REGULATION OF NEW CHEMICALS, PROTECTION OF CONFIDENTIAL BUSINESS INFORMATION, AND INNOVATION

HEARING

BEFORE THE

SUBCOMMITTEE ON ENVIRONMENT AND THE ECONOMY

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED THIRTEENTH CONGRESS

FIRST SESSION

JULY 11, 2013

Serial No. 113–68

Printed for the use of the Committee on Energy and Commerce
energycommerce.house.gov

U.S. GOVERNMENT PRINTING OFFICE

86–392 WASHINGTON : 2014

For sale by the Superintendent of Documents, U.S. Government Printing Office
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CONTENTS

REGULATION OF NEW CHEMICALS, PROTECTION OF CONFIDENTIAL BUSINESS INFORMATION, AND INNOVATION

THURSDAY, JULY 11, 2013

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

The Subcommittee met, pursuant to call, at 9:43 a.m., in Room 2322 of the Rayburn House Office Building, Hon. Phil Gingrey [Vice Chairman of the Subcommittee] presiding.

Members present: Representatives Gingrey, Murphy, Latta, Cassidy, Johnson, Tonko, Green, McNerney, Barrow, and Waxman (ex officio).

Staff present: Nick Abraham, Legislative Clerk; Charlotte Baker, Press Secretary; Sean Bonyun, Communications Director; Jerry Couri, Senior Environmental Policy Advisor; David McCarthy, Chief Counsel, Environment and the Economy; Andrew Powaleny, Press Secretary; Jacqueline Cohen, Democratic Senior Counsel; Greg Dotson, Democratic Staff Director, Energy and Environment; and Caitlin Haberman, Democratic Policy Analyst.

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

Mr. GINGREY. The committee will come to order. The chair recognizes himself for 5 minutes for an opening statement.

Last month, the subcommittee held a hearing on the history and the impact of Title 1 of the Toxic Substance Control Act, better known as TSCA. The June 13 hearing was a good start to understanding a law as complex as it is broad. Today, we take a deeper dive and focus on new chemical regulation protection of sensitive businesses' information, and their effect on innovation. I believe evaluating TSCA Sections 5, New Chemicals, and 14, Disclosure of Data, is fundamental to judging progress in new technologies and manufacturing frontiers in our country.

Testimony in our June 13 hearing supports this notion. American companies are on the cutting edge of chemical innovation, and the new chemical structure in TSCA has allowed us to lead the world. For example, the European Union's new chemical requirements saw 3,000 new chemicals introduced, while the United States saw six times as many new chemicals introduced over that same period of time. One out of six of the chemicals currently used in commerce did not exist in 1979.

TSCA Section 5 does not merely set out the notification requirements for these chemicals, it provides EPA an opportunity to review and evaluate information about a chemical to determine if its manufacture, if its processing, commercial use, or disposal should be limited, delayed, or prohibited. To do this job, pre-manufacturing notices, PMNs, submitted to EPA include information on chemical identity, description of byproducts, anticipated production volumes, molecular formula, intended categories of use, and other available information on the substance. EPA can employ predictive modeling technologies to help it decide if a new chemical raises concerns. EPA then may also extend the review period of a chemical or new use of a chemical if it needs more than 90 days to consider all of the facts before acting. EPA then decides whether entry into commerce is allowed, allowed with restrictions, allowed after submission of additional data, or allowed with certain regulatory or testing actions applied. As of May, 2013, I am told that 52 percent of chemicals for which EPA received a pre-manufacturing notice, PMN, actually went to market. According to former EPA Chemicals Office Director Charlie Auer, who testified at our June hearing, 90 percent of new chemicals program decisions are made within 90 days, and over 15,000 new chemicals, or 30 percent, have received some kind of regulatory action under TSCA Section 5.

We want EPA to have information to make good decisions about a chemical; however, we must be careful about disclosure of that detailed information, obviously. In a recent paper on trade secret privacy, William Fitzpatrick and two others suggested that approximately 70 percent of the market value of U.S. firms resides in their trade secrets and their intellectual properties. This is what drives innovation.

TSCA Section 14 protects information submitted to the EPA as a privileged and confidential trade secret. Disclosure by EPA employees is not permitted, except to other federal employees, or when necessary to protect the health or the environment. Beth Bosley, who with six employees operates a specialty chemical maker in Pittsburgh, reinforced these points at our last meeting: one, disclosure of chemical identity may be all it takes to give a way a competitive advantage to an offshore manufacturer; and second, the majority of Freedom of Information, FOIA Act requests to EPA on new chemicals come from potential competitors, many of which are overseas, not curious members of our public.

While we cannot have a system that prevents regulators from having access to information that allows them to make important judgments on risk, I think we should not be naive about the value of this information to non-regulatory interests, their cleverness in trying to obtain and exploit, and the real damage its leak could cause to American jobs and our prosperity.

I want to thank our distinguished witnesses for joining us today to help us get a better handle on what the law is, how EPA has been implementing it, what it is like being regulated under it, and where witnesses think its successes and shortcomings lie. I urge members of the subcommittee to make every effort at this hearing to learn the fundamentals of these sections of this law, TSCA.

[The prepared statement Dr. Gingrey follows:]

PREPARED STATEMENT OF HON. PHIL GINGREY

Last month, the subcommittee held a hearing on the history and impact of Title I of the Toxic Substances Control Act (TSCA). The June 13th hearing was a good start to understanding a law as complex as it is broad. Today, we take a deeper dive and focus on new chemical regulation, protection of sensitive business information, and their effect on innovation.

I believe evaluating TSCA sections 5 (new chemicals) and 14 (disclosure of data) is fundamental to judging progress in new technologies and manufacturing frontiers in our country. Testimony in our June 13th hearing supports this notion: American companies are on the cutting edge of chemical innovation, and the new chemical structure in TSCA has allowed us to lead the world. For example, the European Union's new chemical requirements saw 3,000 new chemicals introduced while the United States saw six times as many new chemicals introduced over the same period in time.

One out of six of the chemicals currently used in commerce did not exist in 1979. TSCA Section 5 does not merely set out the notification requirements for these chemicals; it provides EPA an opportunity to review and evaluate information about a chemical to determine if its manufacture, processing, commercial use, or disposal should be limited, delayed, or prohibited.

To do this job, Pre-Manufacturing Notices (PMNs) submitted to EPA include information on chemical identity, description of byproducts, anticipated production volumes, molecular formula, intended categories of use, and other available information on the substance. EPA can employ predictive modeling technologies to help it decide if a new chemical raises concern. EPA may also extend the review period of a chemical or new use of a chemical if it needs more than 90 days to consider all the facts before acting. EPA then decides whether entry into commerce is allowed, allowed with restrictions, allowed after submission of additional data, or allowed with certain regulatory or testing actions applied.

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We want EPA to have information to make good decisions about a chemical. However, we must be careful about disclosure of that detailed information. In a recent paper on trade secret piracy, William Fitzpatrick and two others suggested that approximately 70 percent of the market value of U.S. firms resides in their trade secrets and intellectual properties. This drives innovation.

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Beth Bosley, who—with six employees—operates a specialty chemical maker in Pittsburgh, reinforced these points at our last hearing:

1. Disclosure of chemical identity may be all it takes to give away a competitive advantage to an offshore manufacturer, and

2. The majority of Freedom of Information Act requests to EPA on new chemicals come from potential competitors, many of which are overseas, not curious members of the public.

While we cannot have a system that prevents regulators from having access to information that allows them to make important judgments on risk, I think we should not be naïve about the value of this information to non-regulatory interests, their cleverness in trying to obtain and exploit it, and the real damage its leak could cause to American jobs and prosperity.

I thank our distinguished witnesses for joining us today to help us get a better handle on what the law is, how EPA has been implementing it, what it is like being regulated under it, and where witnesses think its successes and shortcomings lie.

I urge members to make every effort at this hearing to learn the fundamentals of these sections of this law.###

Mr. GINGREY. I now yield 5 minutes to the ranking member of our subcommittee, Mr. Tonko from New York.

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

Mr. TONKO. Thank you, Mr. Chair. Good morning, and I am pleased to be here this morning for this second hearing on the Toxic Substances Control Act, better known as TSCA. And thank you, Chair Gingrey, Dr. Gingrey. I am sure you will do an excellent job of filling in for our colleague, Chairman Shimkus, who cannot be with us today. It is a pleasure to be with you at the hearing. And welcome to all of our distinguished guests as members of the panel.

Our first hearing provided a very useful overview of the Toxic Substances Program administered by the Environmental Protection Agency. We have an opportunity today to hear from an excellent panel of witnesses on two particular aspects of this law, Section 5, the New Chemicals Review Program, and Section 14, the provision that governs the handling of confidential business information.

The New Chemicals provision was intended to provide an opportunity to screen new chemicals coming into commerce for possible safety problems. The process was also to provide sufficient information about the chemicals in commerce to enable EPA to make a credible evaluation of their safety.

The law currently falls short of these goals. The information available on chemicals has failed to keep pace with the numbers of chemicals in commerce. We have developed incredible analytical, computational, and communications tools over the past few decades. We should be able to apply these tools more effectively to produce reliable information about the chemicals in commerce and make it available to the public, but this has not happened to the extent needed. An effective early evaluation process also provides benefits to industry. Prevention certainly is much less expensive than mitigation. The earlier a company detects a potential problem with their product, the easier and less expensive it is to engineer around that problem or to pursue a different design.

We need chemicals. We use them every day in a wide range of products essential to the quality of our lives and to our modern society. But these products must be safe for people and must be safe for the environment. We need to find the proper balance. The program must enable manufacturers to bring new chemicals to the market while providing assurances to the public that these substances are indeed safe. EPA needs sufficient resources to evaluate chemicals in an expeditious and reliable manner, and the authority to remove problem substances from the market in a timely and orderly fashion. In a fast-paced, competitive global economy, protecting trade secrets is important and is challenging, but an overuse of confidential business information claims is unwarranted and serves only to bar the members of the public from information they need to make informed choices about the products they purchase and that they use.

I expect we will hear a variety of views today on the type of extent of changes that are needed to improve this law. Working together, however, we can update and improve this law so that it works for everyone.

I look forward to the testimony of all of our expert witnesses, and I thank you all for participating this morning and for sharing your

views on what I believe is an incredibly important topic. Thank you.

With that, Mr. Chairman, I yield back.

Mr. GINGREY. I thank the gentleman from New York, and if there are any other members seeking time for an opening statement—seeing none, the chair wishes to recognize Mr. Latta for the purpose of introducing the first two of our witnesses. I yield to the gentleman from Ohio.

Mr. LATTA. Well I thank the chairman for yielding to me, and I appreciate it. I would just like to introduce our two first witnesses today, and both from Ohio. You know, in the Buckeye State, we like to stick together.

Our first witness that will be testifying today is Mr. Craig Morrison, and Mr. Morrison is the President and Chief Executive Officer of Momentive Performance Materials Holding, and its operating subsidies—subsidiaries. It is based in Columbus, Ohio, and Momentive is a world leader in specialty chemicals and materials.

Our next witness that will be testifying is from Procter and Gamble, and that is Mr. Len Sauers, who is Vice President for Global Sustainability, Product Safety, and Regulatory Affairs. Of course, Procter and Gamble is located in Cincinnati.

I just want to thank you both for being here to testify, and with that, Mr. Chairman, I yield back.

Mr. GINGREY. And I will now introduce our other three witnesses. Mr. David Isaacs is Vice President of Government Affairs for the Semiconductor Industry Association. Welcome, Mr. Isaacs. Dr. Rainer Lohmann. Dr. Lohmann is a professor of oceanography from the University of Rhode Island. Welcome, Professor. And last, but certainly not least, Ms. Heather White, Executive Director of the Environmental Working Group. So I welcome all of our witnesses, and our first witness, we will start with Mr. Morrison. You are recognized for 5 minutes.

I want to tell the witnesses that I am going to have a soft gavel, so don't worry about—I am not going to let you go 10 minutes, but I certainly could let you go 5 ½ to 6, and anything that you want to say that you don't get time to say, I ask unanimous consent for that to be submitted for the record. Hearing none, so ordered, and we will start with Mr. Craig Morrison.

STATEMENTS OF CRAIG MORRISON, CEO OF MOMENTIVE PERFORMANCE MATERIALS HOLDING, LLC, AND CHAIRMAN OF THE EXECUTIVE COMMITTEE, AMERICAN CHEMISTRY COUNCIL; LEN SAUERS, VICE PRESIDENT, GLOBAL SUSTAINABILITY, PROCTER AND GAMBLE; DAVID ISAACS, VICE PRESIDENT, GOVERNMENT AFFAIRS, SEMICONDUCTOR INDUSTRY ASSOCIATION; RAINER LOHMANN, PROFESSOR OF OCEANOGRAPHY, UNIVERSITY OF RHODE ISLAND; AND HEATHER WHITE, EXECUTIVE DIRECTOR, ENVIRONMENTAL WORKING GROUP

STATEMENT OF CRAIG MORRISON

Mr. MORRISON. Thank you, Mr. Chairman. I am Craig Morrison, President and Chief Executive Officer, and Chairman of Momentive Performance Materials based in Columbus, Ohio. I am testifying

today on behalf of the American Chemistry Council, the ACC, where I am currently chairman of the board of directors. On behalf of the ACC and our members, I would like to thank the chairman and the committee for holding today's hearings.

Momentive is a world leader in the development and production of specialty chemicals and materials. Momentive chemistries are used in thousands of products that enhance the safety, convenience, and efficiency of modern life. Our products can be found in automotive, energy, construction, personal care, electronics, and many other segments. In fact, Momentive materials can be found in the semiconductors produced by some of the members of the Semiconductors Industry Association, represented here by my fellow panelist, Mr. Isaacs. Momentive has over $7 billion in sales and operates 90 manufacturing facilities in 37 countries, including 35 manufacturing facilities in 18 States in the U.S., which provides approximately 4,000 American women and men high paying manufacturing jobs.

Innovation is critical to the survival and growth of our industry and the downstream industries that we supply. To remain a market leader, our process of research, development, product testing and introduction is nearly constant. That is why an efficient, effective process to evaluate and approve new chemical innovations is vitally important to the chemical industry and why I will be focusing my comments on Section 5 of the Toxic Substances Control Act, known as the New Chemicals Program.

There is broad agreement among industry and other stakeholders that TSCA needs to be reformed in order to reflect modern understanding of chemicals and today's scientific knowledge. We have been encouraged by the recent introduction of the bipartisan Chemical Safety Improvement Act in the Senate and by this committee's interest in examining current law to gain a better understanding of needed reforms. But it is also widely understood that TSCA's New Chemicals Program works well, a fact that has been reinforced by senior officials from previous administrations of both political parties.

New chemicals undergo a thorough but efficient multi-step regulatory review before being approved for manufacture and marketing. This well-functioning framework has three particular strengths. First, the program ensures a scientifically robust review of the potential hazards and exposures associated with a chemical substance. Second, it allows the EPA to tailor the process to fit the specific characteristics of an individual chemistry. And third, the process and timing of EPA's review generally meets demands of the marketplace.

The program leverages significant data about chemicals already available to the EPA, and employs advanced modeling techniques to predict a new chemical's physical and chemical properties, health hazards, and potential environmental effects. Section 5 also gives the EPA, which it regularly exercises, to request more testing and data about a new chemical if the Agency feels it is necessary, and to manage potential risks appropriately. This sophisticated risk-based approach reduces the cost of innovation and time needed for review and approval of new chemical products. It has facilitated a dialog between manufacturers and regulators that has helped in-

dustry move away from potentially problematic chemistries and has enabled the introduction of even safer and more sustainable chemistries.

Momentive submits, on average, 10 new chemistries for review each year, and has submitted approximately 120 new chemistries for review over the past 10 years. Thanks to the EPA's efficient and well-functioning process, 90 percent of these new products introduced in the last 5 years have been able to come to market without the need for new animal testing. The advantage created by TSCA Section 5 for American innovation and competitiveness is clear. For example, the chemical industry invests $11 billion on average each year in research and development. Roughly 20 percent of all U.S. patents are chemistry-related. Three times more chemical innovations are brought to the market in the U.S. than other major regions of the world, such as Europe and Japan. Taken together with abundant, affordable supplies of domestic natural gas, the current New Chemicals Program helps create a strong incentive for companies that rely on chemistry to invest in the U.S. In fact, as of June, 2013, more than 100 new plants, expansions, and restarts of previously shuttered sites have been announced, which is projected to create 310,000 new American jobs by 2020.

TSCA Section 5 established a rigorous process to evaluate and approve new chemistries in a way that protects health and the environment, enables continuous innovation, and allows new transformative products to come to market. Ensuring that this remains the case as part of any new effort or reform to modernize TSCA should be a top priority.

Thank you very much for allowing me to participate, and I am happy to answer any questions.

[The prepared statement of Mr. Morrison follows:]

TESTIMONY OF CRAIG O. MORRISON
PRESIDENT, CHIEF EXECUTIVE OFFICER AND CHAIRMAN
MOMENTIVE PERFORMANCE MATERIALS HOLDINGS LLC

ON BEHALF OF

THE AMERICAN CHEMISTRY COUNCIL

BEFORE THE

SUBCOMMITTEE ON ENVIRONMENT AND THE ECONOMY
UNITED STATES HOUSE OF REPRESENTATIVES

REGARDING SECTIONS 5 AND 14 OF THE

TOXIC SUBSTANCES CONTROL ACT

July 11, 2013

American Chemistry Council
700 2nd Street, NE
Washington, D.C. 20002

Executive Summary

This testimony is provided by Craig Morrison, President, Chief Executive Officer and Chairman of Momentive Performance Material Holdings LLC (MPMH). The testimony is being provided on half of the American Chemistry Council, the national trade association representing chemical manufacturers in the United States, where I am currently the Chairman of the Board of Directors.

Sections 5 and 14 of TSCA address requirements for the review of new chemicals and protection of confidential business information. These sections provide an important regulatory framework that protects health and the environment, and allows the chemical industry's innovative solutions to come to market.

Implementation of sections 5 and 14 has been partly responsible for the significant competitive advantage the business of chemistry has in the United States compared to other countries and regions. The Subcommittee should consider section 5 one of the key elements of TSCA. Any effort to reform TSCA should be careful to preserve the essential elements of the new chemical review program that protect health and the environment and U.S. commercial and competitive interests.

The ability to protect commercial confidential information from disclosure is another key element in fostering innovation. The U.S. chemical industry's position as a leader in innovation requires an ability to protect trade secrets from disclosure. The protection of confidential commercial information under section 14 of TSCA is crucial to the chemical industry's global competitiveness and the industry's ability to innovate to produce cleaner, safer and more effective products.

The protection of confidential business information must be balanced by appropriate government and public access to health and safety information. In section 14, Congress struck a fairly good balance of those interests. This is particularly the case for confidential chemical identities, which are among the most valuable intellectual property in the chemical industry. ACC strongly opposes any change in policy affecting the opportunity to claim confidentiality in chemical identities, because of the significant impact it would have on our industry's ability to compete in the domestic and global markets. It is appropriate to require that claims for the protection of confidential information be justified in advance.

Future revisions to TSCA must not create disincentives for companies to invest in the development of new chemicals and new applications of existing chemicals. TSCA must continue to strike a balance between the public interest in information about the health and environmental effects of chemicals and exposures to chemicals, and the industry's legitimate commercial intellectual property interests.

Introduction

My name is Craig Morrison. I am the President, Chief Executive Officer and Chairman of Momentive Performance Materials Holding, LLC, based in Columbus, Ohio. I am testifying today on behalf of the American Chemistry Council (ACC), the national trade association representing chemical manufacturers in the United States, where I am currently Chairman of the Board of Directors.

Momentive Performance Material Holdings LLC (MPMH) is the parent company of Momentive Performance Materials Inc. and Momentive Specialty Chemicals Inc. MPMH has approximately $7 billion dollars in revenue and operates some 90 manufacturing facilities in 37 countries, including 35 manufacturing sites in 18 states within the United States. We produce a broad range of advanced specialty chemicals and materials that help industrial and consumer companies deliver products that improve everyday life. For example, we produce more than 50 applications that serve the automotive industry. We are also significant suppliers to the energy, electronics, construction, personal care, mass transportation and numerous other segments that allow us to function on a daily basis. Momentive's operating companies were formed through a series of acquisitions and mergers that took place over a 10 year period, with the most recent taking place in 2010, when the Holding company was formed. While the name Momentive is relatively new, the legacy companies that formed Momentive have long histories that extend back over 100 years and were instrumental in developing key technologies for the chemical industry and ultimately the industries that it serves.

In short, Momentive is a company that relies heavily on the ability to use our expertise in specialty chemicals and materials to innovate.

The American Chemistry Council (ACC) represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. ACC is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing. The business of chemistry is a $770 billion enterprise and a key element of the nation's economy. It is one of the nation's largest exporters, accounting for 12 percent of all U.S. exports. Chemistry companies are among the largest investors in research and development, and rely heavily on the Toxic Substances Control Act (TSCA) to help bring their innovations to market and to protect proprietary commercial information.

TSCA and Innovation

Sections 5 and 14 of TSCA address, respectively, requirements for new chemicals and protection of confidential business information. These sections provide an important regulatory framework that protects health and the environment, and allows our industry's innovative solutions to come to market.

It is fair to say that sections 5 and 14 have been partly responsible for the significant competitive advantage the business of chemistry has in the United States compared to other countries and regions. The law and practice governing new chemicals and protections for confidential information has helped foster a dialogue between EPA and chemical manufacturers. In turn that dialogue has enhanced EPA's expertise in new chemicals review, helped manufacturers identify key health and environmental concerns early in the product development phase, and helped ensure that appropriate data and information is available to EPA in making

decisions. Protecting health and the environment and maintaining the industry's competitive advantage should be key objectives in any Congressional review and revision of TSCA.

Section 5 – New Chemicals and Significant New Uses

EPA's New Chemicals program implements section 5 of TSCA. The program can rightfully be considered one of the major successes of TSCA.

In testimony before this Subcommittee on June 13, 2013, Charles Auer, the former Director of EPA's Office of Pollution Prevention and Toxics (the EPA office that administers TSCA), had this to say about section 5:

> In my view, experience over the past 30+ years has shown that TSCA struck a good balance in its approach to new chemicals under §5 and that the program has been effective and efficient in its oversight of new chemicals. It has encouraged the introduction of safer and greener new chemicals while also working to move industry away from potentially problematic chemicals through both regulatory and voluntary efforts. The new chemicals program has been a driver for innovation in the U.S.

The business of American chemistry is a powerful engine for innovation and creativity. Our industry supplies virtually every manufacturing sector in the United States. Ninety-six percent of all manufactured goods are touched by chemistry at some point in the production cycle. Innovation is at the core of our industry's drive to become the world's preferred solutions provider. We can measure innovation in several ways:

- American chemistry has consistently been one of the largest private-sector investors in Research and Development (R&D). In the decade ending in 2011, the U.S. chemical industry (excluding pharmaceuticals) invested an average of nearly $11 billion annually in R&D, with companies typically allocating 1 to 3% of their annual sales to R&D. Major chemical companies are once again locating their R&D facilities in the United States, in recognition of the market potential and regulatory climate compared to other regions of the world. In 2012 alone, chemical companies invested nearly $15 billion in R&D.
- Patents play a key role in chemistry-related innovation. In general, one-fifth of all patents granted in the United States are chemistry-related. One-half of those patents are granted to the companies directly involved in the business of chemistry, including basic and specialty chemical companies. Of course, not all innovation in the chemical industry

is patentable, so this figure represents only a fraction of the technological developments in chemistry.

- The advent of reliable, affordable supplies of unconventional oil and gas in the United States has spurred significant investment in the industry. Chemistry is a major energy consumer, for both power and feedstock purposes. As of June, 2013, ACC identified over 100 new plants and plant modifications that have been announced for the U.S. to take advantage of that important resource, worth over $72 billion.

These factors would be less compelling without a regulatory structure that ensures innovation in chemistry can be reviewed for potential health and environmental impacts. TSCA Section 5 plays that role. Since TSCA was enacted, EPA has reviewed over 50,000 new chemicals. Those substances account for virtually all of the innovation in chemicals over past 30 years. In fact, three times more new chemical substances are brought to market in the United States compared to other regions of the world, in part because section 5 creates an efficient and effective mechanism for EPA to review new substances.

Section 5 requires a prospective manufacturer of a new chemical to submit information about composition, exposure, and use to EPA for review. Any available health and safety data on the new chemical must be submitted, although there is no requirement to generate a minimum data set. EPA review takes place in 90 days, subject to extensions. EPA can impose restrictions on the PMN submitter where needed, and can extend those or other restrictions to all manufacturers and processors of the chemical through a process of promulgating significant new use rules (SNURs). A chart describing the PMN process is attached to this testimony.

EPA's new chemicals review process has two particular strengths. First, the program ensures a scientifically robust review of the potential hazards and exposures of chemical substances. Although the program does not conduct an exhaustive assessment of new chemical substances, EPA has the necessary expertise and the tools to make a sound decision on PMN applications protective of health and the environment. Second, the process and timing of EPA's

review meets the demands of the marketplace. Most PMN submissions complete review within the 90 day statutory period.

EPA statistics illustrate how well the current program works.[1] From 1979 to 2010, a period of 31 years, EPA reviewed:

- 36,623 pre-manufacturing notices (PMNs).
- 796 test marketing exemption applications
- 10,423 low volume exemption applications
- 77 low release/low exposure (LoRex) exemption applications
- 2,530 polymer exemptions (through 1995, when individual reporting for eligible polymers became unnecessary; many more polymers have been manufactured under that exemption since then)
- For a total of 50,449 submissions (with more since 2010, and not counting polymer exemptions since 1995).

Importantly, EPA has established guidance that inform chemical companies on the data likely to be required to support PMN reviews for certain chemicals. EPA's Chemical Categories Report[2] identifies 56 categories of chemicals which in practice would result in EPA imposing restrictions were PMNs to be filed. Thus, EPA's influence on new chemistry extends well beyond the number of PMNs actually filed.

EPA evaluates PMNs and exemption applications on the basis of the data provided and, as needed, on the basis of modeling. EPA has developed a suite of advanced molecular, exposure, environmental release, and environmental modeling tools to evaluate new chemicals. If actual data on a candidate chemical is not available, EPA scientists can derive information from chemical identity and structure-activity relationship models. In addition, if

[1] EPA, "New Chemicals: Summary of Accomplishments" (2010), available at http://www.epa.gov/opptintr/newchems/pubs/accomplishments.htm.
[2] EPA, "New Chemicals Program Chemical Categories" (2010), http://www.epa.gov/opptintr/newchems/pubs/npcchemicalcategories.pdf.

EPA does not have data on a candidate chemical itself, it may have test data on a structural analog and can use that data as a surrogate in its evaluation. EPA has also developed sophisticated and powerful computer modeling – using data gathered over many years – to help predict a chemical's physical and chemical properties, health hazards, and potential environmental effects. It also has models that can help estimate exposure potentials for a chemical, depending on its anticipated use.

EPA review of new chemicals does result in regulatory actions. EPA's statistics[3] for the period 1979 – 2010:

- 1,848 PMNs were withdrawn due to EPA concerns (4% of the total)
- 1,492 PMNs became the subject of section 5(e) consent orders (4% of the total), and of these 757 (2% of the total) were followed by SNURs
- 797 PMNs became the subject of SNURs without issuance of a section 5(e) consent order (2% of the total)
- More than 300 led to voluntary testing actions
- A total of more than 4,441 PMNs were regulated (12% of the total)

Some observers believe that one of the major shortcomings of section 5 is that it does not require that all new chemicals have a "minimum data set" before EPA review. This criticism is misplaced. EPA has found that 90% of PMNs do not require more detailed information or review because the Agency is able to make decisions on the basis of the information submitted by the manufacturer and/or based on EPA modeling results. To require every new chemical to have a full data set prior to EPA review would have been wasteful, as the Agency did not need the information to reach a decision.

EPA has a robust suite of modeling tools to evaluate new chemicals. Where structure, analogs, or computer modeling is insufficient to support a risk management decision, under

[3] EPA, "New Chemicals: Summary of Accomplishments" (2010), referenced in footnote 1.

section 5 the Agency can and does require companies to develop specific test data before manufacturing can begin. EPA can require PMN submitters to conduct testing through section 5(e) consent orders or through voluntary commitments. In some cases, EPA imposes a section 5(e) consent order to prohibit manufacture beyond a specified volume without submission of test results to EPA for its review.

Momentive's two operating companies submit on average 10 new chemistries for review each year and has submitted approximately 120 new chemistries for review over the past 10 years. Thanks to EPA's efficient and well-functioning process, about 90% of these new products over the last five years have been able to come to market without the need for new animal testing.

For example, our Silicone and Quartz Division focuses on the development of innovative and new chemicals that bring value to consumers and society. These new chemicals are ultimately incorporated into other products to enhance their performance. Some of our products have completed the PMN review process without conducting animal testing through the use of computer modeling and comparison to similar chemicals that have been tested. These include several chemicals that are used in manufacturing tires. When used, these chemicals improve the performance and life of tires through longer wear, less waste from tire production, tire production time efficiency improvements, and improvements in the safety of tires.

EPA has accepted analog chemical (read across) data developed under OECD guidelines and good laboratory practices in its review of many of our PMNs. EPA's flexibility in this regard has aided the development of new high tech silicone materials that our company uses in many applications. For example, these materials are used in improved coatings for automobile parts and smart phones. Our polymer chemistry provides better bonding qualities for auto glass

so it does not shatter during car accidents. In addition, new and innovative chemicals have been used in improving the binding capabilities in fiberglass applications such as in windmill blades, in industrial and commercial coatings to improve protection and water proofing of stone, ceramic, and masonry surfaces, and durability of fabrics. Another example is a chemical developed to improve the binding capability of coatings used to reduce fouling on marine vessels.

In our experience, EPA's review of the entire PMN package focuses on true risks – integrating hazard data/information and use/exposure related information—in ways that a minimum data set would not. EPA often engages in dialogue with companies like Momentive with questions about the new chemical, and where needed EPA requires the company to address these before the PMN process is complete. In our experience, the PMN review process is based upon a solid scientific foundation, a focus on true potential risks, and flexibility. This process has allowed Momentive the opportunity to create new materials and get them to the marketplace before our global competitors, so the materials can be used in safer and more energy efficient applications.

A requirement for a minimum data set could have a devastating impact on innovation. New chemicals are typically introduced into the market at low volumes, a consequence of the pre-manufacturing requirements imposed under TSCA, rather than the pre-marketing review systems in other countries. New chemicals face commercial and technical hurdles; adding the expenses and delays of up-front testing would add significantly to those hurdles. The result would be, among other things, that chemicals intended to replace more hazardous chemicals might never get to market. EPA's implementation of the new chemicals program provides manufacturers of new chemicals the ability to first generate revenues to pay for the testing from

sales of the chemical. Chemicals which fail in the marketplace, as many do, will not reach those production levels, and so the testing costs can be avoided for those chemicals initially manufactured at low volumes that pose little risk to health or the environment.

Compared to the regulatory structures for pharmaceuticals and agricultural chemicals, it is not difficult to understand why section 5 has a significant influence on innovation in chemistry. The U.S. regulatory regimes for pharmaceuticals and agricultural chemicals require significant investments in data, and for good reason. Pharmaceuticals and agricultural chemicals are intended to be biologically active, humans are directly exposed to them, and regulators should have more complete information on the effects of these substances. The costs of bringing a new drug or agricultural chemical to market can easily rise to the tens of millions of dollars.

By contrast, industrial chemicals are not generally intended to have biological effects – they are designed to perform certain functions for a wide variety of industrial manufacturing purposes, as well as in commercial and consumer uses in goods and articles that improve the health and quality of our lives. The flexibility and authority TSCA vests in EPA to obtain the data and information necessary to make decisions that are protective of human health and the environment and protect U.S. economic and competitive interests is a crucial benefit of new chemical regulation under section 5.

In testimony before the Senate Environment and Public Works Committee on February 4, 2011, Dr. Lynn Goldman, the former Assistant Administrator for Prevention, Pesticides and Toxic Substances at the U.S. EPA that managed the TSCA program noted that

> When EPA determines that there is a risk associated with a PMN it has tools that can be used to manage those risks. TSCA Section 5 gives EPA the ability to require additional tests or other measures such as disposal controls and worker protection. Over the years, the new chemicals program has made wonderful efforts to inform the chemical industry about the criteria used to assess chemicals. These efforts have encouraged development

of safer chemicals, and I believe have caused the industry to screen out "bad actors" before presenting them to the EPA in the first instance.

The Subcommittee should consider section 5 one of the key elements of TSCA – a provision for new chemicals review that has undoubtedly met many of the objectives Congress envisioned in 1976. Any effort to reform TSCA should be careful to preserve the essential elements of the new chemical review program that protect health and the environment and U.S. commercial and competitive interests.

Section 14 – Disclosure of Data

The ability to protect commercial confidential information from disclosure is another key element in fostering innovation. For a company like Momentive, our status as a global leader in thermoset resins, silicones and advanced materials depends heavily on our ability to protect our trade secrets from disclosure. Trade secret protection is crucial to my company's global competitiveness. It is crucial to our industry's ability to innovate to produce cleaner, safer and more effective products.

The protection of confidential business information must be balanced, however, by appropriate government and public access to health and safety information. In section 14, Congress struck a fairly good balance of those interests.

Much of the innovation in chemistry depends on protection of confidential chemical identities, which are among the most valuable intellectual property in the chemical industry. Confidential chemical identities do not generally qualify for protection under patent, copyright, and other forms of intellectual property protections; they are considered trade secrets under the Freedom of Information Act. It is crucial that this information receive appropriate protection under TSCA.

It should be noted that CBI claims do not bar EPA access to the data and information. Furthermore, section 14 is absolutely clear that the prohibitions on disclosure do not apply if disclosure is necessary for law enforcement purposes, or if the Administrator determines that disclosure is necessary to protect against an unreasonable risk of injury to health and the environment.

As important as protection of confidential information is for the chemical industry and our ability to innovate, there are limits to that protection. ACC and its members firmly believe that data and information on the health effects of chemical exposures should not be eligible for protection as confidential business information.

Section 14 broadly prohibits EPA from disclosing to the public information which is exempt from mandatory disclosure to the public under the Freedom of Information Act (FOIA). The prohibition on disclosure, however, does not extend to any health and safety study, so long as the chemical substance is in commercial distribution or it is one otherwise regulated under sections 4 or 5 of the Act. In another Congressional nod to the importance of proprietary information, section 14 very clearly bars the disclosure of data on processes used in manufacturing.

Some observers claim that chemical identity is always an essential part of the data from a health and safety study and critical to understanding the study. They assert that chemical identity cannot be claimed CBI and should not be protected unless it falls within one of the exceptions to disclosure of health and safety studies. In 2011, EPA announced plans to change its PMN regulations to prohibit the protection of confidential chemical identities in health and safety studies. This action was the Agency's effort to implement a 2010 change in EPA's interpretation of section 14 to require the disclosure of confidential chemical identity in health and safety

studies. The proposed rule[4] was submitted for review by the Office of Information and Regulatory Affairs (OIRA) in December 2011, but has not cleared the review process.

ACC strongly opposes any change in EPA's policy affecting claims of confidentiality in chemical identities, because of the significant impact it would have on our industry's ability to compete in the domestic and global markets. We have been clear in our support for up-front justification of CBI claims, including claims to protect chemical identity. EPA guidance already requires that a manufacturer claiming a chemical identity confidential must provide a structurally-descriptive generic name for the substance. ACC's analysis has indicated that the generic names actually provide greater access to relevant health and safety studies and information on substances than the specific chemical name or CAS number. Generic names all link to the scientific literature on similarly structured substances. In contrast, chemical identity may be of little value to the public since there may not be published scientific literature on the specific chemical substance, particularly in the case of new or recently developed chemicals.

Section 14 has been criticized by some because of the relatively high number of CBI claims that have been made by manufacturers. Some believe that the large number of claims has kept critical health and safety information from the public.

The truth is that EPA's management of section 14 and industry practices have both contributed to a large number of existing CBI claims. EPA has not systematically reviewed and challenged inappropriate claims, and it has not consistently required that claims be justified. Because of the ease with which a CBI claim can be invoked, industry reflexively made some CBI claims that may not have been warranted. Section 14 does not establish a process for CBI claims to be revoked or waived should they no longer be needed.

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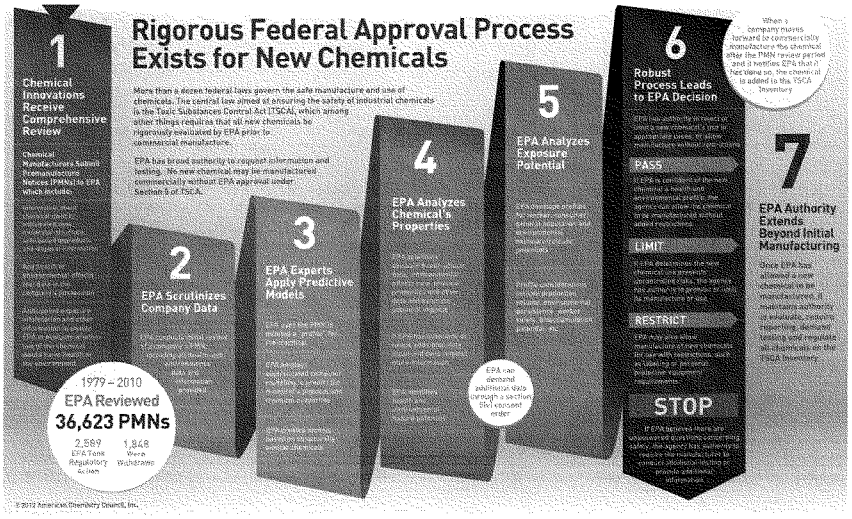
[4] CBI: PMN Amendments Claiming Chemical and Microorganism Identity as Confidential in Data from Health and Safety Studies Submitted under TSCA Prior to the Commencement of Manufacture (RIN 2070-AJ87)

Currently, EPA and industry are addressing this problem in a cooperative effort to "declassify" past CBI claims that are no longer needed. In 2010, EPA identified 22,000 submissions for health and safety studies that it believed may include claims for chemical identity. Since the cooperative review began, 15,700 cases have been reviewed. Over 11,500 cases do not contain any CBI health and safety studies at all. The review has prompted the declassification of nearly 900 CBI claims in health and safety studies. The numbers suggest that the charge of excessive CBI claims may be overstated.

A modernized TSCA must not create disincentives for companies to invest in the development of new chemicals and new applications of existing chemicals. TSCA must continue to strike a balance between the public right-to-know health and environmental effects information about chemicals and industry's legitimate commercial intellectual property interests.

Conclusion

ACC and its members look forward to working with the Subcommittee as you continue your inquiry into the Toxic Substances Control Act. The business of chemistry has a major stake in TSCA, and particularly in sections 5 and 14 of the Act. The sound implementation of both sections is critical not only to protection of health and the environment from the unmanaged risks of exposures to chemical substances, but to innovation, jobs, and economic growth.


Rigorous Federal Approval Process Exists for New Chemicals
More than a dozen federal laws govern the safe manufacture and use of chemicals. The central law aimed at ensuring the safety of industrial chemicals is the Toxic Substances Control Act (TSCA), which among other things requires that all new chemicals be rigorously evaluated by EPA prior to commercial manufacture.
EPA has broad authority to request information and testing. No new chemical may be manufactured commercially without EPA approval under Section 5 of TSCA.
1
Chemical Innovations Receive Comprehensive Review
2
EPA Scrutinizes Company Data
3
EPA Experts Apply Predictive Models
4
EPA Analyzes Chemical's Properties
5
EPA Analyzes Exposure Potential
6
Robust Process Leads to EPA Decision
PASS
LIMIT
RESTRICT
STOP
7
EPA Authority Extends Beyond Initial Manufacturing
1979 – 2010
EPA Reviewed
36,623 PMNs
2,589
EPA Took Regulatory Action
1,848
Were Withdrawn
EPA can demand additional data through a section 5(e) consent order
When a company moves forward to commercially manufacture the chemical after the PMN review period and it notifies EPA that it has begun, the chemical is added to the TSCA Inventory
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Mr. GINGREY. Mr. Morrison, thank you.

We will now hear from Mr. Len Sauers, Vice President of Global Sustainability with Procter and Gamble. Mr. Sauers, 5 minutes.

STATEMENT OF LEN SAUERS

Mr. SAUERS. Thank you, Mr. Chairman and Ranking Member Tonko, members of the committee. Thank you for inviting me here today. As has been said, my name is Len Sauers. I am the Vice President for Sustainability, Product Safety, and Regulatory Affairs at the Procter and Gamble Company.

P&G is the largest consumer products company in the world. Our products are used by 4.6 billion people around the world every day. We have operations in nearly 80 countries, and 99 percent of American households have at least one P&G product in their home. Since our founding over 175 years ago, innovation has been integral to everything we do, and has been critical to our success. To support our innovation efforts today, we have dedicated R&D facilities in five continents, and we employ over 9,000 R&D employees.

P&G supports comprehensive modernization of TSCA for two primary reasons. First, federal action is urgently needed to enhance consumer confidence in the safety of the ingredients that they use in their everyday household products; and secondly, reform will give States confidence in a strong federal chemical management system, and thereby avoid a patchwork of varying requirements across multiple States, which will slow innovation and increase complexity.

I would like to turn now to the regulation of new chemicals. Over the past 30 years, P&G has either submitted or been the major contributor to over 175 pre-manufacture notices. From our experience, we believe that both the law and EPA's governance of the New Chemicals Program have provided for scientifically robust reviews of the potential hazards and exposures of new chemicals entering the U.S. market and ensured appropriate health and environmental protection.

There are many strengths to EPA's New Chemicals Program. One is the ability to tailor customly the data submitted in a PMN to the specific new chemical, as opposed to requiring a minimum data set. This approach assures that the information which is necessary and relevant to evaluate the safety of the chemical is received. EPA also utilizes modern science, such as sophisticated predictive models and structure activity relationships to evaluate new chemicals. New safety data is only requested when necessary to make decisions, thereby avoiding unnecessary animal testing. EPA is very receptive to pre-submission consultations with companies to help them plan for and anticipate the needs that EPA will have during their review. And finally, when deemed necessary, EPA has a broad range of regulatory tools that they can use to limit exposure to a new chemical.

New chemical review is a key element of TSCA. It is P&G's opinion that the new chemical provisions of TSCA function efficiently and effectively.

Now I would like to turn to confidential business information. P&G invests over $2 billion annually in research and development. We have a significant interest in protecting our new to the world

chemistries and confidential business information from public disclosure to our competitors. We rely heavily on the protection of confidential business information afforded by Section 14 of TSCA to remain competitive in the marketplace, and are very concerned with EPA's recent decision to reverse current practice and publically disclose the specific structure of chemicals for which companies currently consider confidential, when the health and safety studies of these chemicals are made public.

P&G fully supports transparency when health and safety information in EPA's administration of TSCA Section 14 and we agree that all health and safety data should be made public, but the disclosure of specific, confidential chemical identities is not needed for one to understand the safety of a new chemical. Structurally descriptive, generic chemical names, like those P&G provides today on its Web site as part of our consumer information program are sufficient. For example, consider P&G's development and market introduction of Tide Cold Water laundry detergent. P&G's scientists discovered a new technology that enabled consumers to get the same cleaning performance in cold water as they expected in hot or warm. This innovation enabled them to save money on their energy bills and meaningfully decrease their greenhouse gas emissions by no longer having to heat water for laundry. P&G submitted two PMNs to EPA to create Tide Cold Water. Over 150 pounds of safety data were submitted with the PMN, and we requested that the specific chemical structure of our new technologies be kept confidential to prevent our competitors from piecing together the required chemistry needed to duplicate the formula. P&G's development costs of the two PMNs totaled about $150 million. EPA'S new interpretation of TSCA Section 14 would have meant disclosing to competitors those confidential chemical identities and allowing them to benefit from our work without an investment on their part.

A modernized TSCA must continue to strike the right balance of protection of confidential business information with public access to health and safety information about chemicals in commerce.

Mr. Chairman, Ranking Member Tonko, thank you again for the invitation to testify this morning. P&G values our partnership with you and this subcommittee, and we remain committed to working with you to develop a practical, scientifically sound, chemical management program that strengthens protection of human health and the environment, and ensures U.S. leadership of sustainable innovation in the global marketplace. Thank you.

[The prepared statement of Mr. Sauers follows:]

Testimony of Len Sauers, PhD

Vice President, Global Sustainability, Product Safety and Regulatory Affairs

The Procter & Gamble Company

United States House of Representatives Energy and Commerce

Subcommittee on Environment and the Economy

Hearing on

"Regulation of New Chemicals, Protection of Confidential Business Information, and Innovation"

Thursday, July 11, 2013

Introduction

Chairman Shimkus, Ranking Member Tonko, members of the Committee, thank you for inviting me to testify today to discuss The Procter & Gamble Company's (P&G) experience with compliance under the Toxic Substance Control Act (TSCA), particularly our experiences with the new chemicals and confidential business information sections when bringing new innovation to the US market.

My name is Len Sauers. I am the Vice President, Global Sustainability, Product Safety and Regulatory Affairs at Procter & Gamble where I am responsible for the company's sustainability program, as well as the product safety and regulatory affairs organization.

P&G serves more than 4.6 billion people around the world with our trusted household and personal care brands. We have on the ground operations in nearly 80 countries worldwide, and dedicated innovation facilities on five continents. Ninety-nine percent of American households contain at least one P&G product. Over 90% of the products we sell in North America are manufactured in the U.S, where we operate 33 manufacturing facilities in 22 states (including California, Delaware, Georgia, Illinois, Iowa, Kansas, Maryland, Massachusetts, Missouri, Nebraska, New Jersey, North Carolina, Ohio, Pennsylvania, Tennessee, Utah, Vermont and Wisconsin). Our trusted, quality, leadership brands, including Pampers, Tide, Pantene, Bounty, Crest, Oral-B, Duracell, Olay, Gillette and many others, touch and improve the lives of consumers in virtually every country.

Innovation is integral to everything we do to improve the value consumers get from putting their trust in P&G brands. Since our founding in 1837, we have been inspired and driven by our Purpose — to touch and improve the lives of our consumers, in small but meaningful ways each and every day. As a company, we have chosen to deliver on our Purpose through innovation. At P&G, we believe innovation is our lifeblood.

I want to thank you, Mr. Chairman and Ranking Member Tonko, for your interest in learning more about TSCA, the need for modernization of the statute, and how this will impact US innovation. P&G recognizes that our consumers are concerned about chemicals used in everyday products and we fully support efforts to enhance public confidence in the safety and management of chemicals through the modernization of TSCA.

P&G supports robust federal modernization of the Toxic Substance Control Act of 1976. Federal action is urgently needed to slow the emergence of new individual state regulations which would result in an unworkable patchwork of varying requirements across the nation that would significantly disrupt innovation and U.S. market distribution. Further, many countries are emulating the European Union's REACH chemical framework which presents a significant barrier to innovation, lacks a science-based chemical prioritization process, or any obligation to systematically affirm the safety of priority chemical substances. The U.S. needs to provide global leadership in the chemical management arena by providing an alternative to REACH that protects human health and the environment and promotes sustainable innovation. P&G remains

committed to help develop workable, scientifically sound legislation that strengthens protection of human health and environmental safety to ensure U.S. leadership of sustainable innovation in the global marketplace.

New Chemicals

P&G believes that new chemical review under a modernized TSCA needs to balance protection against unreasonable risks from exposures to a new chemical with the promotion of innovation in a competitive, global marketplace. Over the last 30+ years, P&G has either submitted or been the major contributor to over 175 Pre-Manufacture Notices (PMNs) that have spanned commodity chemical manufacturing as part of our global P&G Chemicals business, to use of new chemistries in the formulation of our household brands. From our experience, we believe that both the law and EPA's governance of the New Chemicals Program have provided for scientifically robust reviews of the potential hazards and exposures of new chemicals entering the US market to ensure appropriate health and environmental protection.

One of the greatest strengths of the TSCA New Chemicals Program is the ability to custom tailor the safety data and information in a PMN submission to the specific new chemical in question and its potential exposures, rather than require a minimum safety data set that may either provide too little data or information that is not relevant about the new chemical. We believe a minimum data set approach to new chemical review is a wasteful practice that is resource-intensive, time consuming, and needlessly sacrifices the lives of animals. EPA's administration of the New Chemicals Program has followed

a more enlightened approach which fully utilizes all available safety data and information, including reliance on sophisticated predictive models and the development of new safety data when necessary, to make decisions. When developing our PMNs over the years, we have found EPA receptive to pre-submission consultations that have helped us anticipate and plan for the necessary safety data and information that EPA would need during their review. EPA's willingness to dialogue early in the development of a PMN has resulted in our positive experience with the New Chemicals Program and has allowed us the speed to market needed for competitive advantage and ensured our ability to delight our consumers with new-to-the-world innovations.

EPA has administered the New Chemicals Program efficiently by conducting the majority of PMN reviews within a 90 day period, although the Agency can (and does) have the duration of the review extended when needed to obtain additional, targeted safety related data and information about the new chemical. EPA has a broad range of regulatory tools that the Agency will exercise to limit exposure to a new chemical when needed. The restrictions imposed by the Agency can be based on the intended use of the new substance described in a PMN or any other uses of the new substance that raise EPA's concern. EPA's application of a Significant New Use Rule (SNUR) to a new chemical, among other regulatory options, demonstrates the Agency's intent in understanding and managing the full risk potential of a new chemical entering the market, beyond the specific uses described in the PMN.

New chemical review is a key element of TSCA. It is P&G's opinion, and one that is shared broadly by chemical manufacturers and innovative formulators across the industry, that the new chemical provisions of TSCA function efficiently and effectively. We encourage the subcommittee to protect this positive element of TSCA when considering any effort to modernize the statute.

Confidential Business Information

Procter & Gamble invests $2 billion annually in research & development (R&D), which is about 60% more than our next closest competitor and more than most of our competitors combined. We have a significant interest in protecting our new-to-the-world chemistries, our formulation designs and process technology, and other confidential business information from public disclosure to our competitors in order to succeed in the marketplace by delighting our consumers with innovation. P&G holds 55,000 active patents globally, but patents alone are not enough to protect the continual improvements we make to our product designs. We rely heavily on the protection of confidential business information afforded by Section 14 of TSCA to remain competitive in the US and global marketplace. The challenge of a competitive marketplace and of earning the right to win with consumers incentivizes us to continually search for more sustainable innovations that meaningfully improve the lives of our consumers and deliver real environmental benefits.

We recognize that EPA has to carefully balance the protection of confidential business information under TSCA with providing public access to health and safety information

on chemicals in U.S. commerce. P&G fully supports transparency with health and safety information in EPA's administration of TSCA Section 14. However, we believe the broad language of TSCA Section 14 has led to misinterpretations of what constitutes health and safety information. Our particular concern is with EPA's recent decision to reverse 35+ years of practice by requiring in all instances the public disclosure of the confidential chemical identities for which health and safety studies are provided. A specific, confidential chemical identity is not needed to conduct a health and safety study, interpret its results, or communicate the study's observed health effects and conclusions. The external, 3rd party laboratories that P&G contracts to conduct safety studies and interpret the results, complete these tasks without ever knowing the specific, confidential chemical name of the test substance. Structurally descriptive, generic chemical names are sufficient to provide the public with information about the structure of the chemical and its hazard profile, which in turn provides a linkage and access to publicly available, scientific and toxicological literature on similarly structured substances.

P&G's concern with EPA's new practice culminated in late 2011 when EPA sent to the Office of Management and Budget (OMB) for its review a draft proposed rule to amend the PMN regulations. This proposed rule, if ever finalized, could delete the longstanding opportunity of PMN submitters to protect from disclosure the confidentiality of new chemical identities in health and safety studies.

In our industry, confidential chemical identities are often the most valuable type of intellectual property. Disclosure of a specific, confidential chemical identity in a PMN submission that contains supporting health and safety data provides information to competitors about the company's go-to-market plans. P&G files hundreds of patents each year to protect a range of technological options for our potential use, but a PMN is rarer, and when followed by submission of a Notice of Commencement (NOC) to EPA, provides a clear signal to competitors that we are invested in and intend to use the new-to-the-world technology described in the PMN. Disclosure of a specific, confidential chemical identity in a PMN submission can provide competitors with the necessary information to unravel our formulary science, replicate our product formulations, and importantly, benefit from the health and safety assurance of our toxicological studies in the PMN submission – all without investing the same significant time, resources, and billions of dollars in research and development as P&G.

P&G's development and market introduction of Tide Coldwater provides an example of the impact on innovation that EPA's changing interpretations of TSCA Section 14 have created. P&G's formulary scientists discovered a new-to-the-world-surfactant needed for laundry detergents to deliver world-class cleaning performance and stain removal in cold wash water. This innovation led to P&G's introduction of Tide Coldwater in the US market. This technological breakthrough enabled consumers to obtain the same strong performance benefits from washing in cold water that they knew to expect from washing with standard detergents in warm or hot wash temperatures. Tide Coldwater represented a sustainable innovation that delighted consumers by helping them save

money on their energy bills and providing a way in which to meaningfully benefit the environment by reducing CO2 emissions from the energy-intensive process of heating water for the laundry wash cycle. For instance, if every household in the United States used cold water for laundry, the energy savings would be 33 billion kilowatt hours per year which is the equivalent use of electric consumption in 4.4 million households.

P&G submitted two PMNs to EPA to create Tide Coldwater. Both PMNs claimed the chemical identity as confidential to prevent competitors from piecing together the required chain lengths, isomeric structures, and salt derivatives of the sulfated alcohols needed for optimal surfactancy in cold water wash. P&G's development costs of the two PMNs totaled about $150 million. The submitted PMN documents weighed 150 lbs., mostly due to the extensive safety studies provided by P&G. EPA's new interpretation of TSCA Section 14(b) would have meant disclosing to competitors those confidential chemical identities because of the submitted safety studies and thereby risking P&G's ability to succeed in the US marketplace with an innovation that delivered meaningful and measurable environmental benefits.

A modernized TSCA must not create a disincentive for companies to invest in the development of new chemicals and to support the safe use of those chemicals by generating appropriate health and safety studies. A modernized TSCA must continue to strike the right balance of protection of confidential business information with public access to health and safety information about chemicals in US commerce.

Conclusion

Mr. Chairman, Ranking Member Tonko, thank you again for the invitation to testify this morning. P&G values our partnership with you and this Subcommittee and we remain committed to working with you to develop a practical, scientifically sound chemical management program that strengthens protection of human health and the environment and ensures U.S. leadership of sustainable innovation in the global marketplace.

Mr. GINGREY. Mr. Sauers, thank you.

Next witness, Mr. David Isaacs, Vice President of Government Affairs, Semiconductor Industry Association. Mr. Isaacs, you are up for 5 minutes.

STATEMENT OF DAVID ISAACS

Mr. ISAACS. Thank you, Mr. Chairman and Ranking Member Tonko, and members of the subcommittee. My name is David Isaacs, and I am testifying on behalf of the Semiconductor Industry Association.

SIA is the trade association of U.S.-based semiconductor companies that design and manufacture semiconductors, and as many of you know, semiconductors are the integrated circuits or sometimes called computer chips that are the basic building block for all modern electronics. These innovations enable the revolution we have experienced in information technology, communications, transportation, medical devices, and national defense, so they are a fundamental part of our economy and American economic leadership.

Our industry employs directly a quarter of a million people in the United States, and supports over a million indirect jobs. We are consistently among the top export industries in the United States, and a key part of America's advanced manufacturing infrastructure.

So before I speak to our views on the current TSCA system, I wanted to provide some context on our industry's use of chemicals. Our industry relies, in our manufacturing processes, on the—on specific chemicals that have particular chemical and physical properties and unique functional attributes that enable us to produce, you know, up to a billion transistors on a chip the size of your fingernail. We integrate these chemicals in advanced manufacturing equipment with high levels of precision, very rigorous controls, and enclosed processes, high levels of automation, and that results in a very precise process and also an exemplary environmental and safety record. And that background informs our views on the New Chemical Program. We believe that the existing program generally strikes the right balance between environmental protection and the approval of new chemicals that help drive our innovation. It is important to note that semiconductor companies do not traditionally submit PMNs for approval by the EPA, and we rely on our chemical suppliers for that function, but we have a strong interest in ensuring our access to new chemicals that can help drive our advances.

The key attributes of the current system are the risk-based approach, and as others have mentioned, the tailored and customized evaluation of chemical uses. In our industry, the unique attributes of our manufacturing processes result in very low levels of risk and exposure, and we believe that that very much needs to be kept into account in any reform efforts going forward.

My testimony outlines other attributes of the system that we think are very important, such as an expedited timeframe that allows speed to market, and critical exemptions for activities like research and development. And then, of course, the protection of confidential business information is critical to our industry as well. Our industry is very much driven by intellectual property. We in-

vest, on average, 18 percent of revenue into R&D. Last year, that amounted to $32 billion in R&D investments. We are a leader in patents and many of our processes are protected as trade secrets. So the protection of CBI under the TSCA is very, very important to us, and we think it generally works well and strikes the right balance between the need for the public to have available information on health and safety data while at the same time protecting confidential business information.

So going forward, we look forward to working with the Congress and this subcommittee on efforts to modernize TSCA and we would like to play a constructive role in that effort. So thank you very much for the opportunity to testify.

[The prepared statement of Mr. Isaacs follows:]

Testimony of the
Semiconductor Industry Association (SIA)
Before the
Environment and the Economy Subcommittee
Of the
House Energy and Commerce Committee

Hearing on
"Regulation of New Chemicals, Protection of Confidential Business Information, and Innovation"
July 11, 2013

The Semiconductor Industry Association (SIA), the voice of the U.S. semiconductor industry,[1] appreciates the opportunity to testify on "Regulation of New Chemicals, Protection of Confidential Business Information, and Innovation."

Semiconductors are the integrated circuits (commonly called ICs or "chips") that are the enabling technology for all modern electronics found in computers and cell phones, cars and health care devices, communications and military systems, and all other facets of modern technology. Because semiconductors are a foundational technology for virtually all areas of our economy, continued U.S. leadership in semiconductor technology is essential to America's continued global economic leadership. Semiconductors are one of the nation's top exports[2] and a bellwether measurement of the U.S. economy. The industry directly employs about 250,000 employees in jobs with wages that average over $120,000 – well above the average of the rest of US manufacturing – and results in approximately 1.1 million indirect jobs. In addition, semiconductor innovations form the foundation for America's $1.1 trillion dollar technology industry affecting a U.S. workforce of nearly 6 million.

Contrary to the popular perception that most high tech manufacturing has been offshored to Asia, it is important to emphasize that advanced semiconductor manufacturing in the U.S. remains strong and growing sector. The majority of production (56 percent) from U.S. semiconductor firms is located in the United States, and the U.S. is home to more leading-edge process technology manufacturing facilities (i.e., 22 nanometer process technology or less) than any other country in the world.[3] SIA member companies continue to invest and expand in the U.S., with the construction

[1] SIA seeks to strengthen U.S. leadership of semiconductor design and manufacturing by working with Congress, the Administration and other key stakeholders. SIA works to encourage policies and regulations that fuel innovation, propel business and drive international competition in order to maintain a thriving semiconductor industry in the United States. Additional information on SIA is available at www.semiconductors.org.
[2] During the period 2008-12, semiconductors were the second largest export from the U.S., after aircraft. *Source: U.S. International Trade Commission. Industry Defined By: NAIC Codes 336411 (Aircraft); 334413 (Semiconductors); 336111 (Automobiles); 324110 (Petroleum Refinery Products), Based from total exports revenue.*
[3] Source: IC Insights, Global Fab Database.

of new and expanded state-of-the-art fabrication facilities across the country. Overall, U.S.-based semiconductor companies retain over 50 percent of global market share in a highly competitive market. The core mission of SIA is to advance the leadership of U.S. companies in semiconductor research, design, and manufacturing.

I. Semiconductor Manufacturing and Chemicals Innovation

Semiconductor manufacturing is enabled by rapid change and innovation. The industry has successfully introduced new technologies and processes that have resulted in a doubling of the number of transistors on advanced semiconductors roughly every 18-24 months; a semiconductor now contains over a billion transistors on a single chip, at a feature size of 22-nanometer (i.e., 22 billionths of a meter, or roughly a 4,000th the width of a human hair).[4] This pace of advancement has resulted in the revolution in information and communications technology and other technological innovations which have been based on the availability of ever smaller, faster, more energy efficient electronics. To maintain this rapid pace of progress, the semiconductor industry relies on, among other things, attracting the best scientists and engineers from around the world, expending huge capital and research investments, developing and protecting intellectual property, and a flexible regulatory process.

Advancements in chemicals and materials science are one factor that contributes to the continued innovation in the semiconductor industry, and the responsible use of chemicals is essential to maintain the growth and competitiveness of the U.S. semiconductor industry. Accordingly, sound policy governing the regulation of chemicals and materials is a top priority for the industry. SIA's primary goals with regard to chemicals regulation are to protect human health and the environment in a manner that also facilitates continued innovation and the protection of intellectual property. SIA will evaluate all proposals to modify the Toxics Substances Control Act (TSCA) with these goals in mind.

1. Overview of the Semiconductor Manufacturing Process

Semiconductor manufacturing is a highly complex process involving the precise and controlled use of many chemicals and advanced materials. The industry utilizes specialty chemicals with unique chemical and physical properties that make possible the production of advanced semiconductors. The industry also uses bulk chemicals that are widely used and well-understood (e.g., sulfuric acid). In fact, most of the chemicals we use also have uses in other industries, which are likely to give rise to different risks and exposure scenarios. Therefore, a key attribute of an efficient regulatory system is to ensure that chemicals used in the semiconductor industry are evaluated according to the unique use, risk, and exposure models applicable to our industry.

The process of manufacturing semiconductors involves hundreds of carefully controlled steps in which highly advanced pieces of manufacturing equipment (known as "tools")

[4] "Moore's Law: The rule that really matters in tech (Oct. 15, 2012) (available at http://news.cnet.com/8301-11386_3-57526581-76/moores-law-the-rule-that-really-matters-in-tech/).

apply specific chemicals to a thin, round slice of silicon (known as a "wafer") to create numerous patterned layers of the integrated circuit. These processes are conducted in a fabrication facility (a "fab"), a highly complex manufacturing facility where operations are conducted in an environmentally controlled clean room that is over 100 times more sterile than a medical operating room. Fabs are among the costliest capital investments in the world; a state-of-the-art fab can cost in excess of $5 billion. Semiconductor manufacturing operations involve highly automated processes in enclosed systems, with an exceptionally strong level of control during all aspects of the process.

The "fabrication" of a semiconductor device entails a repetitive patterning process in which materials are selectively deposited, modified, or removed from a wafer surface, to produce highly sophisticated structures that are the building blocks of transistors which then become integrated circuits (sometimes commonly referred to as "computer chips"). The key process steps in creating a semiconductor all employ the advanced use of chemicals: in the following ways:

1. Imaging (known as "photolithography") – light is used to transfer a geometric pattern from a photo mask to a light sensitive chemical (photoresist) on the substrate.
2. Deposition (addition of material) – materials such as copper and tungsten are added to the substrate within the open patterned area through processes such as chemical vapor deposition (CVD), epitaxial deposition, doping, and plating.
3. Etch (removal of material) – the selective removal of materials like silicon from the open patterned area, using either chemicals or other processes. The most commonly used form of etching is "plasma etch," in which source gases – typically fluorinated gases ("F-gases") – are excited using radio frequency (RF) energy to create a plasma which releases ions, electrons and chemically reactive neutral molecular species, including fluorine radicals.

As circuit features get ever smaller, the semiconductor industry's precise use of chemicals with specific properties becomes even more critical. The continued ability of the industry to innovate and produce ever smaller, faster, more energy efficient and capable integrated circuits depends, in part, on our industry's access to chemicals with specific functionality. Chemicals are selected based on their unique properties and functionality, and the advanced manufacturing tools are designed to operate using these specific chemicals. As a result, there are typically no "drop-in" replacements for many of the chemicals currently in use in any given manufacturing process. Moreover, the manufacturing technology development process is usually quite long (10 or more years), while actual product lifecycles are relatively short (2-4 years). As a result, changes in manufacturing process technology are very difficult to implement quickly. The manufacturing process also involves continuous improvements and modifications to achieve very specialized circuit function with optimal performance, reliability, and consistency, including ongoing efforts to minimize the quantities of chemicals and to use the least hazardous substances for a given application. Nonetheless, it is typically impossible to replace the critical chemicals once they have been selected for the manufacturing process.

2. The Semiconductor Industry's Controls on the Use of Chemicals

The semiconductor manufacturing process is highly controlled and performed to exacting standards. In order to ensure quality and consistency in the production process, chemicals and materials used in semiconductor manufacturing are subject to significant and often redundant controls and safety measures. The entire process is conducted in a tightly controlled clean room environment, where there are specific controls on temperature, humidity and air contamination. In the semiconductor manufacturing process, uncontrolled particles, chemical vapors and gases are unacceptable from a production standpoint. Highly specialized manufacturing tools and processes deliver exactly the right amount of chemical, in exactly the right place, at exactly the right time. This exceptional level of control is needed in order to build chips with features at the nanoscale.[5]

The highly controlled systems in a fab include enclosed processes, automation, and chemical delivery systems. This results in high levels of protection of both the environment and fab workers. In order to safeguard the environment, the industry has been a leader in phasing out substances of concern[6] and reducing already low levels of emissions.[7] The enclosed processes and automated systems create a barrier between workers and the process, thereby protecting workers against chemical and physical hazards into the work environment. These standards and controls have helped

[5] Nanotechnology is the science, engineering, and technology conducted at the nanoscale, a range from 1 to 100 nanometers (nm). One nanometer is a billionth of a meter, or 10-9 of a meter.) See http://www.nano.gov/nanotech-101. Current leading edge chips have features of 22 nanometers (nm), and the industry is engaged in ongoing development at the scale of 10 nm.

[6] The semiconductor industry has a long history of leadership of substituting chemicals of concern with more benign substances. For example, the industry replaced the use of chlorinated solvents with rubbing alcohol, phased-out glycol ethers with propelyne, and was one of the first industries to eliminate the use of ozone depleting substances (ODSs). More recently, in response to concerns of the environmental and health community associated with the use of perfluorooctanyl sulfonates (PFOS), the semiconductor industry has eliminated the use of PFOS in most applications and emissions have been reduced by 99 percent since 2005. See World Semiconductor Council (2011 Joint Statement) available at: http://www.semiconductorcouncil.org/wsc/uploads/WSC_2011_Joint_Statement.pdf.

[7] According to data in the Toxics Release Inventory (TRI), the entire sector within the Computers/Electronics Products category (334) contributes just 0.1 percent of the total of TRI releases for all industries. The TRI emissions for this sector amounts to 4.459 million pounds out of a total of over 4 billion pounds from all industries, and the semiconductor industry (NAICS code 334413) is just one subset of this larger sector. See http://www.epa.gov/tri/tridata/tri10/nationalanalysis/index.htm. In terms of greenhouse gas emissions, the semiconductor industry contributes 0.08 percent of total emissions in the U.S. EPA data show that out of 6.7 billion metric tons of CO_2-equivalents emitted in the entire US, only 5.4 million metric tons is emitted by the industry. http://www.epa.gov/climatechange/Downloads/ghgemissions/US-GHG-Inventory-2013-Main-Text.pdf. The global industry has an ongoing voluntary program to further reduce its emissions of a group of greenhouse gases known as perfluorinated compounds (PFCs). See World Semiconductor Council (2011 Joint Statement) available at: http://www.semiconductorcouncil.org/wsc/uploads/WSC_2011_Joint_Statement.pdf.

achieve one of the best health and safety records among American industry.[8] And there is no exposure to consumers or the public at large to chemicals or materials that may be contained in finished semiconductor devices, or any release to the environment of these chemicals. The minute amounts of chemicals that may be present in a finished semiconductor are bound to the device in a monolithic fashion, cannot be separated from the device, and are enclosed by "packaging" that becomes part of an assembly that is found in larger electronic products.

II. EPA's Regulation of New Chemicals

Given that the semiconductor industry is a user of chemicals[9] and given the critical role of chemicals with specialized properties and performance attributes in contributing to ongoing innovations in our industry, the industry needs an effective and efficient system for regulating chemicals. This system must effectively balance the protection of human health and the environment with the ability to act promptly. It must employ a well-defined and objective chemical evaluation methodology for the approval of new chemicals and new uses. The evaluation methodology needs to consider the risk and exposure of chemicals in specific uses, and not just the inherent hazards of a chemical. The system needs to prioritize among the uses of specific chemicals and focus on applications with a high potential for exposure and risk. The system needs to account for the rapid pace of innovation in industries such as semiconductor manufacturing. The system also needs to protect confidential business information (CBI).

In general, SIA believes that EPA's existing program under TSCA Section 5 for new chemicals and significant new uses provides effective and balanced regulation of new chemical substances. Perhaps most importantly, the new chemicals program employs an appropriate risk-based approach that takes into account factors such as the conditions of use and exposure scenarios – not simply the inherent hazards of various chemicals. This allows EPA to focus on the highest priorities for the protection of human health and the environment, while also enabling users of chemicals to make technological advancements through the use of new chemicals and materials.

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[8] The following table compares the rates of accidents and injury of the semiconductor industry with other industries:

	All Industry	Semiconductor Industry
Case incidence rates per 100 full time employee (FTEs)	3.8	0.9
Lost workday case incidence rates per 100 FTEs	1.2	0.18
OSHA restricted workday case incidence rates	0.7	0.13

BLS data available at http://www.bls.gov/news.release/osh.t01.htm; semiconductor industry data based on internal benchmarking survey, SIA OHS Annual Benchmark Survey, Work Injuries & Illnesses In the U.S. Semiconductor Industry – 2011 (NAICS 334413).

[9] It is important to note that it is typically the industry's chemical suppliers – not the semiconductor manufacturers – who file and seek the appropriate regulatory approvals for new chemicals.

In contrast, other jurisdictions have employed a hazard-based approach that results in the imposition of high costs with little or no corresponding benefit to health or the environment. For example, a decade ago the European Union adopted a directive that included, among other things, a ban on lead solder, a basic building block of the electronics industry for decades.[10] Despite the lack of evidence of risks from lead solder in electronic products[11] – as opposed to the known risks associated with lead in other applications (e.g., gasoline, paint, etc.) – semiconductor manufacturers and others in the global electronics supply chain were forced to make a costly shift from lead solder to other alternatives. Fortunately, the semiconductor industry was given enough time to implement this complex and costly transition, and the EU properly provided certain critical exemptions when substitutes for lead solder were unavailable. But this example illustrates the problems inherent in a hazard-based approach.

Regarding the "new use" authorities under TSCA section 5, EPA has used its authority to regulate specific chemicals such as perfluorooctanyl sulfonates (PFOS). This chemical was previously used in the industry in numerous applications, including anti-reflective coatings, photoacid generators (an element of photoresists used in the critical photolithography patterning process), and as a surfactant. In response to environmental and health concerns associated with the use of PFOS, the global semiconductor industry has eliminated the use of this chemical in most applications and reduced 99 percent of emissions of this substance. [12] Finding and qualifying substitutes was an extremely complex process, and the industry was given sufficient time and flexibility to identify, test, and deploy suitable alternatives. Despite the complexity of replacing this chemical, an important aspect of EPA's approach in this instance was to provide exemptions for certain critical uses and a reasonable implementation timeline to make necessary adjustments to manufacturing processes.

There are several additional aspects of the new chemicals program under TSCA section 5 that are the key to its effectiveness and practicality.

1. *Reasonable Approval Timeline* – The statute and implementing regulations set forth a reasonable timeline and structure for EPA's review of new chemicals. EPA's review period is generally 90 days, and if EPA takes no action within the 90-day period, manufacture of the new chemical may begin. There is also a shorter review period—30 days – available for low-volume chemicals under the so-called low volume exemption (LVE). Over the years, EPA scientists have developed and refined a review process that enables EPA to evaluate chemicals accurately in these timeframes. Predictable and prompt review is vital to our

[10] Restriction of Hazardous Substances in Electrical and Electronic Equipment (RoHS) Directive (2002/95/EC).
[11] Indeed, a study funded by EPA's Design for the Environment Program conducted a life cycle assessment of lead solder and various alternatives, and concluded that various available alternatives did not benefit the environment as compared with lead solder. "Solders in Electronics: A Life Cycle Assessment Summary" (EPA-744-S-05-001 August 2005).
[12] World Semiconductor Council (2011 Joint Statement) available at: http://www.semiconductorcouncil.org/wsc/uploads/WSC_2011_Joint_Statement.pdf.

industry, and EPA has generally conducted these reviews in a manner that is consistent with our industry's development cycles.

2. *Reasonable Data Requirements* – The current new chemicals program generally involves a reasonable set of test data. Submitters of a premanufacture notice (PMN) provide data that they have on the chemicals and often develop additional data, based on EPA guidance regarding chemical categories associated with certain hazards, which help inform PMN reviews.[13] EPA uses available data and models in its review of each new chemical, and has ample authority to require additional data when necessary. As a whole, the current process provides EPA with the information it needs to review new chemicals while not unduly burdening our industry's suppliers that prepare the PMNs.

3. *Focus on Intended Uses* – EPA's review of a PMN for a new chemical and significant new uses includes detailed information on the intended uses of and exposure for the chemical. Given the semiconductor industry's unique processes and controls, along with the specific chemical properties needed in the materials being used, we believe that it is essential that EPA employ a tailored evaluation of new chemicals and significant new uses of chemicals.

4. *Appropriate Regulatory Exemptions* – The current system has reasonable risk-based exemptions. Some exemptions, like the exemption for research and development, were spelled out in the statute. Others were developed by EPA during rulemaking to implement TSCA in a manner that is practical and appropriate while still enabling the Agency to address potential risks from chemicals. These include exemptions for impurities, byproducts, and chemicals formed incidentally during the manufacture of an article. Another important exemption is for chemical substances that "are not manufactured for distribution in commerce as chemical substances per se and have no commercial purpose separate from the substance, mixture, or article of which they are a part."[14] As stated above, the production of semiconductors involves multiple complex steps of chemical application to silicon wafers, and many of these steps involve reaction with the silicon and/or changes in the chemical substances that are applied. As a result, this exemption is critical for the workability of the regulatory system in an industry like ours, which involves many chemicals that may exist in our processes but never make it into commerce as chemicals per se.

5. *Protection of CBI* – As discussed in the next section, the protection of confidential business information remains vitally important. We believe that the current system allows companies to protect from disclosure valuable information about new chemicals they are bringing to market.

An additional area where we would like to commend the Agency is engagement with our industry on improving exposure modeling. EPA is currently in the process of updating

[13] See, e.g., TSCA New Chemicals Program (NCP) Chemical Categories (October 2002).
[14] 40 CFR § 720.30(h).

exposure scenario documents that are out-of-date for various industries, including the semiconductor industry. SIA has been working with EPA to ensure that these documents are accurate and current, and we appreciate the willingness of EPA to take our input into account.

III. Confidential Business Information (CBI)

The protection of confidential business information is critical to the U.S. semiconductor industry. The semiconductor industry is research intensive. SIA member companies invest, on average, 18 percent of revenues to research and development – one of the highest percentages of revenue of any industry. In 2012, this amounted to approximately $32 billion in research and development. Nearly half of the top 15 American patent recipients are semiconductor companies. The continued success of our industry and continued American leadership in semiconductor design and manufacturing depends on the protection of intellectual property from disclosure.

For purposes of the regulation of chemicals, patents and trade secrets are the primary types of intellectual property sought to be protected by the semiconductor industry. The specific chemicals processes used by a semiconductor company to devise high performance, reliable semiconductors in an efficient manner constitute extremely valuable intellectual property. These processes may include the identity of specific chemicals and chemical formulations, the amounts of chemicals used, and the processing conditions and tool configurations under which the chemicals are used (which are often collectively referred to by the industry as "recipes").

In order to remain globally competitive, a semiconductor company must innovate on an ongoing basis to bring new high performance products to market and improve production capability and efficiency. The disclosure of recipe and related information regarding these processes would expose specific knowledge of proprietary device designs and manufacturing processes, and thereby compromise the trade secrets within a company's recipe portfolio and damage the company's competiveness. For this reason, etch, deposition, and other recipes are frequently handled as trade secrets that are tightly controlled, rather than through the patent process and the public disclosure that accompanies the filing and approval of patents.

Policies that risk the disclosure of CBI threaten to harm the competitive position of the U.S. semiconductor industry. To cite one recent example, SIA is currently working with EPA to resolve ongoing litigation surrounding a final rule[15] that would have been highly detrimental to the industry by forcing the disclosure of proprietary process technology. As part of the greenhouse gas reporting program, this regulation would have required semiconductor manufacturers to disclose individual "recipes" used to etch silicon wafers

[15] Mandatory Reporting of Greenhouse Gases: Additional Sources of Fluorinated GHGs; Final Rule, 75 Fed. Reg. 74,774 (Dec. 1, 2010), Subpart I, codified at 40 C.F.R. § 98.90, et seq. In response to the CBI and other concerns raised by SIA, EPA granted SIA's petition for reconsideration and is the process of finalizing a new rule. See 77 Fed. Reg. 63,538 (Oct. 16, 2012).

in the semiconductor production process.[16] As noted, recipes are often proprietary process technology that is a key aspect of the competitive advantage for U.S. semiconductor companies. The disclosure of these recipes, including types of gases used, and the specific steps employed, and processing conditions would have been highly detrimental to the viability of individual U.S. semiconductor companies as well as the overall competitive position of the U.S. industry. We are relieved that, after a multi-year and costly legal process, EPA has agreed to modify the regulation and protect this valuable information. But this example illustrates the need for regulations to be carefully crafted at the outset to prevent the disclosure of damaging CBI and avoid imposing an unnecessary burden on critical industries like ours.

SIA believes that the current system for managing CBI under the TSCA program is generally working well. EPA has implemented strong internal policies for handling CBI, and the system overall achieves the proper balance between protection of CBI and public disclosure. Submitters of PMNs and other information under TSCA can designate specific information as CBI, and this data is redacted from public documents. When chemical identity is CBI, a generic structurally descriptive name is substituted in public documents. Usually only certain elements of a document are claimed CBI (redacted) and the rest of the document is public. At the same time, the current system has reasonable limits, such as generally not allowing health and safety studies to be claimed to be CBI. We believe that the current system generally requires a reasonable amount of substantiation from companies seeking to protect information as CBI, such as written substantiation for chemical identity if it is going to be listed generically on the TSCA Inventory. Companies may declassify CBI, but CBI does not have a set expiration period. We think this approach is appropriate.

IV. Conclusion

SIA believes that the current system for regulating new chemicals and protecting CBI is working well, and we are carefully watching a number of issues to ensure that the current balance in the system is maintained. Among other things, we are monitoring the following:

1. *Regulatory approach to nanoparticles* – EPA's regulatory approach to nanoparticles will be critical for the U.S. semiconductor industry. In particular, how will EPA define distinct substances that may have to be separately reviewed as new chemical substances? As the semiconductor industry continues to progress towards ever smaller feature sizes in order to enable increased processing power, faster speeds, and reduced energy consumption, the industry may see wide applications of nanoparticles.

2. *Maintain existing exemptions* – Existing exemptions must be maintained in order to make the system workable. For example, existing exemptions

[16] A "recipe" was defined as the "specific combination of gases, under specific conditions of reactor temperature, pressure, flow, radio frequency (RF) power and duration, used repeatedly to fabricate a specific feature on a specific film or substrate." 40 C.F.R. § 98.98 (rescinded under EPA's grant of the SIA petition for reconsideration).

such as the LVE exemption previously noted and the exemption for new chemicals used in small quantities for research and development purposes, are critical to continued innovation in the semiconductor industry.

3. *Chemical risk assessment* – Assessment of a new or existing chemical substance needs to focus on exposure scenarios and risks of concern applicable to specific uses. Semiconductor chemical uses are unique--they involve highly automated processes in enclosed systems, with an exceptionally strong level of control during all aspects of the process. We want to ensure that chemicals continue to be assessed appropriately in any chemical review framework.

4. *Treatment of Articles* – The treatment of "articles" in the current TSCA system is important to our industry, as well as many other industries that market products in finished form that are classified as "articles." Finished semiconductor products are small – most semiconductors weigh no more than a few grams and are about 2 cm squared in size. Many chemicals and materials may be found in extremely small volumes in the semiconductor, deposited as ultra-thin films and subsequently etched or otherwise formed into the layers and sections of the metals, organic-metallic complexes, organics and other materials in the semiconductor product. These materials are bound to the device in a monolithic fashion and cannot be separated from the device and are not released to the environment without taking extreme and unusual destructive measures. As such, it is critical that articles continue to be exempt from the import certification or export notification requirements of TSCA, and that the new chemical review process continue to exclude chemicals that are imported as part of an article. EPA has the authority to regulate chemicals in articles, and it may be appropriate for EPA to exercise this authority under special circumstances where a significant health or environmental risk cannot be adequately addressed through direct regulation of chemical substances or mixtures.

5. *Sufficient Resources for EPA* – We also need to ensure that EPA has adequate resources to implement its existing requirements under TSCA, as well as any new requirements adopted as part of an effort to modernize U.S. chemicals regulation. For example, in order for the industry to maintain its global competitiveness, it is imperative that EPA has sufficient resources to make regulatory determinations in a prompt manner. As discussed above, given the rapid pace of change in the semiconductor industry and our need for expedited regulatory approvals of new materials or new uses of chemicals, it is essential that EPA be in a position to keep up with this pace of change.

6. *Preserve Strong CBI Protections* – As discussed above, EPA needs to maintain strong protections of CBI, while ensuring the public has appropriate access to health and safety information.

7. *International and Domestic Consistency* – The alignment of approaches to regulating chemicals and materials, particularly for regulations related to product content, are also of critical importance given the global nature of today's supply chains and markets. Where feasible and consistent with well-recognized principles of risk assessment, both international and domestic requirements should be consistent. For domestic requirements, it is essential to avoid a situation in which U.S. states enact their own chemical requirements, resulting in different regulation of a material or product depending on the State in which it is made or marketed.

We look forward to working with this subcommittee and the Congress as a whole as it continues its review of U.S. chemicals regulation.

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Thank you for the opportunity to submit this testimony on behalf of the U.S. semiconductor industry. For more information, please contact David Isaacs at disaacs@semiconductors.org.

Mr. GINGREY. Mr. Isaacs, thank you. Yielding back 13 seconds.

Next witness, Mr.—excuse me, Dr. Rainer Lohmann, Professor of Oceanography at the University of Rhode Island. Dr. Lohmann, 5 minutes.

STATEMENT OF RAINER LOHMANN

Mr. LOHMANN. Good morning. Dear members of the House Committee on Environment and the Economy, I want to thank you for inviting me to testify today. I would also like to thank my wife for letting me go to D.C. on our wedding anniversary. My name is—I will be back tonight. My name is Rainer Lohmann. I am professor of oceanography at the University of Rhode Island. I have spent the last 15 years researching organic contaminants around the world. My written testimony contains several more recommendations on TSCA reform that I worked on with my colleagues, Dr. Heather Stapleton from Duke, and Dr. Ron Hites from Indiana. I will use excerpts here.

First, open dialog, not CBI. Let me frame my testimony by quoting Andrew Liveris, CEO of Dow Chemical. "Over the decades, the chemical industry has not done enough to operate with transparency and to lead on matters such as sustainability, spawning legacy issues that we are still resolving today. Further," he said, "the chemical industry went from defiance, then denial towards debate, and finally has reached dialog." In this spirit, I submit that the current use of CBI is in strong conflict with dialog and transparency. TSCA does not limit the period in which a chemical can be considered proprietary or a trade secret. Even new pharmaceuticals, which are much more expensive, are only pertinent for up to 20 years, providing a drug company time to recoup its research investment and make a profit. Within TSCA, the chemical industry should have limited time during which the information submitted to the EPA will be considered proprietary. After this time, information should be publicly available, including site specific production volumes. The public has a right to know what is produced and where. This will foster dialog, build trust, and eventually lead to safer chemicals on the market.

In addition, because research on many chemicals is hindered by a lack of authentic standards, samples of any chemical substance produced or imported into the U.S. should be archived in a national repository funded by the chemical industry. This will open dialog between industry academia and geos to identify worst compounds and assess safer alternatives.

Second, spur innovation. We need safer, newer, and green chemicals as part of chemistry's contribution towards sustainability. How do we get there? First, we need to identify and replace the worst chemicals in commerce, those which are strongly bioaccumulative, persistent, and toxic. Priority should be given to reassessing the chemicals that were grandfathered in TSCA. This will spur industry to invent, establish, and market safer alternatives.

How big is the problem? The TSCA inventory contains probably hundreds to thousands of chemicals that are persistent, bioaccumulative, and toxic at the same time. Many of these are found in the environment and in humans. Recent examples include perfluorinated compounds and brominated flame retardants, both

of which are present in roughly 97 percent of the U.S. population, including children, and the environment.

Our efforts to fully understand the presence and effects of persistent organic chemicals in the environment are hampered by a lack of basic information about the chemical identity, properties, toxicology, and production volumes. Some of that information is currently protected by CBI.

Moving forward, TSCA reform should make use of EU's REACH Program. The information on chemicals that are submitted as part of REACH should be able to be used in the U.S. to move toward safer and greener chemicals at no additional cost, basically.

Third, testing of new chemicals. Dr. Heather Stapleton discovered Firemaster 550 by accident while she was screening house dust samples for PBDEs, which are basically phased out in the U.S. Her research on dust and hand wipe measurements demonstrated that Firemaster 550 is a ubiquitous indoor contaminant, and exposure is highest for infants and toddlers, rather than adults. Last year, she already showed that Firemaster 550 is the second most common flame retardant in residential furniture today, and it might be number one as we speak. In their most recent work, Dr. Stapleton and colleagues demonstrated that prenatal exposure to Firemaster 550 in rats resulted in obesity, early puberty, insulin resistance, and disruptive thyroid hormone signaling.

I would like to stress the effects of exposure to chemicals in our households with typical modern health problems, obesity, early puberty, diabetes. In 2005, EPA issued a consent order requesting that Chemtura, the manufacturer, conduct more testing on Firemaster 550's health effects. Of the four ingredients that the Firemaster has, two were grandfathered in TSCA, so EPA could only require testing on the two new brominated compounds, and not the entire mixture. This highlights the shortcomings of TSCA, and how it violates common sense. If you market a chemical mixture, you should perform toxicity tests on that whole mixture as it will be used and how people will be exposed to it in the environment and in their households.

Professor Stapleton's research on Firemaster 550 is the only study to date to examine health effects from the mixture as it is used today. The data demonstrated that significant effects occur at much lower doses than what the chemical company declared to be safe.

In closing, I would like to note that my research has been funded by the NSF, the U.S. EPA, and the Hudson River Foundation, and I thank you for your attention.

[The prepared statement of Mr. Lohmann follows:]

Known and unknown persistent, bioaccumulative and toxic chemicals in the TSCA inventory

Testimony before the

U.S. House Energy and Commerce Subcommittee on Environment and the Economy

Thursday, July 11, 2013

2322 Rayburn House Office Building

'Regulation of New Chemicals, Protection of Confidential Business Information, and Innovation'

By Rainer Lohmann, Ph.D., Professor of Oceanography

University of Rhode Island, Narragansett, RI 02882

Summary

1. The TSCA inventory contains hundreds to thousands of chemicals that are persistent, bioaccumulative, and toxic at the same time. This clearly violates congressional intent. A major shortcoming of TSCA is the lack of information about chemical identities, properties and potential toxicity.
2. Due to the lack of efficient and forward-looking actions by EPA, the protection of the U.S. public happens only retroactively, after a significant exposure has already occurred. Recent examples include perflourinated compounds and brominated flame retardants which are ubiquitous in the U.S. population and the environment.
3. Within a reformed TSCA, the chemical industry should have a limited time during within which the information submitted to the EPA will be considered proprietary. After this time, information should be publicly available, in the same manner as drugs that are regulated through FDA. Site-specific production volumes should also be publicly available after a reasonable embargo. In addition, because research on many chemicals is hindered by a lack of authentic standards, samples of any chemical substance produced or imported into the United States of America should be archived in a national repository funded by the chemical industry.
4. To adequately protect the American public and the environment from toxic chemicals, chemicals that were grandfathered-in through TSCA in 1976 need to be re-assessed, as exemplified by more recent flame-retardants now on the market, such as Firemaster 550.
5. TSCA reform in the US should make use of data gathered as part of the E.U.'s REACH program. This information can be then be used in the US to move towards safer and greener chemicals, and spur the innovation of less toxic and persistent compounds.

Dear members of the House Committee on Energy and the Environment, I want to thank you for inviting me to testify on new chemical reviews under TSCA and the role of Confidential Business Information (CBI).

My name is Rainer Lohmann, I am a Professor of Oceanography at the University of Rhode Island. I have spent the last 15 years researching the fate and transport of organic contaminants around the world. My particular focus is on persistent organic pollutants, or POPs. These are compounds which we worry about at the local, regional, national and international scale due to their persistence, their ability to travel long distances, their strong bioaccumulation affecting top predators and lastly their adverse effects in organisms. Some of the worst persistent organic pollutants are well-known, such as DDT, PCBs, chlorinated dioxins and furans.

Right now, I am about to publish a viewpoint article on TSCA reform. Together with my colleagues Dr. Heather Stapleton (Duke University), Ron Hites (Indiana University), we discuss, from the perspective of environmental chemists/engineers/toxicologists, what a new TSCA should adhere to. I will enclose this document in my written testimony, and use excerpts here. My testimony today will focus on chemical review within TSCA, its inventory and the role of CBI within TSCA.

1.) The TSCA inventory

Within TSCA, chemicals are all considered innocent until proven guilty. While this approach is appropriate for US citizens accused of a crime, from my perspective, it is a dangerous approach to use with chemicals in commerce. In fact, any new, or existing chemical should be first

holistically evaluated for its safety in its intended use, and in its life after or outside its intended use. The current platform from which TSCA operates holds the American public hostage to the chemical manufacturers. As you know, currently EPA has to first prove that a chemical has the potential to cause harm before it can be banned. While theoretically this may sound reasonable, in practice this has not been effective. While dozens of chemicals have been "voluntarily" phased out due to public pressure and international regulations, legally only five have been banned through TSCA, and the last ban was in 1980s. A major shortcoming of the TSCA is the lack of information about compounds, their identities, properties and potential toxicity. This is not helped by what seems an excessive use of CBI.

2.) Unknown POPs/PBTs hidden in the TSCA inventory

While we will never know the exact number, there are between hundreds to thousands of compounds included in the current TSCA inventory that have the properties of PBTs (Strempel et al. 2012). In other words, these compounds are most likely persistent, bioaccumulative, and toxic. Scientists have highlighted the most worrisome or 'emerging PBTs' in their 'top 50 compounds' to detect and worry about (Howard and Muir 2010; Howard and Muir 2011) .

Some recent examples include

- perfluorinated compounds used as stain repellents in clothing, carpets and in kitchenware which are now routinely detected in the oceans and top predators from the Arctic to the Antarctic (Benskin et al. 2012) and in the blood of almost every American (Calafat et al. 2007);
- flame retardants used in residential furniture, baby products, automobiles and electronic appliances, such as polybrominated diphenyl ethers, that are now present across the globe,

present in almost all animals and found in more than 97% of the American population (Hites 2004);

- or personal care products such as cyclic methylsiloxanes that are found in the Arctic atmosphere and many organisms even in remote places (Krogseth et al. 2013);

Efforts to fully understand the magnitude of persistent chemicals in the environment are hampered by the lack of basic information about the chemicals' identity, properties, toxicology and production volume (Arnot and Mackay 2008; Brown and Wania 2008; Howard and Muir 2010). If TSCA was meant to protect the American public and the environment from toxic chemicals, it has failed spectacularly.

3.) Confidential business information within TSCA

TSCA does not limit the period in which a chemical can be considered proprietary or a trade secret. New pharmaceuticals are patented for up to 20 years, providing a drug company time to recoup its research investment and make a profit. When the patent expires, other companies can produce generic versions of the drug. This arrangement is a suitable compromise between industry's right to a protected market and the public's right to less-costly drugs.

Within TSCA, the chemical industry should have a limited time during within which the information submitted to the EPA will be considered proprietary. After this time, information should be publicly available, including site-specific production volumes. The public has a right to know what is produced, and where.

In addition, because research on many chemicals is hindered by a lack of authentic standards, samples of any chemical substance produced or imported into the United States of America should be archived in a national repository funded by the chemical industry.

4.) Hidden chemical identities and detectives work.

Some of my colleagues are spending a significant part of their time identifying unknown man-made chemicals in the environment. This task is exacerbated by the secrecy surrounding registered chemicals, particularly in the U.S. The first report on PCBs was an accidental find by a Swedish scientist, Dr. Soren Jensen, looking for DDT in human blood in the 1960s. Sadly, serendipity continues to play a role in detecting chemicals in our households, animals and the environment.

I will use the story of how Dr Stapleton from Duke University first discovered the flame retardant Firemaster 550 in household products and dust etc. It highlights the problems with "grandfathering" in chemicals, and the problems with CBI in general.

Dr Stapleton discovered FM 550 by accident while screening house dust samples for PBDEs (flame retardants that are not produced any longer in the US). She pointed out that she often wonders how long it would have taken her to identify FM 550 if she had not stumbled upon this by accident that day.

Her research on flame retardant exposures demonstrated that FM 550 is a ubiquitous indoor contaminant, and exposure is higher for infants and toddlers relative to adults (Stapleton et al. 2008). In 2011 and again in 2012 she and her group demonstrated that FM 550 is the 2nd most common flame retardant applied to both baby products and residential furniture today (Stapleton et al. 2012). Today, FM 550 is poised to become the #1 flame retardant using in baby products and residential furniture due to the recent withdrawal of yet another flame retardant TDCPP (a suspected carcinogen). In their most recent work, Stapleton and co-workers demonstrated that prenatal exposure to FM 550 in rats resulted in obesity, early puberty, insulin resistance, and

disrupted thyroid hormone signaling (Patisaul et al. 2013). And more importantly, the doses they used in these experiments (that resulted in these adverse effects) were an order of magnitude lower than the level the chemical manufacturer (Chemtura Inc.) indicated was the NOAEL (no observed adverse effect level).

In 2005, EPA issued a consent order requesting that Chemtura conduct more testing on FM 550's health effects. However, this testing was limited, and from my perspective, compromised, by TSCA's inherent flaws regarding chemicals that were "grandfathered-in". FM 550 contains four ingredients, two of which are brominated (a brominated benzoate and brominated phthalate), and both have recently been shown to be increasing in the atmosphere around the Great Lakes (Ma et al. 2012). The other two ingredients in FM 550 are organophosphates, which have been used for decades and were grandfathered into TSCA. Therefore, when the consent order was issued, EPA could only require testing on the two new brominated compounds, and not the mixture in its entirety. This highlights the shortcomings of TSCA, and how it violates common sense. If you market a chemical mixture, you should perform toxicity tests on that mixture, as it will be used, and how people will be exposed to it in the environment. Professor Stapleton's research on FM 550 is the only study to date to examine health effects from the mixture as it is used today. Their data demonstrated that significant effects occur at a much lower dose than what the chemical company declared to be "safe" (Patisaul et al. 2013).

Using a different approach, Dr Michael Milligan from SUNY Fredonia is analyzing fish eggs from the Great Lakes for chemical. He has easily identified around 1000 individual compounds that are likely of man-made origin. Again, part of his problem in positively identifying all

compounds is a lack of information on chemical use, their properties, and a lack of available analytical standards to confirm suspected chemical identities.

5.) Other countries regulation of chemicals

As you are fully aware, the European Union has passed sweeping legislation focused on chemical safety called Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) (Christensen et al. 2011). Whether you disagree or agree with REACH, its intent and procedures, it is happening as we speak.

Global chemical industries adhere to the rules laid out by REACH already. It forces companies to provide significant amounts of data on chemicals' properties and toxicity to the European Chemicals Agency. It also intends to instill a cradle-to-grave perspective for both chemical manufacturers and down-stream users of chemicals. Another key aspect of REACH was that they removed the protection for existing ('grandfathered-in') chemicals, thus leveling the playing field, spurring innovation into newer and safer chemicals (Abelkop et al. 2012).

My hope is that TSCA reform in the US will take advantage of the resoures REACH is generating, such that the information gathered through REACH can be used in the US to move towards safer chemicals with a "greener" design. Due to REACH, we know a lot more about the most persistent, bioaccumulative and toxic chemicals. This treasure trove of data should be harnessed as efficiently as possible, to reduce and remove unsafe chemicals from the market, minimize exposure, and spur the innovation of newer and safer chemicals.

Lastly, I want to acknowledge funding from the National Science Foundation, the U.S. EPA and the Hudson River Foundation in supporting my work.

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SCIENCE SHOULD GUIDE TSCA REFORM

(*submitted to Environmental Science and Technology as a Viewpoint on July 9, 2013*)

Rainer Lohmann,[1] Heather M. Stapleton,[2] Ronald A. Hites[3]

[1] Graduate School of Oceanography, University of Rhode Island, Narragansett, RI 02882

[2] Nicholas School of the Environment, Duke University, Durham, NC 27708

[3] School of Public and Environmental Affairs, Indiana University, Bloomington, IN 47405

* corresponding author: lohmann@gso.uri.edu; Tel (401) 874-6612; Fax (401) 874-6811

The Toxic Substances Control Act (TSCA) of 1976 tasks the U.S. Environmental Protection Agency (EPA) with managing chemical safety in the United States. TSCA works by a system of pre-manufacture notifications (PMNs), which are submitted to the EPA by industry when a company wants to market a new chemical or an old one for a new use. The notification to the EPA includes information on the chemical's composition and intended use. However, one of the major shortcomings of TSCA is the lack of health testing of new chemicals. If a company has any toxicity data, they are required to submit the data with the PMN, but there are no requirements to collect health data prior to PMN submission. After reviewing the PMN, the EPA then responds with permission to produce or market the chemical, a request for additional data, or with a denial. Certain substances are generally excluded from TSCA, such as foods, drugs, cosmetics, and pesticides.[1]

TSCA has not been as effective as originally hoped; in fact, some refer to it as the Toxic Substances *Conversation* Act in tribute to its slow pace. Reform is needed. Much has changed

since 1976. PCBs, DDT, mirex, and endosulfan are no longer on the market; the Stockholm Convention on persistent organic pollutants (POPs) has come into force; and the European Union has passed sweeping legislation focused on chemical safety called Registration, Evaluation, Authorization and Restriction of Chemicals (REACH).[2]

TSCA reform is underway. Stakeholders in this effort include governmental, industrial, and non-governmental organizations and academic scientists. While many scientists typically avoid the political process, we maintain that the scientific community has valuable expertise and must be at the table as TSCA is rewritten. With scientific input, the U.S. can learn from past mistakes and benefit from decades of research on chemical fate and effects.

What are the key elements to a reformed TSCA?

1. "Innocent until proven guilty" should not apply to chemicals. TSCA is based on the assumption that a chemical is safe until proven harmful. This is a fatal flaw. Numerous studies have suggested that there are hundreds to thousands of chemicals that have the properties of POPs.[3] New legislation needs to turn the proof of chemical safety over to manufacturers. No agency is capable of adequately assessing all chemicals for their safety. It is the manufacturer's responsibility to demonstrate safety of their product, and the EPA's role to critically review these assessments. This is how REACH is designed.[2]

2. "Grandfathering in" of chemicals spells trouble for the future. When TSCA was implemented in 1976, substances that were or had been produced at that time were exempt from the legislation. Obviously, it was in the chemical industry's best interests to have as many of their products or potential products on this list as possible, and as a result, at least 50,000 substances were exempted from regulation. These exemptions formed the initial TSCA

Inventory, and these exemptions must be re-assessed. REACH provides a mechanism for exemptions, but requires industry to justify the need for an exemption.[2]

3. Single-compound replacements are no alternative for structural reform. When polybrominated biphenyls (PBBs) contaminated Michigan in 1977, they were withdrawn from the flame retardant market and replaced by polybrominated diphenyl ethers (PBDEs). When the environmental ubiquity of PBDEs became apparent in 2000, they were withdrawn from the market and replaced by polybrominated benzoate and phthalate esters.[4] This stepwise approach is not sustainable in the long term, and indeed, the flame retardant industry is shifting to products that save lives but do not leak into the environment.

4. There are many biological and ecological endpoints to consider. Toxicology is a difficult science. What toxic effects should one consider? How does one evaluate long-term chronic exposures? How can particularly sensitive populations (e.g. young and elderly) be protected? Can biochemical, proteomic, or genomic experiments (vs. whole animal experiments) be used for regulatory purposes? Any changes to TSCA should recognize these challenges and be less proscriptive and more holistic.

5. Mixtures of chemicals may have greater environmental impacts than the chemicals alone. Traditional legislation has focused on a single chemical at a time. Yet environment exposures occur in complex mixtures. Key studies have shown that a cocktail of many individual compounds below their respective no observed effect levels can still result in significant adverse effects.[5] While TSCA is currently designed to evaluate chemicals independently, many chemical manufacturers sell their products as mixtures; therefore, evaluations should be conducted not only on individual chemicals, but also on the mixture as marketed. It is also important to assess the toxicity of impurities in mixtures.

6. Restrictions on access to proprietary information submitted to the EPA by industry should not be permanent. TSCA does not limit the period in which a chemical can be considered proprietary or a trade secret. In the pharmaceutical arena, new drugs are patented for up to 20 years, providing a drug company time to recoup its research investment and make a profit. When the patent expires, other companies can produce generic versions of the drug. This arrangement is a suitable compromise between industry's right to a protected market and the public's right to less-costly drugs. Within TSCA, the chemical industry should have a limited time during which the information submitted to the EPA will be considered proprietary. After this time, information should be publicly available. Site-specific production volumes should also be publicly available after a reasonable embargo. In addition, because research on many chemicals is hindered by a lack of authentic standards, samples of any chemical substance produced or imported into the United States should be archived in a national repository funded by the chemical industry.

7. Scientists are willing to help. Many of us have dedicated our professional lives to better understanding chemicals' environmental concentrations, properties, transport, fates, and effects. Can we afford to just stand-by? If TSCA is not reformed, the unrestricted production, use, and release of unsafe chemicals could continue, and with it the on-going exposure of the American public to a complex mixture of these chemicals. We have an obligation to make our voices heard and to promote proven scientific principles as a basis for TSCA reform. We can do this through our scientific organizations and via our representatives in Congress.

Acknowledgements

We acknowledge valuable comments from Dr Todd Royer (Indiana University).

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Mr. GINGREY. Dr. Lohmann, thank you for your testimony.

I will now turn to Ms. Heather White, Executive Director of the Environmental Working Group. Ms. White, 5 minutes.

STATEMENT OF HEATHER WHITE

Ms. WHITE. Mr. Chairman and distinguished members of the subcommittee, I am Heather White, Executive Director of Environmental Working Group, a nonprofit research and advocacy organization based in Washington, Iowa, and California. Thank you for the opportunity to testify.

EWG wants the United States to be the world leader in innovative chemical production. Some of the best and brightest scientists in the world are at the companies represented here today, but innovation is not just about lowering costs and boosting profits. Americans believe that innovation must also mean creating chemicals that are not just cheap, but safe. Strong chemical regulation promotes innovation. We cannot compete internationally on labor or production costs. We will not win that race to the bottom. But America ultimately will win on chemical quality and safety through toxics law reform.

For 20 years, EWG has advocated greater protection of people and the environment from toxic chemicals. Our groundbreaking research detected nearly 300 toxic industrial chemicals in the umbilical cord blood of newborn babies. The reality is industrial chemical pollution begins in the womb. Yet a century into the chemical revolution, we still don't know what these low level exposures to substances, alone or in combination, do to our health, especially our children's health. No one has basic answers, not the government, academic researchers, or the chemical industry.

In 2010, the President's Cancer Panel concluded that the number of cancers caused by toxic chemicals is grossly underestimated. Americans have lost faith in a chemical regulatory system that they suspect, with good reason, doesn't protect them and their children. Many of these chemicals have not been adequately tested for safety under the Toxic Substances Control Act. Its New Chemicals Program is woefully inadequate, and its secrecy provisions threaten human health.

There are three major problems with the New Chemicals Program. First, most Americans assume that a chemical can't be sold until proven safe. Not so. A chemical company can get a new chemical on the market today without providing any information about the toxicity of that chemical. Companies do it every day. In fact, 85 percent of the pre-manufacture submissions have zero information about the toxicity of these new chemicals. Second, EPA faces a chemical Catch-22. The agency cannot demand more test data without solid evidence that the new chemical could be a reasonable risk, and it cannot come up with that evidence without the test data. The law places the burden on EPA, not the manufacturer, to determine whether a new chemical is unsafe before it goes into use. The trouble is that chemicals are entitled to a presumption of innocence. That works in criminal law, but that shouldn't exempt chemicals from investigation. Not surprisingly, EPA attempts to restrict less than 10 percent of new chemicals. Finally, chemical makers don't necessarily know how the chemical might be used when

they make it. After a new chemical is approved, they do not have to tell EPA when the planned use changes.

As for secrecy, the current law's Confidential Business Information scheme is a regulatory black hole where critical information goes in, and little comes out. Even the intelligence community declassifies highly sensitive information after a while, but TSCA confidentiality claims never expire.

Companies have a legitimate interest in keeping some information confidential, but unwarranted claims directly threaten human health and the environment. TSCA permits a manufacturer to claim confidentiality without substantiation for virtually any information it submits to EPA. Confidentiality claims mask the identities of nearly ⅔ of all new chemicals introduced since 1976, including substances used in consumer and children's products.

Chemical makers assert that secrecy protects their competitive advantage, but they knew very well that competitors commonly reverse engineer their products. Everybody else is left in the dark: ordinary citizens, first responders, workers, medical personnel, independent researchers, State and local governments, and fence line communities that are often hotspots of chemical exposure.

We deserve better. Congress can overhaul the broken toxics law to protect public health and the environment, and at the same time, spur development of better, safer, innovative chemicals.

Thank you, and I welcome any questions you may have.

[The prepared statement of Ms. White follows:]

Testimony of Heather White, Esq.

Executive Director
Environmental Working Group

Before the

U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON ENERGY AND COMMERCE
SUBCOMMITTEE ON ENVIRONMENT AND THE ECONOMY

On

Regulation of New Chemicals, Protection of Confidential Business Information, and Innovation

Thursday, July 11, 2013

Mr. Chairman and distinguished members of the subcommittee, my name is Heather White. I am the Executive Director of Environmental Working Group, a nonprofit research and advocacy organization based in Washington, D.C., with offices in Ames, Iowa, and Oakland, California. Thank you for holding this important hearing and the opportunity to testify.

For two decades, EWG has advocated greater protection of people and the environment from exposures to toxic chemicals. EWG has published extensive research on the chemical pollution in people as evidenced by our numerous biomonitoring studies. We have tested more than 200 people for 540 industrial chemicals and found up to 482 of them in people's bodies. In two groundbreaking studies conducted in 2005 and 2009, EWG detected nearly 300 industrial chemicals in the umbilical cord blood of newborn babies.[1] Our research showed that these children were exposed *in utero* to toxic chemicals, including dioxins and furans, flame retardants and active ingredients in stain removers and carpet protectors. Chemicals that were banned more than 30 years ago – including lead, polychlorinated biphenyls (PCBs) and the pesticide DDT – also contaminated these babies. We also discovered the presence of bisphenol A (BPA), a synthetic estrogen that disrupts the endocrine system, and perchlorate, a rocket fuel component and thyroid toxin that can alter brain development. (For more results, see Attachment A.) Modern science shows us – unequivocally – that industrial chemical pollution begins in the womb.

In April 2010, the President's Cancer Panel reviewed the compelling scientific research on biologically active chemicals at low doses and the canon of biomonitoring studies from the Centers for Disease Control and Prevention and other public health organizations. The panel declared: "to a disturbing extent, babies are being born 'pre-polluted.'"[2] The panel also found that the number of cancers caused by toxic chemicals is "grossly underestimated" and warned that Americans face "grievous harm" from largely unregulated chemicals that contaminate air, water and food.[3]

We must reform our federal toxics law to ensure that new chemicals are safe – especially for children, our most vulnerable population – before they are allowed on the market. Toxic chemicals are ubiquitous in our daily lives, in our consumer products and, ultimately, in our bodies, yet many of these substances have never been adequately assessed for safety. Here's why: The federal Toxic Substances Control Act of 1976 (TSCA),[4] the principal law governing the use and safety of the thousands of chemicals on the market, is fundamentally broken. The current federal toxics law has many flaws, but I will focus on two of them today:

- **TSCA's framework for reviewing new chemicals ensures that most new chemicals are on the market before regulators can adequately review them for safety; and**

- **TSCA's provisions for protecting confidential business information invite chemical manufacturers to make overbroad and unwarranted confidentiality claims.**

Make no mistake. EWG wants the United States to be the world leader in innovative chemical production. We have the best and the brightest scientists in our research centers and at many of the companies represented here today. But the goal of innovation cannot be just to reduce cost, increase market share and boost profits. The American public has a much broader notion. Most of us believe that "innovation" must also mean creating chemicals that are not just cheap to produce but *safe* – and that do not contaminate our blood, build up in our bodies and never break down. As our colleagues at the Center of International Environmental Law have noted, strong chemical regulation *promotes* innovation.[5] We cannot compete internationally on labor or production costs. We will not win that race to the bottom. But America *can* win and ultimately *will* win on chemical quality and safety through toxics law reform.

TSCA's New Chemicals Framework Fails to Adequately Protect Public Health.

In the nearly 40 years since the passage of TSCA, more than 23,000 new chemicals have been approved by the U.S. Environmental Protection Agency and added to the agency's "inventory list" of chemicals allowed for use in commerce.[6] As the growing body of evidence on the potential health impacts of toxic chemicals demonstrates, we need to strike a better balance between getting new chemicals to the market quickly and ensuring that these substances do not harm those who are disproportionately affected by exposure, including children, workers, pregnant women and fence-line communities.

There are five major flaws with the new chemical review process under current law:

- When a company is looking to manufacture or import a new chemical into the U.S., current law gives EPA just 90 days to review the substance before it goes on the market. The ultimate effect of this narrow window is to give profits a higher priority than public safety.

- The company must submit a pre-manufacture notice to EPA with basic information on the chemical's name, anticipated uses and disposal, as well as any test data that is known or reasonably ascertainable.[7] EPA cannot require companies to perform even basic health and safety testing before filing that notice, but if the company has health and safety data,

it is supposed to turn it over to EPA for review. This regulatory disconnect actually discourages manufacturers from doing safety testing because doing so would likely invite additional review by the agency. As a result, approximately half of all pre-manufacture notices include no test data at all; nearly 85 percent provide no toxicity data.[8]

- EPA faces a Catch-22 when it comes to new chemicals. The agency cannot request additional data unless it has safety concerns and it cannot adequately address safety concerns without relevant testing data. With no test data to evaluate the safety of a new chemical, EPA must use computer models, chemical comparisons and other analyses to predict how it may affect human health and the environment. At best, it operates on incomplete information. Its models and estimates are based on data about previously studied chemicals, but these do not necessarily predict how a new chemical will behave.

- Even if EPA receives complete information about a new chemical in a pre-manufacture submission, the agency makes its initial assessments based on the uses listed in that notice. The company, however, is not bound to follow those stated uses. A manufacturer can quickly adopt new uses when it goes to market and produce the chemical at much higher volumes than those estimated in the pre-manufacture notice, and EPA and the public receive no notice that the manufacturer is changing its plan.

- EPA evaluates a new chemical against a safety standard of "unreasonable risk of injury to human health or the environment."[9] The agency bears the burden of proof and must provide evidence if it wants to delay or restrict the new chemical. The paradox is that the less information there is about a new chemical's safety, the faster it can reach the market. Not surprisingly, EPA attempts to restrict less than 10 percent of new chemicals.[10]

TSCA is so weak that it effectively presumes that new chemicals are safe without requiring pre-market testing. The law places the burden on EPA, not the chemical manufacturer, to determine whether a chemical is safe before it goes into use. Moreover, the fees companies pay to submit pre-manufacture notices cover just 10 percent of EPA's cost of reviewing these submissions.[11] This framework is inadequate to protect human health and the environment.

TSCA's Secrecy Provisions are Overbroad and Threaten Public Health & Safety.

The provisions for confidential business information under TSCA undermine the public's right to know about substances to which they are exposed in their daily lives, including such basic information as the chemical's name. Companies have a legitimate interest in keeping some kinds of information confidential, but sweeping and unwarranted secrecy claims directly threaten human health and the environment.[12] In practice, TSCA acts as "a regulatory black hole" where critical information goes in and little, if anything, comes out.[13]

TSCA permits a manufacturer to designate as confidential virtually any information it submits to EPA. In most instances, a company does not have to substantiate these confidentiality claims or pay a fee for making them. Moreover, once a secrecy claim has been asserted, it generally exists indefinitely, with no sunset provision. Once it is deemed confidential under TSCA, it almost always remains confidential. Even the National Security Agency releases top secret, highly

sensitive information after a period of time, but trade secret claims under federal toxics law never expire.

EPA can disclose confidential business information only in the most limited of circumstances,[14] and agency employees can face criminal penalties for sharing such information with unauthorized parties.[15] In contrast, a company faces little risk if it abuses confidential business information provisions under TSCA.[16] This lack of penalties for abuse provides a perverse incentive to make frequent and unjustified claims that information is confidential.[17]

To illustrate the pervasiveness of secrecy claims under current law, consider:

- The very identity of approximately 17,000, or 20 percent, of the more than 84,000 chemicals on EPA's inventory is deemed confidential, meaning the public has no access to any information about them[18];
- Industry has made confidential the identity of nearly two-thirds of all new chemicals introduced since TSCA's enactment in 1976, including substances used in numerous consumer and children's products[19]; and
- Approximately 95 percent of all pre-manufacture notices for new chemicals contain information the manufacturers have designated as confidential.[20]

Companies assert that secrecy protects their competitive advantage, but reverse engineering of competitors' products is often just a routine cost of doing business in the chemical world. As a result, the only people left in the dark are typically the public – including scientists, academic researchers, medical personnel, state and local governments, and first responders. And when it comes to health and safety data, there is a huge risk to the public when the identity of the referenced chemicals is kept secret. TSCA prohibits health and safety studies themselves from being deemed confidential,[21] but companies may still mask the specific name of chemicals in these studies on the grounds that disclosing their identity would reveal trade secrets.[22] Even when publicly available studies have tied a specific chemical to an adverse health effect, the chemical's name may be legally redacted because the manufacturer designated it as confidential. In 2008, the Milwaukee Journal Sentinel reviewed more than 2,000 filings submitted to EPA under TSCA and found that chemical identity was designated confidential in more than half of them.[23] In one case, a filing cited a study linking a chemical to liver damage associated with cancer, yet the name of the chemical was redacted.[24] Studies sanitized in this way are largely meaningless for researchers. (See Attachment B). When scientific data is constrained this way, the public pays.

The chemical industry downplays concerns about TSCA's confidential business information protections by arguing that EPA has access to the information and can make informed decisions. But as a practical matter, only a handful of EPA employees have complete access to information that industry deems confidential.[25] Even EPA's own scientists get incomplete information. For example, when EPA reviewed the safety of the flame retardant Firemaster 550 in 2005, information about key chemical ingredients was kept from the agency's leading scientific expert. This secrecy, coupled with the inadequacy of EPA's testing models, resulted in the failure to predict that this flame retardant would accumulate in living organisms.[26] The health concerns of Firemaster 550 only came to light when a university researcher was able to crack the chemical's

code through some groundbreaking research. Recent research has shown that Firemaster 550 can cause hormone disruption, a hazard that EPA should have identified when it approved the chemical.

TSCA makes it nearly certain that medical professionals and first responders do not have access to confidential business information about a chemical even when treating a person harmed by it. The law prevents EPA from sharing this information with state and local governments responsible for developing and carrying out emergency plans. This secrecy directly threatens communities where chemicals are made, as well as "hot spots" where people have been disproportionately burdened with health and environmental problems. Consider the implications in a plant explosion or train accident. When manufacturers have failed to disclose the identities of about 20 percent of all chemicals and nearly two-thirds of all new ones, it is easy to imagine a scenario in which first responders and medical personnel would be in the dark as to how to protect the lives of first responders, workers and bystanders. In addition, communities of color and poor communities often have less access to health care needed to treat exposures to harmful chemicals. Secrecy can make this problem worse. Information relevant to detecting, assessing and responding to chemical exposures should not be shielded by confidentiality.

We applaud EPA's recent efforts to audit secrecy claims for chemical identities in health and safety studies.[27] Since 2010, the agency has declassified nearly 900 previously secret chemicals referenced in these studies.[28] Without fundamental reform to address abuse of the confidentiality provisions, however, the secrecy problem will remain.

We support the following reforms to TSCA's confidential business information provisions:

- Require advance justification and substantiation for confidential business information claims so that EPA can decide if secrecy is legitimate.
- Establish an automatic sunset for confidential business information claims, requiring the maker to establish the need for continued secrecy.
- Make all data in health and safety studies, including chemical identity, ineligible for confidential business information protection.
- Assess fees on companies making secrecy claims to defray the cost of administering EPA's confidential business information review program.
- Create a mechanism to allow the public to track the number of secrecy claims, and the identity of companies that file them, in order to ensure greater accountability.
- Levy penalties against companies for making overbroad or unjustified secrecy claims.
- Allow EPA to share confidential business information within and outside the agency, including its scientists, medical professionals, first responders and state and local governments.[29]

In conclusion, there is widespread consensus that Congress should overhaul TSCA to protect the American public from toxic chemicals while continuing to spur the development of better chemical alternatives. I thank you for the opportunity to speak before you today, and welcome any questions you may have.

ENDNOTES

[1] EWG, Body Burden: The Pollution in Newborns (2005), http://www.ewg.org/reports/bodyburden2/execsumm.php.
[2] President's Cancer Panel, 2008-2009 Annual Report: Reducing Environmental Cancer Risk: What We Can Do Now 98 (2010), http://deainfo.nci.nih.gov/advisory/pcp/annualReports/pcp08-09rpt/PCP_Report_08-09_508.pdf.
[3] Id. at Cover Letter; see also *H.R. 5820, the Toxic Chemicals Safety Act of 2010: Hearing Before the Subcomm. on Commerce, Trade, & Consumer Prot. of the H. Comm. on Energy & Commerce*, 111th Cong. (2010) (statement of Kenneth A. Cook, President, EWG), http://static.ewg.org/files/2010-Ken-TSCA-Testimony.pdf.
[4] 15 U.S.C. §§ 2601-2629.
[5] Ctr. for Int'l Envtl. L., Driving Innovation: How Stronger Laws Help Bring Safer Chemicals to Market (2013), www.ciel.org/Publications/Innovation_Chemical_Feb2013.pdf.
[6] EPA Office Of Inspector Gen., EPA Needs a Coordinated Plan to Oversee Its Toxic Substances Control Act Responsibilities 4 (2010), http://www.epa.gov/oig/reports/2010/20100217-10-P-0066.pdf.
[7] See 15 U.S.C. § 2604.
[8] EPA Office Of Inspector Gen., supra note 6, at 6.
[9] See 15 U.S.C. § 2604(e).
[10] EPA Office Of Inspector Gen., supra note 6, at 4.
[11] Id. at 12.
[12] E.g., EWG, Off The Books: Industry's Secret Chemicals (2009), http://www.ewg.org/sites/default/files/report/secret-chemicals.pdf [hereinafter "EWG, Off The Books"].
[13] Id. at 2.
[14] Susanne Rust & Meg Kissinger, EPA Veils Hazardous Substances, Milwaukee J.-Sentinel, Dec. 20, 2008, http://www.jsonline.com/watchdog/watchdogreports/36514449.html.
[15] 15 U.S.C. § 2613(d).
[16] Rust & Kissinger, supra note 14; see also Wendy Wagner & David Michaels, Equal Treatment for Regulatory Science: Extending the Controls Governing the Quality of Public Research to Private Research, 30 Am. J.L. & Med. 119,130 (2004).
[17] Wagner & Michaels, supra note 16, at 131 ("[F]irms openly concede that it is more cost-effective for them to routinely stamp as much internal information as [confidential] when no substantiation is required.").
[18] EWG, Off The Books, supra note 12, at 2; see also EPA, TSCA Chemical Substance Inventory, http://www.epa.gov/oppt/existingchemicals/pubs/tscainventory/ (last visited July 8, 2013).
[19] EWG, Off The Books, supra note 12, at 2.
[20] *Oversight Hearing on the Federal Toxic Substances Control Act: Hearing Before the Sen. Comm. on Envt. & Public Works*, 111th Cong. (2009) (statement of John Stephenson, Dir. Natural Res. & Envt. U.S. Gov't Accountability Office), http://www.gao.gov/assets/130/123792.pdf.
[21] 15 U.S.C. § 2613(b).
[22] Id.
[23] Rust & Kissinger, supra note 14.
[24] Id.
[25] See Wendy Wagner, Commons Ignorance: The Failure of Environmental Law to Produce Needed Information on Health and the Environment, 53 Duke L.J. 1619, 1703 (2004) ("Staff discussions on [confidential chemicals] must be held in secure areas, documents can be reviewed only in secure environments, meeting notes themselves become confidential documents and must be logged and guarded under lock and key, and computers must have their memories and permanent storage media erased after processing confidential data.").
[26] Michael Hawthorne, Toxic Roulette: Firemaster 550, Touted as Safe, is the Latest in a Long Line of Flame Retardants Allowed onto the Market Without Thorough Study of Health Risks, Chicago Trib., May 10, 2012, http://articles.chicagotribune.com/2012-05-10/business/ct-met-flames-regulators-20120510_1_flame-retardants-ban-chemicals-chemical-safety-law.
[27] EPA, Declassifying Confidentiality Claims to Increase Access to Chemical Information, http://www.epa.gov/oppt/existingchemicals/pubs/transparency-charts.html (last visited July 8, 2013).
[28] Id.
[29] For more information about reforming TSCA's confidential business information provisions, see generally, e.g., Wagner & Michaels, supra note 16.

ATTACHMENTS

ATTACHMENT A: Results of Select Cord Blood Biomonitoring Studies of U.S. Infants
ATTACHMENT B: Sample Health and Safety Study with Confidential Chemical Identity

ATTACHMENT A

ATTACHMENT A: RESULTS OF SELECT CORD BLOOD BIOMONITORING STUDIES OF AMERICAN INFANTS

Nationally, cord blood biomonitoring studies have detected up to 358 chemicals

Chemical class	Chemical subclass	Summary of representative study	No. of newborns tested	Place of birth	No. of Chemicals found
Dioxin & Furan	Brominated dioxin	EWG tested cord blood from 10 newborns for 12 brominated dioxins and furans and found at least one of these chemicals in 7. In the 7 newborns, 6 to 7 different congeners were found. Mean total level was 12 pg/g lipids in blood serum. (EWG 2005)	10	U.S. hospitals	6-7
Dioxin & Furan	Brominated dioxin	EWG tested cord blood from 10 newborns of minority background for 12 brominated dioxins and furans and found at least one in 4 of the subjects. Six different congeners were found. Mean total level was 10.7 pg/g lipids in blood serum. (EWG 2009)	10	Mich. Fla. Wis. Mass. Calif.	6
Dioxin & Furan	Chlorinated dioxin	Researchers from the SUNY Health Science Center tested cord blood from 5 babies delivered via C-section from late 1995 to early 1996 for dioxins, dibenzofurans, and coplanar PCBs. Mean measured levels of total PCDDs, PCDFs, and coplanar PCBs were 165 pg/g for cord blood. (EWG 2005)	5	N.Y.	1
Dioxin & Furan	Chlorinated furan	EWG tested cord blood from 10 newborns for 17 chlorinated dioxins and furans and found at least one in all 10 subjects. Eleven different congeners were found. Mean total level was 56.3 pg/g lipids in blood serum. (EWG 2005)	10	U.S. hospitals	11
Dioxin & Furan	Chlorinated furan	EWG tested cord blood from 10 newborns of minority background for 17 chlorinated dioxins and furans and found at least one in all 10 subjects. Fifteen (15) different congeners were found. Mean total level was 59.7 pg/g lipids in blood serum. (EWG 2009)	10	Mich. Fla. Wis. Mass. Calif.	15
Fire Retardant	Brominated Fire Retardant	EWG measured TBBPA levels in cord blood from 10 newborns of minority background. TBBPA was found in 3 samples with a mean level of 11 ng/g lipids in blood serum. (EWG 2009)	10	Mich. Fla. Wis. Mass. Calif.	1
Metal	Cadmium	Researchers from Harvard measured cord blood concentrations of cadmium in 94 healthy babies, finding concentrations ranging from 0.003 to 0.210 ug/dl, with mean of 0.045 ug/dl. (Rabinowith 1984)	94	Boston, Mass.	1
Metal	Lead	Researchers from SUNY Oswego, the New York State Department of Health, the University of Albany, and Penn State University measured cord blood lead levels in 154 children and correlated lead levels with adrenocortical responses to acute stress in children. They divided cord blood levels into the following 4 quartiles: < 1.0 (1st quartile; n = 37), 1.1–1.4 ?g/dL (2nd quartile; n = 39), 1.5–	154	N.Y.	1

Chemical class	Chemical subclass	Summary of representative study	No. of newborns tested	Place of birth	No. of Chemicals found
		1.9 ?g/dL (3rd quartile; n = 36), and 2.0–6.3 ?g/dL (4th quartile; n = 42). (Gump 2008)			
Metal	Lead	Researchers from Harvard University, Emory University, and University of Massachusetts at Amherst tested lead levels in cord blood from 527 babies born between 1993 and 1998 and found mean levels of 1.45 ug/dL. (Sagiv 2008)	527	New Bedford, Mass.	1
Metal	Mercury	Researchers from Columbia University and the CDC tested for cord blood levels of mercury in women who live and or work close to the World Trade Center site between Dec. 2001 and June 2002. The researchers found a mean cord mercury level of 7.82 ug/L. (Lederman 2008)	289	New York City, N.Y.	1
Musk	Musk	EWG measured nitro and polycyclic musk levels in cord blood from 10 newborns of minority background. Galoxolide was found in 6 samples at a mean level of 0.483 ng/g, and tonalide was found in 4 samples at a mean level of 0.147 ng/g. (EWG 2009)	10	Mich. Fla. Wis. Mass. Calif.	2
PAH	Polyaromatic hydrocarbons (PAHs)	Researchers from Columbia University measured levels of benzoA-pyrene DNA adduct levels in 203 babies from New York City mothers who were pregnant during 9/11. (Perera 2005)	203	New York City, N.Y.	1
PAH	Polyaromatic hydrocarbons (PAHs)	EWG tested cord blood from 5 newborns for 18 polyaromatic hydrocarbons and found at least one in all 5 subjects. Nine (9) different chemicals were found with total mean concentration of 279 ng/g lipids in blood serum. (EWG 2005)	5	U.S. hospitals	9
PBDE	Polybrominated diphenyl ether (PBDE)	Researchers from Columbia University and Johns Hopkins tested 297 cord blood samples from babies born at Johns Hopkins Hospital from Nov. 26, 2004 to March 16, 2005 for 8 PBDE congeners. They report that 94% of the samples contained at least one of the tested congeners. (Herbstman 2007)	297	Baltimore, Md.	7
PBDE	Polybrominated diphenyl ether (PBDE)	Researchers from Indiana University measured levels of 6 PBDEs in 12 paired samples of maternal and cord blood from live births that occurred from Aug. to Dec., 2001. They found that concentrations of PBDEs in both sets of samples were 20-to-106 fold higher than levels reported in a similar study from Sweden, leading them to conclude "human fetuses in the United States may be exposed to relatively high levels of PBDEs." (Mazdai 2003)	12	Indianapolis, Ind.	6
PBDE	Polybrominated diphenyl ether (PBDE)	EWG tested cord blood from 10 newborns for 46 polybrominated diphenol ethers (PBDEs) and found at least one of these chemicals in 10 out of 10 participants. Among all 10	10	U.S. hospitals	27-32

Chemical class	Chemical subclass	Summary of representative study	No. of newborns tested	Place of birth	No. of Chemicals found
		participants who tested positive for the chemicals, 27 to 32 different congeners were found. Mean total level was 4.53 ng/g lipids in blood serum. (EWG 2005)			
PBDE	Polybrominated diphenyl ether (PBDE)	EWG tested cord blood from 10 newborns of minority background for 46 polybrominated diphenyl ethers (PBDEs) and found at least one in all 10 samples. Among all 10 participants who tested positive for the chemicals, 26 to 29 different congeners were found. Mean total level was 72.9 ng/g lipids in blood serum. (EWG 2009)	10	U.S. hospitals	26-29
PBDE	Polybrominated diphenyl ether (PBDE)	Researchers at Columbia University and Johns Hopkins tested 288 cord blood samples from babies born at Johns Hopkins Hospital from Nov. 26, 2004 to March 16, 2005 for 3 PBDE congeners. In all the 288 subjects, all three congeners were found. (Herbstman 2008)	288	Baltimore, Md.	3
PBDE	Polybrominated diphenyl ether (PBDE) Metabolite	Researchers from the School of Public and Environmental Affairs at Indiana University tested PBDE and PBDE metabolities in 20 pregnant women and their newborn babies who had not been intentionally or occupationally exposed. They noted that metabolites in humans seem to be accumulating. (Qiu 2009)	20	Indianapolis, Ind.	10
PCB	Polychlorinated biphenyl (PCB)	Researchers at Columbia University and Johns Hopkins tested 297 cord blood samples from babies born at Johns Hopkins Hospital from Nov. 26, 2004 to March 16, 2005 for 35 PCB congeners. They report levels for 4 of the 35 but note that ">99% (of samples) had at least one detectable PCB congener." (Herbstman 2007)	297	Baltimore, Md.	18
PCB	Polychlorinated biphenyl (PCB)	Researchers from SUNY Oswego investigated cord blood levels of PCBs in children born between 1991 and 1994 and correlated levels with response inhibition when the children were 4.5 years of age. The researchers found that "results indicated a dose-dependent association between cord blood PCBs and errors of commission." (Stewart 2003)	293	Great Lakes states	7
PCB	Polychlorinated biphenyl (PCB)	EWG tested cord blood from 10 newborns for 209 polybrominated diphenol ethers (PBDEs) and found at least one of these chemicals in 10 out of 10 participants. Among all 10 participants who tested positive for the chemicals, 98 to 147 different congeners were found. Mean total level was 6.2 ng/g lipids in blood serum. (EWG 2005)	10	U.S. hospitals	98-147
PCB	Polychlorinated biphenyl (PCB)	EWG tested cord blood from 10 newborns of minority background for 209 polychlorinated biphenyls and found at least one in all 10 samples. Among all 10 participants who tested positive for the chemicals, 98 to 144 different congeners were found. Mean total level was 22.1 ng/g lipids in blood serum. (EWG 2009)	10	Mich. Fla. Wis. Mass. Calif.	98-144

Chemical class	Chemical subclass	Summary of representative study	No. of newborns tested	Place of birth	No. of Chemicals found
PCB	Polychlorinated biphenyl (PCB)	Researchers from Harvard, Emory, and the University of Massachusetts at Amherst tested levels of 51 PCB congeners in cord blood from 542 babies born between 1993 and 1998. No information on levels of individual congeners is given; however, the mean sum of PCB congeners 118,138,153, and 180 is 0.25 ng/g and the TEF-weighted sum of mono-ortho PCB congeners 105, 118, 156, 167, and 189 is 6.75 pg/g lipid. (Sagiv 2008)	542	New Bedford, Massachusetts	>4
PCN	Polychlorinated naphthalene (PCN)	EWG tested cord blood from10 newborns for 70 polychlorinated naphthalenes and found at least one in all 10 subjects. In all, 31 to 50 different congeners were found with total mean concentration of 0.574 ng/g lipids in blood serum. (EWG 2005)	10	U.S. hospitals	31-50
PCN	Polychlorinated naphthalene (PCN)	EWG tested cord blood from10 newborns of minority background for 70 polychlorinated naphthalenes and found at least one in all 10 subjects. In all, 17 to 24 different congeners were found, with total mean concentration of 0.637 ng/g lipids in blood serum. (EWG 2009)	10	Mich. Fla. Wis. Mass. Calif.	17-24
Pesticide	Carbamate	Researchers from Columbia University, the CDC, and the Southwest Research Institute measured the levels of 29 pesticides in cord plasma from 211 babies born into an urban community in New York City between Sept.1998 and May 2001. 48% of the babies had exposure to 2-Isopropoxyphenol, 45% to carbofuran, and 36% to bendiocarb. All of the babies were exposed to at least one carbamate. (Whyatt 2003)	211	New York City, N.Y.	5
Pesticide	Fungicide	Researchers from Columbia University, the CDC, and the Southwest Research Institute measured the levels of 29 pesticides in cord plasma from 211 babies born into an urban community in New York City between Sept. 1998 and May 2001. 83% of the babies had exposure to dicloran, 70% to phthalimide. All of the babies had exposure to at least one fungicide. (Whyatt 2003)	211	New York City, N.Y.	4
Pesticide	Herbicide	Researchers from Columbia University, the CDC, and the Southwest Research Institute measured the levels of 29 pesticides in cord plasma from 211 babies born into an urban community in New York City between Sept. 1998 and May 2001. 38% had exposure to chlorthal-dimethyl and 20% had exposure to Alachor. All had exposure to at least one herbicide. (Whyatt 2003)	211	New York City, N.Y.	5
Pesticide	Imide	Researchers from Columbia University, the CDC, and the Southwest Research Institute measured the levels of 29 pesticides in cord plasma from 211 babies born into an urban community in New York City between Sept. 1998 and May 2001. 83% had exposure to dicloran and 70% had exposure to phthalimide. All had exposure to at least one fungicide.	211	New York City, N.Y.	1

Chemical class	Chemical subclass	Summary of representative study	No. of newborns tested	Place of birth	No. of Chemicals found
		(Whyatt 2003)			
Pesticide	Mosquito Repellent	Researchers from Columbia University, the CDC, and the Southwest Research Institute measured the levels of 29 pesticides in cord plasma from 211 babies born into an urban community in New York City between September 1998 and May 2001. 33% of the babies had exposure to diethyltoluamide. (Whyatt 2003)	211	New York City, N.Y.	1
Pesticide	Organochlorine Pesticide (OC)	Researchers from Harvard, Emory, and the University of Massachusetts at Amherst tested levels of 2 organochlorine pesticides in cord blood from 542 babies born between 1993 and 1998. Mean DDE levels were 0.48 ng/g serum. Levels of HCB were not given. (Sagiv 2008)	542	U.S. hospitals	1
Pesticide	Organochlorine Pesticide (OC)	EWG tested cord blood from 10 newborns for 28 organochlorine pesticides and found at least one in all 10 subjects. In all, 21 different pesticides were found. (EWG 2005)	10	U.S. hospitals	21
Pesticide	Organophosphate Pesticides and Metabolites	Researchers from Columbia University, the CDC, and the Southwest Research Institute measured the levels of 29 pesticides in cord plasma from 211 babies born into an urban community in New York City between Sept. 1998 and May 2001. 71% had exposure to chlorpyrifos (mean 4.7 pg/g) and 49% had exposure to diazinon (mean 1.2 pg/g), the two most commonly detected pesticides. All other pesticides were found in 4% or less of the samples and all babies had exposure to at least one of the organophosphates. (Whyatt 2003)	211	New York City, N.Y.	8
Pesticide	Pyrethroid	Researchers from Columbia University, the CDC, and the Southwest Research Institute measured the levels of 29 pesticides in cord plasma from 211 babies born into an urban community in New York City between Sept 1998 and May 2001. 7% had exposure to trans-permethrin and 13% had exposure to cis-permethrin. (Whyatt 2003)	211	New York City, N.Y.	2
PFC	Perfluorochemical (PFC)	Researchers from CDC, Columbia University, and Johns Hopkins tested cord blood from 299 babies born at Johns Hopkins Hospital between Nov. 26, 2004 and March 16, 2005 for 10 PFCs. They detected PFOS in 99% and PFOA in 100% of samples. Eight other PFCs were detected at lesser frequency. (Apelberg 2007)	299	Baltimore, Md.	9
PFC	Perfluorochemical (PFC)	EWG tested cord blood from 10 newborns for 12 perfluorochemicals and found at least one of these chemicals in 10 out of 10 participants. Among all 10 participants who tested positive for the chemicals, 9 of 12 different chemicals were found with total mean concentration of	10	U.S. hospitals	9

Chemical class	Chemical subclass	Summary of representative study	No. of newborns tested	Place of birth	No. of Chemicals found
		5.86 ng/g in whole blood. (EWG 2005)			
PFC	Perfluorochemical (PFC)	EWG tested cord blood from10 newborns of minority background for 13 perfluorochemicals and found at least one of these chemicals in 10 out of 10 participants. Among all 10 participants who tested positive for the chemicals, 6 of 13 different chemicals were found with total mean concentration of 2.38 ng/g in whole blood. (EWG 2009)	10	Mich. Fla. Wis. Mass. Calif.	6
Plastic	Bisphenol A & BADGE	Researchers from the Environmental Working Group measured BPA levels in cord blood from 10 newborns of minority background. BPA was found in 9 of 10 samples with a mean level of 2.18 ng/L. (EWG 2009)	10	Mich. Fla. Wis. Mass. Calif.	1
Rocket fuel	Perchlorate	Researchers from the Environmental Working Group measured perchlorate levels in cord blood from 10 newborns of minority background. Perchlorate was found in 9 of 10 samples with a mean level of 0.209 ug/L. (EWG 2009)	10	Mich. Fla. Wis. Mass. Calif.	1

ATTACHMENT B

DCN: 88090000206s

PUBLIC COPY

COMPOUND: [redacted]

STUDY TITLE: Acute Inhalation Toxicity in Rats

REPORT OR STUDY NO.: [redacted]

The purpose of this study was to determine the acute inhalation toxicity of the test article [redacted] The study was conducted in accordance with OECD Guideline No. 403. Groups of Wistar rats (5/sex) were exposed nose-only for 4 hours to aerosols of the test article (0 and 61 mg/m^3 measured concentration). MMAD was 1.5 µm with GSD of 1.7. Endpoints included rectal temperature shortly after exposure and body weights and clinical signs during the subsequent 2-week observation period. All rats were sacrificed and necropsied after 2 weeks.

Rectal temperature was significantly decreased following exposure compared to sham-exposed controls. Body weights were reduced after exposure but were comparable to controls for surviving animals by 2 weeks. All exposed animals exhibited labored and irregular breathing, bradypnea, reduced motility, high-legged gait, limp, piloerections, and signs of poor grooming. Four males and 2 females died in the exposed group within 1 day after exposure and exhibited gross lung edema with pleural effusions, collapsed lungs, and discolored parenchymal organs. Four surviving rats had a reduced/impaired grip strength, tonus, and righting reflex on first day after exposure. Limp was noted in 2-3 surviving animals on days 1-4; high-legged gait was noted in 3-4 animals on days 1-4. Surviving rats had discolored lungs at necropsy. Mortality (60% of exposed animals) appeared to be from acute lung edema and surviving animals appeared to recover during the observation period. The LC50 is ~60 mg/m^3, confirming a previous study T5061594.

The reporting criterion under TSCA 8(e) for acute inhalation is a LC50 <2,000 mg/m^3; the LC50 for this test substance of ~60 mg/m^3 meets this criterion. In addition, TSCA 8(e) criteria for reporting include signs of neurotoxicity at any dose level and lasting more than 48 hours after dosing in 2 or more animals that survive to the end of the study.

It is not clear whether the high-legged gait and limp are evidence of neurotoxicity in that the effect was transient and occurred at a dose where mortality was also observed. Nevertheless, meeting any of the above criteria leads to a recommendation for reporting.

Therefore, it is recommended that this report be submitted under TSCA 8(e).

PUBLIC COPY

April 6, 2009

Document Control Officer 8(e) Coordinator
U. S. Environmental Protection Agency – East
Confidential Business Information Center
Mail Code: 7407M
1200 Pennsylvania Avenue. N.W.
Washington, DC 20460

Dear Sir:

In accordance with TSCA 8(e) requirements, [redacted] is submitting [redacted].

The purpose of the study was to determine the acute inhalation toxicity of the test article [redacted]

The information submitted in this study is considered "Confidential Business Information". A sanitized, as well as a confidential version, is being submitted.

Please contact me if you have any questions.

Sincerely,

Company Sanitized

318554

List of Documents
Transferred to RDMB
DATE 4/21/2009

	DCN	CASE NO	DOC TYPE	COUNT	SANITIZED
1	88090000206/S	8EHQ-09-17482	8E	1	Y

[redacted]

[redacted]

By: [redacted]

List of Documents
Transferred to RDMB
DATE 4/21/2009

	DCN	CASE NO	DOC TYPE	COUNT	SANITIZED
1	88090000206/S	8EHQ-09-17482	8E	1	Y

[redacted]

S Coleman

By: [redacted]

Mr. GINGREY. Thank you, Ms. White.

We will now turn to questions from the members of the subcommittee, and each will have 5 minutes. I will say to the members, if you decide to speak for 4 ½ minutes and give a speech, and then ask a question in the last 30 seconds, I will let the witness respond to the question.

I will begin yielding to myself for the first 5 minutes, and my first question is going to be to Monsieurs Morrison, Sauers, and Isaacs, the first three witnesses. How do TSCA regulations for new chemicals and new uses and TSCA provisions on the production of Confidential Business Information affect your ability to innovate? Mr. Morrison first, then Mr. Sauers, then Mr. Isaacs.

Mr. MORRISON. Thank you, Mr. Chairman. For us, innovation is our lifeblood and what allows us to succeed and our economy to succeed is delivering performance capability to our customers, such as the two gentlemen to our left, with unique products, and our chemical formulations are at the heart of those products. What TSCA has allowed us to do is drive that innovation and also ensure that it is safe from a health and environmental standpoint, but protect the necessary information so that it is not disseminated to foreign governments, et cetera.

If you look at our company alone, we have had multiple cyber attacks by foreign governments that we were unaware of that the Federal Government made us aware of and notified us that our IP and other trade secrets had been penetrated and was being downloaded. That is exactly the information we are discussing today and that we need to protect, and that we are talking about if we change TSCA where we voluntarily disclose that information, we lose the very competitive advantage that we deliver to our company, to our customers, and to the U.S. economy.

Mr. GINGREY. Mr. Sauers?

Mr. SAUERS. Thank you, and maybe I will just add to what Mr. Morrison has said. Innovation is quite important to Procter and Gamble, you know, as a company of $90 billion in sales, 9,000 R&D employees. It is something that is very important to us, and what we have appreciated most about TSCA has been our ability to get our chemicals into commerce in a very reasonable timeframe and work with an agency that is highly competent in the evaluation of the safety of these materials. We have appreciated very much the opportunity to sit down with EPA scientists prior to the submission of a PMN to talk about our chemical, talk about the safety needs that TSCA will have, the EPA will have, to make sure that what we bring forward to them is complete. We have appreciated the risk-based approach that the agency has used. We have also appreciated their sensitivity to animal testing. The Procter and Gamble Company has spent about $300 million over the years developing methods to prevent the needless killing of animals for safety testing through the development of predictive methods, structure activity relationships, modeling, and things like that, and we appreciated the EPA incorporating those technologies.

Mr. GINGREY. Mr. Isaacs?

Mr. ISAACS. Mr. Chairman, as I outlined in my comments and in my testimony, we very much rely on the continued access to new chemicals as part of our ability to advance in semiconductor manu-

facturing. We believe that our processes are fundamentally based on automated systems and enclosed processes that result in minimal exposure, very limited releases to the environment, and therefore, we think our responsible use of chemicals, along with other environmental laws, protects human health and the environment in an appropriate manner.

Mr. GINGREY. Thank you. In my time remaining, I am going to—probably I will only time for one more question and I will direct it to Mr. Morrison. How does TSCA's New Chemicals Program work in practice? Could you walk me through manufacture, pre-manufacturing notice submission, that EPA 90-day review, and notice of commencement?

Mr. MORRISON. Yes, sir. Well essentially we start off by conducting our own tests on the chemicals, and then we put together a pre-manufacturing notice, which is the PMN submitted to the EPA. They scrutinize the data. They apply that to predictive models and analogous materials. They then go ahead and assess the various chemical properties. They look at the exposure potentials and risks, and ultimately come out with a ruling that could be a pass, a limited use, a restricted, or in fact, stop the PMN from going forward and require more testing.

If it is approved, either under restricted or fully approved to go ahead, then we are given permission and we issue a notice of commencement of the manufacturing process at that point. Essentially, this usually takes approximately a 90-day period, which is key because it allows us to turn our innovation in a timely manner, and in many industries, like semiconductor and others, that is absolutely critical for their success.

Mr. GINGREY. You heard the testimony from Dr. Lohmann and from Mrs. White—Ms. White, and their concerns. Are there any exemptions, exclusions from the new chemicals provisions of TSCA?

Mr. MORRISON. There are some, such as certain sets of polymers and other materials, that the EPA has very extensive experience with that they know don't pose any hazard or risk, and therefore, they are exempted from the process because it makes the EPA and it makes the chemical companies much more efficient, rather than just submitting everything where there is no added benefit to submission.

Mr. GINGREY. I thank all three of you and I have gone almost a minute over. At this point, I will yield 5 minutes to the ranking member of the subcommittee, the gentleman from New York, Mr. Tonko.

Mr. TONKO. Mr. Chair, the ranker of the Energy and Commerce Committee has a conflict with scheduling, so I would ask if you call upon your——

Mr. GINGREY. Absolutely. I will be glad to yield to the ranking member of the overall Committee of Energy and Commerce, the distinguished gentleman from California, Mr. Waxman, for 5 minutes.

Mr. WAXMAN. Thank you, Mr. Chairman, thank you, Mr. Tonko.

Four years ago, this committee spent a considerable time examining the Toxic Substances Control Act, and worked to craft policy solutions for its failures. It was a challenging endeavor, because we found that even as some in industry claim to want to make our reg-

ulatory system safer, we found strong resistance to actual reform. Mr. Morrison, you testified that Section 5 is "one of the major successes of TSCA, and that we should be careful to preserve its essential elements." I would like to take a moment to examine one chemical that has gone through Section 5 review, Firemaster 550. It is a flame retardant that as Dr. Lohmann has stated is gaining significant market share in the United States.

The maker of this flame retardant, Chemtura, markets this chemical as a safer alternative, saying that it has "an improved environmental profile" compared to its predecessors. In promotional materials, Chemtura touts EPA's review of Firemaster 550 under Section 5 as "extensive" and states that "consumer exposure is extremely low."

But as Dr. Lohmann reports, scientists have shown that consumers are being exposed to this product at significant and dangerous levels.

Dr. Lohmann, can you elaborate briefly on some of the exposure and hazard data that has been produced on Firemaster 550?

Mr. LOHMANN. Thank you for the question. I should point out that is Dr. Stapleton's work from Duke University. What she has shown builds on a legacy—well, it is almost an endless story. It starts off with flame retardants, PBB, polybrominated biphenyls, that were discovered by accident because they contaminated cows in Michigan. They were withdrawn from the market and replaced by polybrominated diphenyl ethers, which were found to accumulate in blood in the U.S. adult population 10 times higher than Europe, so it was finally withdrawn from the market to be replaced by Firemaster 550, which could only be partially evaluated because it was a mix of grandfathered in chemicals and new chemicals. And as all other flame retardants, they are not physically bound or chemically bound to the product, so they escape over time and mostly the exposure for all of us is in our houses through dust.

Mr. WAXMAN. Ms. White, you mentioned in your testimony that EPA didn't have access to all of the information it needed to thoroughly evaluate Firemaster 550 before it went on the market. Can you elaborate briefly on that?

Ms. WHITE. Absolutely. Because of the draconian measures of Confidential Business Information in TSCA, EPA's own scientists weren't actually able to look at the full health and safety profile, so the leading expert actually has said on the record that if she had known about the issues of Firemaster 550, then the chemical would not have been approved and there certainly would have been a request for more chemicals.

Mr. WAXMAN. EPA developed a work plan to conduct a risk assessment of numerous chemicals identified as potentially hazardous, including a chemical that is the active ingredient in Firemaster 550 known as TBB. EPA gave the active ingredient in Firemaster 550 the worst score possible for exposure risks and plans to assess it this year. Yet the promotional materials for the product still say that it has been approved by EPA and that consumer exposure is low.

Mr. Morrison, do you believe that Section 5 has worked in the case of Firemaster 550?

Mr. MORRISON. I think Section 5 in general works very effectively. I haven't studied that in great detail from a scientific standpoint or understand the full history of it. I would be the first to admit that at times, more information comes out and we have an obligation as an industry when we identify a substantial risk, we have to notify the EPA if we have additional data. Additionally, if the EPA determines there is an unreasonable risk, they have every right to go back in and revisit the chemical itself.

Mr. WAXMAN. So you would go back and revisit it, but Ms. White, what do you think? Do you think that Section 5 worked in the case of Firemaster 550?

Ms. WHITE. Absolutely not. I think that that really is a great example of how everything is turned upside down when it comes to the New Chemicals Program, because we have the burden of proof being on the EPA to raise this situation and raise concerns about chemical safety, as opposed to the chemical manufacturer fully disclosing and testing in advance and being required to test the chemicals before they go on the market.

Mr. WAXMAN. Thank you. Firemaster 550 is already on the market, in furniture, in baby products and other consumer goods, and there are now serious questions about its safety. I guess the question I think that raises is would the public have been better served understanding these risks before it was brought into widespread use?

I would like to introduce, Mr. Chairman, into the record a letter from the Center for International Environmental Law dated July 11, 2013. This letter summarizes work CIEL has done to examine trends in chemicals regulation and patent filings to evaluate the impacts of stronger rules for hazardous chemicals on the innovation of new chemical products. They find that stricter regulation of hazardous chemicals drives innovation and creates a safer marketplace. They explained that implementation of Section 5 has resulted in one dangerous chemical being substituted for another dangerous chemical. They point out that when a different approach is taken, when dangerous chemicals are removed from the market, it accelerates the invention of alternative chemical products. It makes a lot of sense to me and I hope we can focus on getting this policy as right as it can be.

Mr. GINGREY. Without objection, the letter is accepted into the record.

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

Mr. GINGREY. We now turn to the subcommittee chairman on oversight, the gentleman from Pennsylvania, Mr. Murphy, for 5 minutes.

Mr. MURPHY. I thank the panel for being here.

I want to start off, because it is always important for me to hear from some of you your corporate philosophy, and I want to ask you this, Mr. Sauers. Your corporate philosophy with regard to dealing with the health and safety of your customers and your employees when it comes to developing chemicals, could you just describe to me what that is?

Mr. SAUERS. Sure. Thank you, Congressman. I mean, I can't think of anything more important to Procter and Gamble than the safety of our customers and employees. Four point six billion people

use our products every day, so it is imperative that we ensure that the products we put on the market are safe for them and safe for the environment. I think to illustrate that best, my department at Procter and Gamble has 700 employees in it, 200 of whom have PhDs in sciences related to human and environmental safety. So everything we evaluate for the—to go on the market has a thorough and comprehensive risk assessment prepared for it to ensure that it is safe.

Mr. MURPHY. Mr. Isaacs, do you have a comment on that?

Mr. ISAACS. Well as an industry, I think we have a similar dedication to the protection of the environment and our workers. My written testimony highlights some of the successes we have had in substituting or phasing out materials of concern in our processes and reducing emissions, and that remains a very high priority for the industry globally.

Mr. MURPHY. And again, Mr. Sauers, in the developing of chemicals in your company, do you—and following what you said as far as your mission of corporate responsibility, do you review chemicals and make decisions that some of them should not be brought to the market because in your determination, they are not passing muster for health and safety?

Mr. SAUERS. Yes, sir. We go through a complete evaluation from the beginning of first proposal by our technologists. Evaluating in the beginning, if we show that materials will be problematic as they are marketed, for example, show unreasonable sensitization, toxicities associated with various organs or things like that, if we think those issues will be a problem considering the exposure that individuals will get to them, we will stop them. We have done that in many instances. As a company, we chose not to market nonylphenol ethoxylates, which were a major surfactant because of environmental quality and their inability to be completely biodegraded. So those decisions are made every day by our toxicologists.

Mr. MURPHY. Thank you. Now for Mr. Morrison, Sauers, and Isaacs, a question. As Congress is probably going to be dealing with the TTIP, that is, dealing with the Transatlantic Trade—Pretrade agreement coming up, one of the questions that is going to come up is with regard to regulations between the United States and European nations, and particularly, I am sure that the question of sharing of CBI with State and foreign governments, the TSCA permits, et cetera. I wanted to ask you if any of you are anticipating any concerns in terms of should States and foreign governments be permitted access to CBI, or if you have begun to put any thoughts into how this would be handled? Mr. Morrison?

Mr. MORRISON. Yes, at this time we do not, as the ACC or I as the CEO of a company, support sharing CBI with foreign governments. We don't feel we have the ability to control and protect that information. We do take a different stance on sharing information with States where they demonstrate an ability to protect the information, as well as an applicable use around safety or environmental purposes. But we do not feel secure in today's environment passing out CBI information internationally, so we would not support that.

Mr. MURPHY. Let me expand this, and the three of you, as it goes through, because it is something we are going to have to deal with, and there are regulatory issues how the United States and the EU will deal with these issues to make sure that any products that are sold across the Atlantic from either side dealing with their environmental concerns and our environmental concerns with health and safety of customers. So how do each of you—what are your thoughts on does the EPA protect trade secrets while still providing a mechanism for evaluation of safety and health review? I will start with Mr. Morrison and go across.

Mr. MORRISON. Yes, I think there is very much a capability to share the pertinent information without giving chemical identity and other things that we currently protect. So the important aspect around safety, environmental and et cetera, we feel we are very capable of sharing that. What we don't agree with is sharing the proprietary information such as chemical identity.

Mr. MURPHY. Do you feel that they protect that information, or does it get out?

Mr. MORRISON. Well, we have ability to protect that with generic names that we talked about before, but we are afraid if you gave out chemical identity, once it goes to other governments you lose control of the ability to protect chemical identity.

Mr. MURPHY. A few more seconds. Mr. Sauers, with regard to the EPA protecting that proprietary data while it is still providing information to help them evaluate health and safety, do you feel confident that they protect that top proprietary information?

Mr. SAUERS. Yes, I do, and I think there is a balance that needs to be weighed here. There no CBI with the EPA itself. I mean, they get full access to all the information and the specific chemical names. I mean, they have full access so they are able to make their evaluation. And then a generic, less descriptive chemical name is given and that is what is made public, which allows the public to be able to draw their own conclusions about the material. And as a toxicologist, that information that is provided is sufficient for individuals to make evaluation and draw to corollary materials, for which there is available information.

Mr. MURPHY. Thank you. Mr. Chairman, I see my time expired but I would hope that that question could also be forwarded to the other panel members and ask for their response as well. Thank you.

Mr. GINGREY. Thank you, Mr. Murphy. We now turn to the ranking member from New York, Mr. Tonko, for 5 minutes.

Mr. TONKO. Thank you, Mr. Chair. Reviews by the Government Accountability Office and testimony that we had heard at our last hearing indicated shortcomings with respect to Section 5 of TSCA. Last year, EPA announced a work plan to conduct the risk assessment of numerous chemicals identified as potentially harming children's health, causing cancer or posing other health concerns. Several of these chemicals were reviewed under TSCA's Section 5 New Chemicals Program, but made it on the market anyway.

So to Dr. Lohmann, my question is if we suspect a chemical harms children's health or has another serious effect, shouldn't we try to understand that before it goes on to the market rather than after?

Mr. LOHMANN. I would fully concur. You would expect these days that we would first make sure a chemical is safe before we produce it. Unfortunately, that is not the way it works in this country right now.

Mr. TONKO. Well how could a stronger Section 5 provide proactive protection for the American public?

Mr. LOHMANN. What you see happening in Europe under the REACH Program is that the manufacturers have to take responsibility for their product and have to convince the regulatory agency, in this case, the European Chemicals Agency, to show that their product is safe in its different uses. So the manufacturer has to go all the way through from cradle to grave what I am producing is safe and where it is going to be used. And that kind of approach really means the responsibility is with the person or the company who makes it, and they have to show it is safe. And that, I think, is a much more forward looking approach than just having here is a new chemical, EPA, just evaluate it quickly and we will market it anyhow.

Mr. TONKO. Thank you. Ms. White, you testified that the current structure of Section 5 leaves EPA without the data it needs to effectively evaluate chemicals and that the structure creates a disincentive to producing that post data. Could you please elaborate on that?

Ms. WHITE. Absolutely. So EPA right now is not able to require testing before a chemical goes on the market. If the industry has tests, it is supposed to disclose them. But in order to request more information, it has to find two things. That one, there is an unreasonable risk of injury, or two, that the chemical is going to be manufactured in such a high volume that there would be a significant human exposure. So what happens is, there is this chemical Catch-22, which EPA has to try to figure out that there may be a risk, but it can't require testing until it has evaluated testing. So it is this really difficult cycle. It is like grading students without actually asking them to take a test. So for example, I will just give you an A because I know that maybe your son was a really good student and maybe you are a neighbor of so-and-so, but I am not actually requiring you to take any tests. So it is a very difficult situation that EPA is in.

Mr. TONKO. EPA can't thoroughly review new chemicals for potential health effects if it doesn't have adequate data to do so. One policy that has been discussed over the years is the concept of requiring a certain minimum amount, minimal amount of data prior to a new chemical being brought onto the market. What do you think of this approach? Does it have merit?

Ms. WHITE. It absolutely has merit, and frankly, I think most Americans assume that that is already in place. They are very surprised to find out that EPA doesn't require a series of tests before chemicals go on the market, so that is absolutely where we should be heading, and that is where we should be targeting reform for Section 5.

Mr. TONKO. And Dr. Lohmann, your thinking on the data requirement?

Mr. LOHMANN. I certainly agree, and that is—most global players who deliver to the European market have to provide this kind of

data now to get onto the European market, get reevaluated, or reassessed, reauthorized for their chemicals. So the best thing the U.S. should do is find an agreement with the European program to use the dossiers that are provided anyhow, and they will all have to provide data. If you have no data on your chemicals, there is no market in the EU. It seems a very logical approach.

Mr. TONKO. Mr. Morrison, it seems to me that building safety into the developmental process earlier is likely to be a better approach to product development. This is the idea, I believe, behind the green chemistry movement. Would you agree with that in concept?

Mr. MORRISON. Well, I think there is a basic underlying assumption in your comment, which is we don't build safety, and I think we do extensive testing. We have the greatest to lose if we put products on the market that are hazardous, that hurt health, that hurt environmental, et cetera, so we do extensive testing when we develop new products. All of that information is turned over to the EPA. They have very extensive databases that they run and they run on analogous materials. And so I think the underlying assumption that if the EPA doesn't force the test it isn't done, they don't have to force the test in many cases because it is already being done by us.

As far as green, we fully support green where appropriate. Our company and many in the industry aggressively push it, but it is one form of innovation. It is not the only form of innovation.

Mr. TONKO. Is there any chance for added safety by requiring the submission of a basic safety data set as part of the initial pre-market review process?

Mr. MORRISON. I actually think it would have an adverse effect, because what you have to take into account is the workload you would put on companies and EPA, you would take the higher hazardous and now be swamped with all chemicals there when there are much more effective and efficient ways to deal with the vast majority. And so you are creating an unneeded workload, which I believe would add very little or no benefit and would, in fact, just swamp the EPA and they wouldn't be able to prioritize their resources. It would also kill innovation. The reason we produce three times more chemical innovation than Europe, Japan, and others is because I think our process works very effectively.

Mr. TONKO. I guess I am also hearing that they might require more resources for EPA also to develop that plan, but I believe I have extended my amount of time, so—exhausted my amount of time, so I will yield back.

Mr. GINGREY. Thank the gentleman, and we now turn to the gentleman from West Virginia, Mr. McKinley, for 5 minutes.

Mr. MCKINLEY. Ms. White, I want to see whether I heard it properly. Did I hear you say that often products going to the market are not confirmed prior to going to market for toxicity?

Ms. WHITE. That is correct. According to EPA, 85 percent of the pre-manufacture notice, this approval process for chemicals, do not have toxicity data. They have not submitted that to EPA.

Mr. MCKINLEY. Are you contending, then, that—are you suggesting that they are trying to circumvent something by doing that?

Ms. WHITE. I am suggesting that the system is broken. There actually isn't incentive for testing. There is an incentive not to test because if you don't——

Mr. MCKINLEY. You think that they are testing themselves?

Ms. WHITE. If they are, they are required to give that to EPA.

Mr. MCKINLEY. OK, thank you.

Ms. WHITE. But in 85 percent of instances, they don't.

Mr. MCKINLEY. The other three panelists, can you respond to that? I thought that was an interesting comment. I guess I did hear that properly. Do you want to respond back to the going to market without testing for toxicity?

Mr. MORRISON. You know, where appropriate and data is required, we of course test for toxicity and the idea that we would put out products where we thought there was a risk simply for economic reasons, first of all, it doesn't make any economic sense because the risks would overwhelm any sales potential. B, we apply the tests that are appropriate but we don't blindly apply all tests to everything. It is not economically viable, either. So I think the underlying assumption is one I don't agree with.

Mr. MCKINLEY. Mr. Sauers?

Mr. SAUERS. And I think we have to distinguish between the EPA's ability to do an evaluation of a chemical, and then the toxicity data that is being mentioned here. You can evaluate the safety of a material without having animal toxicity data. There are other avenues available to you. The EPA has it its disposal, you know, a vast database of animal data on historical chemicals and they are experts in applying structure activity to the relationships and productive modeling type systems to evaluate the safety of materials. So just because they don't get new animal testing data on a chemical that is coming in does not mean that they don't have an ability to evaluate that chemical for safety.

Mr. MCKINLEY. Thank you. Mr. Isaacs?

Mr. ISAACS. Yes, sir. We actually think there would be a benefit to improved tools and better predictive modeling at the agency, and we also think that increased access and transparency to existing data that is out there would benefit the system as a whole. I understand that EPA is making some efforts in that direction and we look forward to seeing the results of that.

Mr. MCKINLEY. Thank you for your responses back on that. I am just curious, the fact that apple juice has arsenic traces, arsenic in it. Should we be banning the drinking of apple juice in America because there is a trace level of toxicity in that material? Ms. White?

Ms. WHITE. We would not say we need to ban apple juice, but certainly a cause for concern when we have all these situations where these low doses of chemicals—and arsenic is a different situation—but when we are talking about chemicals that are manufactured and not required to be tested before they go on the market, that is shocking for most Americans.

Mr. MCKINLEY. Ms. White, I just think I am with you more than you realize, but I am also wondering how often we get to maybe hysteria levels on some things. When we are burning coal, we have the issue of toxicity that people use exaggerated numbers and fears that are unwarranted and it puts the fear in the minds of people, and the same thing. So I really do appreciate the responses that

we have had here today. If people are going to market without checking for toxicity, whether it is internal or through the agency, I think we need to determine that but it sure sounds like the companies are doing the job themselves, it appears, and I would hope that we wouldn't be putting out false concerns to the public if they are out there on that.

So with that, thank you and I yield back the balance of my time.

Mr. GINGREY. Thank the gentleman, and I turn to the gentleman from California, Mr. McNerney, for 5 minutes.

Mr. MCNERNEY. Thank you, Mr. Chairman. I thank the witnesses this morning.

I think it is pretty clear there is a conflict between the industry's legitimate wish to keep trade secrets confidential, and on the other hand, the risk of releasing chemicals whose long-term and low exposure health impacts may not be very well understood, especially when they are put in an environment where they are going to be mixed with other very complex chemicals. So everyone understands that it is in the industry's interest to have consumer safety and consumer confidence. There is no problem there. It is our duty, it is our job as a committee, as a subcommittee, to try and resolve that conflict. We are going to do the best we can and I appreciate your participating this morning.

Mr. Sauers, I think I heard you say that an update of TSCA is urgently needed. One of the reasons is to give consumers confidence in the process, and I think that is pretty well agreed to. But then you said later that the EPA's recent decision to disclose specific confidential information is hurtful. So I see that that is a little bit of a conflict in my mind between wanting to improve consumer confidence and yet thinking the EPA's decisions are problematic.

Mr. SAUERS. Sure, and maybe just to clarify, we just had a discussion about questions being raised about trace levels of arsenic, for example, in apple juice. That does raise concern to consumers' minds about the safety of products that are in the marketplace. Many times a company like Procter and Gamble doesn't have all the credibility as it communicates to consumers about safety. The EPA does, so having and EPA with a very robust system in place that is recognized will give a credibility when they say that materials are safe, and we would support that very much. We think that they do have the tools today to do that with the information that is provided as part of the PMN process.

Mr. MCNERNEY. Well I will just suggest that, you know, implying that EPA's new rules to release the information might actually help in terms of the company's long-term credibility, so that is my two bits on that.

Mr. Lohmann, you mentioned that one of the things we should do is ID and replace the most dangerous chemicals, including grandfathered chemicals. How big of a job would that be?

Mr. LOHMANN. It would certainly be a major undertaking, but luckily, the Europeans are doing that now anyhow, so they are taking care of that and most global companies, like Procter and Gamble, have filed all their dossiers so information on most of those chemicals will be available. As I will also point out, it will actually spur innovation towards safer chemicals so I think it is a worthwhile endeavor.

Mr. MCNERNEY. So it might spur innovation and profitability then?

Mr. LOHMANN. Because some of the comments we have already brought, most right now in the environment were grandfathered in. They had no testing. Some of the new ones we also worry about, but certainly the grandfathered in are—should be reassessed.

Mr. MCNERNEY. Well one of the most striking things you said was that there is a strong correlation between chemicals in households and health problems that we are experiencing in our country. Did you want to expand on that a little bit?

Mr. LOHMANN. Certainly. I guess we can never know for sure because etymology is very difficult to do, but it is striking that a lot of the results that we see from either controlled tests or even in the field of animals to low doses are exactly the health problems that we see in modern society. So I am not saying that chemicals are the sole cause of all the problems, but there is probably a correlation, and that should worry us.

Mr. MCNERNEY. Mr. Lohmann and Ms. White, have you heard of the term chemical trespass, and if so, would you describe what you think that term means?

Ms. WHITE. Yes, chemical trespass means there is unwanted chemicals that are in your body and rather than trespassing on someone's land, in fact, a chemical has trespassed into your body. It is a developing concept in tort law, and there is certainly a lot of concern. Our studies have shown that, in fact, these chemicals that we find in consumer products like lotions and stain removers and laundry detergents and nail polish are actually building up in people's bodies, and as I said in my testimony, also in newborn babies.

Mr. MCNERNEY. Would you, Ms. White, offer some specific suggestions on how to improve the TSCA process?

Ms. WHITE. Absolutely. With respect to the new chemicals provision, we really need to make sure that the burden of proof shifts from EPA to the manufacturers to show that their products are safe before they go on the market. We also do need a minimum data set so we know what the rule are, and so consumers, we hear a lot about confidence. Consumers want to know that when they have a nap mat, you know, where our colleagues at the Center for Environmental Health released a really great study that nap mats have flame retardants it is really concerning. Parents want to know when their kids are taking a nap at preschool that they aren't going to have a chemical in their body, and that certainty would be really key.

Mr. MCNERNEY. Mr. Lohmann, would you agree with that response?

Mr. LOHMANN. I would agree.

Mr. MCNERNEY. I am sorry, I said Mr. Lohmann and I was looking at Mr. Morrison. Mr. Morrison?

Mr. MORRISON. Which element of a response, just to make sure that——

Mr. MCNERNEY. Well, if the—I will let my time expire on that.

Mr. JOHNSON [presiding]. I thank the gentleman for yielding, and Dr. Gingrey went to the floor, so I am going to sit in for him. I am Congressman Bill Johnson from Ohio, and I will take my 5 minutes

now. I would like to thank the panel for—you want me to go ahead? I was next until Dr. Cassidy walked in.

OK, restart the clock. I would like to thank the panel for being here. Thank you so much.

Mr. Sauers, since testing is not required when you first file a Section 5 pre-manufacturing notice, does that mean you have not tested that chemical?

Mr. SAUERS. I think I will maybe answer by saying that evaluations are made of the material and there are many ways of making an evaluation of a chemical for safety. One way is to do safety testing, you know, rodent test like an oral toxicity test in rodents. There are also other ways to evaluate the safety of a material, using tissue culture, using structure activity relationships, predictive modeling, and things like that. So materials are always evaluated. How they are evaluated can be different, depending on the circumstance.

Mr. JOHNSON. Well, if you do testing before submitting a PMN, do you assess a broad range of possible hazards?

Mr. SAUERS. Yes, and it really would depend on the exposure that one expects the material to have. So if it broad scale exposure, you will find testing and evaluation across a variety of toxicity end points. If it is specific for inhalation, it will be different. If it is going to be a large volume exposure versus a very small exposure, the degree of testing could be different.

Mr. JOHNSON. OK. How standard is this practice within the industry?

Mr. SAUERS. I would say that most companies approach it the same way, a risk-based approach of assessing exposure and hazard. Most companies have toxicologists, like Procter and Gamble, that will approach it this way.

Mr. JOHNSON. OK. Do you do additional tests on your own after the PMN has been submitted?

Mr. SAUERS. Generally by the time we have submitted the PMN, the bulk of our testing is done because we are commencing to manufacture and put the material in the marketplace, so we want to have a full assurance of safety prior to that happening. If in the course of marketing something comes through our 800 line or through consumer comments that could cause a question to be raised, we would go back and evaluate it.

Mr. JOHNSON. OK. Mr. Morrison, do you agree with these responses, consistent your——

Mr. MORRISON. Yes, absolutely. You know, as an industry, the chemical industry, we have a responsible care management system that we share across all chemical companies that are part of it, and that is the vast majority, and common best practices are shared and employed, and I think we are very consistent with Mr. Sauers' answers.

Mr. JOHNSON. OK. Do other forms of intellectual properties, such as patents, provide adequate protection to confidential chemical identities, in your view?

Mr. SAUERS. Yes, they do provide some protection, but it is not complete. There are very strict——

Mr. JOHNSON. Operative word was adequate, so do you consider them to be adequate?

Mr. SAUERS. Patents—for the purpose of patents and what they cover, they are adequate.

Mr. JOHNSON. OK, Mr. Morrison?

Mr. MORRISON. There is much confidential information that is not covered by patents, and so while patents are effective for the, you know, actual material that is under a patent, that is fine, but there are many others that come under trade secrets that are just as critical to our business and we don't patent for very specific reasons.

Mr. JOHNSON. OK. Mr. Isaacs, Ms. White and Dr. Lohmann have suggested that TSCA chemical review operate like reviews for drugs by the Food and Drug Administration. What do you think could be a reasonable reaction from your members if this were to occur?

Mr. ISAACS. Well, of course I am not an expert in the drug review process, but I think that would not be the right approach. I think that would be—impose a time delay that would impede the time to market that we require, but at the same time, the key point that we would like to emphasize in all this is the need for chemical assessments to be tailored to the risks and exposure to the use in question. And we are confident that in our industry, with the high degree of controls that we impose on our processes, that the exposure and releases are very, very low and the chemicals that we use are done safely and responsibly.

Mr. JOHNSON. OK. Mr. Sauers, back to you. Doesn't Europe require manufacturers to submit a minimum information set on new chemicals?

Mr. SAUERS. Yes, as part of REACH.

Mr. JOHNSON. OK, so if you are doing it in Europe, why not do the same thing here in the United States?

Mr. SAUERS. I think this is what we appreciate most about TSCA is that the amount of data that is submitted is tailored to the chemical and the exposure that individuals can expect from it and its toxicity. You know, like Procter and Gamble, a new chemical that is going into a laundry detergent, for example, there will be vast exposure to that so that is something you want to have a full, complete toxicity data set on. And you can contrast that all the way back to maybe an intermediate in manufacturing for which there is no exposure. So really the amount of data needed for something like that is minimal. So this ability to tailor the amount of information to the need of the chemical to assure safety is really the best approach.

Mr. JOHNSON. OK, thank you. Thank you all for your answers. At this time, we will go to Mr. Barrow from Georgia.

Mr. BARROW. Thank you, Mr. Chairman. Something we have talked a lot about is the over-classification of Confidential Business Information problem here. We haven't talked much about efforts to declassify stuff that is no longer necessary. Mr. Morrison, in your written testimony, I think you talk about a voluntary effort that is underway between the EPA and the industry to try and declassify stuff that is no longer nor needs to be confidential. Can you share—tell the committee what that effort looks like?

Mr. MORRISON. Yes, it is essentially with the EPA there is an effort to identify what you might consider obsolete and information

that doesn't have to be classified anymore, and actually working through a backlog of that and declassifying, and it is one of the areas of opportunity that we think as the new bill comes out hopefully that we can be more progressive about and more effective with, both in classifying originally on a CBI basis, but also declassifying.

Mr. BARROW. Building on that, and talking about conflicting demands between the right to know between claims that everybody has a right to know everything about this, and there is a legitimate interest in keeping things confidential. I want to shift just a little bit from competing demands about the right to know, to a more pragmatic understanding about what we can do to share information to folks who have need to know. For example, Ms. White, in your testimony you talk about the needs that some folks have, the legitimate needs of first responders in emergency situations, and Mr. Morrison, you talk about efforts to declassify stuff that no longer needs to be kept confidential. Is there any kind of process that you all can agree on that would sort of if not address completely to everyone's satisfaction the issue of one's right to know would still result in a practical dissemination of stuff to folks who have a need to know? Is there some kind of process that we can agree on that would move us forward in that direction? Mr. Morrison, then you, Ms. White.

Mr. MORRISON. There is actually a process in place now that when an emergency situation happens, a spill, other type of emergency situations for emergency responders, there is information that is mandated, including material safety data sheets, et cetera, which are very explicit and the up-front section is all about emergency response to that particular material.

So when you are in an emergency situation, either health or environmental, the rules change automatically and we disseminate information on it on an as-needed basis. So that is already addressed, but we certainly look forward in the new TSCA bill to see if there are any gaps that we can be more effective.

Mr. BARROW. Ms. White, how would you address that subject?

Ms. WHITE. I would say that we all basically want the same thing. We want to make sure that chemicals are proved by a trusted regulator and that the chemical industry is vibrant. I think there is a lot of opportunity here for us to come up with sunset provisions, for example, for Confidential Business Information, also to make sure there is resubstantiation within a certain amount of time. I think that there is an important carve-out for medical personnel and emergency responders, and there is a real opportunity for us to work together.

Mr. BARROW. Thanks. Mr. Sauers, it would be a poor dog who won't wag his own tail, and since you won't do it, I will do it for you. I have enjoyed my visit to P&G's facility in Augusta back in 2010 and look forward to my next visit coming up in the fall. Can you share with us anything about—you talk about the importance of not creating disincentives for innovation in this area. I know there are conflicting views about whether or not total dissemination of everything is going to actually promote innovation or not. What are the disincentives you would want to avoid in a kind of revamp of TSCA?

Mr. SAUERS. I would say that anything that would lead to a loss of competitiveness, and I think this is where the CBI comes in. I think that there is a balance that can be brought between ensuring that everyone has the health and safety information that they need to be able to make a conclusion on a material, and the ability to protect competitiveness for companies like Procter and Gamble. I think the process today where the EPA is given full disclosure of all information, even that which is confidential, enables them to make an assessment, and then the public release of the health and safety information with the generic descriptive form of the chemical enables individuals to get an understanding and draw parallels to other materials that are in the marketplace to ensure health and safety. So I think there can be a balance that can be brought there.

Mr. BARROW. I hope you all understand with votes pending on the floor, no time left on the floor, I am going to yield the rest of my time. Thank you so much. Thank you, Mr. Chairman.

Mr. JOHNSON. I thank the gentleman for yielding back. We will go now to Dr. Cassidy from Louisiana.

Mr. CASSIDY. Let me stress there is no time left to increase my anxiety level. I apologize. I stepped out so if you all addressed some of this, I have a question that is kind of for across the board.

Dr. Lohmann mentioned that REACH in Europe is requiring a lot of things that frankly I gather make some of your proprietary information held by a government agency regarding some of the testing, and I tried to Google it, and REACH is a long, long PDF. I think your point, Dr. Lohmann, was that, heck, this is already being required. It is just being required by the Europeans and not by us. That is kind of an interesting argument. What would you all say to that? Why don't we just do what the Europeans are doing, because frankly, if they are doing it, then your chain is only as strong as the weakest link and the Europeans are kind of the weak link, perhaps, in some of this, so to speak. Or maybe they are the strong link. But how would you all respond to that?

Mr. MORRISON. I mean, we operate under both REACH and the EPA current guidelines, and we find REACH to be excessively bureaucratic and we don't find it necessarily adds incremental benefit. We think that the databases that the EPA has, the analogous materials they work with, we can innovate faster under the EPA system than we can as required under REACH.

Mr. CASSIDY. Then let me ask, because each of you all is so big. I kind of knew that you would be in the European market as here, and that market is so large you can't ignore it. But do you have a different product line, whether it is a U.S. market versus a European market?

Mr. MORRISON. In many cases, our products are modified on a global basis by region, whether it is consumer or others, for a wide variety of reasons, so sometimes there are very significant differences.

Mr. CASSIDY. OK, now they just told me I got to hustle, or else there will be an attack out on me on my next campaign.

So Dr. Lohmann, next question for you. I looked up some of your references. Now for example, eight weak estrogenic chemicals combined at concentration below—produce significant mixture effects. You mentioned this was in rats. What would be required to

produce—put it this way. It is hard to show a negative. Now if we are going to establish safety and we had rat data in which eight chemicals were combined to have an effect, we don't know whether that would translate into humans, and indeed, some of those effects might not be seen for decades. So I guess my question would be the—at what point—these guys could be tied up forever proving safety of something, but you can't ever prove quite that something bad is not going to happen. You see where I am going with this. What would be the standard by which you could accept that something was truly safe?

Mr. LOHMANN. That is a very good question. I am not sure we know the full answer right now, but I think being cautious is helpful. Mix toxicity is the biggest unknown that everybody is working on, because we know we are exposed to hundreds or thousands of chemicals at the same time at trace levels, of course.

Mr. CASSIDY. And we don't know if those trace levels are physiologically important, or pathophysiologically important. It may be, but we don't know that.

Mr. LOHMANN. That is correct, but we also know that toxicity has become much, much more concerned about trace levels over the time.

Mr. CASSIDY. I absolutely can agree with that. Of course, intuitively you know since EPA has been operating our environment has become cleaner, and so if you will, there should have been a higher toxicity exposure in times past than now, and not for everything, but for many things.

Mr. LOHMANN. That is correct. We certainly are cleaner with respect to PCPs, but we certainly have increased in perfluorinated compounds. We have more flame retardants, so it is a give and take.

Mr. CASSIDY. Yes.

Mr. LOHMANN. I am not sure if we are much healthier that way.

Mr. CASSIDY. Much less mercury and much less lead. So I guess—so I am not sure, it would always be a moving target. I am sure we have now decreased lead, we are still seeing something trace. How do we ever prove safety? If we are going to establish safety beyond a doubt, will we ever have anything established?

Mr. LOHMANN. Well, one way to do this is to just wait and see if the Europeans become healthier because of REACH and the U.S. does not.

Mr. CASSIDY. See, the problem is—and I read an article that kind of critiqued this—was that there are so many secular effects, and if you look at the effect of obesity, for example, and the effects of it on breast cancer, it so much outweighs the things that we know have an effect, alcohol, cigarettes, family history, obesity are so powerful that even if there is an effect of a trace element, then that effect might be drowned out by the secular.

It is 33 seconds left. I am about to miss a vote. I have to leave it there. Thank you very much.

Mr. GINGREY. Thank the gentleman, and we are going to actually take a little break. We are waiting for Congressman Green from Texas to return from that vote. He should be here momentarily. I want to ask that all members have 5 days—ask for unanimous consent, of course, that all members have 5 days to submit opening

statements for the record, that letters to this subcommittee from 3M, the Cleaning Institute, and the Consumer Specialty Products Association be included in the record of this hearing, and that members have 10 days to submit questions to the chair that will be forwarded to our witnesses for their responses to be included in the record. Hearing no objection, so ordered.

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

Mr. GINGREY. I now yield to the gentleman from Texas for 5 minutes of questioning, Mr. Green.

Mr. GREEN. Again, thank you, and I know this panel knows we have one vote on the House Floor and you will be seeing us come in and out, although hopefully that vote won't take an hour, only the typical 15 minutes. I appreciate the panel here. I want to thank the majority for calling a number of hearings on TSCA reform. I come from an area where TSCA reform is really important. I have—in fact, I think Procter and Gamble is probably the only company that doesn't have a plant in our district that relates to chemicals. But we know we need to reform and it needs to be done in a reasonable way, so that is what we are hopefully the Bitter-Lautenberg bill or the draft is something we can use on our side, on the House side, as a guide.

Mr. Morrison, I am hoping you would share with our subcommittee some of the end products that are a result of chemicals manufactured by your company.

Mr. MORRISON. Some of the end products would be wind energy blades, solar panels—you are talking about end use markets?

Mr. GREEN. Yes.

Mr. MORRISON. Medical applications in terms of devices we go down into, we have more than 50 applications in automotive, all wood products that you have touched probably use our chemicals. We are in aircraft. We are extremely broad. We are in electronics, so your cell phones, your iPads, we have components and chemicals that go into all of that.

Mr. GREEN. One of the things we may need to look at as a committee, that certain chemicals—we may have a higher standard for baby bottles, for example, or for bottles of Diet Coke or water or anything else, than we would for windmill blades, or even automotive parts that we are not going to have contact in. So you know, that is one of the things we need to factor in on some of the issues.

Do you believe that chemicals developed by Momentive could have developed under the regulatory regime of the European Union?

Mr. MORRISON. In some cases, yes, but in other cases, we believe that the speed is not there, that it is a much more bureaucratic system. It now requires a minimum data set. It doesn't react as quickly, and so in some cases, we would not be able to innovate at the same rate, and that is why the U.S. innovates at approximately three times the rate of the European Union on new chemicals.

Mr. GREEN. Well as a side, since we are talking about North Atlantic Free Trade Agreement, you know, having common standards as something we may need to deal with on a separate venue and hopefully our committee will be able to deal with it instead of just adopting whatever the European community does. You have already given the answer about the regulatory regime provided by

the advantages of our competitive system. In your testimony, you state that EPA and chemical manufacturers developed a dialog over the years that benefits both the EPA and the industry. Is that correct?

Mr. MORRISON. Yes.

Mr. GREEN. Can you share how this dialog would help industry develop new chemicals, particularly as it relates to protecting human health and the environment?

Mr. MORRISON. Yes. A lot of times, when the EPA puts out guidelines, et cetera, dialogs back and forth, we self-regulate in many cases as was described earlier where we will start down a path developing something. If we find it has certain characteristics that may not pass EPA muster or our own muster, we will actually pull that product before it ever goes. Having an ability to communicate back and forth with the EPA allows us to proactively do that. It saves us the time from developing something that won't hit the market, and it also saves the EPA time. Conversely, I think because the process is quite effective and it does lend towards innovation, it also allows us to expedite things that will be successful and bring new innovation quicker to the market than places like Europe.

Mr. GREEN. You noted in your testimony that EPA does not require CBI claims to be justified. Is that correct?

Mr. MORRISON. Yes.

Mr. GREEN. Do you think you could—we could still have the innovation technology if EPA had the authority to say—of course, we also are very proprietary interest, but do you think if EPA had that authority you could still have the success you are having?

Mr. MORRISON. We like to believe that as far as justification of CBI and the new Bitter-Lautenberg bill it actually does change how CBI information is handled. That is one of the modifications that might be an improvement to the process today, and is something we could work with.

Mr. GREEN. Mr. Sauers, can you share two or three reasons why you are opposed to requiring the industry provide a minimum safety data on all new chemicals?

Mr. SAUERS. It can be a waste of resources. As we approach a new chemical, we understand the exposure, we understand the safety testing or the safety evaluation that is needed. We can tailor the program specifically to the needs of that chemical. That is the approach that the EPA uses today as we go forward with them in the PMN process. So this ability to tailor the safety program to the specific needs of the chemical is very important. You don't have that with a minimal set database. Also, the decrease in animal testing that one gets with the current EPA approach is very important. If you look at the minimum data set, it is usually requiring tests like acute oral toxicity tests. I am not sure who runs those tests anymore. They are really not necessary to use animals to conduct such a toxicity evaluation today. There are many other ways of evaluating acute toxicity using structure activity relationships. So a lot of testing will be generated that is just not necessary as part of those minimum data sets.

Mr. GREEN. And I know the EU chemical regimen in your testimony was lacking science-based chemical prioritization process. It

seems today because of CBI and with the advances in reverse engineering is it is almost likely that there is no real secrets that we can deal with, and would you agree that having such a capacity that is readily available for chemicals that should make it ineligible for CBI protection for the industry?

Mr. SAUERS. I would disagree with that. CBI is very, very important for companies like Procter and Gamble to maintain competitiveness. Now with that said, that does not mean that information is held confidential to the point that it prevents an agency from evaluating the safety of a material. You know, there is no CBI for the EPA, for example. They get all the information and then there is a generic-type form of the chemical nomenclature that is released publicly with the health and safety information so the public can make their own evaluations.

Mr. GREEN. Mr. Chairman, I know you have been great with the time. I have some other questions I will submit, but one of them to Ms. White. I represent a very urban district. We have a lot of chemical facilities, refineries in a very urban area. A lot of ours—and we probably have the most monitored air-monitored district in the country, with lots of different levels from the State, our county, our city, and of course EPA has some monitoring there, too. I have some questions I would like to ask on how we can even do better. We want the jobs and the industry, but we also want it to be done as safely as we can.

Ms. WHITE. Absolutely. Thank you, sir.

Mr. GREEN. Mr. Chairman, thank you for your courtesy.

Mr. GINGREY. Absolutely. I thank the gentleman from Texas.

The minority has asked unanimous consent to include a letter from the Department of Toxic Substances Control from the State of California to be included in the record, and without objection, so ordered.

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

Mr. GINGREY. I want to thank all of our five witnesses. I think this has been an excellent hearing. I think all would agree. We apologize for the interruptions, but believe me, if you have been to other hearings you know that this is mild compared to some of the interruptions that we have. And we got through with everything we needed to cover, and I thank all of our witnesses and without objection, the subcommittee is now adjourned.

[Whereupon, at 11:28 a.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

PREPARED STATEMENT OF HON. FRED UPTON

The Toxic Substances Control Act (TSCA) is one of the more important and complex bodies of law in the jurisdiction of our committee. It covers chemicals throughout their lifecycle, starting even before they are first introduced into commerce. TSCA deals with chemical testing, protection against imminent hazards, worker exposure, and a host of other specific issues.

This subcommittee held a hearing last month to build a foundation for members to understand TSCA from the point of view of experts in the field, each of whom brought a unique perspective on the law. We had a thoughtful dialogue between members and witnesses—a valuable exchange that helped create a foundation to broaden our perspective moving forward.

Today we follow up on that hearing by selecting two key areas of the law to explore: regulation of new chemicals and protection of proprietary business informa-

tion. Both issues have a direct effect on American innovation, which is crucial to restoring our economy and creating job opportunities here at home.

EPA cannot do the job we've given them to evaluate new chemicals for introduction into commerce, or to evaluate new uses of previously approved chemicals, unless chemical makers provide EPA some specific and sensitive information about how the chemical is made and how its developers expect to use it.

At the same time, EPA must be careful to not disclose that information. Without information protection there is no incentive to innovate. Without innovation, the economy can't grow and we can't create new jobs.

Beyond protecting information, there are other issues with new chemicals. For example, at our June hearing, one witness commented that new chemicals are often safer and "greener" than the ones they replace. We all benefit when good, new chemicals are cleared for market and ones that aren't ready are held back.

Today we'll be asking our witnesses to help us better understand specific chemical regulations under TSCA as they tackle the following questions, among others:

- How do TSCA regulations for new chemicals and new uses and TSCA provisions on the protection of confidential business information affect your ability to innovate?
- Does EPA have the tools to make informed decisions about new chemicals?
- Is the protection provided to confidential business information under TSCA appropriate?
- Has TSCA implementation been consistent with the original statutory purpose?
- How do other countries treat new chemical production and information protection?

Mr. Chairman, I welcome our witnesses and thank them for helping us to better understand the interplay between EPA and chemical developers.

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PREPARED STATEMENT OF HON. HENRY A. WAXMAN

Today the Committee continues to examine the Toxic Substances Control Act (TSCA). TSCA is an important law because of its role in protecting the American public from dangerous chemicals—and it is long overdue for strengthening.

I understand that the Chairman intends to hold a series of hearings to examine each of TSCA's sections in turn.

Today's hearing focuses on two sections of TSCA, section 5, which provides for EPA's new chemicals program, and section 14, which establishes protections for confidential business information.

Both of these sections are in need of reform, and I welcome the panel and their testimony. Today, we will learn that section 5 has allowed chemicals onto the market that shouldn't have been. And, we'll learn that section 14 has provided a veil of secrecy for the chemical industry.

In recent years, EPA has undertaken a serious effort to addresses the weaknesses in these and other sections. They have audited thousands of confidential business information claims, and have found that nearly 900 chemical identities that had been claimed as confidential business information should have been made publicly available. This information empowers families, researchers, and consumer advocates who wish to educate or understand the chemicals we are exposed to. But this audit is resource intensive and is unlikely to be replicated under today's funding levels.

That's why, over the years, everyone from the EPA Administrator to the Society of Chemical Manufacturers and Affiliates have agreed that unjustified claims of confidential business information must be addressed.

EPA has also developed action plans for some of the most dangerous and ubiquitous chemicals on the market. Some of these dangerous chemicals were initially brought into production under section 5 of TSCA. We now know that these chemicals pose serious risks, butthose risks were not uncovered by the new chemicals program. This is another area that is in vital need of reform.

Four years ago, there was widespread agreement among industry, labor, and nongovernmental organizations that TSCA needs to be reformed. It's good that we are now turning back to this issue.

Recently, there have been suggestions that a new legislative proposal in the Senate will be the vehicle for us to reform TSCA. But I have heard significant concerns about that proposal from a variety of stakeholders, including federal and state agencies, environmental and public health groups, and other stakeholders. That is why this hearing and the future ones to come are so important.

I want to thank the witnesses for appearing today, and I look forward to hearing from them.

The Center for International Environmental Law

Representative Jon Shimkus, Chairman
Representative Paul Tonko, Ranking Member
Subcommittee on Environment and Economy, Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

RE: Submission for Subcommittee hearing on "Regulation of New Chemicals, Protection of Confidential Business Information, and Innovation"

July 11, 2013

Dear Chairman Shimkus, Ranking Member Tonko, and Members of the Subcommittee:

The Center for International Environmental Law (CIEL) appreciates the opportunity to submit comments regarding today's hearing on the "Regulation of New Chemicals, Protection of Confidential Business Information, and Innovation" under the 1976 U.S. Toxic Substances Control Act (TSCA) by the House Subcommittee on Environment and the Economy. Established in 1989 and based in Washington D.C., CIEL is a nonprofit organization that uses the power of the law to protect the environment, promote human rights and ensure a just and sustainable society.

CIEL examined trends in chemicals regulation and patent filings to evaluate the impact of stronger rules for hazardous chemicals on the innovation of new chemicals products. Looking at examples from within the United States and abroad, our study *Driving Innovation*[1] found that stricter regulation of hazardous chemicals can not only drive innovation, but also create a safer marketplace. As overwhelming evidence continues to grow about the financial costs of inaction on the hazardous cocktail of substances to which Americans are exposed daily, the need to direct our effort on innovation toward safer chemicals is particularly salient.

[1] CIEL, *Driving Innovation: How stronger laws help bring safer chemicals to market* (2013), available at: http://ciel.org/Publications/Innovation_Chemical_Feb2013.pdf

While certain chemical manufacturers publicly insist that "there is no evidence that stricter chemical laws promote innovation,"[2] our study found clear and convincing evidence that the prospect of stricter rules on toxic chemicals sparked the invention, development, and adoption of alternatives. For example, in response to stricter rules to protect people and the environment from phthalates, a class of chemicals with hormone (endocrine) disrupting properties, our study of international patent filings shows acceleration in the invention of alternative chemicals and products. Spikes in the patenting of phthalate-alternatives clearly correlate with the timing of new rules to protect people and wildlife from phthalates. As the stringency of measures increased, so too did the number of inventions disclosed in patent filings by the chemical industry. Innovation hinges on the adoption of inventions into the market. Our case studies highlight how stricter rules for hazardous chemicals can accelerate this process--creating incentives that help to pull inventions into the market, and turn invention into innovation. However, barriers exist that prevent the entry of safer alternatives. Overcoming the inertia of entrenched toxic chemicals typically requires the exercise of governmental regulatory authority. Our findings show that stricter rules enable safer chemicals to overcome currently existing barriers to entry, such as economies of scale, the externalization of costs, and the lack of information about chemicals and products on the market today.

The findings from our study offer important insights into the two principle innovation-related issues before the Subcommittee today: Pre-manufacture and Significant New Use Notices under TSCA section 5, and the protection of confidential information under TSCA section 14.

Section 5 of TSCA, Pre -manufacture Notification for New Chemicals or Uses.

History is replete with examples of regrettable substitution, where a hazardous chemical is restricted, but then replaced with a different hazardous chemical. The experience of transitioning from one hazardous flame-retardant chemical to another illustrates not only the dangerous presumption of safety about chemicals on the market in the 1970s, but also the weakness of programs such as those under Section 5 of TSCA to evaluate recently developed chemicals for their hazardous properties.

We found examples of alternative chemicals with a high-degree of structural similarity to the hazardous chemicals they replaced, with inadequate information about the alternative's potentially hazardous properties. For example, new chemical alternatives to hazardous flame retardants—chemicals which are being phased-out under a global treaty for some of the world's most dangerous toxins—entered the market with a startling lack of toxicological information despite structural similarity to known hazardous chemicals. Given their structural similarity, a heightened level of scrutiny is prudent before use of such chemicals in consumer products; however, under existing rules, additional information took years to be requested and provided.

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[2] Pat Rizzuto, *Law Center Says Strict Chemical Controls Foster Innovation, Markets, Protect People*, Chemical Regulation Reporter, 37 CRR 194 (Bloomberg BNA, Feb. 18, 2013), available at: http://ciel.org/Chem/Innovation_BNA_18Feb2013.html

In order to increase the likelihood that safer alternatives will be pulled into the market, chemical laws need to clearly identify hazardous properties that are not acceptable in society, generate information about these properties in all chemicals, and require their substitution with safer alternatives in a systematic way. Under Section 5 of TSCA, new chemicals are not required to be *likely* to meet the safety standard. Moreover, manufactures are not required to generate and provide to regulators *any* health and safety information. Stricter rules for new chemicals can enable a transition to safer alternatives.

Section 14 of TSCA, Protection of Confidential Information

Inventors need access to information about chemical hazards and exposures to develop safer solutions. Consumers and downstream users need access to information about chemicals in products to enable them to choose safer products, thereby incentivizing innovation toward safer alternatives. And regulators need access to hazard and exposure information to restrict the use of hazardous chemicals, enabling the entry of safer alternatives.

Of particular concern to businesses is the need to protect confidential business information (CBI). However, the abuse of CBI privileges under TSCA is well documented,[3] and this represents a serious barrier to the identification of hazardous chemicals and the development and entry of safer alternatives. Recent experiences show that the inability to access information can impede the development and adoption of safer alternatives. Incomplete information on potential alternatives enables "regrettable substitution," i.e. the transition from one hazardous chemical to a different hazardous chemical, instead of safer alternatives.

While respecting the desire to protect legitimate CBI is a means of encouraging businesses to continue to innovate, policy makers around the world have long recognized the potential for the disclosure of information to promote additional innovation. Patents are based on this principle. Recent changes to European laws that increase access to information on substances of very high concern is "the driver for change at the present,"[4] according to a 2012 review of the impact of these stronger laws on innovation. For information to accelerate and steer innovation in a safer direction—and ensure the integrity, efficiency, effectiveness, and accountability of governments, institutions, and industry—health and safety information must be generated and access must be provided to that information.

Although TSCA already recognizes that health and safety information should never be CBI, it still has farther to go in properly balancing these interests. Despite limits to the type of information that may be claimed as CBI, regulators do not always require justification of claims

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[3] Government Accountability Office (GAO), *Chemical Regulation: Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program*, GAO-05-458 (Washington, D.C.: June13, 2005).

[4] Centre for Strategy & Evaluation Services, *Final Report, Interim Evaluation: Impact of the REACH Regulation on the innovativeness of the EU Chemical Industry*, (hereinafter "REACH Innovation Report") pp. xii (emphasis added) (June 14, 2012), available at:
http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/review2012/innovation-final-report_en.pdf

of confidentiality or re-justification of claims after a period of time. A further problem is the practice of allowing the identity of chemicals that are the subject of health and safety studies to be masked as CBI, impeding the identification of chemicals of concern. Unlike patents, which generally expire after twenty years, CBI can be kept confidential in perpetuity. The health and environmental risks of this approach are compounded when important information is inappropriately claimed to be CBI.

Conclusion and Recommendations:

In sum, progressively stricter laws spur the innovation of safer alternatives and can pull safer alternatives into the market, enabling them to overcome barriers to entry. But, changes to TSCA sections 5 and 14 are necessary to ensure that alternatives do not also have intrinsic hazards to better ensure that innovation creates a safer marketplace. To this end, CIEL respectfully offers the following recommendations to strengthen the regulatory framework within and beyond TSCA to accelerate innovation towards safer chemicals:

1. **Ensure the burden of proving chemical safety falls on chemical manufacturers for new and existing chemicals**: Requiring that chemical manufacturers generate information about the intrinsic hazards of both existing as well as new chemicals levels the playing field for safer chemicals and enables a more meaningful assessment of alternatives. This information enables regulators to remove entrenched chemicals of concern, empowers downstream users to deselect hazardous chemicals from their supply chain, and equips chemical manufacturers to innovate towards safer alternatives. Although recent progress has been made by countries around the world in placing the burden of proving chemical safety on chemical manufacturers, greater measures are needed in the United States.

2. **Promote access to information**: Inventors need access to information about chemical hazards and exposures to develop safer solutions. Regulators need access to hazard and exposure information to restrict the use of hazardous chemicals, enabling the entry of safer alternatives. Consumers and downstream users need access to information about chemicals in products throughout the supply chain to enable them to choose safer products, thereby incentivizing innovation toward safer alternatives. Policy makers should ensure that health and safety information is generated and made available to consumers, businesses, and regulators, including information on and awareness of products containing hazardous chemicals. Claims of confidentiality should be justified, periodically re-justified, and never granted for health and safety information to enable the development of safer alternatives.

3. **Phase-out chemicals with certain intrinsic hazards**: U.S. EPA must possess—and exercise—the power to remove hazardous chemicals from the market based on their intrinsic hazards.

4. **Recognize endocrine disruption as an intrinsic hazard that cannot be soundly managed**: Endocrine disruption is an intrinsic hazard of certain chemicals, linked to a myriad of

adverse effects that have been on the rise over the past several decades. As there is no safe level of exposure to endocrine disrupting chemicals (EDCs), they should be recognized as a distinct category of chemicals that needs to be phased out globally, similar to other chemicals with intrinsically hazardous properties.

5. **Internalize the costs of hazardous chemicals**: Not only would this lead downstream users to shift to alternatives with lower costs, it would also incentivize chemical manufacturers to invest in the research and development of safer alternatives.

6. **Craft stronger international laws to ensure a level-playing field for U.S. businesses**: Only a narrow sliver of chemicals of concern on the market are covered under legally-binding global treaties throughout their lifecycle. A broader international regime designed to cover a wider range of hazardous chemicals and chemical-related risks could help to create a level-playing field for American businesses operating in a globalized world.

Respectfully submitted,

Baskut Tuncak
Staff Attorney,
Center for International Environmental Law (CIEL)

Enclosure: CIEL, *Driving Innovation: How stronger laws help bring safer chemicals to market*, (Executive Summary, 2013)

1350 Connecticut Avenue N.W. Suite 1100 • Washington D.C. 20036-1739

Phone: 202-785-8700 • Fax: 202-785-8701 • Email: info@ciel.org • Internet: http://www.ciel.org

15 rue des Savoises, 1205 Geneva, Switzerland

Phone: 41-22-789-0500 • Fax: 41-22-789-0739 • Email: geneva@ciel.org • Internet: http://www.ciel.org

Kevin H. Rhodes
President & Chief
Intellectual Property Counsel

Office of Intellectual Property Counsel

P.O. Box 33427
St. Paul, MN 55133-3427 USA
Phone: 651-736-4533
Fax: 651-736-3833
Email: krhodes@MMM.COM

July 9, 2013

The Honorable John M. Shimkus
Chairman
Subcommittee on Environment & the Economy
Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Paul Tonko
Ranking Member
Subcommittee on Environment & the Economy
Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, D.C. 20515

Re: *Committee on Energy and Commerce, Subcommittee on Environment and the Economy, July 11, 2013 Hearing on "Regulation of New Chemicals, Protection of Confidential Business Information, and Innovation": Statement of 3M Company*

Dear Chairman Shimkus and Ranking Member Tonko:

Thank you for providing 3M Company with the opportunity to submit this letter for the record in connection with the Subcommittee hearing on "Regulation of New Chemicals, Protection of Confidential Business Information, and Innovation." 3M's comments will focus on the role and impact of Sections 5 and 14 of the Toxic Substances Control Act on innovation. Given 3M's long history and recognized commitment to innovation, no provisions of TSCA are of greater importance to 3M.

We urge Congress to uphold the current protections for confidential data under TSCA Section 14 and to maintain the basic framework for new chemical review under TSCA Section 5. These two provisions are working well and achieve the goal of protecting public health and the environment while promoting American innovation at companies such as 3M.

Who We Are and Why We Care about TSCA

Based in St. Paul, Minnesota, 3M is a global, diversified technology company with sales totaling nearly $30 billion in 2012. We market over 50,000 products across 45 technology platforms, including advanced materials, adhesives, films, non-woven fibers, ceramics, and abrasives, almost all of which are regulated by TSCA. 3M's research and development expenditures totaled $1.6 billion in 2012, and 3M has rightfully earned its reputation as an innovative company in the way that we combine our technology platforms to find unique solutions for our customers. 3M has also rightfully earned its reputation for being committed to sustainability, and we have leveraged our technology platforms to create a wide range of products that provide superior environmental, health, and safety performance. In recent years, 3M has introduced, among other new products: films that allow electronic displays to use less energy; Novec™ fire protection and electronics processing fluids that do not contribute to climate change or ozone depletion; materials and components for generation of solar and wind energy; and solvent-free adhesive technologies that eliminate air emissions of volatile compounds. As a company based on bringing innovative new products to its customers, 3M has an intense interest in ensuring that a modernized TSCA promotes our ability to continue to innovate.

TSCA Section 14 – Disclosure of Data

The single most important aspect of TSCA modernization to 3M is ensuring the continued protection of our trade secrets when they are disclosed to EPA in connection with the regulatory review process. As is the case under the current statutory framework, companies should continue to have the right to designate which business data submitted to EPA are entitled to confidential protection, and there should be no predetermined or arbitrary limits placed on the duration of this protection. Rather, the confidentiality of data submitted to EPA should mirror the legal protections afforded by well-settled trade secret law. In other words, data submitted under TSCA should be maintained in confidence by EPA for as long as it continues to be protected as a trade secret – *i.e.*, not generally available to the public, of economic value to the submitter and subject to reasonable measures to keep it secret. 3M relies on the legal rights afforded by trade secrets to protect many of its most important innovations, including some trade secrets that we have carefully maintained for decades. By protecting these investments, 3M can continue to invest in the costly and uncertain R&D efforts that bring new technology, products, and innovation to companies, homes, and lives in the U.S. and around the world.

Congress appropriately recognized the connection between innovation and protection of trade secrets when it passed TSCA in 1976. Congress should continue to maintain these protections under a modernized TSCA because strong protection of trade secrets remains essential to the health of the American economy. In the modern economy, products often come to market only after many years and enormous financial resources are spent on research and development. Research-based companies are rational decision makers when it comes to deciding whether and how much to invest in R&D. When deciding whether or not to make an investment in any given project, many factors are taken into account, including the cost of the project, the technical risk and likelihood of success, and the expected return on investment. In determining the expected return on investment, a critical element is the likelihood that meaningful intellectual property protection – including trade secrets – can be obtained and maintained over time for inventions resulting from the project. Forced public disclosure of trade secrets generated from these investments risks undermining the incentives for continued innovation by allowing competitors to free-ride on those investments. Over time, the risk to domestic R&D may cause American companies to reduce research and development expenditures, resulting in a gradual weakening of American global competitiveness, elimination of high-end jobs, and relocation of operations.

Protection of Trade Secrets Drives Advances in Greener Chemical Technologies

We believe that protection of trade secrets is also a key to driving advances in safer and greener chemical technologies. John C. Warner of the Warner Babcock Institute for Green Chemistry estimates that for approximately 65% of existing products, a greener solution cannot be found without new chemistry -- solutions will not come from selecting among existing alternatives. Protection of intellectual property is certainly necessary for companies to invest in the development of these new chemistries and technologies. As but one example, 3M relies on the protection of confidential data under TSCA for our extensive development and use of innovative solvent-free adhesive technology. This technology enables significant reductions in air emissions, energy use, and waste generation across a wide range of greener industrial and consumer products.

Protection of Chemical Identities Should Be Maintained

The debate regarding protection of confidential data does not center solely on manufacturing and technology information that must be disclosed under TSCA. Rather, often at issue is the ability of a company to protect as confidential the exact chemical identity of a substance. The identity of chemical compounds that must be disclosed to EPA under TSCA are protected from public disclosure under the current statutory framework. 3M urges that this protection be maintained under a modernized TSCA. Chemical identity is a critical type of trade secret information. Disclosing certain chemical identities to the public would reveal to competitors valuable business information, including the direction of a company's product development efforts, the chemical manufacturing capabilities of a company and, in the case of isolated intermediates that must be identified under TSCA, the reaction pathways for manufacturing an end substance.

TSCA Contains Appropriate Checks and Balances for Confidential Data

For those cases in which chemical identity is held as confidential, TSCA contains appropriate checks and balances to ensure the safety of each chemical substance and to safeguard the public's need for information. The chemical identity is disclosed to EPA under specific confidentiality provisions that maintain the trade secret status of the chemical identity, and EPA serves to protect the public's interest by conducting scientific risk assessments and implementing regulatory measures, such as consent orders, to ensure that each confidential chemical substance is safe in commerce. Companies, too, take independent measures to ensure that their chemical substances are safe for their intended uses. Long before submitting a new substance to EPA for evaluation, companies frequently conduct human health and environmental studies on a slate of candidate molecules to find a chemical substance that meets environmental, health, and safety performance requirements, as well as technical performance requirements.

TSCA also appropriately relies on EPA to implement administrative procedures, such as substantiation questionnaires, to protect the public's need for information and to ensure that companies do not make frivolous claims regarding the confidential status of a chemical's exact identity. 3M supports the strengthening of some of these measures, provided that the additional administrative processes provide true public benefits and are not unduly burdensome. Specifically, 3M supports a statutory requirement for companies to provide an up-front substantiation of claims of confidentiality. We believe that up-front substantiation of claims will help address the perception by some parties that companies are making overly broad designations of confidentiality under TSCA's provisions for protecting confidential information.

Data Sharing with Foreign Governments Should Be Limited to Publicly-Disclosed Data

Some of the testimony provided to the Subcommittee during the oversight hearing on June 13, 2013 suggested that EPA should have the right to share confidential data with foreign governments. We believe that such data sharing with foreign governments should be limited to publicly-disclosed data. Even if EPA sought to confirm the ability of a foreign government to protect confidential information, U.S. companies, not EPA, would be the ultimate victims of unauthorized disclosures. U.S. companies harmed by the disclosures of their trade secrets by foreign governments would lack both the means to detect the unauthorized disclosure and sufficient legal remedies for the loss of their trade secrets.

TSCA Section 5 - Manufacturing and Processing Notices

The Basic Framework for New Chemical Review Under TSCA Works Well

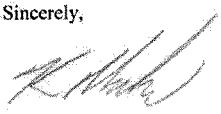
Also central to 3M's ability to innovate and create new technologies under TSCA is the review of new chemicals as authorized under Section 5. Under Section 5, companies file with EPA a Premanufacture Notice (PMN) that contains production, processing, use, and disposal information for new chemicals so that EPA can conduct a risk assessment of the new chemical substance prior to its introduction into commerce. Under Section 5, EPA does not require an up-front minimum data set for new chemical substances. Rather, companies submit existing studies that they possess and EPA uses these studies in combination with data from analog chemical substances or structure-activity relationships to conduct a health-protective risk assessment. The basic framework for new chemical review under Section 5 works well as a tiered, targeted, risk-benefit approach to safety assessment. This basic framework achieves a far better balance between risk and benefit than alternative approaches, such as the European REACH regulation, in which companies are required to generate an expensive – and at times irrelevant – minimum data set for all chemical substances.

EPA Should Be Transparent About the Risk Assessment Process

Although we do not advocate for significant changes to Section 5 of TSCA, we recommend that Section 5 be amended to require EPA to provide submitters with explicit information regarding the Agency's risk assessment methodologies and results. Increased transparency regarding the risk assessment process will enable submitters to provide, in their initial submissions, data directly responsive to the key issues involved in a particular risk assessment. Although 3M has gained some insights into the EPA risk assessment process through participation in voluntary EPA programs such as the Sustainable Futures Program (a program that gives companies access to the risk-screening models that EPA uses so that companies can identify potentially risky chemicals early in the development process), we believe that more transparency will improve the efficiency, predictability, and speed of EPA's review process for new chemicals.

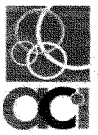
Thank you again for providing 3M with the opportunity to present these views on the role and impact of TSCA Sections 5 and 14 on innovation. As always, 3M remains committed to working with all stakeholders on these important issues. We will be pleased to submit written answers to any questions this statement may raise and to supply any additional information that may be requested for the record.

Sincerely,



Kevin H. Rhodes

KHR/smc



July 11, 2013

Honorable John Shimkus
Chairman
Environment and the Economy Subcommittee
Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20515

Honorable Paul Tonko
Ranking Member
Environment and the Economy Subcommittee
Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20515

RE: Subcommittee Hearing on the Toxic Substances Control Act (TSCA)

Dear Chairman Shimkus and Ranking Member Tonko:

The American Cleaning Institute® (ACI) supports the modernization of TSCA. ACI has called for TSCA improvements since well before the current Congressional efforts to amend the law. ACI is the trade association representing the $30 billion U.S. cleaning products market. ACI members include the formulators of soaps, detergents, and general cleaning products used in household, commercial, industrial and institutional settings; companies that supply ingredients and finished packaging for these products; and oleochemical producers.

ACI and its members are dedicated to improving health and the quality of life through sustainable cleaning products and practices. These products provide essential benefits to consumers while protecting human health and the environment. ACI's mission is to support the sustainability of the cleaning products industry through research, education, outreach and science-based advocacy.

A modernized TSCA has the potential to promote the innovation that our members have long used in developing sustainable cleaning products. In many ways, TSCA has fostered innovative developments in the U.S. and globally. A modernized TSCA would help contribute to improved public confidence in the chemicals used to manufacture consumer products and packaging. ACI commends the Subcommittee for its examination today of TSCA Section 5, addressing the introduction and new uses of chemical substances on to the U.S. market ("Manufacturing and Processing Notices"); and, TSCA Section 14, addressing the treatment of confidential business information (CBI) ("Disclosure of Data"). These sections are particularly important to innovative industries such as ours.

Maintaining a Robust U.S. Chemical Management Law Will Enhance Competitiveness

Any changes to TSCA must be practical and achievable in order to maintain U.S. leadership in the management of chemical substances. The innovative elements of TSCA must be maintained; ACI remains watchful for any regulatory changes to TSCA that would create unnecessarily high hurdles for the entry into the market of sustainable chemistries that our industry makes and uses. As an example, the Act currently allows EPA to review and take action if necessary to mitigate potential risks from a new chemical substance before the substance enters the market, while allowing for research and development flexibility, and the confidentiality of new technological developments maintained during all phases critical to market place innovation. Cleaning product manufacturers are leaders in greener chemistry innovations and these unique and breakthrough developments often stem from existing proprietary "knowledge capital." To that end, maintaining robust, recognized, effective and predictable confidential business information protection is a priority.

Improvements in the law should reflect changes in science and technology and advance innovation. Moreover, any U.S. chemical regulatory and management system must be risk-based and use the best science. EPA needs to take full advantage of information and data in chemical management programs, in addition to TSCA, and of the rapid advances in the science of hazard screening and risk assessment of chemicals. The Agency needs sufficient information to better inform chemical assessment and risk management decisions.

Maintaining Manufacturing Global Competitiveness and U.S. Job Creation Requires Careful Treatment of Confidential Business Information (CBI) and Speed to Market

The protection of confidential business information is essential to innovation, including the development of more sustainable "greener" products which leads to U.S. job creation. The following concepts are aspects to consider with regard to modernizing the statute. Data confidentially provisions must protect proprietary information in the U.S. to encourage innovation and protect businesses from intellectual property losses that may imperil lines of business undermining U.S. job growth. These concerns extend to any limits on the protection of chemical identity, and to any arbitrary time limits on CBI claims. Along these lines, substantiation requirements for CBI claims must be balanced with already well-established criteria. Amendments should not alter the current Freedom of Information Act (FOIA) protection of trade secrets under which rules exist for commercial and financial information that is privileged and confidential under the law. Moreover, placing timeframes for the expiration of CBI are problematic given the nature and substance of submitted information. Consistent with similar provisions in other law, medical and health professionals should be permitted access to confidential chemical identities to diagnose or administer appropriate medical care with appropriate confidentiality agreements. The sharing of CBI with other government authorities must ensure that appropriate safeguards are in place. The protection of CBI is not at odds with a modernized TSCA that would enhance and expand EPA access to chemical health and safety effects information, which ACI supports. In this regard, the continued protection of CBI (e.g., the specific identities of chemicals) remains important. The robust protection of CBI provides industry confidence that they will be able to reap the benefits of their expenditure of both time and resources in research and development efforts to create newer, better products.

New products and greener chemistries get to U.S. consumers as fast as innovation allows because of the efficient and forthright method TSCA provides to accomplish this task. TSCA Section 5 gives EPA the authority to evaluate and regulate new chemical substances for use in the U.S. marketplace. In general terms, EPA accomplishes this through receipt and review of a premanufacture notice, only after which commercial production can commence, which results with the individual chemical substance being listed on an EPA inventory. EPA accomplishes much of this work using information already in its possession; or submitted by manufacturers and processors, or EPA can request additional information. Such requests invariably lead to the submission of information or the withdrawal of the premanufacture notice. It is a better constructed process than any command and control regime demanding reams of data up front irrespective of any regulatory need for the data. Moreover, the law allows EPA to interact and engage chemical substance manufacturers faster and more flexibly than any other global regulatory counterpart. This is a fundamental reason why TSCA Section 5 has worked so well. These important features of minimal delays, robust interactions between government and industry, and data flows to accomplish key health and environmental goals are paramount features that set the U.S. apart from other regimes around the world.

ACI remains committed to continuing as an active participant in bipartisan discussions, hearings, and meetings as well as other processes to advance the modernization of TSCA. ACI appreciates the opportunity to engage as a direct participant with you on the most critical issues related to updating the law in order to promote the safe use of chemicals; build public confidence in the chemical management system; protect American jobs, and maintain the U.S. global leadership role in chemical innovation.

Respectfully submitted,

Ernest S. Rosenberg
President & CEO

cc: Members of the Subcommittee on Environment and the Economy

March 2012

CSPA Position Statement on

Continued Protection of Trade Secret and Confidential Business Information under TSCA

Introduction / Summary

The recommendations presented in this white paper reflect what CSPA member companies of the formulated consumer and commercial products industry believe to be a reasonable framework for continued protection of trade secret[1] and confidential business information under the Toxic Substances Control Act (TSCA) balanced with the U.S. Environmental Protection Agency (EPA) and the public interest for increased disclosure of information related to TSCA-regulated chemicals used in our products.

Intellectual property is a company's most valuable intangible asset, and represents a substantial R&D resource and financial investment that results in the introduction of sustainable and innovative products into the US market. Trade secrets and other confidential business information (CBI) must be carefully safeguarded from competitors to ensure a financial return on the significant R&D investment and preserve brand integrity and distinction. Any valid trade secret protected under state laws (a majority of which are based on the Uniform Trade Secrets Act) and the Federal Freedom of Information Act and/or Federal Economic Espionage Act of 1996 shall *always* be considered confidential under the envisioned approach.

CSPA's supports updates to TSCA to: (1) require upfront substantiation of confidentiality claims and; (2) provide statutory authority for EPA to share CBI with state governments (upon assurances of appropriate safeguards comparable with EPA's CBI safeguards). These two provisions are reasonable improvements to current practices that will ensure continued protection of legitimate CBI under TSCA while providing the Agency with expanded authority to disclose chemical information to federal and state government authorities state are working toward the common goal of robust chemical management.

Definitions and Background

Section 14(a) of TSCA provides authority to EPA pursuant to the Freedom of Information Act (FOIA)[2] to protect the confidentiality of data obtained under TSCA. Under currently applicable law, FOIA specifically prohibits disclosure if the subject information consists of "trade secrets and commercial or financial information obtained from a person and is privileged or confidential."[3]

Section 14(a) of TSCA expressly prohibits EPA from disclosing trade secrets and commercial or financial information that is privileged or confidential.[4] However, there are limited exceptions to the protections provided by Section 14(a); specifically, EPA is allowed to disclose confidential information if the Agency determines that disclosure is necessary to protect against "unreasonable

risk of injury to health or the environment."[5] In addition, Section 14(b) of TSCA creates a limited exception that allows EPA to disclose trade secret-type information if the information consists of "health and safety studies."[6] Notwithstanding these limited exemptions, Congress clearly recognized the importance of protecting trade secrets and CBI by including significant criminal penalties for wrongful disclosure in Section 15 of TSCA.[7]

Proprietary chemical identities for which downstream formulated companies seek protection under TSCA represent significant economic value to individual companies and would inflict serious business harm should this information become prematurely disclosed. Such information can serve as a prime example of trade secret information.

There are increasing demands from the general public, legislators at both the state and federal level, and EPA to significantly limit confidentiality claims and to disclose chemical information previously designated as CBI in historical case files. EPA Administrator Lisa Jackson has embraced this new "transparency" vision as an integral part of ensuring chemical safety in commerce, which she has identified as a priority focus for the Agency in her public addresses. The Agency has taken several chemical management actions in advance of Congressional action. Restricting CBI claims, under the Agency goal of increasing public accessibility to health and safety information for chemicals in US commerce, has been a notable and key component of the Agency's efforts.

Through this set of recommendations, CSPA member companies have sought to carefully balance the need for continued CBI protection that will drive American innovation, domestic jobs and competition in a global marketplace with the public demand for increased disclosure.

Aligned Positions

The recommendations outlined here are solely presented as positions supported by CSPA. The following shared principles, developed in collaboration with affiliated trade associations, have guided CSPA member company discussions on CBI:

- The U.S. chemical management system must protect public health and the environment while also protecting confidential business information, thereby preserving the ability of American companies to drive innovation, create jobs and compete in the global marketplace.
- The EPA regulatory framework for TSCA must include a means by which EPA can obtain reasonable and appropriate use and exposure information from "downstream" formulated companies like those CSPA represents to better inform EPA's prioritization decision-making and subsequent safety assessment work.
- EPA must have adequate resources to successfully manage and meet deadlines and responsibilities under TSCA.

March 2012

1. "Three Bucket" Approach to CBI

CSPA can support the following conceptual "three bucket" approach to CBI, which is based upon REACH Articles 118-119. Currently the EPA requires upfront substantiation of certain confidential information under TSCA (i.e., reporting under TSCA sections 4, 5 and 8); and this section will not supersede those requirements.

Always allowed as confidential Represents Intellectual Property of Owner No Up-front Substantiation No Requirement for Re-substantiation	• Detailed information about manufacturing and/or marketing processes • Sales, production, or other commercial/financial information • Detailed information about processing • Customer lists: links between manufacturer and distributors and downstream users • Precise use, function and application of a chemical or mixture, including information about its precise use as an intermediate • Precise production (including batch production) or import volumes • Compositional details (% of ingredients in mixtures or formulations) • Any valid trade secret protected under state laws (a majority of which are based on the Uniform Trade Secrets Act) and the Federal Economic Espionage Act of 1996 and/or Freedom of Information Act.
***Never* CBI** No Up-front Substantiation	• Health and safety data for commercial chemicals (NB: CSPA excludes confidential chemical identities from the designation of "*Never* CBI" for health and safety data) • Physical/chemical information already publicly disclosed (*e.g.*, listed on Material Safety Data Sheet) • General category information/descriptions of a chemical's use and function (*e.g.*, "surfactant") • Production volume ranges, when EPA aggregates using a validated and publicly available statistical method of aggregation • Classification, labeling, guidance on safe use of the chemical
Eligible for protection when appropriately substantiated for CBI protection	• Precise chemical identity (*e.g.*, CAS name) for proprietary chemical substances. • Degree of purity • Production/import volume ranges linked to an individual company

2. **Going forward, claimants should provide an upfront justification for information eligible for CBI protection (third bucket), including a description of the competitive harm likely to result from disclosure.**

Under current EPA regulations that have been in effect since the mid-1970s, substantiation of CBI requires a showing that: (1) the company has taken and intends to continue to take reasonable measures to protect the confidentiality of the information; (2) no statute specifically requires disclosure of the information; (3) the information is not reasonably obtainable through reverse engineering; and (4) disclosure of the information is likely to cause substantial harm to the company's competitive position. *See* 40 C.F.R. § 2-208. CBI information that has been substantiated would be protected from public disclosure pursuant to a FOIA request, except in very limited circumstances.

3. **EPA may require re-substantiation of certain claims. The same criteria that apply to upfront substantiation should apply to re-substantiation of CBI claims.**

Opportunities for subsequent renewals would not be limited provided that continued CBI protection is justified in a re-substantiation. Re-substantiation does not mean that companies will be held to a higher burden of proof as compared to the data required to substantiate the original CBI claim; however, the re-substantiation will require an explanation of why the original CBI substantiation is still relevant. CBI owners could also choose to provide additional data as needed to support the re-substantiated CBI claim.

4. **CBI claims that have been approved by EPA should continue to be CBI until either: (1) the claimant withdraws CBI claim, or (2) EPA rejects the CBI claim.**

CBI claims that have been approved by EPA should not be subject to arbitrary time limits; however, re-substantiation of certain claims (i.e., "may be considered for CBI") may be required. So long as the data qualifies as a trade secret or CBI, it should be protected from disclosure, subject to appropriate substantiation and re-substantiation.

5. **Allowing EPA to share CBI data with other government authorities**

CSPA can support EPA sharing data with other U.S. federal and state agencies for the purposes of protecting public health and the environment. The Agency would be required to verify that the other government(s) has adequate and equivalent systems in place to protect CBI from disclosure.

TSCA does not currently allow EPA to disclose CBI data to other federal, state or foreign governmental entities. Under a modernized TSCA, sharing of CBI with other U.S. (federal and state) government authorities should be allowed for the purposes of protecting public health and the environment as long as the EPA has a binding data sharing agreement to ensure that adequate safeguards are in place to protect the confidential information.

This type of data sharing among regulatory authorities is supported to maximize the use of existing data and centralize chemical management at the federal level. As part of this, we believe it is also necessary to look closely at the preemption provisions under TSCA. Many state authorities have acknowledged that they do not have the capacity or resources to manage duplicate regulatory systems and would strongly prefer an effective and reliable Federal role for chemical regulation and management. We believe an appropriately modernized federal TSCA statute would serve to reduce the need for regulation of chemicals on a state-by-state basis. Any requests for confidential information by municipal governments should be worked through their respective states – eliminating the need for EPA to share CBI directly with local governments.

Recognizing that it is essential for the CBI owner to track and maintain control of confidential information, the EPA should be required to notify the owner of the CBI when their data is shared with another government with whom the EPA has a data sharing agreement in place. Under this approach, EPA would be required to notify the data owner of its decision to share CBI data with another government authority, and identify: (1) the purpose for which the data are intended to be used; and (2) provide information regarding the CBI protection provisions the receiving government authority has in place to protect CBI from being disclosed.

Discussion Issues

1. Allowing EPA to share CBI with foreign governments.

The sharing of CBI with foreign government authorities is more challenging because it raises the issue of how EPA can ensure that equivalent protection is not only in place but enforced to prevent disclosures of proprietary information of U.S. companies. While CSPA member companies would consider supporting an approach for data sharing, along the lines of the Four Corners Agreement between the U.S. and Canada for working with "favored" foreign governments, in an effort to achieve joint chemical management objectives, we believe that this is a very difficult process to implement. Currently, there is no reliable legal means at the international level to enforce a right to compensation for damages that arise from the loss of intellectual property if a trade secret is disclosed in a way that destroys its secrecy.

2. Chemical Identity

Protecting confidential information is critical to maintaining an economic environment that (1) supports U.S. competitiveness and (2) encourages continued sustainable innovation. New chemicals and new uses and mixtures of existing chemicals often require millions of dollars to research and develop. Public disclosure of proprietary chemical identities could serve to disadvantage U.S. companies by allowing competitors—both in the U.S. and abroad—access to trade secret information.

Any disclosure of chemical identity must balance the need for manufacturers to retain exclusive use of the new substance once in commerce. Perhaps the most compelling reason for the ability to

claim chemical identity as CBI under TSCA is the need to protect proprietary chemical technologies while navigating the New Chemicals Program for addition to the TSCA Inventory. However, we also strongly assert the need to allow a company to substantiate a claim of confidentiality for proprietary chemical identities for existing chemicals under TSCA.

CSPA, along with other trade associations, believe that there is a compelling need to develop a comprehensive reference to define and use chemically descriptive names for disclosure of information on proprietary chemical substances under TSCA. CSPA's experiences in developing the *CSPA Consumer Products Ingredients Dictionary* has provided us assurance that generic nomenclature can serve as a means by which the industry could share meaningful information with the public about the chemical substance while also maintaining confidential chemical identity that is critical to competitiveness and innovation. The *CSPA Consumer Products Ingredients Dictionary* ingredient monographs provide ingredient nomenclature and definitions that are fully consistent with our industry's transparency goals, as well as those of the EPA Design for the Environment, which now requires that its partner products provide chemically descriptive names for proprietary ingredients.

CSPA recognizes that some agreement has been reached among companies and NGOs around the concept of allowing self-specified CBI time limits for the protection of chemical identity in PMN applications. CSPA could also consider an approach that would allow for a self-specified time period for the protection of chemical identity as long as the CBI time period would be the reasonable length of time needed to protect proprietary information, and retain exclusive use and competitive advantage, subject to appropriate substantiation and EPA approval.

3. Length of CBI protection

As a threshold matter, CSPA supports an aligned position that a valid CBI claim does not expire if the claimant appropriately substantiates the claim at the time of submission to EPA. CSPA also supports an aligned position that the EPA could seek re-substantiation of certain claims, and that the same criteria that apply to upfront substantiation should apply to re-substantiation of CBI claims.

Legislative recommendations that set an automatic expiration for CBI based on a time period to ensure return on investment would be extremely difficult to calculate. Moreover, there is no known provision in law for terminating a data owner's trade secret rights in such an arbitrary manner. CSPA supports an aligned position that EPA should determine legitimate CBI claims based on initial substantiation requests and that, if CBI timelines are imposed, EPA must provide an opportunity for CBI owners to re-substantiate the claim(s).

As part of a supported position, we have outlined some options for time limits on CBI claims, each contingent upon the understanding that the opportunity for re-substantiation will be provided:

- **Allow protections to continue until a trigger occurs** (i.e., as new information becomes available or EPA prioritizes the substance for further assessment, etc.). Re-substantiation would be allowed for certain CBI claims (i.e., "3rd Bucket" -- CBI with substantiation). EPA would be required to contact the CBI owner to request a re-substantiation of the CBI claim.
- **Self-Imposed CBI Time Limit.** Rather than an arbitrary or "triggered" timeline for CBI expiration in the statute (e.g., five years), accept the premise that CBI claims should not exist in perpetuity and should be subject to a periodic review requirement. Under this option, the claimant would include a self-specified length of CBI protection in the original CBI claim, provided that the length of time is reasonable and justified (subject to EPA review). At the end of the specified timeframe, the CBI owner could choose to extend CBI protection for a specified time period provided that they submit an appropriate re-substantiation.

In any case of an expiring claim or "triggered" renewal, CSPA supports a position that the EPA should provide some reasonable notification to the CBI owner to allow them to re-substantiate the claim prior to taking any action that would disclose trade secret information.

Endnotes

[1] The Uniform Trade Secrets Act defines the term "trade secret" as: "...information, including a formula, pattern, compilation, program device, method, technique, or process, that: (i) derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use, and (ii) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy. *See* Section 1(4) of the Uniform Trade Secret Act.

[2] 5 U.S.C. § 552.

[3] *Id.* at § 552(b)(4).

[4] 15 U.S.C. § 2613(a).

[5] *Id.* at § 2613(a)(3).

[6] *Id.* at. § 2613(b).

[7] *Id.* at. § 2614(d).

Department of Toxic Substances Control

Matthew Rodriquez
Secretary for
Environmental Protection

Deborah O. Raphael, Director
1001 "I" Street
P.O. Box 806
Sacramento, California 95812-0806

Edmund G. Brown Jr.
Governor

July 10, 2013

The Honorable John Shimkus
Chairman
Subcommittee on Environment and the Economy
Committee on Energy and Commerce
United States House of Representatives
2452 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Paul Tonko
Ranking Member
Subcommittee on Environment and the Economy
Committee on Energy and Commerce
United States House of Representatives
2463 Rayburn House Office Building
Washington, D.C. 20515

RE: HEARING ON REGULATION OF NEW CHEMICALS, PROTECTION OF CONFIDENTIAL BUSINESS INFORMATION, AND INNOVATION BEFORE THE UNITED STATES CONGRESS COMMITTEE ON ENERGY AND COMMERCE SUBCOMMITTEE ON THE ENVIRONMENT AND THE ECONOMY

Dear Chairman Shimkus, Ranking Member Tonko, and members of the Subcommittee:

Thank you for seeking out the California Department of Substances Control's (DTSC) perspective in the discussion of the protection of confidential business information ("CBI") in the regulation of new chemicals and its relation to innovation. As the Director of DTSC, the interplay between the need to protect businesses and promote innovation and the need to protect human health and the environment is something I am faced with almost every day. DTSC recognizes the importance of CBI for companies to continue with research and development ("R&D") and bring new chemicals and products to market. However, DTSC has found that disclosure of information drives innovation in a direction that often reveals safer alternatives to existing technology.

DTSC believes it is critical that CBI claims are valid, and reviewed at the outset of any regulatory program in order to prevent unsubstantiated confidentiality claims, ensure a

level playing field and conserve limited governmental resources. Illegitimate CBI claims are not a mere hypothetical but are a well-documented phenomenon, particularly with respect to chemical information submitted to the U.S. EPA ("EPA") pursuant to the Toxic Substances Control Act ("TSCA"). In fact, there have been extensive efforts by EPA since 2009 to declassify confidentiality claims in order to increase access to chemical information. As of April 2013, EPA has declassified nearly 900 confidential chemical identities as a result of these efforts. Many of these chemicals were declassified because the information claimed as CBI was readily available on the Internet, which underscores the fact that a portion of CBI claims are not legitimate. While the EPA review represents a clear improvement from the status quo, this expenditure of EPA resources could have been avoided by requiring up-front substantiation of CBI claims under TSCA in the first place.

Further, we believe that CBI needs to be reviewed on a periodic basis to ensure that the information still meets the criteria for consideration as CBI. There is currently no requirement under TSCA for companies to periodically reassert CBI claims. Often, information that was at one point held confidential is later disclosed to the public by companies or third parties. Requiring CBI claims to be re-substantiated creates a mechanism to disclose information that no longer qualifies as CBI, while simultaneously shifting the burden of such a review from the regulatory agency to the entity making the CBI claim.

The citizens of California and their government are harmed when CBI is defined too broadly, or not subject to substantiation, because nondisclosure stifles market forces that promote innovation and restricts informed decision-making about the safe use and appropriate regulation of these chemicals throughout their life. A number of poor outcomes can occur when consumers, businesses, and the government remain unaware of the adverse impacts associated with chemical ingredients protected by CBI, including:

- **Directly harming the public** – Past experience with chemicals such as trichloroethylene (TCE), benzene, vinyl chloride and methyl tertiary-butyl ether (MTBE) has shown that potentially irreversible health effects and long-term chronic conditions can burden consumers and increase health care costs, while incurring sizeable mitigation efforts and costs to government and society.
- **Hampering environmental protections** – When CBI claims shield information about potential adverse health and environmental effects, government cannot predict which environmental media or lifecycle stage will be affected by the production, use and disposal of these chemicals. Nor can it effectively protect public health from resulting exposures of concern.

- **Interfering with targeting chemicals of concern** – Many states, including California, are attempting to prioritize among products and chemicals to evaluate and implement safer alternatives. CBI claims that shield chemical information divert the focus toward chemicals and products without CBI claims, rather than assessing and prioritizing risks objectively and equitably based on equal information.
- **Restricting informed choices** – To make informed choices, the public and businesses who design complex consumer products need to know what hazardous ingredients are present in the products they purchase and use. Consumers can choose products formulated without a problematic chemical ingredient and eventually the market will drive manufacturers to reformulate the product to meet demand.In addition, manufacturers need ingredient information to effectively innovate and design products that avoid problematic constituents. Without this transparency the consequences for the public are fewer choices and potentially higher prices.
- **Stifling innovation** – Restricting information about chemical characteristics through CBI claims reduces opportunities to compare alternatives, particularly when searching for safer ones. A protected chemical formulation may be the safest choice among all of the potential alternatives in a particular chemical-product combination, but without available data, such a comparison would be incomplete. Increasing transparency for chemicals within a supply chain helps promote innovation through both direct ingredient preference and improvement.
- **Reducing global competitiveness** – Initiatives such as REACH (Registration, Evaluation, Authorization and Restriction of Chemical substances) in the European Union, and the Chemical Substances Control Law in Japan have created a culture of supply chain disclosure that is expected to drive the development and use of safer alternatives. Manufacturers in the U.S. that resist disclosure will be excluded from this market and the U.S. may become the repository of ingredients and goods that are rejected by these more stringently regulated markets.
- **Favoring short-run benefits over long-run costs** – In the short-term, CBI claims may offer some exclusivity advantages, but the ability of major competitors to easily use current analytical chemistry techniques to reverse-engineer formulations places limits on those advantages. In the meantime the direct and social costs associated with health and environmental effects, restricted choices and limited innovation will continue throughout the life of the chemical.

Finally, EPA must have the authority to share properly claimed CBI data and information with the states, recognizing the need for states to have access to the information they

need to carry out their mission to protect public health and the environment. EPA has indicated a willingness to share data with states that can demonstrate compliance with federal CBI standards, but such sharing is currently prohibited under TSCA. As long as state agencies can ensure that CBI will be protected from disclosure to the same extent as it would be in the hands of federal agencies, there is no reason to prevent such interagency exchanges of information. States can be trusted with CBI data as demonstrated by over 40 years of states' implementation of federally delegated programs such as the federal Clean Water Act (CWA) and Resource Conservation and Recovery Act (RCRA).

DTSC truly appreciates this opportunity to offer our perspective on balancing the need to protect CBI with the ability to innovate safe chemicals. It is our hope that TSCA reform will result in well-founded CBI claims that are periodically reviewed to ensure their continued validity. It is essential for any TSCA reform to give EPA the authority to share CBI with the states, to allow for effective protection of public health and the environment. We understand the importance of protecting companies and their valuable R&D, but also recognize the ability for informed chemical regulation to drive innovation and keep the U.S. competitive in an increasingly discerning global marketplace.

Sincerely,

Deborah O. Raphael

Deborah O. Raphael
Director
Department of Toxic Substances Control

cc: See next page.

cc: The Honorable John Barrow

The Honorable Joe Barton

The Honorable Gus Bilirakis

The Honorable Lois Capps

The Honorable Bill Cassidy

The Honorable Diana DeGette

The Honorable John D. Dingell

The Honorable Paul Gingrey

The Honorable Gene Green

The Honorable Gregg Harper

The Honorable Bill Johnson

The Honorable Bob Latta

The Honorable Doris O. Matsui

The Honorable David McKinley

The Honorable Jerry McNerney

The Honorable Tim Murphy

The Honorable Frank Pallone, Jr.

The Honorable Joe Pitts

The Honorable Jan Schakowsky

The Honorable Fred Upton

The Honorable Henry A. Waxman

The Honorable Ed Whitfield

Are innovation and the law at odds? A closer look shows that stronger laws for the management of hazardous chemicals help to drive innovation in chemical and product sectors. Innovation is especially relevant today as the US$ 4.1 trillion (3.1 trillion euro) global chemical industry faces increasing pressure from consumers, retailers, and investors demanding safer products. At the same time, emerging economies are increasingly well-positioned to become leaders in chemical innovation, potentially leaving Western Europe and the United States behind. Together, all of these forces are instigating changes in how governments, chemical manufacturers, and downstream users of chemicals are working to ensure chemical safety and drive innovation.

The Center for International Environmental Law (CIEL) examined the impact of laws governing hazardous chemicals in terms of their effect on innovation.

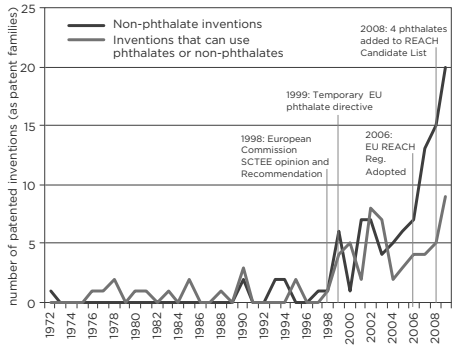
Our Results

The prospect of stronger laws with regard to toxic chemicals sparked the invention, development, and adoption of alternatives. For example, in response to stronger laws to protect people and the environment from phthalates, a class of chemicals with hormone (endocrine) disrupting properties, our study of international patent filings shows acceleration in the invention of alternative chemicals and products. Spikes in the patenting of phthalate-alternatives clearly correlate with the timing of new laws to protect people and wildlife from phthalates. As the stringency of measures increased, so too did the number of inventions disclosed in patent filings by the chemical industry. Similarly, the phase-out of ozone depleting substances also illustrates how progressively stricter rules at the global level can drive a sustained effort to invent safer alternatives.

As innovation hinges on the adoption of inventions, stricter laws for hazardous chemicals can also **help to pull inventions into the market, turning an invention into innovation**, as our case studies highlight. Barriers exist that prevent the entry of safer alternatives. Overcoming the inertia of entrenched toxic chemicals typically requires the power of the government. Our findings show that stronger laws enable safer chemicals to overcome barriers to entry, such as economies of scale enjoyed by the current mix of chemicals, the externalization of costs, and the lack of information about chemicals and products on the market today.

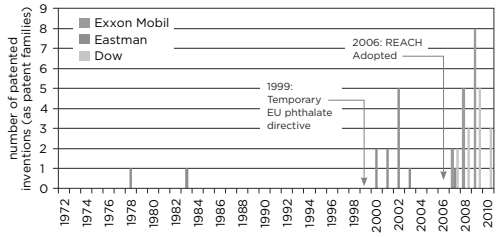
> ***"Over-regulation...is seen as an old problem and there is a lot of truth in that. We are working to overcome it. But we also need to recognize that regulation can be a big driver of innovation."***
>
> *– Peter Droell, Head of Innovation Unit, European Commission*

FIGURE 1
Spike in Patented Inventions Free of Hazardous Phthalates



Exponential growth in the number of patented inventions for phthalate alternatives beginning in 1999, coinciding with the adoption of stricter rules (as captured by the number of patent families for "non-phthalate" and "phthalate-free" inventions)

FIGURE 2
Stricter Laws Trigger Innovation by Major Chemical Manufacturers



Number of patented inventions by Eastman Chemical (formerly Kodak Eastman), Exxon Mobil and Dow Chemical from 1972–2010 for phthalate alternatives.

BOX 1
Demand for Safer Chemicals

In response to consumer concerns and advocacy campaigns, retailers and producers of consumer products are increasingly demanding other businesses in the value chain ensure that their products are free of hazardous chemicals.

- Global clothing brands, Nike, Addidas, H&M, Zara, and others recently announced plans to remove certain hazardous substances from their supply chain by 2015 or 2020, depending on the chemical. Among hazardous chemicals tested and found in garments were phthalates, nonylphenol ethoxylates (NPEs), and certain amines linked to cancer.
- Johnson & Johnson announced plans to remove certain chemicals of concern from most of its adult toiletries and cosmetic products.

But, businesses that take the lead in developing and using safer chemicals are calling on policymakers to craft policies that help to level the playing field, both at home and at the global level. For example, during a U.S. Senate hearing on the need for stricter laws in the United States, a major chemical formulator, stated: "We believe it is essential for the U.S. chemical management system to keep pace with global developments . . . and that our government be a global leader in chemical regulatory policy."

Thus, businesses recognize that consumer demand alone is generally insufficient and government action may be required to enable safer alternatives to enter and compete on a level playing field, both at home and abroad.

Claims of confidentiality should be justified, periodically re-justified, and never granted for health and safety information.

To this end, CIEL provides the following recommendations for policy makers in Europe, the United States, and other countries and regions around the world:

1. Ensure the burden of proving chemical safety falls on chemical manufacturers

Requiring that chemical manufacturers generate information about the intrinsic hazards of both existing as well as new chemicals levels the playing field for safer chemicals and enables a more meaningful assessment of alternatives. This information enables regulators to remove entrenched chemicals of concern, downstream users to deselect hazardous chemicals from their supply chain, and chemical manufacturers to innovate towards safer alternatives.

2. Phase-out chemicals with certain intrinsic hazards

Government authorities must possess—and exercise—the power to remove hazardous chemicals from the market based on their intrinsic hazards.

3. Recognize endocrine disruption as an intrinsic hazard that cannot be soundly managed

Endocrine disruption is an intrinsic hazard of certain chemicals, linked to a myriad of adverse effects that have been on the rise over the past several decades. As there is no safe dose of exposure to endocrine disrupting chemicals (EDCs), they should be recognized as a distinct category of chemicals that needs to be phased out globally, similarly to other chemicals with intrinsic hazards.

BOX 2
The REACH Candidate List: A Key Driver of Innovation

According to the European Commission's interim evaluation of the impact of the EU's REACH Regulation on innovation in Europe (REACH Innovation Report), "the Candidate List is a, if not the, major driver for change at present."

- Registration of chemicals under REACH is projected to have an impact on substitution as some chemicals may not be registered or produced at lower volumes, reducing supply—a "trigger" for innovation. Communication of information about hazardous chemicals along the supply chain made the strongest contribution to stimulating the conception of new products.
- The REACH Candidate List identifies a chemical as being a Substance of Very High Concern (SVHC) based on information about its intrinsic properties, such as: whether it causes cancer, creates genetic mutations, negatively affects reproduction (CMRs); persists in the environment, accumulates in living organisms, and/or are toxic (PBTs or vPvBs); or rises to an equivalent level of concern, such as endocrine disruption.
- The REACH Innovation Report suggests that the Candidate List is driving innovation through substitution, reformulation, and withdrawal.

As more information is provided about the intrinsic hazards of chemicals within the scope of REACH, the Candidate List stands to continue to drive innovation in the chemical industry. With broad criteria for indentifying endocrine disrupting chemicals and information about endocrine disrupting properties of chemicals, it stands to reason that the Candidate List will further drive innovation.

4. Internalize the costs of hazardous chemicals
Not only would this lead downstream users to shift to alternatives with lower costs, but this would in turn incentivize chemical manufacturers to invest in the research and development of safer alternatives.

5. Promote access to information
Inventors need access to information about chemical hazards and exposures to develop safer solutions. Regulators need access to hazard and exposure information to restrict the use of hazardous chemicals, enabling the entry of safer alternatives. Claims of confidentiality should be justified, periodically re-justified, and never granted for health and safety information, to enable the development of safer alternatives.

6. Craft stronger international laws to ensure a level playing field at the global level
Only a narrow sliver of chemicals of concern on the market are covered under legally binding global treaties throughout their lifecycle. A broader international regime to cover a wider range of hazardous chemicals and chemical-related risks is required to create a level playing field for businesses operating in a globalized world.

"Stronger laws present an opportunity to prevent exposure to hazardous chemicals, while accelerating product innovation, job creation, and economic growth."

– Howard Williams, V.P. and General Manager of Construction Specialties, a multinational manufacturer of building materials

DRIVING INNOVATION

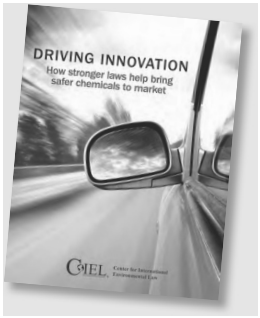
How stronger laws help bring safer chemicals to market

Are innovation and the law at odds? Our study finds that stricter rules over hazardous chemicals can not only drive innovation, but also create a safer marketplace. The study shows how stronger laws spur the innovation of safer alternatives and can pull safer alternatives into the market, enabling them to overcome barriers to entry. But, policies must be in place to ensure that alternatives do not also have intrinsic hazards, to better ensure that innovation leads to safer chemicals and products.

Read the full report to learn more about:

- **regulations that accelerated the innovation of alternatives to hazardous chemicals.**
- **removing barriers that prevent the entry of safer alternatives into the marketplace.**
- **companies that are increasing efforts to innovate as a result of stronger laws.**
- **why investors and businesses are increasingly turning to green chemistry.**

Download the full report at
http://ciel.org/Publications/Innovation_Chemical_Feb2013.pdf



CIEL Center for International Environmental Law

1350 Connecticut Avenue NW, Suite #1100
Washington, DC 20036 USA
(202) 785-8700, www.ciel.org

Founded in 1989, the Center for International Environmental Law (CIEL) uses international law and institutions to protect the environment, promote human health, and ensure a just and sustainable society.

This report was authored by Baskut Tuncak, Staff Attorney at the Center for International Environmental Law (CIEL) with contributions by Daryl Ditz, David Azoulay and Carroll Muffett.

FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED THIRTEENTH CONGRESS

Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225-2927
Minority (202) 225-3641

August 1, 2013

Mr. Craig Morrison
President, CEO and Chairman
Momentive Performance Materials Holdings, LLC
On behalf of
American Chemistry Council
700 Second Street, N.E.
Washington, D.C. 20002

Dear Mr. Morrison:

Thank you for providing testimony to the Subcommittee on Environment and the Economy on Friday, July 11, 2013, hearing entitled "Regulation of New Chemicals, Protection of Confidential Business Information, and Innovation."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions by the close of business on Thursday, August 15, 2013. Your responses should be e-mailed to the Legislative Clerk in Word format at Nick.Abraham@mail.house.gov and mailed to Nick Abraham, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

John Shimkus
Chairman
Subcommittee on Environment and the Economy

cc: The Honorable Paul Tonko, Ranking Member,
Subcommittee on Environment and the Economy

Attachments

MICHAEL P. WALLS
VICE PRESIDENT
REGULATORY & TECHNICAL AFFAIRS

August 14, 2013

The Honorable John Shimkus
Chairman
House Subcommittee on Environment
and the Economy
2125 Rayburn House Office Building
Washington, D.C. 20515

Via email to: Nick.Abraham@mail.house.gov

Re: Responses of Mr. Craig Morrison, President, CEO and Chairman, Momentive Performance Materials Holdings, LLC, to Questions for the Record dated August 1, 2013

Dear Mr. Chairman:

Mr. Craig Morrison testified before your Subcommittee at its July 11, 2013 hearing "Regulation of New Chemicals, Protection of Confidential Business Information, and Innovation" on behalf of the American Chemistry Council. On behalf of both Mr. Morrison and ACC, I am providing responses to the additional questions for the record provided by you and Mr. Waxman.

If we can provide any additional information, please feel free to contact me.

Sincerely,

cc: The Honorable Paul Tonko
Ranking Member
Subcommittee on Environment and the Economy

Attachments

The Honorable John Shimkus

1. What are the strengths of TSCA's New Chemicals Program?

Response: The two greatest strengths of the TSCA New Chemicals Program are the scientific basis of EPA's Pre-Manufacturing Notice (PMN) reviews and the efficiencies inherent in EPA's PMN review.

- Scientifically Robust Review: EPA has developed scientifically robust Structure-Activity-Relationship (SAR) analyses to predict physical-chemical properties, environmental fate and human and environmental effects of new chemicals. EPA is recognized as a world leader in the use of SAR analysis. EPA has also developed other tools to identify chemicals with Persistent, Bioaccumulative and Toxic (PBT) characteristics enabling EPA to readily flag materials with PBT characteristics for more extensive PMN reviews. In addition, other applicable similar chemical data are accepted as part of the review process.
- EPA Review Meets the Demands of the Marketplace: The EPA review allows U.S. companies the advantage of getting their new chemistries to market in a way that is responsive to customer demand and the global marketplace. The system is also flexible enough to accommodate EPA's review needs. If EPA raises questions about a chemical that cannot be answered based on the information it has, the 90 day review clock can be suspended until the submitter either provides EPA the necessary data/information or withdraws the PMN. The Polymer, Low Volume, and R&D exemptions are valuable and scientifically valid processes under TSCA which bring value to the marketplace.

2. How can EPA get more data about a new chemical once a new chemical is on the market?

Response: Under TSCA today, EPA obtains data and information through several methods to make science based decisions about new chemicals that are under review. These methods help protect against unreasonable risks from exposures to these substances. For example, in the PMN review process, EPA uses "read across" information from analog chemicals; it uses structure activity relationship analysis; and it uses other sophisticated models for predicting a chemical's properties, potential effects and exposures. EPA's approach is scientifically rigorous, efficient, and workable within the marketplace.

In addition, EPA can approve the PMN but condition it upon proposal of a Section 5(e) consent order under which EPA can impose restrictions on the chemical, including requirements for testing. The 5(e) consent order takes effect at the end of the PMN review period. These consent orders are specific to the original manufacturer. EPA has also used its section 5 authority to promulgate Significant New Use Rules (SNURs) that can include a requirement applicable to all later manufacturers of the substance to provide new data or information in the event that a new use (beyond that assessed in the new chemical review process). These new uses can include significant increases in volume manufactured. EPA can also halt the PMN review process until additional data or information is provided by the submitter. In these cases, the manufacturer can either provide the data or withdraw the PMN.

EPA also has the authority at any time under section 4 of TSCA to pursue a test rule (or negotiations leading to a consent agreement) for the generation of new data or information.

The practical reality is that if a manufacturer has a significant commercial interest in a new chemical substance, the company will make every appropriate effort to address EPA's concerns, including generating new data.

3. What are some types of trade secrets in the chemical industry?

Response: A confidential chemical identity is a trade secret. Chemical formulations may also be trade secrets. For example, the formulation that makes paint shinier or more chip resistant; or the concentration of a substance in a mixture that conveys special, unique characteristics may be trade secret. Customer lists and specific information about the use, function, volume, market, process, or application of a substance or mixture in a process, mixture, or product are also examples of trade secrets.

4. Why is trade secret protection of confidential chemical identity important to your company and to the chemical industry?

Response: Trade secret protection is crucial to the competitiveness of my company and the U.S. chemical industry. Much of the innovation in chemistry depends on protection for trade secret chemical identities. In the chemical industry, confidential chemical identities are among the most valuable intellectual property. Chemical identities can provide information on chemical structure, composition, formulation, manufacturing process, raw materials, and generally disclose information that puts significant investment in new product development at risk to competitors. Protecting chemical identities from disclosure can be critical for technological innovation. Companies would be reluctant to invest the significant sums of money they dedicate to research and development of new, "greener" or more effective or less costly substitutes if their "secret ingredient" would be freely available to any foreign or domestic competitor once the chemical is on the market.

5. Some critics, and some supporters of strong CBI protections, claim that industry had made excessive CBI claims over the years and that many of those claims are not legitimate, how do you respond?

Response: The charge that industry made excessive claims in the past is due to several factors. First, industry may have made too many claims in some instances. In addition, until recently EPA was not actively reviewing and evaluating CBI claims that were made by industry. Third, there was no mechanism in place to look at past claims and declassify them when those claims could no longer be substantiated.

In 2010, EPA announced a CBI Declassification Challenge requesting industry support in reviewing 22,000 submissions for health and safety studies that EPA believed may include CBI claims for chemical identity. Industry is actively participating in this Challenge and to date, between EPA and industry, 15,700 cases have been reviewed. The vast majority (11,553) do not contain any CBI claims in the health and safety studies. This review has

resulted in 895 health and safety study claims being declassified and 3,304 CBI claims stand. There are 7,675 cases left to be reviewed between now and the end of 2014. EPA has also begun requiring upfront substantiation of CBI claims made on the 2012 Chemical Data Reporting to update the TSCA Inventory, which it had not done in previous years.

In addition, EPA has the authority to challenge any CBI claims as submitted. For instance, EPA has challenged the generic naming used for describing the chemical identity to reveal more details.

6. **You maintain that the current EPA process for reviewing new chemicals under Section 5 of TSCA is sufficiently strong and that it fully protects the American people from any adverse health risks. Do you think that the chemicals that your company manufactures would be approved for manufacturing today if they were submitted to EPA for Pre-manufacturing notification (PMN) review?**

   Response: I am very confident that the chemicals my company produces would be approved if they were submitted for PMN review today.

7. **At our last hearing on TSCA a former EPA chemicals office director, Mr. Auer, testified that rules for significant new uses of chemicals provide a flexible regulatory approach for EPA to get "another bite at the apple" for new chemicals that exceeded their SNUR triggers. Do you agree?**

   Response: I agree. EPA has several ways to obtain more data and information on a new chemical. A SNUR can allow limited production and use, and require new data to be generated when changes to production volume or uses are significant. The limited use allows revenue to be generated to pay for the testing. In short, under a SNUR, once a new chemical PMN is approved and once manufacture begins, EPA can impose a wide variety of requirements on the chemical based on any changes in uses that EPA deems "significant," even changes in production volume.

8. **Should TSCA be revised to enhance the information requirements for new chemicals?**

   Response: No, TSCA should not be revised to impose mandatory minimum information requirements on new chemicals. Such a requirement would have a significant negative impact on innovation, including substantially slowing the pace of innovation. More importantly, a minimum data set does not in and of itself enhance EPA's ability to make judgments on new chemical substances.

   In addition, a minimum data requirement would impose an enormous workload on EPA and the industry, for questionable benefit. Despite what some may think, EPA has a very solid understanding of the chemicals and chemistry in commerce today, so not all chemicals in commerce today require a minimum data set in order to assure that EPA can appropriately review them. Today, EPA can appropriately and efficiently tailor its information needs in reviewing a new chemical.

9. What one or two things do you think could be done to improve the public's confidence in EPA regulation of new chemicals or new uses of existing chemicals?

Response: Momentive has confidence in EPA's new chemicals program and believes that the public should have confidence in EPA's regulation of chemicals. To improve confidence, EPA could make its decision-making processes under TSCA more transparent to the public. Enhanced transparency in how EPA reviews new chemicals, and what data and information it considers, would help the public better understand the scientific basis on which EPA makes its decisions.

The information requirements of the new chemicals program of TSCA today have proven to be sufficient for the review of new chemical substances. They balance well the policy need for EPA to assure a new chemical will not present an unreasonable risk to health and the environment, and the need for EPA to promote innovation in new and improved chemistries.

Although ACC believes that major changes in section 5 are not necessary, we agree that EPA's evaluation of a new chemical would be improved if submitters would provide appropriate hazard, use and exposure information that puts hazards and uses into context. Finally, EPA should be able to gather that basic information through a variety of means (e.g., read-across; structure activity analysis; modeling). We agree that EPA should be able to obtain additional information efficiently, when necessary in the review process.

10. Does Momentive produce any chemicals classified as Persistent Bioaccumulative and Toxic or PBT?

Response: Momentive is a significant producer of various silicones, including polymers that contain volatile cyclic methlysiloxanes ("VMS"). There are some studies on several VMS' indicating those VMS' have a potential to bioaccumulate in certain portions of the aquatic environment. Studies indicate, however, that these substances do not bioconcentrate and do not pose a risk to aquatic organisms or humans. Momentive and other siloxane producers are conducting voluntary studies to look further into this question. Siloxane producers are also in discussions with EPA to implement additional voluntary monitoring to gather data that will assist the agency in characterizing any ecological risk posed by these materials.

11. Please explain a bit more the challenges of introducing new chemicals into commerce.

Response: A major challenge in bringing a new chemical to market is understanding if a market exists for the particular innovation. Under TSCA commercial production is only allowed after PMN approval. In many cases our customers need to test the market for their products commercially which requires the chemicals used to manufacture their products to be approved under TSCA, The PMN review process may result in delaying or limiting feasibility of production in response to EPA action on the PMN.

a. Why do only 50 percent of them get notices of commencement?

Response: The fact that some 50% of PMNs are subsequently commercialized reflects two major considerations: First, TSCA requires early contact with the Agency about new chemicals, well before markets are firmly established. Second, TSCA creates a system that is responsive to the demands of the highly competitive chemical market, in effect creating an incentive to go to EPA early before the commercial potential of a substance has been completely assessed.

b. How easy it is to have a chemical's production stopped or curtailed in the early going?

Response: New chemicals are developed through Research and Development activities (R&D). TSCA exempts R&D chemicals and activities from notification to EPA. There are also exemptions for "low volume" and "low release" chemicals. However, once a company decides to pursue commercial production beyond these exemptions, TSCA requires manufacturers to submit a PMN to EPA. Because commercial production cannot be "ramped up" prior to PMN approval, it may be possible to halt or curtail production if necessary in response to EPA action on the PMN. This is an important aspect of U.S. chemical regulation – the United States employs a "pre-manufacturing" system of review, while other systems generally apply a "pre-marketing" review process. There are regulatory risks inherent in a pre-marketing review assuming that significant investments have been made to manufacture the substance.

12. How critical to your business is protection of CBI?

Response: Protection of CBI information is vital to Momentive specifically and to the U.S. chemical industry generally. Momentive relies heavily on the ability to use our expertise in specialty chemicals and materials to innovate. CBI protections can prevent competitors from reaping the benefits of the R&D that the innovator has conducted to put the new chemical on the market. Protection of CBI allows businesses to remain competitive and differentiate their products from other companies, so it is not only critical to our business, it is critical to the U.S. economy.

13. What other types of confidential commercial information, other than confidential chemical identities, is protected?

Response: Any information of a commercial or financial nature that is held confidentially and the disclosure of which would result in competitive harm is generally considered confidential information. This can be specific information that describes or reveals how a substance, mixture, or article is manufactured, processed, or distributed; marketing and sales information, information identifying suppliers or customers, the identity of constituents in a mixture and the respective percentages of those constituents; specific information about use, function, or application of a substance or mixture in a process, mixture, or product; and specific production or import volumes. These are all examples of CBI.

14. Is confidential information always disclosed to EPA?

Response: Yes, information claimed confidential under TSCA is always disclosed to EPA.

15. What is the purpose of the generic name?

Response: A generic name can be provided in lieu of a confidential chemical identity in order to permit the public to have sufficient knowledge of the chemical structure as to allow an understanding of the intrinsic properties. With a structurally-descriptive generic name, the public can access toxicological information on the potential health and environmental effects of similarly structured chemicals, while not revealing the confidential aspects of the confidential chemical. As noted above, confidential information is always disclosed to EPA.

16. What suggestions would you have to improve the Confidential Business Information provisions in a modernized TSCA?

Response: Improvements to the CBI provisions in a modernized TSCA should include:
a) Requiring upfront substantiation of the CBI claim;
b) Requiring structurally-descriptive generic names in lieu of confidential chemical identity;
c) Regular EPA review and approval CBI claims (or subsets of claims, as appropriate);
d) Authority for EPA to share CBI with state governments in appropriate circumstances as long as adequate protections are in place to protect the CBI from disclosure; and
e) Disclosure of CBI to medical professionals in the case of an emergency and in non-emergencies with confidentiality agreements.

17. Heather White's testimony, on behalf of EWG, suggested there was no incentive for companies to test chemicals under TSCA Section 5's new chemicals program. How does this statement compare with your companies' experiences under TSCA Section 5?

Response: Ms. White's statement does not reflect the realities of manufacturing chemical substances. U.S. law – including tort and product liability law – establish significant incentives for manufacturers to know of and understand the hazards, uses and exposures of the substances they manufacture. The fact that new testing is not required initially for a new chemical under TSCA does not mean that applicable testing has not been done or will not be provided. Companies do understand the hazards, uses, and exposures of their products, and this can often provide EPA with appropriate and adequate information to review and assess a new chemical.

TSCA requires all available information to be provided to EPA, including any available test data. Companies have an incentive to understand the hazards and potential exposures to their substances and provide EPA sufficient information for the Agency to make decisions on them. Generally speaking, a company decides whether to test a chemical based on its potential uses and exposures. For example, if a substance is being developed for a consumer product, there's obviously strong motivation for a company to develop test data. The volume

at which production of a substance is anticipated could also motivate a company to conduct testing.

18. The Center for International Environmental Law (CIEL) recently released a new report, entitled "Driving Innovation," which examined the impact of chemical regulation on innovation. The final report, cited by some Members of this committee, claims that more stringent rules for chemicals foster the creation of safer alternatives, and it encourages global economies to adopt stricter policy on chemical regulation.

a. Can you please discuss how the CIEL report's conclusions compare with the conclusions of a study conducted by the Center for Strategy and Evaluation Services regarding REACH?

Response: The CIEL report concludes, on the basis of information about the increased number of patented inventions for phthalate alternatives between 1999 and 2008, and on the basis of the substitution/reformulation impact of the REACH candidate list of SVHCs, that "regulation" spurs innovation. This conclusion is based on very limited examples, however, since the "regulations" in question are regulations that threaten bans of the chemicals. It shouldn't be surprising that "innovation" into alternatives would be promoted by threats of bans/phase-outs of certain chemicals. The CIEL report does not make clear that a hazard based approach to "regulating" chemicals may produce little ultimate benefit to health/environment, but at huge cost. Chemical ban regulations, based solely on hazard, have a significant adverse economic impact, especially as there may not be appropriate substitutes for the banned substance or alternatives may not be effective to address the hazards.

The study conducted by the Center for Strategy and Evaluation Services (CSES) addressed a broader array of REACH regulations and revealed more nuanced conclusions about the relationship between regulation and innovation. According to the CSES website (http://www.cses.co.uk/new/50/), the study analyzed the results of an EU-wide survey of firms and interviews with experts and national authorities. It assessed the impact of various aspects of the European REACH Regulation on innovative activity and the innovative capacity of firms in the chemicals' sector (manufacturers of chemicals and chemical mixtures and their downstream users).

According to the CSES, some of the main findings of the study were:

- The regulatory burden placed on firms by the REACH Regulation tends to draw staff and funds away from more innovative work. As a result, 43% of companies think the regulation has had a negative impact on innovation while only 13% reported a positive impact so far.
- However, these appear to be mainly short-term effects that are expected to be offset in the longer term as companies reorient their R&D and innovation programs.
- The information creation, capture and dissemination mechanisms created by REACH (e.g. Registration Dossiers, Safety Data Sheets, Substance Information Exchange Fora) have acted as stimuli to product conception or innovation to varying degrees. 72% of companies thought they have led to an increase in access and scrutiny of information about chemical substances and 24% indicated that they had been able

benefit from this through increased knowledge of substances and properties. However, this has come at a significant handling cost to industry.

- The entry of a substance in the candidate list for authorization (use-specific licensing under the REACH program) usually tends to have a positive effect to innovative activity and forces companies to consider substitutes. The community rolling action plan is also creating a similar pressure.
- The authorization and restriction processes have had less impact so far as they have affected only very few firms. Indeed, no authorization applications have been filed to date under the REACH program.

In conclusion, the CSES study suggests that a future assessment would be required to determine whether the current negative impacts of REACH regulation on innovation will be offset in the longer term. The CSES study also suggests that REACH's information requirements and mechanisms have posed significant costs to industry. The CSES study's findings of short term negative effects on innovation are therefore at odds with the CIEL report's broad claims about the positive relationship between regulation and innovation. The CSES study suggests at a minimum that the CIEL report's claims about the impact of REACH regulations on innovation, in particular, are premature.

19. Please discuss your companies' experiences under REACH with respect to its requirements for minimum data sets for new chemicals,

a. What's been the impact of this requirement on innovation in new chemistries in the EU?

Response: Europe's REACH (Registration, Evaluation and Authorization of Chemicals) program requires a minimum data set to be submitted with each registration dossier. The system does not distinguish between new and existing chemicals. Although a final review has not yet been completed, the preliminary evidence suggests that new chemical applications in Europe are down sharply compared to other regions. In a recent assessment of REACH commissioned by the European Commission, the negative impact of REACH on innovation in an emerging technology like nanomaterials was a particular concern.[1] In that study, half of all manufacturers and importers considered that the uncertainties related to the REACH regulation were a challenge to bringing new nanomaterials to market, and that REACH had a negative or very negative effect on the time to market of their nanotechnology products. By contrast, under TSCA section 5 EPA has a track record that demonstrates it can successfully assess the health and environmental impacts of the vast majority of new chemicals very efficiently.

[1] See Final Report, Study on REACH Contribution to the Development of Emerging Technologies, GAIA, October 12, 2012, available at http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/review2012/emerg-techn-final-report_en.pdf.

b. How does that compare to the innovation in the U.S. under TSCA's new chemicals program?

Response: Some allege that the lack of required test data for all new chemicals in the PMN process means EPA approves new chemicals without any data on potential health or environmental effects or potential exposures. These critics call for a "minimum data set" requirement, similar to what's required for FDA approval of pharmaceuticals or EPA approval of pesticides, to assure EPA's decisions are protective.

The call for a "minimum data set" reveals a lack of understanding of the scientifically robust nature of EPA's review of new chemicals. It also ignores the major difference between TSCA and programs regulating pharmaceuticals and pesticides and the negative impacts that a minimum data set requirement would have on the development of new chemicals in the U.S. TSCA chemicals are not designed to be biologically active and they often have many more uses than do pharmaceuticals or pesticides. If every new TSCA chemical were required to provide a minimum set of data about the chemical's potential exposures from their potentially broad anticipated uses, the time required for companies to develop that information and for EPA to review it would be excessive. As a result, companies would go outside the U.S. to introduce new chemicals into the market and the U.S. would be competitively disadvantaged.

Under TSCA today, three times more new chemicals are brought for review in the United States than in any other country or region.

20. Heather White's submitted testimony, on behalf of EWG, cited two EWG studies that "detected nearly 300 industrial chemicals in the umbilical cord blood of newborn babies". Based on these studies, she raised alarms about "pre-polluted" infants.

a. Can you please explain to the Committee the ACC's position on biomonitoring information?

Response: The Centers for Disease Control and Prevention (CDC) regularly measures more than 300 chemicals in Americans' blood and urine. ACC supports the development of exposure information about chemicals and supports the CDC's development of biomonitoring information.

Importantly, biomonitoring information is just one type of exposure information and it has certain limitations: without more information you don't know the source or the magnitude or the duration of the exposure that caused the chemical to be detected in blood or urine. You also don't know what the information means in a risk context. It's ACC's position that biomonitoring information must be interpreted in a risk context if it is to be useful in the regulation of chemicals.

TSCA protects human health from unreasonable risks that may be posed from exposure to chemicals. ACC's position on biomonitoring is consistent with the Centers for Disease Control (CDC)'s interpretation of the information: just because a chemical can be detected in

our bodies does not mean that it causes harm. As a technical matter, the ability to detect the presence of chemicals has outpaced the scientific ability to interpret it in a risk context.

b. What does ACC think of the EWG's suggestion that cord blood testing be required as part of any chemical assessment process?

Response: Because biomonitoring information has the limitations discussed above (about source, magnitude and duration of exposure) and because biomonitoring information, by itself, cannot be interpreted in a risk context, ACC does not believe the EWG suggestion is either practicable or that it would provide value to the chemical assessment process. The suggestion assumes that mothers and the developing fetus will be exposed to all chemicals, which is clearly not the case. Further, this may be a particularly impractical suggestion since cord blood testing is probably more invasive with respect to privacy concerns than just about any other type of biomonitoring. It is not clear to ACC if EWG is suggesting that chemical manufacturers or the government should conduct such testing. If the suggestion is that manufacturers should conduct it, ACC contends that since the basic chemical manufacturers may not be the source of those exposures, it would not be fair to require manufacturers to conduct cord blood testing as a standard requirement of the chemical assessment process. If the EWG suggestion is for government to collect this information on a regular basis, it would be very costly and of questionable value for the government to do so, compared to the blood and urine biomonitoring the CDC currently conducts.

c. Please discuss the CDC's National Exposure Reports on measurement of chemicals in the blood and urine of Americans and the CDC's interpretation of that information?

Response: The CDC measures more than 300 chemicals in the blood and urine of Americans on a regular basis through its National Health and Nutrition Examination Survey. The CDC has been biomonitoring Americans for these chemicals since 2000. While CDC regards this information as valuable for understanding trends in chemical exposures, the CDC is also very careful in each of its National Exposure Reports to make clear that just because a chemical is present in blood or urine does not mean it is causing harm. The CDC reported presence of chemicals in blood or urine suggests only that an exposure has occurred – it does not supply sufficient information on the dose, or the effects of the exposure. Experts agree that more studies are needed to understand what biomonitoring information means in a risk context.

21. **During the hearing, there was quite a bit of discussion on the product Firemaster 550 and what the company or EPA did as part of its development and review process. I know your company does not make this product. In your capacity as Chairman of the American Chemistry Council's Executive Committee, could you please obtain the following information for the Committee from the manufacturer of Firemaster 550? Please include, at a minimum, the following:**

    a. The history of Firemaster 550, including interactions between the manufacturer and EPA

Response: The following information on Firemaster® 550 was provided by the manufacturer, Great Lakes Chemical Corporation, now a subsidiary of Chemtura Corporation.

- The manufacturer submitted a pre-manufacture notification (PMN) to EPA in **April 1995** for the brominated component (tetrabromobenzoate or "TBB") of Firemaster® 550. A PMN was not required for the phosphorous component of the product since it was already on the TSCA inventory. The PMN included information regarding the manufacturing process, chemical identity of the known constituents, estimates of production quantities, and the number of user facilities. EPA was informed that TBB would replace pentabromodiphenyl ether (PentaBDE) in the product.
- EPA and the manufacturer signed a Consent Order in **October 1996** requiring tiered testing of TBB, various stewardship activities, and a limit on TBB production.
- Limited commercial production of TBB began in **May 1997.**
- **Between 1997 and 2003**, the manufacturer submitted all the testing information requested by EPA as part of the Consent Order.
- In **December 2003**, EPA's Design for the Environment (DfE) initiated a review of PentaBDE alternatives, including TBB and Firemaster® 550, under the Furniture Flame Retardancy Partnership.
- In **February 2005**, EPA and the manufacturer signed a second testing agreement to obtain more information about potential effects of TBB on reproduction and/or fetal development as well as the potential for exposure from contact with flexible polyurethane foam.
- In **September 2005**, EPA's DfE assessment concluded that TBB had low persistence and bioaccumulation potential.
- In **fall 2009**, after reviewing results of the additional tests, EPA removed the production limit for TBB. To date, there have been no further requests for additional studies on TBB, Firemaster® 550, or the phosphorous component.
- In **March 2013**, EPA's Office of Pollution Prevention and Toxics announced that it would conduct a risk assessment of 20 flame retardants, including TBB, as part of it Chemical Work Plan Program. EPA did not include the phosphorus component in this assessment. The manufacturer has submitted all of the available data on TBB to EPA in anticipation of the review.

The timeline of interaction between EPA and the manufacture is included in the attached fact sheet.

b. A history of testing on Firemaster 550 and its constituent parts.

- Review of available health, safety, and environmental data of TBB - conducted prior to submission of the PMN.
- Environmental fate, bioaccumulation, and environmental toxicity of TBB – studies conducted between 1996 and 2003.
- Reproductive and developmental toxicity of TBB – studied conducted between 2005 and 2009.

- Exposure assessment – conducted between 2005 and 2009.

c. Information on those studies provided to EPA.

All of the information collected by the manufacturer on TBB was provided to EPA under the Consent Order. The available information was also submitted to EPA's DfE program in late 2003. All the information collected as part of the Consent Order was resubmitted to the Agency in anticipation of the review of flame retardants announced in March 2013, along with information developed for other regulatory agencies.

The manufacturer sponsored an assessment of the phosphorus component of Firemaster® 550 under EPA's High Production Volume (HPV) Challenge chemical screening process. Robust summaries of the available studies were submitted to EPA and posted on the HPV Challenge website in December 2001. EPA was aware that the phosphorus substance was a component of Firemaster® 550, but did not ask for information beyond that submitted as part of the HPV challenge.

d. Whether Section 14 of TSCA prevented EPA from looking at any portion of the submitted data it was provided by the manufacturer.

The manufacturer is not aware that Section 14 inhibited EPA's review of TBB and Firemaster® 550 in any way. Though vital compositional information was claimed to be confidential, no information was withheld from EPA scientists. As required by the PMN process, compositional information, manufacturing processes, and information about the use of the product were fully disclosed to EPA. No health and safety data were withheld from EPA and the information made publicly available by EPA through the PMN was sufficient for any interested party to ascertain the key endpoints related to the PMN substance. The information which was redacted for CBI purposes was simply to prevent another company from obtaining the study in its entirety and using it to support its own new substance notification in another country.

The claims around the confidentiality of the chemical identity of TBB at the time of the PMN submission were necessary to protect trade secrets from foreign competition and conformed to EPA's requirements for claiming CBI. At the time Firemaster® 550 was introduced, foreign competitors were anxious to know what the alternative was so that they could copy it. Disclosure in the U.S. would compromise the manufacturer's ability to protect its investment and our U.S.-based manufacturing jobs.

In accordance with U.S. requirements and globally recognized practices for hazard communications, the hazard information for each of the relevant components of the manufacturer's formulations based on TBB was included at the time it started distributing the products to its customers and amended when needed to include any new hazard information that came to light through the testing it conducted.

e. Information about actions taken by the manufacturer, pursuant to, or EPA, in carrying out, TSCA section 5 as it relates to Firemaster 550 or its constituent substances.

The manufacturer:

- conducted toxicity, environmental fate, and exposure testing;
- developed shipping procedures and best practices for Firemaster® 550 to minimize environmental releases; and
- completed all studies and reported results to EPA within the deadlines established by the consent order.

EPA:

- conducted preliminary assessment of potential health and environmental effects using predictive models and professional judgment during initial PMN review;
- developed the Consent Order establishing testing requirements and product stewardship/ risk management practices;
- reviewed and approved all test protocols for research performed under the Consent Order and conducted compliance audits covering the PMN;
- reviewed persistence, bioaccumulation and environmental toxicity data for TBB submitted by the manufacturer between 1997 and 2003;
- reviewed reproductive and developmental toxicity data for TBB submitted by the manufacturer between 2005 and 2009;
- reviewed exposure data for Firemaster® 550 between 2005 and 2009; and
- removed production limits on TBB in 2009.

f. Other relevant information to inform the Committee on this matter

In its review of the PMN for TBB, EPA took a cautious and measured approach. It identified areas of uncertainty and required the manufacturer to address those uncertainties with data. Throughout the entire process, EPA maintained the authority to limit, and potentially stop, TBB production.

Under Section 4 of TSCA, EPA is authorized to require testing of chemical substances and mixtures. Suggestions that the Agency could not have required testing of the formulated product Firemaster® 550 are inaccurate.

A recent pilot study conducted by academic researchers suggesting health effects in offspring of rats exposed to Firemaster® 550, referenced in the written testimony of Ms. Heather White, conflicts with the results of larger, Good Laboratory Practice (GLP) compliant studies of TBB conducted by accredited laboratories following protocols prescribed and reviewed by EPA.

The Honorable Henry A. Waxman

At the July 11, 2013, hearing, you testified that current disclosures, including structurally descriptive, generic chemical names are sufficient for consumers. Generally, consumers would want to use chemical names to determine whether a product on the shelf has as an ingredient a chemical substance that they wish to avoid.

1. **Please provide an example of a generic chemical name used for a specific chemical in the products of your company that is sufficient to allow consumers to determine which products on the shelf include that specific chemical and which do not.**

Response: I am not able to provide a generic name that Momentive has used in a TSCA filing. Whenever Momentive claims chemical identity as confidential, we also claim confidential our company identity. Consequently, if I were to disclose a generic name that my company has used in this public response to your question, I would be revealing my company's connection to that substance, which would impair Momentive's ability to protect that CBI going forward.

Almost all of Momentive's chemistries are used for industrial purposes, and would be converted, transformed, or derivatized in any consumer-facing product or application. Any Momentive chemistry that is in consumer products is under the regulation of the Consumer Product Safety Commission or the Federal Drug Administration and is not subject to TSCA.

In order to be responsive to your interest in examples of generic names, however, please see the response to question 2 below concerning aryl hydrazide. In addition, I have identified here several generic names used in TSCA filings that were previously associated with confidential chemical identities that were declassified in 2009:

- alkyl salicylaldehyde
- disubstituted quinolone
- alkylpridinium

Much of what is known about chemical risk under the existing TSCA scheme is submitted to EPA and published online in the form of TSCA §8(e) notices. Several examples of such notices are attached. These examples, from the most recent batch posted for the public by EPA, have been redacted to protect information claimed by the submitter as confidential business information (CBI). The redactions include information that a consumer might use to identify the chemical implicated.

Almost the only thing left unredacted is the description of the harms found through chemical testing -"erosions and ulcerations in the forestomach," "severely dysfunctional pathological changes," and "spontaneous death." Clearly, these are chemicals that consumers could reasonably choose to avoid.

One of these notices also provides an example of what a manufacturer views as substantiation of a CBI claim. The manufacturer writes, "Disclosure of this information would harm [REDACTED]'s efforts to commercialize this compound." Given the serious risks identified in the notice, including atrophy of reproductive

organs, it seems quite likely that disclosure of this risk information could harm efforts to commercialize this compound.

2. **In your view, do these redacted notices provide enough information for consumers to make informed choices and avoid these chemicals if they so desire?**

Response: The purpose of TSCA section 8(e) notices is to ensure that the chemical industry provides EPA with timely notice when it obtains information (not otherwise known to EPA) about potentially substantial risks associated with a chemical substance or a mixture so that EPA can design appropriate regulations or other risk management responses. Typically, the source of what is reported to EPA under Section 8(e) is toxicological animal study reports, epidemiological studies, or information about environmental contamination and effects. What is reported under Section 8(e) is chemical substance/mixture specific. (It is generally not information about a chemical's potential risk from use in consumer products -- information that is subject to other federal regulations, such as the Federal Hazardous Substances Act). If consumers are to make informed choices based upon information in toxicological studies reported under TSCA 8(e), they require a certain level of scientific expertise and skills necessary to understand and interpret what the study may or may not mean, and whether the results of any particular study actually translates to an actual risk to human health or the environment. Structurally descriptive generic information about a chemical may provide more relevant information to consumers on the potential health or environmental effects of a substance.

Your question perhaps indicates an interest in highlighting the absence of a generic name in two of the three 8(e) submissions attached to your questions. EPA's TSCA section 8(e) guidance (http://www.epa.gov/oppt/tsca8e/pubs/confidentialbusinessinformation.html) does not require or request that companies claiming confidential chemical identity provide a generic name in a Section 8(e) submission. Therefore, the two submissions that do not contain generic names appear to comply with EPA's requirements for 8(e) submissions from a technical standpoint. ACC and Momentive support the use of structurally-descriptive generic names in all health and safety studies when a chemical identity is claimed CBI.

One of the TSCA section 8(e) notices attached to your questions, dated April 3, 2013, provides a generic name "aryl hydrazide," in lieu of the confidential chemical identity. Entering "aryl hydrazide" into the Toxnet Data Network yields 80 different health and safety studies on aryl hydrazides. In ACC's view, these studies would very likely provide useful information on the potential health and environmental effects to interested persons, as well as to persons who are trained to understand and interpret the information appropriately.

3. **Do you support requirements for up front substantiation of CBI claims?**

Response: The American Chemistry Council and its members support up-front substantiation of CBI claims.

4. In your view is this example substantiation sufficient?

Response: Each of the three 8(e) submissions attached to your questions (including the example quoted in the question) states that the substantiation of the CBI claims is contained in a letter attached to the 8(e) submission. EPA does not make substantiations public. As a result, we are not in a position to answer whether the specific substantiations made by the claimants in these examples were sufficient. However, we would note that searches conducted on the generic descriptions of chemical substances generally return significantly more information related to health or environmental effects than a search of a specific commercial product.

Chemtura

Firemaster® 550 Flame Retardant

Firemaster® 550 is a flame retardant that protects lives and property by significantly reducing the risk of fire. By decreasing the probability of ignition from hazards such as lighters, matches, candles, and smoldering cigarettes, it makes products made with polyurethane foam safer. It is a blend of a brominated flame retardant and a phosphorus flame retardant. Firemaster® 550's high efficiency as a flame retardant is a result of the synergy of these components.

Firemaster® 550 does not contain polybrominated diphenylethers (PBDEs). The commercial introduction of Firemaster® 550 provided an alternative to furniture foam manufacturers that allowed them to rapidly eliminate the use of pentaBDE from the U.S. market. The brominated component of Firemaster® 550, which is comprised of tetrabromobenzoate (TBB), the main ingredient, and tetrabromophthalate (TBPH), provides equivalent fire safety and performance with an improved environmental profile.

Flame Retardants Work

In a 2012 study, researchers at the Fire Technology Research Laboratory at Southwest Research Institute conducted a series of 79 full-scale fire tests using upholstered furniture mockups made from foam, fabrics, and other materials. The study showed that flame retardants used in upholstered furniture were effective in slowing the spread of fire and providing valuable escape time.

About Brominated Flame Retardants

By interacting with fire in the gas phase, bromine works to prevent ignition or slow the spread of a fire. Brominated flame retardants also can be added to materials like plastic with minimal impact on their properties. As a result, flame retardants can be used to reduce the flammability of a variety of flammable materials, including textiles, electronics, building materials, plastics, and foams.

Laboratory tests show that it takes more time for flammable materials to catch fire after they have been treated with Firemaster® 550. This gives people more time to evacuate and call for help.

Products Containing Firemaster® 550 Flame Retardant

Firemaster® 550 reduces the flammability of materials, such as flexible polyurethane foam, which is used as cushioning for a wide variety of consumer and commercial products, including furniture, carpet, transportation, bedding, sound insulation, and packaging.

EPA Extensive Review & Approval Process

The Toxic Substance Control Act (TSCA) is one of more than a dozen federal laws and regulations that ensure chemicals used in commerce are safe for their intended uses.

As required by EPA for any new chemical, the manufacturer filed a Premanufacture Notice for TBB in 1995 and following a nearly two-year review, began limited commercial production in 1997. After that filing, 15 studies were submitted to EPA during the agency's 13-year assessment of TBB. Another 17 studies were conducted on TBB for regulatory authorities in other countries and were submitted to EPA in 2012 as part of its Work Plan Chemicals program. These included studies designed to assess the potential exposure of consumers to the substance, as well as persistence and potential for bioaccumulation. All of this research was conducted at independent laboratories following standardized methods prescribed by organizations such as the Organization for Economic Cooperation and Development (OECD).

Based on these studies, EPA determined that TBB has low potential for persistence and bioaccumulation.

For More Information:

- Read about Firemaster® 550 flame retardant at www.chemturaflameretardants.com
- Visit the North American Flame Retardant Alliance to learn about the wide range of flame-retardant chemistries at flameretardants.americanchemistry.com.

Consumer Exposure is Extremely Low

EPA evaluates the risks of new chemicals before they are manufactured to ensure they do not pose an unreasonable risk. A series of studies was conducted to assess the environmental fate and toxicity of TBB at the direction of EPA. The results indicated the level of exposure that could cause an unfavorable effect in humans is much higher than what a person encounters in the real world.

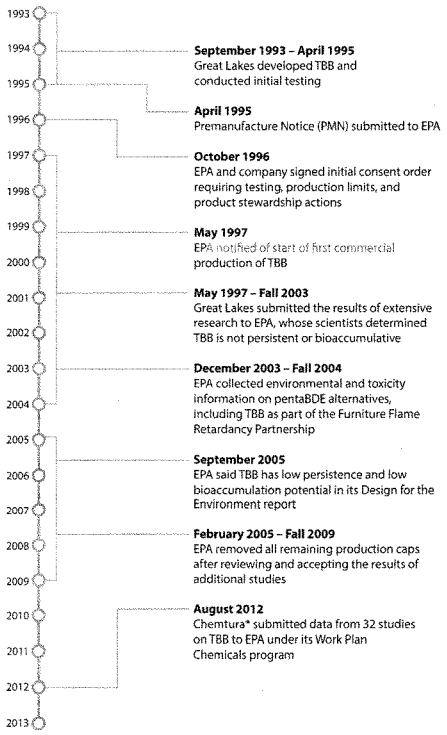
Regulatory Agencies that have Ruled on the Safety of TBB

- U.S. Environmental Protection Agency
- Australian Department of the Environment and Heritage
- Environment Canada

Chemtura

Timeline of EPA's Scientific Assessment

These are some of the steps Chemtura took during the U.S. government's review of tetrabromobenzoate (TBB).



** In 2005, Great Lakes Chemical Corporation completed a merger with Crompton Corporation to form Chemtura Corporation.*

RED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNI
RANKING MEMBER

ONE HUNDRED THIRTEENTH CONGRESS

Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225-2927
Minority (202) 225-3641

August 1, 2013

Dr. Len Sauers
Vice President of Global Sustainability
Procter and Gamble
701 Pennsylvania Avenue, N.W.
Suite 520
Washington, D.C. 20004

Dear Dr. Sauers:

Thank you for providing testimony to the Subcommittee on Environment and the Economy on Friday, July 11, 2013, hearing entitled "Regulation of New Chemicals, Protection of Confidential Business Information, and Innovation."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions by the close of business on Thursday, August 15, 2013. Your responses should be e-mailed to the Legislative Clerk in Word format at Nick.Abraham@mail.house.gov and mailed to Nick Abraham, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

John Shimkus
Chairman
Subcommittee on Environment and the Economy

cc: The Honorable Paul Tonko, Ranking Member,
Subcommittee on Environment and the Economy

Attachments

The Honorable John Shimkus
1. The following two (2) questions relate to testimony provided to the Committee by Heather White, on behalf of EWG.
a. Ms. White suggested there was no incentive for companies to test chemicals under TSCA Section 5's new chemicals program. How does this statement compare with your companies' experiences under TSCA Section 5?

In Procter & Gamble's experience, at the time of our Pre-Manufacture Notice (PMN) submission to EPA in support of a new chemical, we have already invested millions of dollars in research and development work to identify and scale-up production of the novel technology for use in consumer product applications. Our market launch timings are contingent upon the successful EPA review of the PMN under the New Chemicals Program. P&G makes extensive use of consultation meetings with EPA prior to submitting a PMN to help us scope and anticipate the necessary data and information EPA will need during their review in order to successfully complete the 90-day review period. This pre-submission consultation opportunity has greatly benefitted our PMN filing experiences and speed to market.

P&G conducts the necessary research on a new chemical to understand the potential hazards and exposures from intended uses. This research will often include assessment of existing data from structurally similar analogs, application of predictive models (including those that EPA makes publicly available on their website), and may include generation of new safety data through toxicological testing. Because we understand the way in which consumers and the environment will be exposed to the new chemical from our consumer product manufacturing, distribution, use, and disposal, we can generally anticipate the type of data and information EPA will need during the PMN review period, and further refine our understanding and tailoring of our PMN submission based on learnings from EPA during the pre-submission consultation meetings.

EPA's approach to New Chemical Review under TSCA Section 5 is scientifically rigorous, efficient, and workable within the marketplace. EPA obtains data and information through several methods to make science based decisions about new chemicals that protect against unreasonable risks. The Agency uses "read across" information from analog chemicals; structure activity relationship analysis; and other sophisticated models for predicting a chemical's properties, potential effects and exposures.

Under TSCA Section 5(e), EPA has the authority to take regulatory action for any new chemical substance where the existing information is insufficient to permit a "reasoned evaluation" of the substance's health or environmental safety of a material. EPA has used this authority to require testing for many PMN substances prior to market entry. Thus, it benefits a manufacturer to anticipate EPA's data and information needs and supply that which may be needed in the PMN submission to ensure speed to market with the new technology in a competitive marketplace. Ms. White's positioning in her testimony that EPA cannot request additional data unless the Agency has safety concerns is incorrect.

b. Ms. White cited two EWG studies that "detected nearly 300 industrial chemicals in the umbilical cord blood of newborn babies". Based on these studies, she raised alarms about "pre-polluted" infants.
i. Can you please explain to the Committee P&G's position on biomonitoring information?

P&G agrees with the caution expressed by the U.S. Centers for Disease Control and Prevention (CDC) to avoid over-interpretation of biomonitoring data. The mere presence of a particular chemical in human tissue is not an accurate measure of whether or not it will cause harm. People are exposed to thousands of naturally occurring and manmade substances in the foods we eat, water we drink, and air we breathe. As a consequence, many chemicals may be measurable in our bodies, yet have no adverse consequences.

ii. What does P&G think of the EWG's suggestion that cord blood testing be required as part of any chemical assessment process?

Today, scientists are able to accurately measure the presence of selected chemicals in nearly any kind of environmental or biological sample down to parts-per-trillion levels, or lower. Results from such biomonitoring studies have clearly demonstrated that both naturally occurring and manmade chemicals can be found in human blood and urine at measurable quantities. However, the significance of these findings for human health has not been established. The CDC encourages the public to avoid over-interpretation of the results:

> *The presence of an environmental chemical in people's blood or urine does not mean it will cause effects or disease...For most of the environmental chemicals included in the Fourth Report, more research is needed to determine whether exposure at the levels reported is a cause for health concern. (CDC, 2009)*

The presence of trace levels of materials as measured by the CDC indicates that these persons have had contact with these materials – not that they are causing harm. Similarly, cord blood testing would only provide one isolated piece of information (i.e., that the pregnant mother and her unborn child were exposed to a specific chemical), but will not provide the missing pieces of information needed to understand the exposure in context. The toxicity of a chemical is related to its dose or concentration, in addition to a person's individual susceptibility. Small amounts may be of no consequence, whereas larger amounts may cause adverse health effects. Further study is needed for biomonitored chemicals to determine the levels of the chemical that may cause health effects, the levels at which the body produces an adaptive response to maintain homeostasis, and the levels that are not a significant health concern. Furthermore, biomonitoring data provide no information that identifies the source (or sources) of exposure. At best, biomonitoring results provide evidence of exposure, which is information EPA can use to prioritize a chemical for further safety assessment and safety determination. P&G fully agrees with the caution expressed by the CDC to avoid over-interpretation of biomonitoring data and does not agree with the suggestion that biomonitoring following all infant births is a necessary requirement for a modernized US chemical management program.

iii. Please discuss the CDC's National Exposure Reports on measurement of chemicals in the blood and urine of Americans and the CDC's interpretation of that information?

The U.S. Centers for Disease Control and Prevention (CDC) released its *Fourth National Report on Human Exposure to Environmental Chemicals* (Fourth Report) in 2009, which reported the results of CDC's ongoing biomonitoring assessment of the U.S. population's exposure to environmental chemicals by measuring chemicals in people's blood and urine. The *Fourth Report* presents exposure data from the National Health and Nutrition Examination Survey for the civilian U.S. population over a two-year survey period of 2003–2004. In addition to presenting data from 2003–2004, the *Fourth Report* also included the data from 1999–2000 and 2001–2002 as reported in the *Second* and *Third National Report on Human Exposure to Environmental Chemicals* issued in 2003 and 2005, respectively. The CDC website is a one-stop source for the CDC's latest biomonitoring publications and information, including a list of chemicals included in the CDC's biomonitoring program.

Among the substances the CDC has been tracking are heavy metals such as lead and mercury, pesticides, a marker for tobacco smoke, and phthalate metabolic breakdown products.

The CDC expressed caution to the general public with the publication of the *Fourth Report* to avoid the over-interpretation of biomonitoring data:

> *The presence of an environmental chemical in people's blood or urine does not mean it will cause effects or disease...For most of the environmental chemicals included in the Fourth Report, more research is needed to determine whether exposure at the levels reported is a cause for health concern. (CDC, 2009)*

2. Please discuss your companies' experiences under REACH with respect to its requirements for minimum data sets for new chemicals.

a. What's been the impact of this requirement on innovation in new chemistries in the EU?

Europe's REACH (Registration, Evaluation and Authorization of Chemicals) program requires a minimum data set to be submitted with each registration dossier for existing and new chemicals that exceed certain manufacturing or import volume thresholds. Although a complete review has not yet been completed, the preliminary evidence suggests that new chemical applications in Europe are down sharply compared to other regions. By contrast, under TSCA Section 5 EPA has a track record that demonstrates it can successfully assess the health and environmental impacts of the vast majority of new chemicals very efficiently.

EPA thoroughly reviews each PMN under the TSCA New Chemicals Program to determine whether the new chemical presents an unreasonable risk to human health or the environment. EPA's approach to new chemical review tailors the predictive modeling and data/ information requirements to the individual new chemical in question, with careful consideration of the anticipated use and exposure patterns in US commerce. This approach ensures that the expenditure of resources to generate and review data/ information for a new chemical is directly correlated to EPA questions about the new chemical. The minimum data set approach of REACH inevitably wastes resources and can lead to unnecessary animal testing by generating and submitting data/ information that are not relevant to an individual

chemical or does not provide the right type of data/information to answer specific questions about a chemical.

b. How does that compare to the innovation in the U.S. under TSCA's new chemicals program?

Under TSCA, EPA applies a much more tailored approach in requiring only that data and information needed to evaluate each new chemical that enters the US market.

3. Please explain a bit more the challenges of introducing new chemicals into commerce.

a. Why do only 50 percent of them get notices of commencement?

EPA requires submission of a Notice of Commencement (NOC) upon the first commercial production or import of the new chemical in the US market. Customer demand will drive a chemical manufacturer's decision whether to commence manufacture of a new chemical. While a chemical manufacturer may submit multiple PMNs for new technologies that show promise in the research and development (R&D) stage, the manufacturer will only invest resources into the commercial production or import of a new technology for which a customer market exists and from which there is opportunity to recoup initial investment and probability for profit. Customer demand may simply change after a manufacturer submits a PMN, which is a key influencer to a manufacturer's decision of which PMNs to commence.

b. How easy it is to have a chemical's production stopped or curtailed in the early going?

This is really a case-by-case situation. The investment by the manufacturer in a new chemical really determines the impact of stopping or curtailing production. Some companies file a PMN for a new chemical and begin production of small quantities until customer demand increases and a market for the chemical becomes established. At that point, the chemical manufacturer will make a greater investment in the chemical and ramp up production. Stopping or curtailing production will be easier in the very early stages when the manufacturer has not made a significant investment in production quantities or has built dedicated manufacturing lines or new plants. For innovative product formulators like P&G, we have a very clear understanding of the intended use of a new chemical after having completed extensive R&D research in specific product applications. When P&G files a PMN, we are committed to the new technology and schedule product launch timings following the EPA review period. For our PMN chemicals, a large production volume of the substance will be needed to support consumer product manufacture, and widespread exposure will occur due to household consumer use of the product containing the new chemical ingredient. This knowledge directs our safety testing and allows us to specifically customize and tailor the testing to answer specific questions we may have about the chemical, or in anticipation of what EPA may need to complete the new chemical review.

4. When P&G does testing on their chemicals prior to submitting a Pre-Manufacturing Notice:

a. Are there use and exposure patterns that drive chemical testing?

Yes. For example, if a new chemical will be used as an ingredient in an aerosol spray air freshener product, the anticipated consumer use pattern of this product indicates that inhalation will be the major exposure scenario. We will assess the inhalation toxicity of the

new chemical to understand the risk potential of the ingredient in the aerosol spray application and make decisions about overall safety.

b. Do volumetric changes in a chemical change the focus of testing?

The production volume of a chemical is an indicator of exposure, meaning higher production volumes are likely to equate to increased exposure potential. However, it is important to understand the actual exposure of the chemical during intended or reasonably foreseeable use. Actual exposure is determined by multiple factors, including concentration of the chemical, duration of exposure, frequency of exposure and route of exposure, and can target the focus and design of the exposure testing.

5. What is the major criticism of the Pre-Manufacturing Notice program under TSCA?

Lack of Minimum Test Data (i.e., PMNs with "no data"). Some critics allege that the lack of required test data for all new chemicals in the PMN process means EPA approves new chemicals without any data on potential health or environmental effects or potential exposures. These critics call for a "minimum data set" requirement, similar to what's required for FDA approval of pharmaceuticals or EPA approval of pesticides, to assure EPA's decisions are protective.

EPA's approach to New Chemical Review under TSCA Section 5 is scientifically rigorous, efficient, and workable within the marketplace. EPA obtains data and information through several methods to make science based decisions about new chemicals that protect against unreasonable risks to human health or the environment. The Agency uses "read across" information from analog chemicals; structure activity relationship analysis; and other sophisticated models for predicting a chemical's properties, potential effects, and exposures.

EPA's approach to New Chemical Review tailors the predictive modeling and data/ information requirements to the individual new chemical in question, with careful consideration of the anticipated use and exposure patterns in US commerce. This approach ensures that the expenditure of resources to generate and review data/ information for a new chemical is directly correlated to EPA questions about the new chemical. The minimum data set approach inevitably wastes resources and can lead to unnecessary animal testing by generating and submitting data/ information that are not relevant to an individual chemical or does not provide the right type of data/information to answer specific questions about a chemical.

Finally, EPA has the authority to take regulatory action for any new chemical substance where the existing information is insufficient to permit a "reasoned evaluation" of the substance's health or environmental safety of a material. EPA has used this authority to require testing for many PMN substances prior to market entry.

6. Can EPA obtain enough data (without a minimum data set requirement) on which to make a science based decision on whether a new chemical should be introduced into commerce?

Yes. Under TSCA today, EPA obtains data and information through several methods to make science-based decisions about new chemicals that protect against unreasonable risks to

human health and the environment. The Agency uses "read across" information from analog chemicals; structure activity relationship analysis; and other sophisticated models for predicting a chemical's properties, potential effects, and exposures. EPA's approach is scientifically rigorous, efficient, and workable within the marketplace.

7. Does EPA approve new chemicals quickly enough to meet marketplace needs? When does it work well and when does it not work as well?

For the most part, EPA's review of new chemicals is very timely from a marketplace perspective. The vast majority of reviews are completed within 90 days. The willingness of the PMN submitter to consult with the Agency prior to PMN submission and to remain engaged throughout the 90 day review period contributes to EPA's timely review of new chemicals.

8. What is a trade secret and what does TSCA section 14 protect?

Section 14 provides broad protection for trade secret or confidential commercial information. Without this protection, EPA would have broad discretion to release all information provided to the Agency under TSCA, even if sensitive commercial information were involved. This would be problematic from the perspective that sensitive commercial information would be made available to competitors.

9. Can health and safety information be claimed CBI and kept from the public under TSCA?

No, health and safety information cannot be claimed CBI under TSCA. However, confidential information and data that may be contained within the study, such as the confidential chemical name or a company name, can and should be protected while disclosing the potential health and environmental impacts.

A specific, confidential chemical name is not needed to conduct a study, interpret the study results, and communicate the study's observed health effects and conclusions. The external laboratories that P&G contracts to conduct safety studies do all of this without ever knowing the specific chemical name of the test substance. EPA provides guidance on generic names that can be used to replace the chemical identity and ensure public access to appropriate health and safety information. A generic chemical name can also assist with the linkage of a confidential chemical to scientific and toxicological literature on similarly structured substances.

10. What happens when a company submits a health and safety study to EPA under TSCA and the company claims confidential chemical identity?

A company will submit two versions of the study to the Agency. One is the full study complete with the actual chemical identity; the other version of the study redacts the actual chemical name and inserts a structurally descriptive generic name in its place. The Agency and the company may negotiate the actual generic name that is chosen for insertion into the study that will be subject to public disclosure.

11. How critical to your business is protection of CBI?

It's absolutely business critical. Protection of confidential chemical identities and other pieces of sensitive business information preserves our competitive advantage and allows us to bring new innovations to the US market and delight our consumers. Without sufficient CBI protection, our competitors will capitalize on our significant investment in R&D, quickly replicate our innovations, and benefit from the safety assurance of the extensive health and safety data we've developed in support of the new technology.

12. What other types of confidential commercial information, other than confidential chemical identities, is protected?

Customer lists, marketing and sales information, information identifying the customers of a manufacturer, processor, or distributor, precise information about the use, function, or application of a substance or a mixture are all examples of CBI other than the trade secret chemical identity.

13. Is confidential information always disclosed to EPA?

Yes, EPA staff always knows the actual chemical identity and all the confidential commercial information that is not disclosed to the public.

14. What is the purpose of the generic name?

Structurally-descriptive generic names can provide the public with detailed information about the structure of the chemical, which allows the linkage to scientific and toxicological literature on similarly structured substances.

15. What suggestions would you have to improve the Confidential Business Information provisions in a modernized TSCA?

The most important changes that must be made are the following:

- Add clarity about what information can be protected, including chemical identity.
- Allow protection of qualifying information for as long as the need can be substantiated.
- Require up-front justification of claims.
- EPA should review and evaluate CBI claims, proportionate to Agency resource capability.
- Require structurally-descriptive generic names when chemical identity is claimed confidential.
- Allow for the sharing of CBI with US states in appropriate circumstances when the states can provide equivalent CBI protection as US EPA.

16. Hasn't there been disagreement among some stakeholders, as well as EPA, about whether chemical identity can be claimed CBI?

a. Don't they maintain that section 14 requires disclosure of chemical identity in health and safety studies except in two limited circumstances?

The disagreement on the interpretation of section 14 and its application to confidential chemical identity only arose very recently – in 2010. Prior to 2010, more than 35 years of EPA practice permitted chemical identity to be claimed CBI, even in a health and safety

study. For more than 35 years, TSCA has not been encumbered by EPA's recent administration of this new interpretation of TSCA Section 14.

b. If so, what are those?

EPA's recent change in practice reflects a new interpretation that chemical identity ***is*** health and safety data (and therefore, subject to public disclosure). P&G and our industry partners disagree with this interpretation. As discussed in our response to question #9, a specific chemical identity is not information that reveals the relevant health effects from a study. A specific, confidential chemical name is not needed to conduct a study, interpret the study results, and communicate the study's observed health effects and conclusions.

17. What accounts for this disagreement in interpretation?

Unfortunately, section 14 is not entirely clear as written. This lack of clarity has resulted in the differences in interpretation. As part of TSCA modernization, Section 14 should make clear that chemical identity can always be claimed confidential, subject to an up-front justification of the claim and the use of an acceptable generic name.

18. Do Canada and Europe provide CBI protections under their chemical management programs?

Canada and the European Union provide protections for confidential business information under the Chemical Management Plan and REACH (respectively). Canada allows a manufacturer to make a claim of confidential business information subject to substantiation upon request by the Canadian government (generally, in response to a Freedom of Information Act request). The Canadian government will ask the CBI owner for substantiation before releasing any information claimed as confidential. Articles 118 and 119 of REACH provide a broad allowance for substantiated claims of confidential business information, though the European Chemicals Agency has recently pulled back on protecting CBI claims for some pieces of information originally eligible for protection (e.g., company name).

19. Does the TSCA new chemicals program contribute to technological and sustainable innovation?

Yes, the TSCA New Chemicals Program has been a driver for technological and sustainable innovation in the US. One measure of this is the number of U.S. patents related to chemistry: 17% of all US patents are chemistry or chemistry related. The US leads the world in chemistry patents, and review under TSCA section 5 provides a regulatory framework to enable those patents to be commercialized. The chemical industry has designed new chemistries in recent years to make meaningful improvements in safety or environmental protection and have introduced those new chemistries to the US market through the TSCA New Chemical Program.

The Honorable Henry A. Waxman
At the July 11, 2013, hearing, you testified that current disclosures, including structurally descriptive, generic chemical names are sufficient for consumers. Generally, consumers would want to use chemical names to determine whether a product on the shelf has as an ingredient a chemical substance that they wish to avoid.

1. Please provide an example of a generic chemical name used for a specific chemical in the products of your company that is sufficient to allow consumers to determine which products on the shelf include that specific chemical and which do not.

P&G filed a confidential Pre-Manufacture Notice (PMN) for a new polymer in 2004 in which we provided the structurally descriptive chemical name of "substituted acrylic acid maleic anhydride copolymer." The generic chemical name clearly indicated that the PMN material was a polyacrylate polymer and allowed the general public to understand that the results of the health and safety studies that P&G included in the PMN package were attributed to a modified type of polyacrylate polymer. The PMN indicated that this new polyacrylate polymer would be used in granular automatic dishwashing detergents. A review of P&G's corporate product safety website (www.pgproductsafety.com) reveals that "modified polyacrylate" is an intentionally added ingredient to our US marketed granular automatic dishwashing brand (i.e., Cascade ®).

Much of what is known about chemical risk under the existing TSCA scheme is submitted to EPA and published online in the form of TSCA §8(e) notices. Several examples of such notices are attached. These examples, from the most recent batch posted for the public by EPA, have been redacted to protect information claimed by the submitter as confidential business information (CBI). The redactions include information that a consumer might use to identify the chemical implicated.

Almost the only thing left unredacted is the description of the harms found through chemical testing - "erosions and ulcerations in the forestomach," "severely dysfunctional pathological changes," and "spontaneous death." Clearly, these are chemicals that consumers could reasonably choose to avoid.

2. In your view, do these redacted notices provide enough information for consumers to make informed choices and avoid these chemicals if they so desire?

The majority of TSCA 8(e) Notices of Substantial Risk reveal harmful effects observed during testing of Research & Development (R&D) chemicals. The chemical dose in such testing can be greatly exaggerated above anticipated and reasonable exposure levels to specifically elicit a response. Since R&D chemicals are not in US commerce, consumers are not exposed to these chemicals and do not require detailed confidential information about these prototype technologies in order to "reasonably choose to avoid" such chemicals.

We support the use of structurally-descriptive generic names in all TSCA filings that protect confidential chemical identities as CBI. Such generic names can provide the public with detailed information about the structure of the chemical, which allows the linkage to scientific and toxicological literature on similarly structured substances and provides information needed for

consumers to "reasonably choose to avoid" the class of chemical substances that could potentially produce an effect of concern at elevated exposure levels.

Additionally, EPA staff always knows the actual chemical identity and all the confidential commercial information that is not disclosed to the public for a subject chemical of a TSCA 8(e) Notice of Substantial Risk. The Agency can use that information to take necessary regulatory action under TSCA to protect public health and the environment.

One of these notices also provides an example of what a manufacturer views as substantiation of a CBI claim. The manufacturer writes, "Disclosure of this information would harm [REDACTED]'s efforts to commercialize this compound." Given the serious risks identified in the notice, including atrophy of reproductive organs, it seems quite likely that disclosure of this risk information could harm efforts to commercialize this compound.

3. Do you support requirements for up front substantiation of CBI claims?

Yes. P&G fully supports a requirement for upfront substantiation of CBI claims as part of a modernized TSCA.

4. In your view is this example substantiation sufficient?

As detailed on EPA's TSCA 8(e) Notice webpage, all submitters of TSCA 8(e) Notices of Substantial Risk must substantiate any CBI claims by answering 14 substantiation questions. EPA's thorough list of CBI substantiation questions under the TSCA 8(e) program provides a model that could be re-applied to substantiation of all CBI claims under all reporting provisions of a modernized TSCA.

Responsible submitters of TSCA 8(e) Notices of Substantial Risk address the following substantiation questions in order to claim CBI:

1. Is your company asserting this confidential business information (CBI) claim on its own behalf? If the answer is no, please provide company name, address and telephone number of entity asserting claim.
2. For what period do you assert your claim(s) of confidentiality? If the claim is to extend until a certain event or point in time, please indicate that event or time period. Explain why such information should remain confidential until such point.
3. Has the information that you are claiming as confidential been disclosed to any other governmental agency, or to this Agency at any other time? Identify the Agency to which the information was disclosed and provide the date and circumstances of the same. Was the disclosure accompanied by a claim of confidentiality? If yes, attach a copy of said document reflecting the confidentiality agreement.
4. Briefly describe any physical or procedural restrictions within your company relating to the use and storage of the information you are claiming CBI.
5. If anyone outside your company has access to any of the information claimed CBI, are they restricted by confidentiality agreement(s). If so, explain the content of the agreement(s).
6. Does the information claimed as confidential appear or is it referred to in any of the following:
    a. Advertising or promotional material for the chemical substance or the resulting and product;
    b. Material safety data sheets or other similar materials (such as technical data sheets) for the substance or resulting end product (include copies of this information as it appears when accompanying the substance and/or product at the time of transfer

or sale);
c. Professional or trade publications; or
d. Any other media or publications available to the public or to your competitors.

If you answered yes to any of the above, indicate where the information appears, include copies, and explain why it should nonetheless be treated as confidential.

7. Has EPA, another federal agency, or court made any confidentiality determination regarding information associated with this substance? If so, provide copies of such determinations.
8. Describe the substantial harmful effects that would result to your competitive position if the CBI information is made available to the public? In your answer, explain the causal relationship between disclosure and any resulting substantial harmful effects. Consider in your answer such constraints as capital and marketing cost, specialized technical expertise, or unusual processes and your competitors access to your customers. Address each piece of information claimed CBI separately.
9. Has the substance been patented in the U.S. or elsewhere? Is a patent for the substance currently pending?
10. Is this substance/product commercially available and if so, for how long has it been available on the commercial market?
    a. If on the commercial market, are your competitors aware that the substance is commercially available in the U.S.?
    b. If not already commercially available, describe what stage of research and development (R&D) the substance is in, and estimate bow soon a market will be established.
    c. What is the substance used for and what type of product(s) does it appear in.
11. Describe whether a competitor could employ reverse engineering to identically recreate the substance?
12. Do you assert that disclosure of this information you are claiming CBI would reveal:
    a. confidential processes used in manufacturing the substance;
    b. if a mixture, the actual portions of the substance in the mixture; or
    c. information unrelated to the effects of the substance on human health or the environment?

    If your answer to any of the above questions is yes, explain how such information would be revealed.
13. Provide the Chemical Abstract Service Registry Number for the product, if known. Is your company applying for a CAS number now or in the near future? If you have applied for a CAS number, include a copy of the contract with CAS.
14. Is the substance or any information claimed CBI the subject of FIFRA regulation or reporting? If so, explain.

Please see EPA's TSCA 8(e) Notice Webpage for more information about claiming confidentiality in Notices of Substantial Risk:

http://www.epa.gov/oppt/tsca8e/pubs/confidentialbusinessinformation.html

FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED THIRTEENTH CONGRESS

Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225-2927
Minority (202) 225-3641

August 1, 2013

Mr. David Isaacs
Vice President
Government Affairs
Semiconductor Industry Association
1101 K Street, N.W., Suite 450
Washington, D.C. 20005

Dear Mr. Isaacs:

Thank you for providing testimony to the Subcommittee on Environment and the Economy on Friday, July 11, 2013, hearing entitled "Regulation of New Chemicals, Protection of Confidential Business Information, and Innovation."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions by the close of business on Thursday, August 15, 2013. Your responses should be e-mailed to the Legislative Clerk in Word format at Nick.Abraham@mail.house.gov and mailed to Nick Abraham, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

John Shimkus
Chairman
Subcommittee on Environment and the Economy

cc: The Honorable Paul Tonko, Ranking Member,
Subcommittee on Environment and the Economy

Attachment

Responses of the
Semiconductor Industry Association (SIA)

Questions for the Record (QFR)
From the
Environment and the Economy Subcommittee
Of the
House Energy and Commerce Committee

Hearing on
"Regulation of New Chemicals, Protection of Confidential Business Information, and Innovation"
July 11, 2013

Response submitted August 13, 2013

The Semiconductor Industry Association (SIA) is pleased to provide this response to the Question for the Record posed by Chairman Shimkus in his letter of August 1, 2013. Each question is set forth below in bold text, followed by our response. We appreciate the opportunity to provide our views to the Committee.

Questions by Chairman Shimkus

Question 1. ***You spoke in your testimony of the importance to long-term investment decisions by your members.***

a. ***Can your members adjust to abrupt swings in the chemical marketplace? Please give examples.***

The semiconductor industry is characterized by rapid innovation and technological change, but the industry would find it difficult to adjust to sudden changes in the market when it comes to the availability and use of essential chemicals. As stated in our testimony, the industry utilizes specialty chemicals with unique chemical and physical properties that make possible the production of advanced semiconductors, and the industry employs advanced manufacturing tools that are designed to operate using these specific chemicals. As a result, there are typically no "drop-in" replacements for many of the chemicals currently in use in any given manufacturing process. For this reason, the industry depends on a stable supply of these essential chemicals. Furthermore, the manufacturing technology development process in our industry is usually quite long (10 or more years), and therefore changes in manufacturing process technology are very difficult to implement quickly.

The potential challenges with an abrupt change in the chemicals marketplace are illustrated by the industry's experience in responding to the European Union directive on the Restriction of Hazardous Substances in Electrical and Electronic Equipment (RoHS) and the proposed ban several years ago on perfluorooctane sulfonic acid (PFOS) and related precursors. In both instances, the transition to lead-free solders and the phase-out of PFOS were complex undertakings that took several years to implement. Both situations involved identifying and qualifying suitable substitutes, integrating new materials into manufacturing and assembly equipment, and evaluating product reliability. Both instances also resulted in the imposition of

high costs on the industry and required the granting of certain critical exemptions when substitutes were unavailable for specific applications.

The challenge of an abrupt change in the availability of a critical material for the semiconductor industry is further illustrated by the current situation concerning helium, a critical input into the semiconductor manufacturing process. Although this material is not a regulated chemical under TSCA, it nonetheless illustrates the difficulties inherent in sudden limitations on the availability of essential materials. Helium has certain unique physical and chemical properties have made it critical to a broad range of applications in the manufacture of semiconductors, and there is no known substitute for helium in many of these applications. There is currently a global shortage in the supply of helium, and this shortage may become more severe due to the impending cessation of sales of helium from the Federal Helium Reserve, a federal facility that provides 50 percent of domestic supplies and 30 percent of global supplies. Semiconductor companies and other industries that rely on helium are implementing a series of measures to address this shortage, including conservation and recycling efforts and the investigation of substitutes. But in the absence of legislation to authorize continued sales of helium from the Reserve the industry may face a significant disruption. The House has passed bipartisan legislation (H.R. 527) and a Senate committee has approved bipartisan legislation (S. 783), but it is essential that the Congress act promptly to authorize the Reserve to continue sales of helium to private users and avoid damage to critical sectors of the American economy.

b. Should appropriate replacements be available when a chemical is removed from commerce?

In the semiconductor industry, it is critical that the industry has access to appropriate substitutes to any chemical that might be removed from commerce. Several years ago EPA and other countries considered a ban on perfluorooctane sulfonic acid (PFOS) and related precursors, a set of chemicals previously used in the industry in numerous applications, including anti-reflective coatings, photoacid generators (an element of photoresists used in the critical photolithography patterning process), and as a surfactant. Because of the essential uses of PFOS at that time and the absence of available substitutes, an abrupt restriction on this chemical would have been highly disruptive to our industry and our continued ability to produce advanced semiconductors. Fortunately, the industry worked with EPA and others to obtain exemptions for critical uses of PFOS in our industry, with sufficient time to identify and adopt substitutes for this material. As a result, the global semiconductor industry has eliminated the use of this chemical in most applications and reduced 99 percent of emissions of this substance.

Of course, there may be instances where the exposure and risks to humans and the environment are so significant that regulatory bodies must act without replacements being available. But we believe such instances are likely to be rare and inapplicable to the highly controlled uses of chemicals in the semiconductor industry.

Question 2. Your testimony was careful to point out the importance of prioritizing and tailoring the regulatory look to expected uses of the chemical. Why do you consider the exposure part of the risk equation to be so essential?

Chemical risk is a function of hazard (toxicity) and exposure – if there is no exposure, there is no risk. SIA believes that the regulation of chemical substances should be prioritized to focus on chemicals with a high risk, i.e., when the hazard of a chemical and its exposure scenario(s) result in the potential for adverse impacts on human health and/or the environment. Sound

application of basic risk assessment principles necessitates that the chemical assessment process should be tailored to evaluate the specific conditions of use of a chemical.

Exposure scenarios will be different for each specific use of a chemical and the conditions of that use. A chemical may be likely to pose minimal risk for some intended conditions of use but not others. For example, a chemical used as an intermediate or in an enclosed industrial process (as is the case in most semiconductor manufacturing processes) would not be likely to present any risk of concern under such conditions, but the risk profile could be very different if the chemical were an ingredient in a consumer product or otherwise presented a likelihood of exposure.

The semiconductor manufacturing process is designed to minimize exposure to workers and to minimize releases to the environment. The process is highly controlled and performed to exacting standards, with significant and often redundant controls and safety measures, in order to ensure quality and consistency in the production process. The entire process is conducted in a tightly controlled clean room environment, where there are specific controls on temperature, humidity and air contamination, to achieve optimal production results.

The conditions of use of chemicals in the semiconductor industry are different from most other uses of chemicals, and the type or level of regulation of a chemical should take into account the high levels of controls – and resulting low levels of exposure – present in the semiconductor industry. While it might be appropriate to regulate the use of a chemical in some applications that lack the levels of control applicable to our industry, it would be inappropriate to subject the uses of that same chemical in the semiconductor industry to the same levels of control.

Appropriate consideration of uses also is critical for ensuring that the chemical management assessment process functions efficiently. We think that EPA should have clear authority to make decisions at each stage of the process about the appropriate scope of its inquiry and any resulting determinations and requirements. We hope that any legislation would allow and encourage the Agency to focus its attention (and available resources) on the uses and exposures that warrant most attention from a risk perspective.

Question 3. ***I noticed that you wanted to see more financial resources given to EPA for review of chemicals. Is this because you support more robust reviews or because the timeliness of EPA decision is crucial to your own ability to innovate?***

We believe that the Environmental Protection Agency (EPA) should have sufficient resources in order to conduct robust reviews and to do so in a prompt and timely manner. This is important to protect our ability to innovate, but we also think it is necessary for any chemical management system that aims to protect human health and the environmental.

The semiconductor industry is characterized by rapid innovation and technological change, and part of our ability to innovate is linked to the ability to use new chemicals and materials. "Time to market" is a critical factor in our industry, because products typically have short lifespans and processes are continually subject to improvement, and therefore, predictable and prompt review of chemicals is vital to our industry. Given the importance of an effective and efficient system for regulating chemicals to the semiconductor industry, SIA supports providing the EPA with sufficient resources for the review of chemicals. Providing EPA with sufficient resources to conduct appropriate reviews of chemicals will instill a greater level of confidence in the chemical review process among all stakeholders, and therefore provide greater certainty for the continuing use of chemicals that are critical to the semiconductor manufacturing process.

It is important that EPA conduct reviews of chemicals in a manner that includes an evaluation of the specific conditions of use of a chemical, such as in the semiconductor industry, not just the inherent hazards of a chemical. EPA needs sufficient resources to conduct assessments that are tailored to the exposure conditions associated with different uses.

Question 4. ***Could you please explain your views of TSCA treatment of articles and the use of existing TSCA authority to deal with any questions about them?***

Finished semiconductor devices are considered to be "articles" for purposes of U.S. chemicals regulation. Semiconductors are packaged into modules that are then incorporated into larger products that may also be deemed to be "articles." In addition, the specialized manufacturing "tools" – the highly complex manufacturing equipment designed to work with specific chemicals in the manufacturing process that are critical to the success of the industry – are also classified as "articles." Thus, the treatment of articles under TSCA is very important to our industry.

EPA has exercised its TSCA authority as applied to articles in an appropriate manner. Under current regulations, articles generally are exempt from the import certification and export notification requirements of TSCA. While the import and export provisions of the original TSCA do not exclude them, EPA and Customs exempted articles from these provisions as part of the initial implementing regulations promulgated in the early 1980s. (In the case of the import certification obligation, EPA and Customs reserved their right to require import certification for articles on a case by case basis.) Because semiconductors are among the top export industries of the United States and are traded globally in a highly competitive market, maintaining the current import and export exemptions found in TSCA implementing regulations are particularly important to our industry.

The current ability to import and export without onerous notification and certification requirements makes sense as applied to semiconductors. Semiconductors may contain chemicals or materials subject to regulation under the TSCA, but these chemicals and materials are present in extremely small volumes (most semiconductors weigh no more than a few grams and are about 2 cm squared in size). Furthermore, these small volumes of chemicals are etched or otherwise formed into the layers and sections of the metals, organic-metallic complexes, organics and other materials in the semiconductor product, and these materials are bound to the device in a monolithic fashion that cannot be separated from the device or released to the environment without taking extreme and unusual destructive measures.

Thus, it is critical that articles continue to be exempt from the import certification or export notification requirements of TSCA, and that the new chemical review process continue to exclude chemicals that are imported as part of an article. EPA has the authority to regulate chemicals in articles, and it may be appropriate for EPA to exercise this authority under special circumstances where a significant health or environmental risk cannot be adequately addressed through direct regulation of chemical substances or mixtures.

FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED THIRTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225-2927
Minority (202) 225-3641

August 1, 2013

Dr. Rainer Lohmann
Professor of Oceanography
Graduate School of Oceanography
University of Rhode Island
South Ferry Road
Narragansett, RI 02882

Dear Dr. Lohmann:

Thank you for providing testimony to the Subcommittee on Environment and the Economy on Friday, July 11, 2013, hearing entitled "Regulation of New Chemicals, Protection of Confidential Business Information, and Innovation."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions by the close of business on Thursday, August 15, 2013. Your responses should be e-mailed to the Legislative Clerk in Word format at Nick.Abraham@mail.house.gov and mailed to Nick Abraham, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

John Shimkus
Chairman
Subcommittee on Environment and the Economy

cc: The Honorable Paul Tonko, Ranking Member,
Subcommittee on Environment and the Economy

Attachments

THE
UNIVERSITY
OF RHODE ISLAND
GRADUATE SCHOOL
OF OCEANOGRAPHY

THINK BIG WE DO

Narragansett Bay Campus, 215 South Ferry Road, Narragansett, RI 02882 USA p: 401.874.6222 www.gso.uri.edu

August 13, 2013

Rainer Lohmann, Ph.D.
Professor of Oceanography
University of Rhode Island, Narragansett, RI 02882

Response to questions for the record submitted by members of the U.S. House Energy and Commerce Subcommittee on Environment and the Economy hearing on 'Regulation of New Chemicals, Protection of Confidential Business Information, and Innovation'

Question from the Honorable Henry A. Waxman

(1) Do you support placing the burden on manufacturers to demonstrate that their products do not pose risks to consumers, workers, hot spot communities, and vulnerable populations?

Yes, it is the manufacturer's responsibility to demonstrate the safety of their products.

(2) Do you support reduce overclaiming of confidentiality and promoting transparency?

Yes, absolutely. CBI has essentially been abused in the past by overclaiming confidentiality. It should be limited to a few years at maximum, and far stronger guidelines need to be attached to prevent abuse of this rule. Without knowing the chemical identity, little can be done with respect to the detection of worrisome compounds, their toxicity etc.

(3) Should those important principles be included in any effort to reform TSCA?

Yes, these principles need to be addressed in a reformed TSCA!

(4) What other reforms are essential to include in TSCA reform if the statute is to be made effective and protective for everyone, including vulnerable populations?

There are several important reforms to the current TSCA that should be included:
a) Any new TSCA that tasks EPA with conducting safety evaluations has to equip EPA with the financial and personnel resources to perform this task adequately and in a timely manner, preferentially with a fee on new chemicals to be tested.

b) High throughput *in vitro* screening assays that allow for the evaluation of many toxic endpoints should be developed and considered for mandatory testing of new chemicals.

c) TSCA reform should consider that potential effects of chemicals need to be evaluated over long periods of time (i.e. long-term chronic exposure studies), particularly for sensitive populations. TSCA should recognize these challenges and be less proscriptive and more holistic.

d) In the past, legislation has focused on a single chemical at a time. Yet environment exposures occur in complex mixtures. Studies have shown that a cocktail of many individual compounds each present at their no-effect levels can still result in significant adverse effects. TSCA and the Lautenberg-Vitter bill are designed to evaluate chemicals independently, but many chemical manufacturers sell their products as mixtures. Therefore, evaluations should be conducted not only on individual chemicals but also on the mixture as marketed.

e) TSCA does not limit the period during which a chemical and the associated data can be considered proprietary. This should change. The chemical industry should have only a few years during which information submitted to the U.S. EPA will be considered confidential. After this time, information should be publicly available, and this should include site-specific production data. By withholding information on the chemical identity, it becomes almost impossible for academic scientists to identify these chemicals in the environment and assess human exposure levels.

f) In addition, because research on many chemicals is hindered by a lack of authentic standards, samples of any chemical substance produced or imported into the U.S. should be archived in a national repository funded by the chemical industry. Both of these changes will open a dialogue among industry, academia, and non-governmental organizations to identify problem substances and to assess safer alternatives.

g) TSCA should be harmonized with chemical regulations in Europe, Japan, Canada, and Australia; the U.S. does not need to reinvent the wheel.

(5) Are those reforms included in the bill recently introduced in the Senate to reform TSCA?

Only partially. Legislation now before the Senate, called the Chemical Safety Improvement Act of 2013 (TSCA-II), makes some improvements over the original law. TSCA-II would require EPA to classify chemicals as high or low priority for safety assessment and to evaluate the safety of high-priority chemicals entering the marketplace and those already in commerce. Yet the bill introduced in the Senate lacks a stronger protection of consumers, workers, vulnerable populations and the environment by not doing enough to reduce the abuse of CBI. It also does not address the problem of the exposure to complex mixtures in the environment, nor does it attempt to harmonize with recent legislation in other major markets. A strategy to address long-term exposure to chemicals is also missing. These are major lost opportunities unless the bill is significantly improved. Lastly, the new bill needs to ensure that the EPA has the resources to do

a thorough and timely review. Ideally, having a repository for all compounds produced or imported would be a major step forward for scientists to being able to study all compounds on the market.

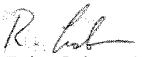
(6) Do you have concerns about that bill?
Yes - the bill introduced in the Senate lacks a stronger protection of consumers, workers, vulnerable populations and the environment by not doing enough to reduce the abuse of CBI. It also does not address the problem of the exposure to complex mixtures in the environment, nor does it attempt to harmonize with recent legislation in other major markets. A strategy to address long-term exposure to chemicals is also missing. These are major lost opportunities unless the bill is significantly improved. Lastly, the new bill needs to ensure that the EPA has the resources to do a thorough and timely review. Ideally, having a repository for all compounds produced or imported would be a major step forward for scientists to being able to study all compounds on the market.

(7) Do you agree with that statement?
No, current disclosures are completely inadequate for scientists, let alone consumers, to understand which compounds are produced and which effects it might have on the US population.

(8) Do these redacted notices provide enough information for consumers to make informed choices and avoid these chemicals if they so desire?
No, in the redacted notices there is so little information left that consumers are unable to make an informed choice.

(9) In your view, should a substantiation like this be sufficient?
No, the substantiation presented by the manufacturer is clearly insufficient. If a given chemical or product is harmful or toxic, consumers need to know so they can avoid it. In fact, such a product should not be marketed at all, or under severe restrictions of use so that the consumers are not exposed to such a produce that clearly has adverse effects.

Sincerely



(Rainer Lohmann)
Professor of Oceanography

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Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225–2927
Minority (202) 225–3641

August 1, 2013

Ms. Heather White
Executive Director
Environmental Working Group
1436 U Street, N.W.
Suite 100
Washington, D.C. 20009

Dear Ms. White:

Thank you for providing testimony to the Subcommittee on Environment and the Economy on Friday, July 11, 2013, hearing entitled "Regulation of New Chemicals, Protection of Confidential Business Information, and Innovation."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions by the close of business on Thursday, August 15, 2013. Your responses should be e-mailed to the Legislative Clerk in Word format at Nick.Abraham@mail.house.gov and mailed to Nick Abraham, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

John Shimkus
Chairman
Subcommittee on Environment and the Economy

cc: The Honorable Paul Tonko, Ranking Member,
Subcommittee on Environment and the Economy

Attachments

Responses to Questions for the Record

Submitted By Heather White, Esq.

Executive Director
Environmental Working Group

Before the

U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON ENERGY AND COMMERCE
SUBCOMMITTEE ON ENVIRONMENT AND THE ECONOMY

On

Regulation of New Chemicals, Protection of Confidential Business Information, and Innovation

Friday, August 16, 2013

The Honorable John Shimkus

1. You make a number of recommendations about changes to the TSCA program.

a. How many of them does EPA already have the authority to do?
b. How many of those remaining from your list could be done administratively versus via statute?

In my testimony, I noted that EPA faces significant challenges with respect to ensuring the safety of new chemicals. Specifically, the federal Toxic Substances Control Act (TSCA) typically gives EPA just 90 days to review pre-manufacturing notices (PMNs),[1] an ambitious schedule for determining whether chemicals may present an unreasonable risk to health.[2] TSCA does not require companies to include toxicity data in PMNs, which means that most are devoid of such information.[3] TSCA places EPA in a "Catch-22" situation where the agency cannot request additional data unless it has tangible evidence that a chemical may pose an unreasonable risk to health, but many times needs that very data to make that determination. According to the U.S. General Accounting Office (GAO), PMNs often lack robust information about how chemicals will actually be used once they go to market.[4] In other words, companies may decide after filing a PMN to produce the chemical in greater volumes or use it in ways that are different than what was described in the PMN.[5] This means that EPA's PMN review may not appreciate actual risks posed by a chemical once on the market.[6]

EPA could theoretically address many of these shortcomings administratively (e.g., rulemakings), but could not strengthen the law's weak "unreasonable risk" standard without the help of Congress.[7] Yet any effort by EPA to make better use of its TSCA authority has faced

staunch opposition from chemical companies, as well as lengthy delays at the U.S. Office of Management and Budget (OMB). For example, EPA used its existing authority to propose a list of high-concern chemicals the agency believes present or may present an unreasonable risk of injury to health or the environment.[8] However, EPA's list continues to languish at OMB where it has been since May 2010.[9]

During her tenure as EPA Administrator, Lisa Jackson directed the agency to make every possible effort to utilize its limited authority under TSCA to reform the way chemicals are reviewed and managed.[10] However, in testimony before the Senate Committee on Environment and Public Works, she noted that legal and procedural hurdles have largely prevented EPA from making progress on this endeavor.[11] For example, Administrator Jackson highlighted the fact that TSCA does not require companies to conduct testing on new chemicals before they enter the market; meaning companies do not have to give EPA all of the information it needs to review a chemical for safety.[12]

Other EPA officials have echoed this sentiment, suggesting that TSCA's limitations have generated significant delays in obtaining data on new chemicals. According to Wade Najjum, EPA inspector general:

> The Agency should have the necessary tools to quickly and efficiently require testing, or obtain other information from manufacturers that is relevant to determining the safety of chemicals, without delays and obstacles currently in place, or excessive claims of confidential business information . . . . TSCA [also] lacks the broad information-gathering and enforcement provisions equivalent to other major environmental statutes. For example, TSCA lacks the administrative authority to seek injunctive relief, issue administrative orders, collect samples, and quarantine and release chemical stocks, among other key authorities. For these reasons and others, there is a compelling case that TSCA must be updated and strengthened.[13]

My testimony also identifies a number of ways to strike a better balance between fostering innovation and protecting public health in the context of protections for confidential business information. In recent years EPA has taken several steps to increase transparency, including reviewing information marked as confidential in health and safety study submissions and declassifying such information when in fact it belonged in the public sphere all along.[14] EPA also has made efforts to encourage voluntary declassification by companies and has published guidance on when confidentiality claims are inappropriate in health and safety studies.[15] More administrative actions to increase transparency should include:

- Giving the public tools to keep better track of the number of claims made for confidential business information, particularly claims made to keep the identities of chemicals secret;
- Requiring justification and substantiation of these claims;
- Requiring re-substantiation of the claims after a period of time; and
- Establishing a presumption that protections for confidential business information will sunset after a period of time unless companies show that protection is still warranted.

However, once again, EPA's efforts to make more of its existing authority under TSCA have been met with vigorous opposition from the chemical industry. Consider a statement made in 2012 by Lawrence Sloan, president of the Society of Chemical Manufacturers and Affiliates, who said that EPA efforts to revise protections for confidential business information could have "significant implications" and "should not be taken lightly."[16]

Congressional action would be required to achieve other necessary improvements to the confidential business information section under TSCA, including:

- Giving EPA authority to impose stronger penalties against companies that make unjustified and overbroad claims of confidential business information;
- Allowing EPA to assess fees for each confidentiality claim made by companies to defray the costs of assessing and auditing whether the information indeed constitutes confidential business information; and
- Making it easier for EPA to share confidential business information with third parties to protect public health and the environment, particularly state and local authorities, first responders, and medical professionals.

2. You state that in contrast to an EPA employee, "a company faces little risk if it abuses confidential business information provisions under TSCA."

a. Does this mean you would support penalties for anyone who abuses CBI, including Third Parties that publish CBI claimed materials?

TSCA already has penalty provisions in place for EPA employees who improperly disclose information designated as confidential.[17] EWG is unaware of any instances where EPA has improperly disclosed such information, suggesting that the criminal penalties for the disclosing party are deterring agency officials from revealing sensitive business information obtained under TSCA to third parties, including state and local regulators, first responders, and medical providers. EWG's view on penalties for third-party disclosure depends on how and whether TSCA's confidential business information provisions are reformed. For example, would penalties be waived if the third party disclosed the information to protect public health? Would penalties be waived if the third party showed that the information had been obtained through reverse engineering or had been publicly disclosed pursuant to other regulatory frameworks at the state level or abroad? Without question, TSCA's provisions protecting confidential business information favor the chemical industry over the public's interest in disclosure. For example, EPA's Office of Inspector General reviewed protections for confidential business information in 2010 and found EPA's procedures for handling confidential business information requests are predisposed to protect industry information rather than to provide public access to health and safety studies.[18] This balance must be recalibrated to increase protections for public health and the environment.

3. **Your testimony, by noting TSCA gives EPA just 90 days to review a Pre-manufacture Notice (PMN) for a substance before it goes on the market, implied this leads to poor decision making by EPA. It's my understanding that the regulatory procedures that accompany this provision require EPA to merely *take* action within 90 days, but those actions include options such as requesting an extension or even rejecting the PMN. As a result, the time it takes for final EPA approval can often be much longer than 90 days – and, in fact, may even be years (during which period of time the product cannot be placed on the market). What is your understanding of, or experience with, the PMN review period, especially for substances that fall into EPA categories of concern?**

Although EPA can extend its review of a chemical, TSCA requires EPA to show good cause to do so, and such decisions are subject to judicial review.[19]

4. **Your statement made several assertions about the lack of testing chemicals under TSCA's new chemicals program, including that:**

   a. **EPA faces a Catch-22 when it comes to new chemicals. The agency cannot request additional data unless it has safety concerns and it cannot adequately address safety concerns without relevant testing data.**
   b. **EPA, with no test data to evaluate the safety of a new chemical, must use computer models, incomplete chemical comparisons and other analyses to predict how it may affect human health and the environment.**
   c. **EPA models and estimates are based on data about previously studied chemicals, not necessarily how a new chemical will be behave.**

   Based on this testimony:

   i. **Do you acknowledge that EPA can and does indirectly require companies to test new chemicals under its PMN program?**

The lack of test data submitted with PMNs is well documented.[20] Further, EPA rarely requests additional data.[21] In 2010, EPA's Office of the Inspector General estimated that 50 percent of PMN submissions have no test data; 85 percent contain no toxicity data.[22] At the same time, EPA cannot readily require that chemical companies develop test data to include in their PMNs. When EPA lacks information to evaluate a new chemical, it may restrict the use of that substance pending the development of additional information only when it substance "may present an unreasonable risk of injury to health or the environment,"[23] or when the substance is "anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure."[24] As explained above, EPA often needs the information it is seeking to determine whether a chemical may present such a risk. As for the exposure prong, EPA may lack complete information about what a chemical's actual use will be once on the market because chemical companies are not bound to follow the production and use descriptions included in their PMNs.

ii. **Do you dispute that EPA's evergreen guidance/Q & As/website on its new chemicals program, for example, make clear that EPA can decide not to approve a PMN without more data/information or to approve a PMN but regulate it more stringently on the basis of default assumptions in the absence of data? See: http://www.epa.gov/oppt/newchems/pubs/qanda-newchems.pdf and http://www.epa.gov/opptintr/newchems/pubs/possible.htm.**

EPA reviews PMNs for evidence that a chemical may present an unreasonable risk to health. Although EPA can make such a finding, its efforts to do so often are hindered by a lack of meaningful data to evaluate the chemical and its potential uses. As stated in EPA's Draft "Questions and Answers Document for the New Chemicals Program," there is no requirement that PMNs contain a "minimum data set" to establish a floor amount of information about a chemical.[25] Further, companies only have to include the data they have in their possession or control.[26]

iii. **Please explain the intersection of your statement with the provisions of TSCA Section 5(e), authority, which allows EPA to impose testing requirements on new chemicals after they are first, introduced into commerce?**

Section 5(e)(1)(A) of TSCA states that EPA may restrict or regulate a new chemical lacking data only when the substance "may present an unreasonable risk of injury to health or the environment"[27] or when the substance is "anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure."[28] Both of these thresholds are difficult to meet based on the limited amount of information typically included in PMNs.

EPA has had a hard time taking proactive steps to protect public health and the environment when there are data gaps with respect to a chemical's toxicity.[29] Congress must amend TSCA to make it easier for EPA to demand that companies conduct and disclose more testing before allowing a chemical on the market. GAO has concluded:

> Although EPA has reviewed new chemicals in a timely manner, its process does not ensure that their potential risks are fully assessed before they enter commerce, EPA usually has few if any test data, and it predicts chemicals' potential effects with mixed results. In addition, the data that EPA uses to assess exposure may change substantially after manufacture begins.[30]

5. **Please explain why and how you differ with your perspectives of former EPA officials, who have noted the scientifically robust nature of predictive analyses – such as SAR, read-across, PBT profilers – for determining whether a new chemical may present an unreasonable risk?**

The lack of toxicity data, coupled with the amount of information designated as confidential, makes it difficult for EWG and others outside of the agency to fully assess how well EPA identifies and responds to the risks posed by new chemicals during the PMN review process. The

staggering number of data gaps for most chemicals makes it virtually impossible to evaluate the robustness of EPA's predictive modeling tools. According to the Organisation for Economic Co-operation and Development (OECD), which reviewed EPA's predictive modeling capacity in 1994, the models have "good predictive capabilities for ecotoxicity, but [ ] limited predictive capabilities for general systemic health effects."[31] More recently, GAO found that EPA modeling can be "problematic because the models are not always accurate in predicting chemical properties," particularly when little information is available about chemicals with similar molecular structures.[32]

To demonstrate the limitations of EPA's new chemical review program, consider the case of Firemaster 550. In 2003, EPA approved the substance as a suitable replacement for the fire retardant Penta PBDE.[33] EPA concluded that Firemaster 550 was "not persistent, bioaccumulative or toxic to aquatic organisms."[34] Yet subsequent problems have come to light about the widespread use of Firemaster 550. Component chemicals have been found in the tissues of marine mammals, suggesting bioaccumulation.[35] Furthermore, EPA's review failed to predict worrisome signs of toxicity to human health — including obesity, early puberty, insulin resistance, and disrupted thyroid hormone signaling, as reported in a recent academic study.[36]

Four former EPA officials note that EPA's predictive modeling tools have played a significant role in EPA's new chemical review. However, these officials go on to urge further refinement of these tools:

> Progress can be made in the future to improve SAR methods using newer insights about toxicology mechanisms and new high throughput technologies for biological assays, as well as providing EPA with additional authority to obtain information when required.[37]

The stakes are high for public health and the environment with respect to new chemicals. That is why Congress must give EPA more authority to compel the development of toxicity data.

6. Your testimony claims that when health and safety data are restricted from disclosure the public pays. However, section 14 specifically provides that EPA "shall disclose [CBI] if the Administrator determines it necessary to protect health or the environment against an unreasonable risk of injury to health or the environment"?

a. Do you dispute that such a provision exists in TSCA section 14(a)(3)?

No. However, showing that an action is necessary to protect against an unreasonable risk of injury to health and the environment is difficult in practice, meaning that it will be used only in the most limited of circumstances.

b. Do you dispute that data from health and safety studies are not protected from release under TSCA section 14(b)?

No. I do not dispute that information from health and safety study submissions are made available to the public. However, this information is virtually useless because the identity of the chemicals in these studies often is kept secret.[38] In 2009, EWG analysis showed that the identity of approximately 17,000, or 20 percent, of the more than 84,000 chemicals on EPA's inventory were designated confidential.[39] As a result, the public cannot take the necessary steps to manage the risks associated with each chemical.

7. Your testimony asserts that 95% of all pre-manufacture notices (PMNs) for new chemicals contain information manufacturers have designated as confidential.

a. Since EPA is the regulator, has the CBI and can review it, and the PMN substances are not in commerce, what is the relevance of this statistic to your testimony?

EPA's new chemicals program staff have access to confidential information. But secrecy claims can limit the access of other scientists within EPA, as well as independent scientists and consumer advocates to information about high-concern chemicals. Consider again the case of Firemaster 550. Dr. Linda Birnbaum, EPA's top expert on fire retardants when Firemaster 550 was reviewed, and now director of the National Institute of Environmental Health Sciences at the National Institutes of Health, expressed concerns that Firemaster 550's ingredients could present health risks similar to those associated with Penta BDE, a flame retardant that was phased out due to toxicity concerns. Firemaster 550's chemical contents were designated confidential under TSCA's provisions for protecting confidential business information. As a result, that information was not readily available for review, apparently even among key EPA officials. According to Dr. Birnbaum, the chemical contents of Firemaster 550 were kept secret from her, even though she was EPA's leading scientist on flame-retardants.[40] Had Dr. Birnbaum and other EPA scientists known the identity of the chemicals in Firemaster 550, the product would likely have faced greater scrutiny from scientists within the agency.

b. Doesn't EPA have the authority not to approve the PMN if the agency is concerned about the potential health or environmental effects of a PMN confidential substance?

Yes, EPA has the authority to limit the use of new chemicals based on information in the PMN regardless of whether it is designated as confidential. However, this does not change the fact that EPA must clear a high threshold to do so, once again based on TSCA's standard that EPA find that a chemical may present an unreasonable risk to health.

c. Can't the agency also approve the PMN but issue a significant new use rule (SNUR) on the chemical if it wants to review the substance again before it is used in any other new application?

Yes, EPA has the authority to issue a SNUR to reevaluate chemicals subsequent to reviewing their PMNs. However, SNURs must be done through lengthy rulemakings, which are costly and take a long time to complete. As a result, practice has shown that EPA uses them infrequently to review chemical substances again. Therefore, EPA's SNUR authority should not be wholly relied on as a cure for the flaws I have identified with respect to the new chemical review program under TSCA.

8. Your testimony applauds EPA for its recent efforts to audit and declassify claims of confidential chemical identity in approximately 900 health and safety studies. As I understand it, EPA's CBI Declassification Challenge to industry actually determined that 11,553 (almost 75%) of 15,752 cases believed to contain CBI, after review, were shown to not contain any CBI at all.

a. Do you dispute that 11,553 of 15,752 cases were found not to contain any CBI?

In 2010, EPA announced a new policy of reviewing health and safety study submissions to declassify information improperly marked as confidential therein.[41] As of Mar. 31, 2013, EPA has reviewed more than 16,200 cases under this policy, looking for health and safety study submissions containing information improperly flagged as confidential and declassifying that information accordingly.[42] Of the 16,2000 cases, 12,043 fell outside of the EPA's parameters of being a health and safety study submission that contains confidential information.[43] Of the 4,258 cases where EPA found information marked as confidential in a health and safety study submission, 909 of them were determined to not to be entitled to confidential treatment.[44] In other words, more than 20 percent of the cases EPA reviewed containing confidential information in a health and safety study submission should have been made public.[45]

b. Does this statistic alter your perception about alleged industry abuses of CBI? If not, why not?

No. This does not allay EWG's views with respect to companies abusing TSCA's protections for confidential business information. Through this initiative, EPA was forced to spend its limited resources and staff time reviewing overbroad and baseless claims made by industry, which kept information out of the public's eye that could be used to identify potential risks associated with chemicals. If anything, EPA's the review underscores the need for upfront substantiation of claims made to keep information confidential and requirements for chemical companies re-substantiate claims after a period of time. Quite often, companies have the ability to reverse engineer their competitors' products, unveiling the names of previously secret chemicals. This creates a situation where it is only the public that is barred access to this information, as well as state and local regulators, medical professionals, academic researchers, and public interest groups.

I also should note the exponential use of TSCA's protections for confidential business information. When the first TSCA inventory was compiled early in the 1980s, approximately 5 percent of the chemical identities included in the inventory were claimed confidential.[46] However, as time has progressed, this number has skyrocketed to include nearly two-thirds of the 20,403 new chemicals added to the list in the past 33 years.[47] The public only has access to the generic names for these chemicals substances.[48]

The Honorable Henry A. Waxman

1. Does the Environmental Working Group still support placing the burden on manufacturers to demonstrate that their products do not pose risks to consumers, workers, hotspot communities, and vulnerable populations?

Yes. EWG believes that manufacturers should have the burden of ensuring the safety of their chemicals *prior* to being placed on the market. Not only does this make sense in terms of protecting public health and the environment, but also in terms of achieving greater efficiency. After all, manufacturers often are in the best position to identify and assess the hazards posed by the chemical substances they produce, as well as the eventual chemical uses. Current law places the burden of assessing chemical hazards on EPA, but the agency is constrained by incomplete data and the fact it cannot readily demand that companies develop safety data. As a result, many chemicals end up on the market that have not been adequately reviewed for safety, thus causing consumers, workers, hot spot communities and other vulnerable populations to bear the burden and risks these chemicals pose to health and the environment.[49] Any meaningful reform of TSCA must create a framework that fundamentally shifts the burden to chemical companies to assess the safety of chemicals.

In addition, companies should have to provide EPA information to show that a chemical can be used with reasonable certainty of no harm. In 1996, Congress passed the Food Quality Protection Act (FQPA) to increase oversight of pesticides to ensure they are safe for people, particularly when pesticide residues are detected on food. One of the hallmarks of the FQPA is its strong safety standard, which requires a finding that a pesticide can be used with "reasonable certainty of no harm," which is far more health protective than TSCA's "unreasonable risk" standard. A reformed TSCA should adopt the safety standard that appears in FQPA. Doing so will go a long way toward ensuring that the chemicals used in consumer products are at least as safe as pesticides. This is particularly critical given the fact that the public is exposed to far more chemicals regulated under TSCA than pesticides.

2. Does the Environmental Working Group still support reducing overclaiming of confidentiality and promoting transparency?

Yes, absolutely. Although EWG recognizes the importance of preserving incentives that spur innovation, particularly in the area of green chemistry, current law allows chemical companies to make overly broad and unsubstantiated claims to protect basic information about the chemicals they produce. This is a great disservice to the public. Further, EPA has limited resources to audit confidentiality claims made by companies and the public is left with few means to evaluate whether they are being given all of the information they need to avoid potentially harmful exposures. The identities of approximately 20 percent of the 84,000 chemicals on EPA's inventory list are treated as confidential,[50] and will likely remain that way without a presumption that confidential claims sunset after a period of time. It is not sufficient that a limited number of officials at EPA have access to such information. In addition, state and local regulators, medical personnel, and first responders must have access to such information, as well. EWG applauds EPA's recent efforts to declassify CBI in health and safety studies, but this is not enough either.

It is abundantly clear that current law must be reformed to strike a better balance between encouraging innovation and protecting public health rather than inviting chemical companies to largely err on the side of secrecy.

3. Should those important principles be included in any effort to reform TSCA?

Yes. Comprehensive reform must include measures that reign in the number of overbroad and unsubstantiated claims made by companies in the name of protecting confidential business information. One of the primary purposes of TSCA is to ensure that adequate data is developed with respect to chemicals.[51] The law's framework for treatment of confidential business information greatly undermines that purpose. Specifically, it does not require companies to pay fees for the number of claims made or substantiation of those claims. It also does not establish a sunset for claims after a certain number of years absent re-substantiation. As long as companies readily withhold important information about chemicals – save for allowing just a tiny handful of EPA employees access to such information – then the more likely it is that chemical risks may fly under the radar until it is too late. This is unacceptable.

4. What other reforms are essential to include in TSCA reform if the statute is to be made effective and protective for everyone, including vulnerable populations?

Comprehensive reform must address a number of critical flaws found in current law. First, EPA must be given authority to review all chemicals in production and use, including those grandfathered in when TSCA was enacted in 1976. Second, the current safety standard, which requires EPA to show that a chemical presents an unreasonable risk, places too heavy of a burden on regulators to act dutifully to protect vulnerable populations from potentially harmful chemical exposures. A reformed TSCA should have a health based safety standard like "reasonable certainty of no harm," which has been the law for pesticides since 1996. Third, manufacturers should be required to submit minimum amounts of toxicity data to ensure that EPA has at least a baseline level of knowledge to assess a chemical's risks. Fourth, EPA should be given greater authority to demand additional testing from companies to fill in any gaps. Fifth, hard deadlines are needed prevent unnecessary delays in the review process. Sixth, more emphasis should be placed on protecting vulnerable populations, for example, allowing EPA to exercise greater caution when chemicals are detected in the cord blood of newborn babies. Seventh, courts need to be directed to give more deference to EPA when it determines that a chemical presents an actionable risk to public health and the environment. Eighth, EPA must have authority to readily ban chemicals such as asbestos that are clearly known are harmful to human health. Finally, we need a law that preserves a complementary relationship between EPA and state and local authorities in an effort to ensure that chemicals are in fact safe.

5. Are those reforms included in the bill recently introduced in the Senate to reform TSCA?

No. The Chemical Safety Improvement Act, S. 1009, is critically flawed, lacking many of the key reforms needed to fix our broken federal toxics law. Although the bill would achieve some improvements, it retains some of the worst features of current law while blocking state and local

efforts to complement EPA's efforts to ensure that chemicals are safe. As a result, the bill in some ways would create a framework that is worse than the one we have under TSCA. For example, the bill perpetuates a weak safety standard and heightened standard of judicial review while blocking many new and existing state laws designed to protect the public from harmful chemical exposures. This cannot be the reform we have been waiting for.

6. Does the Environmental Working Group have concerns about that bill?

There are a host of reasons why EWG believes the Chemical Safety Improvement Act, S. 1009, is an unacceptable vehicle for reforming federal toxics law. EWG's concerns are shared by dozens of other public health and environmental groups, as well as legal experts. In June 2013, EWG sent to Sens. Barbara Boxer and David Vitter several letters signed by these parties that identify some of the most fundamental problems with the bill. Please find copies of these letters in Exhibit A. I have also attached a detailed memorandum (Exhibit B) outlining EWG's concerns with the bill, including its weak safety standard, failure to protect vulnerable populations, its state preemption provisions and its limit on private tort actions.

The TSCA reform principles espoused by the American Chemistry Council (ACC) and EPA suggest the two may have concerns about the Chemical Safety Improvement Act, as well.[52] For example, both the ACC and EPA underscore the need to ensure that EPA has sufficient resources to effectively implement and utilize its authority to regulate chemical safety. The Chemical Safety Improvement Act does not mention fees or cost-sharing — critical components of making sure EPA can accomplish its tasks under federal toxics law. The EPA's principles also state that "manufacturers should be required to provide sufficient hazard, exposure, and use data for a chemical to support a determination by the Agency that the chemical meets the safety standard." However, the Chemical Safety Improvement Act does not require companies to submit a minimum data set placing the burden on EPA to get necessary data from manufacturers. Even the ACC says that companies throughout the chain should be responsible for providing necessary information.

7. At the July 11, 2013 hearing, industry witnesses testified that current disclosures, including structurally descriptive, generic chemical names are sufficient for consumer. Do you agree with that statement?

No. EWG does not agree with that statement. Unnecessary secrecy claims do not serve the public's interest because it shields the ability of public advocates, local and state officials, and scientists from examining the harmful effects of chemicals on the TSCA inventory. To underscore this point, please consider again the example of Firemaster 550. The components of this flame retardant mixture were originally marked as proprietary, therefore the public and independent researchers did not know their identity. However, had this information been known there would have been a clear cause for concern. It was later discovered that one of the chemicals used in Firemaster 550 is bis(2-ethylhexyl) tetrabromophthalate (TBPH). This compound is a brominated version of the known reproductive toxicant bis(2-ethylhexyl)phthalate (DEHP). The other components of Firemaster 550 have little safety information but recent studies have raised

concern that they may disrupt hormone signaling. These discoveries have all been made after Firemaster 550 went to market allowing time for significant human exposure.

8. Do these redacted notices provide enough information for consumers to make informed choices and avoid these chemicals if they so desire?

No. These redacted notices merely put consumers on notice that there are unknown chemicals in use or production that may cause serious health consequences (e.g., severely dysfunctional pathological changes), denying them the ability to avoid exposure by masking information that would allow identification of the referenced chemicals. Allowing redaction of notices in this way unnecessarily puts the public at great risk.

9. **Like many in the public interest community, the Environmental Working Group has sought up-front substantiation of confidentiality claims. In your view, should substantiation like this be sufficient? [Exhibit]**

No. There is no factual basis provided in the exhibit to support such a conclusory statement that disclosing the chemical's identity would harm efforts to commercialize the chemical. If this is all a company has to provide to designate information in health and safety studies as confidential then the public may be put at great risk. For example, the limited toxicity testing described in the exhibit reports that "severely dysfunctional pathological changes" of male and female reproductive organs were observed in addition to adverse hematological effects. This indicates that it is important for the identity of the chemical to be revealed to the public. We believe that secrecy claims must be substantiated upfront with an actual basis. EPA also should require secrecy claims to be re-evaluated periodically, to ensure the fewest restrictions to chemical information while protecting the ability to innovate.

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[1] 15 U.S.C. § 2604; 40 C.F.R. §§ 720.40, 720.75.
[2] See Richard A. Dennison, Ten Essential Elements in TSCA Reform, 39 Envtl. L. Reporter 10020, 10024 (2009), http://www.edf.org/sites/default/files/9279_Denison_10_Elements_TSCA_Reform_0.pdf ("[M]ajor constraints" associated with EPA's ability to review PMNs include the fact that "TSCA grants EPA typically one bite at the apple—a one-time, 90-day review opportunity.").
[3] Oversight Hearing on the Federal Toxic Substances Control Act: Hearing Before the Sen. Comm. on Envt. & Public Works, 111th Cong. 5 (2009) (statement of John Stephenson, Dir. Natural Res. & Envt., GAO), http://www.gao.gov/assets/130/123792.pdf.
[4] Id.
[5] Id.
[6] Id.
[7] See, e.g., John S. Applegate, Worst Things First: Risk, Information, and Regulatory Structure in Toxic Substances Control, 9 Yale J. on Reg. 277, 285 (1992) ("Adoption of the unreasonable risk standard, in sum, has resulted in extraordinary demands for information concerning the regulation of toxic substances.").
[8] Semiannual Regulatory Flexibility and Semiannual Regulatory Agenda, 75 Fed. Reg. 21,872, 21,873 (Apr. 26, 2010) (shifting focus to address high-concern chemicals).
[9] U.S. Office of Info. & Regulatory Affairs, TSCA Chemicals of Concern List Under Section 5(b)(4) of the Toxic Substances Control Act (2070-AJ70), http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201010&RIN=2070-AJ70# (last visited Aug. 14, 2013).

[10] Press Release, EPA, EPA Administrator Jackson Unveils New Administration Framework for Chemical Management Reform in the United States (Sept. 29, 2009), http://yosemite.epa.gov/opa/admpress.nsf/d985312f6895893b852574ac005f1e40/d07993fdcf801c2285257640005d27a6!OpenDocument.
[11] Oversight Hearing on the Federal Toxic Substances Control Act: Hearing Before the Sen. Comm. on Envt. & Public Works, 111th Cong. (2009) (statement of Lisa P. Jackson, Administrator, EPA), http://www.epw.senate.gov/public/index.cfm?FuseAction=Files.View&FileStore_id=07100a89-d2f0-4298-80af-db5597364928.
[12] Id.
[13] EPA Office of Inspector Gen., EPA Needs a Coordinated Plan to Oversee Its Toxic Substances Control Act Responsibilities 20 (2010) [hereinafter EPA OIG, EPA Needs A Coordinated Plan], http://www.epa.gov/oig/reports/2010/20100217-10-P-0066.pdf.
[14] EPA, Increasing Transparency in TSCA, http://www.epa.gov/oppt/existingchemicals/pubs/transparency.html (last visited Aug. 14, 2013).
[15] Id.
[16] Joe Kamalick, US Chem Leader Warns Against Government Disclosure of Technology, ICIS, Mar. 6, 2012, http://www.icis.com/Articles/2012/03/06/9538825/us-chem-leader-warns-against-government-disclosure-of-technology.html.
[17] 15 U.S.C. § 2613(d).
[18] EPA OIG, EPA Needs A Coordinated Plan, supra note 13, at 26.
[19] 15 U.S.C. § 2604(c).
[20] See EPA OIG, EPA Needs A Coordinated Plan, supra note 13, at 4.
[21] Id.
[22] EPA OIG, EPA Needs A Coordinated Plan, supra note 13, at 6.
[23] 15 U.S.C. § 2604(e)(1)(A)(ii)(I).
[24] Id. § 2604(e)(1)(A)(ii)(II).
[25] EPA Office of Pollution Prevention & Toxics, Draft Questions and Answers Document for the New Chemicals Program, http://www.epa.gov/oppt/newchems/pubs/qanda-newchems.pdf (last visited Aug. 14, 2013).
[26] Id.
[27] 15 U.S.C. § 2604(e)(1)(A)(ii)(I).
[28] Id. § 2604(e)(1)(A)(ii)(II).
[29] Dennison, supra note 2, at 10020 ("In the absence of clear evidence of harm, companies have largely been free to produce and use such chemicals as they've seen fit. This policy contrasts sharply with the 'presumed guilty until proven innocent' approach adopted for pharmaceuticals and pesticides.").
[30] GAO, Toxic Substances Control Act: Legislative Changes Could Make the Act More Effective (1994), http://archive.gao.gov/t2pbat2/152799.pdf.
[31] EPA OIG, EPA Needs A Coordinated Plan, supra note 13, at 6.
[32] GAO, Chemical Regulation: Actions Are Needed to Improve the Effectiveness of EPA's Chemical Review Program (2006), http://www.gao.gov/assets/120/114641.pdf.
[33] Heather B. Patisaul et al., Accumulation and Endocrine Disrupting Effects of the Flame Retardant Mixture Firemaster 550 in Rats: An Exploratory Assessment, 27 J. Biochem. Molecular Toxicology 124, 124-36 (2013).
[34] Press Release, EPA, Brominated Flame Retardants To Be Voluntarily Phased Out (Oct. 3, 2003), available at http://yosemite.epa.gov/opa/admpress.nsf/0/26f9f23c42cd007d85256dd4005525d2?OpenDocument.
[35] James C. W. Lan et al., Temporal Trends of Hexabromocyclododecanes (HBCDs) and Polybrominated Diphenyl Ethers (PBDEs) and Detection of Two Novel Flame Retardants in Marine Mammals from Hong Kong, South China, 43 Envtl. Sci. & Tech. 6944, 6944-49 (2009), http://pubs.acs.org/doi/abs/10.1021/es901408t.
[36] Patisaul, supra note 33.
[37] James V. Aidala Jr., et al., Practical Advice for TSCA Reform: An Insider Perspective (2010), http://www.epw.senate.gov/public/index.cfm?FuseAction=Files.View&FileStore_id=86806f67-e47e-4cf3-9612-550104e7685a.
[38] See EWG, Off The Books: Industry's Secret Chemical (2009) [hereinafter EWG, Off The Books], http://www.ewg.org/sites/default/files/report/secret-chemicals.pdf.

[39] Id. at 2.
[40] Linda Birnbaum, Statement at American Public Health Association Conference Panel Discussion Titled "PBDE Flame Retardants: Case Study in Public Health Protection" (Nov. 9, 2004).
[41] Claims of Confidentiality of Certain Chemical Identities Submitted Under Section 8(e) of the Toxic Substances Control Act, 75 Fed. Reg. 3,462 (Jan. 21, 2010).
[42] EPA, Declassifying Confidentiality Claims to Increase Access to Chemical Information, http://www.epa.gov/oppt/existingchemicals/pubs/transparency-charts.html (last visited Aug. 14, 2013).
[43] Id.
[44] Id.
[45] Id.
[46] EWG, Off The Books, supra note 38.
[47] Id. at 2.
[48] Id. at 6.
[49] EWG, Body Burden: The Pollution in Newborns (2005), http://www.ewg.org/reports/bodyburden2/execsumm.php.
[50] Id. at 2; see also EPA, TSCA Chemical Substance Inventory, http://www.epa.gov/oppt/existingchemicals/pubs/tscainventory/ (last visited Aug. 14, 2013).
[51] 15 U.S.C. § 2601(b)(1).
[52] Am. Chem. Council, 10 Principles for Modernizing TSCA, http://www.americanchemistry.com/Policy/Chemical-Safety/TSCA/10-Principles-for-Modernizing-TSCA.pdf (last visited Aug. 15, 2013); EPA, Essential Principles for Reform of Chemical Management Legislation, http://www.epa.gov/opptintr/existingchemicals/pubs/principles.html (last visited Aug. 15, 2013).

EXHIBITS

EXHIBIT A: **Sign-On Letters Expressing Concerns with Chemical Safety Improvement Act**

EXHIBIT B: **EWG Memorandum on Differences Between Chemical Safety Improvement Act and Safe Chemicals Act**

June 12, 2013

Senator Barbara Boxer
Chairman
Environment & Public Works Committee
410 Dirksen Senate Office Building
Washington, D.C. 20510

Senator David Vitter
Ranking Member
Environment & Public Works Committee
456 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Chairman Boxer and Ranking Member Vitter:

We the 24 undersigned environmental and occupational health, environmental justice, and public interest organizations have worked for decades to reform the Toxic Substance Control Act and protect the public from the hazards of chemical exposure.

We respect and appreciate the current effort to identify areas of bipartisan compromise and consensus on chemical safety legislation. However, we believe that the resulting Chemical Safety Improvement Act, S. 1009, has serious limitations and would fall far short of our shared goal of safeguarding human health from the risks posed by exposure to toxic chemicals. As a result, we will oppose this bill as it is currently written unless it is amended to address our key concerns.

The proposed CSIA would fail to provide a policy framework essential to securing much-needed health protections that have been lacking for nearly 40 years under current law. The compromise measure, if passed in its current form, could undermine a number of state protections, including California's Proposition 65 law, without ensuring any real improvement in federal toxic substances controls. CSIA could have a crippling effect on every state's freedom to regulate toxic chemicals and protect its own residents. Many of our organizations have fought for and helped enact state laws restricting the use of hazardous chemicals in consumer products. Most other major federal environmental laws allow states to take more aggressive action to protect citizens from environmental threats. CSIA, in contrast, may actually preempt state laws requiring warning labels on toxic products. Furthermore, the bill may also prevent private citizens from taking action in state or federal court for harm and injury caused by chemical exposure.

We are also troubled by the fact that CSIA would not explicitly protect pregnant women and children. It would not require EPA to consider the cumulative burden of chemical pollution for residents of highly polluted communities and for workers, which is essential for Americans living and working in or near contaminated industrial and military sites; including many in Louisiana, New Jersey, Indiana, Alaska, and California.

In addition, the CSIA would not require that chemicals be shown to be safe before manufacturing begins. EPA would still face the daunting challenge of rapidly assessing thousands of industry submissions on new chemicals, the majority of them containing absolutely no health and safety data. Moreover, the agency would be required to justify any requests for safety testing and would be allowed to grant chemical companies permission to begin production before it completes its safety determination. This practice of "conditional registration" has been widespread in EPA's

pesticides program, which has allowed thousands of pesticides to sidestep important aspects of the traditional approval process.

The proposed bill would do no better at setting up a system to protect the public from the hazards of the 84,000 chemicals already on the market. Overall, it would set a high bar for EPA to enact any restrictions on chemicals, and the burden would remain on the agency to prove that chemicals are harmful, rather than requiring manufacturers to prove they are safe.

CSIA would retain TSCA's current weak safety standard instead of the more protective standard previously proposed by Sen. Lautenberg in his Safe Chemicals Act. Furthermore, it would set no clear timelines to ensure that EPA assesses hazardous chemicals in a timely manner, and it would not establish a quick timeframe for action on chemicals known to be hazardous to human health, including persistent, bioaccumulative toxins.

Finally, the bill would offer too many secrecy protections for chemical companies and may limit the ability of doctors, nurses, first responders and public health departments to obtain vital information about a particular substance to identify and treat people who have been injured by these so-called "secret chemicals."

For these and other reasons the Chemical Safety Improvement Act is not acceptable in its current form. We look forward to working with you to pass legislation that makes public health a priority.

Sincerely,

Pamela K. Miller
Executive Director
Alaska Community Action on Toxics

Robyn O'Brien
Founder
AllergyKids Foundation

Linda Reinstein
President
Asbestos Disease Awareness Organization

Jay Feldman
Executive Director
Beyond Pesticides

Annie Sartor
Policy and Campaigns Coordinator
Breast Cancer Action

Jeanne Rizzo
President
Breast Cancer Fund

Catherine A. Porter
Policy Director
California Healthy Nail Salon Collaborative

Sean Moulton
Director, Open Government Policy
Center for Effective Government

Lois Gibbs
Executive Director
Center for Health, Environment & Justice

Barbara Warren
Executive Director
Citizens' Environmental Coalition

Davis Baltz
Precautionary Principle Project Director
Commonweal

Judy Braiman
President
Empire State Consumer Project

Ken Cook
President
Environmental Working Group

Lisa Archer
Director, Food and Technology Program
Friends of the Earth U.S.

Denny Larson
Executive Director
Global Community Monitor

Rick Hind
Legislative Director
Greenpeace

Gigi Lee Chang
Chief Executive Officer
Healthy Child, Healthy World

Lin Kaatz Chary
Indiana Toxics Action

Paul Ryder
Assistant Director
Ohio Citizen Action

Kristin S. Schafer
Policy & Communications Director
Pesticide Action Network

Eric Uram
Executive Director
Safeminds

Kathy Burns
Sciencecorps

Judi Shils
Executive Director
Teens Turning Green

Erin Switalski
Executive Director
Women's Voices for the Earth

June 12, 2013

The Honorable Barbara Boxer
Chairman
Committee on Environment & Public Works
410 Dirksen Senate Office Building
Washington, DC 20510

The Honorable David Vitter
Ranking Member
Committee on Environment & Public Works
456 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairman Boxer and Ranking Member Vitter:

The undersigned are thirty-four law professors, legal scholars, and public interest lawyers from across the country who have years of collective experience in the fields of administrative, public health, and environmental law, with a particular focus on state and federal toxics policy. We write to express serious reservations with the "Chemical Safety Improvement Act," which was introduced by Sen. David Vitter and the late Sen. Frank Lautenberg on May 22, 2013. Supporters have heralded the bill as a "historic step" toward reforming our broken framework for regulating chemicals on the market. However, for reasons explained herein, we cannot support the bill as written, which must be strengthened to fix current law and ensure that chemicals are safe for people, particularly vulnerable populations such as children.

In our expert opinion, the bill:

• Essentially preserves the same inadequate safety standard used in current law, which has been read by at least one court to require the U.S. Environmental Protection Agency (EPA) to engage in an onerous balancing of costs and benefits to justify restrictions on toxic chemicals;

• Retains the same obstructive standard of judicial review that appears in current law, which requires judges to demand substantial evidence from EPA to justify any safety determination or restriction of a chemical that poses risks to public health and the environment;

• Contains sweeping preemption language that would prevent states from enforcing existing, and adopting new, laws designed to supplement federal law in protecting people and the environment from exposures to harmful substances; and

• Takes the extraordinary step of making any safety determination by EPA dispositive on the question of whether a chemical is safe in federal and state courts. This would effectively bar judges and juries from taking into account other relevant evidence regarding the safety of a chemical, particularly new evidence developed after the determination is made.

Here are our four major concerns presented in detail:

Safety Standard. The bill defines "safety standard" as one that "ensures that no *unreasonable risk* of harm to human health or the environment will result from exposure to a chemical substance." Chemical Safety Improvement Act, S. 1009, 113th Cong. § 3(16) (emphasis added). This definition fundamentally reproduces the same safety standard found in current law.

*See*Toxic Substances Control Act § 6(a), 15 U.S.C. § 2605(a). Unlike strictly health-based standards (*e.g.*, "reasonable certainty of no harm"), laws that use "unreasonable risk" language have been interpreted to require EPA to complete a complex balancing of costs and benefits before the agency can impose a restriction on a chemical to address safety concerns. *E.g.*, John S. Applegate, *Synthesizing TSCA and REACH: Practical Principles for Chemical Regulation Reform*, 35 Ecology L.Q. 721 (2008); *see also* Noah M. Sachs, *Jumping the Pond: Transnational Law and the Future of Chemical Regulation*, 62 Vand. L. Rev. 1817 (2009). Therefore, even without language in the safety standard directing EPA to restrict a chemical using the "least burdensome requirements," Toxic Substances Control Act § 6(a), 15 U.S.C. § 2605(a), by retaining the "unreasonable risk" language, the Chemical Safety Improvement Act might be read to place a heavy burden on EPA to impose even modest restrictions on a chemical. As a result, we believe that the same outcome in *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (5th Cir. 1991) (striking down EPA asbestos ban and phaseout rule) could be possible under the safety standard proposed in this bill, particularly with the heightened judicial review discussed in the next paragraph.

Judicial Review. Courts typically use a reasoned decisionmaking standard to review agency actions, meaning they will not strike down a regulation unless an agency has acted in an arbitrary or capricious manner. *E.g.*, *Allied Local & Regional Reg'l Mfrs. Caucus v. EPA*, 215 F.3d 61, 77 (D.C. Cir. 2000) (EPA consideration of factors listed in statute "adequate to constitute reasoned decisionmaking"); *see also* Administrative Procedure Act, 5 U.S.C. § 706. In contrast, the Chemical Safety Improvement Act, like the Toxic Substances Control Act, would require courts to apply a heightened standard of judicial review when evaluating rules made pursuant to the bill. Specifically, courts would have to set aside rules requiring the development of more test data, safety determinations, and restrictions on chemicals unlikely to meet the safety standard if, in their opinion, EPA has not supported them with "substantial evidence." Chemical Safety Improvement Act, S. 1009, 113th Cong. § 16(2). In practice, this standard can be read to "impose[ ] a considerable burden" on EPA to develop a record that can withstand a hard look from courts, particularly when all of the other procedural hurdles in the bill are factored in. *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1214 (5th Cir. 1991), quoting *Mobile Oil Co. v. Fed. Power Comm'n*, 483 F.2d 1238, 1258 (D.C. Cir. 1973).

Preemption. The Chemical Safety Improvement Act would appear to largely preempt state regulations designed to protect public health and the environment from exposure to harmful chemicals. It would preempt existing and future state regulations that: require the development of test data or information on chemicals for which companies have to submit similar information to EPA; restrict the manufacture, processing, distribution, or use of a chemical after EPA has issued a safety determination for that chemical; or require notification for the use of a chemical substance if EPA has determined that it is a significant new use that must be reported to the agency. Chemical Safety Improvement Act, S. 1009, 113th Cong. § 15(a). The bill also would prohibit states from creating new restrictions on the manufacture, processing, distribution, or use of a chemical that EPA has classified as high- or low-priority. *Id.* § 15(b). This preemption provision is sweeping in nature and raises serious questions as to whether states could even enact or continue to enforce laws that simply require companies to disclose information about chemicals to consumers or require that products carry warning labels. Numerous states have passed laws in recent years in the absence of federal regulatory action to protect the public from

toxic chemicals. *E.g.*, Safer Chemicals Healthy Families, *Healthy States: Protecting Families from Toxic Chemicals While Congress Lags Behind* (2010), http://www.saferstates.com/attachments/HealthyStates.pdf. If this bill were to become law, it would perpetuate many of the Toxic Substances Control Act's shortcomings while preventing states from protecting public health and the environment in the absence of a robust federal law — or in the case of a strong federal regulatory framework, from complementing EPA's efforts to achieve this important goal.

Private Remedies. The bill takes the extraordinary step of making a safety determination by EPA admissible in any federal or state court and dispositive as to whether a chemical substance is safe. Chemical Safety Improvement Act, S. 1009, 113th Cong. § 15(e). As a result, the bill's section on private remedies could significantly encroach on the right of judges and juries to evaluate and weigh relevant evidence regarding the potential injuries caused by toxic chemicals. In turn, this could have the effect of granting chemical companies immunity from legal actions by private parties once EPA has issued a positive safety standard determination, even when subsequent evidence calls into question the agency's reasoning.

In view of these issues, and others identified by public health and environmental groups, we believe the Chemical Safety Improvement Act preserves some of the most problematic features of the Toxic Substances Control Act, while making it harder for state and private actors to ensure the safety of chemicals in the absence of a strong federal backstop for regulating these substances. As a result, the bill, as currently drafted, takes a step backward in the protection of public health. We respectfully ask that the bill be made stronger to achieve meaningful reform of current toxics law and are available to provide substantive recommendations as needed.

Sincerely,

Note: Institutions listed for identification purposes only. The signators do not purport to represent the views of their institutions.

John S. Applegate
Walter W. Foskett Professor of Law
Indiana University Maurer School of Law

Nicholas A. Ashford, Ph.D., J.D.
Professor of Technology and Policy and Director, MIT Technology & Law Program
Massachusetts Institute of Technology

Hope Babcock
Professor of Law and Co-Director, Institute for Public Representation
Georgetown University Law Center

William W. Buzbee
Professor of Law
Emory Law School
Visiting Professor of Law
Georgetown University Law Center (Fall 2012)

Charles C. Caldart
Lecturer in Environmental Law and Policy
Massachusetts Institute of Technology
Director of Litigation
National Environmental Law Center

Alejandro E. Camacho
Professor of Law and Director, Center for Land, Environment, & Natural Resources
University of California, Irvine

Cinnamon P. Carlarne
Associate Professor of Law
Ohio State University Michael E. Moritz College of Law

David W. Case
Associate Professor of Law
University of Mississippi School of Law

Thomas Cluderay
General Counsel
Environmental Working Group
Adjunct Professor of Law
Georgetown University Law Center

Carl F. Cranor
Distinguished Professor of Philosophy and Faculty Member, Environmental Toxicology
University of California

David M. Driesen
University Professor
Syracuse University College of Law

Stephen Dycus
Professor of Law
Vermont Law School

Angelique Townsend EagleWoman (Wambdi A. WasteWin)
Associate Professor of Law and James E. Rogers Fellow in American Indian Law
University of Idaho College of Law

Adam M. Finkel, Sc.D.
Senior Fellow and Executive Director
Penn Program on Regulation University of Pennsylvania Law School *Professor of Environmental and Occupational Health* University of Medicine and Dentistry of New Jersey School of Public Health

Victor Flatt
Tom and Elizabeth Taft Distinguished Professor of Law and Director, Center for Law, Environment, Adaptation, & Resources (CLEAR) University of North Carolina School of Law
Distinguished Scholar of Carbon Markets Global Energy Management Institute University of Houston

Steve C. Gold
Associate Professor of Law
Rutgers University School of Law - Newark Rutgers, The State University of New Jersey

Carmen G. Gonzalez
Professor of Law
Seattle University School of Law

Lisa Heinzerling
Professor of Law
Georgetown University Law Center

Oliver Houck
Professor of Law
Tulane University School of Law

Howard A. Latin
Distinguished Professor of Law and Justice John J. Francis Scholar
Rutgers University School of Law Rutgers, The State University of New Jersey

Albert Lin
Professor of Law
UC Davis School of Law

Mary L. Lyndon
Professor of Law
St. John's University School of Law

Thomas O. McGarity
Joe R. and Teresa Lozano Long Endowed Chair in Administrative Law
University of Texas School of Law

Joel A. Mintz
Professor of Law
Nova Southeastern University Law Center

Joseph A. Page
Professor of Law
Georgetown University Law Center

Rick Reibstein
Adjunct Professor
Boston University
Faculty
Harvard Extension School

John Rumpler
Senior Attorney
Environment America

Noah Sachs
Professor of Law
University of Richmond School of Law

Sidney A. Shapiro
University Chair in Law
Wake Forest University

Amy Sinden
Professor of Law
Temple University Beasley School of Law

William Snape
Fellow and Practitioner in Residence
American University Washington College of Law

Rena Steinzor
Professor of Law
University of Maryland School of Law

Robert R.M. Verchick
Gauthier-St. Martin Chair in Environmental Law
Loyola University New Orleans

Wendy Wagner
Joe A. Worsham Centennial Professor
University of Texas School of Law

June 12, 2013

Senator Barbara Boxer
112 Hart Senate Office Building
Washington, D.C. 20510

Dear Senator Boxer:

As organizations that have fought for decades to protect Californians from the dangers of toxic chemicals, we are writing to express our serious concerns about the Chemical Safety Improvement Act (CSIA) introduced by Senators David Vitter and the late Frank Lautenberg.

While the Toxic Substances Control Act (TSCA) is highly flawed and in desperate need of an overhaul, it is critical that any reform measure provide meaningful protection for our children, communities, workers and other vulnerable populations by fixing TCSA's problems without creating new loopholes and bureaucratic dead-ends. That is the spirit of the toxic chemicals policy reform movement that has gained such dramatic momentum in recent years among consumers, parents, state policy makers and environmentally minded companies. We are extremely disappointed that the Chemical Safety Improvement Act fails to provide the policy framework needed to secure the needed protections and could, if enacted, stymie progress and undermine the long-term push for reform.

Some of our concerns with the bill include a weak safety standard, which on its face allows for "reasonable" injuries to public health from toxic chemicals. The bill contains no clear deadlines for EPA action on or assessment of chemicals, few safeguards for vulnerable populations such as children and pregnant women, and no minimum testing requirements for old or new chemicals. We are also troubled that CSIA does not seem to provide fast action on and special protections from persistent, bioaccumulative and toxic chemicals and does not protect workers or communities disproportionately affected by chemical exposures.

Furthermore, the broad language on state-level preemption could tie California's hands and prevent the state from continuing to be a leader on toxic chemical issues. While the Clean Air Act, the Clean Water Act, TSCA and many other federal environmental laws allow states to take more aggressive action to protect their residents from potential environmental threats, any such action would be severely limited under the Chemical Safety Improvement Act. For these and other reasons, the Chemical Safety Improvement Act is not acceptable in its current form.

We urge you to do all you can to strengthen this draft bill as your committee examines the issue of TSCA reform. We realize that a spirit of compromise is always essential in developing major federal legislation. In the end, however, we must have legislation that explicitly emphasizes the imperative to protect the next generation and beyond from the daily onslaught of chemicals that are polluting our bodies and the planet.

We are deeply grateful for your ongoing commitment to protecting all Americans from dangerous chemicals in their food, air, drinking water, consumer products and workplaces. Your bold leadership on this issue is needed now more than ever.

Sincerely,

Janette Robinson Flint
Executive Director
Black Women for Wellness

Annie Sartor
Policy and Campaigns Coordinator
Breast Cancer Action

Jeanne Rizzo, RN
President
Breast Cancer Fund

Jane Williams
Executive Director
California Communities Against Toxics

Catherine Porter
Policy Director
California Healthy Nail Salon Collaborative

Michael Green
Executive Director
Center for Environmental Health

Bill Magavern
Policy Director
Coalition for Clean Air

James Wheaton
President and Legal Director
Environmental Law Foundation

Ken Cook
President
Environmental Working Group

Martha Dina Argüello
Executive Director
Physicians for Social Responsibility–Los Angeles

Ted Schettler
Science Director
Science and Environmental Health Network

Judi Shills
Executive Director
Teens Turning Green

Jora Trang
Interim Executive Director and Managing Attorney
Worksafe

cc: The Honorable Dianne Feinstein
The Honorable Henry Waxman, Rank Member House Energy & Commerce Committee

ENVIRONMENTAL WORKING GROUP www.ewg.org

MEMORANDUM

Date: June 11, 2013

Re: Key Differences Between Chemical Safety Improvement Act and Safe Chemicals Act

The Chemical Safety Improvement Act takes a dramatically different approach to reforming the federal Toxic Substances Control Act compared to the Safe Chemicals Act, as amended in 2012. This memorandum overviews some of the key differences between the Chemical Safety Improvement Act and the Safe Chemicals Act. Some of those differences include a weaker safety standard, heightened judicial review, lack of minimum data requirements, broad preemption language, lack of fee and cost-sharing provisions, and glaring lack of attention to vulnerable populations and biomonitoring data, among other things. The following comparison is limited by the fact that the Chemical Safety Improvement Act and the Safe Chemicals Act bear very little resemblance to each other. In particular, many of the critical reform provisions that appear in the Safe Chemicals Act, not to mention its predecessor, the Kid-Safe Chemicals Act, are completely missing from the Chemical Safety Improvement Act.

1. **Complete new framework for regulating chemicals compared to Safe Chemicals Act. [Sections 1-2]**

Unlike the Safe Chemicals Act, the Chemical Safety Improvement Act places far less emphasis on whether individual chemicals are safe and focuses very little on the need to protect vulnerable populations.

Title. The name of the bill, the "Chemical Safety Improvement Act," Section 1(a) (p. 1, line 6) [Short Title], emphasizes the issue of chemical safety generally without saying much about the importance of ensuring that individual chemicals are in fact safe. This is a departure from the Safe Chemicals Act, and certainly the Kid-Safe Chemicals Act introduced before that.

Findings. In contrast to the Safe Chemicals Act, the Chemical Safety Improvement Act's findings, policy, and intent section, Section 2 (p. 2), makes no reference to vulnerable populations; the extent to which chemicals burden our bodies as evidenced by biomonitoring studies; increased incidences of diseases and disorders linked to chemical exposures; or the fact that for years the public has been exposed to chemicals that have not been adequately reviewed and may harm human health and the environment. The Chemical Safety Improvement Act's findings suggest that "unmanaged risks," instead of individual chemicals themselves, "may pose a danger to human health and the environment." Section 2(b) (p. 3, line 7-9) [Findings]. The rest of the bill's findings focus on restoring public confidence in federal regulation of chemicals; the importance of chemicals to the economy; and the need for uniform regulation of such substances, among other things.

Missing Themes Throughout. Unlike the Safe Chemicals Act, the Chemical Safety Improvement Act makes no explicit reference in the entire bill to the following terms: "**workers**," "**pregnant**," "**children**," "**kids**," "**aggregate**" or "**cumulative**" exposure. The bill makes one reference to "**bioaccumulation**," "**persistence**," and "**biomonitoring**" in the context of listing the kind of information EPA may consider when developing guidelines for test data. Section 4 (p. 43-44, lines 3-9) [Chemical Assessment Framework, Types of Health & Environmental Data]. The only mention of "**vulnerable**" in the bill is where it mentions "vulnerability of exposed subpopulations" in the context of what kind of exposure information EPA has to consider when conducting a chemical safety assessment. Section 6 (p. 63, lines 3-4) [New Chemicals & Significant New Uses, Hazard, Use & Exposure Information]. (More on this point, the language here indicates that EPA is not being directed to take into account vulnerable populations when assessing hazards, at least not explicitly.)

2. Safety standard substantially less rigorous than one in Safe Chemicals Act [Section 3, 6]

The Chemical Safety Improvement Act's safety standard is defined as a "standard that ensures that no unreasonable risk of harm to human health or the environment will result from exposure to a chemical." Section 3 (p. 9, lines 1-5). This is not a strictly health-based standard like the one used in the Safe Chemicals Act, which, as a matter of law, does not allow for cost-benefit analysis when developing a regulation. Rather, the unreasonable risk language — which is used in current law — has been read to require a cost-benefit analysis because the language implies there is such thing as reasonable or acceptable risk. See John S. Applegate, The Perils of Unreasonable Risk: Information, Regulatory Policy, and Toxic Substances Control, 91 Colum. L. Rev. 261 (1991).

Although the Chemical Safety Improvement Act says that EPA must evaluate whether a chemical meets the safety standard "based solely on considerations of risk to human health and the environment," Section 6 (p. 64-65), this does not change the fact that the safety standard, as defined, still involves some consideration of costs and benefits given the way "unreasonable risk" has been interpreted by the courts and certainly the Office of Management and Budget, which will review any proposed regulatory action by EPA under this bill.

Safe Chemicals Act by Comparison. In contrast, the Safe Chemicals Act would have required EPA to use a far more health-protective standard requiring a showing that there is "reasonable certainty that no harm will result to human health or the environment from aggregate exposure to the chemical substance," SCA Section 7 (p. 100-01), which means that for the safety determination, EPA would not have to consider the benefits of using a particular chemical.

Cumulative and Aggregate Exposures. Finally, note that no reference is made to aggregate or cumulative exposure when applying the safety standard under the Chemical Safety Improvement Act, which are both explicitly mentioned in the Safe Chemicals Act safety standard. Assessing aggregate exposure to chemicals is critical to ensuring public safety and

has been recommended by the National Academy of Sciences. In assessing the safety of a chemical it is necessary to consider exposure from different sources and through different exposure routes. It is also important to consider the cumulative effects from simultaneous exposure to different chemicals that affect the body through the same modes of action (MOA).

3. **Risk management requirements amount to pursuing least burdensome approach like what appears in current law.**
[Section 6]

If EPA determines that a chemical does not meet the safety standard, it must decide which risk-management measures it should take with respect to that chemical. Section 6 (p. 67-72). EPA may pursue a variety of restrictions, including, but not limited to, warnings, use restrictions, production restrictions, phase outs, and bans. Section 6 (p. 67-70). If EPA wants to phase out or ban a chemical, the agency has to conduct and present a careful cost-benefit analysis, including a discussion of technically and economically feasible alternatives, risks posed by each of those alternatives compared to the chemical being considered for regulation, and the economic and social costs and benefits of the proposed restriction compared to potential alternatives, among other things. Section 6 (p. 71-72). Therefore, although the CSIA removes the current law's least-burdensome restriction language, it reads it back into the bill with these requirements to pursue a phase out or ban.

Although the CSIA does not explicitly require the same analysis for other types of restrictions, in practice, it can be expected that EPA will have to perform similar analysis because of the unreasonable risk language in the safety standard. (Once again, this is certainly how the Office of Management and Budget will review any restriction proposed under the CSIA's risk-management provisions.)

In contrast, the Safe Chemicals Act's health-based safety standard does not allow for the same cost-benefit analysis and nothing in the risk-management section of the bill requires EPA to develop a detailed record, studying alternatives, economical and social costs, and the like.

4. **Exemptions allowed without EPA showing 'clear and convincing evidence.'**
[Section 6]

Like the Safe Chemicals Act, the Chemical Safety Improvement Act allows EPA to exempt chemicals from risk management under certain circumstances (e.g., national security interest and avoiding significant economic disruption). However, the Safe Chemicals Act would have required EPA to justify an exemption decision with "clear and convincing evidence," SCA Section 7 (p. 126), whereas the Chemical Safety Improvement Act only says EPA "may exempt the use of a chemical substance from any additional restrictions" if it meets these conditions, with nothing said about EPA's burden of proof to justify the exemption, making

them much more likely. Section 6 (p. 72, lines 4-24) [Safety Assessments & Determinations, Determination Chemical Substance Does Not Meet Safety Standard, Exemptions].

5. **No minimum information set requirements for new chemicals and prioritization. [Sections 4, 5]**

The Safe Chemicals Act had a specific section requiring chemical companies to submit minimum information sets necessary for EPA to evaluate new chemicals, new uses of chemicals, and to evaluate for prioritization, among other things. SCA Section 5 (p. 16) [Minimum Information Sets & Testing of Chemical Substances].

In contrast, the Chemical Safety Improvement Act does not require chemical manufacturers to submit to EPA minimum data sets for new chemicals and chemicals being assessed for safety. It only speaks generally about information EPA may need to evaluate chemicals. E.g., Section 4 (p. 29, lines 17-25 & p. 30, lines 1-4) [Chemical Assessment Framework, Development of New Test Data & Information]. Furthermore, the bill gives EPA the option of letting companies market new chemicals before it has enough information to decide if they are safe. Section 5 (p. 53, lines 11-15) [New Chemical and Significant New Uses, Additional Data and Information].

6. **Broad preemption language. [Section 15]**

The Chemical Safety Improvement Act's section on preemption, Section 15 (p. 114-15), is both explicit and broad in effect and raises serious concerns on its impact of state laws such as California Proposition 65.

The bill states that no state may require additional development of test data or information on a chemical or chemical class for which companies have to submit similar information to EPA (e.g., for EPA chemical assessments). Section 15 (p. 114, lines 10-22) [Preemption]. Under laws such as Proposition 65, regulators have to develop data before listing a chemical or to determine certain safe harbor levels. The Chemical Safety Improvement Act's preemption language raises questions whether states could continue to carry out these steps to develop such data.

The bill goes on to say that no state may create a new, or continue to enforce an existing, restriction on the manufacture, processing, distribution, or use of a chemical after EPA completes a safety determination for that chemical. Section 15 (p. 114, lines 10-25 & 15, lines 1-9) [Preemption]. Further, states are prohibited from creating new restrictions on such chemicals' manufacture, processing, or distribution for chemicals EPA classifies as high- or low-priorities. Section 15 (p. 115, lines 10-24) [Preemption]. At the very least, this language is ambiguous as to whether states could still require companies to disclose to consumers information about chemicals and/or require that products carry warning labels since companies will be likely to argue that "distribution" covers product packaging decisions.

In contrast, the Safer Chemicals Act states that the bill would not affect the ability of individual states to impose additional safety requirements on chemicals, unless complying with state and federal law would be impossible. SCA Section 18 (p. 214).

7. **More protection of confidential business information than in Safer Chemicals Act. [Section 14]**

Chemical identity within health and safety data. In a striking departure from current law, the Chemical Safety Improvement Act would allow information elements—such as chemical identity—within health and safety studies and health and safety data submitted to the EPA in notices of substantial risk to be claimed confidential. Section 13 (p. 99-100).

Grandfathering of claims. The Chemical Safety Improvement Act would grandfather confidential business information (CBI) claims made before enactment, preventing EPA from requiring re-substantiation of such claims, Section 13 (p.113, lines 1-11) [Confidential Information, Applicability], unless the claims covered chemical identities or inventory information for chemicals classified by EPA as high-priority. Section 13 (p. 107, 22-25 lines & 108, lines 1-9) [Confidential Information, Redocumentation].

Access hurdles for Medical Personnel. The Chemical Safety Improvement Act also makes it harder than the Safe Chemicals Act for EPA to share the identity of confidential chemicals to medical personnel when that information is needed for treating patients or managing emergency situations. Section 13 (p. 103-106) [Confidential Information, Exceptions to Protection for Disclosure].

The Safe Chemicals Act would require EPA to disclose upon request confidential information to "public health or environmental health professionals or medical personnel" if EPA found disclosure to be in the public interest; found no conflict of interest or competitive interest on the part of the requester; and obtained a confidentiality agreement from the requester. SCA Section 14 (p. 184-85) [Disclosure of Data, Mandatory Exemptions].

The Chemical Safety Improvement Act makes it harder for public health officials to obtain confidential business information about chemicals from EPA. First, the bill refers to "health professional employed by a Federal or State agency or a treating physician or nurse" in a nonemergency situation rather than using broad language such as "public health officials" or "medical personnel" as the terms appear in the corresponding section of the Safe Chemicals Act. Section 13 (p. 104, lines 17-21) [Confidential Information, Exceptions to Protection for Disclosure]. For emergency situations, the Chemical Safety Improvement Act only allows disclosure treating physicians and nurses, with no mention made of healthcare professionals, regardless of whether they are employed by a federal or state agency. Section 13 (p. 105, lines 18-19) [Confidential Information, Exceptions to Protection for Disclosure].

Second, the Chemical Safety Improvement Act requires EPA to follow more detailed procedures before providing to these parties the confidential information. In nonemergency situations, the requester must first submit a "written statement of need" that contains a reasonable basis to suspect that the information is needed to diagnose or treat someone and that knowledge of the chemical identity will assist with such efforts. Section 13 (p. 104, lines 22-24 & p. 105, lines 1-9) [Confidential Information, Exceptions to Protection for Disclosure]. In emergencies, the bill requires this information to be provided as soon as practicable. Section 13 (p. 106, lines 12-15) [Confidential Information, Exceptions to Protection for Disclosure]. The Safe Chemicals Act did not spell out all of these procedures.

8. **Priority review no longer given to some of most troubling chemicals in use. [Section 4]**

The Safer Chemicals Act specifically focused on the need to make regulating persistent, bioaccumulative, and toxic (PBT) chemicals a top priority. In contrast, the Chemical Safety Improvement Act only mentions concerns about persistence and bioaccumulation in one place where it says EPA has the option of developing test guidelines for use in safety assessments. Section 4 (p. 44, lines 3-9) [Chemical Assessment Framework, Types of Health & Environmental Data & Information].

This same paragraph contains the only reference in the bill to "biomonitoring," where it says EPA may develop test guidelines on the "presence of the chemical substance or mixture in human blood, fluids, or tissue." Section 4 (p. 43-44, lines 3-9) [Chemical Assessment Framework, Types of Health & Environmental Data].

9. **Judges can still require "substantial evidence" from EPA to support rulemaking. [Section 16]**

The Chemical Safety Improvement Act uses the same judicial standard of review that appears in Toxic Substances Control Act, allowing courts to "hold as unlawful and set aside [a] rule if the court finds that the rule is not supported by substantial evidence." Section 16 (p. 122, lines 15-19) [Judicial Review]. As the 5th Circuit noted in Corrosion Proof Fittings v. EPA, 947 F.2d 1201 (1991) (ruling prevented EPA from banning asbestos under TSCA), this standard of review is considered more rigorous and invites considerably more general judicial review than the standard of review used to evaluate rules under other environmental statutes, which only require an agency to show that it acted reasonably. The Safe Chemicals Act would have reformed the Toxic Substances Control Act to replace the substantial evidence standard with a reasonableness standard, SCA Section 19 (p. 214-16).

Further, the Chemical Safety Improvement Act states that safety determinations by the EPA are considered "final agency action," "subject to judicial review." Section 6 (p. 73, lines 3-4) [Safety Assessments & Determinations, Safety Determination, Final Agency Action]. In contrast, the Safe Chemicals Act would have made ineligible for judicial review any safety determination by the EPA, SCA Section 7 (p. 103).

10. **Opportunities for companies to delay review process and absence of clear deadlines.**

Deadlines. Language throughout the Chemical Safety Improvement Act provides no clear deadlines for EPA to complete safety reviews of chemicals, including, but not limited to, EPA's directive to prioritize chemicals and make safety determinations.

The bill directs EPA to "make every effort to complete the prioritization of all active substances **in a timely manner**," Section 4 (p. 18, lines 22-25) [Chemical Assessment Framework, Timely Completion of Prioritization Process] (emphasis added). It also says EPA only has to publish a list of chemicals being considered for prioritization "**from time to time**." Section 4 (p. 19, lines 21-23) [Chemical Assessment Framework, Timely Completion of Prioritization Process] (emphasis added). The bill also gives EPA the opportunity to delay with respect to meeting deadlines for safety assessments and determinations. Section 6 (p. 59, lines 16-24) [Safety Assessments & Determinations] ("deadlines . . . may vary among chemical substances to grant the Administrator **flexibility**; and . . . shall allow for **reasonable extensions** after an adequate public justification") (emphasis added). Moreover, it directs EPA to make safety determinations "**as soon as possible**." Section 6 (p. 64, lines 5-11) [Safety Assessments & Determinations, Safety Determination] (emphasis added). Missing are the hard deadlines that appear in the Safe Chemicals Act. E.g., SCA Section 7 (p. 80-81) (EPA must categorize a first batch of chemicals no later than 180 days after issuing categorization and prioritization regulations).

Additional Opportunities for Delay. The bill gives chemical companies a number of opportunities to delay EPA's review of chemicals, as well. For example, if EPA determines that additional test information is needed to make a safety assessment, the agency is directed to "provide an opportunity for interested persons to submit the additional information," but gives no deadlines for that information to be developed. Section 6 (p. 63, lines 9-13) [Safety Assessments & Determinations, Additional Test Information]. In other words, companies would have the option of taking their time to produce this information if they choose to do so, thus delaying the review process.

11. **Lack of fees and cost-sharing provisions.**

Another significant difference between the Chemical Safety Improvement Act and the Safe Chemicals Act is with respect to giving EPA the ability to require fees from chemical manufacturers to help share the cost of reviewing chemicals for safety and managing associated risks. The Safe Chemicals Act would allow EPA to require by rule "payment of a reasonable fee from any person required to submit data to defray the cost" of administering provisions in the bill. SCA Section 23 (p. 221). In contrast, the Chemical Safety Improvement Act has nothing to say about fees or cost-sharing, making it more difficult for EPA to obtain and develop the test data needed to evaluate the safety of individual chemicals.

12. **Lack of authority to regulate new nanomaterials.**

The Safe Chemicals would give the EPA authority to regulate nanomaterials as separate chemical substances by allowing the agency to consider a variant of a chemical substance as a new chemical substance. SCA Section 4 (p. 9). It also would allow the EPA by order or rule to establish the physical, chemical, or biological characteristics, other than molecular identity, that may significantly affect the risks posed by a chemical substance. SCA Section 4 (p. 13).

In contrast, the Chemical Safety Improvement Act fails to update the definition of "chemical substance" that is contained in current law, which limits the differentiation of chemical substances to particular molecular identities.

13. **No sections on hot spots, green chemistry, or children's health research; little emphasis on information sharing with international partners.**

The Safe Chemicals Act had specific sections addressing "hot spots," or locations with disproportionately higher exposure levels to chemicals, SCA Section 34 (p. 238); creating a children's environmental health research program, SCA Section 29 (p. 224); spurring the development of safer alternatives through green chemistry, SCA Section 31 (p. 234); and encouraging international cooperation to manage and regulate chemical risks, SCA Section 32 (p. 237).

The Chemical Safety Improvement Act has none of these sections. The only discussion of safer alternatives or safe chemistry appears briefly in two places, see Section 2 (p. 4, lines 10-12) [Findings] ("innovation in the development of new chemical substances, especially safer chemical substances, should be encouraged . . . ."); Section 2 (p. 7, lines 1-5) [Intent] ("implement this Act to protect the health of the people . . . in such a manner as not to unduly impede commerce or create unnecessary economic barriers . . . to innovation, including safer chemistry.").