels kept rising. Studies kept showing more health concerns.

In the meanwhile, industry was applying pressure saying they are safe, that we need to protect fire safety standards. We need to keep studying them and basically that everything was fine but we reached a very different conclusion. We decided that if there were better ways, if there were safer ways to flame-retard products in our homes, like TVs, computers, mattresses, furniture, then we should stop using PBDEs and use those safer alternatives, and we found ourselves in the middle of quite a fight. Some very sophisticated folks showed up in Olympia and fought us pretty hard on that and it took awhile but we did finally get there and we passed

the nation's first ban on the deca-form of PBDEs but that was only one State. The other States, several other States had to then go through the same fight, take different approaches and the good news is that enough States did that, that there was a recent announcement of a voluntary phase-out of deca production in the United States.

The bad news is that is not a very good system. It takes too long. It costs too much. It creates this patchwork of regulatory approaches across the country and it lets far too much unnecessary toxic contamination happen in the meantime.

I don't think at the root of this that the problem or the solution is terribly complicated. We need a Federal system that works based on a few commonsense principles. First, before allowing a substance to be put out there into widespread commerce, we should make every reasonable effort to make sure that it is safe. I think that it is fair that that burden rest on industry rather than on EPA and the taxpayers. Second, if we know that there are chemicals out there that are causing environmental or human health problems, government should be able to step in, protect citizens and ban those chemicals. Third, if we know with reasonable certainty that a substance poses problems and there are safer alternatives, we should stop using that and switch to the safer alternative.

With PBTs I think we already know enough that we should be very careful and make every effort to phase-out those uses that we can do without and prevent new uses. These seem to me to be sound, fair principles for a reasonable chemicals policy but it is not the one we have today. I would urge you to fashion such a policy. This isn't about being anti-chemical. It is about being pro-safer-chemical whenever you can and should.

As you look at TSCA, I would ask you to keep in mind the role that the States have played in advancing protections from PBTs and other toxic chemicals. Even with TSCA reform, if another 30 years go by before we revisit it, we are going to need the States to fill in the gaps and be the laboratories of reform, and I would ask you to preserve our ability to do that. And because we at the State level need a strong Federal system, Washington and 12 other States in December issued our principles for reform of TSCA and those were provided to you with my written testimony.

Finally, one other priority that we have in the State of Washington is restoring our Puget Sound to health by 2020. That problem with the Sound is not just about toxic pollution but toxic chemicals are entering the Sound everyday. Now, fixing TSCA won't fix Puget Sound but if we don't fix TSCA, and prevent a lot of that toxic contamination that could be prevented, we are not going to fix Puget Sound, and I don't think we are going to fix a lot of our other waterways, either, and we will continue to experience toxic exposures that just don't need to happen.

So with that, I would like to express my very sincere gratitude for your looking at this issue and I respectfully urge you to craft a strong chemicals management policy that this country very much needs and deserves. Thank you.

[The prepared statement of Mr. Sturdevant follows:]

Testimony of Ted Sturdevant
Executive Director
Washington State Department of Ecology
Before the
Subcommittee on Commerce, Trade and Consumer Protection
Committee on Energy & Commerce
U.S. House of Representatives

March 4, 2010

I appreciate the opportunity to testify on this important issue. My name is Ted Sturdevant, and I am the Director of the Washington State Department of Ecology. In Washington State, we have made the reduction of toxic threats one of our top strategic priorities. One of the foundations of that effort has been our focus on phasing out persistent, bioaccumulative toxics, or PBTs.

I am not a scientist, and I'm sure you will hear from others more qualified to speak to the unique dangers posed by PBTs. These chemicals are often called "the worst of the worst" because they persist in the environment, they build up in our bodies and the food chain, and they are toxic. Over 10 years ago, we recognized that if we were serious about protecting human health and the environment in Washington from toxic contamination, PBTs were the right place to start. Washington was the first state in the nation to target PBTs, developing a PBT strategy in 2000 and adopting regulations in 2006 to phase out their uses and releases. We have since developed and implemented chemical action plans on mercury, PBDE flame retardants and lead, and we are now beginning work on PAHs, or polycyclic aromatic hydrocarbons.

This approach has resulted in the collection and proper disposal of over 14,000 pounds of mercury that otherwise might have been released to the environment or led to human exposure, and helped shape the national program to remove mercury switches from automobiles.

It also led to the nation's first ban on decaBDE, a commonly used flame retardant, after years of research and a great deal of political opposition. Since then, several other states have banned decaBDE, and recently the EPA announced the phase-out of decaBDE production in the U.S. And our action plan on lead resulted in a ban on lead wheel weights, and ongoing work to eliminate the threat of exposure among children to lead paint in older homes.

That may sound like I'm boasting of our success, but the truth is that our approach to protecting people and our environment from toxic chemicals is a failure. It's a failure at the state level, and it's a failure at the national level. We are failing to prevent avoidable harm to our children, we are failing to protect the food chain that sustains us, we are failing to save countless millions of taxpayer dollars that are wasted on health care costs and environmental cleanup, and we are failing to exercise common sense.

After working on toxics issues for the past several years, I have found that behind the science, behind the congeners and the acronyms and the chemistry, the core of this debate is actually quite simple, and it all comes down to common sense, and the old adage that an ounce of prevention is worth a pound of cure. I think the basic principles for a rational chemicals management policy are these:

First: before you allow a substance to be put into widespread use and commerce, it makes sense to take all reasonable measures to first make sure it is safe.

Second: if science tells us that there are toxic chemicals that pose an urgent and unacceptable threat, government should be able to protect the public and ban those chemicals.

Third: if we know with reasonable certainty that a particular substance is dangerous to people or the food chain and doesn't break down; and if we know that allowing continued use of that substance will spread it far and wide; and if there is an alternative substance that could perform the same task much more safely; then the right policy is simple: stop using the dangerous substance, and use the safer alternative. In the case of PBTs, we already know enough that we should make every effort to phase out current uses and prevent new uses.

These concepts seem to me to be sound, fair principles for a reasonable chemicals policy. But none of these principles – precaution, targeted bans when needed, or encouraging the use of safer alternatives – describes current policy. Instead, the burden of proof is on EPA to prove a chemical unsafe, without the proper tools or data to do that job. And even in instances where safer alternatives exist for a chemical for which there is clear cause for concern, there is no effective mechanism to require or encourage switching to the safer alternative.

PCBs provide a good example of how the system doesn't work. The production of PCBs began in the 1920's, and by the 1930's there were already studies suggesting that PCBs were harmful to humans. Production and use continued to increase, as did the data warning of concerns. The EPA finally banned PCBs in 1979, after more than 50 years of widespread use. Since then,

despite the ban and millions of private and taxpayer dollars spent on PCB cleanup in Washington State, significant amounts of PCBs continue to flow into Puget Sound today.

This is a critical point; when we put persistent toxics out into the world, they persist. And if they turn out to be a problem, then the problem becomes enormous, and largely unsolvable. Once out, we cannot ever truly put the PBT genie back in the bottle. This has been an expensive lesson that we all should learn from – when we uncork that bottle, let's be as sure as we can that it makes sense to do so.

Without a system that starts with precaution, allows targeted bans and effectively moves us from less safe to more safe products, we at the state level are forced to fight for and fund solutions on a patchwork basis, as more and more of us recognize that federal chemical policy does not provide the tools we need to carry out our missions to protect our citizens and environments. State by state, chemical by chemical approaches are not efficient or effective ways to address PBTs, which do not respect jurisdictional boundaries.

While I would much prefer a strong federal system, and at long last have great hopes for TSCA reform this year thanks to your interest and leadership, please keep in mind the critical role the states have played in advancing protections from PBTs and other toxic chemicals. Even with effective reform this year, if another 30 years go by before revisiting TSCA, we will need the states to fill in the gaps and serve as the laboratories of reform, and I ask you to preserve our ability to do so.

Because the need is so clear for federal reform, Washington and twelve other states issued in December our Principles for Reform of the Toxic Substances Control Act, outlining our hopes for

an effective federal chemicals management program, which I have provided with my written testimony.

I'd also like to speak to the politics of chemical policy. Not many years ago, toxics issues were widely perceived as being outside the mainstream. Battle lines were commonly drawn along ideological or partisan lines. I believe this has changed significantly in the past few years. As our scientific understanding of impacts from various chemicals has increased, as work on green chemistry and safer alternatives has progressed, and as the public has become aware of holes in the system designed to protect us from toxic exposures, the demand for action has risen dramatically, and not along party lines.

Rather than pitting jobs against the environment, intelligent reform protects both. When we identified a safer alternative to decaBDE, that alternative was being manufactured by some of the same companies that produced decaBDE. The choice is not about *whether* we are able to produce or use critical products like flame retardants, it is instead about using the *least harmful* of those products when it is warranted.

Our ban on decaBDE was a strongly bipartisan vote, and in the last few weeks, the Washington Legislature passed bills to ban certain products containing Bisphenol A by a 36-9 vote in the state Senate, and 95-1 in the state House. We did this with strong bipartisan votes because the bill made common sense – there is legitimate cause for concern over that chemical, and clearly safer alternatives exist for those products named.

There is nothing partisan about the principle of prevention, nor can I see an ideological divide over the principle that when safer alternatives are available that would allow us to avoid human and environmental harm, and save taxpayers money, we should use them.

As you contemplate reform of the Toxic Substances Control Act, I ask you to build a preventive framework that requires reasonable measures to show that chemicals are safe before they are allowed into widespread commerce.

And for those chemicals that are already out there among us, I ask you to create a system that prioritizes chemicals of concern, and provides effective tools to address them. For the worst of the worst, EPA needs to be able to ban them, with PBTs at the top of that list. For others, we need a clear means of determining whether safer alternatives exist, and a mechanism that moves us toward those safer choices.

I appreciate the opportunity to testify today, and I deeply appreciate your interest in strengthening our nation's approach to protecting our citizens and environment from avoidable toxic contamination.

STATES' PRINCIPLES ON REFORM OF THE TOXIC SUBSTANCES CONTROL ACT
DECEMBER 2, 2009

Require Chemical Data Reporting. Chemical and product manufacturers should be required to develop and provide chemical health and safety information, as well as exposure and use data, including the presence of toxic chemicals in products and the associated chemical hazards and risks, to regulators, businesses, and the public.

Demonstrate Chemicals and Products are Safe. Manufacturers should provide the necessary information to regulators to conclude that new and existing chemicals and products in commerce are safe and do not endanger the public or the environment. The public has a right to expect that the products they use are safe.

Prioritize Chemicals of Concern. Government should identify and prioritize chemicals of concern in order to regulate the most problematic chemicals in commerce, and have the authority to take timely action to protect people and the environment. Sufficient resources should be made available to support these actions.

Protect the Most Vulnerable. Chemical regulation should be designed to protect the most vulnerable, including pregnant women and children.

Promote Safer Chemicals and Products. Based on green chemistry principles, manufacturers should be required to assess and identify safer alternatives to problematic chemicals of concern. Government should establish protocols for evaluating potential alternatives to chemicals of concern.

Address Emerging Contaminants. Emerging chemicals of concern, including nanoscale materials, need to be assessed for public and environmental safety before they go into widespread commerce and use.

Strengthen Federal Law & Preserve States' Rights. States acknowledge the need for a strong federal chemical regulation system, while expressly preserving the authority of state and localities to implement measures to manage chemicals of concern.

Fund State Programs. Effective state-federal governance should enhance the role of states in TSCA implementation, promote data and information sharing, and provide sustained funding for state programs. The states are in a unique position to provide innovative, cost-effective solutions for chemicals of concern prioritization, interstate data sharing, and safer chemical alternatives assessments.

States' Principles on Reform of the Toxic Substances Control Act
December 2, 2009 State Signatures

Linda S. Adams, Secretary
California Environmental
Protection Agency

Amey W. Marrella, Commissioner
Connecticut Department of
Environmental Protection

Douglas P. Scott, Director
Illinois Environmental Protection Agency

David P. Littell, Commissioner
Maine Department of
Environmental Protection

Shari T. Wilson, Secretary
Maryland Department of the Environment

Laurie Burt, Commissioner
Massachusetts Department of
Environmental Protection

Steven E. Chester, Director
Michigan Department of Environmental
Quality

Thomas S. Burack, Commissioner
New Hampshire Department of
Environmental Services

Mark N. Mauriello, Acting Commissioner
New Jersey Department of Environmental
Protection

Pete Grannis, Commissioner
New York State Department of
Environmental Conservation

Dick Pedersen , Director
Oregon Department of
Environmental Quality

Justin G. Johnson, Commissioner
VT Department of
Environmental Conservation

Ted Sturdevant, Director
Washington State Department of Ecology

California | Connecticut | Illinois | Maine | Maryland | Massachusetts | Michigan | New Hampshire | New Jersey | New York | Oregon | Vermont | Washington

Mr. RUSH. Thank you very much.

Now, the chair recognizes Dr. Adams for 5 minutes.

STATEMENT OF WILLIAM ADAMS

Mr. ADAMS. Thank you, Mr. Chairman. It is my pleasure this morning to testify and talk about Toxic Substance Control Act and PBT particularly as it applies to metals.

I am the chairman of the North American Metals Council. I am also a scientist and I have worked in the area of PBTs since the late '70s, and specifically, in the 1990s, and more recently on the REACH legislation in Europe. And over the course of time, I have published some hundred papers and I have published a book on PBT, so let me begin.

I would like to give you some details about why PBT, some of the criteria of PBT are not applicable to metals. I would also like to give you some information as to how I think the hazard of metals and inorganic substances should be determined.

Regarding persistence, persistence is problematic for metals because all metals and elements on the Periodic Table are conserved, and hence, they are persistent. The form and availability of the metal can change depending on the environmental conditions. They are also different for each metal element on the Periodic Table and this should be considered. Thus, setting a criterion say of example of removal of 70 percent in 28 days in the water automatically includes all the metals, and this includes the ones that are essential such as copper, zinc and iron, which are essential for life. As a result, applying criteria that were designed for organic substances to the metals then creates problems that are not necessarily needed.

Regarding bioaccumulation, unlike organic substances, bioaccumulation potential of metals cannot be estimated using octanol-water partition coefficients. This is a common approach to estimate the amount of substance will accumulate in the fat of an organism. Bioconcentration and bioaccumulation factors are inversely related to exposure for metals. This is not the case for organics. The consequence of this is that in the most cleanest environments we have, let's take Lake Superior. What we find in that situation is that we have the biggest bioaccumulation factors. PBT criteria used, for example, use a bioaccumulation factor of 1,000 to decide whether a substance is bioaccumulative. All the metals pass that criteria for Lake Superior so, in fact, the whole approach is counterintuitive. The cleanest environments give you the biggest bioconcentration factors. In short, that B does not work for inorganic substances.

Regarding toxicity, metals are generally not soluble. Toxicity results are almost always based on soluble metal salt that has been used in some toxicity tests for some organism. However, those are not the products that are put in the marketplace. By and large, the massive metals, the powders, the oxides, the sulfites are insoluble substances. I would like to point out in our recent discussions with the European Commission, we had this same discussion and after a long period of time and many testimonies the REACH regulations now acknowledge that PBT criteria do not apply to metals, and you can find this in the text of the Annex XIII of the REACH regulation.

Now, I would like to take a moment or two then to propose an alternative. If we argue that P and B are not applicable to metals then let's look at what I think might work.

In 2003, I chaired a SETAC, environmental toxicology and chemistry, sorry, Society of Environmental Toxicology and Chemistry workshop. We invited some 40 scientists from around the world to participate in this and the specific issue at hand was, how do we assess the hazard of metals. At this workshop PBT issues were discussed at length and reported out in a book which I edited.

Consensus was reached at the workshop that the individual criteria, P, B and T, are limited in their ability to assess hazard or to prioritize metal substances. The criteria are not linked or integrated, and they attempt to identify or predict hazards using bioaccumulation and persistence as modifiers of toxicity but without fully incorporating other important fate characteristics, which for metals can include speciation, complexation, precipitation, dissolution, transformation, and sedimentation, and the approach does not consider exposure or release rate so we are essentially assessing hazard but no effort to assess risk.

The science community recommended that a more comprehensive approach be taken for both metals and organics in which a generic hazard ranking could be determined using a model which simulates natural receiving water such as a lake. The model is termed a Unit World Model. The aim is to incorporate partitioning, transport, reactivity, bioavailability, and exposure route to give a single, transparent metric of hazard. It is essentially a critical load approach in which an estimate is made at the rate of which a chemical must be introduced into a common defined environment to achieve a concentration that becomes toxic, and the output of this model then is a calculation of the rate and the amount that has to be released to cause a problem. This allows then a ranking of both metals and organic substances so that you now not only just have criteria that says yes, it is PBT, but you have a ranking of the substances. Following the workshop, efforts have been ongoing to develop and validate this model and we worked on this now for 6 years. This model is now available and it can be downloaded and you can find it at www.unitworldmodel.net.

In conclusion, attempts to universally and indiscriminately apply PBT criteria to all chemical substances and, for example, including metals, would be of concern, and would not necessarily reflect good science. Similarly, PBT information, by itself, cannot determine risk and such criteria should not be used in isolation as a basis for requiring regulatory action. It is important, and I summarize, to understand that persistence and bioaccumulation factors are not particularly useful for assessing metals. I believe the state of the science has moved beyond PBT and we have an opportunity to use more integrated, and a more reliable approach that not only considers the hazard but also considers release rates and processes that occur in nature, and this approach is now available.

I thank you for this opportunity and I would be pleased to take any questions.

[The prepared statement of Mr. Adams follows:]

WRITTEN STATEMENT OF
WILLIAM ADAMS, Ph.D.
CHAIRMAN OF THE
NORTH AMERICAN METALS COUNCIL (NAMC)

AS SUBMITTED TO THE
SUBCOMMITTEE ON COMMERCE, TRADE & CONSUMER PROTECTION

COMMITTEE ON ENERGY & COMMERCE
U.S. HOUSE OF REPRESENTATIVES

ON

"PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT):
STRENGTHS AND WEAKNESSES"

March 4, 2010

Introduction

As Chairman of the North American Metals Council (NAMC), I appreciate the opportunity to submit this testimony for the Subcommittee's consideration. NAMC is an unincorporated not-for-profit group of metals-producing and metals-using associations and companies that focuses on science and policy issues that affect metals in a generic way. On behalf of NAMC members, I am pleased to provide these comments on the use of PBT -- or persistence, bioaccumulation, and toxicity -- for assessing the hazard of chemical substances, including metals and metal compounds.

My background is as a scientist with a Ph.D. in Environmental Science with 14 years work experience in the organic chemical industry and 15 years experience in the metals industry. I have published several papers specifically addressing PBT issues and edited a book on the subject. Over the years, I have developed approximately 100 technical papers in the environmental science field. Additionally, I served on the U.S. Environmental Protection Agency (USEPA or EPA) Science Advisory Board for 10 years. I currently work for Rio Tinto, a global mining company.

As Chairman of NAMC, I am particularly proud of NAMC's cooperative role with EPA in the development of the *Framework for Metals Risk Assessment* (*Framework*).[1] The *Framework* was published in 2007 and outlines key principles on how metals should be considered in health and ecological risk assessments. As recognized by EPA in the *Framework*, inorganic metals and metal compounds present unique issues for risk assessors and generally should not be assessed using models developed for organic substances. It is with this perspective that I offer the following comments.

What Are PBT Criteria and How Are They Used?

PBT criteria are measures of chemical substance properties that have been used since the early 1970s to assess the hazard and key environmental fate attributes of chemicals as a means to identify substances that have the potential to harm the environment. In the U.S., the development of hazard and risk assessment methodologies for chemical substances began in the late 1960s and early 1970s to formalize an approach for selecting product substitutions (for example in the soap and detergent industry and eventually in the pesticide and industrial chemical industry). Hazard (or "toxicity") is defined as a measure of the inherent (intrinsic) capacity of a substance to cause an adverse response in a living organism. Risk is

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[1] EPA. 2007. Framework for metals risk assessment. EPA 120/R-07/001, Office of the Science Advisor Risk Assessment Forum, USEPA, Washington, DC 20460. *Available at* http://www.epa.gov/raf/metalsframework/pdfs/metals-risk-assessment-final.pdf.

defined/described as the integration of hazard and exposure information and is thus not an intrinsic attribute of a substance (*e.g.*, the extent of risk will vary depending on the extent of exposure).

In the context of PBT approaches, "T" or toxicity has been used primarily, but not exclusively, to assess the hazard of substances to aquatic organisms. "B" typically refers to bioaccumulation in fish or other aquatic species; there are no universal metrics of B for humans. "P" refers to persistence and is generally measured as a half-life for degradation in the environment. This can include biological (biodegradation) as well as chemical (*e.g.*, hydrolysis, photolysis) processes. In the 1990s, there was increasing recognition that organic chemicals such as polychlorinated biphenyls (PCBs) and dichlorodiphenyltrichloroethane (DDT) that present properties of P, B, and T are of particular concern for their potential effect on the environment.

There have been several primary uses of PBT information:

- prioritization of substances for further testing;
- environmental hazard classification of substances and use in safety data sheets;
- ranking and/or selection of priority substances;
- selection of contaminated sites for further evaluation; and
- selection of substances for water, soil, and sediment quality guidelines or criteria.

There is considerable literature on the environmental assessment of organic substances focusing on Persistence (P), Bioaccumulation (B), and Toxicity (T).[2,3,4,5] These factors are used in

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[2] Adams, W.J., B. Conard, G. Ethier, K.V. Brix, P.R. Paquin, and D.M. DiToro. 2000. The challenges of hazard identification and classification of insoluble metals and metal substances for the aquatic environment. *Hum. Ecol. Risk Assess.* 6(1): 1019-1038.

[3] Kleka. G, Boethling B, Franklin J, Grady L, Graham D, Howard PH, Kannan K, Larson RJ, Mackay D, Muir D, van de Meent D. 2000. *Evaluation of Persistence and Long-Range Transport of Organic Chemicals in the Environment.* SETAC Press, Pensacola, FL, USA.

Europe, Canada,[6] the U.S.,[7] and elsewhere by national and international agencies (*e.g.*, the Stockholm Convention on Persistent Organic Pollutants[8]). In the U.S., PBT criteria have been used to identify substances of concern for waste minimization, emissions reporting, and for the identification of substances for stricter regulations (air, water, solid waste). In Canada, a PBT-type approach is one avenue used for categorizing substances on the Domestic Substances List (DSL) to determine if a screening assessment is required. Most recently, the use of PBT has been applied in Europe as part of the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) legislation, wherein PBT criteria are used as part of an overall approach for identifying substances that may require Authorization for continued use.

For reasons that I will explain in more detail below, it is very important to recognize that there is acknowledgement in the REACH regulations that these PBT criteria do not apply to metals.[9] The text in Annex XIII, which outlines the criteria for identification of PBT substances, specifically notes that "this annex shall not apply to inorganic substances," which includes metals, although it does apply to organo-metals.

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4 Scheringer M. 2002. Persistence and Spatial Range of Environmental Chemicals: New Ethical and Scientific Concepts for Risk Assessment. Wiley & Sons Inc. Hoboken, NJ, USA.

5 Lipnick RL, Hermens JLM, Jones KC, Muir DCG (eds). 2000. American Chemical Society Symposium Series No.772 *Persistent, Bioaccumulative, and Toxic Chemicals: Volume I*. American Chemical Society, Washington, DC, USA.

6 Government of Canada. 1999. *Canadian Environmental Protection Act (CEPA)*. Government of Canada, Ottawa, ON, Canada.

7 EPA. New Chemicals PBT Policy at http://www.epa.gov/fedrgstr/EPA-TOX/1999/November/Day-04/t28888.htm.

8 Stockholm Convention on Persistent Organic Pollutants at http://chm.pops.int/Convention/tabid/54/language/en-US/Default.aspx.

9 Commission of the European Communities. 2001. Amended Proposal for a Decision of the European Parliament and of the Council Establishing the List of Priority Substances in the Field of Water Policy, Paragraph 20 (Jan. 16, 2001); Official Journal of the European Union, ANNEX XIII - Criteria For The Identification Of Persistent, Bioaccumulative And Toxic Substances, And Very Persistent And Very Bioaccumulative Substances.

Recognized Limitations of PBT Applications

The scientific underpinnings of the use of PBT lie in the fact that these measures are believed to represent inherent or intrinsic properties of the chemical. As such, these properties are independent of environmental changes in temperature, pressure, fish species, etc., or other factors, especially exposure concentration. This turns out to be only partially true, as it is known that biodegradation studies used to measure P are subject to changes in temperature as this affects the rates of biodegradation by microorganisms. B is also affected by temperature and length of the exposure, and the potential for metabolic breakdown (metabolism) which can differ between species.

To overcome these difficulties, standard test methods have been established such that the measures reflect pseudo-intrinsic values. For both P and B, the test results obtained for most organic substances using these methods are independent of test concentration making the measures relevant to real world systems where concentrations often vary. Toxicity, however, is directly related to exposure concentration and duration (*e.g.*, acute versus chronic exposures) and therefore test conditions are standardized to allow for repeatable measures of toxicity to standard species.

In the U.S., PBT was proposed for use by the USEPA in 1997 for selection of substances for waste minimization, identified as a Waste Minimization Prioritization Tool. PBT criteria were used to score chemical substances. In 1999, EPA's Office of Solid Waste developed a list of substances using the PBT tool. At that time, NAMC provided comments on the limitations of the tool for application to inorganic substances, including metals. In 2007, EPA's *Framework* clearly identified the limitations of applying P and B for metals assessment.[10]

Strengths and Weaknesses of the Use of PBT Approaches and Standard Criteria

Strengths -- The main advantage of the use of PBT is its simplicity. It requires only three measures that are easily determined and apply to many classes of organic compounds. The test procedures are standardized and utilized globally. Data bases now exist where the PBT values can be identified and used as needed. The development of the High Production Volume (HPV) program under the Organization for Economic Cooperation and Development (OECD) and by USEPA has generated additional PBT data, and the REACH regulation in Europe should provide yet additional information. All of these efforts lend themselves to making a vast amount of data available for assessing hazard and environmental fate of chemical substances using a PBT approach. The approach has the advantage and reputation of identifying problematic substances that are recognized internationally in the Stockholm Convention on Persistent Organic

10 *Framework* at Section 5.2.5.4.

Pollutants. It is important to note that the PBTs addressed under the Stockholm Convention are limited to organic substances that also have the ability for global environmental transport (*e.g.*, dioxins, furans, PCBs, organochlorine pesticides such as DDT, dieldrin, chlordane, etc.). It is important to recognize that not all organic PBTs have the potential for global transport.

Weaknesses -- The simplicity of the approach is also a drawback to its broad application. The PBT screening criteria assess only hazard and key environmental fate properties, not risk. A substance may pose PBT concerns, but not present risk if exposure is controlled or is minimal. To assess risk, a PBT approach must additionally consider volume of production and release to the environment. PBT assessment provides information on the properties of the substance, but not the probability or likelihood of effects. Other disadvantages include the following:

- PBT does not consider pathways and magnitude of entry to the environment.
- Octanol-water partition coefficients (Kow) have been used as surrogates for measures of B. These measures do not consider the potential for metabolism and are not applicable to some classes of compounds, including metals, silicates, and other inorganic substances.
- Measures of persistence typically focus on biodegradation and not other environmental loss mechanisms that can include hydrolysis, photolysis, complexation, burial in sediments, and remineralization.

In addition, the approach does not consider the benefits of a given chemical substance.

Why PBT Criteria Are Not Appropriate for Metal Substances

Specifically for metal substances, there are several disadvantages and reasons why PBT criteria have limitations to their use, which are outlined below. That is why NAMC supports an alternative approach to PBT assessment for evaluating metals and metal compounds, which is explained later in this testimony.

- Persistence: Persistence is problematic for metals because all metals and elements on the periodic table are conserved[11] and hence, persistent. The form and availability of the metal can change depending on the

[11] Law of Conservation of Mass is a relation stating that in a chemical reaction, the mass of the products equals the mass of the reactants. *See* http://chemistry.about.com/od/chemistryglossary/a/conservmassdef.htm.

environmental conditions. They are also different for each metal element and this must be considered. Thus, setting a criterion such as a half life for degradation of 70% in 28 days in water automatically captures all metals, including those that are essential (iron, copper, zinc, etc). As a result, applying criteria designed for organics to metals can be misleading. A more discriminating approach is needed. This issue becomes significant if PBT criteria are used to identify contaminants of concern and to introduce restrictions on commerce, transportation, and labeling.

- Bioaccumulation: Unlike organic substances, bioaccumulation potential of metals cannot be estimated using octanol–water partition coefficients (Kow). Bioconcentration and bioaccumulation factors (BCFs and BAFs) are inversely related to exposure concentration and are not reliable predictors of chronic toxicity, food chain accumulation, or hazard. The inverse relationship between exposure concentration and BCF results in organisms from the cleanest environments (*i.e.*, background) having the largest BCF or BAF values. This result is counterintuitive to the use of BCF and log Kow as originally derived for organic substances.[12]

- Toxicity: Metals are generally not readily soluble. Toxicity test results based on soluble salts may overestimate the bioavailability and the potential for toxicity for many substances, especially for the massive metals and insoluble sulfide and metal oxide forms. Further, many organisms appear to regulate metal accumulation to some extent, especially for essential metals.

Alternative Approach for Assessing Metal Substances

In 2003, I chaired a workshop which was sponsored by the Society of Environmental Toxicology and Chemistry (SETAC), a professional society that supports practices for protection, enhancement, and management of sustainable environmental quality and ecosystem integrity. At the workshop, PBT issues were discussed at length and reported out in a book.[13] Consensus was

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12 McGeer, J.C., K.V. Brix, D.K. DeForest, S.I. Brigham, J.M. Skeaff, W.J. Adams and A. Green. 2003. Bioconcentration Factor for the Hazard Identification of Metals in the Aquatic Environment: A Flawed Criterion? *Environ. Tox. Chem.* 22(5): 1017-1037.

13 Adams WJ, Chapman PM. 2005. Assessing the Hazard of Metals and Inorganic Metal Substances in Aquatic and Terrestrial Systems: Summary of a SETAC Pellston Workshop. Pensacola (FL). SETAC Press, Pensacola, FL, USA.

reached at the workshop that individual criteria, like PBT, are limited in their ability to assess hazard or to prioritize metal substances. The criteria are not linked or integrated and they attempt to identify or predict effects (hazard) using bioaccumulation and persistence as modifiers of toxicity, without fully incorporating other important fate characteristics, which for metals include speciation, complexation, precipitation, dissolution, transformation, and sedimentation.

It was suggested that a more comprehensive approach be taken for both metals and organics in which a generic hazard ranking be sought using a "unit world" model. The aim is to incorporate partitioning, transport, reactivity, bioavailability, and exposure route information to give a single and transparent metric of hazard. It is essentially a "critical loading" approach in which an estimate is made of the rate at which a chemical must be introduced into a common defined environment to achieve a concentration in a target compartment (such as water or fish) that is deemed to be of concern from toxicity or regulatory objective viewpoints. An LC50 or no-effect level could be used. Hazardous substances will have lower critical emission rates. A group of metals and organics can thus be ranked for a common metric of hazard using this critical loading approach. Following the workshop, efforts have been on-going to develop and validate a Unit World Model.[14] This model is now available for use (www.unitworldmodel.net).

Conclusion

Any attempt to universally and uncritically apply PBT criteria to all chemical substances -- for example, to create lists of chemicals of concern -- would be scientifically inappropriate and would result in misleading if not erroneous outcomes. Similarly, since PBT information, by itself, cannot determine risk, such criteria should not be used in isolation as a basis for requiring regulatory action. If, regardless of these cautions, an attempt is made to base regulatory actions on PBT information for some substances, it is important to understand that persistence and bioaccumulation factors cannot be applied to metal materials because P and B criteria were developed for organic chemicals and are ill-suited to evaluate the hazards of metals. Instead, consideration must be given to an exposure concept of transformation relative to the potential release of forms of metals that are bioavailable.

Thank you for this opportunity.

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14 Farley, K. 2010. Validation of the Unit World Model. Presentation at the ICMM Technical Working Group Meeting, Raleigh-Durham, January 7, 2010. Manuscript I preparation, Manhattan College, New York.

Mr. RUSH. The chair thanks the witnesses again.

And the chair recognizes himself now for 5 minutes of questioning of the witnesses.

And, Dr. Greer, it is my understanding that if we know a given chemical is toxic and there is exposure and then we can determine the risk as defined by the national academics in their 1983 so-called Red Book they laid out the Federal risk assessment process. Risk assessment is "the characterization of the potential adverse health effects of human exposure to environmental hazards." From that, Dr. Greer, can we assume that if a chemical is persistent, bioaccumulative and toxic that it is a PBT and there are known exposures so therefore there is a high risk? I have a couple of other questions that go along with that. When we know that there are PBTs and evidence of exposure, I understand that exposure can be important based on the geographic areas of specific populations, how should we address this concern? Can you answer both of those questions?

Ms. GREER. Sure, let me clarify that it is not my position that risk assessment is not a valuable tool or that it is not important to look at both hazard and exposure, not at all but there are certain chemicals out there that meet the PBT criteria for which we already have evidence of exposure through biomonitoring of human blood or through looking at animals at the top of the food chain. And that combination, in my mind, is definitely sufficient to identify those chemicals for fast action so that the agency does not spend years and years deciding what level is dangerous but start asking questions about use reduction instead. What are do we have critical uses that we have to keep on the market? Do we have, you know, really the opposite, stupid uses that we could get rid of quickly and to start asking reduction questions rather than risk question. So I think that the real problem here is not so much the debate about risk assessment and exposure but really how to get, how to change TSCA so that it is not just about study, study, study but is about taking action instead. Asking the set of use production questions and exposure reduction questions instead of the questions just about hazard which is what the agency has, unfortunately, spent most of its 35 years doing.

And when we look at the uses of these chemicals, we have to look at the patterns of exposure and the patterns of use. We know from experience that there are many communities with hotspots of exposure where certain chemicals have been used in large quantities and have accumulated. Certain patterns in diets that have hotspots of human exposure, et cetera. It is very hard to make a general safety determination that it is going to be okay here and not okay there because we usually lack the information about the widespread and spotty uses of these chemicals combines. I hope that answers your two questions.

Mr. RUSH. Dr. Jones, I have about another minute and a half. Do you generally have a response to the questions?

Mr. JONES. The same questions?

Mr. RUSH. Yes.

Mr. JONES. The agency believes that ultimately we need to evaluate chemicals based on their hazard, their exposure and their risk, and that the reason for that is that by addressing chemicals and

uses that have the highest risk, we are going to get the best protection for the country, and not spending our energies on exposure routes that may pose little or not risk but instead on those exposure routes that are going to present the highest risk.

Mr. RUSH. Okay. The chair recognizes now Mr. Whitfield.

Mr. WHITFIELD. Thank you, Mr. Chairman, and thank you all for your testimony. We appreciate it very much.

Mr. Jones, back in 1991, there was a lawsuit, Corrosion Proof Fittings v. EPA, which evidently in the TSCA Act when you came up with the measure to correct the problem you use the least burdensome standard and evidently in that particular case, the EPA did not use the least burdensome standard. What is the difference in the standards in this in TSCA and in say the Clean Air Act?

Mr. JONES. Unfortunately, I am not particularly expert at the Clean Air Act but I have a high degree of expertise in the pesticide regulatory framework, FIFRA.

Mr. WHITFIELD. FIFRA, okay, let's say FIFRA.

Mr. JONES. Well, I am sorry. My expertise is in pesticides and in TSCA.

Mr. WHITFIELD. Oh, okay.

Mr. JONES. The pesticides program which is sort of similar, it is chemicals.

Mr. WHITFIELD. Yeah.

Mr. JONES. Thus the regular standard is a reasonable certainty of no harm for chemicals used on food and it is a basic risk benefit standard for chemicals that are not used on food. There isn't a least burdensome requirement in those statutes.

Mr. WHITFIELD. Okay, well, under TSCA when we talk about unreasonable risk, how do you define unreasonable risk? How do you determine something has unreasonable risk?

Mr. JONES. Unreasonable risk under TSCA as it exists right now has been interpreted to be a risk benefit standard and that so if the risk of the use outweighs the benefits, it is determined to be an unreasonable risk.

Mr. WHITFIELD. Okay, so it is a risk versus benefit. Now, and that is not always the standard in some other environmental laws, is it?

Mr. JONES. That is correct.

Mr. WHITFIELD. Okay and I would assume that Dr. Greer and Mr. Sturdevant and maybe Dr. Thompson would agree that the more stringent standard would be the best standard and would I be correct in that?

Ms. GREER. I would agree that the track record shows that this standard has not been good for us. For example, in the case that you cite, it kept the agency from taking action against asbestos which I think is widely regarded as a, you know, a dangerous carcinogen.

Mr. WHITFIELD. Yeah.

Ms. GREER. It is not to say though that we don't think that there are critical uses of toxic chemicals that will need to remain on the market.

Mr. WHITFIELD. Right.

Ms. GREER. And so, you know, there needs to be an exit ramp for those uses so that we don't jam ourselves into something unreasonable, in the common language, not in the legal language.

Mr. WHITFIELD. Okay, all right, and I think we all agree on that, I mean, hopefully, that there are chemicals that are quite valuable and yet there is some dangers to most chemicals and, hopefully, we could when we rewrite this Act can come up with a balanced approach that would benefit everyone.

Another question I had for you, maybe, Mr. Jones, or anyone else who wants to talk about it. The Toxic Release Inventory Program which I guess came about because of the Community Right To Know Act, and it is my understanding that EPA in the Toxic Release Inventory Program right now has something like 600 and some chemicals that are on that list. How are those chemicals selected?

Mr. JONES. Largely, based on their toxicity, although there is a special way in which PBTs can be identified and actually have a lower reporting threshold then chemicals that are not PBTs.

Mr. WHITFIELD. Yeah and who actually makes that decision?

Mr. JONES. They are made by the administrator of the Environmental Protection Agency, and over the last 15 years multiple, at multiple points in time different administrators have made that determination.

Mr. WHITFIELD. Yeah but you do have some lab somewhere doing some testing on animals to decide, is that correct?

Mr. JONES. There is a wide range of toxicity information and sources of information. Some of it is generated by manufacturers. Some of it is generated by universities and some of it is generated at EPA laboratories.

Mr. WHITFIELD. Yeah, well, you know, I am no expert in this but last night I was sitting around and I was looking at this inventory list, and I just looked down this list of 600 chemicals and I came across one called metiran, m-e-t-i-r-a-n, which maybe you call are familiar with but I wasn't. And it is on the list of Communities Right to Know and yet when I read that toxicity part of the study, it says when rats were fed a thousand milligrams diet of metiran for 2 weeks, 5 days per week, no symptoms of illness were produced. No ill effect was observed in dogs that received 45 milligrams daily of this fungicide for 90 days, or 7.5 milligrams daily for almost 2 years. There were no negative effects. So I was just curious, how is it determined that this will be on the list of something that communities need to know about?

Mr. JONES. I would need to go back and get some more information around that. I know metiran is a registered pesticide active ingredient so there would be a wide number of toxicity studies that have been generated to support its registration so I should be able to answer that question.

Mr. WHITFIELD. Yeah, well, then do any—Dr. Greer, do you have any comment about that or you, Mr. Sturdevant? I mean, like I said, I am not a scientist and but it seems to me that if you give this particular substance—most of the decisions are made based on the animal studies is my understanding, and if you give animals that much and yet you decide to put it on there, I just wonder what

is the real standard for deciding? What is the precise standard to make that decision?

Ms. GREER. I also don't happen to know about that chemical but like Mr. Jones, I mean I know the criteria that the agency uses to get those chemicals on the list so there is something here that doesn't meet the eye, and I would have to go back and then submit for the record what I think is the rationale for having that chemical on the Toxic Release Inventory.

Mr. WHITFIELD. Yeah, well, is there—if you were at a Rotary Club in your hometown and you were explaining the criteria for placing a chemical on this inventory list, how would you in layman's term explain it to them?

Ms. GREER. Would you like me to?

Mr. WHITFIELD. Yes.

Ms. GREER. I would—in layman's terms I would say they are chemicals that can harm human health or the environment.

Mr. WHITFIELD. They can. Now, that is pretty vague it would seem but that is what you would say, is that correct?

Okay, I am sorry.

Mr. RUSH. I am going to recognize the gentleman from Maryland, Mr. Sarbanes, for 5 minutes.

Mr. SARBANES. Thank you, Mr. Chairman.

And thank you, Dr. Greer, for your answer just then because I am actually speaking to a Rotary Club this evening. If I get any questions like that, I will know what to say.

Ms. GREER. I will come up with a second verb for you.

Mr. SARBANES. I wanted to go right to this discussion you have been having about sort of rapid action versus study because I imagine that will be an important part of our discussion on the reauthorization and will probably lead to some tension of perspectives, as well. What do you have in mind when you talk about rapid action, and maybe you could speak to a category of chemicals that we could view as already having been sort of research tested and understood ad nauseam in terms of the toxic impact they have, using whatever combination of standards is appropriate, that we could really just get moving on in terms of this rapid action? So talk about the category and even some of the particular chemicals that you would identify for that rapid action and then what the rapid action would be that you envision?

Ms. GREER. Well, in our opinion, there are several dozen chemicals, maybe two or three dozen chemicals, not hundreds or thousands or chemicals, but a relatively speaking handful of chemicals that have been extremely well-studied. They have been studied, many of these chemicals, literally for decades. In the case of a chemical like dioxin, you know, there are file cabinet rooms full of studies on these chemicals. It is not most chemicals, Mr. Sarbanes, I mean most chemicals we don't have that amount of study, and so there are really two categories in my mind. The ones that have been extremely well studied, I would put a chemical like TCE on that, a chemical like formaldehyde on that, you know, that we have quite a bit of information. And then the second category would be some of the PBTs, some of the chemicals that we have known for years are, as one of the other testifiers said, you know, the genie is out of the bottle and they have come out and we are now in a

legacy mode of trying to do the cleanup. And for those two categories of chemicals, I would submit that we really don't need more study. What we really need is an action plan to look at what the uses are and to phase-out or reduce the uses and exposures to those chemicals because one more study is not going to make the difference and we already have enough evidence to know that at certain concentrations they will cause problems. So would be the relative minority of chemicals relatively short list but ones that I think are very ripe for action given how long they have been already studied.

Mr. SARBANES. Would you imagine identifying those explicitly in a reauthorized statute?

Ms. GREER. Based on my experience of watching EPA over the years, we learned in other statutes then when that we made lists of chemicals it led to much faster action because the agency took a much, much longer time left to their own devices to do it. So based on experience with implementation really, I would strongly recommend that we put the list into the statute, yes.

Mr. SARBANES. When you look internationally at some of these other conventions and protocols and regulatory regimes that exist, do you see that approach in place?

Ms. GREER. Yes, that is right. When you look, for example, at the Stockholm Treaty, at the POPs Treaty, those chemicals were named and continue to be named in an ongoing process of adding more chemicals to the list.

Mr. SARBANES. And then, Mr. Sturdevant, I was just intrigued by the approach you took. What was the pushback you were getting? Who, you know, you described various parties showing up in the State capitol. Describe a little bit why they were so resistant and where they are now in that you have taken steps. I mean it doesn't appear that the economy of Washington State has collapsed due to the measures you have taken so maybe you could just talk about that a little bit.

Mr. STURDEVANT. Yeah, well, the, you know, in fact, the when we identified an alternative to this flame retardant and some of the same companies that made the PBDE flame retardants also made the alternatives so there wasn't anything really in terms of an economic impact in terms of jobs. There wasn't any impact in terms of flame retardants. It was very interesting and, you know, it felt a little bit like a David and Goliath fight really with the resources that came to bear, very sophisticated resources there. And, you know, as the evidence continued to sort of go our way, the arguments changed and, you know, in the end it there was an attempt to put a deal together where okay, so if we are going to go ahead and take action on PBDEs, let us exchange that for greater fire safety standards in the State on other products basically sort of driving a new market. So, you know, I think that it was so about money, and it was about also I think setting a precedent, you know, that the first, this. It was a hard fight because it was the first ban on that product in the country and others followed and it was all about whether that first domino was going to topple or not.

Mr. SARBANES. Thank you.

Mr. RUSH. I would like to ask before you respond we are going to take an additional 3 minutes for additional questions.

As you can see, we know that the great gulf that we are going to have to cross for TSCA reauthorization is the bulk of chemicals on that, you know, either abandon or come up with another process of identifying that would include a ban in the legislation.

And I would like to get your response, first of all, do you think that these chemicals should be banned in the next, chemicals specifically banned in the next and if you would take a moment or two to support your answer, your rationale and we will start with Mr. Jones.

Mr. JONES. Well, the agency and the Administration has articulated a number of principles. There are five principles in all. The first principle is the chemical should be reviewed against the safety standard that are based on sound science and reflect risk-based criteria protection of human health and the environment. That is probably the principle that most is relevant to the question of should the statute itself ban chemicals. If it is done in a risk-based manner I think that might be consistent with the principle. If it is just a it just names them and bans them with any risk-based criteria related to that it would seem to be inconsistent with that principle.

Mr. RUSH. Dr. Thompson, same question.

Mr. THOMPSON. I think I would just echo those comments and just I would note that internationally under the Stockholm Convention, we do have a scientific review committee that really looks, you know, at these issues very closely, analyzes it, looks at the risks associated with the chemicals and they come forward with recommendations to the countries that participate in the agreements in terms of whether a chemical should, in fact, be banned or should it be restricted in some way, and whether exemptions should exist. So just to echo the comments from my colleague from EPA and note that I do think a very, there is sort of a very similar type of a procedure that we have internationally to actualize quite a similar outcome, I think. Thank you.

Mr. RUSH. Mr. Sturdevant.

Mr. STURDEVANT. I certainly don't have the expertise to say what chemicals should be on that early action list but I would say that you need to look at a couple things. One is so how bad is it and if it is bad enough then I think bans are justified. The other question is are there alternatives and as Dr. Greer said is that use really important or necessary. So I think it is you have to look at both what it is providing and are there alternatives and if there are alternatives that are easily available, and I think it makes that decision a lot easier to make.

Mr. RUSH. Dr. Greer.

Ms. GREER. And I will be quick since I have sort of already answered this question.

Mr. RUSH. Right.

Ms. GREER. I do think that there are a number of chemicals that have a mature docket, so to speak, a Texas new docket that is quite complete and that statutory list would be helpful to get fast action on those chemicals as we reauthorize TSCA.

Mr. RUSH. Dr. Cowan-Ellsberry.

Ms. COWAN-ELLSBERRY. When I worked within the UN on the protocol, that was one of the things that we did emphasize is that it needed to be risk-based, and I think I would also emphasize that any alternatives also need to be assessed because we don't want to move in precipitously to something that could be worse. And having multiple management options and phasing them in as Dr. Greer said, getting rid of alternatives where they are maybe not necessary, would probably be an easy way to go.

Mr. RUSH. Dr. Adams.

Mr. ADAMS. Yes, thank you.

Let me draw upon the experiences currently in progress in Europe at the moment under the REACH legislation. Under that process, chemicals such as Dr. Greer has mentioned and ones that are well-known have been identified and put on a list for further review, not further study. The point being is that the studies are done. They have looked at the toxicology. They have determined them to be hazardous and potentially causing risk but there is then a careful review of the use of the substance, its release to the environment and the cost benefit. So I would favor rather that kind of approach rather than just prescriptively writing substances into the legislation.

Mr. RUSH. Thank you.

The chair now recognizes Mr. Whitfield for 3 minutes.

Mr. WHITFIELD. Yeah, I would ask Dr. Greer what do you say to what Dr. Adams just said there? Do you agree with him or not?

Ms. GREER. I think, well, you know, it is interesting. I think that what the question really comes down to who is in the best position to make some of those evaluations and decisions? Are there some chemicals that the Congress can take a look at and in discussion with effected parties and with EPA say, you know, okay this is a list. This is the chemicals. I think that we can do that and that given how long it has taken the agency which I might add really every time they can tentative decision, you know, is plagued by comments and delay, et cetera, et cetera, I think we could make faster work for them by looking at some of those chemicals so I don't think I have a disagreement at all in concept. I think the question on the table for us as we move forward for TSCA reauthorization is where are those conversations taking place and lets keep an eye on how can we really make this system work. What would be the best solution to make the system work?

Mr. WHITFIELD. Now, Dr. Adams, I know in your testimony you said that a hard and fast PBT criteria would ignore scientific nuances like how a chemical or metal reacts in a particular environment or based upon climate or hydrology and other factors. So you would not want to just see a list to be banned by Congress, I am assuming?

Mr. ADAMS. Well, I think there are a few chemicals. If you consider the POPs Treaty or the POPs Convention, for example, you will see some substances in there that are identified as being extremely hazardous and not to be traded in commerce.

Mr. WHITFIELD. So there are some things we could easily mention.

Mr. ADAMS. There are a few things out there that are kind of no-brainers, if you will, okay and why not. I mean and many of them are PCBs that are not manufactured anymore so it is an easy one.

Mr. WHITFIELD. Right.

Mr. ADAMS. But there are some others that could be an easy choice but by and large, I think we want to consider the uses and we want to consider the risk of substances.

Mr. WHITFIELD. Right, now, could you give me a couple of examples that there would be universal agreement on?

Mr. ADAMS. Well, if you look at many of the chlorinated pesticides that were used in the '60s and '70s, so that is Lindane, Aldrin, Methoxychlor, DDT, DDE, so a number of those kinds of compounds are recognized internationally as being unacceptable.

Mr. WHITFIELD. Now, let me just ask one other question that maybe someone could respond to. We have heard a lot of discussion today about implementation legislation in order to abide by some of these treaties. Can someone just give me a quick synopsis of what we are talking about there? Mr. Jones, do you want to do that or Dr. Thompson?

Mr. THOMPSON. I could give you maybe some brief highlights I think of what is needed. I think in particular there are a number of provisions in the agreements that call for parties to do specific things. Under the Stockholm Convention, for example, we would have difficulties preventing the manufacture or production of chemicals for export and use in other countries. There are a number of other provisions that are related to both export controls and import controls for the different agreements that current domestic authorities don't really cover. And finally, there are some waste-related provisions to prevent the reuse and recycle of persistent, organic pollutants that we would need some tidying up domestically to implement those obligations.

Mr. WHITFIELD. Okay and how many PBTs have actually been banned under TSCA since its inception? Have any?

Mr. JONES. The most notable one is the PCBs were banned by statute.

Mr. WHITFIELD. By statute, yeah.

Mr. JONES. The agency has only taken five other sort of major regulatory bans since the statute was implemented and I am not sure if any of them are PBTs.

Mr. WHITFIELD. Okay, thank you.

Thank you.

Mr. RUSH. The Chair recognizes Mr. Sarbanes for an additional 3 minutes.

Mr. SARBANES. Thank you, Mr. Chairman.

I am just thinking about the different standards by which one could judge our efforts to limit some of these toxic chemicals and their use and our exposure to them and so forth, and there are all kinds of standards. I mean there is the legal standard that would be used in a tort case, for example. There is the standard that the agency sets which can sometimes interfere with or enhance the legal standard where we use to protect or create a higher legal standard. And I guess there is an industry burden standard that operates in our thinking but the one that I am thinking about the

most is what I would just call the kind of member of public consumer commonsense standard.

There are a lot of situations in which these other standards I mentioned from the standpoint of the consumer, if they are more aggressive, they are seen as unreasonable, in other words consumers will say well, you know, that is going a little bit too far. But in this context, it is hard for me to imagine that a member of the public understanding some of the risks that are involved here would not want to adopt the most aggressive standard relative to all these others that was available. And, you know, I imagine people looking back on a hearing like this, we are on a reauthorization of TSCA that doesn't take this step of identifying obviously dangerous chemicals out of the gate, and putting in place a rapid action strategy. I imagine the reaction of the public would be to say, you know, excuse me, what didn't you understand? What more did you need to know to take aggressive steps to address this problem? So going forward, I am going to be pretty strong on the notion that we need to get out of the gate quickly with respect to those chemicals, that category of chemicals where we have a lot of knowledge at our fingertips.

My question was this, describe what you think will happen and it sounds like it may already have begun when our standards fall further and further behind the standards that are being imposed other places. Do we become a dumping ground? I mean, what that gap has got to produce some significant and harmful consequences to it and if anybody would like to speak to that, I would welcome it.

Yes, Dr. Greer.

Ms. GREER. Yeah, I think there are three things that you see and we have actually already seen all three of them. The first is that we could become a dumping ground. We used to worry about when the United States took action on a chemical that was unsafe that maybe that chemical would end up in the Third World, in the developing world and that that would be, you know, something that we would feel morally responsible for because we had decided it wasn't safe enough for us but it could go to Africa or some place where that government was not up-to-speed on that. Well, now we face the real prospect that Europe will ban certain things from products and they will be okay here in the United States because Europe is ahead of our system and that we, the United States of America could become a dumping ground for things that are not safe enough for Europe.

The other two things that you will see, I think and have already seen is that States will start to take action where they have problems, either because they have hotspots or problems in certain rivers or in certain communities, or because their citizens are particularly upset and sensitized to this. And we will get the sort of patchwork regulation that is not really good for industry because different States have different systems and it all gets very confusing.

And the third that you will see, which I think we are already seeing, is what we call retail regulation which is that some in the private sector will say we don't want to sell this. This is what happened with BPA and plastic bottles in baby bottles where they didn't want to wait for the government to take action because their

market was being threatened by the fact that customers didn't want BPA in their baby bottles, and so they took action without the government for their own purposes, for their own business purposes so that they could say to their customers, we have our own systems in place to make things safe for you, and you can feel happy to come shop here and buy those things, and that is sort of random. It is a chemical of the weak system that we think if we had a well-functioning government system it could be more orderly, more systematic, et cetera, et cetera. So I think those are the three consequences that jump to my mind immediately and I actually think we are seeing all three of them already because, of course, the system has been broken for some time now.

Mr. SARBANES. Thank you.

Mr. RUSH. The chair thanks the gentleman.

The chair wants to make sure that you care about our purposes and our continuing work, and the focus of our continuing work, and this will be on reforming TSCA, and not necessarily reauthorizing TSCA. We want to make sure we are clear about that. We want to reform TSCA and it means a lot, you know, and we don't have the right idea of how we are working on it and we might wind up someplace else and we certainly can't afford to wind up someplace else. We need to reform TSCA.

With that said, I want to again thank the witnesses for sacrificing your invaluable time with us. You have been very informative and very enlightening toward this committee, subcommittee, and I for one, feel much more empowered and enlightened because of your comments and your answers to the questions. I want to thank you again for being here with us.

And that said, without objection, I would like to submit into the record some supporting action on PBTs from the Safer Chemicals Healthy Families, they sent letters. The Environmental Working Group has sent letters. The National Council of Churches has sent letters. The Pesticide Action Network of North America, we heard from them in the form of letters and other communications, and the American Public Health Association. It has already been ordered that the American Chemistry Council letter be included, and we have a letter also from the National Petrochemical and Refiners Association. And lastly the chairman of the full committee, Chairman Waxman, has an opening statement that we would also enter into the record without objection. And so without objection, so ordered and these and other associated matters be entered into the record.

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

Mr. RUSH. The chairman would also like to keep the record open for another 2 weeks and would ask the witnesses if there are any members of the subcommittee who want to ask questions in writing, if you would get to you and if you would in a timely manner as promptly as you can, respond to those questions in writing. It would certainly be an enormous help to this subcommittee. Thank you very much.

And the subcommittee now stands adjourned.

[Whereupon, at 12:54 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
"TSCA and Persistent, Bioaccumulative, and Toxic Chemicals: Examining Domestic and International Actions"
Subcommittee on Commerce, Trade, and Consumer Protection
March 4, 2010

Today's hearing examines substances used in commerce known as persistent, bioaccumulative, and toxic chemicals. I commend Chairman Rush for holding this important hearing and I want to welcome Representative Whitfield to his first hearing of this Congress as Ranking Member.

This is the Subcommittee's third hearing reviewing the Toxic Substances Control Act, TSCA (pronounced "TOS-KA"), the nation's primary law for ensuring the safety of industrial chemicals. At the first hearing, the Committee learned of the widespread agreement among industry, labor, and nongovernmental organizations that TSCA needs to be reformed. At the second hearing, we heard testimony on how to prioritize the vast number of chemicals in commerce for which we do not have health and safety information. Today's hearing

discusses how to proceed with a set of chemicals that most agree are at the top of the list of concern.

These hearings are helping us determine how best to modernize TSCA and fix its many flaws. In addition to these hearings, we have been working closely with our colleagues in the Senate and will be reaching out to the many stakeholders in the TSCA process. Just like Chairman Rush, I am hopeful that TSCA reform can proceed on a bipartisan basis and with continued input from stakeholders. We all want legislation that improves protections for public health and the environment, as well as continued innovation and job production.

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

Thank you.

Opening Statement for "TSCA and Persistent, Bioaccumulative, and Toxic Chemicals: Examining Domestic and International Actions"
for Rep. Kathy Castor, FL-11

- Thank you, Chairman Rush, and good morning to my colleagues. We are here today because comprehensive TSCA reform has been put off for a generation.
- We now have an opportunity to confront the threats that persistent toxic chemicals pose and lead the way forward on TSCA reform.
- I am looking forward to hearing the testimony of the witnesses, and I thank them for their contributions to this important process.
- In 1976, when the Toxic Substances Control Act was passed, there were already more than 60,000 chemicals in production in the United States.
- We knew very little then about what health and environmental impacts these chemicals were having.
- But instead of taking a cautious approach with regards to protecting the public from any potential adverse affects, we placed the burden of proof that these chemicals were safe on the chemical companies that manufactured them.
- This approach to consumer protection led the EPA to require testing on a mere 200 chemicals, despite the years of solid science that has shown that many are, in fact, highly toxic.
- Even more concerning, the EPA today regulates just 5 of the more than 80,000 chemicals now in circulation.
- PBTs pose an especially worrisome threat to our communities because they can build up in the food chain and the human body and linger for years, increase the risk of chronic disease, and spread across the globe.
- The good news is, we know much more now than we did in 1976.
- We know that the international community has spoken out on chemicals reform because both developed and developing

nations are experiencing some of the dangerous effects of these toxic substances.

- We also know that environmental chemicals, including PBTS, are widespread in humans and actually tend to be higher in Americans than the people of other nations.
- The Stockholm Convention, which the U.S. has signed, created international agreement that persistent organic pollutants need to be reduced or eliminated across the globe.
- But Congress hasn't taken the steps to implement this agreement, along with others that would provide regulatory structure to the chemicals industry and much-needed safeguards for our communities.
- So, I call on my colleagues to implement these international treaties and to finalize comprehensive TSCA reform.
- After 34 long years, it's time to put this regulatory wilderness behind us.
- It's time to move beyond analysis and take action, starting with the worst offenders, including PBTs, which have been linked to breast cancer, brain cancer, asthma, autism, reproductive disorders, and birth defects.
- It's time to place the burden of proof on the chemical companies where it belongs and move away from the "research and delay" strategy that has benefited the chemical industry and done untold harm to consumers.
- It's time to pursue international agreements that will prevent the United States and its most vulnerable communities from becoming the global dumping grounds for toxic substances like PBTs and formaldehyde.
- There is too much at stake, something we know now, and can no longer make excuses for.
- Thank you all. I look forward to the testimony of our witnesses, and I yield the balance of my time.

MEMORANDUM

March 2, 2010

To: Subcommittee on Commerce, Trade, and Consumer Protection Members and Staff

Fr: Subcommittee on Commerce, Trade, and Consumer Protection Staff

Re: Hearing on "TSCA and Persistent, Bioaccumulative, and Toxic Chemicals: Examining Domestic and International Actions"

On March 4, 2010, at 10:00 a.m. in room 2322 of the Rayburn House Office Building, the Commerce, Trade, and Consumer Protection Subcommittee will hold a hearing entitled, "TSCA and Persistent, Bioaccumulative, and Toxic Chemicals: Examining Domestic and International Actions." This hearing will examine the efforts taken to protect health and the environment from the subset of chemicals that meet the criteria for being labeled as persistent, bioaccumulative, and toxic (PBT), how the Toxic Substances Control Act (TSCA)[1] is currently being used to manage these chemicals, and how the TSCA process might be improved.

I. BACKGROUND

TSCA was enacted in 1976 to address the public health risk of chemicals used in commerce. TSCA requires the Environmental Protection Agency (EPA) to analyze new chemicals for their safety, and authorizes EPA to restrict or ban the use of new or existing chemicals that pose an "unreasonable risk" to public health or the environment. The Subcommittee held two hearings on TSCA in 2009,[2] with the latter focusing on prioritizing chemical substances for safety determination.

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[1] 15 U.S.C. § 2601 *et seq.*

[2] Subcommittee on Commerce, Trade, and Consumer Protection, *Hearing on Revisiting the Toxic Substances Control Act of 1976*, 111th Cong. (Feb. 26, 2009); Subcommittee on Commerce, Trade, and Consumer Protection, *Hearing on Prioritizing Chemicals for Safety Determination*, 111th Cong. (Nov. 17, 2009).

Chemicals with certain properties can be particularly problematic for health and the environment. Persistent chemicals are highly resistant to degradation in the environment and can spread across the globe. Bioaccumulative chemicals can build up in the food chain and in the human body. Toxic chemicals cause adverse health effects in exposed individuals. Chemicals with all three characteristics (PBTs) are considered to be particularly harmful. Exposure to PBTs have been associated with cancer, neurotoxicity, reproductive and developmental toxicity, and genetic mutations. Even with controls to restrict or eliminate their use, they can remain unchanged as long-lasting contaminants in the global environment.

A recent study estimated there are 610 persistent and bioaccumulative chemicals currently used in commerce.[3] Of these, many are also known to be toxic. Examples of PBTs include: chemicals such as polychlorinated biphenyls (PCBs), certain brominated flame retardants, and certain perfluorinated compounds; metals such as lead, mercury and cadmium; and fragrances such as musk xylene. In addition, many pesticides are PBTs, though pesticides are outside the scope of TSCA because they are regulated under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

II. DOMESTIC ACTIONS

1. Federal Actions

In the late 1990s, the EPA initiated actions to consider PBTs uniquely from other toxic substances. In 1998, EPA published a draft strategy "to further reduce risks to human health and the environment from existing and future exposure to priority persistent, bioaccumulative, and toxic (PBT) pollutants."[4] In 1999, EPA lowered the reporting thresholds for specific PBTs[5] and provided guidance on reporting these chemicals in 2001.[6] Also in 1999, EPA published a policy statement that created a PBT category for new chemical substances under TSCA Section 5 pre-

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[3] Howard PH, Muir DCG. *Indentifying New Persistent and Bioaccumulative Organics Among Chemicals in Commerce.* Environmental Science and Technology (Jan. 22, 2010).

[4] Environmental Protection Agency, *Multimedia Strategy for Priority Persistent, Bioaccumulative, and Toxic (PBT) Chemicals*, 63 Fed. Reg. 63926 (Nov. 17, 1998) (Notice of Availability and Solicitation of Public Comment).

[5] Certain chemicals are reported in the Toxic Release Inventory as authorized under the Superfund Amendments and Reauthorization Act. Emergency Planning and Community Right-to-Know Act of 1986, Title III of the Superfund Amendments and Reauthorization Act, Pub. L. No. 99-499.

[6] Environmental Protection Agency, *Emergency Planning and Community Right-To-Know Act – Section 313: Guidance for Reporting Toxic Chemicals: Pesticides and Other Persistent Bioaccumulative Toxic (PBT) Chemicals* (Aug. 2001).

manufacture notice (PMN) provisions.[7] In 2002, EPA finalized a tool to predict whether a chemical may meet criteria for being labeled as a PBT, even when data is limited.[8]

EPA has begun efforts to set baseline contamination levels to be able to analyze whether actions have been effective in reducing PBTs in the environment. In 2009, EPA published the *National Lake Fish Tissue Study* examining 268 PBTs, demonstrating for the first time that certain PBTs are common water pollutants in the continental U.S.[9] In particular, mercury and PCBs were detected in all fish samples. PBTs account for 97% of all fish consumption advisories in 2008.[10] Future studies will need to determine trends in contamination levels in U.S. lake fish.

Levels of environmental chemicals including some PBTs are measured in humans and analyzed by the Centers for Disease Control and Prevention.[11] In their fourth report released in December 2009, PFCs and PBDEs were measured for the first time, and have been found to be "widespread" in humans. Comparing these levels to that found in other countries, U.S. levels tend to be higher.

In September 2009, EPA Administrator Jackson announced a new plan for improving chemical management under current law,[12] which was followed by a December 2009 announcement of action plans on four groups of chemicals. Three of the four action plans are for PBTs: long-chain perfluorinated chemicals (PFCs) used in stain-resistant or non-stick products, polybromodiphenyl ethers (PBDEs) used as flame retardants, and short-chain chlorinated paraffins (SCCP) and other chlorinated paraffins used in metalwork, as plasticizers, and as flame retardants.[13]

2. State Government Actions

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[7] Environmental Protection Agency, *Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances*, 64 Fed. Reg. 60194 (Nov. 4, 1999) (policy statement).

[8] Environmental Protection Agency, *PBT Profiler* (online at www.epa.gov/oppt/sf/tools/pbtprofiler.htm) (accessed Feb. 3, 2010).

[9] Environmental Protection Agency, *National Lake Fish Tissue Study* (Sept. 2009) (online at www.epa.gov/waterscience/fish/study).

[10] Environmental Protection Agency, *2008 Biennial National Listing of Fish Advisories* (Sept. 2009) (online at www.epa.gov/waterscience/fish/advisories/tech2008.pdf).

[11] Centers for Disease Control and Prevention, *Fourth National Report on Human Exposure to Environmental Chemicals* (Dec. 2009).

[12] Environmental Protection Agency, *Enhancing Existing Chemical Management Program* (online at www.epa.gov/oppt/existingchemicals/pubs/enhanchems.html) (accessed Nov. 13, 2009).

[13] Environmental Protection Agency, *Existing Chemicals Action Plans* (online at www.epa.gov/oppt/existingchemicals/pubs/ecactionpln.html) (accessed Jan. 25, 2010).

Washington State is currently the only state in the nation that has a policy to reduce use, releases, and exposure to PBTs within its borders.[14] This PBT Rule, adopted in 2006, establishes criteria to identify and list PBTs, and establishes criteria for selecting PBTs for action to protect health and the environment. Many other States, including Maine, Maryland, Massachusetts, Pennsylvania, South Carolina, and Virginia, have adopted chemical-specific legislation or policies, including on specific PBTs.[15]

III. INTERNATIONAL ACTIONS

Due to the long-range transportation of PBTs, there is general acceptance that there must be a collective international effort to manage their use and release into the environment. There are three relevant international conventions regarding PBTs. The 1998 Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade (PIC Convention) provided a commitment to a shared responsibility for protecting health and the environment in international trade and information exchange of certain hazardous chemicals.[16] In 1998, the Convention on Long-Range Transboundary Air Pollutants (LRTAP)[17] adopted a POPs protocol to provide a reduction or elimination of production and use of certain PBTs.[18] The 2001 Stockholm Convention for Persistent Organic Pollutants (POPs Convention) provided a shared commitment to reduce or eliminate releases of certain PBTs from intentional and nonintentional sources.[19] The LRTAP POPs Protocol entered into force in 2003, and the PIC and POPs Conventions entered into force in 2004. The United States has signed the PIC Convention, the LRTAP POPs Protocol, and the POPs Convention, but Congress has not successfully passed legislation to implement them.[20] Recently, a number of organizations have again called on the United States to implement these treaties.[21]

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[14] Washington State, *Chapter 173-333 WAC, Persistent Bioaccumulative Toxins* (Jan. 13, 2006) (online at www.ecy.wa.gov/biblio/wac173333.html).

[15] Environmental Council of the States, *State Experiences with Emerging Contaminants: Recommendations for Federal Action* (Jan. 2010) (online at www.ecos.org/files/3959_file_January_2010_ECOS_Green_Report.pdf).

[16] Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade (Sept. 10, 1998). *See* www.pic.int.

[17] Geneva Convention on Long-Range Transboundary Air Pollutants (LRTAP) (Nov. 1979).

[18] LRTAP Aarhus Protocol on Persistent Organic Pollutants (June 24, 1998).

[19] Stockholm Convention on Persistent Organic Pollutants (May 22, 2001).

[20] S. 519; H.R. 3849, 109th Cong. (2006); H.R. 4591, 109th Cong. (2006); H.R. 4800, 109th Cong. (2006); H.R. 6421, 109th Cong. (2006); S. 2042, 109th Cong. (2005); S. 1486, 108th Cong. (2004); H.R. 4935, 107th Cong. (2002); S. 2118, 107th Cong. (2002); S. 2307, 107th Cong. (2002).

[21] *See* Letter from Daryl Ditz, et al. to Secretary Hillary Rodham Clinton and Administrator Lisa P. Jackson (Dec. 16, 2009) (online at www.ciel.org/Publications/TSCA_POPs_16Dec09.pdf); The National Congress of American

In addition, a more regional international agreement between the US and Canada is the 1997 Great Lakes Binational Toxics Strategy developed to eliminate PBTs in the Great Lakes region.[22] The 2009 *State of the Great Lakes* report describes recent trends for many indicators, including fish concentrations of PBTs.[23] This report shows a decrease in certain contaminants such as PCBs, but no improvement in other contaminants such as mercury. The authors of this report highlight the need to track concentrations for emerging concerns such as PFCs and PBDEs. The Obama Administration recently released a 5-year *Great Lakes Restoration Initiative Action Plan* highlighting a concern for toxic substances, and PBTs in particular, with the goal to virtually eliminate "the release of any or all persistent toxic substances (PTS) in to the Great Lakes basin ecosystem."[24]

IV. WITNESSES

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Indians, *Resolution #PSP-09-021: 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* (2009) (online at www.ncai.org/fileadmin/resolutions/PSP-09-021_final.pdf); Letter from Andrea Kidd Taylor, Member, American Public Health Association Executive Board, to Congressman Waxman (Feb. 18, 2010); Letter from Safer Chemicals Health Families to Congressman Bobby Rush (Feb. 23, 2010); Letter from Pesticide Action Network North America to Congressman Bobby Rush (Feb. 24, 2010).

[22] Great Lakes Binational Toxics Strategy (online at www.epa.gov/glnpo/bns/index.html) (accessed Feb. 1, 2010).

[23] Environment Canada and United States Environmental Protection Agency, *State of the Great Lakes 2009* (online at binational.net/solec/sogl2009/SOGL_2009_en.pdf).

[24] *Great Lakes Restoration Initiative Action Plan, FY 2010–FY 2014* (Feb. 21, 2010).

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Safer Chemicals
Healthy Families

February 23, 2010

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

CC: Chairman Henry Waxman
Chairman Frank Lautenberg
Senator James Inhofe
Chairwoman Barbara Boxer
Administrator Lisa Jackson

Dear Chairman Rush, Ranking Member Radanovich and Members of the Subcommittee,

Thank you for scheduling the February 11th hearing, *"Examining Domestic and International Actions on Persistent, Bioaccumulative, and Toxic Chemicals (PBTs)"* which was cancelled due to the snowstorm. We are writing to share our concerns about PBTs as members of the Safer Chemicals, Healthy Families coalition and allied organizations, who represent millions of parents, consumers, health advocates, and communities from around the country (www.saferchemicals.org).

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

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

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

Moreover, requiring such chemicals to undergo expensive and time-consuming risk assessments would only delay taking needed action on a class of chemicals for which there is already broad scientific agreement regarding the serious threat they pose to human health and the environment.

As you consider policy options for modernizing the Toxic Substances Control Act (TSCA), we urge you to support immediate action to address these most dangerous of chemicals to which people are being exposed. PBTs should be phased out of commerce on an expeditious but reasonable timeline, with exceptions allowed only for critical uses that lack viable alternatives. In addition, new PBTs should not be approved for use in commerce under a reformed TSCA.

We have experienced first hand in our communities the devastating impacts PBTs can have on wildlife and people. For example:

- In the Northwest, Puget Sound's declining orca whales have become one of the most contaminated populations of marine mammals in the world, in part because of PCBs found in the Puget Sound food chain. PCBs are known endocrine disruptors and probable carcinogens that become highly concentrated in the fatty tissues of top predators. PCBs are the only chemical banned under the original TSCA, yet more than 30 years later they continue to pollute the environment.

- In the Great Lakes, the levels of PBDEs in walleye and lake trout rose exponentially from 1980 to 2000, doubling every 3-4 years. Similarly, PBDEs in Great Lakes region herring gull eggs increased 60-fold between 1981 and 2000.

- In Maine, which is downwind from all the other states, common loons have the highest levels of mercury in the country and the eggs of peregrine falcons have among the highest levels of the decaBDE flame retardant ever recorded.

A growing body of scientific evidence links PBT chemicals to a wide range of serious human health problems, including early onset of puberty, infertility, endocrine disruption, learning disabilities, behavioral disorders and certain cancers. And scientists are now finding evidence that these chemicals contaminate people at levels that are cause for great concern. For example:

- A 2009 study of 302 women residing in North Carolina found that three quarters of them had PBDEs contaminating their breast milk. The highest levels were found in women ages 25-29, in the prime of their child-bearing years. PBDEs can have negative impacts on behavior, brain development and reproduction.
- The Arctic is a hemispheric sink for PBTs, which are transported long distances via atmospheric and oceanic currents. Arctic Indigenous peoples reliant on traditional diets of fish and marine mammals are among the most highly exposed people on earth. A study of the Yupik people of St. Lawrence Island in Alaska found that they carry PCBs in their blood at levels that are 6-9 times higher than the general population in the lower-48 states.

- The Environmental Protection Agency (EPA) estimates that more than 300,000 newborns each year may have increased risk of learning disabilities associated with in utero exposure to methylmercury. EPA scientists indicate that research has found no safe level of mercury exposure.

Most disturbing is that we now know people are being exposed to many of these PBT chemicals as a result of their use in everyday consumer products such as:

- PBDEs and other brominated flame retardants are found in furniture, electronics, and textiles.
- PFCs are widely used in food packaging, clothing and other textiles and cookware.

Governments at all levels are already taking action to phase out the use of these particularly dangerous chemicals. Congress should follow their lead. For example:

- Under the Great Lakes Water Quality Agreement of 1978 and subsequent Great Lakes BiNational Toxics Strategy, the U.S. and Canada pledged to seek the virtual elimination of the discharge of persistent toxic substances to the Great Lakes.
- 32 states have passed mercury products legislation to rid the marketplace of mercury-containing items.
- 14 states have passed legislation to eliminate lead in certain products.
- 12 states have adopted laws to replace PBDEs with safer alternatives.
- Washington State is implementing a comprehensive plan and regulations to target PBTs for reduction and phase out.
- Internationally, the Stockholm Convention on Persistent Organic Pollutants (POPs) and the Protocol on Persistent Organic Pollutants to the Convention on Long-Range Transboundary Air Pollution (LRTAP) have targeted numerous PBTs for global phase-outs.

Companies that make or use PBTs are also acting to reduce or eliminate them:

- Based on the toxicity of perfluorooctanoic acid (PFOA) and related chemicals, and growing evidence they are accumulating in the blood of the U.S. population, EPA negotiated an agreement with DuPont and other producers of these chemicals to phase out their use by 2015.
- SC Johnson has adopted a company policy under which it prohibits use of PBTs in its products.
- Consumer electronics companies such as Apple and Sony Ericsson are on track to eliminate all halogenated substances, including PVC and all brominated and chlorinated flame retardants, from their products.

We cannot wait for continued delay and endless study while these chemicals continue to build up in people and the environment. We urge you to follow the lead of the many U.S. states, nations and companies that are meeting the challenge of eliminating all but essential uses of PBTs.

Thank you for your attention to this important issue. We look forward to working with you toward meaningful TSCA reform that better protects our health and environment.

Sincerely,

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ENVIRONMENTAL WORKING GROUP www.ewg.org

March 3, 2010

The Honorable Bobby L. Rush
Chairman, Subcommittee on Commerce, Trade and Consumer Protection
United States House of Representatives
Washington, DC 20515

Subject: **Industrial chemicals in umbilical cord blood – including persistent and bioaccumulative compounds – need urgent action**

Dear Chairman Rush,

Thank you for holding this hearing, "TSCA (Toxic Substances Control Act) and Persistent, Bioaccumulative, and Toxic Chemicals: Examining Domestic and International Actions," and for your continued leadership on reforming the outdated, broken Toxic Substances Control Act.

Among the most notorious and dangerous chemicals ever put into commerce are so-called persistent bioaccumulative and toxic chemicals (PBTs). This category of pollutants includes DDT, polychorinated biphenyls (PCBs), the Teflon chemicals perfluorooctanyl sulfonate (PFOS) and perfluorooctanoic acid (PFOA), brominated flame retardants, lead and mercury compounds and dioxins.

PBTs have been a priority for the environmental community and the Environmental Protection Agency (EPA) for the past 40 years. In fact, a rare and notable success under the current Toxic Substances Control Act (TSCA) has been EPA's program to keep new PBTs off the market through the Pre-manufacture Notification process.

Environmental Working Group (EWG) has long been deeply concerned about PBTs. Our work over the past decade has been instrumental in achieving phase-out agreements for the persistent and bioaccumulative Teflon chemical, PFOA, and the brominated flame retardants, penta, otca and decabromodiphenyl ether (DecaBDE). EWG strongly supports rigorous controls and bans for existing high-risk PBTs and a policy that keeps new PBTs from entering the market.

But PBTs are just one of several categories of chemicals that demand priority action under a reformed national toxic chemicals policy. The broader and more fundamental question before Congress is how to set priorities in a new federal toxic substances law that will deal effectively with the tens of thousands of chemicals used in consumer products and the many hundreds of these already known to contaminate the human body.

Curbing environmental pollution and human exposure to PBTs must be a priority for reform. But elevating PBTs as a class to a super-priority status could delay progress towards much-needed protections from other substances that pose a threat to Americans as great or even greater than that from many PBTs.

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Children's health must be the top priority

The chemicals that deserve highest priority are those that contaminate the blood of babies before they are born. There is an emerging consensus within scientific and medical communities that the most critical chemical exposures occur before birth, when the brain and other organs are exquisitely sensitive to trace changes in blood chemistry. Any substance, PBT or otherwise, that intrudes upon the womb and threatens a child's normal development must receive our most urgent attention.

EWG has detected nearly 300 chemicals in the cord blood of 20 American newborns. Many of these chemicals are PBTs. But others are not. Among the most troubling substances found in cord blood that are not PBTs are bisphenol A, the synthetic estrogen and plastics component; perchlorate, a thyroid toxin and explosives chemical used in fireworks, airbags and rocket fuel; and phthalates, a class of potent endocrine disruptors linked to birth defects in boys and a common component of soft plastics.

In our view, a chemical's persistence in the environment or its ability to accumulate in living things should render it of very high regulatory concern. But those two criteria should not be the only factors that elevate a chemical to top priority for regulatory action. The test must be the toxicity, including the endocrine-disrupting properties of each substance, and the intensity of exposure faced by high-risk populations such as pregnant women, their fetuses and newborns.

States move to protect children

The absence of a strong federal chemicals policy has led to numerous state initiatives aiming to protect the public, particularly children, from high-risk chemical exposures. Few national organizations have worked harder than EWG to support states' efforts to ban or restrict the chemicals of highest concern in consumer products, where such actions were merited.

EWG's research has helped drive and sustain these efforts, including our 12 studies measuring chemical pollution in 200 people and our analyses of human health risks from exposures to common, toxic consumer product chemicals. EWG experts have testified in support of single chemical bans and broader chemical policy reform legislation in nine states: California, Illinois, Iowa, Maine, Maryland, Massachusetts, Minnesota, Oregon and Pennsylvania, plus the District of Columbia. In California, EWG was the lead sponsor of legislation in 2008 and 2009 to ban BPA in baby bottles and children's cups.

States have helped pave the way to federal policy reform, but state efforts have not been targeted exclusively or even primarily toward PBTs. Instead, state lawmakers have focused on chemicals that present the greatest risks to children.

In 2009 and 2010, legislation was introduced in 21 states and the District of Columbia to ban BPA (not a PBT) in baby bottles and other children's products. BPA bans have been signed into law two states - Minnesota and Connecticut - and are awaiting gubernatorial signatures in three states - Maryland, Washington, and Wisconsin. At the same time at least three states - Oregon, Washington and Maine - have enacted laws to ban high-risk uses of Deca BDE, a PBT flame retardant. Similar Deca ban bills are pending in 12 more states and the District of Columbia.

Maine and Washington have passed broader legislation designed to protect children from high-hazard chemicals in toys and other products intended for children. One of several criteria for targeting chemicals under these laws is whether or not a chemical is a PBT. Washington also has a program to list PBTs and publish action plans to reduce their use and promote alternatives. Initiated in 2000 by the Department of Ecology, the program has listed 27 PBTs to date and has published action plans for three.

No state has passed legislation banning all PBTs as a group, and no state has passed legislation that singles out PBTs as a higher-priority group of chemicals than those with other hazardous characteristics, such as their ability to cause cancer. The Maine Toxic Chemicals in Children's Products Act, for example, designates a chemical's ability to cause cancer, reproductive or developmental harm, or to disrupt the endocrine system along with persistence and bioaccumulation as criteria for being listed as a chemical of high concern (Maine Revised Statutes, Title 38, Chapter 16-D, Sec 1693). All the criteria are equally important under the law.

Congressional action is needed

This steady stream of state bills reflects strong, broad-based support for chemical policy reform at the national level. Comprehensive federal reform, like that proposed in the Kid-Safe Chemicals Act of 2008, would protect the health of all Americans, not just those living in a short list of states currently advancing reforms one chemical at a time.

Only action at the federal level can tackle the sheer number of PBTs in use today. Academic studies estimate that as much as three percent of all chemicals are persistent and bioaccumulative (Howard et al 2010). EPA lists about 140 chemicals as PBTs, among them are lead, mercury and cadmium.

PBTs permeate the economy and reigning them in is an extremely complex task that only the federal government can perform. Of the hundreds of PBTs in use today, some likely present serious health threats. Others probably do not. The absence of state initiatives banning PBTs is in part due to recognition of this fact, and in part due to the fact that some persistent and bioaccumulative compounds are used in important products where a ban is currently difficult to justify. Mercury is used in all energy-saving compact fluorescent light bulbs. PFOS is critical for airplane brakes, and lead is fabricated into a wide range of products from car batteries to crystal chandeliers. Although PBTs share characteristics that make them uniquely problematic, it is critical that actions to reduce and eliminate them, first target high-risk uses.

The American people need and deserve a toxic chemicals policy that sets clear and defensible priorities and targets all the high-risk chemicals on the market, not just those with certain characteristics.

The Kid-Safe Chemicals Act introduced in earlier sessions of Congress proposed comprehensive, yet practicable and effective remedies that would give high priority to PBTs. We strongly support those provisions and believe they could be strengthened to require that any persistent and bioaccumulative chemical be presumed unsafe. Industry would then have one year to rebut that presumption and prove that the chemical meets the safety standard of the law, or it would be taken off the market. This would place PBTs on par with provisions in the bill governing all chemicals found in cord blood, which would also be presumed unsafe until

proved otherwise. But it would not grant PBTs elevated status, and it would apply consistent criteria to both priority groups.

We applaud you for holding this hearing, and we thank you for your leadership in efforts to reform the Toxic Substances Control Act. We look forward to the introduction of your legislation and working with you to ensure its passage.

Sincerely,

Richard Wiles
Senior Vice-President, Policy & Communications

Jane Houlihan
Senior Vice-President for Research

Earth Ministry• Ecumenical Ministry of Oregon's Interfaith Network for Earth Concerns• The Episcopal Church• Evangelical Lutheran Church in America• Friends Committee on National Legislation• GreenFaith• Interreligious Eco-Justice Network• Presbyterian Church (U.S.A.) Washington Office• Maine Council of Churches• Maryknoll Office of Global Concerns• Massachusetts Council of Churches• Minnesota Council of Churches• Missionary Oblates, Justice, Peace/Integrity of Creation Office• National Council of Churches• Pennsylvania Council of Churches• United Church of Christ, Justice and Witness Ministries• The United Methodist Church – General Board of Church and Society• The United Methodist Women• Unitarian Universalist Association• Unitarian Universalist Ministry for the Earth• Texas Impact• Voices for Earth Justice

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

CC: Chairman Henry Waxman
Chairman Frank Lautenberg
Senator James Inhofe
Chairwoman Barbara Boxer
Administrator Lisa Jackson

March 2, 2010

Dear Chairman Rush, Ranking member Radanovich, and Members of the Subcommittee,

As various faith traditions, we are united across theological lines on the need to protect Creation, care for our bodies, and care for vulnerable populations. We believe that all humankind is created in God's image and receives nourishment from the bounty of God's Creation (Genesis 1:26-27). Caring for our own bodies is an essential aspect of our call to care for and honor God's Creation (I Corinthians 6:19; Genesis 2:15). Unfortunately, current chemical policies are failing to protect us. Scientists are finding strong links between serious health concerns and the chemicals we are exposed to in the air we breathe, the food we eat, the water we drink, and the products we use.

We applaud you for hosting a hearing concerning Persistent, Bioaccumulative, and Toxic chemicals (PBTs), a particularly dangerous class of chemicals. These chemicals can last for long periods of time, travel long distances, accumulate in organisms, become more potent as they move up the food chain, and they are highly toxic. **Swiftly phasing out PBTs should be a key component of comprehensive chemical policy reform.**

These chemicals threaten the integrity of God's good Creation, the health of communities in the United States, and our sisters and brothers across the globe. They can even be passed on to future generations through the developing fetus and through the breast milk of nursing mothers. Native communities and other members of Creation in the Arctic are especially vulnerable because PBTs naturally migrate and accumulate at the poles. Low-income communities and communities of color living near incinerators and other sites where PBTs are present are also highly vulnerable. These chemicals are linked to health conditions including cancer, learning and developmental disabilities, early onset puberty, and infertility.

Over the last ten years, many denominations and faith traditions have passed policies to raise awareness in their congregations and have taken bold action to curtail use of specific PBTs such as dioxin, mercury, and lead. We are also concerned about newer classes of PBTs such as polybrominated diphenyl ethers (PBDEs) widely used as flame retardants, and perflourinated compounds (PFCs) such as those used in paper packaging, stain resistant materials, or non-stick cookware. Our communities are responding in faith by making changes in the products used in

homes and congregations, and by advocating on a state level for laws that ensure God's Creation and vulnerable populations are protected from the most dangerous toxic chemicals.

However, individual actions and state laws are only one part of the solution. We need a more comprehensive approach. It is time for the federal government to act and repair chemical legislation that is failing to protect the U.S. population and communities across the globe. The evidence is mounting that toxic chemicals are threatening the health of God's Creation and all of God's children. The United States Government has a moral responsibility to protect Creation, and the citizens in this country and around the world.

As you work to modernize the Toxic Substances Control Act, we urge you to consider immediate action to address the most dangerous of chemicals to which people are being exposed. PBTs should be phased out, with exceptions only for critical uses where we lack a viable, safe alternative.

We hope that we can work with you to reform national chemical laws to ensure the health of Creation, protect vulnerable populations, and enable future generations of God's children to live healthy lives.

Sincerely,

Earth Ministry (Washington State)
Ecumenical Ministry of Oregon's Interfaith Network for Earth Concerns
The Episcopal Church
Evangelical Lutheran Church in America
Friends Committee on National Legislation
GreenFaith (New Jersey)
Interreligious Eco-Justice Network (Connecticut)
Pennsylvania Council of Churches
Presbyterian Church (U.S.A.) Washington Office
Maine Council of Churches
Maryknoll Office of Global Concerns
Massachusetts Council of Churches
Minnesota Council of Churches
Missionary Oblates, Justice, Peace/Integrity of Creation Office
National Council of Churches
United Church of Christ, Justice and Witness Ministries
The United Methodist Church – General Board of Church and Society
The United Methodist Women
Unitarian Universalist Association
Unitarian Universalist Ministry for the Earth
Texas Impact
Voices for Earth Justice (Michigan)

Contact information:
Chloe Schwabe
Environmental Health Program Manager
National Council of Churches
202-481-6932
chloe@nccecojustice.org

Pesticide Action Network NORTH AMERICA

March 3, 2010

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

Honorable Ed Whitfield, Ranking Member
Subcommittee on Commerce, Trade and Consumer Protection
Committee on Energy and Commerce, U.S. House of Representatives
2411 Rayburn House Office Building
Washington, D.C. 20515

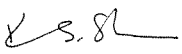
Dear Chairman Rush and Representative Whitfield:

Thank you for holding the upcoming hearing on the important issue of persistent, bioaccumulative toxic chemicals (PBTs).

Enclosed please find a petition from 2,597 of our supporters who are very concerned about the health and environmental impacts of PBTs, and are urging Congress to prioritize action on these dangerous substances. The list represents citizens from 48 states and the District of Colombia, with the most significant numbers from California, New York, Florida, Texas, Illinois, Massachusetts and Pennsylvania.

Pesticide Action Network (PAN) North America is one of five independent regional centers of PAN International, a worldwide network of more than 600 organizations in 90 countries.

Sincerely,



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Kristin S. Schafer
Senior Policy Analyst
PAN North America
Kristins@panna.org

Pesticide Action Network NORTH AMERICA

March 3, 2010

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

Honorable Ed Whitfield, Ranking Member
Subcommittee on Commerce, Trade and Consumer Protection
Committee on Energy and Commerce, U.S. House of Representatives
2411 Rayburn House Office Building, Washington, D.C. 20515

Dear Chairman Rush and Representative Whitfield:

Thank you for holding a hearing on the important topic of "Persistent Bioaccumulative Toxic (PBT) Chemicals." We are writing to express our concern about these chemicals, and our strong support for prioritizing action on PBTs in any efforts moving forward to reform the Toxic Substances Control Act (TSCA).

PBTs are inherently unsafe. They persist in the environment for many years - often decades. They build up in the food chain, and can pass from mother to child during pregnancy. And they are highly toxic, often at very low levels of exposure. Because of the persistence of these chemicals, low but sustained emissions of PBTs will lead to dangerous levels over time. Many health effects from low-level exposure are long term, sometimes even appearing in the next generation. Both of these properties making traditional risk assessment an ineffective tool for determining and reducing the dangers these chemicals pose.

Some PBTs can also travel across borders, accumulating in the Arctic region where they threaten the health and livelihood of indigenous communities, by contaminating traditional foods and reaching astounding levels in the bodies of indigenous peoples.

We urge you and your colleagues to recognize the urgency of taking action on PBTs, as your international colleagues have done through the Stockholm Convention on Persistent Organic Pollutants. It's time to protect the communities of today and future generations of tomorrow from dangerous chemicals. Let's get our house in order on PBTs.

Sincerely,

2,597 concerned citizens from 48 states and the District of Colombia

School of Community Health & Policy

February 18, 2010

The Honorable Henry Waxman
Chair, House Committee on Energy and Commerce
2204 Rayburn House Office Building
Washington, D.C. 20515

Dear Representative Waxman,

Thank you for taking a leading role in the current legislative efforts to strengthen our national chemical policies. Your leadership on issues related to public health is recognized and appreciated in our community. As you know, the American Public Health Association (APHA) has for many years called for reform of the Toxic Substances Control Act to better protect the public from the health impacts of toxic chemicals, and we are pleased that such efforts now appear to be moving forward.

I am writing now to encourage you to prioritize efforts to effectively protect the public from the dangers of persistent, bio-accumulative toxins (PBTs). This group of chemicals poses a particular set of challenges and risks, including health threats from very low levels of exposure and intergenerational effects. I hope that any effort to strengthen our system of addressing national chemicals will include the provision of tools to our regulatory agencies to take rapid action on PBTs. As outlined in APHA Policy #20055 (Dec 2005), PBTs are viewed as an urgent priority among public health professionals.

In addition to supporting reform of TSCA (see APHA Policy 20077; Nov, 2007), the Association has also for many years supported international efforts to address persistent organic pollutants (POPS), as outlined in APHA Policy #20009 (Jan, 2000). Inclusion of strong authority to address PBTs at home will enable the U.S. to provide leadership on POPs at the international level through the Stockholm Convention.

Please feel free to contact me should you have any questions or need more information on APHA's position on PBTs and the current TSCA reform efforts.

Sincerely,

Andrea Kidd Taylor, DrPH, MSPH
Member, APHA Executive Board
Assistant Professor
Morgan State University
School of Community Health & Policy

References:

APHA Policy #20055: Protecting Human Milk from Persistent Chemical Contaminants
http://www.apha.org/advocacy/policy/policysearch/default.htm?id=1321

APHA Policy #20077: Calling on the US Congress to Restructure the Toxic Substances Control Act of 1976
http://www.apha.org/advocacy/policy/policysearch/default.htm?id=1350

APHA Policy # 20009: Support for International Action To Eliminate Persistent Organic Pollutants
http://www.apha.org/advocacy/policy/policysearch/default.htm?id=214

March 3, 2010

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

The Honorable Ed Whitfield
Ranking Member, Subcommittee on Commerce, Trade and Consumer Protection
United States House of Representatives
Washington, D.C. 20515

Dear Chairman Rush and Ranking Member Whitfield:

The House Subcommittee on Commerce, Trade and Consumer Protection is scheduled to hear testimony March 4th from several witnesses concerning persistent, bioaccumulative and toxic (PBT) substances, and their regulation under U.S. and international law. The American Chemistry Council (ACC), a national trade association representing 140 member companies that employ 800,000 workers, requests that ACC's perspectives on this issue be entered into the hearing record.

As I testified before the Subcommittee last year, ACC and its members welcome Congress' review of the Toxic Substances Control Act (TSCA) and the measures that might be taken to modernize the statute. ACC shares the objective of protecting human health and the environment from any significant risks associated with chemicals with PBT properties. It is important that any modifications to TSCA take into account the significant advances in PBT regulation already achieved under both domestic and international law.

PBT substances represent a very small percentage of chemicals in commerce in the United States.[1] Many are either strictly regulated, are not currently in production, or are the by-products of human and natural activity. PBTs encompass a range of substances, including some metals and a variety of organic compounds.

ACC and its members have long supported processes where PBT substances receive priority attention in risk characterization, risk management, and pollution prevention programs. ACC member companies have committed to a goal of minimizing the potential human health and environmental risks that may be associated with PBTs. Through Responsible Care® and similar initiatives, ACC members have worked to characterize their products and processes and take appropriate actions. Although not specific to

[1] A "PBT" is a chemical that persists (P) in the environment, has the potential to bioaccumulate (B) in the food chain to relatively high levels, and is toxic (T). Only those chemicals that exceed EPA criteria in all three categories - P, B, and T,- are considered potential PBTs.

substances with PBT characteristics, to date over 1,000 product safety summaries have been produced by ACC member companies, and are publicly available through ACC's website.[2]

In September 1995, the Board of Directors of ACC (then the Chemical Manufacturers Association) approved a policy statement on PBTs that underscored ACC's commitment to reduce potential risks from PBT materials (i.e., products, byproducts and wastes that contain PBT substances). Simply stated, ACC's policy acknowledges the fundamental properties of PBTs and affirms that substances identified through screening as possible PBTs deserve priority attention in further risk characterization. While screening is a critical step in the process in that it allows larger numbers of materials to be evaluated more rapidly and in a cost-effective manner, it is not by itself a sufficient basis for risk management. In 1996, ACC produced guidance material for its members to use in addressing PBT substances.

In the sequence outlined in the ACC policy, the potential need for and form of risk management of PBTs is determined after a thorough risk characterization of candidate materials identified through screening. This process is consistent with the approach ACC has recommended for modifications to TSCA – a process in which a chemical substance's hazards, uses and exposures are screened and assessed, and appropriate regulatory and risk management decisions are based on an integrated evaluation of hazard, use and exposure information, rather than just hazard information alone.

It is important to note that the Environmental Protection Agency (EPA), and indeed the U.S. government as a whole, has provided significant leadership on PBT issues. In the late 1990's, EPA pursued a National PBT program, which included lower reporting thresholds for PBTs on the Toxics Release Inventory, and the development of a prioritization tool for waste streams containing PBTs.

The signature element of the program, however, was a little-observed change in the Agency's policy for reviewing TSCA pre-manufacturing notices (PMNs) for substances that met PBT related criteria. The PBT PMN policy, adopted in 1999, was the first effort by any government to address new chemicals that exhibit PBT characteristics. EPA's policy sent a clear message to chemical manufacturers and importers that, absent extensive additional data on PBT substances (including use and exposure information), the Agency would generally reject PMN applications meeting the highest PBT category of concern. Although PBT substances have in general been a very small percentage of new chemical applications, the fact remains that the policy has been very effective in reducing the number of new PBT substances and in establishing appropriate risk management measures for those few that have entered the market.

In addition, the U.S. government has long supported the negotiation and implementation of several international instruments designed to reduce the regional and global risks of a subcategory of PBT substances known as Persistent Organic Pollutants (POPs). The Stockholm Convention on POPs and the U.N. Economic Commission for Europe's Protocol on POPs reflect the international community's commitment to reduce, and where possible eliminate, the risks of certain listed POPs which meet established PBT criteria and are also known to undergo, respectively, global or regional environmental transport. Both instruments reflect the significant leadership of the U.S. government, particularly in the criteria for the identification of POPs substances. Both instruments adopt a science based approach to international POPs regulation.

[2] ACC's search tool and portal to the safety summaries is available at http://reporting.responsiblecare-us.com/Search/PSSummarySearch.aspx

ACC strongly supported the negotiation of the international POPs instruments, and has long advocated for U.S. Senate advice and consent to ratification and their reasonable implementation into U.S. law. (See Attachment A) Unfortunately, despite U.S. signature of both instruments, Congress has not approved the changes to TSCA and the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) necessary to implement these agreements in U.S. law. ACC believes that Congress should include appropriate implementing language as it considers modifications to TSCA so that the United States can become a full Party to these agreements. U.S. participation and leadership in the implementation of these agreements is crucial in maintaining the risk-based, science-justified POPs identification and management effort they adopt.

As Congress discusses modifications to TSCA, PBT substances appropriately warrant review and assessment. The recommendations ACC has made for prioritization screening and safety assessments, as reflected in our principles for TSCA modernization, provide a mechanism to address the special health and environmental concerns that may arise from these substances, and an appropriate process by which measures to manage their risks can be taken. (See Attachment B)

In ACC's view, TSCA modifications should reflect the most up-to-date scientific thinking about how to evaluate PBTs and POPs. In 1997 and again in 2008 the Society for Environmental Toxicology and Chemistry (SETAC), sponsored workshops on PBT/POPs substances (aka "Pellston Workshop")[3]. The workshops helped advance the science of PBT characterization by reaching consensus on how to better identify PBTs and POPs at an early stage, using new scientific information and tools, rather than simply defaulting to criteria that have been in place since the late 1970s. This workshop included leading scientists from academia, government, regulatory bodies and industry. Follow-up from the 2008 workshop is underway. Congress should consider this scientific discussion on PBTs and POPs to assure that the most up to date, reliable scientific methods are applied.

ACC and its members look forward to working with you and the Subcommittee members as discussions around modifications to TSCA continue. If we can provide any additional information on ACC's position on TSCA modernization, please contact me.

Sincerely,

Cal Dooley
President and CEO

cc: Subcommittee on Commerce, Trade and Consumer Protection

[3] The Executive Summary of the Proceedings of the Workshop are available at http://www.setac.org/sites/default/files/ExecutiveSummary.pdf

Attachment A

TESTIMONY OF THE

AMERICAN CHEMISTRY COUNCIL

BEFORE THE
HOUSE SUBCOMMITTEE ON ENVIRONMENT AND HAZARDOUS MATERIALS

ON LEGISLATION TO IMPLEMENT
THE STOCKHOLM CONVENTION ON PERSISTENT ORGANIC POLLUTANTS, THE
LRTAP POPS PROTOCOL, AND THE ROTTERDAM CONVENTION ON
PRIOR INFORMED CONSENT

MARCH 2, 2006

Michael P. Walls, Esq.
American Chemistry Council
1300 Wilson Boulevard
Arlington, VA 22209
(703) 741-5000

TESTIMONY OF THE
AMERICAN CHEMISTRY COUNCIL

ON LEGISLATION TO IMPLEMENT
THE STOCKHOLM CONVENTION ON PERSISTENT ORGANIC POLLUTANTS, THE
LRTAP POPS PROTOCOL, AND THE ROTTERDAM CONVENTION ON
PRIOR INFORMED CONSENT
March 2, 2006

I. Introduction

The American Chemistry Council (ACC) appreciates this opportunity to reiterate its strong support for the three international agreements that are the subject of this hearing: the Stockholm Convention on Persistent Organic Pollutants (POPs), the U.N. Economic Commission for Europe's POPs Protocol to the Convention on Long-Range Transboundary Air Pollution (LRTAP POPs Protocol) and the Rotterdam Convention on Prior Informed Consent (PIC). We also appreciate the opportunity to record our strong support for H.R. 4591, Mr. Gillmor's legislation to implement these agreements by amending the Toxic Substances Control Act (TSCA).

Prompt action on H.R. 4591 is required to ensure that the United States can continue its international leadership role under these agreements. H.R. 4591 contains the legislative changes to TSCA necessary for the United States to meet its obligations under these agreements, and it sends a powerful message to other governments – a message that the agreements must be implemented as they were intended, with no more and no less.

II. U.S. Participation is Necessary in Order to Ensure the Reasonable Implementation of these Agreements.

As the Subcommittee is aware, the LRTAP POPs Protocol, the Stockholm Convention and the PIC Convention are all in force. Initial meetings of the parties to these agreements have been held, key positions on subsidiary bodies have been allocated, and work has already begun in those subsidiary bodies. Chemicals of significant importance to U.S. industry have been nominated for inclusion in the conventions. Future decisions on nominated chemicals, review processes and best practices will have a major impact on our industry, which is global in scale. Already the risk-based, science-justified processes for listing new chemicals are under attack by governments who would prefer to ignore those requirements. Yet the ability of the United States to lead and appropriately influence the decisions that have long-term consequences for the operation of the agreements has been significantly reduced because our government is not a Party.

For that reason, we think that it is vital that the Congress take action quickly to adopt H.R. 4591 and allow the United States to join these agreements and deal effectively with their implementation at both the domestic and international level. In ACC's view, H.R. 4591 is the best vehicle for integrating TSCA and U.S. obligations under the agreement.

III. H.R. 4591 Addresses the Key Required Changes in U.S. Statutory Authority

The three international agreements only require modest statutory changes to TSCA. These include:

- Extending EPA authority to prohibit export of current POPs substances for purposes prohibited by the Convention.
- Imposing certification requirements for exports to countries not party to the POPs agreements.
- Codifying the treaty exemptions in TSCA.
- Integrating the Rotterdam PIC export notification provisions into existing TSCA export notification requirements.

In ACC's view, there is no real disagreement that these elements must be addressed in implementing legislation.

The single most controversial issue with respect to these treaties has been how to handle future decisions to add new POPs substances under the agreements as a matter of U.S. law and regulation.

The POPs agreements do not obligate the Parties to establish mechanisms to address future treaty amendments like new chemicals, and the United States could limit its implementing changes to the targeted fixes noted above. But the treaties contemplate the possibility that chemicals will be added to the list of covered substances in the future, and ACC shares the view that legislative economy suggests an adding mechanism should be considered for the legislation. ACC therefore supports the establishment of a new domestic process that would give EPA special new authority to prohibit or restrict the manufacture, use, or export of POPs substances listed by future decisions under the treaties.

The Stockholm Convention establishes a process by which a new chemical will be added to the list of POPs:

1. A Party nominates a chemical for consideration as a POP substance.
2. The treaty Secretariat reviews the nomination to ensure that it meets the minimum criteria established in Annex D (e.g., that the nomination includes information on the persistent, bioaccumulative, and toxic properties of the substances, and the propensity for long-range transport). If the nomination meets the criteria, it is forwarded to the POPs Review Committee (POPRC).
3. The POPRC reviews the nomination, and if further consideration is warranted, the Committee requests information necessary to prepare a Risk Profile on the substance pursuant to Annex E.
4. The POPRC reviews the Risk Profile. If the POPRC decides that further consideration is warranted because long-range transport of the substance will lead to significant health or environmental impacts such that global action is necessary, the

Committee requests information to prepare a risk management evaluation, including information on the socio-economic benefit and alternatives to the nominated substance, pursuant to Annex F.

5. On the basis of the risk management evaluation, the POPRC makes a recommendation to the Conference of the Parties (COP) whether the chemical should be listed in Annex A, B or C of the treaty.
6. The COP then decides whether to amend the Convention to include the new chemical on one of the Annexes.

H.R. 4591 requires EPA to provide public notice and an opportunity to comment at each decision point in this process – upon the nomination of a substance, the preparation of the risk profile and risk management evaluation, and the recommendation to the COP. The process will provide ample public notice of activities under the treaties, and it will assure that U.S. representatives in the POPRC and the COP have all relevant information before them at each stage of the international process.

More importantly, the international agreements adopt a flexible approach to risk management measures. For example, elimination of a substance is not a legal requirement for a POP substance, but constitutes one option to manage the risks of a POPs release. A domestic regulatory process is required to provide the United States sufficient flexibility to determine how it will regulate a particular substance and what, if any, critical uses or exemptions might be necessary. The domestic process should include the risk and cost/benefit considerations envisioned in the treaty. Further, as the treaty provisions and annexes make clear, risk and cost/benefit considerations are not trumped by the need for precaution. Rather, those considerations give substance to the precautionary decisions made through the treaty process.

H.R. 4591 appropriately reflects these risk management considerations in a domestic regulatory process for new POPs substances that mirror the procedural and substantive decisions under the Stockholm Convention and the LRTAP POPs Protocol. When a new substance is adopted under one of these agreements, EPA is granted special new authority to regulate these newly listed substances "to the extent necessary to protect human health and the environment in a manner that achieves a reasonable balance of social, environmental, and economic costs and benefits." In reaching its regulatory decision, EPA is to consider:

- The effects and magnitude of the effects of the substance on health or the environment.
- The benefits of the substance and the availability, risks and economic consequences of alternatives to the substance.
- The economic consequences of the proposed risk management requirement.
- The domestic and international consequences likely to arise as a result of the domestic regulatory action.

EPA is also authorized to consider additional information in the domestic or international record.

The decision-making standard and the first three required elements in EPA's regulatory considerations provide the necessary domestic counterpart to the process outlined in the POPs

agreements. The treaties require that relevant social, economic, environmental and health information is considered in reaching a decision to list a new chemical; H.R. 4591 ensures that the same information is considered in reaching a domestic decision. Between the notice and comment requirements and the international process, EPA will have a robust domestic and international record to consider in reaching a domestic regulatory decision – and a sufficient opportunity to ensure that the record supports its subsequent regulatory actions.

H.R. 4591 sends a powerful signal to those governments that are attempting to weaken the risk/benefit approach set out in the POPs agreements. To date, the international process for evaluating new chemicals is only in the initial stages, but some governments are working to remove or dilute the criteria for evaluating new chemicals, including the evaluation of risk, costs and the potential consequences and risks of any alternatives and potential risk management measures. These efforts further reinforce the need for a clear domestic regulatory process.

The domestic regulatory process in H.R. 4591 sends a clear signal that in order to ensure that the United States can be party to a treaty amendment to list a new chemical, the record must provide appropriate support. The international agreements adopt a risk/benefit approach in implementing appropriate regulatory controls on listed chemicals, and in considering chemicals nominated as potential POPs. The agreements rely on technical and economic considerations to ensure that priority pollutants are targeted and meaningful control actions taken on a global basis. H.R. 4591 does no less – and supports the appropriate use of analytical tools such as risk assessment and cost/benefit analysis that EPA already employs in its decisions to manage the risks of chemicals.

Section 6 of TSCA already provides EPA the necessary authority to prohibit or restrict the manufacture, processing, use, distribution or disposal of a chemical substance. Due to the special global considerations that apply to substances nominated as POPs, the chemical industry has been willing to consider an appropriately narrow modification to the approach used in TSCA Section 6. For example, the H.R. 4591 imposes no requirement on EPA to demonstrate that a substance poses an "unreasonable risk" to health or the environment, does not require EPA to demonstrate that its preferred risk management approach is the "least burdensome regulatory alternative," and imposes none of the procedural elements of Section 6, such as the informal hearings required for proposals under that section.

We also note that H.R. 4591 does not prevent EPA from regulating POPs substances under its existing statutory authority, including TSCA. The United States regulated the existing POPs long before the international agreements were drafted, employing a regulatory process that considered scientific evidence, risks to health and the environment, and socio-economic consequences. The domestic POPs process established in H.R. 4591 simply adapts existing requirements in a manner that ensures the United States can meet its international obligations.

H.R. 4591 also appropriately establishes a requirement that the Executive Branch consult with Congress as amendments to the treaty obligations are considered. This provision constitutes no restriction on the President's power to conduct foreign policy, and ensures that Congress is made aware of significant developments in the future implementation of the agreements.

IV. Conclusion

The American Chemistry Council believes that the Stockholm Convention, LRTAP Protocol, and Rotterdam Convention are significant steps in securing international action on chemicals through coordinated risk management at the global level. The agreements establish a harmonized approach for action on listed chemicals, and should produce meaningful improvements in public health and environmental protection. The United States must become a Party to the agreements as soon as possible.

H.R. 4591 fully implements U.S. obligations under the three agreements into TSCA. It complements EPA's existing regulatory authority, provides proper public notice and an opportunity to comment at all stages of the international process, and ensures that the United States can cooperate with the international community in addressing global risks. We commend Mr. Gillmor for introducing this bill, and urge the Subcommittee and Congress to take quick action on the legislation to ensure that the United States can once again fill its leadership role in international chemical regulatory matters.

Attachment B

American® Chemistry Council

10 Principles for Modernizing TSCA

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

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

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

1. Chemicals should be safe for their intended use.

   - Ensuring chemical safety is a shared responsibility of industry and EPA.

   - Industry should have the responsibility for providing sufficient information for EPA to make timely decisions about safety.

   - EPA should have the responsibility for making safe use determinations for high priority chemicals, focusing on their most significant uses and exposures.

   - Safe use determinations should integrate hazard, use, and exposure information, and incorporate appropriate safety factors.

   - Consideration of the benefits of chemicals being evaluated, the cost of methods to control their risks, and the benefits and costs of alternatives should be part of EPA's risk management decision making, but should not be part of its safe use determinations.

   - Other agencies, such as FDA and CPSC, should continue to make safety decisions for products within their own jurisdictions.

2. EPA should systematically prioritize chemicals for purposes of safe use determinations.

   - Government and industry resources should be focused on chemicals of highest concern.

- The priorities should reflect considerations such as the volume of a chemical in commerce; its uses, including whether it is formulated in products for children; its detection in biomonitoring programs; its persistent or bioaccumulative properties; and the adequacy of available information.

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

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

- EPA should complete safe use determinations within set timeframes.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

WRITTEN STATEMENT OF

NATIONAL PETROCHEMICAL & REFINERS ASSOCIATION (NPRA)

AS SUBMITTED TO THE

SUBCOMMITTEE ON COMMERCE, TRADE AND CONSUMER PROTECTION

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

on

"TSCA (Toxic Substances Control Act) and Persistent, Bioaccumulative, and Toxic Chemicals: Examining Domestic and International Actions."

March 4, 2010

Introduction

NPRA, the National Petrochemical & Refiners Association, appreciates the opportunity to submit written testimony for today's hearing examining persistent, bioaccumulative and toxic (PBT) substances. Our association represents more than 450 businesses, including virtually all U.S. refiners and petrochemical manufacturers, their suppliers, and vendors. NPRA members supply consumers with a wide variety of products used daily in their homes and businesses, including fuels, lubricants, and chemicals that serve as building blocks for everything from plastics to clothing, medicine, and computers.

Background and Overview

NPRA considers the existing federal chemicals regulatory framework to be a strong foundation for the protection of consumer health and the environment, while simultaneously allowing for the development of products that enhance our standard of living. NPRA and its members support a responsible update of the nation's chemicals risk management regulatory framework. Within that context, we understand the Subcommittee's interest in how the federal government should best address persistent, bioaccumulative and toxic substances.

Defining Persistence, Bioaccumulation and Toxicity

Through the Organization for Economic Cooperation and Development (OECD), international consensus has been achieved among regulatory scientists regarding how to appropriately define certain chemicals as persistent, bioaccumulative and toxic. The United States should adhere to those definitions and not diverge into its own classification scheme, which would create a patchwork of varying definitions for PBTs throughout different regions.

Because of advances in analytical chemistry techniques, a substance should not necessarily be classified as bioaccumulative simply if trace (parts per billion or trillion) amounts are found in biomonitoring studies. Scientists are still trying to interpret the implications of finding this many previously undetected substances in the human body at these extremely low levels. It is thus

premature to draw any kind of regulatory conclusion regarding bioaccumulation until there is clear international consensus among regulatory scientists through the OECD.

Consistent with international scientific consensus, a particular substance should not be classified as a PBT unless it is persistent, bioaccumulative *and* toxic. Possessing just one or two of these traits does not present the same potential hazard as possessing all three and should not be viewed as such.

Risk Management for PBTs

Risk management for PBTs should follow the same approach as for any other chemical. A particular PBT, like any other substance, should not automatically be considered a high risk because of its inherent properties. Persistence can be a valuable trait for materials that need to withstand harsh environments. Bioaccumulation does not mean that safety is jeopardized. The human body accumulates, metabolizes and excretes many naturally occurring toxic substances every day. Certain PBTs have been used safely for years in industrial settings by controlling releases and exposures.

Conclusion

NPRA supports Congress providing EPA the authority to regulate persistent, bioaccumulative and toxic substances. The United States should continue to follow international consensus through the OECD on the definitions of persistence, bioaccumulation and toxicity, and on classifications of PBTs. PBTs should be evaluated for risk in the same manner as any other substance in commerce and subjected to a tiered and targeted approach to risk management.

EPA RESPONSES TO CONGRESSIONAL QUESTIONS FOR THE RECORD
March 4, 2010 PBT Hearing
House Energy and Commerce
Sub-Committee on Commerce, Trade, and Consumer Protection

September 15, 2010

The Honorable Bobby L. Rush

1. Biomonitoring can be used to determine the amount that people are actually exposed to certain chemicals. At our last hearing on TSCA in November, we heard from the Centers for Disease Control and Prevention about their biomonitoring program. Their fourth biomonitoring report found "widespread" exposure to emerging chemicals of concern. These include PBTs such as perfluorinated compounds (PFOA) and flame retardants (PBDEs).

a. Do you believe that if a chemical is found to contaminate the human body, there is exposure?

Yes, although presence in the body alone does not tell us what the resulting risk of the chemical may be to human health. The presence of a chemical in the human body is a key factor in Agency decision making regarding both toxicity testing and risk mitigation of chemicals. A number of the Agency's risk reduction actions under TSCA have been focused on chemicals found in the human body in biomonitoring studies, for example, penta- and octa-bromodiphenyl ether as well as a broad class of PFOS and PFAC chemicals. Biomonitoring information is also a selection criterion for the new EPA chemical action plans recently released, and action plans where this was a factor include polybrominated diphenyl ethers, phthalates, long-chain perfluorinated compounds and short chain chlorinated paraffins.

b. Do you believe once we know that a chemical is a PBT and there is exposure, this is sufficient information for EPA to take immediate action to reduce or eliminate the use of PBTs?

Exposure to a PBT is potential cause for concern, although presence in the body alone does not tell us what the resulting risk of the chemical may be to human health, Having said that, as a result of the legal hurdles and procedural requirements TSCA places on EPA prior to collecting data, there are large, troubling gaps in the available data and state of knowledge on many widely used chemicals in commerce. Although there is a review process for new chemicals being introduced into commerce, chemical producers are not required to provide, without further action from EPA, the data necessary to fully assess a chemical's risks.

In the cases where EPA has adequate data on a chemical, and wants to protect the public against well-known risks to human health and the environment, there are legal hurdles that prevent quick and effective regulatory action. Meanwhile, the public may be exposed to chemicals for which we have little understanding of the consequences.

When Administrator Jackson announced that EPA would be taking action on a number of chemicals, she noted criteria EPA would use to identify these chemicals.[1] PBT characteristics were among those criteria. In fact, three of the four chemical groups selected for the initial group of action plans were PBTs.

c. If we know that something is a PBT but we do not know if there is exposure, does EPA think it would be a priority to find out if there is exposure? Can EPA act on PBTs without exposure information?

Persistence and bioaccumulation, as well as toxicity, are certainly very important factors in evaluating a chemical's risks. Filling in gaps in exposure information for PBTs would be a high priority. Currently, under TSCA, exposure information is necessary to determine whether an existing chemical presents or may present an unreasonable risk. The response to the following question outlines EPA's Policy Statement for the consideration of PBTs during the review of new chemicals under TSCA.

d. Do you believe newly developed chemicals that meet the criteria for being a PBT should be restricted from entering commerce?

As outlined in the Administration's principles on TSCA reform, we believe that chemicals should be reviewed against safety standards that reflect risk-based criteria protective of human health and the environment, and that EPA should have clear authority to take risk management actions when chemicals do not meet the safety standard.

That a chemical is persistent and bioaccumulative, as well as toxic, is certainly a very important factor in evaluating a chemical's risks and prioritizing chemicals for action. PBT characteristics are among the factors the Agency has considered in identifying chemical substances for action in both its enhanced existing chemicals management program and its new chemicals program.

Beginning in 1988, EPA first used its accumulated experience to group certain chemical substances with similar physicochemical, structural, and toxicological properties into categories to enable both Pre-Manufacture Notice (PMN) submitters and EPA reviewers to benefit from

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[1] http://www.epa.gov/oppt/existingchemicals/pubs/ExistingChem_Fact_sheet.pdf

the accumulated data and decisional precedents for the assessment and regulation of new chemical substances. In 1999 (Federal Register, 11/4/1999, page 60194-60204), EPA issued a final policy statement regarding the category of persistent, bioaccumulative, and toxic (PBT) new chemical substances. Through the Policy Statement, EPA adopted specific identification criteria and the associated process that EPA would use in evaluating new chemical substances suspected as being persistent bioaccumulators. The Policy Statement made clear to submitters of new chemical notifications under TSCA section 5 that substances meeting these criteria may need to undergo testing on "P" and "B" endpoints which, if confirmed, would be followed by appropriate toxicity testing to identify "PBT chemical substances." In addition, the Policy Statement made clear that control action under TSCA section 5(e) may be needed in varying degrees, based upon the level of risk concern.

e. When there is known exposure to a persistent and bioaccumulative chemical but toxicity is not known, do you believe that this chemical should be limited in commerce or prioritized for toxicity testing?

There are large, troubling gaps in the available data and state of knowledge on many widely used chemicals in commerce. Although there is a review process for new chemicals being introduced into commerce, chemical producers are not required to provide, without further action from EPA, the data necessary to fully assess a chemical's risks. If toxicity is unknown for chemicals known to be persistent and bioaccumulative, this would be an important data gap which should be filled.

As outlined in the Administration's principles on TSCA reform, we believe that chemicals should be reviewed against safety standards that reflect risk-based criteria protective of human health and the environment, and that EPA should have clear authority to take risk management actions when chemicals do not meet the safety standard.

2. The National Research Council in a 2005 report has found biomonitoring to be a "tool with great potential," and the GAO recently testified that EPA has not sufficiently used available biomonitoring data in its chemical risk assessments.

a. Does EPA consider the presence of persistent and bioaccumulative chemicals in the human body to be a trigger for toxicity testing or risk mitigation?

That a chemical is persistent and bioaccumulative, as well as toxic, is certainly a very important factor in evaluating a chemical's risks. When Administrator Jackson announced that EPA would

be taking action on a number of chemicals, she noted criteria EPA would use to identify these chemicals.[2] PBT characteristics were among those criteria.

EPA has used persistence, bioaccumulation, and toxicity (PBT) characteristics in determining toxicity testing needs and risk mitigation activities in the New Chemical Program for over 20 years. Beginning in 1988, EPA first used its accumulated experience to group certain chemical substances with similar physicochemical, structural, and toxicological properties into categories to enable both PMN submitters and EPA reviewers to benefit from the accumulated data and decisional precedents for the assessment and regulation of new chemical substances. In 1999 (Federal Register, 11/4/1999, page 60194-60204), EPA issued a final policy statement regarding the category of persistent, bioaccumulative, and toxic (PBT) new chemical substances. Through the Policy Statement, EPA adopted specific identification criteria and the associated process that EPA would use in evaluating new chemical substances suspected as being persistent bioaccumulators. The Policy Statement made clear to submitters of new chemical notifications under TSCA section 5 that substances meeting these criteria may need to undergo testing on "P" and "B" endpoints which, if confirmed, would be followed by appropriate toxicity testing to identify "PBT chemical substances." In addition, the Policy Statement made clear that control action under TSCA section 5(e) may be needed in varying degrees, based upon the level of risk concern.

More recently, EPA has had the opportunity to incorporate biomonitoring information in conjunction with PBT information in the Existing Chemical Program. In 2005, EPA's Science Advisory Board reviewed a draft risk assessment of perfluorooctanoic acid (PFOA). This assessment was one of the first examples of the use of human biomonitoring and pharmacokinetic modeling in assessing potential human risks, and in fact was highlighted in NRC 2006 report on biomonitoring. The biomonitoring information, in conjunction with the PBT characteristics of PFOA, formed the rationale for the risk mitigation activities and the phase-out of PFOA (as well as the earlier phase out of PFOS). In addition, this information has formed the basis for the toxicity testing requirements, and risk mitigation activities, of all new perfluoro compounds submitted through the PMN program. In September 2009, EPA announced efforts to enhance the Agency's current chemical management progam, which includes the development and release of chemical specific action plans. To date, the Agency has released five action plans, including several chemicals which were selected, in part, on biomonitoring information, and/or known PBT properties, including perfluoroalkyl acids, PBDEs, BPA, and phthalates.

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[2] http://www.epa.gov/oppt/existingchemicals/pubs/Existing.Chem.Fact.sheet.pdf

b. Does EPA have a plan for utilizing biomonitoring data for identification of exposure to persistent and bioaccumulative chemicals?

Characteristics of persistence and bioaccumulation and biomonitoring data are among the factors the Agency has considered in identifying chemical substances for action in its enhanced existing chemicals management program and will continue to use these factors. In addition, the Great Lakes Restoration Initiative (GLRI) is undertaking a biomonitoring study of intensive Great Lakes fish consumers with a focus on chemicals of emerging concern such as brominated flame retardants and perfluorinated compounds. The GLRI is a five year multi-agency effort to restore and maintain the chemical, physical, and biological integrity of the Great Lakes. Under the GLRI, significant new investments are being made to address PBTs, including pollution prevention efforts, such as implementation of the Great Lakes Regional Collaboration Mercury in Products and Waste Phase-down Strategy, as well as in green chemistry and product stewardship activities in the Great Lakes basin. Efforts include further monitoring and surveillance for new and emerging chemicals in the Great Lakes through expanded fish and air deposition monitoring and a new sediment core program to help identify new chemical toxicants which may pose threats to human health and the environment.[3]

3. Mr. Jones, we heard you describe what the EPA is currently doing on PBTs. However, EPA drafted a document in 1998 entitled "Multimedia Strategy for Priority Persistent, Bioaccumulative, and Toxic (PBT) Chemicals." In the years since, it does not appear that that draft document was ever finalized.

a. Is there a plan under this Administration to finalize this strategy document? Similarly, EPA's website says that the PBT program is no longer active. Can you elaborate on this? Do the new chemical action plans you explained in your testimony replace this older PBT program?

EPA does not intend to finalize this document. EPA's current enhanced existing chemicals program, which includes the development and implementation of action plans for chemicals that EPA believes may pose environmental or public health concerns, has superseded this program. Persistence and bioaccumulation, as well as toxicity, are very important factors in evaluating a chemical's risks.

4. EPA's recently announced action plans on 4 chemicals included 3 PBTs.

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[3] http://greatlakesrestoration.us/

a. Do you have any indication how many more chemical action plans in the pipeline will be for PBTs? You have action plans for non-PBTs. With limited resources, is there a preference given to PBTs for an action plan?

At this point, we cannot say how many future action plans may address PBTs. Persistence and bioaccumulation, as well as toxicity, are very important factors in evaluating a chemical's risks.

b. How many actions plans should we expect in total?

As of August 20, 2010, EPA has made public eight chemical specific action plans. EPA will continue to address chemicals that EPA believes may pose environmental or public health concerns.

c. How many PBTs are currently being used in commerce? How many PBTs are no longer used in commerce, yet are still contaminating the environment and our bodies?

We do not know exactly how many exist and their status in commerce. There are more than 84,000 chemicals on the TSCA Inventory, and the Inventory does not include pesticides and other chemicals subject to other statutes. EPA does, however, have information on some new and existing TSCA chemicals. Starting in Fiscal Year 2001, about 6% of all New Chemical notices have been determined to be PBTs. About 2% of more than 2200 existing chemicals in the High Production Volume Challenge program were identified as PBTs using EPA's PBT Profiler screening tool and the new chemicals program protocols.

d. Does EPA know how many new PBTs have entered into commerce since TSCA was enacted in 1976?

The Agency did not begin tracking PBTs until Fiscal Year 2001. Starting in 2001, about 6% of all New Chemical notices have been determined to be PBTs, for a total of 680 through 2008. There does not seem to be a discernible trend that we can identify, but the range is from a low of 56 in 2008 to a high of 109 in 2002.

5. Mr. Sturdevant emphasized the need to transition towards safer alternatives where PBTs are currently used in commerce. To determine safety, we need information on a chemical's toxicity. Currently, EPA is limited in its ability to get this information.

a. Is there a process in place at EPA to require or encourage switching to safer alternatives, as suggested by Mr. Sturdevant?

The Design for the Environment (DfE) Program in EPA pursues two different approaches to promote the transition from chemicals that may pose environmental or public health concerns, including PBTs, to scientifically proven safer alternatives. Under the first approach, the

Program conducts the Safer Product Labeling program to encourage formulators of cleaning and other products to reformulate away from chemicals that may pose environmental or public health concerns towards safer substitutes. The Program uses the Agency's toxicological, chemistry and other scientific expertise to screen chemicals and recommend safer replacements. Products which meet the criteria for every chemical ingredient in the product are allowed to affix a DfE logo to their product asserting safer chemistry.[4]

When safer alternative chemicals are not readily available or not widely used in an industry, DfE uses a different approach, named Alternatives Assessment, to identify and evaluate safer chemicals. These Alternatives Assessments are a collaborative effort with leaders in industry, NGOs, agency scientists and, as appropriate, academic or other stakeholders. Agency science is used to understand the potential for environmental and human health impacts of the alternatives and enable a move to safer chemicals.

The Honorable Ed Whitfield

1. During questioning, I asked what the process was for adding chemicals to the TRI list. Please state for the record what that process is.

The toxic chemicals subject to the TRI requirements are those chemicals on the list in Committee Print Number 99–169 of the Senate Committee on Environment and Public Works, titled "Toxic Chemicals Subject to Section 313 of the Emergency Planning and Community Right-To-Know Act of 1986" and any revisions to the list as may be made pursuant to subsection (d) or (e) of Section 313. The current list has over 600 individually listed chemicals and about 30 chemicals categories.

EPCRA 313(d) provides the authority to add a chemical to the TRI list if the Administrator determines, in his or her judgment and based on available and generally accepted scientific principles or laboratory tests, or appropriately designed and conducted epidemiological or other population studies, that there is sufficient evidence to establish any one of the following:

- The chemical is known to cause or can reasonably be anticipated to cause significant adverse acute human health effects at concentration levels that are reasonably likely to exist beyond facility site boundaries as a result of continuous, or frequently recurring, releases.

[4] http://www.epa.gov/dfe/pubs/projects/gfcp/index.htm.

- The chemical is known to cause, or can reasonably be anticipated to cause in humans (1) cancer or teratogenic effects, or (2) serious or irreversible reproductive dysfunctions, neurological disorders, heritable genetic mutations, or other chronic health effects.

- The chemical is known to cause or can reasonably be anticipated to cause, because of its toxicity, its toxicity and persistence in the environment, or its toxicity and tendency to bioaccumulate in the environment, a significant adverse effect on the environment of sufficient seriousness, in the judgment of the Administrator, to warrant reporting under this section.

EPA must make such a determination by rule. Additions would be proposed through publication of a draft rule to provide notice and opportunity for comment on the addition of the chemical to the TRI list. A final rule would be subject to judicial review. A similar process would occur to delete a listed chemical if the Administrator determined there was not sufficient evidence to establish any of the criteria described above for the chemical.

Under EPCRA 313(e), any person may petition the Administrator to add or delete a chemical and the Administrator must take action within 180 days.

The TRI regulations were augmented with respect to persistent bioaccumulative toxic (PBT) chemicals on October 29, 1999, when EPA published a final rule adding some PBT chemicals to the list of toxic chemicals subject to section 313 of EPCRA and section 6607 of the PPA and to lower the reporting thresholds for certain PBT chemicals including mercury, dioxin, and PCBs.

2. How does a chemical, like Metiram, which the toxicity test showed was not causing a problem in animals, make the list?

Based on the 1994 rulemaking record, Metiram is an ethylene bisdithiocarbamate (EBDC) fungicide, and EPA found that sufficient evidence suggested that ethylene bisthiocarbamate fungicides and ethylenethiourea (a common contaminant, metabolite, and degradation product of these fungicides) caused cancer and adverse developmental effects in experimental animals.[5]

In a 2-year diet study, ethylenethiourea caused liver adenomas and carcinomas in mice, and thyroid follicular cell adenomas and carcinomas in mice and rats.[6] A NOAEL of less than or equal to 5 mg/kg has been reported for ethylenethiourea, based on a rat developmental

[5] 59 FR 1863, 1/12/1994

[6] Support Document for the Health and Ecological Toxicity Review of TRI Expansion Chemicals. U.S. Environmental Protection Agency, Washington, DC (1993), page 95.

toxicity study.[7] Ethylenethiourea caused delayed ossification or hardening of the parietal bone in pups. EPA believed then, as it does now, that there is sufficient evidence for listing metiram on the EPCRA section 313(c) list pursuant to EPCRA section 313(d)(2)(B) based on the carcinogenicity and developmental toxicity data for ethylenethiourea, a metabolite and degradation product of metiram.

3. Please state whether chemicals have been statutorily added to the TRI. Please state whether any of their toxicity profiles are similar to or more benign than that for Metiram.

All of the chemicals that were originally on the TRI list were statutorily added in Committee Print Number 99–169 of the Senate Committee on Environment and Public Works, titled "Toxic Chemicals Subject to Section 313 of the Emergency Planning and Community Right-To-Know Act of 1986."

No chemicals have been added statutorily since the adoption of the law.

With respect to your question regarding whether the toxicity profiles of any of the statutorily added chemicals are similar to or more benign than that for metiram, since there have not been any statutory additions, the Agency does not have anything upon which to base an answer to this question.

4. Please provide a full explanation of the steps EPA must take to ban a PBT. Please state whether there are legal authorities other than TSCA to address PBT chemical risks.

Section 6(a) of TSCA gives EPA the authority to protect against unreasonable risk of injury to health or the environment from chemical substances. If EPA finds that there is a reasonable basis to conclude that the chemical's manufacture, processing, distribution, use or disposal presents an unreasonable risk, EPA may by notice-and-comment rulemaking take action to:

- Prohibit or limit manufacture, processing, or distribution in commerce;
- Prohibit or limit the manufacture, processing, or distribution in commerce of the chemical substance above a specified concentration;
- Require adequate warnings and instructions with respect to use, distribution, or disposal;
- Require manufacturers or processors to make and retain records;
- Prohibit or regulate any manner of commercial use;
- Prohibit or regulate any manner of disposal; and/or

[7] Id.

- Require manufacturers or processors to give notice of the unreasonable risk of injury, and to recall products if required.

TSCA section 6(a) indicates that EPA should apply the least burdensome means of adequately protecting against the unreasonable risk. In developing a rule under 6(a), TSCA section 6(c) directs EPA to consider and publish a statement with respect to:

1. The effect of the chemical substance being regulated on health and the magnitude of exposure of humans to the substance.
2. The effects of such substance on the environment and the magnitude of exposure of the environment to the substance.
3. The benefits of such substance for various uses and the availability of substitutes for such uses.
4. The reasonably ascertainable economic consequences of the rule, after consideration of the effect on the national economy, small business, technological innovation, the environment, and public health.

Only five ban actions have been taken using this authority since TSCA was enacted, along with the predominantly invalidated Asbestos Ban and Phase-out Rule. The 5th Circuit Court of Appeals decision on the asbestos rule in 1991 had a chilling effect on EPA's use of the TSCA ban authority. To the extent EPA has authority to address chemicals in the various media it regulates, it also has the authority to address PBT chemicals. While the PBT nature of the chemicals may be relevant to a risk finding or Agency priority setting, most EPA authorities do not treat PBTs differently as a class. (Note, though, that PBT-listed chemicals are subject to lower thresholds to trigger Toxics Release Inventory reporting. See 40 C.F.R. § 372.28.) Thus EPA has the broad range of authorities in the environmental statutes available to address PBTs.

The Honorable Joe Barton

1. Please state whether the U.S. EPA was the source for recognition and inclusion of Article 3.3 in the Stockholm Convention concerning new chemicals with POPs characteristics. If not, please explain why this fact was stated in EPA's notice finalizing existing U.S. PBT policy.

As of the date of the issuance of the final PBT policy (November 4, 1999), the negotiation of the Stockholm Convention was ongoing and thus Article 3.3 did not yet exist. As stated in the Federal Register Notice announcing the category for PBT new chemical substances:

> "... development of the TSCA new PBT chemicals policy has occurred in coordination with U.S. national, U.S./Canada binational, and international efforts to identify and control the environmental release of persistent organic pollutants (POPs). The proposed TSCA PBT category has been provided to the Criteria Expert Group (CEG) established at

the first session of the Intergovernmental Negotiating Committee (INC) for an International Legally Binding Instrument for Implementing International Action on Certain Persistent Organic Pollutants, in accordance with the mandate given by the Governing Council of the United Nations Environment Programme (UNEP) in paragraph 9 of its decision 19/13 C (http://irptc.unep.ch/pops/gcpops<INF>-</INF>e.html). The CEG is an open-ended technical working group with a mandate to present to the INC proposals for science-based criteria and a procedure for identifying additional POPs as candidates for future international action. The CEG is to incorporate criteria pertaining to persistence, bioaccumulation, toxicity and exposure in different global regions and should take into account the potential for regional and global transport, including dispersion mechanisms for the atmosphere and the hydrosphere, migratory species, and the need to reflect possible influences of marine transport and tropical climates. At its first meeting, October 26-30, 1998 in Bangkok, the CEG recommended that the INC consider developing a provision encouraging countries and regions to include in their new chemicals schemes elements relating to development and introduction of new chemical POPs. The U.S. described its proposed TSCA new chemicals program policy for the category of PBT new chemicals, and the full text of the October 5, 1998 Federal Register notice was distributed to all delegations as a Conference Room Paper. The CEG's recommendation was accepted at the second meeting of the INC (January 25-29, 1999 in Nairobi) and the INC will consider it further in its deliberations." (64 FR 60194, November 4, 1999).

2. Please state whether EPA's policy for new PBT chemicals followed a foreign policy or was the first of its kind internationally.

EPA's policy for new PBT chemicals was the first of its kind internationally, although certain other governments (e.g, Japan) also recognized PBTs as chemicals of potential concern in their domestic regulatory regimes.

3. Has the existing PBT policy been effective -- in that companies have avoided the development and submission of new chemical PBTs except in cases where the exposures and releases were carefully controlled or avoided entirely?

Through the 1999 Policy Statement on New Chemicals Category for PBTs, EPA adopted specific identification criteria and the associated process that EPA would use in evaluating new chemical substances suspected as being persistent bioaccumulators. The Policy Statement made clear to submitters of new chemical notifications under TSCA section 5 that substances meeting these criteria may need to undergo testing on "P" and "B" endpoints which, if confirmed, would be followed by appropriate toxicity testing to identify "PBT chemical

substances.'' In addition, the Policy Statement made clear that control action under TSCA section 5(e) may be needed in varying degrees, based upon the level of risk concern.

Because EPA is not privy to company business decisions regarding which new chemical substances should be developed, it is not possible for EPA to comment on whether companies have avoided the development and submission of new chemical PBTs since the issuance of this policy statement. During the period from FY01 - FY08, EPA received approximately 290 Pre-Manufacture Notices (PMNs) or Significant New Use Notices (SNUNs) and 370 Low Volume Exemption notifications (LVEs) that were identified by the Agency as "potential" PBTs. There does not appear to be a strong trend over this time period. During its review of "potential" PBT notifications, EPA carefully assesses the chemical substance to ensure that exposures and releases are carefully controlled or avoided entirely. EPA will, if necessary, deny an LVE and/or require binding controls on releases and exposures. For PMNs, EPA will, if necessary, regulate the substance through TSCA section 5(e) Consent Orders/Significant New Use Rules (SNURs), non-5(e) SNURs, or will ban the manufacture of the substance pending the development of upfront testing needed by EPA to conduct a reasoned evaluation of the effects of the substance.

4. On Thursday, February 4, 2010, U.S. EPA deleted its web pages specifically designed to address PBT issues. Apparently, the Agency did this to archive materials that were as old as 2002. However, the "archive" contains materials newer than 2002. Please explain why those materials newer than the archive guidelines were archived and what criteria were used in determining which materials to archive.

We archived the site because the program had been superseded by the enhanced existing chemicals program. However, there are links to active efforts including the PBT Profiler, the Toxics Release Inventory program, and some activities ongoing in EPA's Region 5.

5. EPA's web page states "The PBT program is no longer active." Please explain this statement and whether it means EPA no longer supports its new chemicals PBT policy.

EPA continues to implement its new chemicals policy for PBTs. The PBT program referenced on the EPA website addressed existing chemicals and has been superseded by the enhanced existing chemicals program. This program was and is unrelated to EPA's New Chemicals policy for PBTs.

6. Other than taking down the PBT website, please describe what actions the Obama Administration has taken to demonstrate its support for the Sustainable Futures effort. Please describe what improvements, if any, have occurred on your watch.

The Sustainable Futures Program has been strengthened and enhanced during the Obama Administration. Under Sustainable Futures, EPA offers industry and other stakeholders' powerful computerized methods for the evaluation of chemicals. EPA delivers these tools together with training, technical assistance and regulatory incentives for qualifying New Chemicals developed using the Sustainable Futures tools. In December 2009, EPA launched the Analog Identification Methodology (AIM), a web-based tool to facilitate hazard assessment, promote risk reduction, facilitate informed substitution, foster pollution prevention outcomes, and advance the state-of-the-art in chemical risk assessment. AIM is available at http://aim.epa.gov. AIM has been well received by stakeholders, with over 6,700 AIM assessments conducted in the first four months of public release.

7. Work on implementing the Stockholm POPs Convention has progressed since the Convention entered into force. Despite EPA Administrator Whitman, in May 2001, making the United States a signatory to this Convention by signing the agreement, the United States Senate has not ratified the agreement, and Congress has not approved the necessary statutory changes to TSCA and FIFRA required to fully implement the treaty obligations.

a. Please describe the U.S. government's experience with implementation of the Convention since it entered into force.

The Parties have been actively implementing the Convention, including adding nine POPs to the Treaty last year. While the United States has been able to provide technical assistance and capacity-building to help other countries implement their obligations, as a non-party, we are unable to participate fully in the political or technical aspects of the proceedings as the agreement evolves over time and additional chemicals are added to its scope. Had the United States been a Party, we would have been afforded the opportunity to participate in the decisions to add the nine additional substances. The United States may have also had the opportunity to play a leadership role in determining the direction of these and other decisions taken by the members of the Convention.

b. Please state whether the new chemical listing process has proceeded as the United States anticipated under the treaty as negotiated.

Yes, the listing process has proceeded as anticipated. As stated above, as a non-party, we are unable to participate fully in the political or technical aspects of the proceedings as the agreement evolves over time and additional chemicals are added to its scope. Had the United States been a Party, we would have been afforded the opportunity to participate in the decisions to add the nine additional substances. The United States may have also had the

opportunity to play a leadership role in determining the direction of these and other decisions taken by the members of the Convention.

c. Please state whether the treaty as implemented has changed in any respect from the treaty as negotiated by the United States.

The treaty has been amended to include a new Annex G on Arbitration and Conciliation Procedures for Settlement of Disputes, and to include nine new POPs in the Convention. These chemicals are Pentachlorobenzene, C-Octabromobiphenyl ether components, C-Pentabromobiphenyl ether components, Alpha HCH, Beta HCH, Gamma HCH, Chlordecone, Hexabromobiphenyl, and PFOS.

8. EPA established a PMN policy with respect to new PBT chemicals in 1999.

a. Please explain the Agency's experience implementing that policy.

Through the 1999 Policy Statement on New Chemicals Category for PBTs, EPA adopted specific identification criteria and the associated process that EPA would use in evaluating new chemical substances suspected as being persistent bioaccumulators. The Policy Statement made clear to submitters of new chemical notifications under TSCA section 5 that substances meeting these criteria may need to undergo testing on "P" and "B" endpoints which, if confirmed, would be followed by appropriate toxicity testing to identify "PBT chemical substances." In addition, the Policy Statement made clear that control action under TSCA section 5(e) may be needed in varying degrees, based upon the level of risk concern.

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During the period from FY01 - FY08, EPA received approximately 291 Pre-Manufacture Notices (PMNs) or Significant New Use Notices (SNUNs) and 369 Low Volume Exemption notifications (LVEs) that were identified by the Agency as "potential" PBTs. All of these were regulated/restricted by EPA in some fashion or were withdrawn by the submitter during the review period. LVEs that were not withdrawn were either denied by EPA or were bound to the terms of the exemption notice (i.e., strict control on releases and exposures). All of the PMNs/SNUNs that were not withdrawn were regulated with 5(e) Consent Orders/SNURS, non-5(e) Consent Orders, or were banned pending upfront testing.

Of the section 5 notices submitted between FY01 thru FY08, we identified the chemicals in 369 Low Volume Exemptions and 291 PMNs/SNUNs as potential PBTs.

b. Please state the number of new PBT substances that have been introduced into commerce since 1999.

The Agency did not begin tracking PBTs in the new chemicals program until Fiscal Year 2001. Starting in Fiscal Year 2001, about 6% of all new chemical notices have been determined to be PBTs, for a total of 680 through 2008. There does not seem to be a discernible trend that we can identify, but the range is from a low of 56 in 2008 to a high of 109 in 2002.

c. Please describe the risk management measures, if any, the Agency required for those substances.

In our new chemicals program, it is our policy to ban Pre-Manufacture Notice chemicals that have a persistence >6 months and bioaccumulation >5000 pending upfront testing, and, for chemicals with persistence >2 months and bioaccumulation >1000, to regulate under a TSCA section 5(e) order to control exposures and releases, and to require testing.

Based on section 5 notices, between FY01 thru FY08 we identified the chemicals in 369 LVEs and 291 PMNs/SNUNs as potential PBTs. All of these were regulated/restricted by EPA in some fashion or were withdrawn by the submitter during the review period. LVEs that were not withdrawn were either denied by EPA or were bound to the terms of the exemption notice (i.e., strict control on releases and exposures). The PMNs/SNUNs that were not withdrawn were regulated with 5(e) Consent Orders/SNURS, non-5(e) Consent Orders, or were banned pending upfront testing.

d. Please state whether the PMN policies have been effective in minimizing or eliminating risks to human health or the environment, and if so, how.

EPA believes the implementation of the 1999 Policy Statement on New Chemicals Category for PBTs has led to the identification and risk management of PBT chemicals within the New Chemicals program. Through the Policy Statement, EPA adopted specific identification criteria and the associated process that EPA would use in evaluating new chemical substances suspected as being persistent bioaccumulators. The Policy Statement made clear to submitters of new chemical notifications under TSCA section 5 that substances meeting these criteria may need to undergo testing on "P" and "B" endpoints which, if confirmed, would be followed by appropriate toxicity testing to identify "PBT chemical substances." In addition, the Policy Statement made clear that control action under TSCA section 5(e) may be needed in varying degrees, based upon the level of risk concern.

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9. Please describe any steps the Agency is taking to address the findings of the 2008 Society of Environmental Toxicology and Chemistry's Pellston Workshop on PBT characteristics. Please also describe how the Agency is incorporating the developing science and better identifying PBT substances identified by that Pellston workshop, the goal of which was to improve the process of identification and evaluation of chemicals against the PBT criteria.

The Pellston Workshop are Society of Environmental Toxicology and Chemistry (SETAC) sponsored meetings whose purpose is to evaluate current and prospective environmental issues. At the 2008 Pellston Workshop, the principal objective was to develop consensus guidance on how to evaluate chemicals using scientific information such as experimental data, monitoring data, and computer models to determine if they fulfill PBT criteria (Kleèka et al., *IEA&M* 2009, 5:535-538). The workshop results have been presented in a series of technical papers in the October 2009 issue of the journal *Integrated Environmental Assessment and Management* (IEA&M).

Efforts to improve our program in this area include employing a dedicated team of senior scientists to perform predictive calculations for industrial chemicals; updating our bioaccumulation model to include an absorption, distribution, metabolism and excretion (ADME) component which predicts the metabolism of chemicals; and incorporating environmental compartment-specific half-lives into the evaluation of chemical persistence.

10. Please describe the impact of EPA's New Chemicals PBT Policy on the number of new PBT chemicals. Of the new PBT chemicals of which EPA has been notified, please state the general trend for release of these chemicals into the environment?

EPA did not begin tracking PBTs in its new chemicals program until Fiscal Year 2001. Starting in FY2001, about 6% of all new chemical notices have been determined to be PBTs, for a total of 680 through 2008. There does not seem to be a discernible trend that we can identify, but the range is from a low of 56 in 2008 to a high of 109 in 2002. Based on section 5 notices, between FY01 thru FY08 we identified the chemicals in 369 LVEs and 291 PMNs/SNUNs as potential PBTs. All of these were regulated/restricted by EPA in some fashion or were withdrawn by the

submitter during the review period. LVEs that were not withdrawn were either denied by EPA or were bound to the terms of the exemption notice (i.e., strict control on releases and exposures). The PMNs/SNUNs that were not withdrawn were regulated with 5(e) Consent Orders/SNURS, non-5(e) Consent Orders, or were banned pending upfront testing.

11. Your testimony references EPA's PBT Profiler tool, which I have been told was designed largely for industry's use in designing safer/greener new chemicals. Please generally identify the primary users of this tool and describe the benefits derived from that use.

The PBT Profiler was designed to be used by public stakeholders with a wide variety of technical skills and expertise and was jointly developed by industry, Environmental Defense, and EPA. It was released to the public in 2002.

The PBT Profiler interprets the results for non scientists so that a broader array of stakeholders can assess PBT characteristics. The user base of the PBT Profiler is wide and diverse. The methodology is used by industry, the public, NGOs, academic and research institutions, State environmental agencies, and other parts of the U.S. Federal Government, among others. Stakeholders have conducted over 200,000 chemical specific PBT screening studies using the PBT Profiler.

The PBT Profiler offers users many benefits. The tool can be used to estimate PBT characteristics for new chemicals and can be used to compare and contrast existing chemicals for PBT characteristics. This can help drive informed chemical substitution and identify pollution prevention and risk reduction opportunities. As examples, Bayer Chemical Company used the PBT Profiler to compare and contrast alternatives at research and development phase for a new chemical. The Dutch Government used the Profiler to evaluate 50 chemicals detected in harbor sediments. The Federal Aviation Administration used the Profiler to evaluate safety of chemicals used in aircraft components. SC Johnson evaluated chemicals in their supply chain for PBT characteristics. FMC Corporation evaluated 50 chemicals for PBT traits.

12. In responding to a question from Representative Whitfield on the difference in legal standards between TSCA chemicals and FIFRA pesticides, you mentioned the pesticide standard of "reasonable certainty of no harm". Please state whether there are distinct differences between routes of exposure for pesticides, governed under FIFRA, versus other chemicals which could be subject to TSCA.

Yes, "reasonable certainty of no harm" is the standard for issuing pesticides tolerances from the Food Quality Protection Act and the "no significant adverse effects" language is from TSCA. The potential routes of exposure assessed under FIFRA and TSCA are the same; dermal, inhalation,

ingestion (humans), and environmental; it is the context in which those exposures occur that may differ.

Under FIFRA, exposure scenarios are evaluated for all uses of pesticides, such as agricultural applications, home and garden (consumer or certified applicator) applications, and institutional and industrial applications. For example, application of a pesticide/herbicide to a field crop can potentially result in dermal and inhalation exposure to the farmer/applicator and bystander; in run-off to streams and wells with subsequent drinking water (ingestion) exposure to the general population as well as environmental exposure to terrestrial and aquatic organisms; and in ingestion or dietary exposure to the general population from consumption of food. As another example, indoor insecticides are assessed for potential dermal and inhalation exposures to applicators/consumers.

Under TSCA, exposure scenarios for industrial chemicals can include dermal and inhalation exposures to industrial workers during manufacturing and processing, inhalation exposures to the general population due to the volatility of the compound or during incineration of wastes, drinking water (ingestion) exposure to the general population as well as environmental exposures to aquatic organisms from releases to water during manufacturing, processing or use, and dermal and/or inhalation exposures to consumers if the chemical is incorporated into a product (powder, liquid, or article).

RESPONSE TO U.S. COMMITTEE ON ENERGY & COMMERCE,
TSCA & PBT CHEMICALS HEARING ON 3/4/10
By: Ted Sturdevant, Director
WA State Department of Ecology

The Honorable Bobby L. Rush:

1. Mr. Sturdevant, you emphasized the need to transition towards safer alternatives where PBTs are currently used in commerce. To determine safety, we need information on a chemical's toxicity. Currently, EPA is limited in its ability to get this information. Mr. Sturdevant, given the current limitations of TSCA, how can we know if there are safer alternatives for current uses of PBTs?

Your query raises two fundamental questions:

1. How do we determine how safe a particular chemical is?
2. How do we compare chemicals to determine which ones are safer than others?

I'll speak to the second question first. There are a number of tools currently available to determine the relative safety of various chemicals. As in other states, we in Washington State have worked with the creators of a tool called GreenScreen to develop an effective, consistent tool for this very purpose. There are other tools as well, including EPA's Design for Environment Program. However, we would be well served by a consistent, effective approach to making this determination. We're getting there, but more work is needed.

The bad news, as your question points out, is that there is no effective mechanism to ensure that chemical data is available so that we can perform these analyses. Instead, we are forced to hunt around the world for study results on a particular chemical, investigate the studies to ensure they are valid, and hope they provide the data needed for accurate comparison to alternative chemicals. Even when such data exists, it is often classified as confidential business information, and unavailable.

The Washington State Department of Ecology was faced with this question two years ago when we sought to determine whether safer alternatives were available for PBDE flame retardants in computers, televisions and upholstered furniture. Using publically available data, information from Europe, and a variety of studies on toxicity of the identified alternatives, we were able to identify at least one safer alternative for each of these product types. This was an arduous and lengthy process, leading to three additional years of deca-BDE use in consumer products while we waited for sufficient data so that we could make a valid comparison. Even this process would not be possible for every chemical and product we wish to investigate, because the data doesn't exist or is confidential.

The fact that the public should be forced to endure ongoing toxic exposures because manufacturers are not required to ascertain and share safety data reflects the imbalance of the current system. To answer your question directly — *"How can we know if there are safer alternatives for current uses of PBTs?"*— the answer, unfortunately, is that we have to get lucky and be able to find sufficient data on a chemical and its alternatives to determine which is safer. This is why TSCA reform should require manufacturers to provide adequate toxicity information to regulators - both to demonstrate their products are safe before they enter the market, and to enable us to find safer alternatives. But until we have the data and the consistent means for comparison, we can and should operate on the assumption that PBTs are worse than non-PBTs, and act accordingly.

Ted Sturdevant, Director
Washington State Department of Ecology
Response to U.S. Committee on Energy & Commerce,
TSCA & PBT Chemicals Hearing on 3/4/10

The Honorable Joe Barton:

1. Your testimony references the state of Washington ban on certain flame retardant chemicals known as PBDEs. Please state whether this ban permits the use of PBDEs in any capacity under Washington State law. If yes, please explain how you reconcile the permissible use of PBDEs with your statement that these chemicals are the "worst of the worst."

Washington State's ban on PBDEs targeted the largest uses of these chemical flame retardants. For two PBDE formulations, penta-BDE and octa-BDE, all uses were banned, with exemptions provided for transportation vehicles and equipment, military and aviation uses, medical devices, and sale of used products. For the deca-BDE form, the ban applies only to mattresses, televisions, computers, and residential upholstered furniture after it was shown that safer alternatives were available for these uses.

In determining what should and should not be banned, the Washington State Legislature weighed risk against the availability of safer alternatives, and against the negative effects of a ban. Based on that analysis, the legislature crafted a reasoned, but protective ban.

Banning a chemical is a serious undertaking and should not be done lightly. It requires a careful analysis and balancing of the threats posed by its use, as well as the benefits. We do not maintain that every use of every PBT should be banned tomorrow. This would be irresponsible. Likewise, given the particular threats posed by PBTs, it is irresponsible not to move away from them as quickly as is reasonably possible. If a safer alternative exists for a particular use of a PBT, it makes sense to ban the PBT and switch to the safer alternative. If no safer alternative exists, and the particular use of a PBT poses a danger to the public *and* is used in a non-essential or unimportant way, then it makes sense to ban that use. Admittedly, defining "potential danger" and "non-essential or unimportant" demand policy decisions, but we should not shy away from making those decisions. In all cases, I believe that we should err on the side of protecting human health and the environment, particularly those most vulnerable, such as fetuses, infants, and children.

2. This Committee has repeatedly heard testimony that making preventative decisions based upon incomplete or unverifiable science has dramatic impacts on people's lives. You supported a precautionary approach to regulation in your testimony. Please state whether you support a precautionary approach even when regulation is based upon a scientific study that is not supported by valid science, the measurements of the substances in the study are not authentic or sufficiently precise for their intended use, the conditions of the scientific study are not well controlled, and the results cannot be replicated by other scientists.

No, I do not support making decisions based on bad science. Good science is clearly the foundation of good chemical policy. I do advocate a precautionary approach, but one that is informed by good science and common sense. In the debate over chemicals policy, the word "precautionary" often is misinterpreted to mean that maximum safety is the only consideration that should be used to inform decision making. When crossing a busy street, it is precautionary to wait for the traffic light, look both ways, and proceed with caution. It doesn't mean you shouldn't leave home in the morning.

So it is with chemicals policy. Given the well established ability of chemicals to travel and persist, it defies common sense to assert a policy that does not have precaution as a core element. But sound science is also a necessary element, and the two are not mutually exclusive. There is rarely such a thing as "scientific certainty," nor can we often prove the absolute absence of risk. To allow this to prevent us from exercising common sense in making policy decisions is wrong. I further believe that if we are to tilt one way or another – toward protecting people from harm, or toward protecting manufacturers from making changes – I think the precautious choice is clearly the right one.

3. You suggested we should eliminate the use of PBTs by forcing the use of alternative substances that can perform the same tasks in a safer manner. Ms. Greer testified that PCBs were once thought to be nonthreatening based on the science of that time. Please state when you consider a chemical, e.g., a substitute for a PBT, to have been studied enough to assure the public it is safe. Please also state on what you base your conclusion.

There is a big difference between "safe" and "safer." Determining the relative safety of two different chemicals is something we can do, if we have access to data on those chemicals. Establishing that something is safe, or 100 percent free of risk, is not something we can do. To use a cliché, it is said that: "One can drown in a tablespoon of water." Is water "safe?"

Concerns over the safety of PCBs began to appear in the 1930s. As those concerns grew, if a valid scientific comparison had determined an alternative to be safer than PCBs, then I believe it would have been responsible to force the use of the alternative at any point. Had we done so, rather than waiting 40 years for the growing weight of the data to force a ban, Washington State taxpayers would be saving millions of dollars each year that we otherwise spend on ongoing PCB cleanup.

4. You testified, "State-by-state, chemical-by-chemical approaches are not efficient or effective ways to address PBTs, which do not respect jurisdictional boundaries." Yet, your state was aggressive in opposing POPs implementing legislation in the 109th Congress because you argued that state sovereignty was more important than an overall federal structure and having our Executive Branch set treaty policy was of lesser importance. Please explain why you now think state environmental legislation is no longer preferable to federal environmental laws.

Washington State supports development of a strong federal system to regulate chemicals; however, we believe such a system should be the "floor," and not the "ceiling." States need to be able to build from this foundation and protect their citizens as needed. The advances made by many states in preventing toxic exposures would not have been possible had TSCA contained a blanket preemption on such activities for the past 30 years. A patchwork of state approaches is preferable to a *weak* federal system. But a *strong* federal system is preferable to a patchwork approach.

Ted Sturdevant, Director
Washington State Department of Ecology
Response to U.S. Committee on Energy & Commerce,
TSCA & PBT Chemicals Hearing on 3/4/10

Individual states find it challenging to drive changes in the supply chain through legislation in just one state, and our capacity to fund the research and assume the political fights is limited. Likewise, manufacturers find it challenging to design different products for different states. If stronger protections were afforded across the nation, states would not be compelled to take individual action nearly as often as we do. But even under a strong federal system, the states will and should continue to innovate in order to fill in gaps in protection as they are needed. It should not be a question of state environmental laws or federal environmental laws – we need both, and we need both to work.

Regarding POPs legislation, HR 4591 contained such broad preemption language that we believed it would significantly limit Washington State's ability to protect the public from the POPs Treaty chemicals. It would have removed the ability for any state to take any action on a treaty chemical beyond the restrictions adopted by EPA, with the exception of a complete ban or a restriction adopted under the Clean Air Act or another federal law. We argued against this restriction because we believe that it is vital to preserve the ability for states to fill in gaps in federal protections.

5. You testified that we should ban PBTs and establish a system for finding safer alternatives.
a. Please state whether you support a ban on the use of PBTs in products important to the country's needs.
b. Please state whether you support a ban on the use of PBTs even if suitable alternative cannot be found.
c. Please state whether you support a ban on the use of PBTs even if the alternative is unproven as a suitable substitute, its hazard and exposure data unsupported by the science, and its use is unavailable to the marketplace for years.

Any ban should carefully consider a number of factors including whether or not a safer alternative is available, the magnitude of the risk posed by the chemical, as well as the necessity of the product in question. Washington State's ban of PBDEs is a good example of this type of assessment. Decisions should be based on the best available scientific data and consideration of the factors mentioned above.

As for banning PBTs before a safer alternative is available, it depends on the necessity of the particular use. If using that chemical is the only way to flame retard an airplane escape ramp, a ban probably doesn't make sense. But if it is the only way to ensure that a blinking light goes on in a child's tennis shoe when he walks, a ban might make good sense – even if no alternative exists.

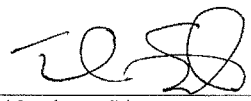
6. Your testimony includes a resolution from Washington and 12 other state environmental programs in support of certain principles for chemicals management reform, representing just 26 percent (about one in four) of all states.
a. Please state whether you sent the resolution to all 50 states.
b. Please provide the names of those states, if any, that declined to sign the resolution.

Ted Sturdevant, Director
Washington State Department of Ecology
Response to U.S. Committee on Energy & Commerce,
TSCA & PBT Chemicals Hearing on 3/4/10

The resolution was based on similar efforts by the U.S. EPA and the National Conference of State Legislators to articulate principles for TSCA reform. Several states with existing chemicals policy reform efforts were interested in collaborating to avoid duplication of effort at the federal level. Our common experience in strengthening protections in our respective states left us with a shared understanding of the inadequacy of protection under TSCA.

Fifteen states were invited to join as they were known to us to be active in Green Chemistry and chemicals policy reform efforts through executive orders, consumer product bans, chemicals policy reform statutes and interstate collaboration on safer chemicals. Minnesota and Virginia did not respond to the invitation.

After the resolution was signed by 13 states, the resolution was disseminated by the Environmental Council of the States (ECOS) to all 50 states. Additional states were not asked to sign the resolution.



Ted Sturdevant, Director
WA State Department of Ecology

Submitted: April 9, 2010

April 9, 2010

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

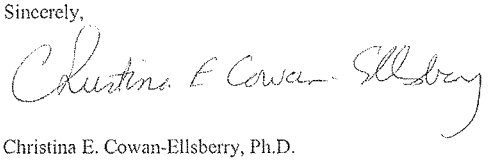
Dear Chairman Waxman;

Thank you for the opportunity to appear before the Subcommittee on Commerce, Trade and Consumer Protection on March 4, 2010 at the hearing entitled "TSCA and Persistent, Bioaccumulative and Toxic Chemicals: Examining Domestic and International Actions."

I appreciated the opportunity as a private citizen and technical expert to contribute to Congress's discussions on this very important topic. As a consumer and citizen of the United States, I am as concerned as you are about chemicals that may be in commerce and that could cause adverse impacts on me, my family and the environment. Furthermore since I have worked on the development of the PBT criteria and the methods for identifying and evaluating the safety of PBTs in several national and international fora within the US, Canada, Europe and the United Nations, I appreciated the opportunity to provide to this committee the history and scientific progress that has been made of the PBT screening and assessment process.

If you, Representative Rush, or Representative Barton, would have any additional questions or seek clarification on any of my responses, you can contact me.

Sincerely,



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The Honorable Bobby L. Rush

1. Dr. Cowan-Ellsberry, you noted in your testimony that an effective PBT program "will encourage technical innovation of new chemicals and products" that will improve lives and benefit our citizens. This is a laudable goal. No one wants an effective PBT program to be detrimental to innovation. How do we get there?

The key components to an effective PBT program that will encourage technical innovation of new chemicals and products will include

- Transparency in the data and the process used to determine if the chemical meets the criteria and definition of a PBT. This transparency is illustrated by the development and public distribution of the PBT Profiler that can be used to determine, for many, but not all chemicals, an initial estimate of a chemical's PBT properties.
- Adoption of a risk-based review process that considers the use and exposure pattern for a given PBT rather than making a decision based solely on the hazard characteristics of the substance.
- Public comment process that encourages the involvement of scientists in industry, academia and environmental groups who have data and information that can be used to inform any PBT evaluation of a specific chemical.
- Incorporation of the most current science and scientific understanding in assessments
- Management actions that include reasonable timeframes and evaluation of any "replacements" to demonstrate that their risk profile is an improvement.

The Honorable Joe Barton

1. You state: "based on the vetting and discussion there is now international consensus that the UN Stockholm Convention and the Canadian TSMP criteria are scientifically-based and appropriate because these criteria are now incorporated into many national PBT regulatory programs". Are you referring to Annex D, E, and F of the Stockholm Convention, related to the POPROC? If so, please explain the importance of having these tools when setting chemicals policy? Is the U.S. TSCA's program more mature and nimble than others in this regulatory universe?

As background to this question, Annex D of the Stockholm Convention contains criteria for screening chemicals for Persistence, P, and Bioaccumulative, B, properties, Potential for Long-range Environmental Transport and Adverse Effects. Annex E contains a list of the additional information that can be used to prepare the Risk Profile which further elaborates on and evaluates the Annex E information and in addition, specifically evaluates if the chemical, as a result of its long-range transport, leads to significant adverse human and/or environmental effects, such that global action is warranted. Annex F contains a list of the relevant information relating to socio-economic considerations that are associated with each

possible control measure. The Canadian Toxic Substance Management Policy (TSMP) contains criteria for screening chemicals for P and B properties. As I state in my testimony and illustrate in Table 1, there is agreement on the B criteria between these two conventions and substantial agreement on the P criteria. Furthermore, the criteria used by US EPA for their new chemical evaluation are in agreement with these criteria. The three distinctive step process outlined in Stockholm Conventions Annexes D, E and F, should be included in any PBT program under TSCA.

EPA's actions in the 1990's to incorporate PBT screening into PMN assessments and how they've embedded PBT evaluations into the choice of substances to regulate in the RCRA and TRI programs plus the EPA's very rapid actions on perfluoro-chemicals (e.g., PFOS), which were followed and adopted globally, demonstrates that EPA was definitely on the forefront of PBT screening and management and when necessary EPA can take action. What is needed to ensure an effective TSCA modernization program for PBT chemicals and to ensure continuing effective actions by EPA is to specifically include a thorough priority setting for chemicals in active commerce.

2. You state that the "process [to identify PBT substances and conduct risk-assessments] can be scientifically challenging". Is this arduousness necessary? In your opinion, would a slimmed down assessment process present any real advantages from a scientific standpoint? Is there is a specific amount of time that is required for good science to occur?

Although this process can be scientifically challenging, it does not need to be unduly arduous or take an unlimited amount of time. Rather it is more important that resources and commitment is made by all parties to reach the final determination. When a chemical is in commerce it is providing a recognizable benefit to society. While screening and priority setting for chemicals can and should happen in a reasonably rapid timeframe, unless there is an imminent risk, no specific timeframe should be designated for coming to the final conclusion that the chemical is a PBT and for instituting management programs, if needed. Instead emphasis should be placed on considering all data and the full weight of evidence as well as the benefit to society to ensure that any final conclusion and management decisions do not result in an unnecessary burden on society. Thus, the most important part of this process is to ensure that the most appropriate and current information and understanding is used to make this determination and to allow sufficient time for addressing questions, developing new data and information as appropriate, ensuring that there is confidence in the weight of the evidence and in the final determination

3. Are you concerned that incomplete assessments or hurried decisions based upon incomplete science will have negative effects or consequences?

a. Why do you consider the "strict pass or fail" criteria that exists for PBTs, like in Europe, to be problematic beyond initial screening of substance characteristics? Please explain how the regulatory criteria/framework does not allow for consideration of the evolved state of the science? Should we be concerned about changes to TSCA that would use this kind of effort?

As mentioned in the response to the previous question, when a chemical is in commerce it is providing a recognized benefit to society so it is not to the benefit of society to make a hasty decision based on

limited information. Unless there is convincing evidence that these chemicals in commerce pose an imminent and present threat and that suitable and safer replacements exist, allowing time for a thorough evaluation before taking any action is to the benefit of society. For example, moving immediately toward management of a chemical based on whether it meets a set of "strict pass or fail" criteria would not allow for evaluation of the full weight of evidence. In fact, a regulatory criteria/framework that does not allow for consideration of advances in the state-of-the-science and understanding will inherently lead to decisions that in my opinion could later be determined to be inappropriate. Thus, any revision to TSCA that will include explicit evaluation and management of PBTs needs to ensure that there is sufficient flexibility and time in the final PBT determination to allow for the consideration of the evolved state of the science in the weight of the evidence.

4. Last week, Dr. Christopher Borgert testified before another one of our subcommittees his concerns with the four pillars of science. He said that they were: measurability, reproducibility, relevance, and reliability. You mention: "the modernization of TSCA should be flexible to incorporate new, validated methods that use advance state-of-the-science methods. Do you agree with Dr. Borgert? How does this comport with the overall general PBT discussion?

When evaluating whether new methods and their results should be included in a specific PBT assessment, I agree with Dr. Borgert that these same four pillars of science should be considered and used to inform the incorporation of these advanced methods in these assessments. This approach also agrees with the recommendations from the Pellston workshop.

5. Please identify what you consider to be the weaknesses in the Canadian and European methods for characterizing and regulating PBTs, and whether there exists a potential negative impact due to these weaknesses.

My biggest concern with both of these programs is that they appear in their early stages of implementation, to not allow for incorporation of the newly developed and advanced methods of evaluation and additional data beyond those directly addressing whether the substance strictly meets the P or B or T criteria. For example, the basis for the scientific concern represented by the bioaccumulation criteria is whether a substance increases in concentration in organisms higher in the food chain. But Canada and Europe do not use information on the fate of a chemical in a food chain to inform the bioaccumulation assessment because the focus of the current approach is only on whether the substance meets the Bionconcentration Factor criteria. As previously stated, a hasty decision that a chemical is a PBT and instituting management without evaluating the full weight of evidence could result in a negative impact on society that could have been avoided.

Secondly, within the Canadian and European PBT regulations, the PB&T criteria are decoupled resulting in substances that meet only one or two of the criteria being prioritized for action. Because these programs fail to evaluate the PBT characteristics in total including a risk-based assessment followed by a cost-benefit analysis, this results in longer lists of chemicals on which action is taken, dilutes the focus from the highest priority substances and promotes hasty action. The TSCA reform should maintain an emphasis on those chemicals that meet all three of the criteria and on a thorough assessment.

6. You testified it is "not possible to predict the final number of PBT substances currently in commerce nationally and internationally". Please explain your statement. Please also explain how you conclude that the number of PBTs in the environment to "appear[s] to be less than 100".

First, it is important to recognize that there is no international consensus on the exact number of chemicals in commerce; this is part of the reason that it is not possible to predict the final number of PBT substances. Never-the-less, evaluations of large numbers of chemicals using similar screening criteria (see Table 1 of my testimony) have all resulted in less than 100 chemicals tentatively identified as PBTs. For example, the Canadian program for evaluating the 23,000 Domestic Substance List (DSL) chemicals for PBT chemicals identified only 77 high priority PBT chemicals. Similarly, the EU PBT evaluation of their 2683 high production volume chemicals resulted in identification of 24 PBT chemicals. The number of chemicals brought forward to the Stockholm Convention for global management is also much less than 100. Furthermore, many of these identified PBT chemicals do not appear to be currently in commerce, are waste products, or are used as site-limited intermediates. With the implementation of PBT screening into the evaluation of New Chemical substances, it is highly unlikely that new PBT chemicals will enter into commerce. Thus, while we won't know exactly how many chemicals actively produced and released to the environment in the U.S. will end up being prioritized for assessment, all these pieces of data support my conclusion that the number of PBT chemicals appears to be less than 100.

While a recent publication (Howard and Muir 2010) based on model predictions and expert judgment evaluations has been reported to conclude that there are hundreds of P&B chemicals in active commerce, a review of the basis for these reports suggests that this is not an appropriate representation of their work. For example, the authors clearly state that they were "flexible with the definition of P&B chemicals rather than ... using guidelines or threshold values". Thus, they did not use the internationally recognized criteria as the basis for their evaluations. In fact, it is unclear in several cases exactly what criteria were used making it difficult to determine how many of these chemicals have real PBT concerns. Also, over 60% of the chemicals identified using these flexible definitions were not reported in the most recent (2006) Inventory Update, indicating that they may not be in active commerce. Furthermore, they call for further study of these chemicals to determine if they are present in the environment especially in organisms in concentrations that could cause concern to determine if these "potential P&B chemicals" truly meet the criteria and concerns of the regulatory PBT programs. Although I do not believe it is appropriate to use this preliminary screening evaluation to draw a conclusion on the number of P&B chemicals in commerce, this publication demonstrates the valuable role of scientists in calling their colleagues to conduct the necessary research to identify those chemicals in commerce that are released to the environment and could cause adverse effects, thus would be of concern. This type of work needs to be supported so that confidence can be increased that the highest priority chemicals of concern have been identified and assessed.

7. You testified we should have a "stronger Federal PBT program to build confidence so that States do not have to take separate and potentially conflicting actions." Please describe what you mean by a "stronger Federal PBT program" and whether tougher regulation alone is sufficient for a stronger Federal program.

A strong Federal PBT program would include 1) a Congressionally mandated TSCA priority setting, assessment and where necessary, management program for PBT chemicals, 2) strong technical expertise in screening and evaluation of PBT chemicals in EPA at the Federal level, 3) development and promulgation of improved methods for identification and assessments, 4) training and assistance of state representatives, and 5) national coordination of PBT chemical assessments and management actions.

8. The Pellston workshop argues that the appearance of a PBT in the environment is not enough to warrant regulation, but rather, body or tissue residues showing a direct causal link to adverse responses are necessary to garner regulatory management.

a. Please state whether you agree with that conclusion.

b. Please state whether you believe body burden studies and the mere presence of a chemical in the body demonstrate a need for regulation, or whether they merely give us useful information on exposure.

It is recognized in the scientific community that a chemical, whether it is a PBT or not, cannot result in toxic or adverse effects on organisms unless it is incorporated into the body or tissue of the organism. There are lots of chemicals that are not taken up by organisms due to their physical and chemical properties. Thus, the presence of the chemical in the abiotic environment, e.g., soil, sediment, water, or air, does not indicate that the chemical is or could cause a significant adverse effect such that regulatory management is warranted. It is also important to recognize that the mere presence of a chemical in the body or tissue of an organism does not mean that an adverse effect is or will occur. The determination of the possibility of adverse effect must compare this body burden or tissue concentration to those concentrations found to cause adverse effects in controlled toxicity studies with appropriate margins of safety. This is equivalent, on the human health side, to the Center for Disease Control (CDC)'s statement that just because people have a chemical in their blood or urine does not mean that it will cause disease or have any adverse health effect because the mere presence of a chemical in the body or tissue of a human isn't enough to conclude that health effects are occurring. The CDC further emphasizes that additional research is required to determine whether the observed levels of a chemical may cause health effects and which levels are not significant health concerns

9. Your testimony states that: "the U.S. EPA initially developed a list of PBT chemicals, which was reduced to 28 organic chemicals and 3 metals based on comments and new information during public comment on the methodology." In addition, you mention that the European Chemicals Bureau identified an initial list of 127 substances, which was finally reduced to 24 substances. What is the difference between the methods and the final substances selected?

The two programs are distinctly different in the program purpose, the starting list of chemicals screened, and the approach used. The US EPA list was developed under the RCRA program from a list of chemicals that could be present in wastes which included industrial chemicals, pesticides and waste products. These PBTs were identified based on a scoring method that included the properties of Persistence, Bioaccumulation and Toxicity that were informed by but were not strictly based on the PBT

criteria used in the new chemicals program. The scoring method also included some scores related to volume in waste based on TRI reporting and presence in the environment. Because of the focus on waste some of the chemicals identified on this list are waste products such as Dioxins/Furans and PAHs which are not intentionally produced chemicals. By contrast the European Chemicals Bureau program started with a list of the IUCLID HPV chemicals which are in commerce. In addition, it should be recognized that the criteria used by the European Chemicals Bureau are not the same as those used by the US EPA in their PBT screening. In fact, only those chemicals that meet the vPvB designation in the EU program could be considered to be equivalent to those meeting the P and B criteria in the US EPA's program. In both cases, public comment and additional data was brought forward to inform and improve the initial screening determinations and thus both final lists were better focused on chemicals with real PBT concerns. Because of the difference in the source list of chemicals that were initially chosen for PBT screening and the purposes of the programs, it is reasonable that there is little overlap in the final lists. Nevertheless, despite these differences in initial chemical list, purpose, criteria and method, when comparing the vPvB sublist of the ECB PBTs with the RCRA list there are 5 chemicals in common (i.e., anthracene, hexachlorobenzene, hexachlorobutadiene, gamma-hexachlorocyclohexane (Lindane) and Endosulfan).

10. You testified, "Since 1999, PBT screening has been an integral part of EPA's New Chemical PMN review under TSCA to avoid approving new PBTs." Please state whether this is a good or bad thing and explain the basis of your conclusion.

An important step to ensure that new PBT chemicals are not approved for commerce is to incorporate screening for PBT properties in the new chemical evaluation process. It was very proactive for US EPA to be one of the first countries in the world to explicitly incorporate this screening into their existing New Chemical PMN review and to do so in a transparent manner. This also reflects the leadership position that the US was taking in the 1990's in the PBT identification process. It should be noted that such screening does not automatically prevent approval of the new chemical, PMN submitters are allowed to bring forward additional information and data to demonstrate that the chemical is not a PBT.

11. U.S. EPA's existing screening efforts under TSCA's New Chemical PMN have been recognized as an extremely valuable contribution to the international community involved in PBT identification and assessments, from regulators to industry and to scientists. U.S. EPA has also been recognized internationally for its expertise in this area.

a. Please state whether you agree with the consensus statement above.

b. Please explain the basis of the international recognition referenced above.

As mentioned in the response to the previous question, the US EPA was one of the first countries to publically announce and incorporate New Chemical screening for PBT characteristics into their PMN evaluations. The US EPA also made publically available the PBT Profiler tool that could be easily and transparently used within the global community to aid in chemical screening for PBT properties. This tool was built using components of the EPISuite QSAR tools and incorporated the expertise of US EPA scientists in how to extrapolate the results of these tools to inform PBT screening. The EPISuite QSAR

tool which was developed and has been continually improved by the US EPA, has been used for decades by governments' globally in chemical evaluations. The fact that both these tools have been used to inform initial screening for the Canadian DSL PBT categorization and the EU PBT assessments demonstrates the high regard held for the US EPA expertise. Another demonstration of the high regard internationally for US EPA expertise was the leadership role that US EPA took in assessing and taking action on perfluoro-chemicals (e.g., PFOS) which lead to subsequent assessment and action within the global community.

12. You state: "Initially, in all these conventions, toxicity identification was determined by a risk based assessment called a risk profile but more recently a numeric criterion has also been incorporated in addition to the risk profile." Please clarify which Conventions employ this feature, including whether there is such numeric criteria for toxicity under the Stockholm Convention. Please state whether the risk profile from Annex D and E are the most important criteria, rather than a "toxicity criteria", because that is what is sent to the Conference of the Parties by the POPs Review Committee?

To assist in the screening of chemicals for PBT properties, in some jurisdictions such as the Canadian DSL PBT screening and the US EPA New Chemical PMN review, toxicity criteria have been developed. These criteria are used to prioritize chemicals that meet the P and B criteria by identifying those substance that are most toxic as well as meeting P and B criteria. However, as in the Stockholm Convention, the final determination of whether the substance is a PBT and is causing significant adverse effects that warrant management action is determined by the risk profile. In any revision to the TSCA regarding PBT screening and assessment, the role of toxicity criteria as well as the P and B criteria should be limited to prioritizing substances and not serve as the basis for determining if the substance warrants immediate management action. This designation must result from a risk-based assessment.

13. Does EPA's current approach have a "toxicity criteria"? What role do you think the numeric criterion has for screening vs. the risk profile?

In addition to the P and B criteria, the New Chemical Program uses "toxicity criteria" in the evaluation of PBT characteristics. A chronic (long-term) toxicity value called a Fish ChV is used to estimate a chemical's relative toxicity. The toxicity criteria chosen are < 10 mg/l for TSCA 5e Action, Significant New Use Rule (SNUR) Pending Testing and < 0.1 mg/l for TSCA 5e Action, Ban Pending Testing. Using such criteria for screening is important as it recognizes that if a chemical is not toxic (i.e., has a ChV > 10 mg/l) that it is unlikely to be causing a significant adverse effect on organisms and thus warrant regulatory action even if the P&B criteria are meet. Using toxicity criteria in addition to the P & B criteria in the screening assessment allows for prioritizing substances for further review and development of the risk profile to determine if regulatory management is needed for the chemical.

14. During the hearing, there was a discussion about the need to create a list of PBT chemicals. Please state whether it is more important to have a list of PBT chemicals for regulation or a general direction for how U.S. EPA should screen, assess, and take action, if warranted, on these substances.

In several of the international conventions, lists of globally agreed PBT chemicals have been included after years of scientific discussion and international negotiation. In TSCA modernization the critical need is to have Congress direct EPA to establish a priority chemical program that includes prioritized PBTs. Congress should defer to EPA scientists on the development of such a list as well as the development of an effective and workable program that incorporates the most current science and scientific understanding for screening, evaluating and developing effective risk management, if warranted, of these types of substances.

HENRY A. WAXMAN, CALIFORNIA
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March 23, 2010

Dr. William J. Adams
7760 North Boulder Drive
Lake Point, UT 84074

Dear Dr. Adams:

Thank you for appearing before the Subcommittee on Commerce, Trade, and Consumer Protection on March 4, 2010, at the hearing entitled "TSCA and Persistent, Bioaccumulative, and Toxic Chemicals: Examining Domestic and International Actions."

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.

Please provide your responses by April 9, 2010, to Earley Green, Chief Clerk, via e-mail to Earley.Green@mail.house.gov. Please contact Earley Green or Jennifer Berenholz at (202) 225-2927 if you have any questions.

Sincerely,

Henry A. Waxman
Chairman

Attachment

The Honorable Joe Barton

1. Ms. Greer testified that PBTs cannot be adequately assessed using risk assessment approaches. Please state whether you agree with this view.

I would disagree with that statement recognizing that many successful risk assessments have been performed on dioxins, furans, PCBs, hexachlorobenzene and other PBT substances that have lead to remedial decision or evaluation of exposure levels. Perhaps Ms. Greer's statement is aimed at pointing out that risk assessment methods to date have resulted in few PBT substances being removed from the market place. In that regard, I would submit that it is not the fault of the risk assessment methodology, but the manner in which the TSCA laws and regulations have been implemented.

2. Please explain how disjointed PBT policy can affect legal authorities under RCRA or other Federal environmental statutes. Please also explain how a disjointed PBT policy can effect proper recycling and disposal efforts.

EPA has long ranked recycling as more environmentally sound than disposal in its solid waste hierarchy. A disjointed PBT policy – particularly one that inappropriately classifies metals as PBTs or seeks to use a PBT classification in lieu of risk assessment approaches – can impose higher burdens on management and recycling of used materials, resulting in their diversion to hazardous waste disposal facilities. This has adverse effects of two types: less recycling means (1) greater need for new materials (and primary metals), and (2) increased reliance on costly and environmentally disfavored disposal alternatives. The consequences include not only higher costs, but a negative net environmental outcome.

3. Mr. Sturdevant testified the government should make decisions about chemical substitutions and product replacement. You testified that industry, based on hazard and risk methodologies, began to formalize an approach for selecting product substitutions in the 1960s. Please describe the lessons derived from the chemical substitution efforts of the 1960s and 1970s that make having the government in charge of these decisions a bad idea.

The development of the PBT concept in the 1960s had its origin in assessing soap and detergent products that were causing foaming on may river systems in the US. This led to the development of safer alternative by industry without intervention. Products were developed that were less toxic and more biodegradable; LAS (linear alkylbenzene sulfonate – used in may soap products) is one such product. With the discovery of both DDT and PCBs in the Great Lakes, the PBT approach was used to look for alternative products. Use of DDT was banned (government action) and Monsanto Company voluntarily stopped product of PCBs and substituted more environmentally friendly products. Back at this time, DOW Chemical Company, Union Carbide, Proctor & Gamble, Monsanto and other were all using a PBT "like" approach to assess chemical hazard and to identify product with better environmental properties. These are examples where industry has made many decisions on what product to bring to the market. At

presnt the Johnson Company, Rohm and Haas and other have internal programs that lead them in selection of "green" products. The negative side of government involvement has been that the PBT criteria are used in isolation from volume of product, product use and release rate. These factors are important in assessing whether or not a product presents risk.

4. Please explain why using "hazard-only" PBT criteria is an unscientific way to regulate PBTs. Please also explain how crucial it is to include exposure criteria in this assessment.

As indicated above, PBT criteria are often used in isolation from volume of product, and release rate. These factors are important in assessing whether or not a product presents risk. Risk result from the combination of exposure of the substance to humans or wildlife and hazard (toxicity potential). Rate of release determines potential for exposure. Substances which are produced in small volumes (<1000 lbs), even though they may be highly toxic, rarely show up a significant environmental contaminants. Additionally, not considering exposure misses the fact normal environmental processes, such as hydrolysis, photo-oxidation, transformation and sorption to particles and sediments may limit bioaccumulation and toxicity.

5. Numerous witnesses have testified before this Committee regarding the negative aspects of the REACH proposal, but you testified Europe's regime appropriately treats metals. Please explain your conclusion.

The procedures used to assess the metals under REACH were developed in cooperation with the European Commission. The metals industry began to work with the European Commission 5 years before the regulation went into effect. The copper and lead industry agreed to complete a voluntary risk assessment for all uses of all products following the spirit of the REACG regulations. The cadmium, nickel and zinc industry also performed similar risk assessments, but these were done at the request of the Commission. The information gained from these extensive risk assessments were used to help shape the REACH regulations. These 5 industries spent some $35M in collecting information on the toxicity of their respective metal substances to evaluate effects on human health, aquatic life, soil organisms and multiple wildlife species. Additionally data were gathered on water, air, soil and sediment concentrations across Europe as part of the exposure assessment. Having expanded such an enormous effort across 5-6 years, extensive data sets now exist on these metal substances and their uses. While the exposure assessment in Europe may not be appropriate for the United States, clearly the toxicological data sets are applicable and useful. The metals industries see no reason why this vast array of knowledge could not be used across regulatory jurisdictions.

6. Please explain whether, in your opinion, "hard-and-fast" PBT criteria ignore the scientific nuances of these chemicals, including how they react in the environment based upon climate, hydrology, and other factors. Please state whether you believe using "hard-and-fast" PBT criteria could result in scientifically unsupportable or

imperfect regulatory decision-making.

My comments on PBT were specifically aimed at the application of the PBT criteria to metal substances, i.e., inorganic compounds. In my following comments I explain why they are not applicable to metals and inorganic metallic substance. I realize my answer is narrowing the field to inorganic substances, but this was the focus on my testimony. "Hard and Fast" PBT criteria for metals will not work as the PBT criteria were designed for substances with a carbon base.

7. Please describe the difference between a Persistent Organic Pollutant and a chemical that is persistent, bio-accumulative, and toxic. Please explain whether this difference is important.

If you translate the words persistent organic pollutant in the strict sense then it only covers substances that have a carbon base and do not biodegrade. The term persistent organic pollutant (POP) was coined to differentiate chemicals with a carbon (C)) base from inorganic / metallic substances. Substances that are commonly listed as POPs under the POPs treaty are also PBT substances. Considering the chemicals listed as POPs under the POPS treaty there is no difference that is significant.

8. Please explain your assertion that it is both significant and problematic to use PBT criteria to identify contaminants of concern, and to introduce restrictions on commerce, transportation, and labeling based upon these criteria.

My statement in this regard was aimed at inorganic substances (non-carbon based substances such as metals). The measures of persistence and bioaccumulation that have been developed to date have been developed for organic carbon based substances. They are not appropriate descriptors of the properties of metals. While bioaccumulation factors (B) for organic substances are independent of concentration and hence, useful across a wide range of environments, the same is not true for metals (inorganic substances). Bioaccumulation factors for metals are in fact inversely related to concentration. As a consequence the metal bioaccumulation factors for the cleanest environments are larger than those for contaminated environments. As a result they predict clean environments to be a problem. This is counter intuitive. Likewise for the "P" this does not work for metals. Persistence for organic compounds is considered bad, but for metals and inorganic substances, persistence is absolutely critical. These substances must be persistence to sustain life. All elements on the periodic table are persistent. Our universe is built on this principal. Hence, my statement follows that PBT approaches should never be applied to metals and inorganic substance. This is recognized in the USEPA Metals Framework Risk Assessment document and is recognized in the European Union regulations pertaining to REACH.

If PBT criteria are use to regulate inorganic substances including metals this is indeed problematic and not in agreement with science based facts.

9. You testified "individual criteria are limited in their ability to assess hazard or to prioritize metal substances" because they are not linked or integrated. In addition, you testified that PBT criteria attempt to identify or predict hazards using certain modifiers without fully incorporating other important fate characteristics. Please explain why this is important.

My comments prior to question No. 9 were focused on metals and inorganic substances. For this question my response is applicable to both metals and inorganic substances. The P – B – T criteria are independent of each other. Thresholds are set for each of the three criteria. The substance either meets the criteria or not. The scientific community has recognized that to properly assess the risk of substances one has to assess the integration of persistence (degradation) with potential for accumulation and toxicity after environmental factors have occurred that may alter exposure. Bioaccumulation does not occur independent of exposure concentration, neither does toxicity. Hence, an integrated approach is required to have a full understanding of the potential for effects. The PBT approach comes out of the late 1960s and 1970s. We now have much better computing ability and we recognize we need to assess the bioavailability of the test substance to organisms and there is a need to integrate loss of substance from the water column (Persistence) with reduced bioaccumulation (B) and resulting potential for inherent toxicity (T). Consequently, we have developed model to integrate these three parameters in a way that mimics natural lake systems. This model is entitled the Unit World Model and is available at www.unitworldmodel.net. Details on this integrated approach can be found in a book published by the Society of Environmental Toxicology and Chemistry (SETAC).

Adams WJ, Chapman PM. 2005. *Assessing the Hazard of Metals and Inorganic Metal Substances in Aquatic and Terrestrial Systems: Summary of a SETAC Pellston Workshop. Pensacola (FL).* SETAC Press, Pensacola, FL, USA.

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