

TESTING OF CHEMICALS AND REPORTING AND
RETENTION OF INFORMATION UNDER TSCA
SECTIONS 4 AND 8

HEARING
BEFORE THE
SUBCOMMITTEE ON ENVIRONMENT AND THE
ECONOMY
OF THE
COMMITTEE ON ENERGY AND
COMMERCE
HOUSE OF REPRESENTATIVES
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TESTING OF CHEMICALS AND REPORTING AND RETENTION OF INFORMATION UNDER TSCA SECTIONS 4 AND 8

TUESDAY, FEBRUARY 4, 2014

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON ENVIRONMENT AND THE ECONOMY,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 10:03 a.m., in room 2123 of the Rayburn House Office Building, Hon. John Shimkus (chairman of the subcommittee) presiding.

Members present: Representatives Shimkus, Pitts, Murphy, Latta, Harper, McKinley, Bilirakis, Johnson, Barton, Upton (ex officio), Tonko, Green, DeGette, McNerney, Schakowsky, Barrow, Matsui, and Waxman (ex officio).

Staff present: Nick Abraham, Legislative Clerk; Gary Andres, Staff Director; Charlotte Baker, Press Secretary; Sean Bonyun, Communications Director; Jerry Couri, Senior Environmental Policy Advisor; David McCarthy, Chief Counsel, Environment and the Economy; Brandon Mooney, Professional Staff Member; Chris Sarley, Policy Coordinator, Environment and the Economy; Alison Cassady, Democratic Senior Professional Staff Member; Greg Dotson, Democratic Staff Director, Energy and the Environment; Caitlin Haberman, Democratic Policy Analyst; and Elizabeth Letter, Democratic Press Secretary.

Mr. SHIMKUS. I would like to ask the committee to come to order. I will now also recognize myself for 5 minutes for the purpose of doing an opening statement.

OPENING STATEMENT OF HON. JOHN SHIMKUS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS

Today marks our fifth hearing in this Congress on the Toxic Substances Control Act. Our focus today is on two sections in TSCA dedicated to getting EPA relevant testing data and other information on chemical substances in United States commerce. Past application of Section 4 by the EPA to obtain information about existing chemicals has been frustrated by judicial interpretation. We need to push beyond re-litigating those cases and focus on what authorities the EPA has now, or could reasonably use in the future to produce tailored, necessarily, and high-quality test data, and other information to carry out TSCA. We will also pick up on the discussion from the last hearing on standards for data quality, and the use of the best available science. The goal is credible decisions

using high quality data. Information management will be one of the toughest areas to get right, but it is also one of the most important.

I want to remind everyone that last summer former TSCA program director Charlie Auer testified before our committee that simply improving the way EPA is able to get information under Section 4 would have profound impact on improving TSCA's overall operation. Let us not kid ourselves, though; information collection and analysis on thousands of chemicals will become time consuming and very expensive. EPA will have to be smart and efficient to make this program work, especially when it comes to using available information, particularly exposure history, in deciding whether more testing is needed, and who should do the testing.

Today's hearing will also focus on reporting for the thousands of chemicals in commerce. Section 8 requires the EPA to develop and maintain an inventory of all chemicals, or categories of chemicals, that are manufactured or processed in the United States. It also gives the EPA authority to require certain businesses involved with a chemical substance to maintain records and submit health and safety information report, particularly adverse health incidences caused by the chemical to the EPA.

Within these reporting requirements, there are exemptions for polymers, microorganisms, and naturally occurring substances. We should find out if these make sense, and should be continued, and what the incremental gain, if any, in public health, resources, or protection occurs without these exemptions. We also need to focus on the definition of processor, and whether the definition is right-sized to the person's activities and information EPA is receiving.

With that, I want to welcome our witnesses and thank them for their expertise and candor. We expect them to provide a variety of perspectives on when testing should be required, and what we can do to improve testing techniques so we can speed up analysis and reduce use of animals in that testing. We look forward to their views.

And before I yield to the ranking member, I want to go off script and also thank you. I think, in our questions and response, candor is going to be important. There is a lot of excitement in trying to move a bill, and move it properly. And the other thing is, I was going back into the records, and I think 1976 is when this was authorized and put into law, and I had just graduated high school at that time, and started my first year in college. So, suffice it to say that probably a review and update of this law is timely, but we have to do it right. A lot of you all here will help us muddle through that process, and point out the good, and the bad, the ugly, and maybe, working with my colleagues, we could find areas of compromise.

[The prepared statement of Mr. Shimkus follows:]

PREPARED STATEMENT OF HON. JOHN SHIMKUS

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Past application of section 4 by EPA to obtain information about existing chemicals has been frustrated by judicial interpretation. We need to push beyond re-litigating those cases and focus on what authorities EPA has now or could reasonably

use in the future to produce tailored, necessary and high-quality test data and other information to carry out TSCA.

We'll also pick up the discussion from the last hearing on standards for data quality and the use of best available science. The goal is credible decisions using high quality data. Information management will be one of the toughest issue areas to get right, but it's also one of the most important.

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Mr. SHIMKUS. With that, I would like to yield to the ranking member of the subcommittee, Mr. Tonko, for 5 minutes.

OPENING STATEMENT OF HON. PAUL TONKO, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW YORK

Mr. TONKO. Thank you, Mr. Chair, and good morning, and thank you for holding this hearing on the Toxic Substances Control Act, or TSCA. This is the subcommittee's fifth hearing, as we have been told, on this program. The hearings have been very instructive, and are providing us with a good foundation from which to evaluate the current law, and to develop legislation to improve it. Reform of this legislation is long overdue. I hope, Mr. Chair, that we will be able to work together and find common ground in this effort, which I think is critically important.

The two sections of TSCA we are focusing on today, Section 4, on chemical testing, and Section 8, on information reporting and retention, have not provided sufficient reliable information to support assessment and regulation of chemicals. The authorities provided to EPA in these sections are weak and cumbersome to implement. As a result, there is too little information gathered on the toxicity or environmental risks associated with chemicals, and the inventory of chemicals in commerce does not provide sufficiently detailed and contemporary data on the chemicals being used in the United States. Currently, the burden is on EPA to demonstrate that information is needed, rather than on industry to provide the information to demonstrate that their product has been adequately tested, and will present little risk when used properly.

The tragic situation in Charleston, West Virginia demonstrates several failings of our chemical safety laws. Not all aspects of this incident can be blamed on the faults with TSCA, but the lack of information needed to respond to this situation illustrates the failure of this law. When the water supply for the people of Charleston, West Virginia was contaminated with chemicals that leaked from a storage tank, there was little reliable information to provide the public, emergency responders, or to the water company to guide their response actions. As a result, there was public confusion and concern about the advice offered by public officials and the water company. There was little understanding of the fate of the chemical in the water supply, or what health or environmental effects might result from the spill.

This illustrates the importance of having adequate information to inform decisions about the protection of human health and our environment. Reform of TSCA must result in better information, and clear authority for EPA to act. The agency must have sufficient information to evaluate the risks of chemicals currently on the market, and basic information should be available before we have an accident, not slapped together in the midst of a crisis.

The agency must be able to assess the risk of new chemicals before they enter into commerce. Dr. Paulson informs us, in his testimony, that a substantial portion of chemicals are known to have a wide range of adverse, and most irreversible, effects on child health. That is a prime warning. So it is important that we move forward with a law that recognizes that fact, and offers adequate protections for everyone.

I look forward to the testimony of our witnesses today, and I thank you all for being here to share your views on what is a very important topic. And, again, I thank you, Mr. Chair, and I yield back.

Mr. SHIMKUS. I thank my colleague. Now the Chair recognizes the chairman of the full committee, Mr. Upton, for 5 minutes.

OPENING STATEMENT OF HON. FRED UPTON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. UPTON. Well, thank you, Mr. Chairman. Today we are going to continue our examination of TSCA with a focus on the nuts and bolts of chemical information. For sure we want to develop a system for chemical regulation that is the gold standard for the rest of the world. It doesn't mean the most precautionary, or the most commercially free-wheeling. It means a balanced system rooted in the best science and highest-quality information so that all of us can be confident that if a chemical is in our stream of commerce, it is safe, and commerce flows freely across State lines and across borders.

The foundation of that confidence should be information, and that information must be grounded in rigorous science available for everyone to review, organized by category, and backed up by state-of-the-art testing when needed. The technology of testing has vastly advanced since 1976, and it will continue to evolve in a positive way. High power of computers will simulate and sort exposure date and analyze chemicals in batches by category so that time spent testing for biological effects, and the need to test on live organisms,

is, in fact, reduced. We have also got to make sure that we don't go overboard and become obsessed with data collection for its own sake. There are thousands of chemicals in everyday life that are understood to pose no unreasonable risk when used as intended. We need to identify those based on information that we already have. Then we can focus our resources, information, development on the ones that we aren't so sure about. It is often said that the job of the manager is to know when to stop taking data, and start making decisions. That is the challenge for EPA under a reformed TSCA.

It is also the challenge that we on the committee face as we transition from our examination of current law to developing our own ideas for how to modernize, after nearly 4 decades, this body of regulation. So I look forward to working with every one of our committee members as we set out on that path. And I have every confidence in you, Mr. Shimkus, to chart a successful course to get this job done. Really, I do. And I also appreciate the leadership of Mr. Waxman, and Mr. Tonko, and every member of this subcommittee for the hard work that they have put in.

We need to chart a path that, yes, not only will reach the House floor, but ultimately reach the President, and it needs to happen this year. All of us have stayed focused through these hearings and developed the policy expertise that will benefit each of us in our deliberations. It is hard work that attracts little publicity, but in the long run, our world is certainly going to be better for it. And I yield back.

[The prepared statement of Mr. Upton follows:]

PREPARED STATEMENT OF HON. FRED UPTON

Today we continue our examination of TSCA with a focus on the nuts and bolts of chemical information. We want to develop a system for chemical regulation that is the gold standard for the world.

That doesn't mean the most precautionary, or the most commercially free-wheeling. It means a balanced system rooted in the best science and highest quality information so we can all be confident that if the chemical is in our stream of commerce it is safe, and commerce flows freely across State lines and across borders.

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It's often said that the job of the manager is to know when to stop taking data and start making decisions. That's the challenge for EPA under a reformed TSCA.

It's also the challenge we on the committee face as we transition from our examination of current law to developing our own ideas for how to modernize, after nearly four decades, this body of regulation. I look forward to working with all of our committee colleagues as we set out on that path.

Thank you, Chairman Shimkus, Mr. Tonko, and all the subcommittee members for the hard work you've already put in. You've stayed focused through these hearings and developed the policy expertise that will benefit each of us in our deliberations. It's hard work that attracts little publicity, but in the long run, our world will be better for it.

Mr. SHIMKUS. The gentleman yields back his time. I want to make sure I get that clip and send it to my spouse, so that she knows that I am working—

Mr. UPTON. And your high school science teacher.

Mr. SHIMKUS. No, I don't want to go there. Now, and this will be the first of many times that we get to recognize the ranking member, but, being the first one, I want to congratulate Henry on his announcement. I don't expect him to go away quietly. I do expect involvement after Congress still with us and our issues. But, with that, let me yield 5 minutes to the ranking member and chairman emeritus, Mr. Waxman, for 5 minutes.

OPENING STATEMENT OF HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. WAXMAN. Thank you very much, Mr. Chairman. I am going to also give you a clip that you can share with your family, because I agree with Chairman Upton. This is a time for us to work together, and I want to work with you on reform of the Toxic Substances Control Act. I believe TSCA is a flawed law that must be updated, and we need to work together to do this.

Last month, State and Federal officials in West Virginia were left scrambling when they could not find meaningful health and safety data on a chemical that had polluted the drinking water of 300,000 people. This disaster illustrated some serious problems with the current law. New chemicals enter the market without basic toxicity data. Untested chemicals remain on the market, and chemical manufacturers often are not required to submit tests that they do to EPA. This is an area ripe for Congressional action, and holding a serious of hearing is a step in the right direction.

But we also need to start bipartisan talks to see if we can reach a compromise that protects the public from dangerous toxic chemicals without unduly burdening industry. It is an open secret that the majority staff is drafting a TSCA bill, but at this point, they have shared nothing with the staff on our side of the aisle. They haven't shown us language, or explained their concepts for TSCA reform. Of course, Mr. Chairman, this is your prerogative, but the reality is that an unbalanced proposal simply isn't going to become law.

The Senate also has drafted a proposal for TSCA reform. The chemical industry strongly supports it, but the public interest community is deeply concerned about the proposal. We need to strengthen TSCA, yet most environmental groups believe that the Senate draft would actually weaken the current law. This looks like a recipe for a stalemate, and we don't need too many recipes for a stalemate. We get stalemates all the time without a recipe.

If we are going to succeed, however, in reaching a compromise that will become law, we need a formulation that both sides, industry and environmentalists, can support, and I think there is a way we can achieve this. It is not commonly known, but in 2011 the American Chemistry Council, representing industry, and the Safer Chemicals Health Family Coalition, representing public health groups, sat down to see if they could find common ground on TSCA reform. They found many areas of agreement, and documented the

agreement in a memorandum prepared by the Meridian Institute. I believe this consensus between industry and public health groups could be a basis for productive discussions in this committee.

Later today I will be sending a letter to these groups and requesting they share their results with our committee. And, Mr. Chairman, I would like to invite you to join me in sending this letter. The result of their careful policy discussions just might be a blueprint for success in our committee.

In recent days I have been asked a lot about my views of Congress, particularly since I announced I am leaving. Now people want to know what I think about Congress. Well, I have said that although there are aspects of Congress today that I strongly dislike, I remain convinced that Congress can still be a powerful force for good for our Nation. I hope we can demonstrate that once again by working together on TSCA reform. Only when we work together do we see successful legislation all the way through to the President's signature. That is what we need to do, initiate successful legislation in this committee, and see it all the way through. We have a history of that in our committee, and I hope we can go back to that pattern again. Thank you, Mr. Chairman. Yield back my time.

Mr. SHIMKUS. Gentleman yields back his time. Now, again, the Chair, I would like to welcome you all here. You will all be given 5 minutes for your opening statement. Your full statements will be recorded into the record. So we will start from left to right. We will start with Mr. Charles Drevna, President of the American Fuel and Petrochemical Manufacturers. You are recognized for 5 minutes. Welcome.

STATEMENTS OF CHARLES T. DREVNA, PRESIDENT, AMERICAN FUEL & PETROCHEMICAL MANUFACTURERS; ROBERT A. MATTHEWS, MCKENNA, LONG & ALDRIDGE, LLP, ON BEHALF OF THE CONSUMER SPECIALTY PRODUCTS ASSOCIATION; BRENT GRAZMAN, VICE PRESIDENT, QUALITY ASSURANCE, VIASYSTEMS GROUP, INC., ON BEHALF OF IPC-THE ASSOCIATION CONNECTING ELECTRONICS INDUSTRIES; BETH D. BOSLEY, PRESIDENT, BORON SPECIALTIES, ON BEHALF OF THE SOCIETY OF CHEMICAL MANUFACTURERS AND AFFILIATES; CATHERINE WILLETT, DIRECTOR, REGULATORY TOXICOLOGY, RISK ASSESSMENT, AND ALTERNATIVES, THE HUMANE SOCIETY OF THE UNITED STATES; JENNIFER SASS, SENIOR SCIENTIST, NATURAL RESOURCES DEFENSE COUNCIL; AND JEROME PAULSON, CHAIRPERSON, EXECUTIVE COMMITTEE OF THE COUNCIL ON ENVIRONMENTAL HEALTH, AMERICAN ACADEMY OF PEDIATRICS

STATEMENT OF CHARLES T. DREVNA

Mr. DREVNA. Chairman Shimkus, Ranking Member Tonko, and Full Committee Chair Mr. Upton, and Mr. Waxman, members of the subcommittee, I am Charlie Drevna, President of American Fuel and Petrochemical Manufacturers. As the name implies, AFPM represents high tech manufacturers. While most people are familiar with the fuels they use every day, many are not familiar with the petrochemicals. Petrochemicals are the industrial building blocks that make the materials, ingredients, and processing agents

that appear throughout a variety of manufacturing supply chains. Whether it is the plastic casing of your cell phone, excuse me, the aspirin in your medicine chest, or even the helmet worn by a loved one in the military, petrochemicals, such as ethylene and propylene play a critical role in manufacturing, and in our lives every day.

TSCA is a unique statute in that it has much to do with commerce and the manufacturing supply chain as it does with human health, and the environment. TSCA gives the EPA broad power to regulate chemicals in commerce. While AFPM supports rational modernization of TSCA, great care must be taken so that the manufacturing supply chains are not disrupted. This is one statute where our members believe that a strong Federal role is required to maintain the interstate flow of raw materials and goods.

Since its enactment in 1976, we have learned that the implementation of TSCA has been challenging for EPA in certain areas, and there is still debate over whether the challenges have been due to the statute, or due to some of the choices the agency has made. I believe it is time to take a fresh look at how we control chemicals in commerce, and again try to strike that balance between helping the environment, and a globally competitive manufacturing supply chain.

The U.S. is on the brink of a manufacturing renaissance, due in large part to dramatic reductions in the cost of energy and raw materials. Shale development has fostered the most globally competitive positioning for American manufacturers I have ever witnessed. Given this opportunity, when it comes to laws that affect the feed stocks driving the manufacturing renaissance, we must get TSCA modernization right. To begin, AFPM supports a bipartisan effort to modernize TSCA. That means a new starting point for discussion, and a constructive dialogue. I echo Mr. Waxman's comments there. The current TSCA statute provides a solid backbone for chemical regulation, but AFPM does see room for improvement.

One area for improvement is more guidance from Congress that directs the EPA to prioritize chemicals in commerce. AFPM views prioritization efforts under the Canadian chemical management program as a reasonable, achievable model. The approach used in Canada is a screening level look at chemical hazard and exposure to tell scientists whether or not more work is needed to deem a substance safe for its intended use, and the conditions of that use. Currently the EPA has sophisticated and protective models that it uses to evaluate the potential hazards of chemicals. The agency collects data under the chemical data reporting rule to determine the exposure potential of chemical substances. So there are no technical or practical reasons that EPA cannot prioritize chemicals for further work.

Congress should also include provisions that increase scientific quality and transparency at the agency. Specific language should require EPA to develop criteria by which the agency and public can judge the quality of scientific studies under consideration, as well as EPA risk assessments.

An important part of TSCA is Section 4, which authorizes the EPA to require laboratory testing of certain chemicals. I tend to agree that under Section 4, the prerequisite for EPA to find a risk posed by a chemical before it can require testing for that chemical

does not make sense. The exposure finding, on the other hand, is a built in check and balance to prevent EPA from demanding unreasonable animal intensive tests that will not lead to a further and better understanding of safety. AFPM firmly believes that there should be an exposure basis before EPA can require animal testing.

AFPM's highest level principles state that TSCA should be a tiered, targeted, and risk based approach. This is especially true for testing and data collection. A tiered approach begins with the use of existing information, protective models, and structure activity relationships. If there is an unreasonable amount of scientific uncertainty at a screening level, then the substance would be subject to the next tier, in which information is collected to reduce the uncertainty.

When it comes to Section 8, which authorizes the EPA to collect information that provides an accurate reflection of chemicals to commerce, Congress should also provide specific guidance. For example, the chemical data reporting rule, EPA is required for producers to use exposure information.

In closing, there are other sections of TSCA that may need updating, but I am confident that the subcommittee will address those issues at a later date. Thank you Mr. Chairman, Ranking Member Tonko, and subcommittee members for allowing us the opportunity to express our views.

[The prepared statement of Mr. Drevna follows:]



**WRITTEN STATEMENT OF AMERICAN FUEL & PETROCHEMICAL
MANUFACTURERS**

AS SUBMITTED TO THE

SUBCOMMITTEE ON ENVIRONMENT AND THE ECONOMY

**House Committee on Energy and Commerce
United States House of Representatives**

on

**“Testing of Chemicals and Reporting and Retention of Information under TSCA Sections
4 and 8”**

Tuesday, February 4, 2014

**Charles T. Drevna
President
American Fuel & Petrochemical Manufacturers**

About AFPM:

The American Fuel & Petrochemical Manufacturers (“AFPM”) is a national trade association of more than 400 companies, including virtually all U.S. refiners and petrochemical manufacturers. AFPM members operate 122 U.S. refineries comprising approximately 98% of U.S. refining capacity. AFPM petrochemical members make the chemical building blocks that go into products ranging from medical devices, cosmetics, furniture, appliances, TVs and radios, computers, parts used in every mode of transportation, solar power panels and wind turbines. AFPM members manufacture and import chemicals and are regulated under TSCA.

Getting TSCA Modernization Right:

AFPM supports rational modernization of TSCA and sees opportunities for improvement. The United States is on the brink of a manufacturing renaissance, which is largely due to abundant and affordable energy and raw materials. Shale development has enabled the U.S. petrochemical industry to be globally competitive for the first time in decades. Over 80 billion dollars in petrochemical infrastructure investment has already been announced.

Since petrochemicals are building blocks that affect many different manufacturing supply chains, it is imperative that health and environmental considerations are balanced with manufacturing and supply chain considerations. Strong federal preemption, therefore, is necessary to prevent a disparate set of state-level regulations that would disrupt the flow of interstate commerce and bring the manufacturing supply chain to a halt.

Equally important for American manufacturing competitiveness is the protection of intellectual property. The ability to claim intellectual property, including the specific identities of newer chemicals, as confidential business information (CBI) affords American manufacturers a competitive advantage in the global marketplace. AFPM acknowledges limitations of the current statute, which prevents the Environmental Protection Agency (EPA) from sharing CBI with state government officials. AFPM believes that TSCA could be modified to allow EPA to share certain confidential information with state governments, as long as those states can ensure the protection of intellectual property shared.

Another general area that could lead to improved chemical regulation is the inclusion of provisions that address scientific quality and transparency at EPA. The Agency should be required to develop criteria that explicitly and transparently evaluate the quality of data so that EPA and other scientists are able to compare the scientific weight (validity) of one study versus others. These criteria should be proposed and finalized as part of a public notice and comment process to ensure timeliness and transparency.

Sections 4 and 8 of TSCA address the ability of EPA to effectively collect appropriate information for risk assessment. Under an improved TSCA it is likely that information collection under these sections will be centered on the Agency’s need to prioritize chemicals and conduct full risk assessments for high priority chemicals. AFPM supports Congress authorizing EPA to prioritize all chemicals in commerce to allow the agency to identify those substances that require further work to reduce uncertainty related to chemical safety.

Background:

The Toxic Substances Control Act (TSCA) was enacted in 1976 and is unique in that it is as much a statute about commerce as it is about human health and the environment. TSCA gives the US EPA broad authority to regulate the entire lifecycle of a chemical, from the point of manufacture through the point of use, all the way to disposal. Although TSCA generally works very well, AFPM acknowledges that EPA has experienced challenges during decades of TSCA implementation, some due in part to legal hurdles posed by certain statutory provisions, and some in part to key EPA decisions. AFPM believes that it is time to start a new dialogue on TSCA modernization that seeks to improve a workable statutory framework.

A key area in TSCA, which is one of the focuses of this hearing, is chemical testing under TSCA Section 4. The current statute authorizes EPA to require the testing of certain chemical substances which either presents an unreasonable risk to human health or the environment, or presents significant exposures to people. During the 1980s and 1990s, EPA expressed difficulty in issuing Section 4 test rules, which authorizes EPA to require companies to conduct laboratory testing on certain chemicals. A reason for the difficulties was that the Agency did not use its data gathering authority under Section 8 to collect relevant exposure information prior to issuing the test rules. Recent experience, however, has been profoundly different. To overcome challenges with finding significant exposures, EPA expanded the Inventory Update Rule ("IUR"), which requires companies to report the chemicals they currently make. The expanded information requirements include use and exposure information pertaining to the reported chemicals, allowing the Agency to justify new testing requirements. Since the expanding the IUR, EPA has successfully issued a series of test rules for high production volume chemicals that have gone unchallenged.

The other area of focus for this hearing is TSCA Section 8, which authorizes EPA to require the collection, maintenance and reporting of information related to hazard, exposure and risk for chemicals, as well as information that accurately reflects chemicals that are currently in commerce. After EPA expanded the reporting requirements to update the TSCA Inventory, it finalized a new system called the Chemical Data Reporting (CDR) rule to better align with the statutory provisions under Section 8. CDR reporting requires companies to provide the identities and amounts of chemicals they manufacture and import, the uses of those chemicals, and information regarding potential human exposure to those substances.

Toxicity Testing and Hazard Information under TSCA Section 4:

Under the current TSCA statute, before the Agency can issue a test rule requiring companies to conduct laboratory testing on that particular chemical, EPA must find that a chemical either poses an unreasonable risk of harm to human health or the environment, or that a significant number of people could be exposed to the substance. AFPM acknowledges that it is irrational to require a demonstration of unreasonable risk before requiring test data that would help demonstrate that risk. The finding of unreasonable risk should be deleted in Section 4.

The Agency should focus its resources on collecting information that will help prioritize chemicals and reduce scientific uncertainty with respect to risk. Moreover, there should be a basis of significant exposure before EPA can require companies to conduct animal studies. To guide EPA, Congress should require the Agency to promulgate a Section 8(a) Preliminary Assessment Information Rule (PAIR) to collect the necessary exposure information prior to proposing a test rule that involves animals. PAIR

actions under Section 8(a) are not subject to review by the Office of Management and Budget (OMB), so the rules should present a minimal burden to the Agency. The exposure finding in Section 4 should be retained.

One of the criticisms concerning Section 4 under TSCA is the rulemaking burden placed on EPA. AFPM believes that some of that criticism is misplaced because EPA must follow procedural requirements that fall under other statutes, such as the Administrative Procedures Act. Another idea that has been discussed among stakeholders is to provide EPA with order authority, under which EPA could require companies to conduct laboratory testing without having to go through a public notice and comment process. AFPM believes that order authority may be appropriate to a certain degree, as long as there is an exposure basis for the order. For situations where EPA is seeking animal-intensive testing – for example, a multigenerational animal study – EPA should be required to go through rulemaking. For *in vitro* and other non-animal tests, order authority may be more appropriate; again, as long as there is some sort of exposure basis for the order.

Non-animal methods have been developed to measure the potential hazards of particular chemicals. Many *in vitro* methods have been validated over the years to avoid animal testing and still provide a screening-level view of potential toxicity. Currently, there are efforts underway to examine the use of high-throughput screening for evaluating the potential toxicity of substances. High-throughput screening is a non-animal laboratory method that uses cell cultures to test for specific toxicity effects. AFPM strongly supports more research in this area. High-throughput screening methods should be validated using the same scientific scrutiny to which all other methods have been held. While this new area of screening holds great promise, many of the methods are not yet ready for use in a regulatory context. When modernizing TSCA, care should be taken so as not to preclude valid non-animal testing approaches in the future.

Information Collection under TSCA Section 8:

Each subsection under Section 8 of TSCA provides EPA with tools to collect information that can help inform prioritizations and safety assessments. Generally, Section 8 should not undergo significant change. EPA has been able to effectively implement the tools authorized under Section 8, so any changes should be subtle in the following areas.

Sections 8(a) and 8(b)

EPA should be required to develop a reporting method to make the TSCA Inventory more reflective of actual chemicals in commerce. Many people have the false impression that there are 80,000 chemicals in commerce. That has never been the case. According to EPA data, there are less than 10,000 chemicals in commerce that are produced in commercial quantities during any given year, excluding polymers, which EPA has determined to be safe, and substances used in research and development. Fundamentally, there is no process by which chemicals can be removed from the Inventory when they are no longer in commerce. EPA does collect up-to-date information as part of the Chemical Data Reporting (CDR) rule, now under Section 8(a); however, there should be some type of Inventory reset to identify specific substances that are currently in commerce, or active, and those that are not actively in commerce but were placed on the Inventory when it was created. After an Inventory reset, CDR reporting should be sufficient to maintain an accurate view of chemicals in commerce.

Equally important to an accurate Inventory is the collection of accurate exposure-related information. If EPA is going to continue to collect use and exposure information under the CDR, it should, where appropriate, include processors in reporting. The same holds true for collecting use and exposure information under Section 8(a) PAIR rules. Petrochemicals and other commodities are traded in the open markets as futures, NYMEX being a typical venue. Commodities can also go through extensive and complex distribution markets, where the producers relinquish ownership early in the supply chain and distributors physically sell the chemicals. For these reasons it is improbable that the original producer of a commodity chemical would know where their particular chemical ends up in the supply chain, let alone how it would be used and by whom. The inclusion of processors will be integral to use and exposure information collected and used by the Agency.

Prioritization of Chemicals in Commerce:

AFPM strongly urges Congress, when updating TSCA, to include provisions that require EPA to prioritize all chemicals in commerce. The prioritization process should not necessarily have the objective of regulation. Rather, it should be a prioritization for further work, similar to the approach used in the Canadian Chemicals Management Plan. Under this process, EPA would use existing information and consider potential hazards and exposures to make screening-level risk evaluations. If the Agency found that a particular chemical could pose a risk or if there was insufficient information to make that judgment, then the Agency would place that substance into a high priority for further work. EPA could then use its testing and information collection rules to help reduce any uncertainty pertaining to that chemical's safety.

The Office of Pollution Prevention and Toxics (OPPT) at EPA employs competent scientists with a high degree of technical expertise in risk assessment. OPPT has developed sophisticated methods and models to predict potential hazards and exposures, and has a great deal of experience evaluating substances that do not have an abundance of measured laboratory data. The predictive models used by the Agency are sufficiently protective, which EPA has pointed out through retrospective studies. There is no technical or logistical reason that EPA would not be able to prioritize all chemicals in commerce.

Making Chemical Information Publicly Available:

EPA has made great strides over the past 10 years to make chemical safety information available to the public. The Agency collects data on over 2,000 chemicals from the High Production Volume (HPV) Challenge program available through its HPV Information System. In addition, EPA just launched its new web-based portal, ChemView, which was created to provide one-stop shopping for those seeking health and safety data on chemicals regulated under TSCA. EPA does not release CBI through these internet sites. AFPM supports EPA's efforts to make appropriate information on chemicals publicly available, as long as the information systems continue to protect intellectual property.

Conclusion:

AFPM supports rational modernization of TSCA and believes that Congress should take the opportunity to improve certain parts of the statute and provide more guidance to the Agency. Because chemicals are used throughout the manufacturing supply chain, and supply chains for most products cross many state

lines, strong federal preemption is paramount. Without strong preemption provisions, supply chains and the interstate movement of raw materials and goods will be disrupted.

Sections 4 and 8 are key components of TSCA that allow EPA to collect information related to chemical hazard, exposure and risk, which can assist the Agency in prioritizing chemicals for further work and in its risk assessment activities. AFPM does not see a need for dramatic change in these sections as they provide a strong regulatory framework and tools for the EPA to collect information. The risk finding under Section 4 should be deleted and the exposure finding should be retained. In addition, EPA should be required to collect use and exposure information under Section 8(a) before issuing a test rule. The Agency should have the authority to use test orders; however, any new testing required by EPA should have an exposure basis.

The TSCA Inventory is out of date and should be reset. Congress should guide EPA in how to reset the Inventory with an objective of accurately reflecting which chemicals are actively in commerce and which are not. Furthermore, processors should be included in reporting use and exposure information, as they are more likely than producers to possess this type of information.

To improve TSCA and its implementation, Congress should explicitly require EPA to prioritize all chemicals in commerce for further work within a reasonable amount of time. Further, Congress should require the Agency to develop criteria by which to judge the quality of studies it considers in its hazard characterizations, exposure assessments and risk assessments.

In closing, TSCA is a law that affects commerce as much as it does human health and the environment. The current TSCA statute provides a solid regulatory framework for chemical regulation and does not see a need for dramatic overhaul. AFPM supports the rational modernization of TSCA and sees this as an opportunity for Congress to make improvements.

Mr. SHIMKUS. Thank you, Mr. Drevna. Now the Chair recognizes Mr. Robert Matthews from McKenna, Long, and Aldridge, on behalf of the Consumer Specialty Products Association. Sir, you are recognized for 5 minutes.

STATEMENT OF ROBERT A. MATTHEWS

Mr. MATTHEWS. Thank you. Good morning, Mr. Chairman, Ranking Member Tonko, members of the committee. It is a pleasure and privilege to appear before this committee on behalf of the Consumer Specialty Products Association. It is our firm's oldest client. We have been representing their interests for over 5 decades. So it is my privilege to appear on their behalf, and before your subcommittee.

In fact, this year CSPA celebrates its 100-year anniversary serving as the premiere trade association representing the interests of companies both large and small. A good half of their companies are small businesses, the companies that formulate and market household and institutional products.

In our written testimony, and in my comments today, we refer to our members as formulators, which is a segment of the downstream companies that are more generally referred to as processes. CSPA and its member companies have consistently advocated for the need to update the TSCA statute, and, importantly, recognize the role of downstream formulators in that process. CSPA's role and interest in TSCA is to assure the process is working in a way that protects public health and the environment, allows companies to continue to operate effectively and efficiently in commerce, and maximizes consumer confidence in chemical safety, and by extension, in the branded products that we place on the market.

CSPA's support for modernizing TSCA is rooted in three principle considerations. First, it is critical, as I just mentioned, that consumers have confidence in these formulated products. Maintaining that high level of confidence in the safety of chemicals used in their products placed on the market is of utmost concern to CSPA and its member companies.

Second, CSPA member companies who sell formulated household and institutional products increasingly face a multitude of State regulations, indeed, not only at the State, but at the local level, as legislative and regulatory entities are simply not waiting for Congress to act to modernize this statute. So we support modernization because it will create a more predictable environment in which companies can engage in interstate commerce.

And, finally, among the reasons we have continually supported changes and modernization of TSCA is because our companies, like others in industry, are impacted by the adoption and globalization of the EU Reach program, with its focus on regulation by hazardous properties of chemicals, and its calls for massive data into the system that is often unnecessary, costly, and burdensome. We think this is an opportunity for the United States to assert its leadership in establishing risk based global chemical management programs.

So I am now, with that background, pleased to share with you our very specific thoughts on how CSPA and its member companies can meaningfully participate in the TSCA statute that would

emerge after modernization. So we have focused in particular on the issues that impact our members. Those include in particular one that is before this committee today. That is Section 8, and the reporting provisions thereunder. We have also focused considerable attention on the confidential business information, or CBI, provisions of Section 14. So I will largely focus on Section 8, as this committee has requested, and the impact of that section on the prioritization program under Section 4.

The key to a modernized TSCA is an affirmation of a risk based chemical management system, meaning that at the time that EPA is prioritizing chemicals for review, and setting standards, they are focused not only on the hazard, or intrinsic properties of that chemical, but the manner in which those chemicals are used, and the potential exposures that they create.

But as it supports a risk based approach, CSPA has also recognized three related points. First, indeed, a risk based system starts with prioritization, where EPA screens chemicals in commerce to identify which ones should be subject to further review, and potentially to a safety assessment. Given the large number of chemicals in process, it is imperative that there be an effective screening process. Second, to properly screen, and indeed, again, potentially to conduct risk assessments, EPA must have information on how those chemicals are being used, and their potential exposure scenarios that they create. And that leads to the third point, which is EPA has to have the means to get that information from where that information lies, which is principally with the downstream community, who know much more about use and exposure than do the raw material manufacturers.

So the role of formulators under a revised TSCA, therefore, can be very much defined and targeted for that purpose. We have spent considerable time focusing on the elements that would be useful in that regard that would impact our member companies. So we have done so in a manner that aligns what we think is EPA's needs at the prioritization stage with the information that we have. So we would propose to submit to the agency information that involves chemicals that will be placed in products, information on chemicals that are placed in products intended for use by children, information on the concentration range of the chemicals in those products, and, indeed, the number of workers, that is, who are involved in formulating those materials. Combined with the hazard materials, that is to say the hazard information, that EPA would have from the chemical producers, this would give EPA all that it needs in regard to prioritization.

So I have much more to say about confidential business information. Perhaps that will come up, but that is the principle focus of our efforts, is to get that kind of use and exposure information into the agency. Thank you.

[The prepared statement of Mr. Matthews follows:]



Testimony of
The Consumer Specialty Products Association

Robert A. Matthews, Esq.
McKenna, Long & Aldridge L.L.P.

Before
The U.S House of Representatives
Subcommittee on Environment and the Economy
Of the Committee on Energy and Commerce

“Testing of Chemicals and Reporting and Retention of Information
under TSCA Section 4 and 8”

February 4, 2014

CSPA Testimony: Summary of Key Points

- There is broad consensus that changes are needed in order to modernize TSCA's chemical assessment programs. As we look to those areas where the statute needs to be updated, a key goal is to determine how to (1) ensure the Agency has the tools and information it needs to review and assess chemical safety; and (2) better focus priority reviews by using the best available information to identify those chemicals of highest priority for further review and safety assessment.
- One key to implementing an efficient and effective chemical assessment program should start with a screening level process to identify chemicals requiring further review and possible safety assessment. As we have stated previously, any screening level priority setting must be risk-based, taking into consideration a chemical's hazards and the nature of extent of its uses and potential exposures.
- Industry, including CSPA, strongly supports a risk-based approach to chemical management. In order to ensure that EPA has the information required to make sound, scientific-based decisions on prioritization, CSPA recognizes first, that EPA needs use information, and second, that much of that information is in the hands of downstream processors. Accordingly, in order to properly prioritize chemicals and ultimately to conduct safety assessments, a revised TSCA should expressly allow the Agency to collect necessary use information from downstream processors to better inform their review of exposure potential.
- Support for reporting use information must be seen in tandem with support for rigorous and effective CBI protections. Reporting under Section 8 of TSCA must allow for companies to assert substantiated CBI claims to protect innovation, minor and specialty uses for chemicals, and proprietary product formulations and mixtures. Most information, except company name and CBI chemical names, would be public in the form of aggregated reporting by EPA, provided such aggregation can protect CBI interests of the submitter.

Chairman Shimkus, Ranking Member Tonko, and members of the Subcommittee, my name is Bob Matthews, and it is my privilege to appear before this Subcommittee on behalf of the Consumer Specialty Products Association (CSPA). I am an environmental attorney with the law firm of McKenna Long & Aldridge L.L.P with over forty years' experience representing clients in counseling and litigation matters across a broad spectrum of international environmental laws and regulations. Our firm has provided legal counsel to the CSPA on chemicals management issues since 1939.

The Consumer Specialty Products Association greatly appreciates the opportunity to present its views on the need to modernize the Toxic Substances Control Act (TSCA) and specifically on the role of downstream formulators under Sections 4 and 8 of the statute.

CSPA is a national trade association representing the interests of approximately 235 "consumer facing" companies engaged in the manufacture, formulation, distribution and sale of more than \$100 billion annually in the U.S. of familiar consumer products for household and institutional customers. In 2014, CSPA is proud to celebrate 100 years representing the interests of the household and institutional products industry. CSPA members are committed to manufacturing and marketing safe, innovative and sustainable products that provide essential benefits to consumers while protecting human health and the environment.

As a threshold matter, CSPA and its member companies remain committed to the goal of modernizing TSCA. We want to emphasize, first, that TSCA is a *chemical* management statute that primarily regulates the activities of manufacturers of chemicals that are then placed into commerce for use or processing by an expansive universe of companies, many of which formulate and market other goods and services. CSPA represents one segment of that universe—which is the formulated household and institutional products industry. CSPA's role and interest in TSCA is to ensure the process is working in a way that protects public health and the environment; allows

companies to continue to operate effectively and efficiently in commerce; and maximizes consumer confidence in chemical safety, and by extension, the branded consumer products in which chemicals are formulated.

CSPA believes that a modern TSCA should reflect the nearly four decades of scientific and technological advancements that have emerged since the statute was enacted in 1976. Building on those advancements, a modernized TSCA must be designed to achieve the dual goals of protecting the health and safety of consumers, workers and the environment, including vulnerable subpopulations, while promoting and supporting the flow of interstate commerce through chemical innovation, jobs and economic growth.

Like others represented at this table, CSPA has developed and shared principles for TSCA modernization. Several of these elements are the focus of today's hearing:

- Chemicals management under TSCA must be risk-based; which means the EPA should consider both hazard and exposure of chemicals in commerce as part of a safety determination.
- A first step in this process should be prioritization directing the Agency to screen chemicals using existing and available information to quickly identify those chemicals of highest concern for further Agency review and assessment.
- To better information prioritization and safety assessment under a risk-based approach to chemical management, the Agency must have the means by which it can obtain the necessary information on both the hazard properties of chemicals and how those chemicals are used.
- The system must protect public health and the environment while also protecting

confidential business information (CBI), thereby preserving the ability of U.S. companies to drive innovation, grow jobs and compete in the global marketplace.

Motivators for Downstream Support

CSPA's consistent and continuing support for TSCA reform is rooted in three factors: consumer confidence in chemical safety, preservation of interstate commerce resulting from consistent federal and state regulation, and U.S. global leadership toward risk-based chemicals management.

Enhancing consumer confidence on chemical safety: Developing reasonable and necessary revisions to update the TSCA statute is vitally important for CSPA member companies. Downstream formulated product companies are, in many respects, the public face of the U.S. chemical industry. The products manufactured by CSPA member companies are in virtually every home and institution around the country. The company name is on every one of their products. Therefore, maintaining a high level of consumer confidence in the safety of the chemicals used in their products is a responsibility that all CSPA member companies take very seriously.

Consistent Regulation of Commerce in All 50 States: In the absence of a modernized TSCA, companies in the chemical industry face a multitude of regulation at the state level, as legislative and regulatory entities seek to develop and implement their own chemical management programs. An amended TSCA should create a more predictable environment in which companies can engage in interstate commerce.

Supporting Global Leadership for a Risk-based Approach to Chemical Review and Assessment: Chemical regulation is changing rapidly and significantly around the globe. Many of CSPA's member companies operate in the international marketplace—and face costly and burdensome requirements to comply with the onerous hazard-based approach taken under Europe's Registration, Evaluation and Authorization of Chemicals (REACH) regulation. It is essential that the

U.S. chemical management system keep pace with global developments and that our government resumes its role as a global leader in chemical regulatory policy. The U.S. chemical industry is unified in its support for the adoption of a risk-based system under TSCA—which means the EPA will consider *both* hazard and exposure in the Agency’s determination that a chemical is safe for its intended uses.

Examining Current TSCA Section(s) 4 and 8

There is broad consensus that changes are needed to modernize TSCA’s chemical assessment programs. As we look to those areas where the statute needs to be updated, a key goal is to determine how (1) to ensure the Agency has the tools and information needed for the review and assessment of chemical safety; and (2) to better focus priority reviews by using the best available information to identify those chemicals of highest priority for further review and safety assessment.

Sec. 4. CSPA therefore agrees that a key to implementing an efficient and effective chemical assessment program should start with a screening level process to identify chemicals requiring further review and possible safety assessment. As CSPA has stated previously, any screening level priority setting must be risk-based, taking into consideration a chemical’s hazards and the nature and extent of its uses and potential exposures. Chemicals identified as high priorities for assessment should be those with the highest hazards and the highest potential exposures. EPA has identified a number of available data sources from which to obtain information on chemical hazards and indicators of exposure to swiftly identify the subset of chemicals that need priority assessment. One of those sources is periodic reporting under Section 8 of TSCA.

However, as EPA’s recent experience with the Work Plan chemicals has demonstrated, very little information is readily available to the Agency on how chemicals are used in U.S. commerce in order to fully inform prioritization and to assess the human health and environmental risk of these

chemicals.

Sec. 8. Although current TSCA authorizes the Agency under Section 8 to obtain information from “processors” on chemicals regulated under TSCA, the Agency has not regularly exercised this authority. Instead, EPA has utilized Section 8(a) of TSCA to require reporting of chemical information from manufacturers and importers, who may have limited information on some uses. Where the information is sufficient, the EPA can move forward. Where it is not, the Agency needs to obtain additional information. CSPA views prioritization as an ongoing process; as the EPA obtains more refined information, it should act to raise or lower a priority level, as appropriate.

A risk-based approach to chemical prioritization evaluates information on the uses of chemicals in commerce in order to identify potential exposures. Much of the information on chemical uses is in the hands of downstream processors. CSPA supports the position that in order to better inform EPA’s understanding of exposure potential during prioritization and subsequent safety assessments of high priority chemicals, a modernized TSCA should expressly allow the Agency to collect necessary use-related information from downstream formulators of consumer and commercial products. Most downstream formulators have not been subject to such EPA information requests, and therefore these new provisions would represent a significant change under TSCA. Carefully defining the applicable scope of these new reporting provisions in statute will properly align the frequency and content of formulator use reporting with the Agency’s actual need for such information as part of priority decision making and screening level review.

CSPA’s support for the inclusion of formulator use reporting provisions in Section 8 of a modernized TSCA was developed through dialogue among our member companies, with some of our “sister” trade associations, key representatives from the NGO community, and EPA. CSPA’s Board-approved use reporting proposal is meant to reflect a level of reporting that is practical and

not unduly burdensome from member companies' perspective, while offering EPA useful information with which to better inform prioritization decision making. We recognize and emphasize that this level of reporting may not be appropriate for other industry sectors, or for processors as a whole. Importantly, any level of processor use reporting should be targeted and implemented by EPA on an as needed basis as part of prioritization and safety assessment.

CSPA's Recommendations for Statutory Amendments: First, TSCA's information reporting provisions in Section 8 would need to specifically authorize EPA to collect specific chemical use information from formulators necessary to assist the Agency in prioritization decision making. Second, the scope of EPA's authority to collect use information during prioritization would be targeted to the following exposure-related elements: intentionally-added substances; an indication of use in children's products; the concentration range of the chemical in the formulation/mixture; and the number of commercial workers potentially exposed at the formulating facility. For purposes of conducting a safety assessment on high priority chemicals, EPA would have the authority to determine whether and to what extent additional use or other information is required from processors.

Confidential Business Information

Finally, when formulators provide use information to the Agency, this may include confidential business information (CBI) and trade secrets. Intellectual property is a company's most valuable intangible asset, creating the opportunity for more sustainable and innovative products to enter the market. Therefore, support for reporting use-related information must be viewed in tandem with support for rigorous and effective CBI protections. Reporting under this section must allow for companies to assert substantiated CBI claims to protect innovative technologies, minor and specialty uses for chemicals, and proprietary product formulations and mixtures. Most information provided to EPA as part of formulator use reporting, except company name and CBI

chemical names, would become public in the form of aggregated reporting by EPA, provided such aggregation can protect CBI interests of the submitter.

Goal to Minimize Animal Testing

The consumer products industry applauds the efforts to ensure minimal animal testing under any chemical management reform measures. To minimize animal testing, EPA could be required, where practicable, to use existing data, to reduce reliance on animal testing methods, and to use non-animal testing methods to conduct safety assessments. Our industry is committed to mandatory measures that minimize unnecessary animal testing. We believe that the development, governmental acceptance and use of alternative test methods validated by internationally recognized principles that protect human health and the environment while reducing, refining and replacing animal tests should be encouraged under any chemical management program. EPA should also encourage, where practicable, the grouping of similar chemicals to limit testing to representative substances and the formation of industry consortia to conduct joint data development. The household and institutional products industry would support such consortia as long as there are parameters to adequately protect confidential business information in its operation.

About CSPA

The Consumer Specialty Products Association (CSPA) is the premier trade association representing the interests of companies engaged in the manufacture, formulation, distribution and sale of more than \$100 billion annually in the U.S. of familiar consumer products that help household and institutional customers create cleaner and healthier environments. CSPA member companies employ hundreds of thousands of people globally. Products CSPA represents include disinfectants that kill germs in homes, hospitals and restaurants; candles, and fragrances and air fresheners that

eliminate odors; pest management products for home, garden and pets; cleaning products and polishes for use throughout the home and institutions; products used to protect and improve the performance and appearance of automobiles; aerosol products and a host of other products used every day. Through its product stewardship program, Product Care®, and scientific and business-to-business endeavors, CSPA provides its members a platform to effectively address issues regarding the health, safety and sustainability of their products. For more information, please visit www.cspa.org.

Mr. SHIMKUS. Thank you. Now the Chair recognizes Dr. Brent Grazman, Vice President for Quality Assurance, Viasystems Group, Incorporated, on behalf of the IPC, Association Connecting Electronics Industries, and more importantly from the St. Louis Metropolitan area, which is where I reside. So with that, welcome. You are recognized for 5 minutes.

STATEMENT OF BRENT GRAZMAN

Mr. GRAZMAN. Thank you, Mr. Chairman, and members of the committee for the opportunity address you today. Viasystems is a global manufacturer of printed circuit boards. We are headquartered, as the Chairman mentioned, in St. Louis. We employ over 2,000 people in the U.S. in eight different factories, including North Jackson, Ohio, and Littleton, Colorado. We make printed circuit boards that are used by leading manufacturers of transportation, telecommunications, medical, defense, and aerospace products.

I am also here to represent IPC, the Association Connecting Electronics Industries. IPC is a global trade association representing over 2,000 electronics manufacturers in the U.S. As a member of IPC's government relations committee, I want to emphasize that IPC and its members, including Viasystems, are all strong advocates for science-based regulation that improves the environment, protects human health, and stimulates the economy. In my testimony I will highlight our concerns about TSCA Section 8 as it applies to byproducts reporting.

It is critical that Congress reform TSCA in a way that directs the Environmental Protection Agency to focus and prioritize its regulation of chemicals. Selection of priority chemicals should be based on sound science. Substances that exhibit the greatest hazard and impose the greatest exposure to consumers should be given priority for review for testing, and as needed for regulation. A targeted, prioritized approach will allow the EPA and industry to both more effectively use our limited resources to protect human health and the environment.

An example of EPA's failure to prioritize chemical regulation is the treatment of byproducts. Under TSCA, the EPA treats byproducts as new chemicals if they are sent for recycling. But if we sent them for disposal, there is no TSCA requirement invoked. As a new chemical, the byproduct sent for recycling must be listed on the TSCA inventory, and is subject to the full regiment of TSCA recordkeeping, reporting, and enforcement. Let me emphasize all of these regulatory obligations arise solely because a manufacturer, like Viasystems, sends a byproduct for recycling, rather than just disposing of it.

TSCA contains specific exemptions for byproducts, but the EPA has narrowly interpreted these exemptions to apply only if the recycler does not use a chemical reaction to recover substances from the byproduct. Recovery of metals, like gold, tin, and copper, that are in our byproducts is impossible without the use of the chemical reaction. We manufacture printed circuit boards like this one. We don't manufacture chemicals.

The EPA requires us to know, at a molecular level, what the recyclers of our byproducts do with our byproducts. The recycler's

processes are outside of our control. They are often proprietary, and they can change day to day, based on the market conditions that those recyclers see. The result is a regulatory policy that forces companies to report data based on incomplete information and assumptions, ultimately compromising the data quality. EPA's overreaching interpretation affects a lot more facilities and companies than those represented by the IPC. Manufacturers from many industries are burdened by reporting their byproducts as new chemicals at the point when they send them for recycling.

Much of the data that we report about byproducts under TSCA is also required by the Resource Conservation and Recovery Act, and the Emergency Planning and Community Right to Know Act. Under TSCA, the recyclers are required to report the new chemicals they manufacture from our byproducts. The EPA unnecessarily burdens industry with the reporting of vast and duplicative data for some unknown future uses.

As a Nation, we recognize reduce, reuse, and recycle as goals. The EPA undercuts those goals with regulatory policy that effectively discourages us from recycling. We encourage Congress to explicitly exempt all byproducts, including those that are sent for recycling. As I mentioned earlier, we manufacture printed circuit boards, not chemicals. The focus of TSCA, pardon me, should remain on ensuring the safety of chemicals in commerce. EPA's authority to regulate articles, like printed circuit boards, should be limited to situations where regulating the chemicals themselves is not enough to protect human health and the environment.

In conclusion, IPC supports cost effective, science based environmental regulation. As I have discussed, it is critical that Congress reform TSCA in a way that directs the EPA to focus and prioritize its regulation of chemicals. We believe that EPA's reporting requirements for byproducts sent for recycling are burdensome, unnecessary, and, as I mentioned, they actually discourage recycling.

Thank you again for this opportunity to appear before you. I will be happy to answer any questions when the time is right.

[The prepared statement of Mr. Grazman follows:]

Testimony of
Dr. Brent Grazman
Vice President
Viasystems Group, Inc.

On behalf of
IPC – the Association Connecting Electronics Industries

Before the
Subcommittee on Environment and the Economy
Committee on Energy and Commerce
U.S. House of Representatives

“Testing of Chemicals and Reporting and Retention of Information
under TSCA Sections 4 and 8”

February 4, 2014

Good day, my name is Dr. Brent Grazman and I am the Vice President – Quality for Viasystems Group, a leading world manufacturer of printed circuit boards. Viasystems is headquartered in St. Louis, Missouri and employs approximately 2,150 people in the United States in manufacturing facilities located in Anaheim, Milpitas and San Jose CA; Cleveland and North Jackson, OH; Littleton, CO; Forest Grove, OR; and Sterling, VA. Viasystems manufactures circuit boards used by some of the leading manufacturers of cars, telecommunications equipment, data storage systems, as well as industrial, medical and aerospace equipment.

I am also here to represent IPC – the Association Connecting Electronic Industries. IPC is a global trade association, which represents all facets of the electronic interconnection industry, including design, printed board manufacturing and electronics assembly. IPC has nearly 3,500 member facilities, including over 2,000 located in the United States. As a member-driven organization and leading source for industry standards, training, market research and public policy advocacy, IPC supports programs to meet the needs of an estimated \$1.7 trillion global electronics industry.

As a member of IPC's Government Relations Committee, I want to emphasize that IPC and its members, including Viasystems, strive to do the "right things." We are strong advocates for scientifically-based environmental regulations that improve environmental conditions, protect human health, and stimulate the economy. IPC is heavily involved in a number of voluntary environmental initiatives including several of EPA's Design for the Environment partnership projects and the development of the Electronic Product Environmental Assessment Tool (EPEAT) standard.

I am here today to encourage Congress to reauthorize the Toxic Substance Control Act (TSCA) in a manner that enables the Environmental Protection Agency (EPA) to better protect our nation's health and natural environment through focused, clear, and prioritized chemical regulations. In my testimony, I will highlight our concerns about TSCA regulation of byproducts and the negative effect that these regulations have on their recycling.

Under EPA's interpretation of TSCA, byproducts sent for recycling must now be listed on the TSCA Inventory and are subject to the full regimen of TSCA recordkeeping, reporting, and enforcement provisions as newly manufactured chemicals. While we teach our communities to reduce, reuse & recycle, this interpretation effectively discourages industry from doing the same thing, by subjecting us to complex, burdensome and unnecessary reporting.

While we understand the importance of environmental reporting, much of the data collected about byproducts under this interpretation of TSCA is already required by EPA under RCRA and EPCRA. We believe that EPA should set priorities and gather only the data that is needed for specific purposes and programs, instead of collecting vast data sets for undefined future uses.

It is critical that Congress reauthorize TSCA in a way that directs EPA to focus and prioritize its regulation of chemicals. Selection of priority chemicals should be based on sound science, not the latest headlines. Substances that exhibit the greatest hazards, such as those known to

cause cancer, developmental or reproductive harm, those that are persistent, or bioaccumulate in the environment, and those that pose the greatest exposure to consumers and their families, should be given priority for review, testing and, as necessary, regulation. A targeted, prioritized approach will allow EPA and the affected industries to more effectively use our resources to ensure the utmost protection of both human health and the environment.

EPA's Misguided Interpretation Requires the Reporting of Byproducts under TSCA Section 8

One example of EPA's failure to prioritize chemicals regulation is their treatment of byproducts reporting. While TSCA contains specific exemptions for byproducts, the EPA's interpretation and guidance has been so narrow as to effectively eliminate any meaningful distinction between products and byproducts. Under their interpretation of TSCA Section 8, EPA requires reporting of byproducts unless they are landfilled or treated as inert. Consequently, materials which are already regulated under the Resource Conservation and Recovery Act (RCRA), suddenly trigger reporting under TSCA, which was intended to regulate "new" chemicals. Under EPA implementation of Section 8, a byproduct sent for recycling is considered a new chemical, or "manufactured substance," unless its only commercial purpose is "use by public or private organizations that burn it as a fuel, dispose of it as a waste, or extract component chemical substances from it for commercial purposes."¹

Under the EPA TSCA Chemical Data Reporting Rule (CDR), byproducts sent for recycling must now be listed on the TSCA Inventory and are subject to the full regimen of TSCA recordkeeping, reporting, and enforcement provisions as newly manufactured chemicals. For byproducts, these TSCA reporting and recordkeeping requirements are in addition to and in some cases contradict RCRA and Emergency Planning and Community Right-to-Know Act (EPCRA) reporting and recordkeeping requirements. The TSCA requirements include new chemical notification and significant new use restrictions under Section 5, restrictions under Section 6, reporting obligations under Sections 8(a), 8(d), and 8(e), recordkeeping under Section 8(c), reporting obligations under Section 12(b), and associated penalties or enforcement provisions. If the byproducts are not listed on the Inventory, recycling cannot lawfully occur. I would point out that all of these regulatory obligations arise solely because a manufacturer is trying to do the right thing by sending the waste byproducts for recycling rather than disposing of them in a landfill.

Current EPA regulations exempt byproducts if the manufacturers' only commercial purpose is to "extract component chemical substances from it." EPA has narrowly interpreted this byproduct extraction exemption (without benefit of notice and comment rulemaking) to apply only if the extracted chemical component in the byproduct is removed through a process that does not involve a chemical reaction. This interpretation requires byproduct manufacturers, to have detailed knowledge, on the molecular and atomic level, of all chemical reactions that

¹ 40 C.F.R. § 720.30(g).

occur during the recycling process after it leaves their hands.

This narrow interpretation means that the recovery of any waste metals like gold, tin or copper that are dissolved in Viasystems' byproducts cannot be exempted as byproducts if they are recycled—because the only way to recover them is through a chemical reaction.

We were shocked to discover that the CDR rule published by EPA in 2011 impacts us and probably every member of IPC. We manufacture electronics, not chemicals. We responsibly use chemicals in the manufacture of our printed circuit boards, and are already subject to multiple regulations. We certainly did not consider ourselves to be chemical manufacturers and therefore subject to TSCA. IPC has vigorously opposed EPA's interpretation and engaged the Agency in multiple communications in order to convince them their interpretation would discourage and reduce recycling.

We are in the business of manufacturing printed circuit boards, not byproducts such as spent plating baths and wastewater treatment sludge. Under their interpretation, sending our waste byproducts for recycling would be considered by EPA to be the manufacturing of a new chemical for commercial purposes - subjecting us to registration and reporting of our waste byproducts under TSCA.

EPA's narrow interpretation bases the applicability of notification and reporting requirements on the recycler's actions, yet requires the byproduct manufacturer to make this determination. When the byproduct manufacturer sends the byproduct for recycling, the byproduct manufacturer does not have the information needed to determine regulatory applicability. The byproduct manufacturer is simply sending the byproduct for recycling.

EPA's over-reaching interpretation affects far more facilities and companies than those represented by IPC. Manufacturers of all sorts, from almost every manufacturing industry, will now be further burdened by reporting their waste byproducts as new chemicals.

TSCA Data Collection is Burdensome

Compliance with Section 8 recordkeeping and reporting requirements imposes a significant burden on manufacturers. General reporting requirements under Section 8 include the volume of each chemical that is "manufactured," providing data on the downstream processing and use of the chemical (or byproduct in our case), and identifying consumer and commercial uses of the chemical (byproduct in our case).

The reporting of byproducts as new chemicals under TSCA Section 8 requires us to have very detailed knowledge about what will be done with and to our byproducts by the recycler after those materials have left our possession. A typical circuit board factory uses over 20 different manufacturing processes and has some 75 individual chemical tanks or process baths. Many of these chemical baths are composed of many separate ingredients, many of which are

purchased from and proprietary to different suppliers, and each with its own material safety data sheet (MSDS). Many of these MSDSs identify between 3 and 6 separate chemical compounds in a single ingredient. So our database of chemicals contains well over 300 entries. In each of these process baths a number of chemical reactions occur, generating temporary byproducts that appear for an instant and disappear as well as the long-lived species we want to send for recycling.

In order to report completely under current TSCA regulations, for each byproduct that we intend to send for recycling, we need to identify all chemical compounds or substances generated in each process, determine whether any chemical reactions will occur during the recycling process, determine the quantity of any chemical component that will be reacted, and compare the quantities of the any reacting chemicals to the TSCA reporting thresholds.

Difficulties in Reporting Byproducts will affect the Quality of Data

EPA's interpretation of TSCA Section 8, as it pertains to byproducts, requires the byproduct manufacturer to understand and report based upon each of the specific chemical reactions that will occur during recycling. This information may be available to the recycler, however, the recycler usually considers it a trade secret and therefore withholds it from us. Furthermore, they may use different processes at different times to recycle our byproducts, and we would have no way to know it. Each different process they use results in the formation of different types and ratios of chemical substances that are beyond our knowledge or control. The result is regulatory policy that forces us to complete our EPA reports based on guesswork, ultimately compromising data quality.

TSCA originally only required the reporting of data that was known or "readily obtainable." This standard protected reporters from requirements to extort proprietary information from their recyclers, or to engage in extensive and costly analysis when it was unwarranted. It also helped ensure companies submit accurate and useful data. Under TSCA's revised reporting standard, all information considered "known or reasonably ascertainable by" a chemical user is required. This standard significantly alters the universe of data that must be submitted to EPA. Manufacturers are more likely to submit more data that is of lower quality because they must gather it from outside sources that may or may not be credible. Under this standard, the Agency is the ultimate subjective judge regarding what assumptions chemical users should or should not be making regarding how their chemicals react, what is being generated and how much, as well as what those users should or should not know about their recycled byproducts. The result is questionable data.

Review of the TSCA Inventory provides a further glimpse into the chaos. Some specific chemical compounds are listed 3 or 4 times under slightly different names. In addition, there are many listings for mixtures from specific processes —not named by chemical, but by the manufacturing process. This is because it is easier to file a Premanufacture Notice (PMN) for an entire mixture rather than it is to determine its exact composition. For example, the listing for

our wastewater treatment sludge, which was required before we can send it for recycling of valuable copper byproducts, allows us to just report the gross total of the sludge. Therefore, I am not required to distinguish copper species, but it calls into question the usefulness of data submitted to EPA. When EPA lifted the reporting exemption for inorganic substances in 2002, they knew that hundreds of inorganic substances were routinely used in commerce and not yet on the TSCA Inventory. At that time, many chemical users faced reporting requirements for every one of these substances as if they were newly developed chemicals. This required manufacturers to submit PMNs for placing the chemical substance on the Inventory which is a huge burden, particularly for small companies that have never considered themselves to be chemical manufacturers and might not have a technical staff or a laboratory.

Deterrent to Recycling

We are succeeding in teaching our communities that “reduce, reuse, & recycle” are national goals. By requiring reporting and recordkeeping of byproducts that are sent for recycling, EPA undercuts these important goals.

We simply want to recover, or sell to have others recover, as much as possible from our byproducts and waste streams. Over the years, industry has increasingly and appropriately developed recycling techniques to extract commercially valuable metals or other materials that previously were disposed of as waste. Such recycling practices have been encouraged by EPA as a means to reduce the quantity of waste generated, reduce the hazardous properties of such wastes when disposed of,² and “prevent pollution” as encouraged by Congressional policy underlying RCRA and the Pollution Prevention Act of 1990 (PPA).³ Industry recycling practices have enhanced human health and environmental protection, while stimulating the economy, by encouraging the economic savings created by well-managed recycling and pollution prevention management practices.

For many recycling operations, and especially those containing metals, extraction of valuable chemical components can only be achieved through chemical reaction processes. Thus, manufacturers sending their byproducts for recycling operations would not be exempted under current EPA interpretation. For example, chemical reactions are necessary to chemically reduce metal oxide pollution control dusts to metallic form, or when precipitation (*e.g.*, formation of an insoluble salt) is used to recover metals from a solution of soluble metal compounds in wastewater. In many cases, the metals extracted from these processes are very valuable. Recycling these metals allows reduced need for further mining of raw ore, which again,

² See the Sustainable Materials Management (SMM), <http://www.epa.gov/smm>, a voluntary effort implemented by EPA’s Office of Solid Waste and Emergency Response, the EPA office that implements RCRA.

³ 42 U.S.C. § 6901 *et seq.*; 42 U.S.C. § 13101 *et seq.*

supports the overall goal of sustainability.

We encourage Congress to directly exempt all byproducts, including those that are sent for recycling, in order to encourage material recovery and reuse thus furthering EPA's overall goals.

EPA Should Collect Only Necessary Data

For the first 25 years of the TSCA program, inorganic chemicals, including the valuable metal salts contained in our byproducts and waste byproduct streams were exempted from reporting because the risks from these chemicals were correctly assessed as being relatively low.

EPA should set priorities and gather data that is needed for specific purposes and programs, rather than request vast data sets from which the Agency may pick and choose pieces for undefined future uses.

Much of the data collected about byproducts is already required by EPA under RCRA and EPCRA. Furthermore, the Occupational Safety and Health Administration (OSHA) has their own exposure standards for known inorganic toxins. Viasystems already complies with these regulations. We believe that EPA's application of Section 8 reporting requirement to substances sent for recycling is duplicative of existing regulations.

For example, under EPCRA, the Toxics Release Inventory (TRI) program already requires manufactures to report chemical release data to EPA. The release data provided in the TRI program is very similar to that required under the CDR. The TRI program requires reporting on substances with presumed or established environmental, health, and safety risks. TSCA collects data on substances that may already have been reported through TRI.

Another example of duplicative reporting in the CDR rule is the requirement that manufacturers must report worker exposure data. OSHA collects extensive data on worker exposures through existing regulations and standards.

In the 2011 final *TSCA Inventory Update Reporting Modifications; Chemical Data Reporting Rule*, EPA indicated a willingness to reexamine the applicability of the CDR rule on byproducts sent for recycling based on the data received during the 2012 reporting cycle, stating,

“The Agency intends to examine the collected information related to byproducts, recognizing the importance of recycling, to identify whether there are segments of byproduct manufacturing for which EPA can determine that there is no need for the CDR information for the 2016 or other future reporting cycles.”⁴

⁴ 50832 Federal Register / Vol. 76, No. 158 / Tuesday, August 16, 2011 / Rules and Regulations.

We ask that EPA follow through on the commitment to analyze the collected notification and reporting data pertaining to byproducts sent for recycling from the 2012 CDR reporting cycle, and provide an explanation of how the data is being used, and a rationale for why this data continues to be needed.

Additional Issues of Concern

I would like to highlight a few other areas of concern to IPC members.

Preemption

We recognize that federal preemption is a challenging issue. As a practical matter, electronics companies cannot manufacture unique products for sale only in a particular state, nor do we or our customers down the supply chain sell products on a state-by-state basis. Unique state-specific chemical requirements are unworkable, so we urge Congress to protect interstate commerce which depends upon consistent regulation across all states.

Reporting of Transitory Substances

Whatever rule we end up with must retain strong provisions exempting the reporting of “transitory” substances. Appropriate regulatory controls must be focused on what is actually present in the materials being controlled at the time they might be exposed to the environment. We respectfully ask that temporary or transitory substances continue to be exempt from regulation. Industry is wasting time and resources in reporting about substances that have come and gone long by the time we are ready to send the byproducts for recycling.

Treatment of Articles under TSCA Reform Legislation

As a printed circuit board manufacturer, we rely on our chemical suppliers to provide us with materials that are safe for us to use and for the environment. We believe that the focus of TSCA should remain on ensuring the safety of chemicals in commerce and that regulation of chemicals in articles should be limited.

Treatment of articles under TSCA reform legislation should be required to be consistent with existing policy to focus resources on chemicals in articles that pose the most risk to human health and the environment. TSCA reform legislation should require EPA to focus on articles that consumers are most likely to be exposed to and the EPA should be required to prove the need to regulate chemicals in articles by providing adequate scientific evidence that action on the chemical or mixture alone is not sufficient to adequately address human health and environmental concerns. EPA should also be required to prove that the presence of the chemical in a specific article would significantly contribute to human health and environmental risks within the U.S. before adding to the regulatory maze that already exists.

Restrictions of Substances

The evaluation and prioritization of substances must be based on both hazard and exposure assessments in order to ensure a genuine benefit to human health and the environment. Hazard and exposure assessments are complimentary and must both be evaluated in order to ensure substances with the greatest impact are selected for further evaluation or restriction. Only by considering both the potential hazard of a substance and the potential for exposure can one properly understand the risk associated with the use of a substance. Consideration of both hazard and exposure when prioritizing substances will ensure that the substances selected for restriction will result in the largest possible reduction in risk to human health and the environment.

Further, EPA should not be given the authority to restrict or ban a substance based solely on hazard information or without fully evaluating viable alternatives. The decision to restrict or ban a substance should not be undertaken lightly. Electronics manufacturers use specific materials because of their unique properties including energy efficiency, safety or performance characteristics. Commitment of scarce societal resources must be guided by the best available science. Otherwise resources will be wasted and the environment and human health will suffer as resources are squandered pursuing goals that do not provide an environmental or health improvement over the status quo. Elimination of specific substances requires a great deal of research and development of alternative substances, requiring the investment of time and resources by electronics manufacturers including their entire supply chain from the mine to the maker of the latest mobile devices. Similarly, implementing and enforcing regulations requires significant investment by authorities. It is essential that any substance restrictions be supported by strong scientific evidence in order to accomplish the goal of maximum human health and environmental protection.

The restriction of substances prior to evaluating alternatives can result in unintended consequences, leading to a net effect of no increased environmental benefit or even worse, an outcome that harms the environment and human health. As an example of the importance of considering alternatives, following the restricted the use of lead in electronics under the European Union Restriction of Hazardous Substances in Electrical and Electronic Equipment (RoHS) Directive, the U.S. EPA conducted a lead-free solder study⁵ that evaluated the environmental impacts of tin-lead solder versus lead-free alternative solders. The study found that the increased energy use associated with the higher operating temperatures required for manufacturing lead-free soldered electronics would cause higher air pollution, acid rain, stream eutrophication and global warming impacts than tin-lead soldered electronics. EPA's study serves as an important reminder that there are environmental tradeoffs when substituting one substance for another.

⁵ U.S. Environmental Protection Agency, August 2007. Solder in Electronics: A life Cycle Assessment. Available at <http://www.epa.gov/dfe/pubs/solder/lea/lea-summ2.pdf>.

Lessons Learned from the EU REACH Regulation

TSCA reform should seek to maintain an efficient process for the assessment and management of chemicals that allows the chemicals industry to provide manufacturers of articles with the materials we need on a timely basis.

The European Union Registration, Evaluation and Authorization of Chemicals (REACH) regulation is arguably the most comprehensive chemicals regulation across the globe. A separate agency, the European Chemicals Agency (ECHA), was formed in order to implement and enforce the regulation. TSCA reform legislation should aim to leverage existing information already gathered under REACH rather than attempt to replicate it. Using information already gathered will help minimize duplicative efforts and efficiently manage chemicals.

Conclusion

IPC supports cost-effective, science-based environmental regulations. As I have discussed, it is critical that Congress reauthorize TSCA in a way that directs EPA to focus and prioritize its regulation of chemicals. We believe that EPA's reporting requirements for byproducts sent for recycling are burdensome and unnecessary, and serve to discourage recycling. Congress must encourage EPA to set priorities and gather only the data that is needed for specific purposes and programs.

Thank you again for the opportunity to appear before you today. I would be happy to answer any questions you have.

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Mr. SHIMKUS. Thank you, sir. Now the Chair recognizes Dr. Beth Bosley, President, Boron Specialties, on behalf of the Society of Chemical Manufacturers and Affiliates. You are recognized for 5 minutes. Welcome.

STATEMENT OF BETH D. BOSLEY

Ms. BOSLEY. Good morning, Chairman Shimkus, Ranking Member Tonko, and members of the subcommittee. I am pleased to testify—

Mr. SHIMKUS. Can you just pull that microphone just a little bit closer to you?

Ms. BOSLEY. There we go. I am pleased to testify once again on behalf of the Society of Chemical Manufacturers and Affiliates regarding TSCA today on Section 4 and Section 8. Just a background on SOCMA, over 80 percent of our members are small businesses. For example, my business just hired its eighth employee. Even with that small staff, we are committed to responsibly manufacturing our products here in the United States. We produce unique chemicals by novel manufacturing techniques that are used in the electronics, aerospace, and nuclear energy sectors.

SOCMA members' unique niche in the chemical industry is known for its innovation, entrepreneurship, and customer focus. I would like to begin by saying that SOCMA remains committed to strengthening TSCA, and appreciates the subcommittee's work in this aspect.

We should avoid approaches to TSCA reform that would treat the vast universe of TSCA chemicals like the far narrower universes of food additives, drugs, and pesticides. In particular, the sheer number of new chemicals that are submitted to EPA each year, and the evolving market needs, mean that use by use approvals make sense for drugs and pesticides will not work for industrial chemicals in general. A TSCA reform bill should be fundamentally risk based, as you have heard from other witnesses at the table, and it should require EPA to look at a chemical's inherent hazards, along with its exposures, when making regulatory decisions.

An improved Section 4 should be tiered, targeted, and risk based. Generally stated, the real problem with TSCA has been the treatment of existing chemicals. Section 4 gives the EPA authority to require testing of existing chemical substances and mixtures once certain criteria are met. In this section, that allows EPA to obtain measured data on existing chemicals of currently available data and experience, are insufficient to reasonably predict their effects.

The major shortcoming in this section is actually procedural. EPA is required to go through a rulemaking process, which has contributed to delays in EPA getting the data that they need. For example, EPA has taken years to finalize a number of high production volume chemical test rules, even though the industry has strongly supported such test rules. Voluntary efforts and enforceable consent agreements have helped streamline the testing process, but this section of TSCA could be strengthened by considering authorization for EPA to issue orders similar to the way it issues orders for new chemicals.

Any orders for testing approaches should be tiered and targeted. That is, they should start off at a screening level, and focus the

testing where the risk is greatest. A screening level analysis may show that hazard is sufficiently low that additional test data will not be necessary. The same goes for scenarios where exposures are highly unlikely. We support the notion that EPA should have to abide by basic standards of scientific quality, and specify in accepting screening and testing data. We also believe alternatives to animal testing should be supported, where they are sufficient validated.

The second major shortcoming of Section 4 is the lack of any requirement that EPA act on a specific number, or a percentage of existing chemicals, by any particular time. Congress should remove obstacles to more comprehensive EPA evaluation of inventory chemicals by mandating EPA to review a minimum number of chemicals annually via a risk-based prioritization process. We believe EPA has the expertise to do this. There are very talented scientist and engineers at EPA. Unfortunately, they don't have the resources to do that at this time. Reforms to Section 8 could give EPA a better understanding of the exposure scenarios and able it to prioritize more efficiently.

As mentioned above, testing of existing chemicals, should be tiered, targeted, and risk-based. Improvements to TSCA Section 8 could help EPA determine whether an existing chemical warrants testing. One way Section 8 could be improved is by requiring an inventory reset to ensure that the inventory of existing chemicals is current. This effort will also pare down the initial number of chemicals to be evaluated. It is a concept we have supported for many years, and believe it is a vital first step to a robust and efficient existing chemicals policy.

Another significant problem with Section 8 is that it does not authorize EPA to collect use or exposure information from anyone downstream of manufacturers or processors. The result is that, in many cases, manufacturers are forced to make educated guesses about the end use markets and exposure scenarios surrounding the use of their products. SOCMA would like to see an expansion of this section to allow collection of information from non-consumer downstream entities.

Finally, we urge you to amend Section 8(e) to authorize manufacturers, processors, and commercial downstream distributors and users to file reports with the EPA regarding non-adverse findings about chemicals. Currently there is no mechanism to report such non-adverse data. The result is that the public database on existing chemicals is unnecessarily limited and biased toward the bad news. With reasonable amendments, TSCA could provide an easier mechanism to submit such information.

As I conclude, it is important to mention that the Lautenberg-Vitter Chemical Safety Improvement Act introduced into the Senate last year is a remarkable example of well-reasoned bipartisan TSCA legislation, and we endorse it as a vehicle for reform. The subcommittee should be able to leverage much of the work done there, including the work on Sections 4 and 8. Thanks for this opportunity. I will be happy to answer any questions.

[The prepared statement of Ms. Bosley follows:]



Testimony
of
Dr. Beth D. Bosley

President
Boron Specialties

On behalf of the

Society of Chemical Manufacturers & Affiliates

Before the

U.S. House of Representatives

Energy and Commerce Committee
Subcommittee on Environment and the Economy

On

“Testing of Chemicals and Reporting and Retention of Information
under TSCA Sections 4 and 8”

February 4, 2014

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Good morning, Chairman Shimkus, Ranking Member Tonko, and members of the Subcommittee. My name is Beth Bosley, and I am the President of my company, Boron Specialties in Pittsburgh, Pennsylvania. I am pleased to testify before this subcommittee once again on behalf of the Society of Chemical Manufacturers and Affiliates (SOCMA) regarding the Toxic Substances Control Act (TSCA) – in this case, Sections 4 and 8.

SOCMA is the leading trade association representing the batch, custom, and specialty chemical industry. SOCMA's 200-plus member companies employ more than 100,000 workers across the country and produce some 50,000 products – valued at \$60 billion annually – that make our standard of living possible and contribute to the chemical industry's position as one of the nation's largest exporters.

SOCMA member companies produce chemicals that are used in thousands of products vital to consumers and US industry. Our members produce materials that allow the manufacture of life saving drugs, ensure an abundant and safe food supply, and enable the production of thousands of other products that are vital to the US economy, including international brands we all know. Over 80% of SOCMA's active members are small businesses, and many have very small staffs. For example, my company has just hired our eighth employee; we are committed to manufacturing our products in the US, and produce unique chemicals via novel manufacturing techniques that are used in the electronics, aerospace, and nuclear energy sectors. SOCMA members' unique niche in the chemical industry – specialty/batch manufacturing – is known for its innovation, entrepreneurship, and customer focus.

I would like to begin by saying that SOCMA remains committed to strengthening TSCA and appreciates the Subcommittee's continued work on the issue. Below, I will repeat SOCMA's basic principles for TSCA reauthorization. Then I will turn to the issues that are the specific focus of this hearing.

I. General comments on TSCA reform: Congress must update TSCA with carefully tailored fixes.

The fate of the TSCA reform effort is important to us, especially given the nature of our sector. As SOCMA has testified in the past, Congress should avoid emulating the Europe's Registration, Evaluation, and Assessment of Chemicals (REACH) process. REACH is currently the single largest trade barrier for Small to Medium-Sized Enterprises (SMEs) in the United States trying to export to the EU. An approach like REACH in the United States could devastate our members.

We should also avoid approaches that would treat the vast universe of TSCA chemicals and uses like the far narrower universes of food additives, drugs and pesticides. In particular, the sheer number of new chemicals that are submitted to EPA each year (roughly 20/week) and the constantly evolving universe of new uses mean that the detailed scrutiny and use-by-use approvals that make sense for food additives, drugs and pesticides will never work for industrial chemicals more generally. The new chemicals review process under Section 5, including the exemptions under that Section, has worked exceptionally well and should be maintained.



Finally, a TSCA reform bill should be fundamentally **risk-based**; it should require EPA to look at a chemical's inherent properties, or its hazards, along with its potential exposures when making regulatory decisions. That way, we can continue to innovate, create jobs and make our standard of living possible, while enhancing public confidence and protection of human health and the environment. This will also help ensure we avoid delays in getting low-risk chemicals to market and keep up with our customers' demands including those who formulate chemicals.

II. Updates to sections 4 and 8 should improve EPA's ability to attain a more complete picture of risk and expedite review of existing chemicals.

A. An improved Section 4 should be tiered, targeted and risk-based.

Generally stated, the real problem with TSCA has been the treatment of existing chemicals. These are chemicals that have been placed on the TSCA inventory and remain there, even if they are no longer in use at any given time. Section 4 gives EPA authority to require testing of existing chemical substances and mixtures once certain criteria are met. It is this section that allows EPA to obtain measured data on existing chemicals if currently available data and experience are insufficient to reasonably predict their effects.

The major shortcoming in this section is procedural. EPA is required to go through a rulemaking process, which has contributed to delays in EPA getting the data they need. For example, EPA has taken years to finalize a number of high production volume (HPV) chemical test rules, even though industry has strongly supported issuance of the rules. EPA has demonstrated some ability to implement this section more expeditiously, but has still ended up taking well over a year from proposed rule to final rule in all cases. Voluntary efforts and enforceable consent agreements (ECAs) have helped streamline the testing process, but this section of TSCA could be strengthened by considering authorization for EPA to issue orders.

In giving EPA such order authority, however, Congress should not authorize unnecessary blanket or one-size-fits-all testing requirements. Any testing approaches should be tiered and targeted. That is, they should start off at a screening level and focus on where exposures are most likely. A screening level analysis may show that the hazard is sufficiently low that additional test data will not be necessary. The same goes for scenarios where exposures are highly unlikely. In this connection, we support the notion that EPA should have to abide by basic standards of scientific quality in specifying and accepting screening and testing data – although we are also sensitive to concerns that the process of establishing those standards not unduly delay action under Section 4. We also believe alternatives to animal testing should be supported, where they have been sufficiently validated.

The second major shortcoming of Section 4 is the lack of any requirement that EPA act on any specific number or percentage of existing chemicals by any particular time. Absent such a mandate, EPA has allocated its resources to other, more pressing obligations. Congress should remove obstacles to more comprehensive EPA evaluation of inventory chemicals by mandating EPA to review a minimum number of chemicals annually via a risk-based prioritization process. We believe EPA has the expertise to do this (although it needs to be adequately resourced); we also believe EPA needs specific statutory direction to do so.

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B. Reforms to Section 8 could give EPA a better understanding of potential exposure scenarios and enable it to prioritize its resources and efforts where risks are highest

As mentioned above, testing of existing chemicals should be tiered, targeted and risk-based. Improvements to TSCA Section 8 could help EPA determine whether an existing chemical warrants testing. As I highlighted to this committee last June, EPA continues to improve its ability to collect information on chemicals under this authority, but more could be done.

One way Section 8 could be improved is by requiring an inventory reset to ensure that the inventory of existing chemicals is current. It could do so by placing chemicals in active and inactive buckets. This is a concept we have supported for many years and believe it is a vital first step in a robust and efficient existing chemicals policy.

Another significant problem with Section 8 is that it does not authorize EPA to collect use or exposure information from entities downstream of manufacturers and processors. The result is that, in many cases, manufacturers are forced to make educated guesses about the end use markets and exposure scenarios surrounding the use of their products. SOCMA would like to see an expansion of this section to allow collection of information from non-consumer downstream entities.

The onus under Section 8 has always been on manufacturers to obtain use and exposure data from their customers and other industrial or commercial downstream entities, even though such entities oftentimes do not want to share such proprietary market information. This is understandable -- no company wants to risk giving up its market to a potential competitor. But the consequence is an incomplete picture of a chemical's potential exposures, and hence its risks.

In principle, information should be sought from the entities in possession of the information. Downstream entities are naturally in a better position to provide information on the uses and exposure scenarios for the chemicals used in their plants. Such downstream entities could report directly to EPA to avoid the risks of promoting anticompetitive behavior or compromising Confidential Business Information (CBI).

Additionally, EPA should not necessarily be restricted in the purposes for which it uses information it collects, but it should be required to explain how it uses that information. The Subcommittee should explore with EPA ways to encourage greater sharing of use and exposure data where doing so does not raise antitrust concerns. EPA should be able to utilize more narrow approaches to requesting information, rather than relying solely on the broader chemical data reporting (CDR).

Finally, we urge you to amend Section 8(e) to authorize manufacturers, processors, and commercial downstream distributors and users to file reports with EPA regarding non-adverse findings regarding chemicals, whether gathered through research or anecdotally. Currently there is no mechanism to report such non-adverse data, and EPA resists companies making such "FYI" filings. The result is that the public database on existing chemicals is unnecessarily limited and

biased towards "bad news." With reasonable amendments, TSCA could provide an easier mechanism to submit such information -- and could require EPA to utilize it.

As I conclude, it is important to mention that the Lautenberg-Vitter Chemical Safety Improvement Act (S. 1009) introduced in the Senate last year is a remarkable example of well-reasoned, bipartisan TSCA legislation, and we endorse it as a vehicle for reform. The Subcommittee should be able to leverage much of the work done in there, including the work on sections 4 and 8.

I thank you for this opportunity to share with you our perspectives and I would be happy to answer your questions.



Mr. SHIMKUS. Thank you. And before I go to Dr. Willett, we did have Senator Vitter and the new co-sponsor, Senator Udall, here for a hearing on this bill, and we applaud their work, and look forward to building on that.

The chair now recognizes Dr. Catherine Willett, Director of Regulatory Toxicology Risk Assessment and Alternatives from The Humane Society of the United States of America. Welcome, and you are recognized for 5 minutes.

STATEMENT OF CATHERINE WILLETT

Ms. WILLETT. Thank you, Chairman Shimkus and Ranking Member—

Mr. SHIMKUS. Pull that mike just a little bit closer to you, because we want everyone to hear you.

Ms. WILLETT. OK. Thank you. Thank you, Chairman Shimkus, and Ranking Member Tonko, for the opportunity to testify on behalf of The Humane Society of the United States, the Humane Society Legislative Fund, two members of the Nation's largest animal protection organization. We strongly support animal protection, and also public health and environmental safety for the animals that are in our environment, and we believe that the Environmental Protection Agency should have the tools necessary to appropriately regulate chemicals in the United States.

I am excited to be here to discuss the opportunities for 21st century science to impact Section 4 of the Toxic Substances Control Act. I have been a bench scientist for 20 years, and some of those years I was a practicing toxicologist. For the past 7 years I have worked internationally on chemicals policy.

As mentioned by Chairman Upton, the science that underpins chemical characterization has undergone a radical transformation in recent years, as outlined in a 2007 report by the National Research Council, and which has also been taken up by EPA in their recent strategic plans. The report's conclusion is that reduced reliance on whole animal testing leads to a more relevant and efficient toxicity testing paradigm, resulting in increased protection for humans and the environment.

Rather than relying on a rote battery of animal tests, this new approach involves an iterative process of chemical characterization, toxicity testing, and extrapolation modeling, informed by population based data and human exposure information. This transformation is in response to challenges the EPA has experienced in obtaining data on the tens of thousands of chemicals to which people and the environment are potentially exposed, and in accommodating increasingly complex issues, for example, life stage susceptibility, the effect of mixtures, varying exposure scenarios, and cumulative risk.

Any effective modification of TSCA must allow for, and encourage, adoption of these evolving strategies. By articulating this in any legislative proposal, Congress will also send a strong message that more effective chemical regulation is dependent on more effective, and humane, chemicals testing. To do this, we urge Congress to be mindful of the following considerations. As also mentioned by Chairman Upton, computational cell and tissue based methods can now be used to prioritize chemicals, or groups of chemicals, that

are of primary concern. These methods can also be used to satisfy information needs in some cases for some chemicals. Further development and application of these methods for use in risk assessment should be encouraged.

Updated legislation should be flexible enough to allow the inclusion of new testing methods and strategies as they are developed. New legislation should provide EPA with significant commitment for creating the necessary infrastructure to do this. New legislation should also offer strong incentives for companies to fund, develop, and use new methods and testing strategies. And, as non-animal alternative methods become available, the use of such methods should be required in place of animal tests. We foresee a time when the principle of animal testing is a last resort.

Protecting human health and the environment is a critical goal of effective chemicals regulation. In order to achieve this goal, it is necessary for any new legislation to allow and support the continuing evolution of the science of chemical assessment. The Humane Society of the United States hopes that we will have the opportunity to work with you on any legislative language to reauthorize aspects, or the entirety of TSCA. Thank you very much.

[The prepared statement of Ms. Willett follows:]

TESTIMONY OF
THE HUMANE SOCIETY OF THE UNITED STATES and the
HUMANE SOCIETY LEGISLATIVE FUND

BEFORE THE
HOUSE COMMITTEE ON ENERGY AND COMMERCE
SUBCOMMITTEE ON ENVIRONMENT AND THE ECONOMY

ON ISSUES PERTAINING TO
REAUTHORIZING THE TOXIC SUBSTANCES CONTROL ACT
SECTION 4

FEBRUARY 4, 2014

Catherine Willett, PhD
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I. Introduction

Thank you Chairman Shimkus and Ranking Member Tonko for the opportunity to testify on behalf of The Humane Society of the United States (HSUS), the nation's largest animal protection organization, and the Humane Society Legislative Fund on Section 4 of the Toxic Substances Control Act (TSCA). We strongly support animal protection, public health and environmental safety for people and the animals in our environment and believe the Environmental Protection Agency should have the tools necessary to appropriately regulate chemicals in the United States.

The current law authorizing the EPA to regulate chemicals, the Toxic Substances Control Act (TSCA), enacted in 1976, has many shortcomings that have been extensively documented and have led to a chorus of disparate voices urgently calling for an update of this now 28 year-old legislation.¹ Our testimony focuses on one critical aspect of this reform: the process used to evaluate chemical safety in Section 4.

While estimates of the number of chemicals in commerce differ, there could be environmental exposure to anywhere between 10,000 and 100,000 chemicals. Understanding the potential health and environmental risks posed by chemicals currently in the environment, while ensuring new chemicals are safe for use, presents a monumental challenge. For ethical, scientific, and practical reasons, this challenge cannot be met using the current assessment approaches that rely heavily on animal testing.

The current TSCA Inventory contains approximately 80,000 chemicals; in order to review this

¹ Including several non-governmental organizations (<http://www.edf.org/health/policy/chemicals-policy-reform>; <http://www.saferchemicals.org/resources/tsc.html>), the Environmental Protection Agency (<http://www.epa.gov/oppt/existingchemicals/pubs/principles.html>), and the American Chemistry Council (<http://www.americanchemistry.com/Policy/Chemical-Safety/TSCA>).

number of chemicals over 10 years, the EPA would have to review approximately 6,000 – 8,000 chemicals each year (approximately 20 each day), at heavy expense to the taxpayer if current assessment approaches are used. Currently, the EPA's Office of Pollution, Prevention, and Toxics—the office that would be charged with implementing this legislation—reviews about 1000 pre-manufacture notices (PMN) each year² – review of existing chemicals would be in addition to these PMN reviews.

Evaluation of this tremendous backlog of existing chemicals, as well as the generation of robust information regarding new chemicals, is simply not feasible under the current toxicity testing paradigm used by the EPA and other regulatory agencies. This paradigm is largely based on experiments on animals, particularly rodents, rabbits, and dogs, and uses methods that were developed as long ago as the 1930s and 40s - tests that are time-consuming, expensive, and in some cases use thousands of animals apiece. For example, a single two-generation reproductive toxicity study requires a minimum \$380,000, 2,600 rats and two years to perform (data interpretation and regulatory decisions based on that information would involve additional costs).

According to EPA's 2009 Strategic Plan for Evaluating the Toxicity of Chemicals, the traditional approach of animal testing has "...led over time to a continual increase in the number of tests, cost of testing, use of laboratory animals, and time to develop and review the resulting data. Moreover, the application of current toxicity testing and risk assessment approaches to meet existing, and evolving, regulatory needs has encountered challenges in obtaining data on the tens of thousands of chemicals to which people are potentially exposed and in accommodating increasingly complex issues (e.g., lifestage susceptibility, mixtures, varying exposure scenarios, cumulative risk, understanding mechanisms of toxicity and their implications in assessing dose-

² <http://www.epa.gov/oppt/ar/2007-2008/reviewnewchem/index.htm>

response, and characterization of uncertainty).”³ There are simply not enough laboratories in the world to conduct all the testing required in a reasonable time- frame.

In addition, the current testing paradigm has a poor record of predicting effects in humans (Seidle and Stephens, 2009; Knight and Bailey 2006a, 2006b; Ennever and Lave, 2003; Olson et al., 2000) and an even poorer record of leading to actual regulation of hazardous chemicals (Seidle 2006).

In light of these concerns, the Environmental Protection Agency (EPA) realized that the current toxicity testing paradigm is in urgent need of overhaul and contracted with the National Academy of Sciences’ National Research Council (NRC) to assess the current system and recommend actions to improve it. The resulting report, “Toxicity Testing in the 21st Century: A Vision and Strategy” outlines a testing paradigm that, rather than relying on a battery of animal tests, envisions an iterative process of chemical characterization, toxicity testing, and dose-response and extrapolation modeling informed by population-based data and human exposure information (NRC 2007). The report calls for the development of a suite of human-based cell and tissue assays instead of whole-animal tests for hazard assessment and regulatory decision-making.

Not only would use of these new technologies increase the depth and breadth of information available about each chemical, they would dramatically decrease the time required to evaluate each substance. The result is that a vastly larger number of chemicals could be evaluated within a shorter period of time. This approach could also address currently intractable problems such as the toxic effects of chemical mixtures and nanoparticles, synergistic effects of chemicals,

³ The U.S. Environmental Protection Agency’s Strategic Plan for Evaluating the Toxicity of Chemicals, March 2009 (http://www.epa.gov/spc/toxicitytesting/docs/toxtest_strategy_032309.pdf)

susceptibility of sensitive sub-populations, sensitivity at different life stages, gene-environment interactions, the need to test the effects of chemicals over wider dose ranges, and the effects of chemicals at very low, environmentally relevant doses (Gibb 2008). The conclusion of the report is that the reduced reliance on whole-animal testing leads to a more human-relevant and efficient toxicity testing paradigm, resulting in increased protections for people and the environment.

II A Transformation in Chemical Safety Assessment is Underway

While the 2007 NRC report outlines a way forward that will take time to fully achieve, currently available methods and technologies can be applied to the prioritization of chemicals today (Andersen 2009). EPA Office of Research and Development is implementing the ToxCast Program that uses automated assays (called "high-throughput screening assays") to evaluate potential effects of chemicals on living cells and tissues.⁴ According to EPA, "These innovative methods have the potential to limit the number of required laboratory animal-based toxicity tests while quickly and efficiently screening large numbers of chemicals." EPA, along with NIH's National Chemical Genomics Center (NCGC) and the Food and Drug Administration are collaborating on Tox21 to use a collection of automated assays to "screen thousands of chemicals for potential toxicity, using screening data to predict the potential toxicity of chemicals and developing a cost-effective approach for prioritizing the thousands of chemicals that need toxicity testing."⁵ The FDA has partnered with the Defense Advanced Research Projects Agency to provide \$70 million in funding to develop human-based "organs-on-a-chip" that can be used to study chemical effects on organs and multi-organ systems.⁶ The sponsored work at the Wyss Institute at Harvard in Cambridge, MA, is proceeding much faster than

⁴ <http://www.epa.gov/ncct/toxcast/>

⁵ <http://epa.gov/ncct/Tox21/>

⁶ http://www.darpa.mil/Our_Work/DSO/Programs/Microphysiological_Systems.aspx

expected; they have developed functional lung and intestine micro-tissues and are working on several other organ types.⁷

EPA is developing methods to interpret the data to both prioritize chemicals and to profile each chemical with respect to its potential to cause toxicity (Sipes et al., 2013; Wambaugh et al., 2013; Wetmore et al, 2013). Currently this screening information is intended to be used to target further testing; however, it has the potential to identify the most potentially harmful chemicals and greatly improve the efficiency of their safety characterization (Cote et al., 2014).

These new technologies are elements of a predictive approach that involves combinations of several of these tools in an “integrated testing strategy” that, through combinatorial testing, provides toxicity information that can be used in making safety decisions about chemicals (Bradbury et al., 2004; Cooper et al., 2006; Becker et al., 2007). Used in isolation, these tools provide only part of the total picture. To increase confidence in the application of these tools in integrated strategies, the concept of biological pathways is critical. The 2007 NRC report mentioned above used this understanding to propose that toxicity can be more efficiently and accurately evaluated by probing networks of key biological pathways for their response to chemical disturbances (NRC, 2007). A normal pathway becomes what the NRC authors refer to as a “toxicity pathway” when it has been perturbed or disrupted to the point where it can no longer correct itself (also known as an “adverse outcome pathway;” Ankley et al., 2010). Information obtained using the tools described above can be used to test steps along the pathway to predict toxicity of a chemical. The pathway concept is relatively new, and most pathways are not yet well characterized. In addition, there are not yet non-animal tests for many steps in the pathways and therefore, in the near term, information requirements for chemical safety may

⁷ <http://wyss.harvard.edu/viewpage/100/biomimetic-microsystems>; Keynote talk at ASCCT 2013 Annual meeting.

involve animal testing. However, as the pathways become more well described, and assays developed to query critical steps in the pathways, reliance on animal testing will be reduced and eventually eliminated.

Many regulatory bodies around the world, including the US EPA, the European Commission's Joint Research Centre, and the Organization for Economic Coordination and Development (OECD), are developing pathways, guidance on harmonizing pathway development and documentation, and large complex databases to store the pathways and the relational information necessary to use the pathways for predicting toxicity (OECD, 2013).⁸

III. Relevant Principles from Existing Chemicals Legislation

Recent changes in chemical legislation in Europe, i.e. the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) regulation, has presented a similar challenge of scale (EC 2006). In an attempt to ensure that REACH is successful, European, American, and multi-national bodies such as the Organization for Economic Cooperation and Development (OECD) have drafted strategies to streamline toxicity testing and risk assessment. The REACH legislation also requires that animal tests be used only as a last resort, after all avenues to obtain the required information without animals (i.e. existing data, read-across from similar chemicals) have been exhausted.

In addition to the mandatory use of suitable non-animal testing methods, REACH includes:

- An emphasis on the acquisition and use of existing information
- Use of chemical categories with similar properties

⁸ <http://www.epa.gov/ord/priorities/docs/aop-wiki.pdf>; http://ihcp.jrc.ec.europa.eu/our_activities/alt-animal-testing-safety-assessment-chemicals/improved_safety_assessment_chemicals/adverse-outcome-pathways-aop

- Use of weight-of-evidence approaches
- Incorporation of non-guideline test results in weight-of-evidence approaches
- Criteria for identifying situations where testing is not feasible
- Exemption of chemicals with no exposure potential

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

IV. Common-sense guidelines for chemical prioritization

A first step in implementing updated TSCA regulations will be setting priorities for assessment and regulatory action. We suggest the following guidelines when determining how to set priorities:

1. Review of TSCA inventory: It is important to get a true picture of the chemicals currently manufactured or imported within the U.S., and the current and near future use and exposure patterns, in order to evaluate and prioritize information needs.
2. Tabulate and review all existing data: Companies should submit to the EPA all unpublished studies for manufactured or imported chemicals relating to physical-chemical properties, environmental dispersal, toxicity, and human and environmental exposure. The EPA should also gather information from other governmental bodies, such as Health and Environment Canada and the European Chemicals Agency, and solicit any additional information from public sources.
3. Make regulatory determinations where possible: Using available data, make determinations of safe use or put necessary risk management controls in place where

possible and warranted. Here, special emphasis should be placed on chemicals with known high exposure profiles or those with high potential to remain in the environment after an accidental release.

4. Group chemicals according to common modes of action or structural class: Assessing chemicals as members of scientifically-supported categories has several advantages, the strongest of which is that in some cases hazard information from one or more chemicals can be extrapolated to other members of the category lacking information. Methods mentioned in (5) can support the formation of categories, as can regulator or scientist experience.
5. Apply non-testing approaches (e.g. predictive computer programs), high-throughput and other non-animal tests to prioritize chemicals and design integrated strategies for further testing, if warranted. For some chemicals, cellular and computation methods can be used to fill information needs; in other cases these methods can be used to detect priority chemicals and endpoints that require further study.
6. Determine and fulfill information needs according to exposure: Prioritization should be based on potential risk, including potential exposure. For example, chemicals that are produced within a verified closed system may not need extensive hazard information. In addition, a data “gap” is not necessarily a data “need”, and the EPA should be given the flexibility to determine the information needed to make a regulatory decision without requiring a fixed list of data requirements that would apply comprehensively to all chemicals. Testing should be tailored to the chemical based on its toxicity profile and expected exposure. Testing beyond such a determination would waste time, money, and animal lives.

7. Prevent duplicative testing. Incentives should be provided to get companies to share data where appropriate, in order to prevent duplicative testing on the same chemical or category of chemicals.

V. Ensure Implementation of New Technology

The next decade will see extensive development of new high-throughput and high-content cell, tissue, and computer-based toxicity testing methods. Any effective modernization of TSCA must allow for and encourage adoption of this evolving technology. By providing legislative support to this effort as it modernizes TSCA, Congress will also send a strong message: that more effective chemical regulation is dependent on more effective and humane testing methods. To do this, we urge the Congress to be mindful of the following considerations:

1. The principle of animal testing as a “last resort” should be a foundation of US policy.
2. Computational, cell and tissue-based methods can be used now to prioritize chemicals or groups of chemicals that are of primary concern. These methods can also be used to satisfy information needs for some chemicals. Further development and application of these methods for use in risk assessment should be encouraged in the new legislation.
3. Updated legislation should be flexible enough to allow the inclusion of new testing methods and Integrated Testing Strategies as they are developed, and should not prescribe a minimum data set/check-list of toxicity tests to which all chemicals must be subject.
4. New legislation should provide EPA with significant funding and organizational support, guidelines for an efficient and flexible peer review process, and clear benchmarks of success, to ensure rapid implementation of better testing methods.

5. New legislation should offer strong incentives for companies to fund, develop, and use new methods and testing strategies; and, as non-animal/alternative methods become available, require the use of such methods in place of animal tests.

VI. Some Input Related to Section 4, S.1009, the Chemical Safety Improvement Act of 2013

On review of the Senate bill, there are provisions within S. 1009 that reduce animal testing and lead to more efficient assessment by the EPA, beginning with Section 2: Findings, Policy and Intent that states that EPA “should minimize the use of animal testing through the use of scientifically reliable and relevant test methods, where appropriate.”

Section 4: Chemical Assessment Framework; Prioritization Screening; Testing, includes a flexible framework that for thorough evaluation of all existing data is essential for designing an effective chemical assessment; it allows EPA to not only understand what is known, but to design a clear path to obtain the information that it needs to make a determination. This approach recognizes that not all chemicals are the same and assessments need to be tailored to the chemical and to the Agency’s needs. Importantly, this approach also allows a rapid identification of chemicals that are a high priority for assessment.

The framework outlined in Section 4 also emphasizes the need to collect and interpret mechanistic information – characterization of the mechanism of action of a chemical is fundamental to being able to make better predictions about its potential biological activities – and this is critical to improving risk assessment of all chemicals, but particularly of new chemicals.

In describing the conditions for developing new test data, Section 4 also includes options to minimize animal testing, including requiring an evaluation of all existing information before considering any new vertebrate testing, encouraging the use of scientifically reliable and relevant

alternative methods, and the use of a structured evaluation framework to focus testing where it is needed.

Section 4(i), "Reduction of Animal-based Testing," reinforces the use of integrated and tiered assessment strategies and the use of methods that replace or reduce the use of animals. It also provides for the development and use of non-animal methods by requiring EPA to develop a strategic plan for implementation that includes the development of pathway-based systems, computational and high-throughput tools. Finally, it authorizes the agency to fund and carry out research for development and translation of these tools. There is also a detailed provision in this section for waiving animal testing in certain circumstances.

V. Summary and Conclusion

As the NRC and EPA⁹ both state, advances in computational and cellular technologies will allow more predictive and protective toxicological assessments of chemicals than animal testing. While this vision is being progressively realized, existing methods and approaches can be used in addition to exposure variables, physical-chemical information, and existing knowledge to prioritize chemicals for regulation or further study.

Protecting human health and the environment is the critical goal of effective chemical regulation. In order to achieve this goal, it is necessary to reform chemical testing methods along with policy. The current toxicity-testing paradigm relies on animal testing and is slow, sometimes misleading, open to uncertainty and varying interpretation, and as a consequence of these factors, cannot adequately protect human health. Prioritization of chemicals and endpoints to be tested, based on potential for hazard and exposure, is essential in order to avoid

⁹ The U.S. Environmental Protection Agency's Strategic Plan for Evaluating the Toxicity of Chemicals, March 2009 (http://www.epa.gov/spc/toxicitytesting/docs/toxtest_strategy_032309.pdf).

unmanageable bottlenecks that would further stymie environmental protections.

While the language in Section 4 of S1009 falls short of implementing an overarching policy of animal testing as a last resort, we believe that it presents an improvement over the existing of the Toxic Substances Control Act by providing increased authority for EPA to request and use information to protect human and environmental health, while minimizing animal use by focusing testing where it is needed. In addition, by supporting new pathway and systems biology tools, these provisions also allow EPA to better implement its current shift from an imperial, animal-testing based assessment process, toward a more predictive process built on thorough understanding of chemistry and biology.

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Mr. SHIMKUS. Thank you. The Chair now recognizes Dr. Jennifer Sass, Senior Scientist, National Resources Defense Council. You are recognized for 5 minutes. Welcome.

STATEMENT OF JENNIFER SASS

Ms. SASS. Thank you very much, Chairman Shimkus, and Ranking Member——

Mr. SHIMKUS. Also, just pull that, there you go.

Ms. SASS. Closer? OK.

Mr. SHIMKUS. And if you can point the microphone to where your mouth is?

Ms. SASS. Nobody ever complains about not hearing me, so I want——

Mr. SHIMKUS. Well, our transcribist was freaking out over there, so——

Ms. SASS [continuing]. It on record. Thank you for the invitation to be here, and to testify on this very important issue. As Mr. Waxman stated in his opening comments, TSCA is a statute that has failed to protect the public, and that is certainly true of its provisions regarding testing and data collection, which we are here to discuss today. TSCA needlessly impedes the collection of such information, with predictable results.

In the wake of the recent spill in West Virginia, the impact of the information gaps in TSCA are more visible. The leaking of 4-methylcyclohexanemethanol, the MCHM, and other chemicals into the Elk River in West Virginia brought home, literally into peoples' homes, the disturbing reality that no useful information is available to the public, or those who serve them. In fact, a Pugh Health Group research fact sheet put out in 2010 found that roughly 3,000 chemicals used in over one million pounds annually in the U.S., these are the HPV, or high production volume chemicals, may have no information regarding potential developmental or pediatric toxicity. Nonetheless, over 700 of them are used in consumer products. CDC bio-monitoring has found over 200 synthetic chemicals in the blood and urine of Americans.

TSCA provisions set an excessively high bar that has effectively prevented EPA from getting information. First EPA must essentially prove that a chemical poses an unreasonable risk to health or the environment before it can require the needed testing that would show a potential risk. This is like requiring a doctor to prove that a patient has cancer before being able to order a biopsy. It is a catch-22 construction of EPA's testing authority that has greatly constrained the agency from getting data through testing in a timely manner. Second, to require testing of existing chemicals, EPA must complete a full formal rulemaking. Other programs, including the pesticide program, and even TSCA's new chemical program, instead allow EPA to require testing by issuing an order, which is a much more streamlined process.

As a result of these systems of hurdles and procedural hurdles, in the nearly 40 years since TSCA's enactment, EPA has required a full set of testing data on only a few hundred of the 62,000 grandfathered chemicals that came in under the law in 1976. The good news is that the flaws in Section 4 of TSCA can be resolved relatively easily by eliminating the catch-22 provisions of Section

4 and allowing the agency to require testing by order, rather than by rule, the bottleneck would largely be eliminated, and the agency would begin to get more information in a timely manner necessary to inform and protect the public.

The failure of TSCA, and the subsequent action at the State level to collect information, and to limit the use of harmful chemicals, has prompted renewed discussion of TSCA reform, which is useful, but the Chemical Safety Improvement Act, S 1009, as introduced will not solve the problems with current TSCA, and in some respects, will make things worse. The introduced bill would prevent EPA from requiring testing for a chemical until it has already been identified as a high priority substance. This essentially replicates the existing catch-22. EPA would generally need evidence of hazard or exposure for a chemical to be designated high priority in the first place. Although EPA would be allowed to require testing for high priority chemicals by order, the universe of potential chemicals for which EPA could require testing would likely be greatly reduced.

We also need more detailed use and exposure information for chemicals, as has been mentioned by other speakers, beyond what is currently captured in EPA's chemical data reporting rule. Unfortunately, the chemical industry has routinely failed to provide updated production use and exposure data, and strenuously resisted government action to collect it.

Various proposals have been made to reset the TSCA inventory as part of TSCA reform. If this is undertaken, Congress should not in any way delay efforts currently underway to take expedited action on substances, such as chemicals that are PBTs, the persistent bio-cumulative and toxic ones, or other chemicals for which we already have sufficient information to know that they are unsafe, or slow, for example, EPA's current efforts to review its work plan chemicals.

Second, if a substance is taken off the TSCA inventory, it should not be able to re-enter the inventory without going through a review process. A disturbing example is the firemaster 550, which ended up back in products, and in blood and breast milk. It is possible to have a balanced information regime that would protect the public, while helping industry by increasing public confidence in its products. The committee can play a critical role in this, and we are happy to work on that, but we are not there now.

Thank you.

[The prepared statement of Ms. Sass follows:]

Testimony of Jennifer Sass, Ph.D.
Senior Scientist, Natural Resources Defense Council and,
Professorial Lecturer, George Washington University
Washington, DC

On
Testing of Chemicals and Reporting and Retention of Information
under TSCA Sections 4 and 8

Before the Energy and Commerce Committee's
Subcommittee on Environment and the Economy
U.S. House of Representatives

Tuesday, February 4, 2014, at 10:00 a.m.
2123 Rayburn House Office Building

Chairman Shimkus, Ranking Member Tonko, members of the Committee, thank you for inviting me to testify today. I am Dr. Jennifer Sass, a Senior Scientist at the Natural Resources Defense Council (NRDC), and a Professional Lecturer at George Washington University, Department of Environmental and Occupational Health. NRDC appreciates this subcommittee's continuing series of hearings on the strengths and weaknesses of the current Toxic Substances Control Act (TSCA), and the search for ways to address its serious deficiencies. Today's hearing is on two sections of TSCA that are primarily focused on data and information, Section 4, which addresses the testing of chemical substances and mixtures and Section 8 which addresses the reporting and retention of information.

Testing and data collection are fundamental elements of any meaningful system to protect public health and the environment. To adequately assess the potential effects of a chemical, information is needed about its potential hazards. And to conduct a risk assessment of a particular chemical or mixture, or of class of chemicals, it is also necessary to have information about use and exposure.

More specifically, to ascertain the potential hazards of a chemical requires a basic set of data and information on a number of potential endpoints including:

- Chronic toxicity and disease outcomes
- Acute toxicity
- Environmental fate and effects
- Physical characteristics

And to ascertain the potential for exposure requires basic information and data about the chemical's physical properties and use patterns, including:

- Persistence in the environment
- Bioaccumulation
- Bioavailability

- ADME – once in the body, how the chemical is absorbed, distributed, metabolized, and excreted from the body
- Uses in commercial and consumer products
- Known and potential releases into the environment, including surrogate data like production volume

Current TSCA makes it very difficult for EPA to get such information for most chemicals. Unfortunately, the reform bill in the Senate, the Chemical Safety Improvement Act (S.1009), as introduced, will not solve the problems with current TSCA, and in some respects will make things worse. This Committee can play a critical role in removing the fetters that have prevented EPA and the public from obtaining the information needed to assess the safety of substances used in commerce.

The recent spill in West Virginia highlighted how important it is to ensure that information is available. The leaking of 4-methylcyclohexanemethanol (MCHM) and other chemicals into the Elk River in West Virginia brought home - literally into people's homes - some of the ways that timely access to updated and accurate information is a basic requirement for both informing and protecting the public. The Elk River spill presented an acute situation: the public drinking water supply for thousands of people was suddenly contaminated with a chemical about which virtually nothing was known, other than it smelled and tasted so badly that people found the water undrinkable in many cases. Contamination of a tap water supply – and of course the water was being used for drinking, cooking, bathing, laundry and other uses leading to direct skin contact and consumption – is one of the starkest situations any community may face. It was surprising to many people – and wholly unacceptable – that thousands of gallons of a hazardous chemical could be stored and spill upstream of a drinking water intake – and that there was essentially no useful information available for the public, drinking water system operators, state or

federal public health officials, or medical professionals and first responders, as to the safety or potential health and environmental effects of the substance.

But if we take a step back and consider the broken system of TSCA, the picture is even more disturbing: the truth is that we are routinely exposed to hundreds, even thousands of chemicals in our daily lives – even before we are born – in an infinite number of combinations and mixtures – and for most chemicals we do not have the information necessary to know whether or not those chemicals are safe. The lack of information – and lack of action at the federal level – has prompted numerous states to take the initiative and begin to obtain data on chemical hazards, uses and exposure pathways. Federal inertia is also in contrast to the system adopted in Europe that is now moving into a more mature phase of implementation and is serving as a model for businesses and governments around the world.

Section 4 of TSCA – Testing of Chemical Substances and Mixtures

Section 4 of TSCA is the source of EPA's authority to require chemical manufacturers and processors to conduct testing on a chemical substance. Unfortunately, in practice, the authority given to EPA has proven to be heavily constrained; the amount of information EPA has been able to obtain under Section 4 has been extremely limited. As with other sections of TSCA, this problem stems from both the substantive and procedural requirements EPA must meet before it can seek information.

For EPA to require testing of a chemical substance or mixture it must find either that A) the chemical “may present an unreasonable risk of injury to health or the environment” *and* there is insufficient data and experience with the chemical to reasonably determine or predict its effects on health or the environment, *and* testing is necessary to develop the needed data; OR B) that the chemical “is or will” be produced in substantial quantities *and* it enters or may reasonable be anticipated to enter the

environment in substantial quantities or there is or may be significant or substantial human exposure to the substance or mixture *and* that there are insufficient data and experience with the chemical to reasonably determine or predict its effects on health or the environment, *and* testing is necessary to develop the needed data.

Thus, TSCA creates multiple significant hurdles for EPA to obtain data on many chemicals. In the first place, EPA must essentially be able to prove that a chemical poses an unreasonable risk to health or the environment – based on either hazard or exposure information -- in order to get the data it needs to determine whether the substance poses that risk. This “Catch-22” construction of the EPA’s testing authority has greatly constrained EPA from being able to require testing more broadly. The second hurdle – the process one - is that EPA must conduct a formal notice and comment rulemaking (as well as an opportunity for a public hearing if requested) to be able to require chemical testing. Such rulemakings are extremely burdensome on agency resources, costing the agency much money and taking considerable time -- frequently years -- to prepare, propose and finalize -- all just to get the information needed to determine whether regulation is in order. As a result of these hurdles, in the nearly forty years of TSCA, EPA has required a full set of testing on only a few hundred chemicals of the 62,000 grandfathered under the law in 1976.

The good news is that the flaws in section 4 can be resolved relatively easily. By eliminating the “Catch-22” provisions of section 4, and allowing the agency to require testing by order rather than by rule – as is done under the pesticide program – the bottleneck would be largely fixed, and the agency would begin to get more of the information necessary to inform and protect the public. Another step would be to enable EPA to require minimum sets of information for chemicals or classes of chemicals. The agency should retain flexibility to increase or decrease the particular data requirements for a chemical or class,

but could more easily ensure that the basic information needed to do at least a screening-level assessment of chemicals is routinely produced.

These fixes would reduce the prospects for another embarrassment like West Virginia, where nobody has had a useful set of information about the hazard characteristics of the main chemical spilled. Unfortunately, the Senate bill to reform TSCA, as introduced, leaves EPA without the tools it needs to get information, even though some individual provisions are improved. The Chemical Safety Improvement Act (S.1009) as introduced does amend Section 4 to allow EPA to issue test orders in certain circumstances, and eliminates the general Catch-22 threshold requirements for EPA to show sufficient evidence of hazard or exposure. But the bill then erases the impact of those advances by eliminating EPA's current testing authority for the first, key step it creates in the process – deciding whether a substance is a high or low priority. That's a major problem because that priority designation effectively determines whether a chemical can be regulated at all under the bill.

To be designated a high priority substance under the introduced bill EPA must have evidence of hazard or exposure. (Lack of data can be a factor in designating a chemical high priority, but not the sole factor). But under the introduced bill, EPA has no authority whatsoever to get that information; it must rely on whatever industry submits voluntarily based on what they've already developed. In effect, the bill's provisions eliminate the existing Catch-22 only to replace it with a new one.

The Catch in the bill is especially serious because being designated "low priority" for assessment, would also mean that states would be preempted from taking action on those "low-priority" chemicals – and EPA itself would face new restrictions on obtaining or requiring additional information about the low-priority substances. The introduced bill appears to impose similar new constraints on EPA's ability to

require testing for new chemicals and to prevent new chemicals from entering commerce in the absence of fulfilling the requirements to provide the necessary data. Thus, under the introduced version of the CSIA, EPA would actually *lose* its existing authority to require testing by rule for non-prioritized existing chemicals and by administrative order for new chemicals. While a relatively small number of substances may already have enough hazard and exposure information in their profiles that EPA can begin working in earnest on them – like the eighty-three Workplan chemicals and presumably a larger universe of substances from which the eighty-three chemicals were selected – for a much larger universe of chemicals on the inventory, EPA may never have the authority necessary to obtain the information it needs to assess such chemicals.¹

Any reform legislation, including the CSIA, must ensure that EPA can obtain information without the long-standing barriers of the existing law, or new hoops and hurdles to replace the old ones.

Information needed to assess the potential hazards of chemicals

TSCA also needs to allow EPA to use its scientific expertise in determining the nature of what tests need to be used. While that discretion does not need to be entirely unconstrained, Congress should not try to bias the nature of testing or freeze in place the science of the moment. For example, over time the viability of non-animal test methods may improve. In some cases there are non-animal testing protocols that are already being effectively deployed, and in other cases animal tests are still the most reliable protocols. Lacking adequate chemical hazard information, neither government, industry, nor the public can make informed choices about how to manage potential risks. This is the situation we are in now,

¹ These problematic provisions are in addition to numerous other problems with the introduced version of the CSIA as outlined in testimony before this subcommittee from Andy Igrejas, Director of the Safer Chemicals Healthy Families coalition (<http://docs.house.gov/meetings/IF/IF18/20131113/101468/HHRG-113-IF18-Wstate-IgrejasA-20131113.pdf>) and from my NRDC colleague Daniel Rosenberg before the Senate Environment and Public Works Committee (<http://www.nrdc.org/health/drosenberg-131114.asp>).

where public trust in government is eroded, and its mistrust of the chemical industry is so low that it ranks 15th out of 18 business sectors; only mass media, banks, and financial firms are less trusted than the chemical industry, according to a 2013 survey reported in Chemical Week Magazine titled, “Who do you trust? Chemical makers forming poor bond with public”.² The article goes on to note that, *“Stakeholders are placing greater emphasis on engagement and integrity-based attributes, such as ... exhibiting ethical and transparent practices”*. A BASF spokesperson emphasized that, *“Ensuring safety, minimizing our environmental impact, and complying with all applicable laws and regulations are the only path[s] to earning and maintaining public trust”*. The status quo benefits no one.

The introduced version of the Chemical Safety Improvement Act takes an extreme approach in this area, imposing multiple redundant and confusing requirements on the agency, including several different frameworks, plus a slew of policies, procedures and guidance documents, all of which will slow any progress by EPA to less than a crawl – preventing EPA from getting through even the first step of prioritization for years. In addition, the CSIA imposes numerous requirements of science and methodology that, although supported by the chemical industry, are in conflict with the recommendations of the National Academy of Sciences. We understand efforts are underway to revise the introduced version of the CSIA to address these problems, and we look forward to reviewing those changes to ensure new and unnecessary burdens and approaches are not mandated.

Section 8: Reporting and Retention of Information

Section 8 contains several provisions which provide EPA with the authority to require some information reporting, or require the retention of records by manufacturers and processors.

² Chemical Week Magazine cover story. May 31, 2013. Robert Westervelt.
http://www.chemweek.com/sections/cover_story/Who-do-you-trust-Chemical-makers-forming-poor-bond-with-public_52450.html

Section 8 (a) authorizes EPA to issue rules requiring manufacturers and processors to maintain records and submit required information. It is under the authority of section 8(a) that EPA has periodically promulgated its Inventory Update Rule (IUR), renamed the Chemical Data Reporting rule (CDR) in 2011. EPA can also use its authority under section 8(a) to gather one-time snapshots of basic information regarding production, exposure and release from specific facilities for particular substances. EPA has a template form for these rulemakings, called Preliminary Assessment Information Rules (PAIR). At times, EPA has used section 8(a) rulemaking to obtain data necessary to meet the evidence thresholds for a Section 4 test rule.

Section 8(b) establishes the TSCA Inventory of chemicals that may be used in commerce. It is commonly estimated that there are currently roughly 84,000 chemicals on the TSCA inventory, comprised of the 62,000 substances grandfathered under the law, and the approximately 22,000 substances that have subsequently been added to the inventory through the new chemicals program.

Section 8(c) requires manufacturers and processors to retain records of “significant adverse reactions” to health or the environment that are alleged to be caused by the substance (or mixture) or its manufacturing, distribution or processing. These records are intended as an “early warning system” that a substance may pose an unanticipated health or environmental risk, for example harm to workers using the substance.

Section 8(d) authorizes EPA to require manufacturers, reporters and distributors to provide EPA with copies of health studies that they have conducted, know about or are ascertainable. Section 8(d) has also been used to gather information to support section 4 test rules.

Section 8(e) requires manufacturers, processors and distributors to inform EPA immediately after obtaining information which “reasonably supports” the conclusion that a substance or mixture presents a substantial risk of injury to health or the environment. EPA has received a significant number of 8(e) notices, and it has also taken enforcement action against parties who fail to provide EPA notice of substantial risk information as required. Unfortunately, much of what is provided to EPA under 8(e) is claimed as Confidential Business Information (CBI). As a result, the public can read summaries of studies finding that a particular chemical poses a substantial risk of injury to health or the environment but never find out what chemical poses the risk.

EPA has used these different provisions of Section 8 over the years to varying degrees, and they have varied in the amount of useful data they have yielded the agency. Besides its maintenance of the TSCA inventory and review of Section 8(e) notices, the most active area for the agency in recent years has been its revisions and implementation of the Chemical Data Reporting rule (CDR) under section 8(a). The CDR requires site-specific reporting on manufacturing and uses (at the industrial use category level) above a certain threshold. This birds-eye level snapshot of higher level production and importation of chemicals – which requires reporting electronically once every four years – is an important tool for EPA to prioritize chemicals for assessment purposes. For example, information on chemicals used in commercial and consumer products helped inform EPA’s selection of Work Plan chemicals. The CDR calls for a general level of reporting by manufacturers (and some processors) for chemical manufactured above a certain per site volume threshold. The most recent CDR rule expanded the amount of information to be reported in several important respects, and will ensure additional information is reported in the next reporting period in 2016. However, the reporting thresholds and other constraints limit the number of chemicals for which data is gathered to roughly 7,000 and provide only a general birds-eye view of exposure and use information for those substances. We need more

detailed use and exposure information for many more chemicals than are currently captured by the CDR.

Unfortunately, although the chemical industry insists that exposure data must be factored-in to any assessment or regulation of chemicals, it has also strenuously resisted action and advance on collecting even this general level of production, use and exposure information. And the introduced version of the CSIA appears to narrow the scope of EPA's authority under Section 8(a) in a manner that could fundamentally undercut the CDR. Whereas now the law authorizes requiring reporting of information "that the Administrator may reasonably require" the CSIA would only authorize reporting requirements "to the extent the Administrator determines the submission of reports is necessary for the effective enforcement of the Act." Narrowing the scope of EPA's existing authority under Section 8 is yet another step backward in the introduced bill that needs to be corrected and that any House-generated legislation should avoid.

One area of potential action for TSCA reform is the TSCA Inventory. Some industry representatives bristle at the 84,000 number that is generally used as the figure identifying the number of substances on the TSCA inventory because it is not necessarily reflective of the number of substances actually in use in commerce. The estimates of what the actual number might be vary fairly widely, even among industry representatives. Various proposals have been made to "re-set" the TSCA inventory as part of TSCA Reform, in part to provide a more "realistic" picture of the number of chemicals in commerce. Congress should hold firm to two principles about any "inventory reset" approach. First, such a process should not in any way delay efforts by EPA to take expedited action on substances such as PBTs for which we have sufficient information to know they are unsafe, or to slow the process generally contemplated in TSCA reform --and already underway for the Workplan Chemicals -- of EPA prioritizing,

assessing and (where necessary) regulating substances. Second, if a substance is taken off of the TSCA inventory because it is no longer in use, or has not been in use for a reasonable period of time, it should not be able to reenter the inventory without going through a thorough review process for health and environmental safety, including the development of a minimum set of data and information about the substance. Without such a limitation, previously used chemicals of unknown safety could re-enter the market without ensuring their safety – simply perpetuating the mistakes that have already been made under TSCA.

Generally speaking, any substance on the TSCA inventory can be manufactured or processed for any use, and in any amount, without requiring any reporting to, or registration with, EPA. This is a central reason why EPA and the public have so little idea of what chemicals are used in what amounts, for what purposes, and in what products. It is also a major reason why reporting, testing, assessment and regulation authorities need to be strengthened by Congress to inform and protect the public. Substances on the inventory – whether grandfathered “existing chemicals” or those approved in the new chemicals program based on particular assumptions about uses and production volumes may subsequently be adopted for other uses and at much higher production levels that greatly expand the potential for environmental or human exposure. One disturbing example that illustrates this fact is the persistent, bioaccumulative and toxic flame retardant Firemaster 550, promoted by its manufacturer as a “safe substitute” for certain PBDE flame retardants that were being phased out after they had been identified in the blood and breast milk of most Americans as well as wildlife at the North Pole. Now Firemaster 550 is being ubiquitously found in house dust and wildlife³. Some of the chemical components of Firemaster 550 had been on the TSCA inventory for decades before showing up in the mix of this particular flame retardant.

³ See http://articles.chicagotribune.com/2012-05-10/business/ct-met-flames-regulators-20120510_1_flame-retardants-ban-chemicals-chemical-safety-law

Finally, the identities of approximately 16,000 of the substances on the inventory have been classified as (CBI and are currently a secret kept from the American public, although a confidential inventory is not authorized under the Act. The TSCA inventory is supposed to inform the public about what chemicals are available for use in commerce. Allowing roughly 25% of the inventory to be kept secret fundamentally undermines the public right to know and needs to be addressed.

The Chemical Safety Improvement Act does contain provisions to “re-set” the TSCA inventory. We have some concerns about elements of the proposal as introduced, including its limitations on EPA’s ability to prioritize “inactive” or phased-out substances for assessment, and its unnecessarily cumbersome process for implementing a “reset” of the inventory.

Conclusion

TSCA has failed to provide the public and its representatives with adequate information about chemicals. Its failings stem from the basic structure of the law, many of them in Sections 4 and Section 8, which contain many of the Act’s testing and information provisions. Implementation issues, such as the unconstrained use of CBI, have made the problem even worse. At least in hindsight, the design of TSCA was almost guaranteed to limit the information and testing available about chemicals. Congress should not make the same mistake again by moving forward with the introduced version of the CSIA, which would leave EPA with even less ability to gain the information it needs and the public expects. It should be possible to come up with an information and testing regime in statute that is balanced and effective at protecting the public, while enabling the chemical industry to dissipate the cloud of suspicion that is growing around many of its products. But that will require learning from past mistakes.

Mr. SHIMKUS. Thank you. And last, but not least, we have Dr. Jerry Paulson, who is the chairperson of the Council on Environmental Health, Department of Federal Affairs, American Academy of Pediatrics. Sir, you are welcome, and you are recognized for 5 minutes.

STATEMENT OF JEROME PAULSON

Mr. PAULSON. Good morning, Chairman Shimkus, and Ranking Member Tonko, and members of the subcommittee. Thank you for this opportunity to testify today about the testing and data collection requirements under the Toxic Substances Control Act of 1976. I am Dr. Jerome Paulson, and I am here representing the American Academy of Pediatrics, a non-profit professional organization of 60,000 pediatricians dedicated to the health, safety, and well-being of infants, children, and adolescents. As mentioned, I currently serve as the chair of the AEP's council on environmental health. I will summarize my written statement, a full copy of which I have submitted for the record.

Chemical management reform is an important policy that uniquely impacts children's health. Children are not little adults. They have unique physiologic, behavioral, and developmental differences that amplify their exposure to chemicals in the environment. For example, infants may be exposed to contaminants in water used in formula preparation. Nobody else drinks formula. Toddlers engage in normal mouthing behaviors, where they put objects into their mouths, that may expose them to dangerous toxins. Children spend more time on the floor, or the ground, and come into more contact with contaminants on those surfaces. If we had kids in the hearing room today, they wouldn't be sitting on chairs.

U.S. Centers for Disease Control and Prevention researchers have found measurable levels of over 200 common industrial chemicals in body tissues and fluids of children of all ages, including cord blood. A number of hazardous chemicals also appear in breast milk. A substantial proportion, as Mr. Tonko mentioned, of chemicals known to have adverse, and mostly irreversible, effects on child health, such as lowering IQ, negative behavioral effects, and low birth weight, and reduced head circumference.

The safety testing requirements under Section 4 of TSCA are inadequate to protect children's health, and place too great a burden for safety testing on the public sector. Chemicals introduced into commerce when the law was enacted are subjected to scant oversight. For new chemicals, the process basically doesn't work, and unless this legislation is reformed, with the tens of thousands of chemicals in need of review, and the multi-year process for each undertaking, it would require many decades just to review high production volume chemicals. These flaws limit EPA's ability to protect the most vulnerable, including children and pregnant women, because the agency faces substantial barriers to obtain the information needed to make effective risk management decisions.

Under Section 8, TSCA has created a non-evidence based system for chemical management. Concerns about chemicals are permitted to be kept from the public. In their notifications to EPA, chemical companies may declare large amounts of information to be confidential business information. This broad exemption has effectively

prevented the Environmental Protection Agency from sharing information about potential hazardous chemicals with community groups, local and State governments, and other organizations. Certainly an effective management system must include greater transparency than currently exists.

Given the current urgent ongoing threat to children posed by chemical exposures, the American Academy of Pediatrics respectfully submits the following key recommendations for reforming the Toxic Substances Control Act. Under Section 4, manufacturers should be required to provide minimum data sets, with information that is relevant to the special needs of pregnant women and children regarding reproductive, developmental, neurodevelopmental toxicity, and endocrine disruption. Furthermore, EPA needs the flexibility to change data collection processes as new methodologies for testing become available.

Under Section 4, the EPA should have a simple process to require additional testing when information suggests the need, especially for chemicals associated with child populations. The CDC's bio-monitoring program must be expanded to serve as an early warning system for exposures. Aggregate and cumulative exposure concepts similar to those in the Food Quality Protection Act should be considered by EPA. Companies must develop public information documents for each new chemical marketed that utilizes lay language, and is updated regularly.

In conclusion, strong chemical management policy must integrate evidence-based decision-making for chemical use to adequately protect children, and other vulnerable populations from harm. The American Academy of Pediatrics looks forward to working with you to advance sound and protective chemical management policy during the 113th Congress. And I will be happy to entertain questions.

[The prepared statement of Mr. Paulson follows:]

American Academy
of Pediatrics



DEDICATED TO THE HEALTH OF ALL CHILDREN™

February 4, 2014

Testimony of
Jerome Paulson, MD, FAAP

On behalf of the
American Academy of Pediatrics

Before the
**House Energy and Commerce Subcommittee on the Environment and the
Economy**

**"Testing of Chemicals and Data Reporting of Information Under Toxic
Substances Control Act (TSCA) Sections 4 and 8."**

Jerome A. Paulson, MD, FAAP
American Academy of Pediatrics
"Testing of Chemicals and Data Reporting of Information under
Toxic Substances Control Act (TSCA) Sections 4 and 8"
February 4, 2014

Good morning Chairman Shimkus, Ranking Member Tonko, and other members of the Subcommittee on Environment and the Economy, and thank you for the opportunity to testify today about the testing and data collection requirements under the Toxic Substances Control Act of 1976 (TSCA) under Sections 4 and 8.

My name is Dr. Jerome Paulson; I am here representing the American Academy of Pediatrics (AAP), a non-profit professional organization of 60,000 primary care pediatricians, pediatric medical sub-specialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of infants, children, adolescents, and young adults. I currently serve as chair of the AAP's Council on Environmental Health.

In addition to my role within the AAP, I also serve as Director of the Mid-Atlantic Center for Children's Health and the Environment, this region's Pediatric Environmental Health Specialty Unit (PEHSU), housed at Children's National Medical Center. I am also a professor of pediatrics and of environmental and occupational health at George Washington University.

Chemical Management Reform Is an Important Child Health Policy Priority

Chemical management reform is an important policy that uniquely impacts child health. Children are not little adults. They have unique physiologic, behavioral, and developmental differences that amplify their exposure to environmental chemicals. Because children are smaller than adults, their surface area-to-body mass ratio is greater. Children eat more food and drink more water per unit of body weight than do adults. The respiratory minute ventilation—inspired air per unit time adjusting for weight—is greater in young children than in adultsⁱ.

As children grow and mature, their bodies may be especially vulnerable to certain chemical exposures during critical windows of development. For example, infants may be exposed to contaminants in water used in formula preparation and chemicals that may leech from bottles used during feeding. Toddlers engage in normal mouthing behaviors where they put foreign objects into their mouths that may expose them to dangerous toxins. Children of all ages spend more time on the floor or ground than do adults and come into more contact with contaminants on these surfacesⁱⁱ.

Not only do children have more opportunities to be exposed to environmental chemicals, extensive evidence supports a causal relationship between prenatal and childhood exposure to environmental chemicals and a variety of health effects in the fetus and the child.

Jerome A. Paulson, MD, FAAP

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A substantial proportion of chemicals are known to have a wide range of adverse – and mostly irreversible -- effects on child health. Metals such as lead, mercury, and arsenic can have negative developmental and behavioral effects at very low levels of exposure. Polychlorinated biphenyls exposure is associated with reduced intelligence. Prenatal exposures to phthalates and bisphenol A (BPA), used in plastics, cosmetics, and other household products, are associated with behavioral abnormalities. Prenatal exposure to brominated flame retardants can be linked to cognitive impairments, and prenatal exposure to perfluorinated chemicals used for nonstick pans has been linked to decreased infant birth weight and head circumference. U.S. Centers for Disease Control and Prevention (CDC) researchers have found measurable levels of over 200 common industrial chemicals in body tissues and fluids of children of all ages, including in cord blood. A number of hazardous chemicals also appear in breast milkⁱⁱⁱ.

Understanding children's unique susceptibility to chemical exposure and the lifelong health impacts, the AAP published a 2011 policy statement titled, *Chemical-Management Policy: Prioritizing Children's Health*, which calls for reform of TSCA, the primary federal law that governs chemical management in the United States. In addition, the American College of Obstetricians and Gynecologists, American Medical Association, American Public Health Association and American Nursing Association have endorsed the need for changes to TSCA.

Unfortunately, the law as written is not protective of the health of children and pregnant women and has not undergone any meaningful revision since its passage. Within nearly four decades, TSCA has been used to regulate only 5 chemicals or chemical classes: polychlorinated biphenyls; fully halogenated chloroflouroalkanes, dioxin, asbestos, and hexavalent chromium.

Each time one of these chemicals or classes of chemicals was regulated, it required Congress to specifically amend the legislation. The law as currently written does not allow the U.S. Environmental Protection Agency (EPA) to collect adequate data on safety to make regulatory decisions. As a result, there are tens of thousands of other chemicals in commerce where adequate information about health and safety is lacking.

The AAP's policy statement outlines an extensive set of concerns but consistent with the scope of today's hearing, my testimony will primarily focus on testing requirements and data collection and reporting.

Jerome A. Paulson, MD, FAAP
American Academy of Pediatrics
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Toxic Substances Control Act Section 4 Testing Requirements Are Inadequate.

The safety testing requirements under Section 4 of TSCA are inadequate to protect child health and place too great of a burden for safety testing on the public sector. Chemicals introduced into commerce when the law was enacted have little oversight because TSCA distinguished between chemicals in existence in 1976 and those introduced after the passage of the law. Those on the market decades ago were assumed to be relatively safe and in need of less testing than "new" chemicals. To pursue regulation of these "existing" chemicals, the EPA must demonstrate that a chemical has a high likelihood of causing harm before it can order testing to determine if there is a health risk. Between 1979 and 2005, the EPA has used its authority to require testing on fewer than 200 chemicals in commerce.^{iv}

The reason for this dearth of testing data from chemical companies to EPA on existing chemicals is directly tied to the inadequacies of Section 4 of TSCA. Section 4 directs the EPA to require chemical manufacturers and processors to conduct testing on existing chemicals under certain circumstances. EPA has the authority to do so when the manufacture, distribution, processing, use, or disposal of those chemicals may present an unreasonable risk of injury to health or the environment, or when those chemicals are produced in substantial quantities and there is a significant or substantial potential for environmental release or human exposure. Additionally, EPA must determine that existing data on the chemical are insufficient to predict the effects of human exposure and environmental releases, and that testing is necessary to develop such data^v.

This structure of Section 4 is fundamentally flawed because it significantly burdens EPA with requirements to adequately demonstrate the potential danger of a chemical to human health or the environment before it may move forward with compelling companies to conduct testing on these chemicals. In doing so, TSCA places the majority of the burden of obtaining information about the potential toxicity of a chemical on the public rather than the manufacturer. This limits EPA's ability to protect the most vulnerable, including children and pregnant women, because they face substantial barriers to obtaining the information they need to make effective risk management decisions.

An additional flaw that compounds these issues within Section 4 is that TSCA does not allow review of chemicals by group, instead requiring regulation on a chemical-by-chemical basis. With tens of thousands of chemicals in need of review and the multiyear process for each such undertaking, it would require many decades to review just the high-production chemicals. This compounds the inefficiencies of Section 4 and prevents the timely analysis of the safety of thousands of chemicals^{vi}.

Jerome A. Paulson, MD, FAAP
American Academy of Pediatrics
"Testing of Chemicals and Data Reporting of Information under
Toxic Substances Control Act (TSCA) Sections 4 and 8"
February 4, 2014

Toxic Substances Control Act Data Gathering and Reporting Standards Under Section 8 Need Reform.

Under TSCA Section 8, companies are required to keep a file of allegations of significant adverse reactions (to human health or the environment) of any chemical they manufacture, import, process or distribute. Companies must also provide this information to EPA upon request. Companies may be required to submit to EPA a list and/or copies of unpublished studies that address the health or safety issues of certain listed chemicals^{vii}.

Companies are under a duty to report to EPA within 30 days any new information they have which reasonably supports the conclusions that a substance or mixture they manufacture, import, process or distribute presents a substantial risk of injury to health or the environment. The law also requires that notices be submitted within 30 calendar days after obtaining information that a substance or mixture presents a substantial risk^{viii}.

TSCA has created a non-evidence-based system for chemical management. As a pediatrician, I can attest that parallels currently exist, such as within prescription drug regulation, which could provide guidance as to how EPA's authority could be strengthened with regard to data gathering and reporting.

Under current law, concerns about chemicals are permitted to be kept from the public. In their notifications to the EPA, chemical companies may declare large amounts of information to be confidential business information (CBI). This broad exemption has effectively prevented the EPA from sharing information about potentially hazardous chemicals with community groups, local and state governments and foreign governments or international organizations^{ix}.

Certainly, an effective management system must include greater transparency than what is currently in existence. There are many important regulatory practices that protect public health while supporting innovation, which could be incorporated into TSCA reform efforts.

Jerome A. Paulson, MD, FAAP
American Academy of Pediatrics
"Testing of Chemicals and Data Reporting of Information under
Toxic Substances Control Act (TSCA) Sections 4 and 8"
February 4, 2014

Recommendations for TSCA Reform.

Given the urgent and ongoing threat to child health posed by chemical exposures, the AAP respectfully submits the following key recommendations for reforming TSCA:

- 1) **Under Section 4, manufacturers should be required to provide minimum data sets that provide information that is relevant to the special needs of pregnant women and children and provide data on reproductive, developmental, neurodevelopmental toxicity and endocrine disruption. Furthermore, EPA needs the flexibility to change data collection processes as new methodologies for testing become available.**
- 2) **Under Section 4, the EPA should have a simple process to require additional testing when information suggests the need for such testing.**
- 3) **Federal biomonitoring programs such as the CDC's National Biomonitoring Program must be expanded. It is well recognized that this program provides secondary prevention, but it may serve as an early warning system. Stored samples may allow look-backs when new problems develop in the future.**
- 4) **When appropriate for hazard determination, there must be consideration of aggregate and cumulative exposure concepts similar to those of the Food Quality Protection Act (FQPA). For example, the law standardized and mandated a health-based standard for pesticides used in foods. It also provided special protections for babies and infants, streamlined the approval of safe pesticides, established incentives for the creation of safer pesticides, and required that pesticide registrations remain current.**
- 5) **Companies must develop a public information document for each new chemical marketed. This document should be in lay language and approved by EPA before the chemical is marketed. A companion document should be updated with each new formulation every three years.**

Conclusion.

In conclusion, strong chemical management policy must integrate evidence-based decision making for chemical use to adequately protect children and other vulnerable populations from harm.

Jerome A. Paulson, MD, FAAP

American Academy of Pediatrics

"Testing of Chemicals and Data Reporting of Information under
Toxic Substances Control Act (TSCA) Sections 4 and 8"

February 4, 2014

There have been a number of legislative proposals introduced to revise federal chemical management policy. It is important to note that while the AAP strongly supports bipartisan engagement within Congress to enact TSCA reform; the organization has not supported or endorsed the Chemical Safety Improvement Act of 2013.

The AAP looks forward to working with you to advance sound and protective chemical management policy during the 113th Congress. I welcome the opportunity to answer your questions.

ⁱ American Academy of Pediatrics, Council on Environmental Health. *Pediatric Environmental Health*, 3rd Edition. 2012.

ⁱⁱ American Academy of Pediatrics, Council on Environmental Health. Policy Statement: Chemical-Management Policy: Prioritizing Children's Health. *Pediatrics*. 2011; 127(5): 983-990.

ⁱⁱⁱ American Academy of Pediatrics. Toxic Chemicals: An Untested Threat to Child Health. Policy Brief. October 2013.

^{iv} American Academy of Pediatrics, *Pediatrics*. 2011; 127(5): 983-990.

^v Schierow, Linda-Jo. Congressional Research Service. The Toxic Substances Control Act (TSCA): A Summary of the Act and Its Major Requirements. February 23, 2011.

^{vi} American Academy of Pediatrics, *Pediatrics*. 2011; 127(5): 983-990.

^{vii} Schierow, Linda-Jo. Congressional Research Service. The Toxic Substances Control Act (TSCA): A Summary of the Act and Its Major Requirements. February 23, 2011.

^{viii} Ibid

^{ix} Gomeze, Alfredo. Chemical Regulation: Observations on the Toxic Substances Control Act and EPA Implementation. Testimony before the Subcommittee on Environment and the Economy, Committee on Energy and Commerce, House of Representatives. June 13, 2013.

Mr. SHIMKUS. Thank you very much. Now I would like to recognize myself for 5 minutes for the first round of, maybe the only round of, opening questions.

So my first one goes to Mr. Drevna. Section 8 contains regulatory exemptions, as currently written. Some of these are for polymers and naturally occurring substances. Would you have concerns if a TSCA reform would invalidate those practices?

Mr. DREVNA. Well, Mr. Chairman, I believe that Section 8 needs some reform, but I think there is a major misconception about, you know, what is out there, the 80,000 or so that some people say of chemicals that are out there, and really the 10,000 or so that are in commerce. So I think what Congress should do is direct the EPA to say, OK, this is what is out there, and what is out there has to be, as many of the witnesses have said, has to, you know, any regulation has to be tiered, targeted, and risk-based.

I believe, from hearing most of the witnesses here, if not all, but I think we all agree on it. I think it is what the definition of that is, and what the ultimate goal of the modernization of TSCA should be. So I think if we can agree on what is out there, allow EPA to do a tiered, targeted, risk-based approach, we can all get to the end goal here.

Mr. SHIMKUS. Thank you. Now, you know, we are not adversarial, so what I would like to do is try to get answers quickly. And it is a big panel, so this is for everyone on the panel, but for everyone to get through, please be as concise as possible. Does it make sense to have information quality standards for EPA to make decisions about chemicals? Mr. Drevna?

Mr. DREVNA. It makes sense for EPA to have the authority to find out what is out there, and, again, do the tiered, targeted, risk-based approach, and have the authority to do the testing—

Mr. SHIMKUS. Quickly.

Mr. DREVNA [continuing]. Get rid of Section 4, the risk assessment first. We agree to that.

Mr. SHIMKUS. Mr. Matthews?

Mr. MATTHEWS. It is always hard to argue with the notion that we should have quality standards in what EPA does. So, yes, we support EPA using the best available science and modern techniques.

Mr. SHIMKUS. Mr. Grazman?

Mr. GRAZMAN. Yes, sir, we agree with you too.

Mr. SHIMKUS. Thank you. Dr. Bosley?

Ms. BOSLEY. Yes, absolutely. Information quality is of utmost importance.

Mr. SHIMKUS. Dr. Willett?

Ms. WILLETT. Yes, and EPA and other regulatory agencies have some of these, but they might be improved.

Mr. SHIMKUS. Dr. Sass?

Ms. SASS. My concern about having them hardwired into the system, while I think everybody agrees in principle, I think the process that the agencies are taking now to develop those in a public and transparent way, with public comment, is the approach that should be taken.

Mr. SHIMKUS. Dr. Paulson?

Mr. PAULSON. Quality standards are important, but I don't think they should be in the legislation. The EPA needs the flexibility to change with time. And, as new technologies for chemical testing come on the market, they need to be able to respond to that.

Mr. SHIMKUS. And my next question follows along on that response. Should different standards apply to testing? Mr. Drevna?

Mr. DREVNA. Yes.

Mr. SHIMKUS. Thank you. Mr. Matthews?

Mr. MATTHEWS. Yes.

Mr. SHIMKUS. Grazman?

Mr. GRAZMAN. I have got to defer. We are manufacturers, not—

Mr. SHIMKUS. Right. Very good. Dr. Bosley?

Ms. BOSLEY. Sure, should be based on risk.

Mr. SHIMKUS. Dr. Willett?

Ms. WILLETT. I am not sure I understand the question, I am sorry.

Mr. SHIMKUS. Chemicals and processes are not all the same, so the question is should there be different standards applied, or should there be different standards to the level of risk-based chemical that might be out there?

Ms. WILLETT. Yes, I believe that is true, but I think I may tend to agree that it might not be a legislative issue.

Mr. SHIMKUS. Dr. Sass?

Ms. SASS. I think your question is about whether we should treat chemicals differently depending not only on their hazard, but also on their exposure. And while I agree that there is some intelligence to that, the concern is that we have very little exposure information, so there is a practicality that is lacking.

Mr. SHIMKUS. Thank you. Dr. Paulson?

Mr. PAULSON. Mr. Shimkus, here again I think the EPA needs to have some flexibility. For example, had we only used hazard information on the chemical that was spilled in West Virginia, which was an industrial chemical, never intended for human exposure, other than the workers, then that chemical would not be reviewed. But, in retrospect, we are obviously in a situation where we wish it had been. So the EPA needs some flexibility. And we know, with the current law, the legislation has boxed them in in such ways that they can't function. We should not repeat that.

Mr. SHIMKUS. Thank you. I am going to take prerogative for a last question to Dr. Grazman. You raised in your opening statement this issue about how current TSCA law inhibits the ability to recycle. Many of us are very concerned about recycling. Mr. Green's concerned about electronic recycling. Recycling is a good thing, not a bad thing. How does current TSCA law hurt recycling aspects?

Mr. GRAZMAN. So if I took the byproducts from—

Mr. SHIMKUS. Pull the mike close.

Mr. GRAZMAN. If we chose to just landfill, or get rid of the byproducts from our process, there is no TSCA obligation at all. When we choose to recycle, the TSCA obligations hit us in their full weight. So, all things being equal, sometimes it is easier not to recycle.

Mr. SHIMKUS. Thank you. We had that issue on ink and oil a couple Congresses ago, and the EPA kind of addressed it partially, but not fully, so that is an issue that we have raised in this committee before.

Thank you very much. Now I turn to the ranking member, Mr. Tonko, for 5 minutes.

Mr. TONKO. Thank you, Mr. Chair. This subcommittee has heard at previous hearings that EPA's ability to require testing of new and existing chemicals under TSCA has been dangerously limited. TSCA requires any company planning to manufacture or import a new chemical substance to submit what is called a pre-manufacture notice. It is supposed to include information such as the chemical identity, use, anticipated production volume, exposure and release information, existing available test data. According to EPA, 85 percent of the pre-manufacture notices that agencies receive are accompanied by no toxicity data whatsoever.

Dr. Sass, what kind of concerns does this raise for you?

Ms. SASS. Well, not having any information at all means that EPA doesn't know how to move forward. It means that EPA has very little power or ability to request that information. There are restraints and constraints put on EPA in order to move forward and collect that information. And I think it burdens the agency unnecessarily. I think the burden should be placed on the industry to provide the information that EPA needs to do risk assessment, but previous to that, do a proper hazard assessment.

Mr. TONKO. Thank you. For existing chemicals, Section 4 of TSCA requires EPA to show that a chemical poses an unreasonable risk before requiring additional testing. Dr. Paulson, how has this requirement helped to undermine the law?

Mr. PAULSON. This requirement basically has created the non-evidence based system that I referred to, and industry is basically penalized if they develop information in advance, because then they are required to report it to EPA, and that may adversely affect their bottom line. But with no reporting requirement, and then no ability to request information because you don't know there might be a problem, EPA is totally stymied.

Mr. TONKO. Thank you. With any reform, we must make sure EPA has adequate authority to require testing to protect human health and the environment. In the Senate there is a proposal to require EPA to categorize each chemical as either high priority or low priority. Under that proposal, EPA would be blocked from requiring testing on low priority substances.

My question, Dr. Sass, would that proposal increase testing of the chemicals we are exposed to every day, or would it make the problem worse?

Ms. SASS. I think it would make the problem worse. It would hamstring EPA. It adds an additional catch-22 to EPA, because it needs information to do an informed prioritization, and without that information, it may miss many chemicals that are very hazardous, and may be very important not only for hazard, but also for exposure. It would miss that information, and then it would not be allowed to go back and have the authority to review the low priority chemicals, and, furthermore, at the State level they may also be hampered. So those chemicals may actually slip through what

is not just a hole in the net, but really the whole net just doesn't exist because of those chemicals being able to fall through.

Mr. TONKO. OK. And, Dr. Paulson, what does the Academy of Pediatrics think about blocking EPA from requiring testing on these so-called low priority chemicals?

Mr. PAULSON. Mr. Tonko, there does need to be a prioritization system for sure, but the EPA needs flexibility to move chemicals around, and any a priori blocking of chemical evaluation would imply that we would never learn anything. So if some miracle occurred, and new information came, the EPA couldn't use that new information, so that just really makes no sense. We have waited 40 years to modify this law. We should not create more barriers with a new law that will take another 40 years to improve.

Mr. TONKO. Thank you. The recent West Virginia chemical spill has brought this debate to life in many ways. The chemical that spilled into the Elk River, spelled MCHM, was shrouded in mystery. State and Federal officials had to scramble to uncover the few health and safety tests that had been conducted on that chemical. Dr. Sass, how did the lack of health and safety data on MCHM hinder the CDC, and other officials, when responding to that chemical spill?

Ms. SASS. The data for those chemicals didn't come out for some time, and that created a concern, not only for public health officials at the State and local level, to be able to advise the community, and advise businesses about what to do, but also for the population as a whole, for citizens. The CDC was held back because it wasn't able to do the kinds of calculations and evaluations that it needs to provide informed and timely advice to the community. And, also, health officials and first responders weren't able to get information rapidly. They were having to advise and treat under a situation where they were essentially blindfolded because of that situation.

Mr. TONKO. Thank you. I see my time is exhausted, so I yield back.

Mr. SHIMKUS. The gentleman yields back his time.

The Chair now recognizes the chairman emeritus, Mr. Barton, from the great Republic of Texas, for 5 minutes.

Mr. BARTON. If only we were still a republic. You know, that is water under the bridge. Well, thank you, Mr. Chairman, and Ranking Member, for holding this hearing. I don't have too many questions. My first question would be to Mr. Drevna, and you might not know the answer. Do you know how many chemicals right now are in the TSCA inventory?

Mr. DREVNA. I am sorry, sir, I didn't hear you.

Mr. BARTON. Do you know how many chemicals right now are in the TSCA inventory? We talking hundreds of thousands, millions?

Mr. DREVNA. Eighty to 100,000, I would imagine, if not more.

Mr. BARTON. OK. Anybody dispute that? Do you know how many new ones are listed each year, approximately?

Mr. DREVNA. I don't know, 700,000? Not 700,000, 700 to 1,000, something like that.

Mr. BARTON. OK. I know this whole hearing is on testing and disclosure, and then we have the issue of the animal testing, but other than that, is there any major controversy on how these new chemicals are tested?

Mr. DREVNA. I believe that the testing for new chemicals is pretty well established. Much as I criticize the EPA, they have done a nice job, in my understanding, doing the new——

Mr. BARTON. OK, let us go to the young lady. What is your dispute with what Mr. Drevna just said about the——

Ms. SASS. There is very little testing done on new chemicals, so EPA has issued some test rules, but it has been on a very few number of chemicals. EPA is restrained in a number of ways from issuing those test rules. There is timing on those. There are authority limitations for EPA. There is the requirement that it needs to actually find some hazard before it can issue new test rules, that catch-22 that several witnesses, including myself, mentioned. So, actually, it has been very ineffective. There has been very few chemicals that have been tested.

Mr. BARTON. Now, is your complaint that the EPA has tended to engage in what we call a voluntary procedure, as opposed to the more complicated mandatory procedure? Is that a complaint, or——

Ms. SASS. Well, it is a complaint in where it hasn't worked. So there have been a number of voluntary initiatives that have been larger, and there has been some information that has been gathered from those, but not very much. So I would say that they haven't been effective overall, and there have been Congressional reviews that have shown that.

But at the chemical by chemical level, so as chemicals are coming through the program, mostly, instead of EPA issuing test rules, because they are very cumbersome, and because they can be challenged, the EPA tends to negotiate with the company about what test rules it will issue. I am not opposed to that, so I am not complaining about that process, except where it has held back on EPA from being able to issue the kind of test rules that it needs to make a proper hazard evaluation.

Mr. BARTON. Dr. Paulson, you raised your hand.

Mr. PAULSON. I think that the voluntary programs have been ineffective. They have produced very little in the way of new information. The current legislation, and the judicial interpretation of that legislation, effectively block the EPA's ability to ask companies for toxicologic information on the chemicals that they are introducing into the market. And that results in playing catch up, where years later individual scientists at universities do studies, and, lo and behold, we find chemicals in human bodies that were never intended to be in human bodies, and we find that those chemicals have adverse effects on those human bodies. There are just numerous examples of that.

Mr. BARTON. Give me one example.

Mr. PAULSON. Brominated flame retardants, perfluorinated chemicals, of which Teflon is one brand name. Those are two examples.

Mr. BARTON. And those chemicals were improperly tested, or improperly used, or illegally used?

Mr. PAULSON. None of the above, sir. They weren't adequately tested before they were marketed. They were used in ways that, presumably, industry thought was safe because they themselves did not have the data to indicate that they were getting into human bodies until later. And they didn't have the data that they were harming human bodies until later. So I am not suggesting

any malfeasance here, it is just that, unless we develop the data before the chemicals come on the market, we are always subject to playing catch up.

Mr. BARTON. My time did expire, and I want to thank the panel.

Mr. SHIMKUS. I want to thank my colleague. I just want to just follow up real quick on one of the answers. It is my understanding the burden of proof is in Section 4, not Section 5, so we have got to be careful that we are conflating the authority under this law. That is why, going through this legislative process and our hearing is going to be very difficult, because we found that this language is very tough. So, with that, I would like to yield to my colleague, Mr. Green from Texas, for 5 minutes.

Mr. GREEN. Thank you, Mr. Chairman, and I appreciate your interest in e-waste, and hopefully we can have a legislative hearing sometime so we can—

Mr. SHIMKUS. I am sorry, I am not hearing you.

Mr. GREEN. I am sorry. I can't imagine how hard it was in 1976 for Congress to do TSCA, and that is probably why, for the last 38 years, it hasn't been revisited, because of the complexity of it. My first question is, before a company introduces something into a product, should there be some minimum level of due diligence? Because, Dr. Paulson, you talked about, the companies don't know. Should there be some type of due diligence by that company, just to make sure that, both for the folks producing that product, but also for the consumers, that they should have that due diligence on the toxicity of that product?

Mr. PAULSON. Yes, sir, that should be the basic function of any chemicals management policy, and we don't have that now.

Mr. GREEN. OK. We heard testimony today about how difficult it is for EPA to make the required findings to require the generation of additional information on chemicals under existing provision Section 4. What additional authority should EPA have to mandate the testing? Like you said, maybe we ought to say there is a requirement by a company to do some basic due diligence, and then EPA should have the authority to ask for that information?

Mr. PAULSON. Companies should be required to release information to EPA. EPA should not have to ask for it. It should be part of the process before a chemical goes on the market that information goes to EPA. EPA is then able to evaluate that information, and make a decision. We also have to recognize that, even under the best of all possible circumstances, chemicals will receive approval that later turn out to be problematic, so EPA needs a mechanism to require companies to do post-market surveillance, provide the information on post-market surveillance—

Mr. GREEN. I understand that, and I have heard that, you know, in any given day or week, at least in the last 38 years, how many different chemical substances have been entered into the market? Now, somewhere along the way, you know, if we have literally thousands of companies, and for them to give that information to EPA, and then to empower EPA to then go forward, I agree that, you know, EPA should have the authority to request that information and those testing levels. But I am just wondering, you know, how big EPA would have to be to be able to deal with the complexities of the market now. And I know, from our manufacturers and

our specialty companies, it has got to be huge numbers of chemicals that are developed literally almost every day. Can you all just give us an idea on that?

Ms. BOSLEY. Well, EPA looks at 20 chemicals a week, 20 new chemicals a week. That is their statistics. And beyond that, industry develops other chemicals that don't go forward, certainly. But the resources EPA needs to look at new chemicals are very different than what they have been given to look at existing chemicals. They have no mandate, really, to look at existing chemicals, and, therefore, that is not where the resources are spent.

Mr. GREEN. Well, and that is part of our concern. I want to make sure, you know, our lifestyle has been built over the use of these chemicals. And granted there are times, for example, in West Virginia that nobody knew about that chemical. Even the first responders didn't know how to deal with it. So we need to deal with those, and that's the job of our subcommittee, to come up with something that will do that. Drevna?

Mr. DREVNA. Mr. Green, you are right. The thing about Section 4, which we agree, to an extent, that the finding requirement should be eliminated, but the hazard requirement should stay. So, I mean, you could, in essence, limit the number of chemicals that have to be looked at if you grant EPA the authority for testing, but they have to still have a component of that that says, wait a minute, there is a need out there for an exposure and a hazard requirement. So that would go a long way to remedying the situation.

And, I mean, there have been criticisms of TSCA because it inhibits the EPA from collecting information, but there are other statutes that come into play too. Administrative Procedures Act, things like that. So look at it holistically also. And, you are right, though, Mr. Green, we have got so many, you know, large volume chemicals that they are intermediates, that never really see the market.

Mr. GREEN. And, Chairman, I know I am almost out of time, but also the low priority and high priority, obviously something that is exposed vulnerable populations, should be a higher priority even, you know, and so there is a way, I think we can draft this, but it is not going to be easy, any more than it was in 1976. So thank you, Mr. Chairman.

Mr. SHIMKUS. The gentleman's time has expired. The Chair now recognizes the gentleman from Pennsylvania, Mr. Murphy, for 5 minutes.

Mr. MURPHY. Thank you. I appreciate this panel. We are learning a lot from all of you here. Mr. Drevna and Mr. Matthews, I think, Dr. Grazman, you may have talked about this too, about this whole prioritization process, how it works. And I believe, Mr. Drevna, in your testimony you wrote that there was not 80,000 chemicals, am I correct that was in yours, and there are really only about 10,000? How do we prioritize the safety of these in making some determinations? How do we set these rules up? All of our concern is that which is not forbidden is permitted, or that which is permitted is not forbidden, and we want to make sure we do this right. How would you recommend wording of this work?

Mr. DREVNA. Well, I will go back to what I said earlier, Congressman Murphy, tiered, targeted, and risk-based. If you give EPA

the authority through statute to use that kind of mentality when addressing whatever chemical it is, whether it is a high volume chemical, or whether it is something that is, you know, a daily household product, if you do it tiered, targeted, and risk-based, and understand what, you know, what the hazards are, what the toxicity is, what the exposure is, and that will go a long way to giving EPA the right tools to address the situation.

Mr. MURPHY. OK. Mr. Matthews, do you have anything to add?

Mr. MATTHEWS. Well, I appreciate the doctor.

Mr. MURPHY. We didn't want to write "doctor."

Mr. MATTHEWS. Well, we agree, but let us be clear, the impression shouldn't be formed that there isn't substantial information on a lot of these chemicals that are in commerce, including existing chemicals, not just new chemicals. EPA has substantial information. It allows it to start to make some judgments about which are the chemicals that should be first put through a screening process, part of prioritization. What we have said is, they have substantial information, but they are missing a key component, and that is the use and exposure related information. So we think that EPA can do a proper screening process, even of the tens of thousands of chemicals that are already out in the marketplace. They need to do that. Make no mistake, this can't be done overnight. The numbers we are talking about are substantial. But, in order to get to the right choices first, they need not only the information they have historically been receiving, but additional use and exposure information, and start the process of getting through these existing chemicals that have been on the market.

Mr. MURPHY. Thank you. And, Dr. Bosley, can you explain the importance of how you protect the chemical identity of information that is submitted to EPA's—

Ms. BOSLEY. Certainly. So we in the chemical industry, first and foremost, not one of us wants our chemical to cause harm to human health or the environment. By the same token, we live in the market reality, and we are faced with competitors every day. For instance, my company, very, very small. My competitors all know who I am. If I were to submit something to EPA with the chemical identity revealed, they would know immediately what sort of research I was doing, and, because my markets are so limited, they would know exactly where that end market would be. So it is not that I want to hide any hazard information that I have. I don't. I want to send that all out, but I would like to keep my chemical ID confidential. As long as there is a robust generic name, such that the public, the NGOs, and the EPA can all see what the generic name, and what the hazard is.

Mr. MURPHY. Thank you. Dr. Sass, I believe you, if I am correct, are recommending we adopt some of the standards the Reach program has in Europe. Do you think that would be more effective for us to do that?

Ms. SASS. That wasn't in my testimony. Is that your question?

Mr. MURPHY. Yes, that is my question. Do you think that would be—

Ms. SASS. Do I think it would be more effective? Well, I do think it would be more effective to have harmonization, and the other speakers have also mentioned that. I mean, having a patchwork

approach across continents, across countries, across States, isn't any good for anybody. And I do think that the approach we should use should be the highest bar to protect human health and the environment. I think that not only saves costs and liabilities for the producers, manufacturers, users, and retailers, but also insurers in the healthcare. So, I mean, the difference between having a cancer and treating it, and never having had the cancer in the first place is huge, not only on personal cost, but on economic cost. So I think everybody has an interest in preventing problems. I think everybody agrees to that. The difference is how we are going to address them, and at what stage we are going to address them.

So I would support a system that would give the regulatory agencies the authorities not only to have early comprehensive and timely testing, but to make decisions on what they have. Some of the other speakers have mentioned, and I agree, that we have substantial data on a number of chemicals, and I think we can take action on those.

Mr. MURPHY. I know we are almost out of time, but, Dr. Bosley, I would like you to submit also your responses to that, in terms of how the Reach requirements would contribute, being a big trade barrier for the United States.

I am going to also add this too. I was recently meeting with a company in my district, Halgon Carbon. This little bottle of granulated activated carbon is what is used in many cases to clean up some of these chemical aspects. One gram of this, and there are about five grams in a pack of sugar, has more surface area than a football field. And I would hope that, as we are looking at these TSCA issues too, that we include in the whole package of analysis here not only what are the toxic levels in some of these chemicals, but also the cleanup process that would mitigate these things is a critically important part, by which we take a chemical of concern to a chemical of safety.

And with that I yield back, Mr. Chairman.

Mr. SHIMKUS. The gentleman yields back the time. The Chair now recognizes the ranking member of the full committee, Mr. Waxman, for 5 minutes.

Mr. WAXMAN. Thank you, Mr. Chairman. A number of today's witnesses have testified in support of a risk-based approach to chemical regulation, and I would like to explore this topic.

Dr. Sass, I would like to see if you could help us understand what a risk-based approach means. To understand the risk a chemical poses, EPA would have to need information on both the hazard the chemical presents, as well as information about exposure. Can you tell us what information EPA would need to implement a risk-based system that the American people can have faith in?

Ms. SASS. Well, sure. So EPA already does conduct risk assessments on chemicals, and that means that it has both how bad the chemical is, the hazard information, and what are the chances, or probabilities, that you are going to be exposed to it, the exposure information, and that is important. But, earlier than that, EPA has to be able to collect both those sets of information, and what this is trying to get at is hazard. It is important to separate those out, because later, when you make risk management decisions, they will take into account exposure as well.

But, at this stage, doing a hazard assessment, it is critical to focus on the hazard only. There are a number of reasons why. For one thing, we have more of that data than we do about exposure information. Exposure information is very, very expensive, and difficult to get. I wish that the chemical industry could give us the kind of exposure information that they have all testified that EPA should have. But it is——

Mr. WAXMAN. Well, without this information, we wouldn't be able to understand the risk a chemical presents, is that what you are saying?

Ms. SASS. That is right. Half the equation would be gone. We don't have that information.

Mr. WAXMAN. Dr. Paulson, do you agree?

Mr. PAULSON. Yes, Mr. Waxman.

Mr. WAXMAN. I would like to turn to Mr. Drevna. In your testimony, you suggested EPA should first make screening decisions. That is, EPA should determine whether a chemical should be a high priority or a low priority based on existing information about what you describe as "potential hazards and exposures". Are you recommending that EPA make decisions without having actual information about hazards and exposures?

Mr. DREVNA. No, sir, not at all. We are recommending——

Mr. WAXMAN. Is your mike on there?

Mr. DREVNA. Yes, it was.

Mr. WAXMAN. OK.

Mr. DREVNA. No, sir, not at all. We are recommending that, you know, you can adopt a system, like the Canadians have adopted, where you can have, you know, you rank chemicals, you understand the molecular structure to most of them, you know, and you can use current technologies to figure out, you know, rank them, do the exposures. We are recommending that EPA have the authority to ask for exposures under a new Section 8(a), you see in my testimony. Absolutely, no, we are recommending that——

Mr. WAXMAN. I appreciate that. So under the Senate proposal, the screening level decision would be a very important one, because once a chemical is designated as a low priority, the chemical is shielded from further study and review. Dr. Sass and Dr. Paulson, is there sufficient existing information in most cases for EPA to determine that chemicals are low priority, and shouldn't be subject to any further scrutiny?

Ms. SASS. No, that concerns me. Determining something is a low priority, or not hazard, should be a very high bar. For example, the International Agency for Research on Cancer under the World Health Organization has, I think, only one or two chemicals in that category. It should be a very high bar to actually put something aside and not look at it anymore from a public health and environmental protection perspective.

Mr. WAXMAN. Is there sufficient information?

Ms. SASS. Without sufficient information.

Mr. WAXMAN. Dr. Paulson?

Mr. PAULSON. No, sir. I think, particularly for new chemicals, by definition, there is not sufficient exposure information.

Mr. WAXMAN. Um-hum.

Mr. PAULSON. And even for chemicals that have been around for a number of years, there may not be bio-monitoring methodologies that are available. There may not be methodologies for measuring those chemicals in soil, or other organisms besides humans. So, as Dr. Sass mentioned, exposure information is often extremely limited.

Mr. WAXMAN. OK. Well, in Mr. Grazman's testimony, he objects to EPA collecting certain information. For example, he objects to the collection of information about worker exposure. He also seems to object to reporting about the volume of each chemical that is manufactured, and the consumer and commercial uses of chemicals. Dr. Sass, this seems like important information for understanding exposure. Can EPA evaluate exposure, and therefore risk, if it doesn't have information on how chemicals are used, and how exposure might occur?

Ms. SASS. You know, Mr. Waxman, you are exactly right. EPA needs much more use and production, and also downstream use information, and it needs to be able to update that information in a timely manner as that chemical travels through commerce, and has different—

Mr. WAXMAN. If we want EPA to make good decisions, then that means we don't want them guessing. That means you can't have both a risk-based system, and an unwillingness to provide EPA with adequate information, is that your—

Ms. SASS. That is correct. I agree.

Mr. WAXMAN. And Dr. Paulson, would you care to comment on this issue from a children's health perspective?

Mr. PAULSON. While adult workers obviously aren't children, they are often sentinels, and we need to be able to gather information on worker exposure and use that information to help understand, perhaps, either gaps that we need to fill about children, or be able to extrapolate to children in the instances where you can. So just in that one narrow area that you are talking about, I certainly agree that blocking the EPA's ability to collect and use that data will make it much more difficult to make decisions about chemicals.

Mr. WAXMAN. And thank you, Mr. Chairman.

Mr. SHIMKUS. The gentleman's time has expired. The Chair now recognizes the gentleman from Ohio, Mr. Latta, for 5 minutes.

Mr. LATTA. Mr. Drevna, if I can again start with you, how do you believe the coordination between the EPA and the TSCA inter-agency testing committee has been?

Mr. DREVNA. That is a good question. I mean, I really don't know what they have done. I don't.

Mr. LATTA. Have you heard anybody else talking about it? No one? OK. Well, maybe we ought to check into that. Mr. Matthews, if I could ask you currently, TSCA includes processes within the scope of Section 8, and in your testimony you discuss how a revised TSCA should expressly allow the EPA to collect necessary use information from downstream processors. How does this improve upon the existing construct? And then, just as a follow-up, then, do all processors support the view? Do all processors support this view?

Mr. MATTHEWS. Well, OK, I mean, I am here to speak on behalf of CSPA. I was at pains to say we are a segment of that industry. One of the problems the EPA has is they have had difficulty defining who a processor is. We circulated a 190 page document they created that attempted to define processor, but in the end, it couldn't, so it is a very broad category.

And, coming back to your first question, one of the problems, I think, is that EPA literally fears sending out an information request or demand from "processors" because it will produce more information than they can conceivably manage. What we have proposed is a more targeted and focused information flow of use and exposure information from that segment of the processor community that we represent, which is household and institutional products, which, during that screening phase, during the prioritization phase, will actually align with the kinds of issues that EPA is considering. And I would go back to the questions that have been asked about hazard, you still need hazard information, and there is substantial information on hazard that has already been generated, and EPA has its authorities in that regard.

But you would combine that with the kind of information about exposures that EPA is concerned about, as it says, how do we work through tens of thousands of chemicals in a logical way? Which should be our priorities? And on that basis, the kind of information that we would provide I think would go a long way to answering those questions.

Mr. LATTA. Thank you. Dr. Grazman, what is the EPA doing with all this duplicative byproduct data that they are collecting?

Mr. GRAZMAN. That is a good question, sir, and I don't know the answer. We have seen no evidence that they are doing anything. And part of this, and it actually goes back to the kind of—Mr. Waxman made quote in my written testimony, as I mentioned, we are a manufacturer. We make our products through a series of chemical and physical steps. None of the chemical steps is perfectly balanced. Each one produces a byproduct.

And so right now, when I say we find it very difficult to report to EPA the amount and nature of each byproduct, it is because I have got 30 chemical processes that might use five different chemicals that we buy, and then I have to understand the amount of each component that is left over, how they may react, and how any recyclers I send it to may process it. So if you imagine that EPA is not only trying to handle the data from chemical manufacturers, but from people like us, it truly would be overwhelming.

Mr. LATTA. Let me follow up. Even if these byproduct manufacture were to be exempted from reporting, companies manufacturing new chemicals from recycled byproducts would still be required to report on the manufactures they are manufacturing. Is that what would be happening, then, that they would—

Mr. GRAZMAN. Yes, sir.

Mr. LATTA. Yes.

Mr. GRAZMAN. The processors of our byproducts are reporting on what they make out of them.

Mr. LATTA. OK. Mr. Drevna, if I could go back to you, I was kind of interested in what you were saying about Canada, and about the

model that they use up there. How would you rate the model that they use in Canada?

Mr. DREVNA. Congressman, I think it is one that Congress should help EPA adopt. I think it is a good program. As one of the witnesses says, it would help, you know, categorize. It would help eliminate, and it is working for our friends to the north.

Mr. LATTA. And I know that Mr. Murphy had asked a question a little bit earlier about this, or kind of touched on it, also in your testimony I found it interesting that many people are of the false impression that there are 80,000 chemicals in commerce, and you say it is something less than 10,000. Where did it ever come up that people thought there were 80,000?

Mr. DREVNA. Well, I think once a chemical is out there on the list, it never gets off, and there are so many intermediates. It is a, you know, it is like the Hotel California, you can come in, but you can't check out.

Mr. LATTA. OK. On that Eagles note, I will yield back.

Mr. SHIMKUS. Showing your age. So thank you. Now the Chair recognizes the gentlelady from the Denver Broncos, I mean from the great State of Colorado, Ms. DeGette, for 5 minutes.

Ms. DEGETTE. Thank you so much, Mr. Chairman. And, in an attempt to be bipartisan, I will say we are working together very well on this TSCA reauthorization, and I am pleased that we are having this hearing. There is a group of us on this side of the aisle who really do want to work in developing this legislation, as we discussed last night, and I am hoping we can do it as it goes along.

I think there is consensus that some of the biggest problems we have with the implementation of TSCA are rooted in the procedure requirements under Section 4 for testing existing chemicals, and so I want to focus on that during the first part of my questioning.

Dr. Bosley, I wanted to ask you, yes or no, should the EPA have to go through a rulemaking every time it needs data on an existing chemical?

Ms. BOSLEY. No, absolutely not.

Ms. DEGETTE. And, Dr. Sass, what is your view on that?

Ms. SASS. No, it should not, I agree.

Ms. DEGETTE. OK. So it seems to me, I think everybody pretty much agrees on this, one of the easiest ways to improve TSCA would be to allow the EPA to request testing by order than rule-making, especially for existing chemicals where the data probably already exists. Everybody is nodding, so, Mr. Matthews, I am going to pick on you for a second.

I know you have got extensive experience providing counsel to chemical companies, and I am assuming that chemical companies, legitimate ones, like your clients, perform basic testing of the products they sell in order to determine they are safe. Is that right?

Mr. MATTHEWS. Well, mind you, we are the downstream purchasers of—

Ms. DEGETTE. OK.

Mr. MATTHEWS [continuing]. Raw materials from upstream. It is upstream where that actual testing of the chemical itself takes place, but our companies go to great lengths to ensure that the chemicals they put into their products are safe, so they are—

Ms. DEGETTE. Right.

Mr. MATTHEWS [continuing]. Looking at that data.

Ms. DEGETTE. So both the manufacturers, but your clients too, they are not going to put those things on the market unless they are pretty sure they are safe?

Mr. MATTHEWS. That would be absolutely correct.

Ms. DEGETTE. And so both the downstream and upstream folks are going to have information on file about the effects of the products, right?

Mr. MATTHEWS. I mean, I think often the manufacturers say it is not readily ascertainable to us as to how it is being used, and what kind of exposures are being created. So they have some, but not enough, for EPA's purposes. That is where we come in.

Ms. DEGETTE. OK. So what you said in your written testimony is exactly that, very little information is readily available to the agency on how chemicals are used in U.S. commerce in order to fully inform prioritization, and to assess the human health and environmental risk. That is exactly the point. So I guess I would like it if you could just spend a second talking to me about what you think about the current process of rulemaking, and what could be done to help the EPA access this information better. Would your clients agree with a different system, and what would it be?

Mr. MATTHEWS. Indeed we would. We would propose that there actually be statutory changes that would address a more direct and meaningful role of the downstream community that has—

Ms. DEGETTE. I mean, we are drafting the bill, so what kinds of changes would you support?

Mr. MATTHEWS. We would support a statute directing EPA when it goes through this screening process, I mean, we are trying to thread the needle here. They have to—

Ms. DEGETTE. Right.

Mr. MATTHEWS [continuing]. Screen to get the prioritization to get a list of substances that will go through a safety assessment process. So, as they conduct that initial screening, they have substantial information at their disposal. And we are talking—

Ms. DEGETTE. So you would support them providing that information to the EPA?

Mr. MATTHEWS. I think the EPA generally has a lot of that information, but yes, any updated information should—

Ms. DEGETTE. Without rulemaking?

Mr. MATTHEWS [continuing]. From the manufacturers.

Ms. DEGETTE. Right.

Mr. MATTHEWS. And now we would propose adding to that provisions that would direct the agency to also, then, collect, for the substances under review, use and exposure information from the companies that have it.

Ms. DEGETTE. Great. Thank you. Now, Dr. Paulson, I want to talk for a minute about the EPA authority, because, you know, they have got 83 existing chemicals right now, so that is good, but as the EPA studies those priority chemicals, science will evolve, and we might know more about those chemicals that are not on the priority list. So, Dr. Paulson, you support a simpler process for the EPA to gather data. Can you just talk briefly about how our understanding has evolved, and how chemicals affect infants, children, and other vulnerable populations?

Mr. PAULSON. Yes, ma'am, thank you. Children have periods of vulnerability from the time that really actually start before conception, if we can understand that, conceptualize that, and then, after conception, throughout pregnancy, and the brain finally finishes developing somewhere around 25 years of age, in terms of final myelination of coding of the nerve cells in the frontal part of the brain. Likewise, the lungs continue to develop until children reach whatever their adult height is, so this is a process that takes many, many years, and damage that is done before the process has finished, whether you are talking about the lungs, or the brain, or the kidney, often is irremediable. You don't get to start over or do-over in the human body.

So data that is collected to make decisions on the safety of chemicals needs to acknowledge these periods of vulnerability, test around issues that pertain to these periods of vulnerability, and then use that information in decision-making.

Ms. DEGETTE. Thank you, Mr. Chairman.

Mr. SHIMKUS. The gentlelady's time has expired. I do look forward to working with her, and if you check on 8(d), I am not going to read this part, but part of that is in current law too, and that is part of the problem of some of the things that you asked about.

The Chair now recognizes the gentleman from West Virginia, Mr. McKinley, for 5 minutes.

Mr. MCKINLEY. Thank you, Mr. Chairman. Several of the panelists, and some of the Members of Congress, have mentioned and drawn attention back to the problem they had down in the 2nd District in West Virginia, down in the southern part of the State. And I join with you in the disgust and the fury internally I have over the breakdown of why that could occur. So I am hoping that, from this hearing and elsewhere, we will learn more, and not do a knee-jerk reaction, but we will try to get this thing resolved. I know the Attorney General is looking into it, and a series of others are looking into that.

But let me go back to Dr. Paulson, and some of your remarks. In your testimony you said that, under TSCA Section 8, companies are required to keep a file of allegations of significant adverse reactions to human health or the environment of any chemical they manufacture, and the companies must also provide this information to the EPA upon request. Now, I am just curious, given the MCHM issue of a discharge into the Elk River, do any of you know, was there a request that was denied about the MCHM?

Mr. PAULSON. I am sorry, can you state the last part of that question again? Just didn't quite hear you.

Mr. MCKINLEY. Did the EPA, did they seek information about this? Because that is what it says, companies must provide this information to the EPA upon request. Did the EPA request information about this chemical, one of two chemicals that was discharged into the Elk River?

Mr. PAULSON. In the post-leak time phase, I don't know, sir.

Mr. MCKINLEY. OK. Well, let us go just a little bit further with that. Is there something more that they can do? Because I heard a little bit ago you were saying, I think, in your testimony that these things deal with confidentiality. I am just wondering whether or not that was also an item that—was it held back because of—

or, Dr. Sass, do you know whether or not either of these things has occurred?

Ms. SASS. So I do not know the specifics of conversations that may have happened early in the spill between EPA and West Virginia, but I think what the speakers had talked about, if I am correct, referring to your question, is the idea that, if there is an accident, or a spill, or an incident like this, that it should be reported to EPA.

And the model, I think, is FIFRA 6(a)(2), which is the pesticide model, so that if there is an incident, or a spill, or a poisoning, that a report has to be made to EPA under FIFRA 6(a)(2), and that data is kept there, and that the obligation to make that is the registrant, the chemical manufacturer in this case. And that way EPA has a docket of these. And so later, when EPA is reviewing those pesticides, which it does every 15 years on a routine basis, and updates the science, it can look and see if there has been a problem with fish kills, with worker poisonings, child poisonings, things like that.

Mr. MCKINLEY. How we can strengthen it, how we can make this thing work better, because was this information even available? That is what I am trying to find out about the MCHM, was it out there?

Mr. PAULSON. We do know—

Mr. MCKINLEY. Because the first responders needed to know. There was the delay in reporting. We have got to find out how to make this thing better, and so I am looking under Section 8, how we might be able to modify that.

Mr. PAULSON. Well, we do know that the company, Eastman, did provide some additional information, and I don't know whether that was at the request of EPA, the agency for Toxic Substances and Disease Registry—

Mr. MCKINLEY. OK. So—

Mr. PAULSON [continuing]. The West Virginia Department of Health. So they did, in relatively short order, provide some additional information. Then the Federal agencies needed to analyze that, which, of course, takes time. I think that, had this information been provided to the government before the spill, there might have been a quicker turnaround.

Mr. MCKINLEY. Well, that is what I am trying to find out, is why it failed under Section 8, that they didn't provide that information prior to this. That is what I am trying to find out about.

But let me just close in the few seconds we have left that I join with you in this concern about what happened down there, and the need to work on TSCA. I am with you on that, as one of just two engineers here in Congress. We need to work on this. But I wish I could have seen the same fury from you all about the situation in Bud, West Virginia. Bud, West Virginia, for those of you that aren't aware, they have been without water, this is their sixth month.

And for a community, Dr. Willett, you are only concerned with the animal, where are they getting the water? Because it is untreated. And these people, for six months, have gone without water down in Wyoming County, West Virginia. Six months. And I haven't seen anything in the headlines about that. You know, peo-

ple chasing that issue, take care of those families, the children looking for water in their fountains, and their school districts are closed. I know you don't have jurisdiction over that, but I would think many of the advocates out there in America would have raised this issue, that that is not an acceptable way for a community to exist. They have to rely for six months on bottled water.

Afraid my time is over.

Mr. SHIMKUS. The gentleman's time has expired.

The Chair now recognizes the gentleman from California, Mr. McNerney.

Mr. MCNERNEY. Did the gentleman yield?

Mr. TONKO. Mr. Chair, if I might, I think that that line of questioning from our colleague is important, because it highlights one of the failures of the existing law, in that it didn't require the company to notify the EPA of the substance, so vast improvements are required here.

Mr. SHIMKUS. I thank my colleague. I would just remind my colleagues that there is Federal law called the Emergency Planning and Community Right to Know Act, under which they should have filed with the local first responders. The second thing, under Section 8(e), is peril authority, and so is 8(c), that this information should have been filed with the EPA. So, having that, I will turn to Mr. McNerney for 5 minutes.

Mr. MCNERNEY. I thank the Chairman. I just want to say, all the testimony I have heard this morning was very constructive, very positive, in terms of where we should be going, and I appreciate that.

Dr. Paulson, in your testimony, you raised concern about chemical companies claiming that important health and safety data is confidential business information. Have CBI claims made it difficult for key stakeholders to gain information about potentially hazardous chemicals?

Mr. PAULSON. To the extent that we don't know what is included in the CBI claims, I can't answer that definitively, but certainly that is a big concern. I think there is information that should be available to the public that these companies know, and they are making claims of CBI that lock the public's right to know.

Mr. MCNERNEY. Well, today the committee received a letter from the Center for Environmental Health regarding today's hearings on Sections 4 and 8 of TSCA. Mr. Chairman, I request that this letter be made a part of the hearing.

Mr. SHIMKUS. Without objection, so ordered. I think we have already seen it.

Mr. MCNERNEY. Thank you. According to the letter, the Center for Environmental Health, and I quote, "is particularly concerned with whether or not the EPA has enough data to make appropriate designation for individual chemicals. Any revision of TSCA must ensure that the EPA has adequate data to demonstrate that the chemical truly has a reasonable certainty of no harm before the agency deems the chemical to be a low priority". Then they go on to note that the law must require chemical companies to submit minimum information sets in a timely manner, equipping the EPA to evaluate new chemicals and new uses of chemicals, and to evaluate chemicals for prioritization.

Mr. Paulson, what is your biggest concern about what the revision of TSCA might not do?

Mr. PAULSON. My biggest concern is that a revision to the Toxic Substances Control Act would not allow EPA to collect sufficient data to make decisions. And they can't make good decisions without good data. There need to be identified minimum data sets that will collect information that pertains to children and pregnant women, at least from my standpoint, as a pediatrician. They are not the only groups that need protection, but let me just talk as a pediatrician, and that, unless any new legislation gives them that authority, gives them the authority to request additional information when they feel that it is necessary, and gives them the authority to continue to receive information after a marketing decision has been made, then we will all be right back here, talking about problems with chemical management policy.

Mr. MCNERNEY. Thank you. Dr. Sass, do you have additional concerns about what the new legislation may not accomplish?

Ms. SASS. I think that my biggest, is actually that it won't give EPA the authority to actually make a decision to take action, that it will hold EPA in a holding pattern forever, collecting information, and needing more information, and waiting for information, and that would be sad, because there are huge initiatives across all agencies to develop more rapid and less costly testing. And I think that Dr. Willett had mentioned some of these. We can start to do mixtures, we can do formulations, we can look at interactions, different life stages. There are some exciting new scientific data on the horizon, the near and the far horizon. Computational toxicology will be really exciting, and it would be a shame if EPA was hamstrung in an old dinosaur science framework.

Mr. MCNERNEY. Thanks. Mr. Drevna, what is your biggest concern about what the new legislation may do?

Mr. DREVNA. Two things, Congressman. One, we have to keep in mind that this is a health and an environment statute, and it is a commerce statute. And one of the things of a major concern to us is Federal pre-emption. We would urge Congress, in its revisit and rewrite of TSCA, to make sure that, you know, as I said, that we don't, you know, inhibit the manufacturing renaissance by having a patchwork quilt of kinds of various State regulations. I mean, this is a statute that calls for Federal pre-emption.

Mr. MCNERNEY. Anyone else on the panel wish to answer that question? What is your biggest concern about what the legislation may do? All right.

With that I will yield back, Mr. Chairman.

Mr. SHIMKUS. The gentleman yields back his time. The Chair now recognize the gentleman from Ohio, Mr. Johnson, for 5 minutes.

Mr. JOHNSON. Thank you, Mr. Chairman, and I too want to thank the panel for being with us today. Let me start with Dr. Willett and Dr. Bosley, if I could.

How do you respond to the call for a minimum data set on all chemicals on the TSCA inventory, and why? Dr. Willett, you go first.

Ms. WILLETT. I believe that our science and technology is at the point where we can redefine what minimum data set means.

Mr. JOHNSON. OK. Dr. Bosley?

Ms. BOSLEY. I think that the general industrial chemicals are not a one size fits all, and I think a minimum data set is the wrong approach. I think that the data sets that EPA needs should be based on the risk of the chemical.

Mr. JOHNSON. OK. For both of you, a follow on, is every data gap a data need, in your opinion, and why?

Ms. WILLETT. That is a tough question. No.

Mr. JOHNSON. OK.

Ms. WILLETT. I think EPA should be allowed to figure out which data gap is really a data need. They are, as I said, very talented scientists and engineers there, and they know what data they need.

Mr. JOHNSON. OK. Dr. Willett, a follow on for you. You mentioned that a single two-generation reproductive toxicity study requires at least \$380,000, 2 years, and 2,600 rats. Is this kind of test normal under a minimum data requirement?

Ms. WILLETT. It depends on the chemical sector, but it is a common test that is required now.

Mr. JOHNSON. So it would be considered normal? OK. Mr. Grazman, how are you today?

Mr. GRAZMAN. Good, thank you, sir.

Mr. JOHNSON. How are things back in North Jackson?

Mr. GRAZMAN. North Jackson is doing well.

Mr. JOHNSON. Good. Mr. Grazman, Section 9 of TSCA directs the EPA to coordinate TSCA actions with actions taken under other Federal laws to avoid unnecessary duplication. As a manufacturer, are you aware of any steps that EPA has taken to coordinate reporting requirements—

Mr. GRAZMAN. No, sir—

Mr. JOHNSON [continuing]. Or processes?

Mr. GRAZMAN [continuing]. We are not aware of any.

Mr. JOHNSON. You are not aware of any coordination—

Mr. GRAZMAN. We have—

Mr. JOHNSON [continuing]. Done?

Mr. GRAZMAN. We report, and for understandably good reasons, to multiple divisions of government, and organs of government, that ask for the data.

Mr. JOHNSON. OK.

Mr. GRAZMAN. Whether it is the first responders in our area, whether it is the environmental pluses of business, it is everybody from our insurers, and our own shareholders, and our own systems, so—

Mr. JOHNSON. Same data?

Mr. GRAZMAN. Pardon?

Mr. JOHNSON. Same data?

Mr. GRAZMAN. Yes.

Mr. JOHNSON. OK. Can you describe for the subcommittee the environmental reporting that your company undertakes under other laws? Now, you just mentioned a few of them, and how that may overlap with reporting requirements under Section 8 of TSCA?

Mr. GRAZMAN. To do a complete job, I would really rather follow up with you later and—

Mr. JOHNSON. OK.

Mr. GRAZMAN [continuing]. That information.

Mr. JOHNSON. Yes, if you could get us that, that would be great.

Mr. GRAZMAN. Yes, sir, happy to.

Mr. JOHNSON. What steps does your company take to ensure the responsible use, storage, and transfer of chemicals? What laws, for example, regulate these activities?

Mr. GRAZMAN. Every material that we bring in our factory is evaluated for its safety in terms of its storage, its handling to our workers, and its possible interactions with the other chemicals that we use. Everybody from our insurance company to the third party registrar of our environmental management system audits our facilities against both the chemical and the handling aspects of those things. We have customers doing audits, because when a Department of Defense program is buying their circuit boards from us, if our factory fails, potentially they fail. So they are in making sure that our processes are safe, and will provide a continued stream of products that they need.

Mr. JOHNSON. OK.

Mr. GRAZMAN. And then we have actually instituted a program called layer process audits, where literally every day every part of the factory is being looked at against checklists for safety and efficiency.

Mr. JOHNSON. Are there any regulatory gaps that we should worry about closing?

Mr. GRAZMAN. I think the aspect of the regulation that surprised us when we chose to start recycling, that we got hit as if we were manufacturing chemicals. I would like to see that closed, and I think that would also help EPA in reducing the data they need so that they can focus on those that are necessary for—

Mr. JOHNSON. OK.

Mr. GRAZMAN [continuing]. Their effectiveness.

Mr. JOHNSON. Well, thank you for that.

Mr. Chairman, I yield back.

Mr. SHIMKUS. The gentleman yields back his time. The Chair now recognizes my colleague from the State of Illinois, Ms. Schakowsky, for 5 minutes.

Ms. SCHAKOWSKY. Thank you, Mr. Chairman, and to our panel. I really apologize, I was at another hearing and couldn't come and hear your testimony, but I do have a few questions.

As written, Section 4 of TSCA makes it extremely difficult for the EPA to require testing of existing chemicals, but that doesn't mean, as has been discussed, the chemical companies never conduct any tests on these chemicals. They may conduct safety testing for a variety of reasons, apart from any requirement on TSCA. A company could conduct safety tests to comply with the State law, to meet European requirements, if you want to export, or a company may want to conduct testing to assess potential tort liabilities.

So, Dr. Bosley, is that right, that companies may conduct safety tests on a chemical for a variety of reasons?

Ms. BOSLEY. Yes. We conduct tests whether or not EPA asks for them in general.

Ms. SCHAKOWSKY. And Mr. Matthews?

Mr. MATTHEWS. Yes—are not doing the actual toxicity testing, but they don't put a product on the market where they haven't re-

viewed the toxicity of each of the chemicals they put in those products.

Ms. SCHAKOWSKY. But the EPA and other health officials often don't see these tests. As we have discussed also, Section 8 only requires chemical companies to immediately submit to the EPA information they obtained that, quote, "reasonably supports the conclusion" that a chemical, quote, "presents a substantial risk of injury to health or the environment".

So, Dr. Paulson, in your testimony, you say that TSCA has created a non-evidence based system for chemical management. Can you explain what you mean by this?

Mr. PAULSON. In medicine, in the latter part of the 20th century, in the early part of the 21st century now, we talk about practicing evidence based medicine, that the decisions that we make should be based on rigorously collected information to inform those decisions. So I have taken that term that is used in medicine and applied it to a different arena. And what I am suggesting here is that, in terms of new chemicals, the companies are, in essence, penalized if they do research, because they are required then to report that research to EPA, and EPA might then use that research to make a decision the company doesn't want made.

And, in terms of the chemicals currently on the market, the quote that you just read, in terms of the definition of substantial, that makes it very easy for companies to decide that it is not substantial. And I think the standard should be that companies need to disclose information that they have.

Ms. SCHAKOWSKY. Thank you. The recent chemical spill in West Virginia, which you have also talked about, illustrates the problems created when chemical testing data isn't widely shared and available. On January 11 the Centers for Disease Control told West Virginians that the water would be safe to drink at one part per million of the chemical of concern, MCHM. Four days later CDC said it obtained new animal studies leading it to recommend that pregnant women not drink the water at all. EPA told committee staff that the agency didn't have any studies on the chemical. A week after the chemical spill was discovered, Eastman, the chemical manufacturer, finally made public the summaries of several safety studies.

Dr. Sass, how did this slow disclosure of the relevant safety studies affect your ability, as a scientist, to assess whether government was doing enough to protect public health?

Ms. SASS. Well, in the first few days, the public was completely blindsided, and blinded, with no information. The LD-50, the lethal dose that kills 50 percent of test animals, which is very crude, and not the kind of test we want to use to set a drinking water standard for a population, was the only test that seemed to be available. I found it on an MSDS, or a material safety data sheet. That is what CDC used initially.

Later they found a no effect test in rodents, a 28 day rodent test, which they used. That is more informative. The problem with that test is that only the conclusions of the study were provided to the public, so there was no way to analyze those data, or to re-analyze the data, or to confirm it was a, you know, trust us, we are the experts type of study from the industry, and that is wholly inappro-

priate for public health agencies, first responders, scientists, and the public to get any confirmation. So I think that it violated the public trust, and it put public interest groups in a blinded position, and it hamstrung the Federal agencies considerably.

Ms. SCHAKOWSKY. Let me just say that I think that it really affected the confidence of the West Virginians, both in the safety of their water, and in the government's ability to respond.

Thank you, I yield back.

Mr. SHIMKUS. The gentlelady yields back her time, and we want to thank you all. We think it was a great hearing. I want to ask unanimous consent that all subcommittee members have 5 days to submit opening statements for the record. Without objection, so ordered. Members will have 10 requisite days to submit questions for the record, so if you follow up with questions, if you would submit those back to us? I think it is very, very important because, as you see, we had a lot of active members very interested in this.

I think it is safe to say that there is need for reform across the board. I think there is desire by the stakeholders and members. I think also the status quo is really not acceptable. I think people concur with that. Cautionary note is don't let the perfect be the enemy of the good as we try to work through this process.

And, with that, I want to thank my colleagues for attending, and I will now adjourn the hearing.

[Whereupon, at 12:07 p.m., the subcommittee was adjourned.]

