Summary of Testimony of
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Submitted on June 11, 2013
to
Subcommittee on Environment and the Economy
U.S. House of Representatives
Committee on Energy and Commerce

Regarding a June 13, 2013, Hearing on

"Title I of the Toxic Substances Control Act:

Understanding Its History and Reviewing Its Impact"

The TSCA regulatory process is logical and simple. New chemicals must be notified to EPA and can be allowed into commerce for commercial purposes following the end of a 90-day review period. For any chemical listed on the Inventory, EPA has the authority to gather existing, updated information through various provisions under TSCA Section 8. If that information is believed by EPA to be insufficient to make a risk assessment, EPA is authorized to require manufacturers and/or processors of chemicals to generate additional data under TSCA Section 4. After assessing the information gathered under Section 8 and/or Section 4, if EPA decides regulatory restrictions are needed to abate risks, EPA is authorized under Sections 5 and/or 6 to apply additional risk management controls.

The TSCA Inventory should not be viewed as a list of all chemicals in commerce. Once a chemical is listed, it remains on the list regardless of whether it falls into disuse. A more reasonable measure of TSCA-regulated chemicals in commerce might be the listing of chemicals reported under the Chemical Data Reporting rule under TSCA Section 8.

In the areas under TSCA where regulated entities are required to submit certain notifications or reports, EPA appears to be successful in compiling information needed to conduct risk assessments. EPA has been constrained when trying to use other TSCA authorities, particularly those that require rulemakings, because the current rulemaking process is long and complicated.

Likewise, the existing chemical reviews have not been as successful as the new chemical reviews. EPA could implement a prioritization process for existing chemical review. There is nothing in the legislative language prohibiting that action.

Confidential Business Information is incredibly important. TSCA compels industry to provide a wealth of sensitive data and while there are very legitimate needs for EPA to have this type of information to achieve its statutory goals, there are also very legitimate needs for business to have that information remain confidential.

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Good morning. My name is Kathleen Roberts. I am here today to provide an overview of the regulatory program under the current Toxic Substances Control Act -- a TSCA 101, if you will. Rest assured, my remarks today will not be a comprehensive, in-depth analysis of TSCA, but instead will be a briefing that is intended to assist Committee members to recognize how the various sections of TSCA fit together to provide a comprehensive program for the management of risks from chemicals.

I have spent more than 20 years working with chemical companies to understand and comply with TSCA implementing regulations enforced by the U.S. Environmental Protection Agency (EPA). I was with the American Chemistry Council for 17 years and have been with Bergeson & Campbell, P.C., a Washington, D.C. law firm, for four years where I work as a non-attorney professional. I currently am Vice-President of Bergeson & Campbell, P.C.'s affiliate, B&C Consortia Management, L.L.C., an organization that provides management services to chemical consortia involved in advocacy, research, testing, and communications.

My remarks today are on my own behalf, and do not necessarily reflect the views of my employer or any client of either organization.

General TSCA Overview

TSCA was enacted in 1976. TSCA provides EPA with broad authority to review new chemicals before they are manufactured, gather information on existing chemicals, and regulate chemicals as necessary. TSCA is not the only statute that regulates chemicals. TSCA's scope does not include chemicals used in pesticide active ingredients and products containing pesticides, tobacco, nuclear materials, and food, drugs, and cosmetics because those substances are regulated under other laws.

TSCA Framework

In my view, the TSCA regulatory process is logical and almost elegant in its simplicity. New chemicals must be notified to EPA and can be added to the TSCA Inventory and allowed into commerce for commercial purposes following the end of a 90-day review period. For any chemical listed on the Inventory, EPA has the authority to gather existing, updated information through various provisions under TSCA Section 8. If that information is believed by EPA to be insufficient to make a risk assessment, EPA is authorized to require manufacturers and/or processors of chemicals to generate additional data under TSCA Section 4. After assessing the information gathered under Section 8 and/or Section 4, if EPA decides regulatory restrictions are

needed to abate risks, EPA is authorized under Sections 5 and/or 6 to apply additional risk management controls. I will briefly review these various sections in more detail.

TSCA Inventory

I would like to start with the TSCA Inventory. When TSCA was first enacted, companies informed EPA which chemicals were produced or imported into the United States at that time. The goal was to get an accurate baseline of chemicals in commerce. That list of chemicals resulted in the initial TSCA Inventory, which was issued around 1979. This initial list of chemicals is also sometimes referred to as "grandfathered" chemicals because EPA conducted no assessment of any chemical listed on the initial Inventory. Any chemical subject to TSCA that was developed and marketed AFTER 1979 has gone through a new chemical assessment under TSCA Section 5, which I will briefly cover in a moment.

A common misperception is that the TSCA Inventory is a list of all chemicals in commerce, but that is not accurate. The TSCA Inventory has been added to since 1979, and now contains approximately 83,000 chemicals. Once a chemical is listed, it remains on the list regardless of whether a chemical falls into disuse. Hotel California comes to mind -- you can check out, but you can never leave. It is my belief that a large number of listed chemicals are no longer in production, but they nonetheless remain listed on the Inventory.

A more reasonable measure of TSCA-regulated chemicals in commerce might be the listing of chemicals reported under the Chemical Data Reporting (CDR) rule under TSCA Section 8. That listing includes all chemicals manufactured in the United States in quantities over 25,000 pounds at a site per year. Admittedly, that does not include chemicals manufactured at lower levels or chemicals that might be exempt from CDR reporting -- such as polymers -- but in my view, this listing is a more realistic number of chemicals currently being manufactured and distributed in commerce today. During the last CDR reporting cycle in 2012, there were about 7,700 chemicals reported.

New Chemical Review

Chemicals not already listed on the TSCA Inventory are subject to premanufacture review by EPA and must undergo a new chemical notification under TSCA Section 5 before they can be manufactured and used in commerce for commercial purposes. Under Section 5, an entity wishing to commercialize a chemical substance considered "new" must submit a premanufacture notice (PMN) to EPA. Information included on a PMN includes chemical identity, description of byproducts, anticipated production volumes, molecular formula, intended categories of use, and other available information. There is no requirement to test a new chemical prior to submitting a PMN, but if the submitter has any test data, it must submit those data to EPA along with the PMN.

When EPA reviews a PMN, it conducts an initial review and develops a hazard profile. A question that is often raised is how does EPA develop a hazard profile if no hazard data were submitted with the PMN? Over the years, EPA has developed numerous approaches and methods for hazard review. It often relies on the fact that chemicals of similar molecular structures often have similar hazard profiles. This is known as structure activity relationship (SAR). So, while EPA may not have data on the chemical that is the subject of the PMN, it may have data on an analog chemical -- one that has structural similarities -- and EPA can and does rely on those data in its initial evaluation. I should note EPA does such modeling with some fairly conservative assumptions. So a lack of data on a specific chemical does not mean that the EPA review is more lenient than if data were available. In fact, it is more likely the opposite. The hazard profile includes not only health effects, but also environmental effects and environmental fate.

EPA then develops profiles looking at anticipated releases into the environment; and occupational, consumer, and general population exposures. In addition to the information provided in the PMN, EPA uses the outputs from numerous computer modeling programs to assist in the development of these exposure and release profiles.

EPA's decision options for entry into commerce by the subject chemical are (1) entry into commerce not allowed, (2) entry into commerce with no restrictions, (3) entry into commerce allowed after submission of additional data by the submitter, or (4) entry into commerce allowed with certain regulatory and/or testing actions applied. These regulatory actions involve either (1)

a consent order under Section 5(e) that imposes certain restrictions on the manufacturer of the subject chemical or (2) a significant new use rule (SNUR) under Section 5(a)(2) that imposes certain restrictions on the manufacturer of the subject chemical and all future manufacturers. Many consent orders under Section 5(e) eventually become regulations under Section 5(a)(2).

Assuming EPA has allowed the chemical to enter into commerce, the manufacturer typically submits a notice of commencement (NOC) of manufacture to EPA, and at that time, the "new" chemical is added to the TSCA Inventory and becomes an existing chemical. In some cases, even though entry into commerce can occur, the manufacturer never submits the NOC. In that case, the chemical is not added to the Inventory and thus is not considered an existing chemical despite the fact EPA has reviewed the chemical.

The new chemical notification program under TSCA Section 5 is generally viewed as science-based and reasonable. EPA can and does use its authorities as part of the new chemical notification program to compel additional data and implement certain restrictions. The computer modeling developed by EPA for the new chemical review process is, in my opinion, top-notch. EPA has made that software publicly available, as well as issued guidance on chemical categories of concern. Industry's awareness and understanding of what chemicals are of concern to EPA and why enables entities to focus their research and development work accordingly, and to avoid chemicals that are perceived to cause problems and to develop chemicals that will pass EPA's review process.

Existing Chemicals

All existing chemicals -- those listed on the TSCA Inventory -- are subject to regulations under Sections 4, 5, 6, and 8. There are other sections of TSCA that also apply to existing chemicals, but I do not plan to cover those in my remarks today.

Section 8 -- as I already mentioned -- is focused on information collection.

Section 8(a) authorizes EPA to issue rules requiring companies to submit information on categories of use, quantities, byproducts, and/or health and environmental effects. This information collection occurs only when EPA promulgates a rulemaking. As of 2006, EPA issued 33 8(a) rules covering about 1,200 chemicals.[1]

There is also another information gathering exercise under TSCA Section 8(a) -- the Chemical Data Reporting rule. The CDR is an existing, cyclical reporting requirement under which manufacturers are required to report production, process, and use information for chemicals manufactured or imported over 25,000 pounds per year at a site. The last reporting cycle was in 2012, and information on about 7,700 chemicals was submitted. The cyclical reporting occurs every four years, so the next reporting cycle is in 2016.

[1] EPA, Office of Pollution Prevention and Toxics, "Overview: OPPT Laws and Programs" (Mar. 2008) at 16, available at http://epa.gov/oppt/pubs/oppt101-032008.pdf.

Under TSCA Section 8(c), EPA is authorized to require companies to record and retain allegations of significant adverse reactions to any chemical substance. If EPA issues a TSCA Section 8(c) data call-in, companies must submit this information to EPA. EPA has only issued two such call-ins under Section 8(c).[2]

Under TSCA Section 8(d), EPA is authorized to issue rules requiring companies to submit lists/copies of ongoing and completed unpublished health and safety studies. As of 2006, EPA has issued 51 8(d) rules on about 1,200 chemicals. In response, EPA received 50,000 studies covering a broad range of health and ecological endpoints, as well as information on chemical/physical properties, environmental fate, and exposure.[3]

Under TSCA Section 8(e), entities are required immediately to report information that reasonably supports the conclusion that a chemical substance or mixture presents a "substantial risk." As of 2006, there were about 16,500 Section 8(e) notices submitted and about 7,500 follow-up submissions. According to EPA statistics, around 200 8(e) notices are submitted per year.[4]

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2 *Id*.

3 *Id*.

4 *Id*. at 17

EPA can use the information collected or submitted under these Section 8 provisions, particularly 8(e) submissions, to identify whether a particular chemical is of concern, or if more information is needed. If that is the case, EPA can require testing under Section 4.

TSCA **Section 4** authorizes EPA to issue test rules requiring companies to conduct certain tests on specified chemical substances. To issue a TSCA Section 4 test rule, EPA must make one of two findings:

- EPA must determine that existing data show that the subject chemical "may present an unreasonable risk of injury to health or the environment" and that the probability of exposure to the subject chemical substance is more than just theoretical; and/or

- EPA must show that the chemical is produced or imported in substantial quantities, and either enters the environment in substantial quantities or there is substantial or significant human exposure.

Information to support either of these findings should be available through the Section 8 reporting requirements.

In addition to these findings, EPA must also find that existing data are inadequate for risk assessment, and that testing is needed to develop the data necessary to conduct the needed risk assessment. In other words, EPA cannot require testing simply for testing's sake.

Since EPA began reviewing chemicals in 1979, EPA has required testing for about 200 existing chemicals under Section 4 test rules or under enforceable consent agreements. Keep in mind, however, that EPA can require testing under Section 5 during its new chemical notification review. More than 300 chemicals have been tested as part of that process. The type and amount of testing required by EPA varies, depending on what EPA needs to evaluate the chemical.

Sections 5 and 6

Should EPA determine that a subject chemical presents an unreasonable risk, TSCA Section 6 authorizes EPA to issue rules to manage those risks for existing chemicals. The risk management options include production level restrictions, warning labels, and restrictions for certain uses and/or releases into the environment. As noted earlier, under TSCA Section 5, EPA is authorized to issue restrictions on new chemicals before they are introduced into commerce. Section 5 restrictions can also apply to existing chemicals pursuant to EPA's Significant New Use Rule authority. Under this authority, EPA is authorized to require advance notification on uses deemed "significant and new" for existing chemicals. While only six chemicals have been subject to Section 6 restrictions, EPA has applied restrictions to thousands of chemicals through the Section 5 new chemical notification rule. Those restrictions remain in place after the

chemical is added to the Inventory. In addition, EPA can also use its authorities under Section 5 to apply new use restrictions for existing chemicals.

That only six chemicals have been subject to regulation under Section 6 seems odd. And in referring to Section 6, I am not referring to TSCA Section 6(e), which addresses PCBs. EPA has developed a mature and very successful program under TSCA Section 6(e), which really stands alone as it addresses a very specific problem.

For EPA to be authorized under TSCA Section 6, EPA must find that there is a reasonable basis to conclude that a chemical substance "presents or will present an unreasonable risk of injury to health or the environment," where "unreasonable risk" is a risk-benefit standard. EPA must consider risks, costs, and benefits of a substance to be regulated, including the availability of substitutes. TSCA requires that EPA select the "least burdensome" regulatory measure that provides adequate protections. Therefore, in promulgating regulations under TSCA Section 6, EPA must consider:

- The effects of the chemical substance on health and the magnitude of human exposure;

- The effects of the chemical substance on the environment and the magnitude of environmental exposure;

- The benefits of the chemical substance and the availability of substitutes; and

- The economic consequences of the rule.

Attachment 1 is a depiction of the framework that I just reviewed. I want to clarify that the framework does not necessarily require an action under Section 8 before EPA can use its authorities under Section 4, Section 5, or Section 6, shown on the flowchart with the dotted lines. Nonetheless, I think the drafters of the original TSCA legislation were brilliant in the logical flow provided in the legislation to ensure EPA can access information needed for risk review.

Attachment 2 -- perhaps no longer simple or elegant -- is much more detailed of the specifics that I just reviewed. I hope the attachments may be helpful as a reference in the future.

Challenges

In the areas under TSCA where regulated entities are required to submit certain notifications or reports -- including Section 5 new chemical notification, Section 8 Chemical Data Reporting, and Section 8(e) significant risk notification -- EPA appears to be successful in compiling information needed to conduct risk assessments. In my view, EPA has been particularly constrained when trying to use other TSCA authorities, particularly those that require rulemakings, because the current rulemaking process is long and complicated. These challenges

are not unique to TSCA rulemakings as all rulemakings are cumbersome, and often take three to five years to complete. This is not a deficiency in TSCA, *per se*.

Likewise, while I see great output from EPA in its new chemical review process, there is less so in the existing chemical arena. In my view, that is because the new chemical review includes a statutory deadline -- a 90-day review period for a new chemical notification -- so there is a well understood EPA process and prioritization of work to be conducted. EPA could implement a prioritization process with specified timelines for existing chemical review. There is nothing in the legislative language prohibiting that action. In fact, EPA has begun a small prioritization process -- involving 83 chemicals -- where EPA is conducting focused risk assessments for these 83 chemicals under its TSCA Work Plan Chemicals program.

Finally, the issue of Confidential Business Information (CBI) is often raised as a red flag for TSCA. In my view, CBI is incredibly important. I believe that the members of Congress that drafted the original TSCA language were very cognizant of what type of information would be required under this law, and that is why they built in the strong protections for CBI under Section 14. Keep in mind that TSCA compels industry to provide a wealth of sensitive data, such as:

- Chemical identity for a new substance that may not yet have received patent protection;

- Detailed information on how new chemicals will be manufactured and processed;

- Volume produced, which would signal to competitors the potential market size for the chemical;

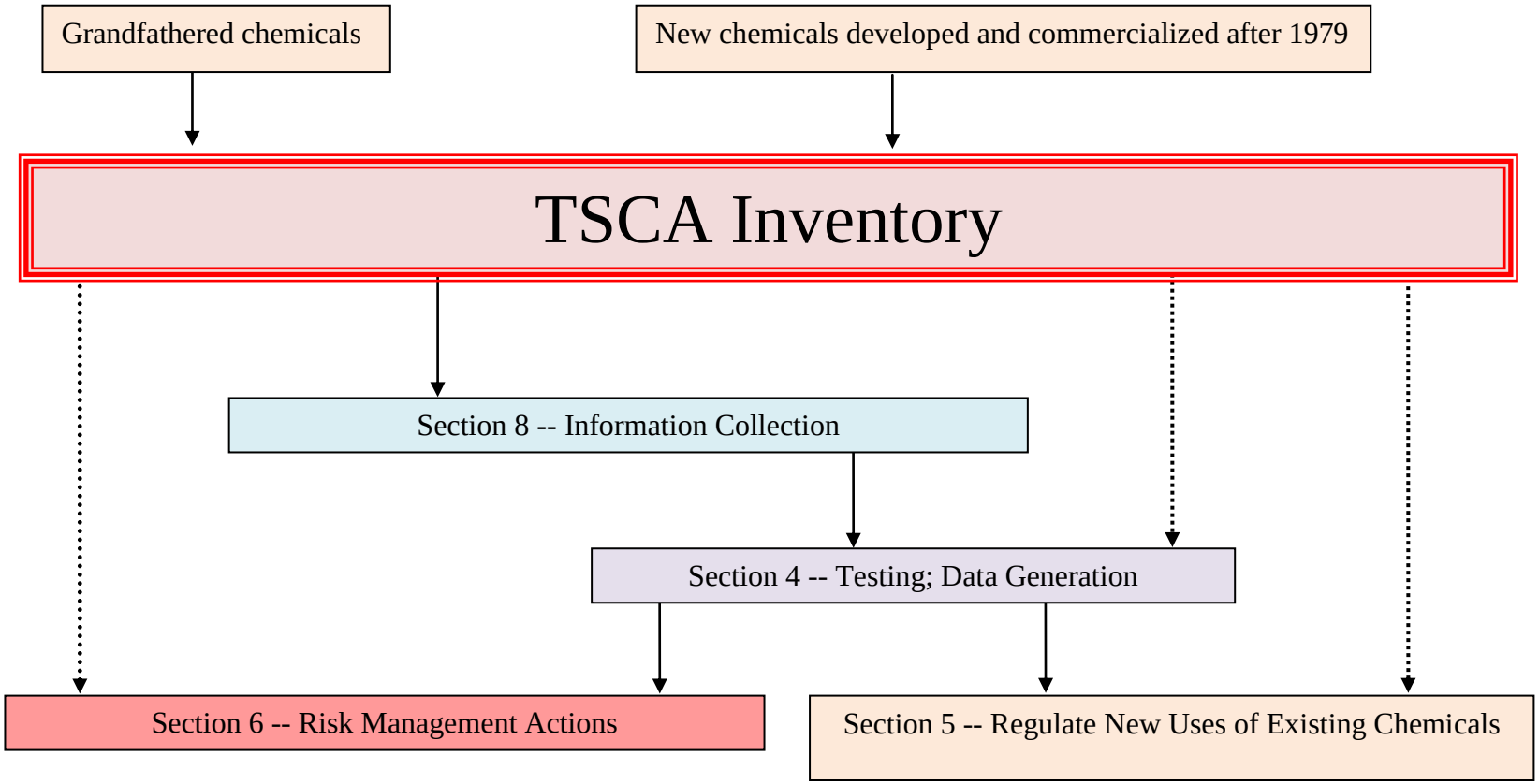
- Molecular weight range for a new commercially valuable polymer; and

- Impurities, which can signal key information on process or precursor substances.

And while there are very legitimate needs for EPA to have this type of information to achieve its statutory goals, there are also very legitimate needs for business to have that information remain confidential.

Thank you very much for this esteemed opportunity. I would be pleased to answer any questions at this time.

Attachment 1: Simple TSCA Flowchart



Attachment 2: Detailed TSCA Flowchart

Section 5: "New" chemicals not on TSCA Inventory must be notified before manufacture

New chemical premanufacture notice (PMN) submitted to EPA. Information on PMN includes chemical identity; anticipated impurities; description of byproducts; estimated production volumes; anticipated categories of use; molecular formula (Class 1 substances) or chemical precursors or structural diagram (Class 2 substances); information on manufacturing, processing and use operations; worker exposure; environmental releases; and any test or risk data in the possession of submitter.

EPA conducts initial review. Establishes candidate chemical profile.

EPA's Structural Activity Team reviews PMN. Uses information from structurally similar substances. Evaluates health effects, environmental effects, environmental fate, and establishes health/environmental hazard potential.

EPA develops exposure/release profiles. Considers occupational, consumer and general population exposures, and environmental releases.

EPA holds focus meeting/if needed, review with more detailed assessment. EPA decision options for entry into commerce (EIC) listed below. Regulatory actions involve Section 5(e) consent orders and/or Section 5(a)(2) significant new use rules.

- EIC allowed without restriction
- EIC allowed, but with regulations under 5(e) or 5(a)(2), which could include restrictions in use, production volumes, or releases
- EIC allowed after additional data submitted and evaluated
- EIC not allowed

Notice of Commencement (NOC) of manufacture submitted. Substance added to the TSCA Inventory.

NOC not submitted. Substance never commercialized.

TSCA Inventory: Represents all chemicals commercialized under TSCA since its inception; chemicals on Inventory subject to Sections 4, 5, 6, 7, 8, 12, and 13

Section 8(a): Gives EPA authority to issue rules requiring companies to submit information on categories of use, quantities, byproduct, health, and environmental effects.

Chemical Data Reporting: Existing 8(a) cyclical reporting requirement in which manufacturers (and importers) report production, process, and use information for chemicals manufactured or imported over 25,000 pounds per year.

Section 8(c): Requires companies to record and retain allegations of significant adverse reactions to any substance. If EPA issues a rule, companies must submit this information to EPA.

Section 8(d): Gives EPA authority to issue rules requiring companies to submit lists/copies of ongoing and completed unpublished health and safety studies.

Section 8(e): Requires companies immediately to report information which reasonably supports the conclusion that a chemical substance or mixture presents a substantial risk.

Section 4: Gives EPA authority to issue test rules requiring companies to conduct certain tests on specified chemical substances.

Section 5: In addition to giving EPA authority to regulate and restrict new substances, Section 5 gives EPA authority to regulate existing chemicals' "significant new uses" under 5(a)(2).

Section 13: Requires certification that imported chemicals comply with TSCA regulations.

Section 6: Gives EPA authority to implement rules to address unreasonable risks, through use restrictions, limitations, warning labels, recordkeeping, compliance, customer notifications, or product bans.

Section 12: Requires companies to provide notification of export of certain chemicals.