

TESTIMONY OF THE
AMERICAN CHEMISTRY COUNCIL

BEFORE THE
SENATE ENVIRONMENT AND PUBLIC WORKS COMMITTEE

ON THE
TOXIC SUBSTANCES CONTROL ACT

August 2, 2006

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

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I. Introduction

The American Chemistry Council (ACC) appreciates this opportunity to appear before the Committee to discuss the U.S. chemical regulatory control framework, notably the Toxic Substances Control Act (TSCA). In our view, TSCA is a sound statutory and regulatory system. It is a robust vehicle that can effectively address emerging chemical issues, while retaining sufficient flexibility to promote innovation and the active involvement of chemical manufacturers in the safe management and use of chemicals.

ACC is the national trade association whose member companies represent more than 90 percent of the productive capacity for basic industrial chemicals in the United States. ACC member companies are on the cutting-edge of technological innovation and progress, whose products provide significant benefits – benefits that save lives, improve health, protect our food supply, and provide jobs throughout the Nation.

ACC member companies are committed to implementing a set of goals and guidelines that go above and beyond federal regulation on health, safety, security, and the environment. Since the Council adopted Responsible Care® in 1988, our members have reduced emissions by 75 percent and achieved a safety record more than four and a half times better than the average for the manufacturing sector overall. ACC supports the safe management and use of chemical products. The industry's regulatory compliance and proactive product stewardship programs allow ACC's members to manage appropriately the wide range of products made by the business of chemistry.

These comments address the statutory and regulatory safeguards built into the current framework for the management of chemicals; some of the voluntary programs that our industry has committed to that build on those safeguards; and why it is important to ensure that TSCA remains a flexible, science-based statute that can address new scientific challenges and promote technological innovation.

II. The Overall Framework for Chemicals Management

TSCA is not the only statute that controls risks from chemicals products on the market, although it is an important piece of the overall regulatory framework. Other statutory requirements focus on chemical uses that may create direct human exposures. For example, information and registration requirements for pesticides are covered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The standards for manufacturers of pharmaceuticals, food additives, food packaging, and cosmetics are addressed in the Federal Food, Drug and Cosmetic Act (FFDCA). The Federal Hazardous Substances Act (FHSA) applies

to substances used in consumer products. Some 14 different federal statutes play a role in regulating chemical manufacture, use, distribution and disposal, complemented by state regulatory programs in specific areas.

Unlike the environmental media-driven statutes such as the Clean Air Act, Congress did not set specific metrics or deadlines for actions under TSCA. Instead, Congress has provided the Environmental Protection Agency (EPA) tools to gather information so that risks can be identified and managed, and unreasonable risks eliminated. TSCA was enacted in 1976 in order to prevent “unreasonable risk of injury to health or the environment associated with the manufacture, processing, and distribution in commerce, use, or disposal of chemical substances.” Congress properly recognized that while a variety of laws existed to ensure the safety of products, EPA needed tools to identify potential risks to health and the environment, and to take the steps to manage those risks appropriately.

TSCA was intended to be flexible enough to enable a variety of regulatory responses, and address a variety of needs, including support for regulatory action under other statutes. ACC counts this flexibility as one of the key strengths of TSCA, particularly as science, technology, and our ability to understand hazards, mechanisms of action, and exposures to chemicals have evolved.

In TSCA, Congress gave EPA a variety of tools to empower the agency to gather information, assess that information, and initiate action to address any risk which, in the agency’s view, is unreasonable. Key provisions of TSCA authorize EPA to:

- Establish an inventory of chemical substances which had been on the market when TSCA was enacted (the “existing” substances), as well as any substance later reviewed and approved by EPA under the “new substance” provisions. (TSCA Sec. 8(b))
- Require the review and approval of any “new” substance prior to manufacturing that substance. Companies submitting a pre-manufacture notice (PMN) are required to submit any available health or environmental test information that they may already have in their possession. In addition to available test information, the manufacturer must provide information on the chemical identity and structure, and anticipated uses, production volume, by-products, human exposures and disposal practices. EPA has established some 35 PMN policies that provide early guidance to submitters on substances that have particular characteristics. EPA has also developed sophisticated and powerful computer modeling – using data gathered over many years – that help predict a chemical’s physical and chemical properties, health hazards, exposure potential, and potential environmental effects. If EPA finds the information provided inadequate, EPA has the authority to ask companies for additional information under this provision. (TSCA Sec. 5)
- Limit “new” uses of existing chemical substances under authority known as a “significant new use rule.” Using this authority, EPA has successfully restricted well over 1,000 substances. These restrictions range from establishing maximum production

amounts, dictating allowable uses, instructing on appropriate disposal methods, or other measures designed to manage risk. (TSCA Sec. 5)

- Require companies to test chemicals to assess potential risks to health or the environment. Chemicals that may need test data are brought to EPA's attention in a variety of ways. For example, the Interagency Test Committee (established under TSCA and comprised of experts from eight designated federal agencies and institutes, and a number of other liaison members) regularly evaluates and recommends chemicals to test. EPA may also select chemicals on the basis of information provided under any of the information collection sections of the statute. (TSCA Sec. 4)
- Regulate existing chemical substances through a variety of mechanisms, including use restrictions, production limitations, warning labels, record keeping, customer notifications, or in the most extreme cases, outright bans. Although EPA has successfully pursued a number of actions under this part of TSCA, one case is routinely cited (in ACC's view, incorrectly) for the proposition that "Section 6 demonstrates that TSCA is broken." Contrary to popular perception, the *Corrosion Proof Fittings* opinion does not establish a failing in the statute – it simply established that EPA did not follow Congress' directive. In fact, EPA has successfully regulated other substances under TSCA section 6 including halogenated aromatic compounds, heavy metals, and fibers. (TSCA Sec. 6)
- Require companies to: (a) keep records on allegations of significant adverse reactions; (b) report information on chemical uses and exposures; (c) provide EPA with copies of unpublished health and safety studies; and (d) submit all information in their possession that suggests a chemical presents a substantial risk of injury to health or the environment. (TSCA Sec. 8)
- Require companies to provide notifications of anticipated exports of substances subject to test rules under Section 4, and those subject to orders or rules under Sections 5, 6 and 7.

The facts around TSCA implementation comprise an impressive record:

- From 1979 through 2003, EPA reviewed approximately 36,000 new chemicals. More than 3,000 were subject to some form of regulation as a result of EPA's reviews. More than 1,200 chemicals are subject to consent orders negotiated by the manufacturers with EPA. Such consent orders typically prescribe limitations on use, workplace practices, labeling requirements, and release and disposal restrictions.
- In more than 500 other cases, EPA permitted the new substance to be produced without a consent order, but at the same time promulgated a "significant new use rule" (SNUR) that prohibits certain uses of the substance without further prior review by EPA. In approximately 870 cases, the submitter of the pre-manufacture notice agreed to conduct additional testing in response to EPA requests. In some 1,550 cases, the submitter

withdrew the pre-manufacture notice in the face of EPA concerns and likely regulatory requirements.

- Since TSCA was enacted, several hundred existing chemicals have been subject to testing requirements imposed by EPA under TSCA Section 4. In addition to TSCA testing requirements, many companies conduct hazard and environmental fate and effects testing on their products, including sometimes very sophisticated testing that goes well beyond the testing requirements typically imposed by EPA under TSCA. Indeed, the volume of testing that occurs outside of TSCA on a voluntary basis far exceeds testing conducted pursuant to regulatory requirements. When toxicity testing of chemicals is conducted under the auspices of a chemical specific panel of the American Chemistry Council, a copy of the final study report is automatically provided to EPA and several other regulatory agencies.
- EPA has developed a Preliminary Assessment Information Rule (PAIR) reporting form that it frequently uses to gather information about the manufacture, use, potential for workplace exposure and environmental release of specific chemicals. To date, EPA has required manufacturers to complete this form for approximately 475 chemicals. EPA also has exercised its authority to require the submission of existing health and safety data for approximately 1,000 chemicals.
- Since TSCA was enacted, well over 10,000 “substantial risk” reports have been filed with EPA under Section 8(e).

III. VOLUNTARY PROGRAMS UNDER TSCA

As noted earlier, TSCA provides flexibility to EPA in adapting voluntary programs and initiatives that complement the Agency’s regulatory programs. The High Production Volume Challenge (HPV) Program, for example, has provided more hazard information, on more chemicals, faster than any other program EPA has ever established.

HPV Challenge Program

In 1998, the chemical industry, working with EPA, Environmental Defense and others, developed the HPV Program. This unprecedented voluntary initiative had the goal of making uniform health and environmental screening information on high production volume (HPV) chemicals publicly available by the end of 2005. Through the HPV Challenge Program, more than 300 sponsoring manufacturers volunteered to provide hazard-screening information on 2,222 HPV chemicals.

For each of the chemicals sponsored in the program, industry has provided 17 types of information, including summarized results in four categories: physical-chemical properties, environmental fate, and potential to induce toxicity in aquatic organisms and humans. Data to be summarized for human toxicity include studies assessing acute toxicity, sub chronic toxicity, genotoxicity, and developmental and reproductive toxicity.

All of the information collected under the HPV Program is important and relevant for evaluating a chemical's potential impact on human health and the environment. Additionally, test categories such as genotoxicity and acute, developmental and reproductive toxicity are specifically relevant to protecting children's health.

The standard battery of toxicity tests employed by EPA for HPV (and harmonized internationally under OECD) includes tests specifically designed to evaluate endpoints that provide information on a substance's potential to pose a health hazard:

- to development in the womb;
- to growth and reproduction;
- from acute poisoning;
- to cell components that could possibly trigger transformation into cancer later in life;
- to the nervous system (observation for toxicological effects on the nervous system are included as a component of the protocol in every animal toxicity test);
- to all major organ systems, including the nervous system.

Thus, the standard battery of TSCA HPV tests is both relevant and important to assessing potential health hazards. Results from these tests can and are being used to decide what specific, additional toxicity tests are scientifically warranted and necessary to more completely understand specific organ-system hazards, and to more fully characterize the dose-response relationship.

The HPV program, supported by EPA's HPV Information System (HPVIS), has made existing health and environmental effects data sets publicly available on approximately 95% (by volume) of the chemicals currently in commerce in the US.

More importantly, EPA is using the HPV data to make decisions on priorities for further review. All HPV data – which was always intended for screening purposes and not as a complete data set – are being assessed in EPA's screening mechanism. The HPVIS screening process was designed by an EPA stakeholder group (the National Pollution Prevention and Toxics Advisory Committee) after detailed review of the needs of a variety of data users. The first step is an automated review, resulting in a prioritization of all chemicals for detailed evaluation. ACC supports that process, and looks forward to its timely completion.

Extended HPV Program

In March 2005, before the end of the HPV Challenge Program, the chemical industry extended and broadened its current work on HPV chemicals in two ways. First, companies are asked to provide health and environmental information for 574 "new" HPV chemicals – chemicals that did not qualify as HPV chemicals at the start of the original program, but which now meet the volume threshold according to EPA's 2002 Inventory. Second, the EHPV Program increases the scope of information being collected for all HPV chemicals. In addition to gathering health and environmental information, companies are asked to provide information on use and exposure for both the "Extended" HPV as well as the original "Challenge Program"

substances. In this way, the EHPV Program will provide EPA and the public with an extensive source of chemical safety information on HPV chemicals.

Together, these voluntary programs are exemplary illustrations of how industry has taken responsible action, supported through the flexibility inherent in TSCA. All of the important information generated in these voluntary programs will be used by EPA to prioritize HPV chemicals for further evaluation, risk characterizations and risk assessment.

Voluntary Children's Chemical Evaluation Program

EPA announced its pilot Voluntary Children's Chemical Evaluation Program (VCCEP) in December 2000 to assess certain chemicals for potential risks to children through a series of tiered screens and tests. It was developed as an alternative to a TSCA Section 4 test rule. The VCCEP pilot is evaluating both hazard and exposure information on 20 chemicals voluntarily submitted by thirty five companies and ten consortia. The key question that the VCCEP aims to answer is whether the potential hazards, exposures, and risks to children have been adequately characterized, and if not, what additional data are necessary.

Companies participating in VCCEP present a hazard assessment, exposure assessment and risk assessment on their chemical to an independent peer consultation panel which then makes a recommendation to EPA about additional data needs under the tiered evaluation framework of the program. EPA then makes a data needs assessment about the chemical.

The program is proceeding well and is currently about half completed. Industry has lived up to its commitments under the program. ACC believes this pilot program has been very successful at affirming the viability and improved efficiencies of tiered approaches to chemical evaluation. It has also improved the practice of children's health exposure assessments and has proved the value of an independent peer consultation panel to make data needs recommendations. Although EPA data needs decisions have taken a long time, the pilot VCCEP has successfully evaluated many important chemicals, including brominated flame retardants, vinylidene chloride, benzene, and acetone.

The program has shown that a one-size fits all, single tier test battery approach to children's health questions would be wasteful of laboratory animals, costly, inefficient and not nearly as informative as the approach taken under VCCEP. At the end of the day, VCCEP is providing a strong, scientific basis for deciding whether children's risks from exposure to chemicals have been adequately characterized and additional information is needed to make those characterizations.

Voluntary programs are conducted under the auspices of TSCA and they play an important role in implementing the objectives of TSCA. They permit companies to demonstrate their commitment to product safety, and often result in information developed in ways that are faster or less burdensome than would be the case under a regulatory mandate.

III. TSCA Meets New Scientific and Technological Challenges and Promotes Innovation

As science evolves, we learn more and more about the relationship between chemistry and health. TSCA's framework is flexible enough to meet new scientific questions that might be raised about the impact of chemicals on health. Rather than amending TSCA to impose new requirements each time these new questions arise about chemicals, the law and EPA's implementation of it are flexible enough to address these questions under a science and risk based framework. Concerns about endocrine disruption, children's health, biomonitoring information and nanotechnology can and are being addressed today under TSCA's information collection, reporting, testing and risk management provisions, (as well as under other existing statutes such as the Food Quality Protection Act of 1996). These are just today's questions. New scientific questions will continue to arise as science evolves. TSCA provides a dynamic framework for anticipating these issues and developing the scientific information needed to apply its many risk management tools as appropriate.

TSCA's framework also promotes the development of innovative chemistries and technologies. More new chemical notifications are filed under TSCA than in any other major regulatory system, including Europe and Japan. As a result, the business of chemistry in the United States is acknowledged to be a world-leader in solutions that improve science and technology. ACC has no doubt that TSCA has helped foster innovation and a significant competitive position for the industry in the world economy. Further, TSCA has contributed greatly to the national economy and the relative position of the U.S. chemical industry in the global business of chemistry.

The term "green chemistry" has become a popular term recently, and some have argued that TSCA does not do enough to encourage the production of chemicals that have little or no toxic effects. ACC members believe in green chemistry – in fact they are among the premier practitioners of green chemistry, a fact demonstrated by the regular recognition of ACC member companies in programs such as the Presidential Green Chemistry Awards.

It is important to recognize that green chemistry is a framework that aligns technology and innovation with improvements in the health and environmental "footprint" of materials used in our society. Green chemistry is not just about products, it is also about the improvements and enhancements in production processes.

ACC agrees that government can and should provide encouragement for such collaborations through the sharing of expertise, financial support for research, information exchange and public education. In fact, a variety of federal agencies (including EPA and DOE), companies, professional associations such as the American Chemical Society, and universities are working together to encourage green chemistry strategies.

However, it is inappropriate to blame TSCA for the alleged lack of "green chemistry" approaches. The fact that the statute does not explicitly address green chemistry is not surprising, nor is it important. In ACC's view, TSCA appropriately does not dictate how the process of innovation and collaboration should occur, and in what areas.

IV. Conclusion

The American Chemistry Council believes that the Toxic Substances Control Act provides a high level of health and environmental protection in the manufacture and use of chemical substances. Through TSCA, EPA has significant regulatory authority to take measures necessary to prevent or mitigate unreasonable risks. Moreover, TSCA complements the industry's product stewardship programs, as do the legal and marketplace forces that affect the industry.

ACC and its member companies appreciate this opportunity to comment on TSCA.