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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

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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.

[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

Chemical Manufacturers Submit Premanufacture Notices (PMNs) to EPA which include:

- Information about chemical identity, anticipated uses, molecular structure, anticipated byproducts and disposal information
- Any health or environmental effects test data in the company's possession
- Anticipated exposure information and other information to enable EPA to evaluate whether use of the chemical would harm health or the environment

1979 – 2010

EPA Reviewed 36,623 PMNs

2,589 EPA Took Regulatory Action

1,848 Were Withdrawn

2 EPA Scrutinizes Company Data

EPA conducts initial review of a company's PMN, including all health and environmental data and information provided

3 EPA Experts Apply Predictive Models

- EPA uses the PMN to develop a "profile" for the chemical
- EPA employs sophisticated computer modeling to predict the chemical's physical and chemical properties
- EPA creates models based on structurally similar chemicals

4 EPA Analyzes Chemical's Properties

- EPA scientists evaluate health effects data, environmental effects data, physical properties and other data and estimate potential impacts
- If EPA has questions or needs additional data, it can and does request more information
- EPA identifies health and environmental hazard potential

EPA can demand additional data through a section 5(e) consent order

5 EPA Analyzes Exposure Potential

- EPA develops profiles for worker, consumer, general population and environmental exposure/release potentials
- Profile considerations include production volume, environmental persistence, worker safety, bioaccumulation potential, etc.

6 Robust Process Leads to EPA Decision

EPA has authority to reject or limit a new chemical's use in appropriate cases, or allow manufacture without restrictions

PASS

If EPA is confident of the new chemical's health and environmental profile, the agency can allow the chemical to be manufactured without added restrictions

LIMIT

If EPA determines the new chemical use presents uncontrolled risks, the agency has authority to prohibit or limit its manufacture or use

RESTRICT

EPA may also allow manufacture of new chemicals for use with restrictions, such as labeling or personal protective equipment requirements

STOP

If EPA believes there are unanswered questions concerning safety, the agency has authority to require the manufacturer to conduct additional testing or provide additional information

When a company moves forward to commercially manufacture the chemical after the PMN review period and it notifies EPA that it has done so, the chemical is added to the TSCA Inventory

7 EPA Authority Extends Beyond Initial Manufacturing

Once EPA has allowed a new chemical to be manufactured, it maintains authority to evaluate, require reporting, demand testing and regulate all chemicals on the TSCA Inventory