

CRS Report for Congress

The Toxic Substances Control Act (TSCA): Implementation and New Challenges

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The Toxic Substances Control Act (TSCA): Implementation and New Challenges

Summary

Title I of the Toxic Substances Control Act (TSCA) of 1976 has never been amended, but recent legal, scientific, and technological changes are prompting some policy makers to reexamine the law. H.R. 6100/S. 3040 would amend TSCA to significantly reshape U.S. chemical assessment and management. TSCA regulates potential risks of industrial chemicals in U.S. commerce, based on three policies: (1) Chemical manufacturers are responsible for testing chemicals to determine their potential effects on health and the environment; (2) EPA should regulate chemicals that present an unreasonable risk to health or the environment; and (3) EPA's implementation of the law should not create unnecessary economic barriers to technological innovation. Few have expressed concern about the last TSCA purpose, but TSCA's progress in achieving the first two goals has been debated: where some see success, others see failure, and both sides of the debate point to EPA's history of implementation and its voluntary initiative for collecting data on high production volume chemicals in support of their views. To date, EPA has compiled an inventory of roughly 82,000 chemicals that have been produced in, or imported into, the United States at some time since 1976. The agency has promulgated regulations to restrict production or use of five chemicals under TSCA.

Recently, many states and localities have acted to regulate chemicals not regulated under TSCA using state or local authority. Some large chemical manufacturers, processors, and distributors object to the emerging legal patchwork. Multinational companies also are faced with a variety of national laws restricting international commerce in chemicals. International cooperation to harmonize regulations, and to eliminate certain persistent pollutants, has led to several international agreements that aim to ease the legal confusion, but amendments to TSCA would be required if the United States is to fully implement the agreements. New laws in other nations also have provided alternative models for chemical regulation, which some would prefer to TSCA. Others defend the U.S. approach, arguing that TSCA is based on sound, risk-based science.

Recent changes in science and technology pose challenges to EPA implementation of TSCA. For example, scientists now know that the timing and duration of exposure to a chemical can determine its effects, as can the age, gender, and heritable traits of people who are exposed. Biotechnology and nanotechnology have created genetically modified organisms and nanomaterials, respectively, which EPA must categorize as "existing" or "new" and manage as "chemical substances" under TSCA.

Faced with these challenges to TSCA, some analysts, and most in the regulated community, nevertheless believe that TSCA has performed as intended, and they support TSCA in its current form. They praise TSCA as a flexible, efficient, and effective limit to over-regulation. Other legal commentators and analysts want to amend TSCA, because they think that it has not accomplished the tasks laid out for it by Congress, and is unlikely to do better in the future.

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The Toxic Substances Control Act (TSCA): Implementation and New Challenges

Introduction

Recent legal, scientific, and technological developments affecting chemicals in U.S. commerce are prompting legislators to reexamine the Toxic Substances Control Act of 1976 (TSCA).¹ This is a change from the situation that prevailed in most of the previous thirty years since it was enacted; during that time, most legislators have demonstrated little interest in amending the law, despite the long-standing concerns of a few Members. The basic TSCA provisions in Title I have never been amended.² Companion bills in the 110th Congress, H.R. 6100 and S. 3040, would amend TSCA to significantly reshape U.S. chemical assessment and management.

This report provides an overview of basic TSCA provisions, briefly examines the history of TSCA implementation by the U.S. Environmental Protection Agency (EPA), and describes the legal, scientific, and technological developments that are being used to provide support to calls for TSCA reform. For more detailed information about the provisions of TSCA Title I, particularly those that address polychlorinated biphenyls, or for information about Titles II, III, IV, or V, which concern asbestos, radon, lead, and school environments, respectively, see CRS Report RL31905, *The Toxic Substances Control Act: A Summary of the Act and Its Major Requirements*, by Linda-Jo Schierow.

TSCA Overview

Federal legislation to regulate U.S. commerce in chemical substances was originally proposed in 1971 by the President's Council on Environmental Quality (CEQ). Its report, "Toxic Substances," defined a need for comprehensive legislation to identify and control chemicals whose manufacture, processing, distribution, use, and/or disposal was potentially dangerous, and not adequately regulated under other environmental statutes. The House and Senate each passed bills in both the 92nd and 93rd Congresses (in 1972 and 1973, respectively), but controversies over the scope of chemical screening prior to commercial production and distribution, level of costs, and the relationship to other regulatory laws stalled final action. Episodes of environmental contamination — including contamination of the Hudson River and

¹ 15 U.S.C. 2601-2692.

² Four titles have been added to address specific concerns — asbestos in 1986 (Title II, P.L. 99-519), radon in 1988 (Title III, P.L. 100-551), lead in 1992 (Title IV, P.L. 102-550), and, in 2007, school environments (Title V, P.L. 110-140).

other waterways by polychlorinated biphenyls (PCBs), the threat of stratospheric ozone depletion from chlorofluorocarbon (CFC) emissions, and contamination of agricultural produce by polybrominated biphenyls (PBBs) in the state of Michigan — together with more exact estimates of the costs of imposing toxic substances controls, opened the way for final passage of the legislation. President Ford signed TSCA into law on October 11, 1976.

Title I contains the original, general provisions of TSCA, which are the subject of this report.

Policies and Intent

TSCA established three general federal policies with respect to chemical substances and mixtures in U.S. commerce, “ ... that —

- [A]dequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such data should be the responsibility of those who manufacture and those who process such chemical substances and mixtures;
- [A]dequate authority should exist to regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment, and to take action with respect to chemical substances and mixtures which are imminent hazards; and
- [A]uthority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose of this act to assure that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment.”³

In addition, Congress expressed its intent in TSCA, Section 2(c):

It is the intent of Congress that the Administrator shall carry out this Act in a reasonable and prudent manner, and that the Administrator shall consider the environmental, economic, and social impact of any action the Administrator takes or proposes to take under this Act.

The scope of TSCA is very broad, covering all “chemical substances,” as defined in Section 3(2).

... the term “chemical substance” means any organic or inorganic substance of a particular molecular identity, including —

- (i) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and
- (ii) any element or uncombined radical.

The law excludes from this definition substances that are otherwise regulated, such as mixtures, pesticides, tobacco, nuclear material, substances subject to certain taxes

³ TSCA, Section 2(b).

(e.g., alcohol), and food, drugs, cosmetics, and devices regulated under the Federal Food, Drug, and Cosmetic Act.

Chemical Testing

To attain these policy goals, TSCA Section 4 directs EPA to require chemical manufacturers and processors to conduct tests for existing chemicals if: (1) the manufacture, distribution, processing, use, or disposal of the chemical “may present an unreasonable risk” of injury to health or the environment; or (2) the chemical is produced in very large volume and there is a potential for a substantial quantity to be released into the environment or for substantial or significant human exposure. Under either condition, EPA must issue a rule requiring tests (known as a test rule) if: (a) existing data are insufficient, and (b) testing is necessary to develop the data.

Because there were roughly 61,000 chemicals covered by TSCA and in U.S. commerce at the time EPA was to begin developing test rules, Congress established a special interagency committee to help EPA determine which chemicals should be considered first, and to coordinate testing needs and efforts among government agencies.⁴ At least every six months the Interagency Testing Committee (ITC) must consider candidate chemicals for inclusion on a list of substances that the ITC recommends to EPA for development and promulgation of test rules.⁵ TSCA directs the ITC to “designate” a subset of chemicals for EPA action within 12 months. In response to a new listing on this Priority Testing List of chemicals designated for testing, EPA is required to publish a *Federal Register* notice within 12 months either to propose a test rule, or to provide reasons for not doing so.⁶ The Priority Testing List can contain no more than 50 designated chemicals at any time.

EPA also is authorized under TSCA Section 8 to collect existing information about chemicals to help evaluate the potential risks of exposure. Section 8(a) allows EPA to issue rules requiring record keeping and reports by manufacturers and importers for specified chemicals. Required elements of such reports may include the chemical identity, molecular structure, and names; categories of use; amount manufactured or processed and expected to be manufactured or processed; description of any byproducts; existing environmental and health effect data; number of individuals exposed occupationally and duration of exposure; and the manner of its disposal.

⁴ The potential chemical universe (the universe of chemicals that could be synthesized and those that exist but which have not yet been identified) has been described as “unimaginably immense” (Christian Daughton, 2005, “‘Emerging’ Chemicals as Pollutants in the Environment: a 21st Century Perspective,” *Renewable Resources Journal*, v. 23, n. 4, p. 9). The known universe of chemicals is a small fraction of that potential chemical universe: As of February 16, 2007, the Chemical Abstract Service had indexed more than 30 million organic and inorganic chemicals, 12 million of which it classifies as “in commerce” worldwide, although it is not clear how this number is determined, and it is much larger than would be expected based on the numbers in national inventories. Roughly 245,000 chemicals are regulated or inventoried. [<http://www.cas.org/expertise/cascontent/regulated/>].

⁵ TSCA Section 4(e).

⁶ Interagency Testing Committee homepage. [<http://www.epa.gov/opptintr/itc/>].

TSCA Section 8(c) requires chemical manufacturers, processors, and distributors to maintain records of “significant adverse reactions to health or the environment ... alleged to have been caused by the substance or mixture.” All records must be maintained for five years, and records of employee allegations must be kept for 30 years. Under Section 8(d), EPA must require that manufacturers submit lists of unpublished health and safety studies known to have been conducted, and copies of such studies. Finally, Section 8(e) requires that any commercial chemical manufacturer, processor, or distributor who has information that “reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment” must immediately inform EPA.

Other data may be collected through federal research programs. TSCA Section 10 directs EPA to conduct and coordinate among federal agencies research, development, and monitoring that is necessary to the purposes of the act. In addition, TSCA Section 27 authorizes research and development of test methods for chemicals by the Public Health Service in cooperation with EPA.

Pre-Manufacture Notices and Significant New Use Notices

EPA also is required to prevent future risks through pre-manufacture screening and regulatory tracking of new chemical products. Section 5 of TSCA requires manufacturers, importers, and processors to notify EPA at least 90 days prior to producing or otherwise introducing a new chemical product into the United States. At the same time, those submitting a Pre-Manufacture Notice (PMN) also must submit any information or test data that are known to, reasonably ascertainable by, or in possession of the notifier, and that might be useful to EPA in evaluating the chemical’s potential adverse effects on human health or the environment. Exemptions from these requirements are provided or allowed upon application under certain circumstances.⁷

For existing chemicals, a similar notification procedure may be required, if the Administrator has determined by rule that new uses of a particular chemical may produce significant changes in human and environmental exposures and therefore require notification. The 90-day notice required by a Significant New Use Rule (SNUR) provides EPA with the opportunity to evaluate the chemical use and, if necessary, to prohibit or limit such activity before it occurs, to prevent unreasonable risk of injury to human health or the environment.

EPA has 90 days after notification (or up to 180 days if it extends the period for good cause) to evaluate the potential risk posed by the chemical that is the subject of a PMN or SNUR. If EPA determines that there is a reasonable basis to conclude that the substance presents or will present an unreasonable risk, the Administrator *must* promulgate requirements to protect adequately against such risk.

EPA may determine that the proposed activity related to a chemical may present an unreasonable risk based on the available scientific evidence with respect to

⁷ Exemptions are authorized at TSCA §5(h), §5(i), and §12. For EPA interpretations of these authorities, see 40 CFR §§720.30, 720.36, and 720.38 and 723.

potential for exposure and adverse effects, or, when no data exist to document such effects, on what is known about the effects of chemicals with similar chemical structures. The latter method, known as structure-activity relationship analysis, often is used to screen new chemicals.

If data are inadequate to make an informed judgment about inherent hazard and potential for exposure, and (1) manufacture, processing, distribution in commerce, use, or disposal may present an unreasonable risk, *or* (2) a chemical is to be produced in substantial quantities, and the potential for environmental release or human exposure is substantial or significant, EPA may issue a proposed order to prohibit or limit such activities until sufficient data are submitted.

Although the legislative history of TSCA includes a presumption that testing of new products would take place before they were widely used, either as the chemical was developed, or as its markets grew, TSCA forbids promulgation of blanket testing requirements for all new chemicals. This prohibition arose due to concern that uniform testing requirements might stifle innovation in the chemical industry. Thus, EPA must decide which chemicals, or categories of chemicals, warrant the costs of testing.

Regulatory Controls for Hazardous Chemicals

TSCA Section 6 requires EPA to control unreasonable risks from existing chemicals when they become known. Under TSCA Section 4(f), if EPA receives test data in response to a test rule or in connection with a PMN or SNUR, or any other information that indicates “there may be a reasonable basis to conclude that a chemical substance or mixture presents or will present a significant risk of serious or widespread harm to human beings from cancer, gene mutations, or birth defects,” within 180 days of receiving such information EPA is required to initiate action to prevent or reduce that risk, or to publish a finding that such risk is not unreasonable. The decision to publish a finding (and not to initiate rulemaking) is subject to judicial review.

The law directs EPA to regulate manufacturing, processing, distribution in commerce, use, or disposal under TSCA, if a chemical poses an unreasonable risk of injury to health or the environment, and the risk cannot be reduced to a sufficient degree under another federal law administered by EPA. (Alternatively, TSCA Section 9 allows EPA to refer cases of chemical risk to other federal agencies that have the authority to prevent or reduce the risk.) TSCA Section 6 provides various regulatory alternatives. EPA has authority to:

- prohibit or limit the amount of production or distribution of a substance in commerce;
- prohibit or limit the production or distribution of a substance for a particular use;
- limit the volume or concentration of the chemical produced;
- prohibit or regulate the manner or method of commercial use;
- require warning labels and/or instructions on containers or products;
- require notification of the risk of injury to distributors and, to the extent possible, consumers;

- require record-keeping by producers;
- specify disposal methods; and
- require replacement or repurchase of products already distributed.

EPA also may impose any of these requirements in combination or for a specific geographical region. However, EPA is required by TSCA to regulate only “to the extent necessary to protect adequately” against a risk, and to use the “least burdensome” regulatory approach in controlling unreasonable risks.

Chemical Production Inventory

Section 8(b) of TSCA requires EPA to gather and disseminate information about chemical production, use, and possible adverse effects to human health and the environment. It directs EPA to develop and maintain an inventory of all chemicals, or categories of chemicals, manufactured or processed for commercial purposes in the United States.

To aid EPA in its duties under TSCA, the agency was granted considerable authority to collect information from industries. EPA may require maintenance of records and reporting of: chemical identities, names, and molecular structures; categories of use; amounts manufactured and processed for each category of use; descriptions of byproducts resulting from manufacture, processing, use, and disposal; environmental and health effects; number of individuals exposed; number of employees exposed and the duration of exposure; and manner or method of chemical disposal.

TSCA provides broad protection of proprietary confidential information about chemicals in commerce. Disclosure by EPA employees of such information generally is not permitted, except to other federal employees, or when necessary to protect health or the environment. However, data from health and safety studies of chemicals is not protected from disclosure, unless it would reveal a chemical process or chemical proportion in a mixture. Wrongful disclosure of confidential data by federal employees may result in criminal penalties.

Role of the States

All of the mandates in Title I are federal: there is no provision for authorizing state programs to implement Title I provisions. Neither does TSCA provide special access for state officials to confidential business information that is reported to EPA.

TSCA Section 18(a) does not allow a state or local law to remain in effect if it restricts the use of a chemical for which EPA has promulgated a rule or order under Section 5 or 6, if the federal rule is intended to protect against a risk of injury to health or the environment. State or local law is permitted only if it is identical to the federal requirement, adopted under another federal law, or prohibits the use of such substance or mixture within the relevant jurisdiction (except use in manufacture or processing of other substances). TSCA Section 18(b) allows states or localities to petition EPA to issue a rule exempting a state or local law, if compliance would not cause a violation of federal law, it provides a significantly higher degree of protection

from such risk than the federal requirements, and does not unduly burden interstate commerce.

Judicial Review

TSCA Section 19 authorizes any person to file a petition for judicial review of specified rules within 60 days of issuance under TSCA. The court is directed to set aside specified rules if they are not supported by “substantial evidence” in the rulemaking record taken as a whole.

Implementation

EPA efforts to implement TSCA include (1) developing and collecting data relevant to risk assessment of chemicals under TSCA Sections 4 and 8, and (2) regulating chemicals that pose an unreasonable risk under TSCA Sections 5 or 6 in a manner that does not unduly oppress innovation and commerce. This section summarizes available information relevant to EPA performance under TSCA so that readers might have an objective basis for evaluating statements of opinion regarding its effectiveness. A recently updated report for EPA’s Office of Pollution Prevention and Toxics (OPPT) describes TSCA implementation in greater detail.⁸ A slightly older report by the U.S. Government Accountability Office (GAO) also describes EPA efforts to regulate chemicals under TSCA.⁹

Chemical Inventory

TSCA directs EPA to establish requirements that would distinguish between chemicals already in U.S. commerce and chemicals that would enter commerce after enactment of TSCA. The first version of the inventory of existing chemicals was compiled under TSCA Section 8(b) between 1978 and 1979. It identified approximately 61,000 chemicals¹⁰ that manufacturers and importers reported had been produced in, or imported into, the United States for commercial purposes after January 1, 1975.¹¹ This included naturally occurring as well as synthetic chemicals.

⁸ EPA, Office of Pollution Prevention and Toxics. Overview: Office of Pollution Prevention and Toxics Programs. January 2007. [<http://www.epa.gov/oppt/pubs/oppt101c2.pdf>].

⁹ GAO. Chemical Regulation: Options Exist to Improve EPA’s Ability to Assess Health Risks and Manage Its Chemical Review Program. June 2005. GAO-05-458.

¹⁰ U.S. EPA. 2007. Overview: Office of Pollution Prevention and Toxics Programs. p. 5. [<http://www.epa.gov/oppt/pubs/oppt101c2.pdf>].

¹¹ 42 *Federal Register* 64572.

Table 1. Numbers of Chemicals in U.S. Commerce

Original inventory in 1979	61,000
Added since 1979	20,700
Inventory in 2006	82,700
Reported in 2006 inventory update	9,000

Note: Some chemicals on the 2006 Inventory may no longer be in commerce. Also, chemicals need only be reported for an inventory update if a facility produced or imported more than 10,000 pounds during the previous year (2005).

EPA has added new chemicals to the TSCA inventory whenever manufacturers have submitted a Notice of Commencement (NOC) indicating that a chemical not on the current inventory (for which a PMN was submitted) was about to be manufactured and enter commerce.¹² As of December 2006, roughly 20,700 new chemical substances had entered U.S. commerce and been added to the inventory.¹³ A few chemicals have been removed from the inventory, generally because they were reported in error and were not being produced commercially. (EPA does not list chemicals if they are only produced in small quantities for purposes of experimentation or research.) As of September 2006, EPA estimated that there were 82,700 chemical substances on the inventory, meaning that they had, at least for a while, been in U.S. commerce after 1976.¹⁴ Included in this number were 50,200 organic substances that are not polymers, 29,500 polymers, and 3,200 inorganic chemical substances.^{15 16}

Beginning in 1986 and every four years thereafter, EPA has collected information about the volume of chemicals produced and the locations of plants where chemicals are produced or imported in amounts greater than 10,000 pounds (5 tons) per year. In recent years, roughly 2,500 facilities (1,000 companies)

¹² Although a NOC technically means the chemical has entered commerce, in fact it may or may not ever be marketed, according to EPA (Charles Auer, personal communication, August 5, 2007).

¹³ EPA Overview, p. 7.

¹⁴ The American Chemistry Council (ACC), a trade group for chemical manufacturers, has a fact sheet, "TSCA Myth vs. Fact," on their website that takes issue with statements claiming that there are some 80,000 chemicals in commerce. The ACC argues that many chemicals on the original inventory are no longer "in commerce." [http://www.americanchemistry.com/s_acc/bin.asp?SID=1&DID=3384&CID=433&VID=115&DOC=File.PDF].

¹⁵ EPA Overview, p. 6.

¹⁶ A polymer is a compound, usually large, composed of numerous copies of a much simpler compound (known as the monomer) which form long chains. Many polymers are not toxic, and therefore are of limited concern to EPA. Criteria for determining whether a polymer is eligible for exemption from PMN requirements may be found at 40 CFR 723.250.

submitted inventory update reports for about 9,000 chemicals.^{17 18} The most recent inventory update was conducted in 2006. The next update will be done in 2011, because EPA amended the general rule governing inventory updates (issued under TSCA Section 8(a), changing the frequency of future updates to once every five years.¹⁹ EPA also amended the inventory update rule to require reporting for inorganic chemicals (for which reporting has not been required in recent years), and to raise the threshold for chemical production volume that triggers reporting.²⁰ The new rule requires reports from roughly 3,000 facilities that produce more than 25,000 pounds, as opposed to the old level of 10,000 pounds, of chemical per year.²¹ In addition, information about the current uses and exposures of chemicals will be required from facilities that produced or imported more than 300,000 pounds of a chemical per year.²²

Review and Management of New Chemicals

All chemicals not on the TSCA chemical inventory are, by definition, “new” and subject to the Pre-Manufacture Notice (PMN) provisions of Section 5. However, EPA rules under Section 5(h)(4) establish exemptions from providing a PMN for a new chemical produced or imported at 10,000 kilograms (roughly 22,000 pounds) or less annually; if the chemical releases to the environment and human exposure are very low; or for certain polymers meeting specific requirements.²³ EPA has received approximately 40,000 PMNs since 1976, between 1,000 and 2,000 annually.²⁴ EPA protects from public disclosure the identities of as many as 90% of these new chemicals due to formal assertions by manufacturers that the information is confidential business information.²⁵

¹⁷ ACC. Questions and Answers About Chemical Testing and Regulations. July 11, 2005.

¹⁸ 68 *Federal Register* 884, January 7, 2003.

¹⁹ 70 *Federal Register* 75059-75070, December 19, 2005.

²⁰ 68 *Federal Register* 847-906, January 7, 2003.

²¹ EPA, Office of Pollution Prevention and Toxics. “Economic analysis for the amended inventory update final rule,” August 2002, pp. 3-11. This document is available through the EPA docket (OPPT-2002-0054) for the rule, at [<http://www.regulations.gov>].

²² *Ibid.*

²³ 40 CFR 723.50.

²⁴ EPA Overview, p. 10. The EPA report states that the total number of PMNs is 36,600, but that is the same as the number that appeared in the 2003 version of the report. Adding 1,500 notices per year results in the 40,000 estimate, which also corresponds to the other EPA statement that roughly half of PMN chemicals enter commerce, or some 20,000 chemicals.

²⁵ *Ibid.*, p. 10. That percentage drops to 65% for new chemicals that actually enter commerce.

Roughly 33% of PMN submissions include test data on the chemical properties. Only about 15% of submissions include data on health effects.²⁶ Due to the paucity of data for most new chemicals, EPA has developed databases and models to estimate physical-chemical properties, environmental fate, and human and environmental effects associated with more than 55 classes of chemicals.²⁷ These models are based on relationships the agency has observed between molecular structures and properties of chemicals that determine their impact on the environment and human health. Such models usually are referred to as structure-activity relationships (SARs), or sometimes quantitative structure-activity relationships (QSARs).

As of September 30, 2005, EPA reported it had taken 3,899 regulatory or voluntary actions to gather data or restrict use of roughly 10% of all PMNs.²⁸ EPA issued 1,320 Consent Orders under Section 5(e), subjected 575 new chemicals to SNUR requirements without an accompanying 5(e) order,²⁹ took four actions to protect against unreasonable risks under Section 5(f), and received information gathered through voluntary testing for at least 300 chemicals. In addition, 1,705 PMNs were “withdrawn often in face of action.”

EPA also has acted proactively to encourage the development of chemicals that are likely to be less hazardous. To that end, the agency has shared a set of its models, known as the P2 Framework, with chemical manufacturers so that they may avoid designing or developing chemicals that are likely to raise concerns and prompt requests for additional data.³⁰ For example, one of the models in the set, EPI Suite™ evaluates chemical structures and estimates the melting and boiling points, vapor pressure, and other physical and chemical characteristics of new chemicals. Another model, the Cancer Expert System, which is registered under the trademark OncoLogic™, analyzes chemical structures to determine the likelihood that they might cause cancer.³¹ By using EPA’s models, some manufacturers have been able to design “greener” products that do not require investments in extensive toxicity tests.

²⁶ Ibid., p. 8.

²⁷ EPA. “Economic analysis for the amended inventory update final rule,” August 2002, pp. 2-5.

²⁸ Ibid., p. 10.

²⁹ Because consent orders only bind the PMN submitter, EPA sometimes issues a Significant New Use Rule under Section 5(e) to ensure that other producers or processors must adhere to the same restrictions that were imposed on the PMN submitter. According to EPA (Overview, p. 11), 734 Consent Orders for PMN chemicals were accompanied by SNURs through September 30, 2005.

³⁰ EPA. Sustainable futures — Voluntary pilot project under the TSCA new chemicals program; Notice. December 11, 2002, *67 Federal Register* pp. 76285-86286.

³¹ EPA Overview, Appendix B-50.

Review and Management of Chemicals on the Original Inventory

Data Collection and Risk Assessment Authorized by TSCA. The TSCA Interagency Testing Committee (ITC), which was established under TSCA Section 4(e) to assist EPA in setting priorities among chemicals, has reviewed more than 40,000 chemicals and submitted 59 reports to EPA. The committee has selected for reporting or testing about 4,500 chemicals for which it had concerns about toxicity or exposure and for which there were few or no data on ecological effects, environmental fate, or health effects.³² These substances were added to a Priority Chemicals List. In response to ITC recommendations, EPA must promulgate rules adding these chemicals to a list in the Code of Federal Regulations for which reporting is required under the TSCA 8(a) PAIR rule and TSCA Section 8(d), the Health and Safety Data Reporting rule. The ITC has reviewed more than 10,200 studies submitted in response to 8(d) rules.

In addition, the ITC may “designate” up to 50 substances per year for testing under TSCA §4(e). The ITC reviewed roughly 2,000 to 6,000 chemicals before 1999 for possible addition to the Priority Testing List, and 1,000 to 2,000 were in fact added to the Priority Testing List.³³

EPA has addressed its responsibilities for screening and managing the 61,000 “existing” chemicals (on the original inventory) by categorizing them according to relative risk, based primarily on the information reported by manufacturers between 1975 and 1979.³⁴ Many chemicals have been assigned a low priority for evaluation and management, because they are thought to pose no risk or a relatively small risk of harm, generally because they are produced in quantities less than 10,000 pounds per year, per site, or because they are polymers. EPA has not required reporting for such chemicals under the TSCA 8(a) inventory update rule. As a result, it is not known whether many of them still are produced and distributed within the United States.

EPA has estimated that roughly 15,000 organic and inorganic chemicals are produced at significant volumes (more than 10,000 pounds per year) and are not polymers that are generally of less concern.³⁵ Of these, about 3,000 were produced

³² John D. Walker, Director, TSCA Interagency Testing Committee. Personal communication. October 6, 1999. Updated information requested from EPA but not provided. ITC website, Frequently Asked Questions. [<http://www.epa.gov/opptintr/itc/pubs/faq.htm>].

³³ Walker, personal communication. Updated information requested from EPA but not provided.

³⁴ U.S. Congress. Senate. Committee on Environment and Public Works, Subcommittee on Toxic Substances, Research and Development. Hearing held July 13, 1994, “Reauthorization of the Toxic Substances Control Act.” S. Hrg. 103-776. Statement of Lynn R. Goldman. U.S. Govt. Print. Off. Washington, DC, p. 136.

³⁵ EPA Overview, p. 15.

in volumes of one million pounds or more annually, across all U.S. companies.³⁶ These are known as High Production Volume (HPV) chemicals. HPV chemicals generally have received greater EPA scrutiny, because of the presumption that they have a relatively high potential for human and environmental exposure. Many of these HPV substances are considered likely to be benign. Others have risks that, while considerable, are well understood. (Chlorine gas or hydrogen peroxide are examples.) For most HPV chemicals, however, basic information about chemical properties is lacking.

When EPA becomes concerned that a chemical may pose an unreasonable risk, the agency first gathers data that is already available by using record keeping and reporting rules. For example, under TSCA Section 8(a), in addition to the inventory update rule, EPA has promulgated Preliminary Assessment Information Reporting (PAIR) rules.³⁷ They direct manufacturers to report within 90 days on the quantities of specified chemicals produced and released, and the extent of worker exposure. Such information is useful for determining whether exposure is sufficient to pose an unreasonable risk. Through September 2006, EPA had issued 33 PAIR rules, requiring reporting for about 1,200 chemicals.³⁸

In addition, under the authority of TSCA Section 8(c), EPA has promulgated rules requiring manufacturers, processors, and distributors of chemicals to keep records of allegations of significant adverse reactions to chemical exposure.³⁹ Through 2006, EPA had issued two reporting rules to collect such records for two chemicals and two chemical categories.⁴⁰

EPA rules under TSCA Section 8(d) require manufacturers to submit lists and copies of unpublished health and safety studies.⁴¹ As of September 2006, EPA had issued 51 reporting rules for 1,200 chemicals.⁴² In response, EPA received more than 50,000 studies.⁴³

Under TSCA Section 8(e), which requires submission of information that “reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment,” EPA has received and

³⁶ The estimated number of such chemicals, roughly 3,000, has not changed since the late 1970s, but chemical identities have changed: some chemicals produced in high volumes at that time no longer are produced at such high levels, while others are being produced at high volumes now that were not then. Moreover, some chemicals qualify intermittently as high-production volume, being produced in greater volumes in some years and lesser volumes in others.

³⁷ 40 CFR 712.

³⁸ EPA Overview, p. 16.

³⁹ 40 CFR 717.

⁴⁰ EPA Overview, p. 16.

⁴¹ 40 CFR 716.

⁴² EPA Overview, p. 16.

⁴³ *Ibid.*

reviewed more than 16,500 initial notices and 7,750 supplemental or follow-up notices since 1977. These notices contained data concerning serious adverse health effects, ecotoxicological effects, and exposures.⁴⁴ EPA receives roughly 200 new 8(e) submissions and 100 supplemental submissions each year.⁴⁵ EPA has established lists of these studies and made the studies themselves available to the public,⁴⁶ but the internet links provided on EPA's webpages are to databases that have not been updated in recent years.⁴⁷ Moreover, the value of the studies, or the lists of studies, is greatly reduced by the confidentiality claims of the submitters: in most cases, the identity of the chemical is concealed.

To track testing, production, uses, and regulations of all TSCA inventory chemicals (the so-called "existing chemicals"), EPA began using a "Master Testing List" (MTL) in 1990. The MTL presents a consolidated listing of OPPT's priorities for testing, as well as those brought forward to OPPT by other EPA Program Offices, other Federal agencies, the ITC, and international organizations such as the Organization for Economic Cooperation and Development (OECD). However, EPA's online Master Testing List is from 1996, and has not been updated.⁴⁸

When reporting rules fail to generate data that EPA believes are needed to assess risks, EPA has used its authority under TSCA Section 4 to require data generation (or submission, if data are in company files). EPA has issued test rules under Section 4 for approximately 254 existing chemicals: 60 chemicals using Enforceable Consent Agreements (ECAs), 24 chemicals under negotiated testing agreements, and about 170 chemicals covered by final test rules.⁴⁹

⁴⁴ EPA. Interagency Testing Committee. Substantial Risk Information. TSCA Section 8(e). [<http://www.epa.gov/oppt/itc/pubs/sect8e.htm>].

⁴⁵ EPA Overview, p. 17. The apparent inconsistency between EPA's annual and total numbers is a result of the voluntary Compliance Audit Program (CAP) which allowed manufacturers to file overdue notices and pay pre-set penalties of up to one million dollars. CAP began in 1991 (56 FR 4128, February 1), ended on May 15, 1996 (68 FR 33131, June 3, 2003), and brought in as many as 10,000 notices. [<http://www.epa.gov/opptintr/tscas8e/pubs/basicinformation.htm>].

⁴⁶ EPA. Toxic Substances Control Act Section 8(e) Notices. [<http://www.epa.gov/oppt/tscas8e/pubs/basicinformation.htm#paccess>].

⁴⁷ The link to the TSCATS database through the National Library of Medicine's Toxline is at least two years out of date. Information in EPA's own online database is current only through 2005. Syracuse Research Corporation's website includes submissions through 2004. The database available through Scorecard was last updated May 18, 2000.

⁴⁸ EPA. 1996 Master Testing List. [<http://www.epa.gov/opptintr/chemtest/pubs/mtl.htm>]. Schweer, Greg (Chief of the Chemical Information and Testing Branch in OPPT.) Personal communication. July 27, 2007.

⁴⁹ Although the EPA Overview states on page 15 that test data have been generated for about 200 chemicals, that number was not updated from the 2003 draft. It omits the 51 chemicals addressed in test rules published March 16, 2006 (71 FR 13707-13735) and April 26, 2004 (69 FR 22402-22441). [<http://www.epa.gov/opptintr/chemtest/pubs/4final.htm>].

EPA Assistant Administrators for OPPTS sometimes have criticized TSCA provisions concerning data collection. For example, former Assistant Administrator Lynn Goldman testified in 1994 that “Our available tools for gathering testing data about these chemicals are cumbersome.”⁵⁰ She later explained that under the provisions of TSCA Section 4, “It’s almost as if ... we have to, first, prove that chemicals are risky before we can have the testing done to show whether or not the chemicals are risky.”⁵¹ This situation results in high transaction costs due to legal challenges when test rules are promulgated: the regulated community generally can argue that there is insufficient evidence supporting the agency’s determination that a rule is needed.⁵² Goldman testified:

For example, in July 1993 we promulgated a TSCA section 4 multi-chemical toxicity end point test rule covering 10 chemicals. In October 1993, however, we were sued by the Chemical Manufacturers Association [now the American Chemistry Council]. Settlement was only reached earlier this month [May 1994]. We also promulgated a final TSCA section 4 test rule on October of 1993 on four chemicals, and were sued by the manufacturers for two of those four chemicals. Settlement negotiations are still underway for those.⁵³

In a recent report on federal requirements for toxicity testing, the National Research Council agreed with Dr. Goldman and noted that,

TSCA authorizes EPA to review existing chemicals, but toxicity and exposure information on them is typically so incomplete that it does not support the review process. EPA can require testing if it determines that a chemical meets a specific set of criteria; however, in vitro and whole-animal tests are rarely required. Thus, the basis for establishing priorities and requiring testing for industrial chemicals in the united States has not progressed much over the last 20 years.⁵⁴

The current head of OPPTS has a different opinion. According to Assistant Administrator James Gulliford, who testified before the Senate Committee on Environment and Public Works in August 2006:

⁵⁰ U.S. Congress. Senate. Committee on Environment and Public Works, Subcommittee on Toxic Substances, Research and Development. Hearing held May 17, 1994, “Reauthorization of the Toxic Substances Control Act.” S. Hrg. 103-776. Statement of Lynn R. Goldman. U.S. Govt. Print. Off. Washington, DC, p. 6.

⁵¹ *Ibid.*, p. 8.

⁵² As explained in an earlier section, the provisions of Section 4 authorize test rules only if EPA determines that a chemical “may present an unreasonable risk,” or that there is a potential for a substantial quantity to be released into the environment or for substantial or significant human exposure.

⁵³ U.S. Congress. Senate. Committee on Environment and Public Works, Subcommittee on Toxic Substances, Research and Development. Hearing held May 17, 1994, “Reauthorization of the Toxic Substances Control Act.” S. Hrg. 103-776. Statement of Lynn R. Goldman. U.S. Govt. Print. Off. Washington, DC, p. 6.

⁵⁴ National Research Council. 2006. *Toxicity Testing for Assessment of Environmental Agents: Interim Report*. The National Academies Press, Washington, DC, pp. 100, 112.

TSCA provides the agency with the necessary authority to ensure that new chemicals are adequately reviewed, that EPA can require reporting or development of information needed to assess existing chemicals, and that those chemicals that pose an unreasonable risk can be effectively controlled. Using TSCA as the foundation for our efforts, EPA has, over the decades, developed a wide array of regulatory and voluntary approaches and tools to assist us in our goal to protect both human health and the environment. Using the strengths of both regulatory and partnership approaches we have ensured effective, timely chemical management decisions.⁵⁵

Some of those voluntary approaches and tools are described below.

Voluntary Initiatives to Gather Data. EPA also obtains data about chemical properties through various voluntary programs, some aimed at particular chemical groups (such as certain fluorinated compounds),⁵⁶ and others aimed at entire categories of chemicals. Several High Production Volume (HPV) testing programs are examples of the latter type.⁵⁷ The regulated community considers the flexibility of TSCA that permits such voluntary programs to be one of the TSCA's greatest strengths.⁵⁸

EPA efforts to develop toxicity data on HPV chemicals date back to the late 1980s. At that time, the Organization for Economic Cooperation and Development (OECD), an intergovernmental organization consisting of 29 developed countries, including the United States, began developing a voluntary program to develop basic toxicity information for chemicals produced in volumes greater than 2.2 million pounds per year in at least one member country or in the European Union.⁵⁹ As of 2004, the OECD had listed 4,843 such HPV chemicals. In 1990, OECD countries agreed to generate and gather data sufficient to allow an informed judgment with respect to the hazard potential of certain of these high production volume chemicals. The necessary data elements are referred to as the Screening Information Data Set, or SIDS. A SIDS has been, or is being, compiled for approximately 600 of these substances.⁶⁰

EPA's HPV Challenge Program began in 1998, when Vice President Gore and EPA Administrator Browner called on the chemical industry to produce health and

⁵⁵ U.S. Congress. Senate. Committee on Environment and Public Works. Hearing held August 2, 2006, "Oversight on the Toxic Substances Control Act and the Chemicals Management Program at EPA." Submitted testimony of James B. Gulliford.

⁵⁶ EPA Overview, p. 17.

⁵⁷ Overview, pp. 30-33.

⁵⁸ Roberts, Kathleen M. (Senior Director, Regulatory and Technical Affairs, American Chemistry Council.) Personal correspondence, September 5, 2007.

⁵⁹ Organisation for Economic Co-operation and Development. Description of OECD work on investigation of high production volume chemicals. [http://www.oecd.org/document/21/0,2340,en_2649_201185_1939669_1_1_1_1,00.html].

⁶⁰ EPA. OECD SIDS voluntary testing program for international high production volume chemicals. [<http://www.epa.gov/oppt/chemtest/pubs/oecdsids.htm>].

environmental effects data for approximately 2,782 chemicals produced in, or imported to, the United States in amounts greater than one million pounds per year, according to reports filed under the 1990 TSCA Inventory Update Rule. That challenge was prompted by studies conducted during the late 1990s that documented a lack of basic health and safety data for most chemicals in U.S. commerce.⁶¹ According to the original program goals, all basic data were to be submitted by the end of 2004 and made public by the end of 2005. EPA plans to make all the data it receives as a result of the HPV program available to the general public, consistent with a recommendation of the National Pollution and Prevention Toxics Advisory Committee (NPPTAC).

Environmental Defense, an advocacy group that helped to design the program, has issued three reports on the status of the HPV program to date.⁶² According to Richard Denison, senior scientist with Environmental Defense who has been tracking the HPV chemicals, through July 2007, chemical manufacturers had committed to providing EPA information on roughly 1,300 chemicals produced in high volumes.⁶³ Data sets still were incomplete for 536 of the HPV chemicals on the original list, as of July 2007, according to Denison. Furthermore, he said that no manufacturer had committed to providing information for about 265 chemicals on that list.⁶⁴ By April 2007, EPA had entered data received for 873 chemicals into its new High Production Volume Information System, Denison reported.⁶⁵

More than 500 chemicals not on the original list now qualify as HPV chemicals; 231 of these are being sponsored by manufacturers through an Extended HPV Program, according to Denison.⁶⁶ On the other hand, about 327 of the chemicals on the original list are no longer produced in such high volumes, according to the most recent reports filed in response to inventory update rules in 1998 and 2002.^{67,68} EPA plans a final report on the HPV Challenge Program in 2008.

⁶¹ Roe, David, William Pease, Karen Florini, and Ellen Silbergeld. 1997. *Toxic Ignorance*. Environmental Defense Fund, Washington, DC. EPA, Office of Pollution Prevention and Toxics. 1998, *Chemical Hazard Data Availability Study*. EPA, Washington, DC.

⁶² Denison, Richard A. and Karen Florini. 2003. *Facing the Challenge: A Status Report on the U.S. HPV Challenge Program*. Environmental Defense, Washington, DC. Denison, Richard A. 2004. *Orphan Chemicals in the HPV Challenge: A Status Report*. Environmental Defense, Washington, DC. Denison, Richard A. 2007. *High Hopes, Low Marks: A Final Report Card on the High Production Volume Chemical Challenge*. Environmental Defense, Washington, DC.

⁶³ Denison, Richard A. 2007. *High Hopes, Low Marks*. Environmental Defense. Washington, DC. p. 11-12.

⁶⁴ *Ibid.*, p. 11.

⁶⁵ *Ibid.*, p. 21.

⁶⁶ *Ibid.*, p. 23.

⁶⁷ *Ibid.*, p. 11.

⁶⁸ Willis, Jim. High Production Volume (HPV) Challenge Program — Future Directions. Presentation to the First U.S. Conference on Characterizing Chemicals in Commerce: Using Data on High Production Volume (HPV) Chemicals, Austin, Texas, December 13, 2006.

The U.S. HPV Challenge Program is similar to an international program organized by chemical trade groups known as the International Council of Chemical Associations (ICCA). The ICCA initiative aims to test and assess an additional 734 chemicals produced in volumes greater than 22 million pounds annually.

Another, much smaller, U.S. initiative is the Voluntary Children's Chemical Evaluation Program (VCCEP). It aims to provide detailed information about risks to children potentially posed by a small group of 23 chemicals. Manufacturers have volunteered to conduct basic tests for 20 of these chemicals.⁶⁹

The American Chemistry Council has noted that through the HPV program (and related OECD program), the chemical industry has developed and submitted to EPA data for "more than 95% of all chemicals in commerce today, by volume," and the public has electronic access to these data through EPA's High Production Volume website ([<http://www.epa.gov/hpv>]).⁷⁰ However, the HPV program only collected information for about 2,000 chemicals.⁷¹ The MPV program will address another 7,000 or so chemicals.

Despite the noteworthy progress being made through these voluntary programs, which is greater than under any previous TSCA initiative, most existing chemicals still lack toxicity data relevant to hazard assessment.^{72 73} Data also are lacking on production volume and use, which are critical for determining the potential for human and environmental exposure and for risk assessments that would permit priority setting for EPA action.⁷⁴ Moreover, with respect to new chemicals, roughly two-thirds of PMN submissions do not include test data on chemical properties, and almost 85% of PMN submissions provide no data on health effects.⁷⁵

Some lawyers argue that TSCA acts as a disincentive to data production, and therefore to data submission, by punishing any failure to report information about

⁶⁹ EPA Overview, p. 34.

⁷⁰ American Chemistry Council. 2006. "TSCA Myth vs. Fact." Note, that this percentage refers to the volume of HPV chemicals produced, rather than to the number of different chemicals in commerce. [http://www.americanchemistry.com/s_acc/bin.asp?SID=1&DID=3384&CID=433&VID=115&DOC=File.PDF].

⁷¹ The basic screening data being collected includes data for four health-related endpoints (acute toxicity, chronic toxicity, mutagenicity, and reproductive effects/developmental toxicity), ecological effects, and environmental fate endpoints.

⁷² EPA, Office of Pollution Prevention and Toxics. 1998. *Chemical Hazard Data Availability Study*. EPA, Washington, DC.

⁷³ Physicians' Committee for Responsible Medicine. "The Availability of HPV Chemical Data" at [http://www.pcrm.org/resch/anexp/hpv_report.html]. Conrad, James W. Jr. 2006. Open Secrets: The Widespread Availability of Information about the Health and Environmental Effects of Chemicals. *Law & Contemporary Problems*, v. 69 (Summer) pp. 141- 165.

⁷⁴ EPA, Office of Pollution Prevention and Toxics. "Economic analysis for the amended inventory update final rule," August 2002, pp. 2-8.

⁷⁵ EPA Overview, p. 8.

adverse health impacts, but not requiring testing to determine whether such impacts might occur.⁷⁶

Risk Management. EPA has used its Section 6 authority on eight occasions to restrict manufacture or use of six chemicals.⁷⁷ Two of these regulations were later superseded by regulations under other environmental laws.⁷⁸ Four chemicals remain regulated to some extent under TSCA Section 6: metalworking fluids, hexavalent chromium use to treat water in comfort cooling systems (that is, cooling towers dedicated exclusively to heating, ventilation, and air conditioning or refrigeration systems), PCBs, and new uses of asbestos.⁷⁹ Regulation of PCBs is required explicitly by TSCA Section 6(e).

According to Ed Brooks, of EPA's Chemical Control Division, EPA used Section 6 authority sparingly because "With respect to the unreasonable risk issue, ... the Agency came to view Section 6 rulemaking as an inherently large and complex undertaking that offered little prospect of resulting in success."⁸⁰

In four instances, EPA referred chemicals for regulation to another federal agency. In 1983 and 1984, EPA referred six chemicals to the Occupational Safety and Health Administration under TSCA Section 9(a).⁸¹ In 1990, EPA sent a 9(a) report to the Food and Drug Administration (FDA) on dioxins and furans in wood and paper products.⁸² In testimony before the Senate Committee on Environment and Public Works, Subcommittee on Toxic Substances, Research and Development, Lynn R. Goldman, then Assistant Administrator of EPA's Office of Pesticides, Prevention, and Toxic Substances, testified that "the formal referral mechanism [of

⁷⁶ Wagner, Wendy E. 2004. Commons ignorance: The failure of environmental law to produce needed information on health and the environment. *Duke Law Journal*, v. 53, pp. 1619-1745. Case, David. W. 2005. The EPA's HPV Challenge Program: A toxic tort liability trap? *Washington & Lee Law Review*, v. 62, pp. 147-206.

⁷⁷ EPA Overview, p. 20. EPA also devotes significant resources to so-called "national program chemicals," which include dioxin, mercury, and the chemicals addressed explicitly by TSCA Section 6(e) and Titles II through IV, PCBs, asbestos, radon, and lead, respectively. With respect to these chemicals, EPA coordinates federal activities as well as international efforts to reduce risks.

⁷⁸ EPA Overview, p. 20.

⁷⁹ EPA Overview, p. 20. Also see 40 CFR Parts 747, 749, 761, and 763, respectively.

⁸⁰ Brooks, Ed. 1996. Evolution of Risk Management of Existing Chemicals Under TSCA. In: *TSCA at Twenty, Chemicals in the Environment: Public Access Information*, Issue 4 (Fall). EPA 749-R-96-001. EPA, Washington, DC.

⁸¹ The chemicals were 4,4-Methylenedianiline (48 *FR* 42898, September 20, 1983), 1,3-Butadiene (48 *FR* 20524, May 15, 1984), and four glycol ethers (51 *FR* 18488, May 20, 1986).

⁸² 55 *FR* 53047, December 26, 1990.

Section 9] has proven burdensome to EPA and cumbersome as a mechanism for obtaining prompt consideration by applicable agencies.”⁸³

Impact of a 1991 Decision by the Fifth Circuit Court on Section 6 Rulemaking.⁸⁴ In 1991, the U.S. Court of Appeals for the Fifth Circuit vacated and remanded an EPA rule promulgated under Section 6 that prohibited the manufacture, importation, processing, and distribution of asbestos in almost all products.⁸⁵ The substantive heart of the *Corrosion Proof* decision was its conclusion that EPA had insufficiently justified its ban. The ruling is described in more detail in the Appendix to this report.

With very limited exception, legal commentators have viewed TSCA section 6, particularly as construed in *Corrosion Proof Fittings*, as imposing high evidentiary hurdles on EPA regulators, so that little regulation under its authority may be expected.⁸⁶ As explained by Robert B. Haemer, *Corrosion Proof Fittings* “may have done the most damage to EPA’s ability to regulate chemical substances.” He continues:

The fact that the court found ten years of rulemaking and a 45,000 page record inadequate to support a ban on asbestos makes it appear that EPA management has good reason to avoid rulemaking altogether. Requiring EPA to use the balancing approach recommended by the *Corrosion Proof* court would result in the agency making tough policy choices that cannot be resolved solely by science. The time and effort required to flawlessly follow rulemaking procedures affects [sic] EPA’s decisions about whether to pursue section 6 rulemakings, especially considering that more procedure may not necessarily produce better administrative decisions. It is even more difficult for EPA to surmount an overly restrictive interpretation of reasonable risk....⁸⁷

The court’s remand of the asbestos rule in *Corrosion Proof Fittings* indicates that TSCA’s failure is tied to its structure, not the lack of need for the statute itself. The balancing of risks in the face of a very high hurdle of scientific uncertainty

⁸³ U.S. Congress. Senate. Committee on Environment and Public Works, Subcommittee on Toxic Substances, Research and Development. Hearing held July 13, 1994, “Reauthorization of the Toxic Substances Control Act.” S. Hrg. 103-776. Statement of Lynn R. Goldman. U.S. Govt. Print. Off. Washington, DC. p. 140.

⁸⁴ This section of the report was written chiefly by Robert Meltz, Legislative Attorney, CRS American Law Division.

⁸⁵ *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (5th Cir. 1991).

⁸⁶ See, for example, Thomas O. McGarrity, *Professor Sunstein’s Fuzzy Math*, 90 Geo. L. J. 2341, 2376 (2002); Thomas Sullivan (ed.), *ENVIRONMENTAL LAW HANDBOOK* 573 (16th ed.) (2001); Robert B. Haemer, *Reform of the Toxic Substances Control Act: Achieving Balance in the Regulation of Toxic Substances*, 6 *Envtl. Lawyer* 99, 115 (1999); and Joyce Merritt, Comment, *Standard of Review Under the Toxic Substances Control Act: Corrosion Proof Fittings v. EPA*, 8 *J. Nat. Res. & Env’tl. L.* 167, 176 (1992/1993).

⁸⁷ Haemer, Robert B. 1999. Reform of the Toxic Substances Control Act: Achieving balance in the regulation of toxic substances. *Environmental Lawyer*, v. 6, n. 99, pp. 118-119.

under TSCA leaves EPA almost paralyzed to take action to regulate toxic substances.⁸⁸

A 1993 study by the Carnegie Commission on Science, Technology, and Government, *Risk and the Environment: Improving Regulatory Decision Making*, concluded, “Regardless of whether the statute, the courts, the agency, or others should be faulted in this case, it is unsettling that EPA could not satisfy TSCA’s requirements for promulgating a single rule after a decade’s effort.”⁸⁹

The only favorable comment by a legal scholar regarding TSCA and *Corrosion Proof Fittings*, as revealed by CRS research, was the following statement by the current EPA Assistant Administrator for Enforcement and Compliance Assurance—

Contrary to the criticisms of those who would rewrite toxic substance control statutes, or restrict the scope of judicial review under these statutes, *Corrosion Proof Fittings* illustrates the importance of the substantive protections accorded private parties under the current toxic substances regulatory statutes. ... *Corrosion Proof Fittings* is a case study in how judicial review can prevent inefficient and wasteful regulation of toxic substances.⁹⁰

Recent Events and Trends

Few legislators have expressed much interest in TSCA during its thirty-year history: Congress has held few oversight hearings on its implementation, and the basic TSCA provisions in Title I have never been amended. However, recent legal, scientific, and technological developments, which appear to be increasing legislative interest, are discussed below. Recent Congressional and Administrative initiatives that address the purported weaknesses of TSCA also are summarized.

State Laws and Local Ordinances

Many states and localities have enacted laws in recent years restricting the sale or use of various chemicals⁹¹ or categories of substances that are federally managed

⁸⁸ Id. at 126.

⁸⁹ Carnegie Commission on Science, Technology, and Government. 1993. *Risk and the Environment: Improving Regulatory Decision Making*. Carnegie Commission on Science, Technology, and Government, New York.

⁹⁰ Nakayama, Granta. 1992. *Corrosion Proof Fittings v. EPA: No Death Penalty for Asbestos Under TSCA*. *George Mason Independent Law Review*, v. 1, pp. 99-101.

⁹¹ A general compendium of information about state chemical policies is provided electronically by the University of Massachusetts, Lowell, at [<http://www.chemicalspolicy.org/usstatelevel.shtml>], visited June 27, 2007. Recent restrictions include a total ban on decabrominated diphenyl ether in Washington and restrictions on formaldehyde emissions from certain wood products by the California Air Resources Board. “Washington state passes PBDE ban. Policy news.” April 27, 2007. *Environmental Science & Technology*, v. 41, n. 9, online edition. [<http://pubs.acs.org/subscribe/journals/esthag-w/2007/apr/policy/>]
(continued...)

under TSCA. For example, numerous state and even local governments have enacted laws regulating bioengineered organisms, although EPA treats such organisms as “new chemical substances” (see below).⁹² Those promoting revisions to TSCA argue that state laws and local ordinances restricting chemicals are evidence that TSCA is not effective in controlling chemicals in the marketplace, and that citizens have lost confidence in the ability of the act to adequately protect public health and the environment.⁹³ Some California legislators have been modeling proposals based on the laws of other nations. For example, a law recently enacted in California that restricts formaldehyde emissions from certain wood products is similar to a law in the European Union. Other bills in the California Assembly or Senate have specifically referenced Canadian or Dutch law.⁹⁴

A number of California’s legislative proposals derive from a University of California (Berkeley) report commissioned in January 2004 by Members of the California legislature.⁹⁵ That report concluded that the cause of the chemical challenges facing California is the failure of TSCA to provide an effective vehicle to motivate chemical producers to generate and distribute adequate information on the toxicity of their products. This “information deficit,” the report continues, makes it “difficult for businesses and consumers to choose safer chemicals” and has “undermined the efficient operation of the market.” As a result, the market is driven by the function and price of chemicals more than by their toxic properties, according to the report’s principal author.⁹⁶ He also suggested that the process is self-sustaining: because the market is driven by knowledge of what chemicals can do and what they cost, he claims that new graduates with Ph.D.s in chemistry from major universities can lack even a rudimentary understanding of toxicology.⁹⁷ The solution

⁹¹ (...continued)

n1_PBDEs.html]. Whetzel, Carolyn. 2007. “California Adopts Emission Standards For Formaldehyde From Wood Products.” *Daily Environment Reporter*, May 2, 2007, p. A-2. [<http://www.arb.ca.gov/regact/2007/compwood07/compwood07.htm>].

⁹² National Conference of State Legislatures. Agriculture: Biotechnology Statutes Chart. [<http://www.ncsl.org/programs/agri/biotchl.htm>].

⁹³ Ditz, Daryl. 2006. “Cloudy Skies, Chance of Sun: A Forecast for U.S. Reform of Chemicals Policy.” Center for International Environmental Law: Washington, DC. Watson, Traci. States and cities move to curb toxic substances the EPA hasn’t,” *USA Today*, May 5, 2007, online version. [http://www.usatoday.com/news/washington/2007-05-07-epa-chemicals_N.htm?csp=34].

⁹⁴ Rau, Jordan. “Legislature Targets Toxic Risks in Products,” *Los Angeles Times*, May 30, 2005. [http://www.safecosmetics.org/newsroom/la_times_5_30_05.cfm]. California Senate bill SB 973, Chemicals of Concern. Introduced February 23, 2007. [http://www.leginfo.ca.gov/pub/07-08/bill/sen/sb_0951-1000/sb_973_bill_20070223_introduced.html].

⁹⁵ Wilson, Michael P. 2006. *Green Chemistry in California: A Framework for Leadership in Chemicals Policy and Innovation*. California Policy Research Center, University of California, Berkeley. Hereafter cited as Wilson, *Green Chemistry*. [http://coeh.berkeley.edu/news/06_wilson_policy.htm].

⁹⁶ *Ibid.*

⁹⁷ “Stakeholders mull need for strategy to address emerging chemical issues.” Special (continued...)

for California, the report concludes, is for it to take a leadership role in chemicals policy.⁹⁸

As the number of state and local restrictions on chemicals increases, compliance becomes more difficult and costly for chemical manufacturers and distributors who operate in multiple states.⁹⁹ The emerging legal patchwork may also be less firmly based on sound science. For these reasons, some large chemical makers might lean toward TSCA reform to preempt state and local regulatory action. TSCA currently does not prevent state and local regulation of chemicals, unless they are already regulated under the act.¹⁰⁰

International Agreements on Chemicals

Globalization of commerce in chemicals also is forcing some reconsideration of TSCA. International commerce in chemicals has grown significantly during the thirty years of TSCA's existence, and most of the largest chemical manufacturers, processors, and distributors now operate internationally. This means that they must adjust their business practices to accommodate the expectations of diverse governments, labor forces, and customers. Proliferating and sometimes conflicting obligations with respect to the chemical industry have prompted some multinational firms to advocate for international harmonization of regulations.¹⁰¹

The Executive Branch, working through the State Department and EPA, has sought to smooth the way for American businesses abroad (at the same time that it reduces its own burden for data collection and chemical risk assessments), through informal agreements and formal treaties. Business interests and other non-governmental organizations often have participated in negotiations. Domestic implementation of such agreements, however, is constrained by U.S. environmental statutes.

Between 1998 and 2001, the United States signed two international treaties and one executive agreement to ban or strictly regulate certain toxic chemicals that persist and bioaccumulate in the environment. The agreements apply to all production,

⁹⁷ (...continued)

report. April 30, 2007. *Daily Environment Report*. p. B-1.

⁹⁸ Wilson, Michael P. Testimony before the California Senate Environmental Quality Committee, June 28, 2006, Sacramento, CA.

⁹⁹ Phibbs-Rizzuto, Pat. 2007. "State efforts to restrict chemicals rising, speakers at global chemical conference say," *Daily Environment Report*, March 12, 2007. p. A-4.

¹⁰⁰ TSCA Section 18 preempts state and local actions that establish or continue in effect requirements applicable to a chemical substance or mixture that is regulated federally under TSCA Section 5 or 6, unless a state requirement is identical to the federal requirement, implements another federal law, or prohibits use of the substance or mixture within the state. Section 18 allows a state to ask EPA to allow a state requirement that provides a significantly higher degree of protection from risk than does the federal requirement.

¹⁰¹ American Electronics Association. AeA International Environment Overview. Issues Summary. [http://aeanet.org/GovernmentAffairs/gamb_EnvOverview.asp].

import, export, use, and disposal of the listed chemicals. But TSCA Section 12(a) explicitly excludes chemicals intended solely for export from regulation under TSCA, deferring to the authority of the importing nations to impose any necessary restrictions on chemical imports or uses. To implement the international agreements, TSCA would have to be amended to permit regulation of chemical production for export, at least in the case of the chemicals specified in the treaties.

Although there is broad U.S. support for all three international agreements, stakeholders and policy makers have not been able to agree on implementing legislation targeted specifically to the necessary TSCA changes. Legislators appear preoccupied by the larger issues that surround TSCA specifically (discussed in the following section of this report) and chemical regulation more generally. Until these larger issues are resolved, implementing legislation seems unlikely to be enacted. Meanwhile, multinational chemical company representatives and international environmental protection groups can be expected to continue pushing for legislative action. For more information about these international agreements, see CRS Report RS22379, *Persistent Organic Pollutants (POPs): Fact Sheet on Three International Agreements*, by Linda-Jo Schierow.

New Chemical Laws in Other Nations

Recent legislation in the European Union (EU) addressed many of the broader questions about how chemicals should be regulated. The legislation

- is based on the EU version of the precautionary principle;¹⁰²
- requires data production and reporting for most chemicals in commerce;
- shifts responsibility for demonstrating a chemical's safety from regulators to chemical makers and processors;
- reverses the default status for certain chemicals without data from safe to unsafe; and
- requires reduced use of specified toxic chemicals when safer substitutes are available.

Adopted in December 2006, the new law for the Registration, Evaluation, and Authorization of Chemicals, known as REACH, is heralded by some as a model for other countries that are striving to develop sustainable economies based on the precautionary principle. Others are concerned about the potential negative effect of REACH on the European economy and international commerce.

¹⁰² Generally, the European Commission describes the precautionary principle as a risk management strategy used when “there are reasonable grounds for concern that potential hazards may affect the environment or human, animal or plant health, and when at the same time the available data preclude a detailed risk evaluation.” In applying the precautionary principle, the EU strives to achieve a high level of protection by taking protective action before all relevant scientific knowledge is available. The EU definition of the precautionary principle is being refined over time by case law and through the diverse contexts in which it is employed. For a thorough discussion of the precautionary principle see the Communication from the Commission of the European Communities which was issued in the year 2000. [http://ec.europa.eu/dgs/health_consumer/library/pub/pub07_en.pdf].

U.S. chemical exporters, and even manufacturers whose products contain certain chemicals, will have to meet REACH requirements, which are to be phased in over the next 11 years. Many U.S. environmentalists hope that REACH implementation in the EU will demonstrate the feasibility of its approach to chemical regulation, and show the way to TSCA reform. Some argue further that failing to amend TSCA in the near term will reduce (or further reduce) U.S. stature as a leader in global environmental policy.¹⁰³

Others reject the approach taken by REACH and defend TSCA, arguing that the U.S. approach continues to provide the leading example of chemical regulation based on sound, risk-based science.¹⁰⁴ As stated in an American Chemistry Council (ACC) factsheet:

The United States chemical management regulatory system is based on the use of credible scientific information and embodies several layers of precaution that are protective of human health and the environment.¹⁰⁵

Moreover, the new trilateral Montebello Agreement reportedly is seen by some as an American alternative to REACH that will focus resources efficiently on chemicals of greatest concern.¹⁰⁶

Implementation of REACH will provide the world with evidence regarding the pros and cons of its approach to chemicals policy. These lessons will probably influence the debate about future U.S. chemical policy generally, and TSCA in particular. In addition, REACH will force multinational firms to produce toxicity and exposure data in order to market their products in Europe. Once reported to the EU, those data might become public or might be provided to EPA. For more information about REACH, see CRS Report RS22673, *Chemical Regulation in the European Union: Registration, Evaluation, and Authorization of Chemicals*, by Linda-Jo Schierow. For comparisons of REACH and TSCA, see Government Accountability Office report GAO-07-825, *Chemical Regulation: Comparison of U.S. and Recently Enacted European Union Approaches to Protect against the Risks of Toxic Chemicals*, or Richard Denison's 2007 report *Not That Innocent*.¹⁰⁷ Denison's report also compares REACH and TSCA to the Canadian Environmental Protection Act of 1999.

¹⁰³ Purvis, Meghan. 2006. "EU: Burden of proof shifted to chemical maker," *The Forum: Who's Ahead In Environmental Protection: The United States or the European Union?* *The Environmental Forum*, (March/April), p. 50.

¹⁰⁴ ACC. Registration, Evaluation, and Authorization of Chemicals. [http://www.americanchemistry.com/s_acc/sec_policyissues.asp?CID=621&DID=2217].

¹⁰⁵ ACC. TSCA Fact Sheet. August 2, 2006. [http://www.americanchemistry.com/s_acc/bin.asp?SID=1&DID=2766&CID=433&VID=115&DOC=File.PDF].

¹⁰⁶ Rizzuto, Pat. Canadian, U.S. Trade Associations Praise Trilateral Agreement on Chemical Reviews. *Daily Environment Report*, August 22, 2007. p. A-2.

¹⁰⁷ Denison, Richard A. 2007. *Not That Innocent*. Environmental Defense, Washington, DC.

Scientific Developments and Issues

Toxicology. Toxicology is the study of how chemicals adversely affect the health of individuals. It is an ancient area of study, but its modern form emerged only recently, largely during the 1960s and 1970s. The first textbook of toxicology was published in 1972.¹⁰⁸ Since that time, the science has grown and developed rapidly. The Presidential/Congressional Commission on Risk Assessment and Risk Management, which was established by Congress in the Clean Air Act Amendments of 1990, recommended in 1997 that TSCA “be updated to reflect advances in toxicology and regulation” since TSCA was enacted.¹⁰⁹

TSCA reflects the concerns of the early days of toxicology, and the knowledge and methods of that first toxicology book. At the time TSCA became law, concerns focused on acute effects, birth defects, or cancer due to accidental poisoning incidents, pharmaceutical drugs, or occupational exposures. Thus, TSCA addresses individual chemicals and does not account for the variety of metabolic processes leading to toxicity, vast individual differences in sensitivity and vulnerability to toxic effects (and consequently, the inherent difficulty of proving that an individual case or group of cases of disease resulted from a particular exposure), or for effects on neurological development, reproduction, the immune system, or endocrine systems.

In recent years, Congress has directed EPA to conduct its risk assessment taking into account potential:

- vulnerability and sensitivity of developing human embryos and children, as well as other major identifiable subgroups of consumers, to toxic chemicals;¹¹⁰
- ability of chemicals to disrupt the functioning of endocrine systems;¹¹¹
- exposure from a variety of sources and environmental media (for example, drinking water as well as workplace air);¹¹² and
- cumulative exposure from different chemicals that have similar effects on the body.¹¹³

¹⁰⁸ Casarett, Louis J. and John Doull (Eds.). 1975. *Toxicology: The Basic Science of Poisons*. New York: Macmillan.

¹⁰⁹ Commission on Risk Assessment and Risk Management. 1997. *Risk Assessment and Risk Management in Regulatory Decision-Making*. Final Report, Vol. 2. p. 126.

¹¹⁰ Food Quality Protection Act of 1976, P.L. 104-170, Section 405, which amended the Federal Food, Drug, and Cosmetic Act, Section 408(b)(2)(C) and (D).

¹¹¹ Food Quality Protection Act of 1976, P.L. 104-170, Section 405, which amended the Federal Food, Drug, and Cosmetic Act, Section 408 by adding subsection (p). Safe Drinking Water Act, 42 USC Sections 300F-300j-26.

¹¹² Food Quality Protection Act of 1976, P.L. 104-170, Section 405, which amended the Federal Food, Drug, and Cosmetic Act, Section 408(b)(2)(D).

¹¹³ *Ibid.*

Although such factors are not excluded as considerations under TSCA, public health advocates have argued that they do not influence decisions enough, given the uncertainties of the toxicology and the need to balance risks and benefits under TSCA.¹¹⁴

Computational Toxicology. The most recent innovation with respect to toxicology emerged in the late 1990s and is developing rapidly: computational toxicology.¹¹⁵ Computational toxicology refers to computer-assisted techniques for estimating risks to human health or the environment based on mathematical models that link scientific knowledge about various chemicals, environmental media (air, water, land, etc.), and the biology of human and other potentially affected organisms. Computational toxicology is particularly valuable for comparing and analyzing large amounts of very detailed biological data, for example on the molecular structure of the human genome and the functions of its parts. This has allowed scientists to identify genetic variations that may make some individuals more or less vulnerable to damage from exposure to certain chemicals. For more information about these emerging techniques, see the interim report by the National Research Council's Committee on Toxicity Testing and Assessment of Environmental Agents.¹¹⁶

Computational toxicology also is expected to improve the scientific basis for EPA's decisions about whether to require data collection or to regulate particular chemicals for which data are lacking. Data can be easily and relatively quickly collected on the identities of proteins produced within living cells as they respond to different chemicals or other stressors.¹¹⁷ Such data indicating biological effects of exposure are generated using rapid, so-called "high-throughput" biochemical tests and recorded in vast databases. The databases then are analyzed for patterns, which may be used to inform models intended to predict the environmental and toxicity characteristics of chemicals not yet tested. By matching this information on the biological response to toxic substances with genomic information, scientists can identify genetic variations more or less susceptible to toxic effects of exposure. A

¹¹⁴ Children's Environmental Health Network. April 2005. In Support of Child-Safe U.S. Chemical Policies: Statement of Principles. [<http://www.cehn.org/cehn/chemicals%20&%20Vccep/Child%20Safe%20Chemicals%20Statement%20of%20Principles.htm>].

¹¹⁵ Computational toxicology also is referred to as *in silico* toxicology, as opposed to *in vitro* toxicology, which refers to toxicology based on experiments using tissues grown in laboratory glassware, or *in vivo* toxicology, referring to toxicology based on observation of living organisms.

¹¹⁶ Committee on Toxicity Testing and Assessment of Environmental Agents, National Research Council. 2006. *Toxicity Testing for Assessment of Environmental Agents, Interim Report*. Washington, DC: The National Academies Press. pp. 194-221.

¹¹⁷ The application of computers to analyze biological information is known as bioinformatics. When the biological information being studied is the proteins being manufactured within the cells of a particular tissue at a particular time, the field of study is known as proteomics. When the focus is on the function of various portions of a genome (human or otherwise), the field is called genomics. When the focus is on how genomes are affected by exposure to toxic substances, the field is called toxicogenomics.

recent report calls for amendments to TSCA that would require such tests, with the aim of more rapidly developing these tools for toxicity assessment.¹¹⁸

As mentioned previously, EPA already relies heavily on its quantitative structure-activity relationship (QSAR) models for setting priorities and conducting screening-level risk assessments. These models quantitatively correlate what is known about particular chemical structures and the biological activity or chemical reactivity of the chemicals in which such structures are found. The correlations then are used to predict the activity or reactivity of other chemicals with similar structures but for which data are lacking.

If these models become even more reliable predictors of chemical properties, the question may arise whether QSAR is a sufficient basis for an unreasonable risk determination.¹¹⁹ EPA may make this decision on its own authority, but Congress also might wish to weigh in on that decision. One former EPA Assistant Administrator argues that the empirical basis for SAR is weak, and that “SAR has allowed both EPA and the chemical industry to defend the TSCA program and to claim that it adequately protects the public.”¹²⁰ The empirical basis for SAR is expected to strengthen over time, however, and many scientists see SAR positively, as a potentially powerful tool that, in the long term, may reduce costs for the regulated community and reduce the need to require some animal-based toxicity tests.

Exposure Data. When TSCA was enacted, risk assessment was a primitive tool based on simple toxicological models, usually of a single incident of exposure to a single chemical, followed (usually relatively quickly) by an obvious health effect. Multiple, low-level, episodic, or chronic exposures to multiple chemicals were thought to be too complex to model. Today EPA routinely models long-term, low-level exposure through multiple pathways, and sometimes looks at cumulative exposure to different chemicals with similar modes of action.¹²¹ Such complex exposure assessment was mandated by the Food Quality Protection Act of 1996 and is conducted routinely for pesticides.

Research also has determined that the timing of an exposure can be important, especially to a developing fetus or a young child. Thus, if there are data indicating that exposure to a chemical is likely to adversely affect fetal or infant development, rat or mouse experiments may be conducted in which exposure is restricted to

¹¹⁸ Snir, Reut. 2007. *Applying Toxicogenomics Data in Chemical Regulation*. Foresight and Governance Project, Woodrow Wilson International Center for Scholars, Washington, DC. 29 pp.

¹¹⁹ No one has argued to date that QSAR is suitable for any purpose other than screening.

¹²⁰ Davies, J. Clarence. *EPA and Nanotechnology: Oversight for the 21st Century*. 2007. Woodrow Wilson International Center for Scholars, Project on Emerging Nanotechnologies. Washington, DC, p. 18. [<http://www.nanotechproject.org>].

¹²¹ For a description of modern techniques for toxicity testing, see Chapter 2 in *Toxicity Testing for Assessment of Environmental Agents, Interim Report*, by the Committee on Toxicity Testing and Assessment of Environmental Agents, National Research Council, published in 2006 by the National Academies Press in Washington, DC.

particular periods, for example, before or after mating, during the gestation period, or soon after birth.¹²²

TSCA does not prevent consideration of aggregate or cumulative exposure or of its timing, but neither does it require them. TSCA also does not provide guidance with respect to the use of such information in regulatory decisions. For example, if an unreasonable risk results from exposure to two or more chemicals, it is not clear whether TSCA authorizes EPA to control the individual chemicals contributing to the risk.¹²³ Amendments to TSCA might address such issues.

Technological Developments and Issues

Advances in science and technology also are raising some concerns about TSCA, particularly with respect to whether and how EPA's procedures for identifying and managing unreasonable risks might be applied to new forms of chemical substances like genetically modified organisms or nanoparticles.

Genetically Modified Organisms. Soon after TSCA was enacted, entrepreneurs began applying new technologies for cutting, copying, and pasting pieces of genetic material obtained from one organism into another. The resulting genetically modified organisms (GMOs) are useful for various purposes. For example, some could produce specialty enzymes for use by industry or proteins that control plant pests, while others could break down pollutants in the environment. These products of recombined DNA could not have occurred as a result of normal reproduction, but instead required significant human intervention.

Public concerns about the possible human health or environmental effects of GMO products led federal agencies to adopt in 1986 a "Coordinated Framework for Regulation of Biotechnology." The Framework established a federal policy in favor of regulating GMOs that are not naturally occurring and combine genetic material from different genera,¹²⁴ or that are capable of causing disease (that is, "pathogens"). In accord with the policy, federal agencies regulate GMOs according to their properties and intended uses under existing statutory authority.¹²⁵ For example, EPA

¹²² Ibid.

¹²³ However, there may be a precedent for EPA action based on potential effects due to combinations of chemicals. According to EPA, metal working fluids were regulated because they could combine with nitrates or nitrites to form carcinogenic nitrosamines (Charles Auer, personal communication, August 5, 2007).

¹²⁴ That is, the covered organism has genetic material from two organisms that would not be joined in nature because they are not of the same species. "Genera" is plural for genus, "a level in a classification system based on the relatedness of organisms" as defined in the EPA fact sheet at [<http://www.epa.gov/oppt/biotech/pubs/pdf/fs-002.pdf>].

¹²⁵ Kingsbury, David T. 1990. Regulation of Biotechnology: A. Perspective on the US 'Coordinated Framework,' Chapter 14. In: *SCOPE 44 Introduction of Genetically Designed Organisms into the Environment*, H.A. Mooney & G. Bernardi eds., Wiley, U.K. [<http://www.icsu-scope.org/downloadpubs/scope44/chapter14.html>].

regulates GMOs that produce or contain pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act.

EPA regulates GMOs that are not pesticides as new chemical substances under TSCA, unless they are outside the TSCA definition of a chemical substance.^{126 127} (For example, a GMO that is food or that produces pharmaceuticals would be regulated by the Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act.) EPA also oversees significant new commercial uses of existing microbes under TSCA Section 5.¹²⁸ EPA policy with respect to bioengineered organisms is based on its 1986 interpretation of what constitutes a “new” microorganism, as explained in an EPA Fact Sheet:

New microorganisms are those microorganisms formed by combining genetic material from organisms in different genera (intergeneric). A genus (pl. genera) is a level in a classification system based on the relatedness of organisms. EPA believes that intergeneric microorganisms have a sufficiently high likelihood of expressing new traits or new combinations of traits to be termed “new” and warrant review.¹²⁹

Some have criticized this interpretation and the resulting regulatory arrangement. For example, a critic noted in 1988, “The first difficulty is that the TSCA gives the EPA authority to regulate “chemical substances,” and there is some question as to whether living microorganisms developed for deliberate release fall within this definition.”¹³⁰ A 2004 report by the Pew Initiative on Food and Biotechnology raised the same point.¹³¹ The definition of “chemical substances” subject to TSCA is described above, in the subsection “Policies and Intent” of the section “TSCA Overview.” Nevertheless, EPA includes microorganisms that are not intergeneric on the inventory of existing “chemical substances” and requires PMNs for intergeneric microorganisms.¹³² At least eight microorganism PMNs have been

¹²⁶ Rules for products of biotechnology may be found in the Code of Federal Regulations, Title 40, Part 725. The rules also are posted online at [http://www.epa.gov/biotech_rule/].

¹²⁷ U.S. Congress. House of Representatives. Hearing before the Committee on Agriculture, Subcommittee on Conservation, Credit, and Research, June 17, 2003. Testimony of Stephen Johnson, Assistant Administrator, Office of Prevention, Pesticides, and Toxic Substances, U.S. EPA.

¹²⁸ Ibid.

¹²⁹ EPA. Microbial products of biotechnology: Final regulations under the Toxic Substances Control Act summary (fact sheet). [http://www.epa.gov/biotech_rule/pubs/fs-001.htm].

¹³⁰ Marchant, Gary. 1988. Modified Rules for Modified Bugs: Balancing Safety and Efficiency in the Regulation of Deliberate Release of Genetically Engineered Microorganisms. *Harvard Journal of Law and Technology*, v. 1, (Spring), pp. 163-208.

¹³¹ Pew Initiative on Food and Biotechnology. 2004. Issues in the Regulation of Genetically Engineered Plants and Animals. Executive Summary. p. 9. [<http://pewagbiotech.org/research/regulation/>].

¹³² 40 CFR §725.3.

received by OPPT, according to EPA.¹³³ OPPT has reviewed bacteria for degradation of hazardous wastes, enhanced nitrogen fixation in plants, and for closed system production of enzymes.¹³⁴

Other critics of the current federal Framework believe that the policy (if not the underlying statutes) is dated, particularly in light of the recent use of biotechnology to engineer large animals for various purposes.¹³⁵ They raise the question, are cloned mammals or the substances they produce also “new chemical substances” under TSCA? Investment in developing markets for such bioengineered livestock and products reportedly is suffering from a lack of clear federal rules.¹³⁶

On the other hand, many support the current regulatory framework, arguing that the dangers of genetically modified organisms are adequately controlled.¹³⁷ Although they admit that there is a possibility that a dangerous new microbe might be created inadvertently, they maintain that the risk is small, and, “Now that genetically altered bacteria have been handled for more than 20 years without disaster, earlier anxieties about mutant germs have diminished.”¹³⁸

Nanotechnology. More recently, scientists and engineers have begun to examine, design, and manipulate materials at the molecular level, or nanoscale.¹³⁹ At this scale, particles have chemical, physical, and biological properties that vary, depending on particle size and shape, even when particles are made of the same elements. Recent work in biochemistry, physical chemistry, and materials science has advanced to the point that a rapid increase in commercial applications of nanomaterials is expected. Many patents for commercial applications of nanotechnology already are pending, and hundreds of products are being marketed,

¹³³ EPA Overview, p. 12.

¹³⁴ EPA Overview, Appendix, p. B-11.

¹³⁵ Pew Initiative on Food and Biotechnology. 2004. *Issues in the Regulation of Genetically Engineered Plants and Animals*. Executive Summary. pp. 6-7. [<http://pewagbiotech.org/research/regulation/>].

¹³⁶ Pollack, Andrew. Without U.S. rules, biotech food lacks investors. *New York Times*, July 30, 2007. Online edition. [<http://www.nytimes.com/>].

¹³⁷ U.S. Congress. House of Representatives. Hearing before the Committee on Agriculture, Subcommittee on Conservation, Credit, and Research, June 17, 2003. Testimony of Stephen Johnson, Assistant Administrator, Office of Prevention, Pesticides, and Toxic Substances, U.S. EPA.

¹³⁸ Grace, Eric S. 2006. *Biotechnology Unzipped: Promises and Realities*, Revised 2nd edition. Washington DC: Joseph Henry Press. p. 216.

¹³⁹ A nanometer is one-billionth of a meter, which is about 1/75,000 of a human hair or the width of ten hydrogen atoms in a line. A bacterium is a few hundred nanometers across. Nanoscience may be defined as the study of the fundamental principles of molecules and other structures with at least one dimension roughly between 1 and 100 nanometers. For a more detailed explanation of nanotechnology, see *Nanotechnology: A Gentle Introduction to the Next Big Idea*, by Mark and Daniel Ratner (2003; Prentice Hall: Upper Saddle River, NJ). For standard terminology relevant to nanotechnology, see ASTM Standard E 2456 — 06 at [<http://www.astm.org/>].

including many cosmetics, sunscreen, tennis balls, food additives, clothes washers, and odor-free clothing.

While the potential economic gains and beneficial uses for nanotechnology are exciting prospects, the potential risks associated with nanoparticles are a concern for some scientists, policy makers, and industrial trade, consumer, and environmental groups.¹⁴⁰ There is scientific evidence that some nanoparticles may be hazardous. For example, certain nanoparticles are known to be toxic to microbes,¹⁴¹ and EPA has reported studies that have found nanoparticles generally (but not always) are more toxic than larger particles of identical chemical composition.¹⁴² Yet, such studies are rare, and nanoparticles are diverse, so that one study with one kind of particle may not be informative with respect to the properties of other kinds of particles. Research into the inherent properties and behaviors of various nanoparticles in living organisms or ecosystems is only beginning.¹⁴³

According to EPA, despite the scientific uncertainties surrounding nanoparticles, “EPA has the obligation and mandate to protect human health and safeguard the environment by better understanding and addressing potential risks from exposure to these nanoscale materials and products containing nanoscale materials.”¹⁴⁴ Different stakeholders have different views about which TSCA provisions they would like to see used for nanomaterials. Some environmental groups have argued that all products of nanotechnology are new and should be subject to PMN requirements.¹⁴⁵ Others would prohibit uses of nanomaterials that were untested or unsafe, require a “full lifecycle environmental, health, and safety impact assessments and robust testing prior to commercialization of a nanotechnology-based product,” and ensure “full and meaningful participation” by

¹⁴⁰ Environmental Defense and American Chemistry Council. Nanotechnology Panel Joint Statement of Principles. Comments on EPA’s Notice of a Public Meeting on Nanoscale Materials, 70 *Federal Register* 24574, June 23, 2005. [http://www.environmentaldefense.org/documents/4857_ACC-ED_nanotech.pdf].

¹⁴¹ Silver, for example, is toxic, and some product manufacturers have made antibacterial claims for their products containing nanosilver. In addition, research has demonstrated the toxicity of C₆₀ fullerenes to bacteria in water under laboratory conditions (Fortner, J.D., D.Y. Lyon, C.M. Sayes, et al. “C60 in water: Nanocrystal formation and microbial response,” *Environmental Science & Technology*, v. 39, (2005), pp. 4307-4316.)

¹⁴² Science Policy Council. 2007. U.S. Environmental Protection Agency’s Nanotechnology White Paper, EPA 100/B-07/001. U.S. Environmental Protection Agency, Washington, DC, p. 54.

¹⁴³ Naturally occurring nanoparticles exist, and some (for example particles in exhaust from diesel fuel) have been studied for years.

¹⁴⁴ EPA Fact Sheet for Nanotechnology under the Toxic Substances Control Act. [<http://www.epa.gov/oppt/nano/nano-facts.htm#usf>].

¹⁴⁵ Balbus, John, Richard Denison, Karen Florini, and Scott Walsh. 2005. “Getting Nanotechnology Right the First Time,” *Issues in Science and Technology*, Summer, pp. 65-71.

the public and workers.¹⁴⁶ One analyst has suggested that EPA regulation should focus on the specific products of nanotechnology, rather than on more generic nanomaterials.¹⁴⁷ Another view is that the relevant TSCA authority for regulating nanomaterials depends on each material's properties: If the nanomaterial has unique properties that would not be predictable based on the properties of larger forms of the same chemical, then it might be considered "new."¹⁴⁸

Recently, EPA released a document outlining its historical approach to determining whether a chemical is "new" to the TSCA inventory.¹⁴⁹ According to that document, EPA intends to continue to apply this current approach to nanomaterials on a case-by-case basis. On July 12, EPA asked for public comments on the approach. With respect to "existing" nanomaterials, to date, EPA has not issued a rule directing manufacturers to notify the Agency if new nanoscale uses are proposed for an existing chemical substance. The question that arises then is whether EPA is even notified about the existence of most commercially produced nanomaterials, and if so, whether the agency is evaluating them for hazard potential prior to entry to the U.S. market.

It is clear, however, that EPA has been working to become informed about new nanotechnologies, and conferring with stakeholders, as well as counterpart agencies in other nations, about how best to address nanomaterials. The agency plans to more formally gather data about nanotechnologies through a voluntary stewardship program known as the Nanoscale Materials Stewardship Program (NMSP). Formally announced October 18, 2006, the program was launched January 28, 2008.¹⁵⁰ Stakeholders were asked to respond within six months. As of July 14, 2008, EPA reportedly had received available information from four firms, been promised data from another 12 firms, and had no firms volunteer for the "in-depth" part of the program.¹⁵¹

¹⁴⁶ Natural Resources Defense Council. 2006. "Health facts: Nanotechnology's invisible threat: Small science, big consequences." December. [<http://www.nrdc.org/health/science/nano/fnano.pdf>].

¹⁴⁷ Davies, p. 23.

¹⁴⁸ Rizzuto, Pat. 2006. "EPA Reviews 15 New Nanoscale Chemicals," *Daily Environment Report*, v. 158, (August 16), p. A-7.

¹⁴⁹ EPA. 2007. TSCA Inventory Status of Nanoscale Substances — General Approach. [<http://www.regulations.gov/fdmspublic/component/main?main=DocumentDetail&d=EPA-HQ-OPPT-2004-0122-0057>].

¹⁵⁰ EPA. Nanotechnology under the Toxic Substances Control Act. [<http://www.epa.gov/oppt/nano/#stewardship>].

¹⁵¹ Rizzuto, Pat. As deadline nears, 16 firms to participate in nanoscale materials stewardship program. *Daily Environment Report*, July 14, 2008, p. A-1.

J. Clarence Davies, who was EPA Assistant Administrator for Policy, Planning and Evaluation during the administration of President George Herbert Walker Bush, and who helped author the original legislative proposal that became TSCA, recently evaluated the law as a means of regulating nanotechnology. His report concluded that the law “is extremely deficient in many respects and needs to be amended.”¹⁵²

In the absence of federal regulation, at least one city has acted to regulate nanotechnology. Berkeley, California issued an ordinance December 13, 2006, which requires facilities that handle engineered nanoscale materials to disclose information to the city about the amounts of materials they handle, uses of such material, and benefits and toxicity of the materials.¹⁵³ If toxicity and exposure data are unavailable, nanomaterials will be considered by the city to be “toxic” and therefore subject to the same requirements for risk management as other toxic chemicals.

For more information about engineered nanomaterials and some challenges associated with regulating nanotechnology, see CRS Report RL34332, *Engineered Nanoscale Materials and Derivative Products: Regulatory Challenges* or CRS Report RL34511, *Nanotechnology: A Policy Primer*.

Legislative and Administrative Initiatives

Legislation. Companion bills in the 110th Congress, H.R. 6100 and S. 3040, would amend TSCA, adding a new title to the end of the act, to significantly reshape U.S. chemical assessment and management. Known as the “Kid-Safe Chemicals Act of 2008,” H.R. 6100/S. 3040 aims to “eliminate the exposure of all children, workers, consumers, and sensitive subgroups to harmful chemicals distributed in commerce by calendar year 2020.” To that end, the bill would establish a safety standard for chemicals in commerce that —

- (A) provides a reasonable certainty that no harm will be caused by aggregate exposure of a fetus, infant, child, worker, or member of other sensitive subgroup to the chemical substance; and
- (B) is requisite to protect the public welfare from any known or anticipated adverse effects associated with the chemical substance.

Chemical manufacturers would be required to submit to EPA: 1) a statement that each chemical they manufacture or import meets the safety standard, or that there are insufficient data to determine whether that is the case, and 2) “all reasonably available information” regarding chemical properties, uses, production volume, exposure, and fate. Based on all available information, EPA then would be required to categorize all chemicals in commerce based on criteria relating to human exposure, known health effects, and persistence in the environment, and to identify at least 300 high-priority chemicals. The bills would direct EPA to evaluate manufacturers’ safety and data statements for those 300 chemicals within four and a half years of

¹⁵² Davies, p. 5.

¹⁵³ Phibbs-Rizzuto, Pat. “Toxic substances makers, users of nanomaterials in Berkeley must provide certain data to city by June,” *Daily Environment Report*, v. 86, May 4, 2007, p. A-3.

enactment of the Kid-Safe Chemicals Act. H.R. 6100/S. 3040 would require EPA to evaluate statements within 15 years for all chemicals in commerce as of the date of enactment. No new chemical would be permitted to enter U.S. commerce unless EPA found that the manufacturer had demonstrated conformance with the safety standard. If manufacturers failed to submit required statements or data for a chemical, or if the EPA Administrator determined that a chemical failed to meet the safety standard, then manufacture, importation, and distribution of that chemical in the United States would be prohibited. EPA would be authorized to prohibit or permit specific uses.

H.R. 6100/S. 3040 establishes an incentive for manufacturers to conduct studies to determine the level of risk posed by their chemicals by changing the regulatory default status for chemicals lacking toxicity and exposure data from generally permitted to generally banned. EPA would no longer have to prove that an unreasonable risk may exist in order to require data to be developed. Manufacturers who failed to produce and submit required safety data would lose the right to market their chemicals in the United States. The bill's requirements for proving safety before marketing, together with its establishment of new programs to inform the public about chemical hazards and uses, and to fund development of "safer" or "greener" chemicals and processes, would be likely to reduce use over time of the more toxic chemicals in commerce. Reduced use of toxic chemicals has long been a goal of environmental groups.

H.R. 6100/S. 3040 has the strong support of environmental and public health advocacy groups,¹⁵⁴ but is opposed or supported only with reservations by trade groups representing the chemical industry.¹⁵⁵

EPA's Initiatives. In August 2007, EPA announced that the United States, Mexico, and Canada had reached an agreement at Montebello, Quebec, at the Security and Prosperity Partnership of North America (SPP) Leaders' Summit.¹⁵⁶¹⁵⁷ The three countries committed to coordinate efforts to assess and manage risks of approximately 9,000 chemicals produced or imported in quantities greater than 25,000 pounds per year. The EPA commitments under the SPP are being fulfilled by the Chemical Assessment and Management Program (ChAMP). EPA will apply the results of EPA's work on HPV chemicals and extend its efforts to moderate

¹⁵⁴ For example, see the comparison of current law and law as it would exist under H.R. 6100/S. 3040 on the website of the Environmental Working Group. [<http://www.ewg.org/kidsafe>].

¹⁵⁵ For example, see the May 21, 2008, press release of the American Chemistry Council. [<http://www.americanchemistry.com/newsroom>].

¹⁵⁶ EPA. EPA Newsroom. U.S., Canada and Mexico Take Lead to Manage Industrial Chemicals. August 21, 2007. [<http://yosemite.epa.gov/opa/admpress.nsf/d0cf6618525a9efb85257359003fb69d/77660c0da9fe643e8525733e0065d48b!OpenDocument>], visited November 1, 2007.

¹⁵⁷ Regulatory Cooperation in the Area of Chemicals. 2007 Joint Statement: Prime Minister Harper, President Bush and President Calderón. North American Leaders' Summit, August 21, 2007. Security and Prosperity Partnership of North America. [http://www.spp.gov/pdf/spp_reg_coop_chemicals.pdf], visited June 25, 2008.

production volume (MPV) chemicals, relying in part on work completed by Canada's Chemical Management Program. That program was announced by the Canadian government on December 8, 2006,¹⁵⁸ but Canada has been screening and categorizing all 23,000 chemicals on its Domestic Substances List, its equivalent of the TSCA Inventory, since 1999.¹⁵⁹ The Canadian approach to prioritizing chemicals for review, assessment, and management has resulted in new data reporting requirements for the chemicals of highest priority.¹⁶⁰ "EPA plans to use the Canadian results as a starting point for U.S. efforts to assess the hazards of moderate-volume chemicals, using available data and hazard estimation approaches to prepare initial scientific assessments."¹⁶¹ No new U.S. data will be collected. However, EPA plans to summarize available data and make it available to the public. The first hazard characterizations for HPV chemicals have been posted online.¹⁶²

Conclusion

It is widely agreed that the regulation of chemicals in U.S. commerce should be based on sound science, cost-benefit analysis, and relative risks, that stakeholders should be involved in developing and evaluating risk-reduction measures, and that chemicals posing unreasonable risks to the environment or public health should be adequately controlled. Congress enacted the Toxic Substances Control Act in 1976 to generate scientific information needed for chemical risk assessment, and to regulate chemicals in a way that would balance public health and environmental risks with economic costs and benefits.

Analysts and policy makers currently are evaluating TSCA performance over the past 30 years and considering how the law is likely to perform in the future. Some analysts, and most in the regulated community, believe that TSCA has performed as intended, and they support TSCA in its current form. They praise TSCA as a flexible, efficient, and effective limit to over-regulation. Other policy analysts and legal commentators want to amend TSCA, because they think that it has not accomplished the tasks laid out for it by Congress and is unlikely to do better in the future, given recent and emerging changes in science and technology.¹⁶³

¹⁵⁸ Government of Canada. Chemical Substances. [<http://www.chemicalsubstances.chimiques.gc.ca/en/>], visited November 1, 2007.

¹⁵⁹ Environment Canada. Existing Substances Evaluation, CEPA Registry, Domestic Substances List Categorization and Screening Program. [<http://www.ec.gc.ca/substances/ese/eng/dsl/dslprog.cfm>], visited November 1, 2007.

¹⁶⁰ Denison, Richard A. 2007. *Not That Innocent*. Environmental Defense, Washington, DC. p. IV-3.

¹⁶¹ EPA. Press release. August 21, 2007.

¹⁶² EPA. HPV Chemical Hazard Characterizations. [http://iaspub.epa.gov/oppphpv/hpv_hc_characterization.get_report], visited July 17, 2008.

¹⁶³ Wilson, *Green Chemistry*, p. 16.

The available evidence indicates that EPA has had limited success using TSCA to gather information about new chemicals, but has demonstrated creativity and expertise in making use of available information to categorize such chemicals based on hazard potential, thereby reducing risks potentially associated with exposure to chemicals entering U.S. commerce. The agency has had some success in gathering information about existing chemicals, but has regulated only a handful. Based on a lack of expressed concern by stakeholders and the competitive strength of the U.S. chemical industry, EPA also appears to have avoided imposing a regulatory burden that unduly oppresses innovation and commerce.

Whether the amount of chemical regulation in the United States adequately controls unreasonable risks is a key policy question. However, it is clear that a few chemicals posed risks that Congress found unreasonable and TSCA (Title I) failed to control: Congress amended TSCA on three occasions to control risks associated with asbestos, lead, and radon. Some remain dissatisfied with TSCA. For example, S. 742, as reported by the Senate Committee on Environment and Public Works in the 110th Congress, would ban many asbestos-containing materials. Numerous states also have acted to control risks from chemicals that are not regulated under TSCA. In addition, many nations have joined together to regulate persistent, organic, pollutants and persistent, bioaccumulative toxic substances in ways that the United States cannot under the current provisions of TSCA.¹⁶⁴ The European Union recently adopted a new law, REACH, that takes a new approach to the regulation of chemicals, eliminating the distinction between new and existing chemicals and requiring manufacturers to identify hazards and manage risks for all uses of their chemicals. Multinational companies, therefore, may have to comply with multiple, possibly redundant or conflicting regulations.

Even if one concludes that TSCA has performed successfully in the past, it may be reasonable to question the adequacy of a 1976 chemical law in the light of thirty years of scientific and technological advances. In particular, nanotechnology and GMO advances pose new challenges that many feel require clarified and possibly augmented authority under TSCA, to protect human health and the environment.

¹⁶⁴ However, the United States does regulate these chemicals. For more on these international agreements and issues related to them, see CRS Report RS22379, *Persistent Organic Pollutants (POPs): Fact Sheet on Three International Agreements*, by Linda-Jo Schierow.

Appendix. A Key Court Case

In 1991, the U.S. Court of Appeals for the Fifth Circuit vacated and remanded an EPA rule promulgated under Section 6 that prohibited the manufacture, importation, processing, and distribution of asbestos in almost all products.¹⁶⁵ The substantive heart of the *Corrosion Proof* decision was its conclusion that EPA had insufficiently justified its ban. This conclusion was based on two grounds. First, the court said that EPA failed to give adequate weight to Section 6(a) insistence that the regulatory approach chosen by EPA be the “least burdensome” to achieve the agency-determined acceptable level of (non-zero) risk. EPA’s burden was especially difficult here, because the court noted that in imposing an asbestos ban, EPA chose the *most* burdensome of the options afforded by Section 6(a). By analyzing only two scenarios — the ban and no TSCA regulation at all — the court held that EPA failed to show, as TSCA requires, that there was not some *intermediate* regulation that would achieve the acceptable risk level. “[T]he proper course for the EPA to follow is to consider each regulatory option, beginning with the least burdensome, and the costs and benefits of regulation under each option.”¹⁶⁶ Only such an exercise assures that the agency has not skipped a less-burdensome alternative.

Second, the court said EPA also must present a stronger case for a ban of products for which substitutes are not now available (as describes some of the asbestos products covered by the ban here), than of products for which substitutes are available. This it did not do. As to asbestos products for which substitutes *are* now available, EPA declined to consider the harm from a probable substitute’s increased use, even where it is a known carcinogen, the court added. Thus, EPA cannot assure that its ban will increase workplace safety, depriving the ban of a reasonable basis. To be sure, EPA need not seek out and test every possible substitute, but where interested parties introduce evidence showing the toxicity or decreased safety of probable substitutes, EPA must consider the comparative toxic costs of each — that is, whether its chosen section 6(a) option is increasing workplace safety at all.

As another facet of this insufficient evidence issue, the court determined that EPA failed to consider adequately the *costs* imposed by its ban. Under section 6(a), EPA may regulate only to address “unreasonable risk” — that is, whether “the severity of the injury that may result from the product, factored by the likelihood of the injury, offsets the harm the regulation itself imposes upon manufacturers and consumers.”¹⁶⁷ The high costs imposed on industry by the asbestos ban, compared to the small number of lives predicted to be saved, suggested to the court that EPA could not have given the former serious consideration.

Finally, the court examined *both* the failure to examine intermediate options (first ground above) and the insufficiency of evidence (second ground above) as these issues affected specific asbestos products covered by the ban, spelling out the deficiencies in greater detail. For example, in the case of friction products, EPA failed to study the effects of non-asbestos brakes on automotive safety, despite evidence that non-asbestos brakes could increase the number of highway fatalities.

¹⁶⁵ *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (5th Cir. 1991).

¹⁶⁶ *Id.* at 1217.

¹⁶⁷ *Id.* at 1222.