United States Government Accountability Office

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Report to Congressional Requesters

August 2007

# CHEMICAL REGULATION

# Comparison of U.S. and Recently Enacted European Union Approaches to Protect against the Risks of Toxic Chemicals

GAO-07-825

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Highlights

Highlights of GAO-07-825, a report to congressional requesters

## Why GAO Did This Study

Chemicals play an important role in everyday life. However, some chemicals are highly toxic and need to be regulated. In 1976, the Congress passed the Toxic Substances Control Act (TSCA) to authorize the Environmental Protection Agency (EPA) to control chemicals that pose an unreasonable risk to human health or the environment, but some have questioned whether TSCA provides EPA with enough tools to protect against chemical risks. Like the United States, the European Union (EU) has laws governing the production and use of chemicals. The EU has recently revised its chemical control policy through legislation known as Registration, Evaluation and Authorization of Chemicals (REACH) in order to better identify and mitigate risks from chemicals.

GAO was asked to review the approaches used under TSCA and REACH for (1) requiring chemical companies to develop information on chemicals' effects, (2) controlling risks from chemicals, and (3) making information on chemicals available to the public. To review these issues, GAO analyzed applicable U.S. and EU laws and regulations and interviewed U.S. and EU officials, industry representatives, and environmental advocacy organizations.

GAO is making no recommendations.

www.gao.gov/cgi-bin/getrpt?GAO-07-825.

To view the full product, including the scope and methodology, click on the link above. For more information, contact John Stephenson at (202) 512-3841 or stephensonj@gao.gov.

## What GAO Found

REACH requires companies to develop information on chemicals' effects on human health and the environment, while TSCA does not require companies to develop such information absent EPA rule-making requiring them to do so. While TSCA does not require companies to develop information on chemicals before they enter commerce (new chemicals), companies are required to provide EPA any information that may already exist on a chemical's impact on human health or the environment. Companies do not have to develop information on the health or environmental impacts of chemicals already in commerce (existing chemicals) unless EPA formally promulgates a rule requiring them to do so. Partly because of the resources and difficulties the agency faces in order to require testing to develop information on existing chemicals, EPA has moved toward using voluntary programs as an alternative means of gathering information from chemical companies in order to assess and control the chemicals under TSCA. While these programs are noteworthy, data collection has been slow in some cases, and it is unclear if the programs will provide EPA enough information to identify and control chemical risks.

TSCA places the burden of proof on EPA to demonstrate that a chemical poses a risk to human health or the environment before EPA can regulate its production or use, while REACH generally places a burden on chemical companies to ensure that chemicals do not pose such risks or that measures are identified for handling chemicals safely. In addition, TSCA provides EPA with differing authorities for controlling risks, depending on whether the risks are posed by new or existing chemicals. For new chemicals, EPA can restrict a chemical's production or use if the agency determines that insufficient information exists to permit a reasoned evaluation of the health and environmental effects of the chemical and that, in the absence of such information, the chemical may present an unreasonable risk. For existing chemicals, EPA may regulate a chemical for which it finds a reasonable basis exists to conclude that it presents or will present an unreasonable risk. Further, TSCA requires EPA to choose the regulatory action that is least burdensome in mitigating the unreasonable risk. However, EPA has found it difficult to promulgate rules under this standard. Under REACH, chemical companies must obtain authorization to use chemicals that are listed as chemicals of very high concern. Generally, to obtain such authorization, chemical companies need to demonstrate that they can adequately control risks posed by the chemical or otherwise ensure that the chemical is used safely.

TSCA and REACH both have provisions to protect information claimed by chemical companies as confidential or sensitive business information but REACH requires greater public disclosure of certain information, such as basic chemical properties, including melting and boiling points. In addition, REACH places greater restrictions on the kinds of information chemical companies may claim as confidential.

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## Tables



### Abbreviations

| | |
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| CBI | confidential business information |
| EINECS | European Inventory of Existing Commercial Chemical Substances |
| EPA | Environmental Protection Agency |
| EU | European Union |
| HPV | High Production Volume |
| IUR | Inventory Update Rule |
| MTBE | methyl-t-butyl ether |
| NPPTAC | National Pollution Prevention and Toxics Advisory Committee |
| OECD | Organization for Economic Cooperation and Development |
| OPPT | Office of Pollution Prevention and Toxics |
| PBT | persistent, bioaccumulative, and toxic |
| PCB | polychlorinated biphenyls |
| PMN | premanufacture notice |
| REACH | Registration, Evaluation and Authorization of Chemicals |
| SAR | Structure Activity Relationship |
| SNUR | significant new use rule |
| TSCA | Toxic Substances Control Act |
| VCCEP | Voluntary Children's Chemical Evaluation Program |
| vPvB | very persistent, very bioaccumulative |

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**United States Government Accountability Office**
**Washington, DC 20548**

August 17, 2007

The Honorable Barbara Boxer
Chair, Committee on Environment and Public Works
United States Senate

The Honorable Frank R. Lautenberg
United States Senate

Each year thousands of chemicals are used by U.S. industries to produce items widely used throughout society, including consumer products such as cleansers, paints, plastics, and fuels as well as industrial solvents and additives. While chemicals play an important role in people's everyday lives, some may adversely affect human health and the environment and need to be regulated to address health and safety risks. Because of concerns that current legislation may not be adequate to protect human health and the environment, congressional interest in revising chemical control laws has heightened in recent years.

In 1976, the Congress passed the Toxic Substances Control Act (TSCA), which authorizes the Environmental Protection Agency (EPA) to obtain existing data from and require testing by chemical companies concerning the environmental and health effects of chemical substances. TSCA authorizes EPA to promulgate rules to regulate the manufacture, distribution, or use of chemicals once EPA has determined the chemicals present an unreasonable risk of injury to health or the environment. In promulgating a rule to control activities based on a finding of unreasonable risk, EPA must consider, among other things, (1) the chemical's effects on human health and the environment and the magnitude of human and environmental exposure to the chemical; (2) the benefits of the chemical for various uses and the availability of substitutes for those uses; and (3) the reasonably ascertainable consequences of the rule, after consideration of the effect on the national economy, small businesses, technological innovation, the environment, and public health.

TSCA addresses those chemicals manufactured or imported into the United States, but it excludes certain substances because they are regulated under other laws, such as pesticides that are regulated under the Federal Insecticide, Fungicide, and Rodenticide Act, and pharmaceuticals that are regulated under the Federal Food, Drug, and Cosmetics Act. Whereas other environmental and occupational health and safety laws generally control only disposal, environmental releases, or workplace

exposures, under TSCA, EPA can control the entire life cycle of chemicals from their production, distribution in commerce, and use, to their disposal.

TSCA authorizes EPA to assess chemicals before they enter commerce (new chemicals) and those chemicals already in commerce (existing chemicals). EPA maintains a list of chemicals in commerce called the TSCA inventory. Of the over 82,000 chemicals currently in the TSCA inventory, about 62,000 were already in commerce when EPA began reviewing chemicals in 1979. Since then, EPA has reviewed more than 45,000 new chemicals, of which approximately 20,000 were added to the inventory after chemical companies began manufacturing them.

To implement TSCA, EPA has developed programs to assess and require testing of chemicals, and manage identified potential risks from new and existing chemicals. To assess risks, EPA reviews information it obtains from companies and other sources on a chemical's potential exposure levels and its potential adverse effects on human health and the environment. If EPA finds that a reasonable basis exists to conclude that a chemical presents or will present an unreasonable risk to human health or the environment, EPA can promulgate a rule to ban or restrict the chemical's production, processing, distribution in commerce, use, or disposal, or to require that warning labels be placed on the chemical.

Information about a chemical's effects on human health or the environment are useful to the public in making informed decisions about the products they use and the risks of chemicals that may be produced or used in nearby facilities. Information about a chemical's hazards includes data on physical properties (such as melting point or flammability) and health and environmental effects (such as skin irritation, cancer, birth defects, or toxicity to plants and animals). However, certain information, such as the chemical's identity, that EPA collects under TSCA is not always available to the public. In order to protect trade secrets and privileged or confidential commercial or financial information, TSCA allows chemical companies to designate information provided to EPA as confidential and, if it meets certain criteria, EPA must protect this information from disclosure.

Like the United States, the European Union (EU) has laws and regulations governing the manufacturing and use of chemicals. However, the EU has recently revised, but has not yet implemented, its chemical control policy through legislation known as Registration, Evaluation and Authorization of Chemicals (REACH). The purpose of REACH is to ensure a high level of

protection of human health and the environment while enhancing competitiveness and innovation in the chemical industry. REACH went into effect on June 1, 2007, and many of its provisions will be phased in over an 11-year period. A newly created European Chemicals Agency that will administer REACH is currently being organized and staffed.

In this context, you asked that we provide comparative information on TSCA and REACH. Specifically, you asked that we compare the approaches used under TSCA and REACH for (1) requiring chemical companies to develop information on their chemicals' effects on human health and the environment; (2) controlling risks from the production, distribution, or use of chemicals; and (3) making information on chemicals available to the public while protecting confidential business information (CBI). In addressing these issues, we also obtained information on some of EPA's voluntary chemical control programs designed to complement TSCA. In addition, we identified some legislative revisions that we have reported on in previous reports as options for strengthening EPA's ability to assess and regulate chemicals under TSCA. Information on these revisions is presented in appendix III.

To compare TSCA and REACH in their approaches to identifying chemicals harmful to public health and the environment, controlling chemical risks, and disclosing chemical data to the public while protecting confidential business information, we identified and analyzed the policies and guidelines of the United States and the EU on these issues. These efforts were augmented by interviews with (1) EPA officials responsible for implementing TSCA including the Director of EPA's Office of Pollution Prevention and Toxics (OPPT), the EPA office with primary responsibility for implementing TSCA, and (2) EU officials who helped develop and who will be involved in implementing REACH, including the Environment Counselor for the Delegation of the European Commission to the United States. We also interviewed representatives of the American Chamber of Commerce to the European Union, American Chemistry Council (a national chemical manufacturers association), Environmental Defense (a national, nonprofit environmental advocacy organization), the European Chemical Industry Council (an EU chemical manufacturers' association), the European Environmental Bureau (a federation of environmental advocacy organizations based in the EU), and the Synthetic Organic Chemical Manufacturers Association (a national, specialty chemical manufacturers' association). We also gathered documentation on EPA's voluntary programs. A detailed description of our scope and methodology is presented in appendix I. We performed our work between January 2006

and May 2007 in accordance with generally accepted government auditing standards.

## Results in Brief

REACH generally requires chemical companies to develop and share with government regulators information on the effects of the chemicals they produce on human health and the environment, while TSCA generally does not. For example, under REACH, chemical companies provide, and in some cases develop, information on chemicals' physical/chemical properties and health and environmental effects for both new and existing chemicals produced over specified volumes. REACH also provides regulators the general authority to require chemical companies to provide additional test data and other information when necessary to evaluate a chemical's risk to human health and the environment. In contrast, TSCA places the burden on EPA to demonstrate that data on health and environmental effects are needed before requiring chemical companies to develop the data. In this regard, while TSCA requires chemical companies to notify EPA before producing or importing a new chemical, it does not require chemical companies to develop and provide data on health and environmental effects unless EPA promulgates a rule requiring them to do so. In promulgating such a rule, EPA must demonstrate that data already available are insufficient and that either (1) the chemical may present an unreasonable risk or (2) the chemical is or will be produced in substantial quantities and that there is or may be substantial human or environmental exposure to the chemical.

REACH is based on the principle that chemical companies have the responsibility to demonstrate that the chemicals they place in the market, distribute, or use do not adversely affect human health or the environment, while TSCA generally requires EPA to demonstrate that chemicals pose risks to human health or the environment prior to controlling risks related to their production, distribution, or use. Under REACH, chemical companies must obtain authorization to continue to use a chemical of very high concern, such as a chemical for which there is scientific evidence of probable serious health or environmental effects. Generally, to obtain such authorization, each chemical company needs to demonstrate that it can adequately control risks posed by the chemical, such as by requiring that workers wear safety equipment when working with the chemical or otherwise ensuring that the chemical is produced under safe conditions. If the chemical company cannot provide evidence of adequate control, authorization would be granted only if the socioeconomic advantages of a specific use of the chemical are greater than its potential risks, and if there are no suitable alternatives or

technologies. Under TSCA, EPA has differing authorities to control the risks posed by new and existing chemicals. For new chemicals, EPA can restrict a chemical's production or use if the agency determines that insufficient information exists to permit a reasoned evaluation of the health and environmental effects of the chemical and that, in the absence of such information, the chemical may present an unreasonable risk to human health or the environment; the chemical is or will be produced in substantial quantities and either enters or may reasonably be anticipated to enter the environment in substantial quantities; or there is or may be significant or substantial human exposure to the substance. For existing chemicals, EPA may regulate those chemicals for which it finds a reasonable basis exists to conclude that they present or will present an unreasonable risk to human health or the environment. In this regard, EPA can promulgate a rule that bans or restricts the chemical's production, processing, distribution in commerce, use, or disposal, or that requires warning labels be placed on the chemical. However, TSCA requires EPA to choose the least burdensome requirement on the chemical industry that will adequately protect against the risk.

TSCA and REACH both have provisions to protect information claimed by chemical companies as confidential or sensitive business information; however, REACH requires greater public disclosure of certain information, including information about (1) basic chemical properties such as melting and boiling points and (2) analytical methods that make it possible to detect a dangerous substance when discharged into the environment and to determine the effects of direct exposure to humans. In addition, REACH places greater restrictions on the kinds of information companies may claim as confidential or sensitive. For example, REACH generally does not allow confidentiality claims to apply to the chemical's trade name, it and does not allow such claims to apply to guidance on the chemical's safe use.

## Background

In the last several decades, Congress has passed various legislation to increase federal agencies' abilities to identify and address the health and environmental risks associated with toxic chemicals and to address such risks. Some of these laws, such as the Clean Air Act; the Clean Water Act; the Federal Food, Drug and Cosmetic Act; and the Federal Insecticide, Fungicide, and Rodenticide Act authorize the control of hazardous chemicals in, among other things, the air, water, and soil and in food, drugs, and pesticides. Other laws, such as the Occupational Safety and Health Act and the Consumer Product Safety Act, can be used to protect workers and consumers from unsafe exposures to chemicals in the

workplace and the home. Nonetheless, the Congress found that human beings and the environment were being exposed to a large number of chemicals and that some could pose an unreasonable risk of injury to health or the environment. In 1976, the Congress passed TSCA to provide EPA with the authority to obtain information on chemicals and regulate those substances that pose an unreasonable risk to human health or the environment.[1] While other environmental and occupational health laws generally control only the release of chemicals in the environment, exposures in the workplace, or the disposal of chemicals, TSCA allows EPA to control the entire life cycle of chemicals from their production and distribution to their use and disposal.[2]

In October 2003, the European Commission[3] presented a proposal for a new EU regulatory system for chemicals. REACH was proposed because the Commission believed that the current legislative framework for chemicals in the EU did not produce sufficient information about the effects of chemicals on human health and the environment. In addition, the risk assessment process was slow and resource-intensive and did not allow the regulatory system to work efficiently and effectively. Under REACH, authority exists to establish restrictions for any chemical that poses unacceptable risks and to require authorization for the use of chemicals identified as being of very high concern. These restrictions could include banning uses in certain products, banning uses by consumers, or even completely banning the chemical. Authorization will be granted if a given manufacturer can demonstrate that the risks from a given use of the chemical can be adequately controlled if a threshold can be determined for the chemical. Or, if no threshold can be determined, the manufacturer has to demonstrate that the socioeconomic benefits outweigh the risks associated with continued use and that there are no suitable alternatives or technologies available. In addition, a key aspect of REACH is that it places the burden on manufacturers, importers, and downstream users to ensure that they manufacture, place on the market,

[1]Pub. L. No. 94-469, 90 Stat. 2003 (1976) (codified at 15 U.S.C. §§ 2601-2692).

[2]TSCA does not apply to certain substances such as nuclear material, firearms and ammunition, pesticides, food, food additives, tobacco, drugs, and cosmetics.

[3]The European Commission is one of the three primary institutions governing the EU. One of the primary roles of the European Commission is to propose and implement legislation for the EU. The other two governing bodies are the European Parliament and the Council of the European Union. Among other responsibilities, the Parliament and the Council jointly adopt new European laws in many policy areas.

or use such substances that do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary principle.[4] REACH was approved in December 2006 and went into effect in June 2007. To avoid overloading regulators and companies with the work arising from the registration process, full implementation of all the provisions of REACH will be phased in over an 11-year period (or by 2018).

## REACH Requires Chemical Companies to Develop More Information than TSCA on the Effects of Chemicals on Human Health and the Environment

TSCA does not require companies to develop information for either new or existing chemicals, whereas REACH generally requires companies to submit and, in some circumstances, requires companies to develop such information for both kinds of chemicals. For new chemicals, TSCA requires companies to submit to EPA any available human health and environmental data, but companies do not have to develop additional information unless EPA requires additional test data through a test rule or other EPA action. For existing chemicals, companies do not have to develop such information unless EPA requires them to do so. In contrast, companies generally are required under REACH to provide and develop where needed the European Chemicals Agency with health and environmental data. The extent of such data depends on the annual production volume of the chemical.

### TSCA Does Not Require Chemical Companies to Develop Information on the Hazards of New Chemicals

TSCA does not require chemical companies to test new chemicals for their effect on human health or the environment, but it requires companies to submit such information if it already exists when they submit a premanufacture notice (PMN) notifying EPA of their intent to manufacture a new chemical. This notice provides, among other things, certain information on the chemical's intended uses and potential exposure. TSCA also requires chemical companies to submit data and other information on the physical/chemical properties, fate, or health and environmental effects of a chemical, which we refer to in this report as "hazard information," that the companies possesses or is reasonably ascertainable by them when they submit a PMN to EPA. In part because TSCA does not require chemical companies to develop hazard information before submitting a PMN, EPA employs several other approaches for

[4]In general, the precautionary principle means that where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to reduce risks to human health and the environment.

assessing hazards, including using models that compare new chemicals with existing chemicals with similar molecular structures for which test data on health and environmental effects are available. In June 2005, we recommended that EPA develop a strategy for improving and validating the models that EPA uses to assess and predict the hazards of chemicals.[5] EPA is currently devising such a strategy, according to agency officials.

EPA receives approximately 1,500 new chemical notices each year, half of which are exemption requests,[6] and has reviewed more than 45,000 from 1979 through 2005.[7] PMNs include information such as specific chemical identity estimated maximum production volume for 12 months of production a description of how the chemical will be processed and used and estimates of how many workers may be exposed to the chemical. Additionally, EPA requires that the following information be submitted with a PMN: all existing health and environmental data in the possession of the submitter, parent company, or affiliates, and a description of any existing data known to or reasonably ascertainable by the submitter. EPA estimates that most PMNs do not include test data of any type, and only about 15 percent include health and safety data—such as acute toxicity or skin and eye irritation data.

In some cases, EPA may determine during the review process that more data are needed for an analysis of a chemical's potential risks and often will negotiate an agreement with the chemical company to conduct health hazard or environmental effects testing. According to EPA, more than 300 testing agreements have been issued since EPA began reviewing new chemicals in 1979. In some cases, however, the chemical company may voluntarily withdraw the PMN rather than incur the costs of hazard testing requested by EPA, or for other reasons. EPA does not maintain records as

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

[6]EPA may exempt a chemical company from the PMN requirement upon application from the company showing to EPA's satisfaction that the chemical will not present any unreasonable risk of injury to human health or the environment and under such restrictions as EPA deems appropriate. EPA regulations relating to premanufacture notice exemptions, including the restrictions applicable to specific exemptions, appear at 40 C.F.R. part 723.

[7]According to EPA, about half of the premanufacture notices the agency receives from chemical companies are for new chemicals that, for various reasons, never enter the marketplace. These chemicals are not listed on the TSCA inventory.

to how many PMNs chemical companies have withdrawn because of potential EPA action.

## TSCA Does Not Require Chemical Companies to Develop Hazard Information for Existing Chemicals, and EPA Uses Regulatory and Voluntary Programs to Gather Such Information for Certain Chemicals

While TSCA does not require chemical companies to develop information on the harmful effects of existing chemicals on human health or the environment, TSCA provides that EPA, by issuing a test rule, can require such information on a case-by-case basis. Before promulgating such a rule EPA must find, among other things, that current data are insufficient, testing is necessary, and that either (1) the chemical may present an unreasonable risk or (2) the chemical is or will be produced in substantial quantities and that there is or may be substantial human or environmental exposure to the chemical. EPA officials responsible for administering the act said that TSCA's test rule provision and data-gathering authorities can be burdensome and too time consuming for EPA to administer. Because EPA has limited information on existing chemicals and the difficulty in promulgating test rules, EPA uses voluntary programs to help gather more data to assess risks on certain chemicals.

While TSCA authorizes EPA to require testing of existing chemicals, the act does not authorize the agency to do so unless EPA first determines on the basis of risk or exposure information that the chemicals warrant such testing. TSCA provides EPA the authority to obtain hazard information needed to assess chemicals by issuing rules under Section 4 of TSCA requiring chemical companies to test to determine the health and environmental effects of chemicals and submit the test data to EPA. However, in order for EPA to issue a test rule, the agency must determine that a chemical (1) may present an unreasonable risk of injury to health or the environment or (2) is or will be produced in substantial quantities and (a) there is or may be significant or substantial human exposure to the chemical or (b) it enters or may reasonably be anticipated to enter the environment in substantial quantities. EPA must also determine that there are insufficient data to reasonably determine or predict the effects of the chemical on health or the environment and that testing is necessary to develop such data. Once EPA has made the required determination, the agency can issue a proposed rule for public comment, consider the comments it receives, and promulgate a final rule ordering chemical testing. OPPT officials responsible for implementing TSCA told us that finalizing rules under Section 4 of TSCA can take from 2 to 10 years and require the expenditure of substantial resources. EPA has used its authority to require testing for about 200 existing chemicals since the agency began reviewing chemicals under TSCA in 1979. EPA does not maintain estimates of the cost of implementing these rules. However, in

our September 1994 report on TSCA, we noted that EPA officials told us that issuing a rule under Section 4 can cost up to a $234,000.[8] Given the difficulties and cost of requiring testing, EPA could review substantially more chemicals in less time if it had authority to require chemical companies to conduct testing and provide test data on chemicals once they reach a substantial production volume. In June, 2005, we stated that Congress may wish to consider amending TSCA to provide EPA such authority.[9]

As an alternative to formal rule making, EPA asserts that Section 4 of TSCA provides EPA implied authority to enter into "enforceable consent agreements" with chemical companies that would require them to conduct testing when there is insufficient data available to assess a chemical's risk. EPA uses enforceable consent agreements to accomplish testing where a consensus exists among EPA, affected manufacturers and/or processors, and interested members of the public concerning the need for and scope of testing. According to EPA, these agreements allow greater flexibility in the design of the testing program and negotiating these agreements is generally less costly and time consuming than promulgating test rules. EPA has entered into consent agreements with chemical companies to develop tests for about 60 chemicals where the agency determined additional data were needed to assess the chemical's risk.

Under Section 8 of TSCA, EPA promulgates rules directing chemical companies to maintain records and submit such information as the EPA Administrator reasonably requires. This information can include, among other things, chemical identity, categories of use, production levels, by-products, existing data on adverse health and environmental effects, and the number of workers exposed to the chemical. Section 8(d) authorizes EPA to promulgate rules under which chemical companies are required to submit lists or copies of any health and safety studies to EPA. Finally, Section 8 requires chemical companies to report any information to EPA that reasonably supports a conclusion that a chemical presents a substantial risk of injury to health or the environment.

According to EPA, the agency has issued about 50 Section 8(d) rules covering approximately 1,000 chemicals. As a result of these rules, EPA

[8]*GAO, Toxic Substances Control Act: Legislative Changes Could Make the Act More Effective*, GAO/RCED-94-103 (Washington, D.C.: Sept. 26, 1994).

[9]GAO-05-458.

has received nearly 50,000 studies covering environmental fate, human health effects, and environmental effects. However, TSCA Section 8(d) only applies to existing studies and does not require companies to develop new studies.

The TSCA Inventory Update Rule (IUR),[10] currently requires chemical companies to report every 5 years to EPA the site and manufacturing information for chemicals in the TSCA inventory that they manufacture or import in amounts of 25,000 pounds or greater at a single site. For the most current reporting cycle and for subsequent reporting cycles, chemical companies must report additional information—such as uses, the types of consumer products the chemical will be used in—including those intended for use by children, and the number of workers who could potentially be exposed—for chemicals manufactured or imported in amounts of 300,000 pounds or more at a single site.[11]

In response to the lack of information on existing chemicals and the relative difficulty the agency faces in requiring companies to conduct additional testing under TSCA, EPA has taken efforts to increase the amount of the information it can access on chemicals by implementing a voluntary program called the High Production Volume (HPV) Challenge Program. The HPV Challenge Program focuses on obtaining chemical company sponsors to voluntarily provide data on approximately 2,800 chemicals that chemical companies reported in 1990 were domestically produced or imported at a high volume—over 1 million pounds. Through this program, sponsors develop a basic set of screening level information on the chemicals either by gathering available data, using models to predict the chemicals' properties, or conducting testing of the chemicals.

[10]In 1977, EPA promulgated a rule under TSCA, Section 8(a), to compile and keep current an inventory of chemicals in commerce in the United States. This inventory is called the TSCA Chemical Substance Inventory or TSCA Inventory. In 1986, EPA promulgated the Inventory Update Reporting (IUR) regulation to facilitate the periodic updating of the TSCA Inventory and to support activities associated with implementing TSCA. The 1986 regulation required chemical companies to report to EPA every 4 years the identity of and basic manufacturing information for organic chemicals produced annually in quantities of 10,000 pounds or greater at each plant site they own or control. In 2003, EPA amended the IUR, expanding the range of chemicals (inorganic chemicals are now included as well as organic chemicals) and plant sites reporting, expanding the types of exposure and use data reported, and raising the production volume threshold that triggers reporting. EPA published additional changes in the TSCA Inventory Update Reporting Revisions in 2005, including changing the reporting frequency from every 4 years to every 5 years.

[11]The reporting for 2005 data—the most current cycle—ended in March 2007.

The six data endpoints collected under the HPV Challenge Program are acute toxicity, repeat dose toxicity, developmental and reproductive toxicity, mutagenicity, ecotoxicity, and environmental fate.[12] EPA believes that these basic data are needed to make an informed, preliminary judgment about the hazards of HPV chemicals. In June 2005, we recommended that EPA develop a methodology for using information collected through the HPV Challenge Program to prioritize chemicals for further review.[13] EPA's Director of OPPT told us the agency developed such a methodology as data from chemical companies became available and are currently applying the methodology to assess HPV chemicals. The methodology was developed based on input received from an advisory committee, the National Pollution Prevention and Toxics Advisory Committee (NPPTAC).[14]

Despite these promising voluntary efforts regarding high-production-volume chemicals, several difficulties remain, as we have noted in our prior work.[15] For example, (1) chemical companies have not agreed to test approximately 300 chemicals identified by EPA as high-production-volume chemicals; (2) additional chemicals will become high-production chemicals in the constantly changing commercial chemical marketplace; and (3) chemicals without a particularly high-production volume may also warrant testing, based on their toxicity and the nature of exposure to them. In addition, this program may not provide enough information for EPA to use in making risk-assessment decisions. While the data in the HPV Challenge Program and the new exposure and use reporting under the IUR may help EPA prioritize chemicals of concern, the data may not provide sufficient evidence for EPA to determine whether a reasonable basis exists to conclude that the chemical presents an unreasonable risk of injury to health or the environment and that regulatory action is necessary. Although the chemical industry may be willing to take action, even before

[12]An endpoint is the chemical or biological effect that is assessed by a test method.

[13]GAO-05-458.

[14]NPPTAC is a national advisory body chartered under the Federal Advisory Committee Act to provide advice, information and recommendations on the overall policy and operation of programs managed by EPA's Office of Pollution Prevention and Toxics in performing its duties and responsibilities under TSCA and the Pollution Prevention Act. EPA has not held a NPPTAC meeting since the resignation of three NPPTAC members in October 2006, which resulted in an imbalance in representation on the Committee. EPA is evaluating options for NPPTAC's future.

[15]GAO-05-458.

EPA has the evidence required for rule making under TSCA, the industry is nonetheless large and diverse, and it is uncertain that all companies will always take action voluntarily.

To ensure that adequate data are made publicly available to assess the special impact that industrial chemicals may have on children, EPA launched the Voluntary Children's Chemical Evaluation Program (VCCEP). In December 2000, EPA implemented VCCEP first as a pilot program. EPA's goal is to learn from this pilot program before a final VCCEP process is determined and before additional chemicals are selected. For the VCCEP pilot, EPA identified 23 commercial chemicals to which children have a high likelihood of exposure and the information needed to assess the risks to children from these chemicals. Recently, EPA requested comments on the implementation of the pilot program from stakeholders and other interested parties but has not yet responded to the comments or evaluated the program for its effectiveness.

EPA is running a pilot of the VCCEP so it can gain insight into how best to design and implement the VCCEP in order to effectively provide the agency and the public with the means to understand the potential health risks to children associated with exposure to these and ultimately other chemicals to which children may be exposed. EPA intends the pilot to be the means of identifying efficiencies that can be applied to any subsequent implementation of the VCCEP. Another purpose for running the pilot is the opportunity it will offer to test the performance of the peer consultation process. For the VCCEP pilot, the purpose of the peer consultation process is to provide a forum for scientists and relevant experts from various stakeholder groups to exchange scientific views on the chemical sponsor's data submissions and in particular on the recommended data needs.

Under the VCCEP pilot, EPA is pursuing a three-tiered approach for gathering information, with tier 3 involving more detailed toxicology and exposure studies than tier 2, and tier 2 involving more detailed toxicology and exposure studies than tier 1. EPA asked companies that produce and/or import 23 specific chemicals to volunteer to sponsor their chemical in the first tier of the VCCEP pilot. EPA selected these 23 chemicals because the agency believed them to be especially relevant to children's chemical exposures, such as the presence of the chemical in human tissue or blood, in food and water children eat and drink, and in air children breathe. In addition, many of these chemicals were known to be relatively "data rich" in that chemical data were already available. Chemical companies have volunteered to sponsor 20 of the 23 chemicals in the

VCCEP. EPA believes that these 20 chemicals provide an adequate basis for evaluating the VCCEP pilot.

Chemical companies volunteering to sponsor a chemical under the program have agreed to make chemical-specific public commitments to make certain hazard, exposure, and risk assessment data and analyses publicly available. For toxicity data, specific types of studies have been assigned to each of the three tiers. For exposure data, the depth of exposure information increases with each tier. If data needs are identified through the peer consultation process, the sponsor will choose whether to volunteer for any additional data generation or testing and whether to provide additional assessments in subsequent tiers. However, company sponsors are under no obligation to volunteer for tiers 2 and 3, even if EPA determines additional information is needed. After the submission of tier 1 information and its review by the peer consultation group—consisting of scientific experts with extensive and broad experience in toxicity testing and exposure evaluations—EPA reviews the sponsor's assessment and develops a response, focusing primarily on whether any additional information is needed to adequately evaluate the potential risks to children. If additional information is needed, EPA will indicate what information should be provided in tier 2. Companies will then be given an opportunity to sponsor chemicals at tier 2. EPA plans to repeat this process to determine whether tier 3 information is needed. Information from all three tiers may not always be necessary to adequately evaluate the risk to children.

According to EPA officials, since the program's inception, sponsors have submitted 15 of the 20 assessments on chemicals to EPA and the peer consultation group. The peer consultation group has issued reports on 13 of the 15 chemical submissions. EPA has issued Data Needs Decisions on 11 of these 13 chemicals for which EPA determined that 5 chemicals needed additional data. One of the sponsors agreed to commit to tier 2 and to provide the additional data to EPA. The sponsor of two other chemicals declined to commit to tier 2 since it had ceased manufacturing the chemicals in 2004. The sponsor of the other 2 chemicals told EPA it will decide whether to commit to the additional testing by the end of July 2007.

In November 2006, EPA requested comments on the implementation of the pilot program from stakeholders and interested parties. As part of its request for comments, EPA included a list of questions that the agency believed would be helpful in its evaluation of the pilot program. The questions ranged from asking about the sufficiency of the hazard,

exposure, and risk assessments provided by the chemical sponsors; to the effectiveness and efficiency of the peer review panel; to the timeliness of the VCCEP pilot in providing data. EPA received comments from 11 interested parties, including from industry representatives, environmental organizations, children's health advocacy groups, and other interested parties. Generally, the industry groups provided positive comments about the pilot while the children's health advocacy and environmental groups provided negative comments about VCCEP. For example, the American Chemistry Council commented that the pilot is proceeding well, the current tiered approach is sound, and that only minimal improvements are needed. One of the improvements the chemistry council suggested is that EPA should make the data generated under the pilot more accessible to the public, other EPA program offices, and to other federal and state agencies. Conversely, the American Academy of Pediatrics[16] commented that the VCCEP pilot is failing in its goal to provide timely or useful information on chemical exposures and their implications to the public or to health care providers. EPA plans to prepare a comments document summarizing the comments received from the stakeholders and publish it on the VCCEP Web site.[17] In addition, EPA plans to have a final evaluation of the effectiveness of the VCCEP pilot in late 2007.

## REACH Requires Chemical Companies to Submit Hazard Information for New and Existing Chemicals That Meet Specified Production and Toxicity Levels

REACH created a single system for the regulation of new and existing chemicals and, once implemented, will generally require chemical companies to register chemicals produced or imported at 1 ton or more per producer or importer per year with a newly created European Chemicals Agency.[18] Information requirements with registration will vary according to the production volume and suspected toxicity of the chemical.

For chemicals produced at 1 ton or more per producer or importer per year, chemical companies subject to registration will be required to submit information for the chemical, such as the chemical's identity; how it will

[16]The Academy is a nonprofit organization of primary care pediatricians and pediatric specialists dedicated to the health, safety, and well-being of infants, children, adolescents, and young adults.

[17]The program's Web site address is http://www.epa.gov/chemrtk/vccep.

[18]Existing chemicals will be registered during an 11 year phase-in period, while new chemicals will be registered prior to production above 1 metric ton or their introduction to the marketplace.

be produced; how it will be used; guidance on its safe use; exposure information; and study summaries of physical/chemical properties and their effects on human health or the environment. REACH specifies the amount of information to be included in the study summaries based on the chemical's production volume, i.e., how much of the chemical will be produced or imported each year. The information requirements may be met through a variety of methods, including existing data, scientific modeling, or testing. REACH separates the production volume information requirements into four metric tonnage bands—1 ton or more, 10 tons or more, 100 tons or more, and 1,000 tons or more. Hazard information must be submitted for each tonnage band with each higher band requiring the information for the lower bands in addition to the ones specified for that band.[19] For example, at the one or more tonnage band, REACH requires information on environmental effects that include short-term toxicity on invertebrates, toxicity to algae, and ready biodegradability. At the 10 or more tonnage band, REACH requires such information in addition to a chemical safety assessment, which includes an assessment of the chemical's human health and environmental hazards; a physiochemical hazard assessment; an environmental hazard assessment; and an assessment of the chemical's potential to be a persistent, bioaccumulative, and toxic pollutant, which are chemicals that create pollutants that persist in the environment, bioaccumulate in food chains, and are toxic.

Table 1 shows the total number of chemical endpoints—the chemical or biological effect that is assessed by a test method—required for chemicals produced at various production volumes, where applicable, for TSCA, the HPV Challenge Program, and REACH. While industry participation in the EPA's HPV Challenge Program is voluntary, we have included information on the number of endpoints to be produced for chemicals in the program for comparison purposes. As the table shows, companies will provide a greater number of endpoints on chemicals under REACH than TSCA or the HPV Challenge Program. Additionally, appendix IV provides a listing of specific information requirements or endpoints for three testing

[19]According to the Environment Counselor for the Delegation of the European Commission to the U.S., REACH places the onus on industry to provide adequate information but testing under REACH is to be a last resort from an ethical point of view and from a cost-effectiveness point of view. It is industry's responsibility to present a satisfactory level and quantity of information to comply with the requirements set out in the annexes of REACH which could include using scientific models to estimate chemical effects, using existing test data, or conducting new testing if needed.

categories: physical/chemical, human health, and environmental effects/fates.

**Table 1: Comparison of the Number of Chemical Tests Potentially Occurring by Production Volume under TSCA, the HPV Challenge Program, and REACH (shown in metric tons)**

| | U.S. TSCA chemicals | | | | | | |
|---|---|---|---|---|---|---|---|
| | New[a] | Existing[b] | U.S. HPV Challenge Program | EU REACH | | | |
| | 100 metric tons or more | | 454 metric tons or more[b] | 1 metric ton or more[c] | 10 metric tons or more | 100 metric tons or more | 1,000 metric tons or more |
| Physical/chemical | 1 | 0 | 5 | 14 | 17 | 17 | 17 |
| Human health | 4 | 0 | 6 | 5 | 12 | 15 | 16 |
| Environmental effects/fate | 9 | 0 | 7 | 3 | 7 | 16 | 21 |

Source: GAO analysis of TSCA, HPV Challenge Program, and REACH data.

Note: The number of tests shown is approximate and represents high-end estimates as many of the tests are conditional and may not need to be conducted if the data or endpoints can be obtained from other sources such as existing data or modeling, or are not relevant for the applicable chemical.

[a]For TSCA, we have included test data for new chemicals that chemical companies plan to produce at high volumes within a few years of introducing the chemical to the marketplace. While TSCA does not require companies to produce or provide this information, EPA officials said that companies generally produce and provide this information if EPA requests it or if required to under the terms of a TSCA Section 5(e) order.

[b]Under TSCA, existing chemicals have no test/endpoint data requirements.

[c]The production volume for the HPV Challenge Program of 1 million pounds was converted to metric tons for comparison purposes.

## TSCA Generally Requires EPA to Demonstrate That Chemicals Will Cause Unreasonable Risk While REACH Requires Chemical Companies to Ensure No Adverse Chemical Effects

Both TSCA and REACH provide regulators with authorities to control chemical risks by restricting the production or use of both new and existing chemicals. Under TSCA, EPA must generally compile data needed to assess the potential risks of chemicals and must also develop substantial evidence in the rule-making record in order to withstand judicial review. However, REACH is based on the principle that chemical companies—manufacturers, importers, and downstream users[20]—should ensure that the chemicals they manufacture, place on the market, or use do not adversely affect human health or the environment.

### EPA Has Had Difficulty Proving That Chemicals Pose Unreasonable Risks and Has Regulated Few Existing Chemicals under Section 6 of TSCA

Even when EPA has toxicity and exposure information on existing chemicals, the agency has had difficulty demonstrating that chemicals present or will present an unreasonable risk and that they should have limits placed on their production or use. Since the Congress enacted TSCA in 1976, EPA has issued regulations under Section 6 of the act to limit the production or restrict the use of five existing chemicals or chemical classes. The five chemicals or chemical classes are polychlorinated biphenyls (PCB), fully halogenated chlorofluoroalkanes, dioxin, asbestos, and hexavalent chromium. In addition, under Section 5(a)(2) of TSCA, for 160 existing chemicals, EPA issued significant new use rules that require chemical companies to submit notices to EPA prior to commencing the manufacture, import, or processing of the substance for a significant new use.

In order to regulate an existing chemical under Section 6(a) of TSCA, EPA must find that there is a reasonable basis to conclude that the chemical presents or will present an unreasonable risk of injury to health or the environment. Before regulating a chemical under Section 6(a), the EPA Administrator must consider and publish a statement regarding

[20]Under REACH, a downstream user is an entity within the supply chain, other than the manufacturer or importer, who uses a substance, either on its own or in a preparation.

- the effects of the chemical on human health and the magnitude of human exposure to the chemical;
- the effects of the chemical on the environment and the magnitude of the environment's exposure to the chemical;
- the benefits of the chemical for various uses and the availability of substitutes for those uses; and
- the reasonably ascertainable economic consequences of the rule, after consideration of the effect on the national economy, small business, technological innovation, the environment, and public health.

Further, the regulation must apply the least burdensome requirement that will adequately protect against such risk. For example, if EPA finds that it can adequately manage the unreasonable risk of a chemical through requiring chemical companies to place warning labels on the chemical, EPA could not ban or otherwise restrict the use of that chemical.

Additionally, if the EPA Administrator determines that a risk of injury to health or the environment could be eliminated or sufficiently reduced by actions under another federal law, then TSCA prohibits EPA from promulgating a rule under Section 6(a) of TSCA, unless EPA finds that it is in the public interest considering all aspects of the risk, the estimated costs of compliance, and the relative efficiency of such action to protect against risk of injury.

Finally, EPA must also develop substantial evidence in the rule-making record in order to withstand judicial review. Under TSCA, a court reviewing a TSCA rule "shall hold [it] unlawful and set [it] aside…if the court finds that the rule is not supported by substantial evidence in the rule-making record." According to EPA officials responsible for administering TSCA, the economic costs of regulating a chemical are usually more easily documented than the risks of the chemical or the benefits associated with controlling those risks, and it is difficult to show by substantial evidence that EPA is promulgating the least burdensome requirement.

According to EPA officials in OPPT who are responsible for implementing TSCA, the use of Section 6(a) has presented challenges as the agency must, in effect, perform a cost-benefit analysis, considering the economic and societal costs of placing controls on the chemical. Specifically, these officials say that EPA must take into account the benefits provided by the

various uses of the chemical, the availability of substitutes, and the reasonably ascertainable economic consequences of regulating the chemical after considering the effects of such regulation on the national economy, small business, technological innovation, the environment, and public health.

EPA's 1989 asbestos rule illustrates the evidentiary requirements that TSCA places on EPA to control chemicals under TSCA Section 6(a). The rule prohibited the future manufacture, importation, processing, and distribution of asbestos in almost all products. Some of the manufacturers of these asbestos products filed suit against EPA, arguing that the rule was not promulgated on the basis of substantial evidence regarding unreasonable risk. In October 1991, the U.S. Court of Appeals for the Fifth Circuit agreed with the manufacturers, concluding that EPA had failed to muster substantial evidence to justify its asbestos ban and returning parts of the rule to EPA for reconsideration.

In reaching this conclusion, the court found that EPA did not consider all necessary evidence and failed to show that the control action it chose was the least burdensome reasonable regulation required to adequately protect human health or the environment. As articulated by the court, the proper course of action for EPA, after an initial showing of product danger, would have been to consider the costs and benefits of each regulatory option available under Section 6, starting with the less restrictive options, such as product labeling, and working up through a partial ban to a complete ban. The court further criticized EPA's ban of asbestos in products for which no substitutes were currently available stating that, in such cases, EPA "bears a tough burden" to demonstrate, as TSCA requires, that a ban is the least burdensome alternative.

The court's decision on the asbestos rule is especially revealing about Section 6 because EPA spent 10 years preparing the rule. In addition, asbestos is generally regarded as one of the substances for which EPA has the most scientific evidence or documentation of substantial adverse health effects. Since the U.S. Court of Appeals for the Fifth Circuit's ruling in October 1991, EPA has not used TSCA Section 6 to restrict any chemicals. However, EPA has used Section 6 to issue a proposed ban on certain grouts, which was later withdrawn when industry agreed to use personal protection equipment to address worker exposure issues, and issue an Advance Notice of Proposed Rule Making for methyl-t-butyl

ether[21] because of widespread drinking water contamination. Although TSCA's Section 6 has been used infrequently, the Director of OPPT and other EPA officials responsible for implementing TSCA told us that they believe that taking action under this section remains a practicable option for the agency.

## TSCA's Section 5 Provides Limited Authority to Restrict New Chemicals

Section 5(a)(2) requires chemical companies to notify EPA at least 90 days before beginning to manufacture or process a chemical for a use that EPA has determined by rule is a significant new use. EPA has these 90 days to review the chemical information in the premanufacture notice and identify the chemical's potential risks. Under Section 5(e), if EPA determines that there is insufficient information available to permit a reasoned evaluation of the health and environmental effects of a chemical and that (1), in absence of such information, the chemical may present an unreasonable risk of injury to health or the environment or (2) it is or will be produced in substantial quantities and (a) it either enters or may reasonably be anticipated to enter the environment in substantial quantities or (b) there is or may be significant or substantial human exposure to the substance, then EPA can issue a proposed order or seek a court injunction to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of the chemical. Under Section 5(f), if EPA finds that the chemical will present an unreasonable risk, EPA must act to protect against the risk. If EPA finds that there is a reasonable basis to conclude that a new chemical may pose an unreasonable risk before it can protect against such risk by regulating it under Section 6 of TSCA, EPA can (1) issue a proposed rule, effective immediately, to require the chemical to be marked with adequate warnings or instructions, to restrict its use, or to ban or limit the production of the chemical or (2) seek a court injunction or issue a proposed order to prohibit the manufacture, processing, or distribution of the chemical. According to the Director of OPPT, it is less difficult for the agency to demonstrate that a chemical "may present" an unreasonable risk than it is to show that a chemical "will present" such a risk. Thus, EPA has found it easier to impose controls on new chemicals when warranted.

Despite limitations in the information available on new chemicals, EPA's reviews have resulted in some action being taken to reduce the risks of

[21]Methyl-t-butyl ether (MTBE) is a chemical compound that is used as a fuel additive in gasoline. 65 Federal Register 16094, Mar. 24, 2000.

over 3,800 of the 33,000 new chemicals that chemical companies have submitted for review since 1979.[22] These actions included, among other things, chemical companies voluntarily withdrawing their notices of intent to manufacture new chemicals, and entering into consent orders with EPA to produce a chemical only under specified conditions. In addition, EPA has promulgated significant new use rules requiring chemical companies to notify EPA of their intent to manufacture or process certain chemicals for any uses that EPA has determined to be a "significant new use."

For over 1,700 chemicals, companies withdrew their PMNs sometimes after EPA officials indicated that the agency planned to initiate the process for placing controls on the chemicals, such as requiring testing or prohibiting the production or certain uses of the chemical. The Director of OPPT told us that after EPA has screened a new chemical or performed a detailed analysis of it, chemical companies may drop their plans to market the chemical when the chemical's niche in the marketplace is uncertain and EPA requests that the company develop and submit test data or apply exposure controls. According to EPA officials, companies may be uncertain that they will recoup costs associated with the test data and controls and prefer to withdraw their PMN. In addition, for over 1,300 chemicals, EPA issued orders requiring chemical companies to implement workplace controls or practices during manufacturing pending the development of information on the risks posed by the chemicals and/or to perform toxicity testing if the chemicals' production volumes reached certain levels.

For over 570 of the 33,000 new chemicals submitted for review, EPA required chemical companies to submit notices for any significant new uses of the chemical, providing EPA the opportunity to review the risks of injury to human health or the environment before new uses begin. For example, in 2003, EPA promulgated a significant new use rule requiring chemical companies to submit a notice for the manufacture or processing of substituted benzenesulfonic acid salt for any use other than as described in the PMN.

[22]The 33,000 new chemicals do not include those that EPA has exempted from the PMN requirements, such as low volume chemicals and polymers. EPA may exempt a chemical company from the PMN requirement upon application from the company showing to EPA's satisfaction that the chemical will not present any unreasonable risk of injury to human health or the environment. Following EPA's approval of an exemption request, the company must manufacture and use the chemical in accordance with the terms of the exemption. Thus, all exemption chemicals are subject to controls per the terms of the exemption request and relevant exemption regulations.

## REACH Requires Chemical Companies to Request Authorization to Use Certain Hazardous Chemicals and Search for Safer Substitutes

To control chemical risks, REACH provides procedures for both authorizing and restricting the use of chemicals. Authorization procedures under REACH have three major steps. First, the European Chemicals Agency will publish a list of chemicals—known as the candidate list—that potentially need authorization before they can be used. The chemical agency will determine which chemicals to place on the candidate list after it has reviewed the information that chemical companies submit to the agency at the time the chemicals are registered under REACH and after considering the input provided by individual EU member states and the European Commission. In making this determination, the agency is to use criteria set forth in REACH, covering issues such as bioaccumulation, carcinogenicity, and reproductive toxicity. Secondly, the European Commission will determine which chemicals on the candidate list will require authorization and which will be exempted from the authorization requirements. According to the Environment Counselor for the Delegation of the European Commission to the United States, some chemicals may be exempted from authorization requirements because, so far, sufficient controls established by other legislation are already in place. Finally, once a chemical has been deemed to require authorization, a chemical company will have to apply to the European Commission for an authorization for each use of the chemical.

The application for authorization must include an analysis of the technical and economic feasibility of using safer substitutes and, if appropriate, information about any relevant research and development activities by the applicant. If such an analysis shows that suitable alternatives are available for any use of the chemical, then the application must also include a plan for how the company plans to substitute the safer chemical for the chemical of concern in that particular use. The European Commission is generally required to grant an authorization if the applicant meets the burden of demonstrating that the risks from the manufacture, use, or disposal of the chemical can be adequately controlled, except for (1) PBTs; (2) very persistent, very bioaccumulative chemicals (vPvBs); and (3) certain other chemicals including those that are carcinogenic or reproductive toxins.[23] However, even these chemicals may receive authorization if a chemical company can demonstrate that social and economic benefits outweigh the risks. In addition, 6 years after REACH

[23]Substances classified as PBTs are chemicals that can persist in the environment, bioaccumulate in food chains, and are toxic. Substances classified as vPvBs are chemicals that are very persistent and very bioaccumulative, but not necessarily toxic.

goes into effect (or in 2013), the European Commission will review whether endocrine disrupters[24] should also be excluded from authorization unless chemical companies can demonstrate that the social and economic benefits outweigh their risks.

Eventually, all chemicals granted authorizations under REACH will be reviewed to ensure that they can be safely manufactured, used, and disposed. The time frame for such reviews will be determined on a case-by-case basis that takes into account information such as the risks posed by the chemical, the availability of safer alternatives, and the social and economic benefits of the use of the chemical. For example, if suitable substitutes become available, the authorization may be amended or withdrawn, even if the chemical company granted the authorization has demonstrated that the chemical can be safely controlled.

In addition to such authorization procedures, REACH provides procedures for placing restrictions on chemicals that pose an unacceptable risk to health or the environment. The restriction may completely ban a chemical or limit its use by consumers or by manufacturers of certain products. REACH's restrictions procedures enable the EU to regulate communitywide[25] conditions for the manufacture, marketing, or use of certain chemicals where there is an unacceptable risk to health or the environment. Proposals for restrictions will be prepared by either a Member State or by the European Chemicals Agency at the request of the European Commission. The proposal must demonstrate that there is a risk to human health or the environment that needs to be addressed at the communitywide level and to identify the most appropriate set of risk reduction measures. Interested parties will have an opportunity to comment on the restriction proposal. However, the final determination on the restriction proposal will be made by the European Commission. Because no chemicals have undergone REACH's authorization and

[24]Endocrine disputing chemicals can alter the endocrine system and may cause adverse health effects such as cancer. The endocrine system is a complex system consisting of glands that produce hormones, including the thyroid in the throat and the pituitary gland in the brain that helps guide the development, growth, and reproduction of humans and animals.

[25]Communitywide refers to the EU's member states. As of January 2007, the EU had 27 member states. The member states are Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, and the United Kingdom.

restriction procedures, it is not possible to comment on the ability of these procedures to control the risks of chemicals to human health or the environment.

## Both TSCA and REACH Have Provisions to Make Certain Information Available to the Public, but REACH Requires Greater Public Disclosure

TSCA and REACH require public disclosure of certain information on chemicals and both laws protect confidential or sensitive business information, although the extent to which information can be claimed as confidential or sensitive varies under the two laws. In this regard, one of the objectives of REACH is to make information on chemicals more widely available to the public. Accordingly, REACH places greater limitations on the kinds of information that companies may claim as confidential or sensitive.

### EPA's Ability to Share Data Collected under TSCA Is Limited

TSCA has provisions to protect information claimed by chemical companies as confidential or sensitive business information, such as information on chemical production volumes and trade secret formulas. Health and safety studies, however, generally cannot be considered confidential business information, and TSCA has provisions for making such studies available to the public. Additionally, EPA can disclose confidential business information when it determines such disclosure is necessary to protect human health or the environment from an unreasonable risk. EPA interprets the term health and safety study broadly and, as such, it may include but is not limited to epidemiological, occupational exposure, toxicological, and ecological studies.

However, TSCA generally allows chemical companies to claim any information provided to EPA, other than health and safety studies, as confidential. TSCA requires EPA to protect the information from unauthorized disclosure. More specifically, TSCA restricts EPA's ability to share certain information it collects from chemical companies, such as information about the company (including its identity); the chemical's identity; or the site of operation, including with state officials or with officials of foreign governments. If a request is made for disclosure of the confidential information, EPA regulations require the chemical company to substantiate the claims by providing the agency information on a number of issues, such as whether the identity of the chemical had been kept confidential from competitors and what harmful effects to the company's competitive position would result from publication of the

chemical on the TSCA inventory. State environmental agencies and others are interested in obtaining chemical information, including that claimed as confidential, for use in various activities, such as developing contingency plans to alert emergency response personnel of the presence of highly toxic substances at local manufacturing facilities. Likewise, the general public may find information collected under TSCA useful to engage in dialogues with chemical companies about reducing chemical risks and limiting chemical exposures at nearby facilities that produce or use toxic chemicals.

While EPA believes that some claims of confidential business information may be unwarranted, challenging the claims is resource-intensive. According to a 1992 EPA study, the latest performed by the agency, problems with inappropriate claims were extensive. This study examined the extent to which companies made confidential business information claims, the validity of the claims, and the impact of inappropriate claims on the usefulness of TSCA data to the public. The study found that many of the confidentiality claims submitted under TSCA were not appropriate, particularly for health and safety data. For example, between September 1990 and May 1991, EPA reviewed 351 health and safety studies that chemical companies submitted with a claim of confidentiality. EPA challenged the confidentiality claimed for 77, or 22 percent of the studies and, in each case, the submitter amended the confidentiality claim when challenged by EPA. Currently, while EPA may suspect that some chemical companies' confidentiality claims are unwarranted, the agency does not have data on the number of inappropriate claims.

As we reported in June 2005, EPA focuses on investigating primarily those claims that it believes may be both inappropriate and among the most potentially important—that is, claims relating to health and safety studies performed by chemical companies.[26] According to the EPA official responsible for initiating challenges to confidentiality claims, the agency challenges about 14 such claims each year, and the chemical companies withdraw nearly all of the claims challenged.

Chemical companies have expressed interest in working with EPA to identify ways to enable other organizations to use the information given the adoption of appropriate safeguards. In addition, chemical company representatives told us that, in principle, they have no concerns about

[26] GAO-05-458.

revising TSCA or EPA regulations to require that confidentiality claims be periodically reasserted and reviewed. However, neither TSCA nor EPA regulations require periodic reviews to determine when information no longer needs to be protected as confidential. In our June 2005 report, we recommended that EPA revise its regulations to require that companies reassert claims of confidentiality submitted to EPA under TSCA within a certain time period after the information is initially claimed as confidential.[27] In July 2006, EPA responded to Congress that the agency planned to initiate a pilot process, using its existing authorities, to review selected older submissions containing CBI claims. According to EPA officials, the agency is examining PMNs and notices of commencements submitted to EPA from fiscal years 1993 thorough March 2007 and plans to compile statistics on the numbers and percentages of submissions and the types of CBI claims made. Based on the agency's review, and in light of its other regulatory priorities, EPA will consider whether rule making is appropriate to maximize the benefits of a reassertion program, including benefits to the public. However, no completion date has been determined for the pilot.

## REACH Has Provisions to Protect Confidential Business Information but Allows Greater Public Access to Chemical Information than TSCA

Similar to TSCA, REACH has provisions to protect information claimed by chemical companies as confidential or sensitive, including trade secret formulas and production volumes. In addition, REACH treats some information as confidential, including the following, even if a company did not claim it as confidential: (1) details of the full composition of the chemical's preparation; (2) the precise use, function, or application of the chemical or its preparation; (3) the precise tonnage or volume of the chemical manufactured or placed on the market; or (4) relationships between manufacturers/importers and downstream users. In exceptional cases where there are immediate risks to human health and safety or to the environment, REACH authorizes the European Chemicals Agency to publicly disclose this information.

Furthermore, unlike TSCA, REACH places substantial restrictions on the types of data that chemical companies may claim as confidential. Consistent with one of the key objectives of REACH, the legislation makes information on hazardous chemicals widely available to the public by limiting the types of hazard information that chemical companies may claim as confidential, and generally does not allow confidentiality claims

[27] GAO-05-458.

related to, among other things, guidance on the chemical's safe use, and the chemical's physical chemical properties, such as melting and boiling points, and results of toxicological and ecotoxicological studies, including analytical methods that make it possible to detect a dangerous substance when discharged into the environment and to determine the effects of direct exposure to humans. In addition, other information, such as study summaries and tonnage band information will be available unless the chemical companies justify that disclosing the information will be harmful to its commercial interests.

REACH also requires that safety data sheets for PBTs and vPvBs and other chemicals classified as dangerous be provided to ensure that commercial users—known as downstream users and distributors of a chemical, as well as chemical manufacturers and importers, have the information they need to safely use chemicals.[28] The data sheets, which chemical companies are required to prepare, include information on health, safety, and environmental properties, and risks and risk management measures.[29]

Similar to TSCA, REACH requires public disclosure of health and safety information and has provisions for making information available to the public. REACH also includes a provision for public access to basic chemical information, including brief profiles of hazardous properties, labeling requirements, authorized uses, and risk management measures. The European Union's rules regarding the public's access to information combine a variety of ways that the interests of the public's right to know is balanced with the need to keep certain information confidential. As such, nonconfidential information will be published on the chemical agency's Web site. However, some types of information are always to be treated as confidential under REACH, such as precise production volume.

REACH also includes a provision under which confidential information can generally be shared with government authorities of other countries or international organizations under an agreement between the parties provided that the following conditions are met: (1) the purpose of the agreement is cooperation on implementation or the management of legislation concerning the chemicals covered by REACH and (2) the

[28]Substances classified as PBTs are chemicals that can persist in the environment, bioaccumulate in food chains, and are toxic. Substances classified as vPvBs are chemicals that are very persistent and very bioaccumulative, but not necessarily toxic.

[29]Commercially sensitive information will not be required to be exchanged.

foreign government or international organization protects the confidential information as mutually agreed. In our June 2005 report, we suggested that Congress should consider amending TSCA to authorize EPA to share with the states and foreign governments the confidential business information that chemical companies provide to the agency, subject to regulations to be established by EPA in consultation with the chemical industry and other interested parties that would set forth the procedures to be followed by all recipients of the information in order to protect the information from unauthorized disclosures.[30] Furthermore, chemical industry representatives told us that chemical companies would not object to Congress revising TSCA to allow those with a legitimate reason to obtain access to the confidential business information provided that adequate safeguards exist to protect the information from inappropriate disclosures. In addition, EPA officials said that harmonized international chemical assessments would be improved if the agency had the ability to share this information under appropriate procedures to protect confidentiality.

## Concluding Observations

Substantial differences exist between TSCA and REACH in their approaches to obtaining the information needed to identify chemical risks; controlling the manufacture, distribution, and use of chemicals; and providing the public with information on harmful chemicals. Assuming that the EU has the ability to review chemical information in a timely manner, specific provisions under REACH provide a means for addressing long-standing difficulties experienced both under TSCA and previous European chemicals legislation in (1) obtaining information on chemicals' potentially harmful characteristics and their potential exposure to people and the environment and (2) making the chemical industry more accountable for ensuring the safety of their products. Furthermore, REACH is structured to provide a broader range of data about chemicals that could enable people to make more informed decisions about the products they use in their everyday lives.

We have identified, in our previous reports on TSCA, various potential revisions to the act that could strengthen TSCA to obtain additional chemical information from the chemical industry, shift more of the burden to chemical companies for demonstrating the safety of their chemicals,

[30] GAO-05-458.

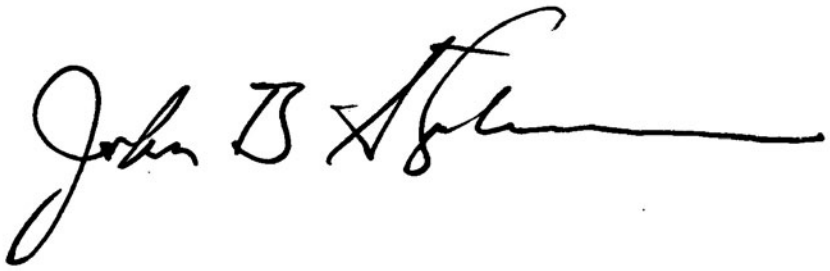
and enhance the public's understanding of the risks of chemicals to which they may be exposed.

## Agency Comments and GAO Response

We provided EPA and the Environment Counselor for the Delegation of the European Commission to the United States a draft of this report for review and comment. Both EPA and the Environment Counselor for the Delegation of the European Commission provided technical comments, which we have incorporated into this report as appropriate. EPA also provided written comments. EPA highlighted the regulatory actions it has taken under TSCA and noted that TSCA is a "fully implemented statute that has withstood the test of time" and that, in contrast, "REACH is not yet in force, and there is no practical experience with any aspect of its implementation." Furthermore, while EPA agreed that it is possible to compare the approaches used to protect against the risks of toxic chemicals under TSCA and REACH, "it is not yet possible to evaluate or compare the effectiveness of the different chemical management approaches or requirements." EPA's written comments are presented in appendix V.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies of this report to the congressional committees with jurisdiction over EPA and its activities; the Administrator, EPA; and the Director, Office of Management and Budget. We also will make copies available to others upon request. In addition, the report will be available at no charge on the GAO Web site at http://www.gao.gov.

If you have any questions about this report, please contact me at (202) 512-3841 or stephensonj@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. Key contributors to this report are listed in appendix VI.



John B. Stephenson
Director, Natural Resources
and Environment

# Appendix I: Scope and Methodology

Our objectives were to describe how Toxic Substances Control Act (TSCA) compares with Registration, Evaluation and Authorization of Chemicals (REACH) in its approaches to (1) identifying chemicals harmful to public health and the environment, (2) controlling chemical risks, and (3) disclosing chemical data to the public while protecting confidential business information. In addressing these issues, we also obtained information on Environmental Protection Agency's (EPA) voluntary chemical control programs that complement TSCA. We reviewed the relevant provisions of TSCA, identified and analyzed EPA's regulations on how the new and existing chemical review and control programs work, including the handling of confidential information, and determined the extent of actions taken by EPA to control chemicals. These efforts were augmented by interviews with EPA officials in the agency's Office of Pollution Prevention and Toxics (OPPT), the EPA office with primary responsibility for implementing TSCA, the High Production Volume (HPV) Challenge Program, and the Voluntary Children's Chemical Evaluation Program (VCCEP) pilot. In addition, we interviewed representatives of the American Chemistry Council (a national chemical manufacturers association), Environmental Defense (a national, nonprofit, environmental advocacy organization), and the Synthetic Organic Chemical Manufacturers Association (a national, specialty chemical manufacturer's association). We also attended meetings of EPA's National Pollution Prevention and Toxics Advisory Committee (NPPTAC)[1] and attended various conferences sponsored by EPA and others. We selected the industry and environmental experts we interviewed based on discussions with NPPTAC representatives and based on our prior work on TSCA. Finally, we obtained and reviewed EPA documents related to its chemical program.

For reviewing REACH, we obtained laws, technical literature, and government documents that describe the European Union's (EU) chemical control program. We also interviewed EU officials who helped develop and who will be involved in implementing REACH, including the Environment Counselor for the Delegation of the European Commission

[1]NPPTAC is a national advisory body chartered under the Federal Advisory Committee Act to provide advice, information and recommendations on the overall policy and operation of programs managed by EPA's Office of Pollution Prevention and Toxics in performing its duties and responsibilities under TSCA and the Pollution Prevention Act. EPA has not held a NPPTAC meeting since the resignation of three NPPTAC members in October 2006, which resulted in an imbalance in representation on the Committee. EPA is evaluating options for NPPTAC's future.

to the United States and representatives from the European Commission and the European Parliament. Our descriptions of these laws are based on interviews with government officials and written materials they provided. In addition, we interviewed representatives of the American Chamber of Commerce to the EU, American Chemistry Council (a national chemical manufacturers association), Environmental Defense (a national, nonprofit environmental advocacy organization), the European Chemical Industry Council (an EU chemical manufacturers association), the European Environmental Bureau (a federation environmental advocacy organization based in the EU Member States),[2] and the Synthetic Organic Chemical Manufacturers Association (a national, specialty chemical manufacturer's association). Furthermore, we interviewed staff from the U.S. Mission to the EU. Finally, for the purposes of this report, we compared TSCA to the REACH legislation that was approved in December 2006, as the basis for analysis.

Our review was performed between January 2006 and May 2007 in accordance with generally accepted government auditing standards.

[2]As of January 2007, the EU consists of 27 member states. The member states are Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Lativa, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, and the United Kingdom.

# Appendix II: Comparison of Selected Provisions of U.S. Toxic Substances Control Act and the EU's Registration, Evaluation and Authorization of Chemicals

| | TSCA | | REACH |
|---|---|---|---|
| **Enactment date** | 1976 | | Approved in December 2006 and entered into force June 2007 |
| **Definition of new and existing chemicals** | New chemicals are those not on the TSCA inventory.<br>Existing chemicals are those listed in the TSCA Inventory. | | REACH creates a single system so that there will be virtually no distinction between new and existing chemicals.[a] |
| **Approximate number of chemicals covered by legislation** | Originally 62,000. Of the more than 82,000 chemicals currently in the TSCA inventory, approximately 20,000 were added to the inventory since EPA began reviewing chemicals in 1979.[b] | | EU officials estimated the number of chemicals with production or import levels of at least 1 metric ton (2,205 pounds) to be about 30,000. Chemical registration will be phased in over 11 years after enactment of REACH.[c] |
| **Notification requirement** | **New chemicals**:<br>Companies are required to notify EPA prior to manufacturing a new chemical. Companies notify EPA of its intent to manufacture a new chemical through submission of a Premanufacture Notice (PMN) or of an application for exemption. After the PMN review period has expired and within 30 days of the chemical's manufacture, companies submit a Notice of Commencement of Manufacture or Import to EPA. The chemical is then added to the TSCA Inventory, and the chemical is classified as an existing chemical. | **Existing chemicals**:<br>TSCA generally does not require chemical companies to notify EPA of changes in use or production volume. However, every 5 years companies are required to update EPA on information such as the processing, use, and production volume of chemicals produced at over 25,000 pounds.<br>Companies must also notify EPA if the company obtains information that reasonably supports the conclusion that the chemical presents a substantial risk to human health or the environment. | In general, REACH treats new and existing chemicals the same. Chemical companies register chemicals with the European Chemicals Agency once production or import of a chemical reaches 1 metric ton (2,205 pounds).<br>After registration, companies are required to immediately notify the European Chemicals Agency of significant changes in use or production volumes of the registered chemical. |

| | TSCA | | REACH |
|---|---|---|---|
| **Method used to prioritize chemicals for further review** | **New chemicals**:<br>Based on information compiled through a series of steps, including a chemical review strategy meeting, structure-activity relationship analysis, and exposure-based reviews, EPA makes a decision ranging from "dropping" a chemical for further review to banning a chemical pending further information. | **Existing chemicals**:<br>TSCA does not require EPA to systematically prioritize and assess existing chemicals.<br>However, TSCA established an Interagency Testing Committee—an advisory committee created to identify chemicals for which there are suspicions of toxicity or exposure and for which there are few, if any ecological effects, environmental fate, or health-effects testing data—to recommend chemicals to which EPA should give priority consideration in promulgating test rules.<br>EPA also plans to use the High Production Volume (HPV) Challenge Program and the information under the Inventory Update Rule to help the agency prioritize the chemicals it will review.[d] | The European Chemicals Agency will develop the criteria for prioritizing chemicals for further review based on, among other things, hazard data, exposure data, and production volume.<br>Member states may use these criteria when developing their list of chemicals to be reviewed. |
| **Notification of significant changes in uses of existing chemicals** | **New chemicals**:<br>New chemicals once they have commenced manufacture are added to the TSCA Inventory. Such former new chemicals can be subject to significant new use rules (SNUR) or restrictions on the manufacture, processing, distribution in commerce, use, or disposal of the chemical under TSCA 5(e) consent orders. | **Existing chemicals**:<br>Chemical companies report use information once every 5 years under TSCA's Inventory Update Rule (IUR),[e] which is primarily used to gather certain information on chemicals produced at the threshold of 25,000 pounds or more.<br>However, in the absence of a SNUR on a particular chemical, there is no requirement for chemical companies to notify EPA of significant new uses of existing chemicals in the intervening years or for chemicals produced at less than 25,000 pounds.<br>Manufacturers and processors of existing chemicals subject to a SNUR must notify EPA 90 days before manufacture of or processing for significant new use. | Chemical companies must immediately inform the European Chemicals Agency in writing of new uses of the chemical about which the company may reasonably be expected to have become aware. |

| | TSCA | | REACH |
|---|---|---|---|
| **Requirement for chemical companies to complete risk assessments** | **New chemicals**:<br>Chemical companies are not required to perform risk assessments on the risks of new chemicals. However, if a company has voluntarily performed risk assessments, they must submit these data with the PMN. | **Existing chemicals**:<br>Chemical companies are not required to complete assessments on the risks of existing chemicals.<br>However, TSCA requires chemical companies to notify EPA immediately of new unpublished information on chemicals that reasonably supports a conclusion of substantial risk. | Chemical companies must conduct a risk assessment in addition to European Chemicals Agency review for all chemicals produced at a level of 1 ton or more per year. Additionally, chemical companies must conduct a chemical safety assessment for all chemicals produced at a level of 10 tons or more per year. |
| **Encourages minimizing animal testing** | **New chemicals**:<br>TSCA contains no specific language relating to reducing animal testing. However, according to EPA officials, TSCA's approach of not requiring companies to test new chemicals for health hazards or environmental effects absent EPA action, combined with EPA's use of Structure Activity Relationship (SAR) analysis reduces the need for animal testing compared with requiring a base set of data without the use of SAR analysis. | **Existing chemicals**:<br>No specific language relating to reducing animal testing. However, under the HPV Challenge Program, EPA encourages companies to consider approaches, such as using existing data, sharing data, and using SAR and read across approaches that would reduce the amount of animal testing needed. Further, EPA does not require retesting for chemicals with adequate Screening Information Data Sets data. EPA has expressed its commitment to examining alternate test methods that reduce the number of animals needed for testing, that reduce pain and suffering to test animals or that replaces test animals with validated in vitro (nonanimal) test systems.<br>In addition, under the Voluntary Children's Chemical Evaluation Program (VCCEP), EPA encouraged participating companies to reduce or eliminate animal testing. | REACH states that testing on vertebrate animals for the purposes of regulation shall be undertaken as a last resort. To reduce the amount of animal testing, REACH encourages the sharing and joint submission of information. REACH implementation guidance encourages the use of SAR and read across approaches. Further, registrants may use any study summaries or robust study summaries performed within the 12 previous years by another manufacturer or importer to register after due compensation of the costs to the owner of the data.[f] |

| | TSCA | | REACH |
|---|---|---|---|
| **Requirement for the disclosure of production quantities** | **New chemicals**:<br>Chemical companies must provide EPA a reasonable third year estimate of the total production volume of a new chemical at the time a PMN is submitted. | **Existing chemicals**:<br>Chemical companies report production quantities every 5 years for those chemicals on the TSCA inventory and produced at quantities of 25,000 pounds or more through the Inventory Update Rule (IUR). | Chemical companies must include information on the overall manufacture or import of a chemical in metric tons per year in a technical dossier with their registration. Chemical companies must immediately report any significant changes in the annual or total quantities manufactured or imported. |
| **Downstream user responsibilities** | **New chemicals**:<br>No specific requirement relating to downstream users. | **Existing chemicals**:<br>No specific requirement relating to downstream users. | Downstream users are required to:<br>Assemble and keep available all information required to carry out duties under REACH for a period of at least 10 years after the substance has been used. Prepare a chemical safety report for any use outside the conditions described in an exposure scenario or if appropriate use and exposure category described in a safety data sheet or for any use the supplier advises against.<br>Downstream users may also provide information to assist in the preparation of a registration. |

| | TSCA | | REACH |
|---|---|---|---|
| **Regulation of hazardous chemicals** | **New chemicals**:<br>EPA can issue a proposed order or seek a court injunction to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of a chemical if EPA determines that there is insufficient information available to permit a reasoned evaluation of the health and environmental effects of a chemical and that (1) in the absence of such information, the chemical may present an unreasonable risk of injury to health or the environment or (2) it is or will be produced in substantial quantities and (a) it either enters or may reasonably be anticipated to enter the environment in substantial quantities or (b) there is or may be significant or substantial human exposure to the substance. | **Existing chemicals**:<br>TSCA requires EPA to apply regulatory requirements to chemicals for which EPA finds a reasonable basis to conclude that the chemical presents or will present an unreasonable risk to human health or the environment. To adequately protect against a chemical's risk, EPA can promulgate a rule that bans or restricts the chemical's production, processing, distribution in commerce, use or disposal, or requires warning labels be placed on the chemical.<br>Section 6(a) authorizes EPA to regulate existing chemicals, including restriction or prohibition. EPA is required to apply the least burdensome requirement and the rule must be supported by substantial evidence in the rule-making record. | Chemicals may be regulated under provisions known as authorization and restriction.<br>Authorization is required for the use of substances of very high concern.[9] This includes substances that are (1) carcinogenic, mutagenic, or toxic for reproduction; (2) persistent, bioaccumulative, and toxic or very persistent and very bioaccumulative; or (3) identified as causing serious and irreversible effects to humans or the environment, such as endocrine disrupters.<br>Restrictions on substances relating to its manufacture, marketplace, or use, including banning, may be required where there is an unacceptable risk to health or the environment. |
| **Enforcement mechanisms** | **New chemicals**:<br>EPA maintains compliance officials to monitor compliance with TSCA. | **Existing chemicals**:<br>EPA maintains compliance officials to monitor compliance with TSCA. | Reach requires EU Member States to monitor compliance with provisions of REACH. |
| **Substitution requirement** | **New chemicals**:<br>No specific language relating to substitution or finding safer alternatives. | **Existing chemicals**:<br>No specific language relating to substitution or finding safer alternatives. | Authorization applications (for chemicals of very high concern) require an analysis of possible alternatives or substitutes. |
| **Protection of Confidential Business Information (CBI)** | **New chemicals:**<br>TSCA allows companies to make confidentiality claims on nearly all information it provides EPA. | **Existing chemicals**:<br>TSCA allows companies to make confidentiality claims on nearly all information it provides to EPA. | REACH allows chemical companies to make confidentiality claims; however, it places restrictions on what kinds of information companies may claim as confidential. |

| | TSCA | | REACH |
|---|---|---|---|
| **Public availability of chemical information** | **New chemicals**:<br>TSCA requires that existing health and safety-related information must be made available to the public. | **Existing chemicals**:<br>TSCA requires that existing health and safety-related information must be made available to the public.<br>EPA uses its HPV Challenge Program to voluntarily gather information from industry and ensure that a minimum set of basic data on approximately 2,800 high-production-volume-chemicals is available to the public. | REACH requires public disclosure of information such as the trade name of the substance, certain physicochemical data, guidance on safe use, and all health and safety-related information. |
| **Requirements addressing children's health** | **New chemicals**:<br>No specific language relating to children's health. | **Existing chemicals**:<br>No specific language relating to children's health. However, under the TSCA Inventory Update Reporting Regulation of December 2005, manufacturers of chemicals in volumes of 300,000 pounds or more must report use in or on products intended for use by children. | No specific language relating to children's health. |

Source: GAO analysis of U.S. TSCA New Chemicals and HPV Programs and EU REACH regulation.

Note: This table is not meant for purposes of legal comparison but only to provide some basic information to compare the U.S. and EU approaches to regulating chemicals.

[a]Under REACH, chemical substances are now described as nonphase-in (i.e., those not produced or marketed prior to the enactment of REACH) and phase-in (i.e., those substances listed in the European Inventory of Existing Commercial Chemical Substances—EINECS , or those that have been manufactured (produced) but not placed on the European market prior to the enactment of REACH).

[b]The TSCA Inventory contains about 82,000 chemicals; however, EPA officials say that the majority of the listed chemicals are either (1) not produced at all, (2) are produced in small quantities (less than 10,000 lbs. per year) or (3) are polymers.

[c]All chemicals (approximately 100,000) reported as being on the European market between January 1, 1971, and September 18, 1981 (those listed in the European Inventory of Existing Commercial Chemical Substances—EINECS—or those manufactured but not placed on the European market in the last 15 years) were classified as existing chemicals, and all chemicals (over 3,800) introduced after 1981 were termed new chemicals prior to the enactment of REACH and need not be registered under REACH unless a change in volume produced or marketed occurs.

[d]EPA invited chemical companies to voluntarily sponsor these chemicals and submit data summaries of existing information along with a test plan proposing a strategy to fill data gaps for either an individual chemical or for a category of chemicals.

[e]The TSCA IUR is primarily used to gather certain information on chemicals produced at more than a basic threshold volume in the year reported. Among other things, chemical companies that produce or import chemicals at or above the 25,000 pound per site threshold are to report the number of workers reasonably likely to be exposed to the chemical at each site and has a reporting threshold of 300,000 pounds per site at or above which chemical companies must report readily obtainable exposure-related use and processing information.

[f]Data older than 12 years is regarded as public domain.

[9]Applicants for authorization must demonstrate that risks associated with the use of the chemical are adequately controlled, that socioeconomic benefits outweigh the risks to human health and the environment, and that no suitable alternatives exist. All applications must be accompanied by an analysis of potential substitutes.

# Appendix III: Additional Options For Strengthening EPA's Ability to Assess and Regulate Chemicals under TSCA

As requested, we identified a number of options that could strengthen EPA's ability under the TSCA to assess chemicals and control those found to be harmful. These options have been previously identified in earlier GAO reports[1] on ways to make TSCA more effective. Representatives of environmental organizations and subject matter experts subsequently concurred with a number of these options and commented on them in congressional testimony. These options are not meant to be comprehensive but illustrate actions that the Congress could take to strengthen EPA's ability to regulate chemicals under TSCA.

The Congress may wish to consider revising TSCA to place more of the burden on industry to demonstrate that new chemicals are safe. Some of the burden could be shifted by requiring industry to test new chemicals based on substantial production volume and the necessity for testing, and to notify EPA of significant increases in production, releases, and exposures or of significant changes in manufacturing processes and uses after new chemicals are marketed.

To put existing chemicals on a more equal footing with new chemicals, the Congress could consider revising TSCA to set specific deadlines or targets for the review of existing chemicals. These deadlines or targets would help EPA to establish priorities for reviewing those chemicals that, on the basis of their toxicity, production volumes, and potential exposure, present the highest risk to health and the environment. The Congress could also consider revising TSCA to shift more of the burden for reviewing existing chemicals to industry. If more of the responsibility for assessing existing chemicals was shared by industry, EPA could review more chemicals with current resources. In deciding how much of the burden to shift to industry, the Congress would need to consider the extent to which providing data to show that chemicals are safe should be a cost of doing business for the chemical industry.

To ensure that EPA can implement its initiatives without having to face legal challenges and delays, the Congress may wish to consider revising TSCA to

[1] GAO/RCED-94-103 and GAO-05-458.

- provide explicit authority for EPA to enter into enforceable consent agreements under which chemical companies are required to conduct testing,
- clarify that health and safety data cannot be claimed as confidential business information,
- require substantiation of confidentiality claims at the time that the claims are submitted to EPA,
- limit the length of time for which information may be claimed as confidential without reaffirming the need for confidentiality,
- establish penalties for the false filing of confidentiality claims, and
- authorize states and foreign governments to have access to confidential business information when they can demonstrate to EPA that they have a legitimate need for the information and can adequately protect it against unauthorized disclosure.

# Appendix IV: Summary of Chemical Hazard Information Requirements under REACH and TSCA by Production Volume

In general, TSCA does not require chemical companies to test the chemicals they produce for their hazardous effects on human health and the environment absent EPA rule making, whereas REACH requires chemical companies to develop such data based on the production volume of the chemical. Table 2 provides information on the total number and types of data on chemical hazards required for chemicals produced at various production volumes, where applicable, for REACH, TSCA, and the HPV Challenge Program. While TSCA does not require chemical companies to develop data on chemicals' effects on human health or the environment, absent EPA action, we have included data requirements for new chemicals that chemical companies plan to produce at high volumes within a few years of introducing the chemical to the marketplace. While TSCA does not require companies to provide this information, EPA says that companies generally agree to provide this information through negotiated consent orders. In addition, while industry participation in EPA's HPV Challenge Program is voluntary, we have included information on the number of tests likely to be produced for chemicals in the program.

**Table 2: Comparison of Chemical Information Requirements by Increasing Production Volume for the EU and the United States (highlighted)**

| | EU REACH 1 ton or more[a] | EU REACH 10 tons or more | U.S. TSCA New Chemicals 100 tons or more[b] | EU REACH 100 tons or more[c] | U.S. HPV Challenge Program[d] | EU REACH 1000 tons or more[c] |
|---|---|---|---|---|---|---|
| Weight range in pounds per year | 2,205 or more | 22,046 or more | 220,460 or more | 220,460 or more | 1,000,000 or more | 2,204,600 or more |
| Weight range in metric tons per year | 1 or more | 10 or more | 100 or more | 100 or more | 454 or more | 1,000 or more |
| Approximate number of chemicals per category | [a] | 5,800 chemicals | [e] | 3,000 chemicals | 2,800 chemicals | 3,700 chemicals |
| **Physical/Chemical properties tests** | | | | | | |
| Boiling point | ● | ● | | ● | ● | ● |
| Dissociation constant | | | | ● | | ● |
| Explosive properties | ● | ● | | ● | | ● |
| Flammability | ● | ● | | ● | | ● |
| Flash point | ● | ● | | ● | | ● |
| Granulometry | ● | ● | | ● | | ● |
| Melting/freezing point | ● | ● | | ● | ● | ● |
| Oxidizing properties | ● | ● | | ● | | ● |
| Partition coefficient: n-octanol/water | ● | ● | | ● | ● | ● |

| | EU REACH 1 ton or more[a] | EU REACH 10 tons or more | U.S. TSCA New Chemicals 100 tons or more[b] | EU REACH 100 tons or more[c] | U.S. HPV Challenge Program[d] | EU REACH 1000 tons or more[c] |
|---|---|---|---|---|---|---|
| Relative density | ● | ● | | ● | | ● |
| Self-ignition temperature | ● | ● | | ● | | ● |
| Stability in organic solvents and identity of relevant degradation products | | | | ● | | ● |
| State of the substance at 20°C | ● | ● | | ● | | ● |
| Surface tension | ● | ● | | ● | | ● |
| Vapor pressure | ● | ● | | ● | ● | ● |
| Viscosity | | | | ● | | ● |
| Water solubility | ● | ● | ● | ● | ● | ● |
| **Total tests for physical/chemical properties** | **14** | **14** | **1** | **17** | **5** | **17** |
| **Human health effects tests** | | | | | | |
| Acute toxicity (by oral route, inhalation, dermal route)[f] | ● | ● | ● | ● | ● | ● |
| Carcinogenicity | | | | | | ● |
| Eye irritation (in vitro) | ● | ● | | ● | | ● |
| Eye irritation (in vivo) | | ● | | ● | | ● |
| Genetic toxicity: In vitro cytogenecity in mammalian cells or in vitro micronucleus study | | ● | ● | ● | ● | ● |
| Genetic toxicity: In vitro gene mutation study in bacteria | ● | ● | ● | ● | ● | ● |
| Genetic toxicity: In vitro gene mutation study in mammalian cells | | ● | | ● | | ● |
| Repeated dose toxicity short term | | ● | ● | ● | ● | ● |
| Repeated dose toxicity subchronic | | | | ● | | ● |
| Reproductive toxicity: Prenatal development toxicity | | | [g] | ● | ● | ● |

| | EU REACH 1 ton or more[a] | EU REACH 10 tons or more | U.S. TSCA New Chemicals 100 tons or more[b] | EU REACH 100 tons or more[c] | U.S. HPV Challenge Program[d] | EU REACH 1000 tons or more[c] |
|---|---|---|---|---|---|---|
| Reproductive toxicity: Reproductive/developmental toxicity testing | | ● | [g] | ● | ● | ● |
| Reproductive toxicity: two-generation reproductive toxicity testing | | | | ● | | ● |
| Skin irritation (in vivo) | | ● | | ● | | ● |
| Skin irritation or skin corrosion (in vitro) | ● | ● | | ● | | ● |
| Skin sensitization | ● | ● | | ● | | ● |
| Toxicokinetics | | ● | | ● | | ● |
| **Total tests for human health effects** | **5** | **12** | **4** | **15** | **6** | **16** |
| **Environmental effects tests** | | | | | | |
| Abiotic degradation: Stability in water (hydrolysis) | | ● | ● | ● | ● | ● |
| Activated sludge respiration | | ● | ● | ● | | ● |
| Aquatic toxicity: Long-term/chronic toxicity testing on fish | | | | ● | | ● |
| Aquatic toxicity: Long-term/chronic toxicity testing on invertebrates | | | | ● | | ● |
| Aquatic toxicity: Short-term/acute toxicity testing on fish | | ● | ● | ● | ● | ● |
| Aquatic toxicity: Short-term/acute toxicity testing on invertebrates | ● | ● | ● | ● | ● | ● |
| Aquatic toxicity: Toxicity to aquatic plants (algae)/ Growth inhibition | ● | ● | ● | ● | ● | ● |
| Biotic degradation: Anaerobic biodegradation | | | ● | | | |
| Biotic degradation: Ready biodegradability | ● | ● | ● | ● | ● | ● |
| Biotic degradation: Further biotic degradation testing[h] | | | | ● | | ● |
| Identification of degradation products | | | | ● | | ● |

| | EU REACH 1 ton or more[a] | EU REACH 10 tons or more | U.S. TSCA New Chemicals 100 tons or more[b] | EU REACH 100 tons or more[c] | U.S. HPV Challenge Program[d] | EU REACH 1000 tons or more[c] |
|---|---|---|---|---|---|---|
| Soil biodegradation | | | • | | | |
| **Environmental fate** | | | | | | |
| Adsorption/desorption screening | | • | | • | | • |
| Adsorption/desorption, further information | | | | • | | • |
| Bioaccumulation in aquatic species | | | | • | | • |
| Birds: long-term or reproductive toxicity | | | | | | • |
| Further information on environmental fate and behavior | | | | | | • |
| Photodegradation | | | • | | • | |
| Sediment organisms: long-term toxicity | | | | | | • |
| Terrestrial organisms effects: Effects on soil micro-organisms | | | | • | | • |
| Terrestrial organisms effects: Long-term toxicity testing on invertebrates | | | | | | • |
| Terrestrial organisms effects: Long-term toxicity testing on plants | | | | | | • |
| Terrestrial organisms effects: Short-term toxicity to invertebrates | | | | • | | • |
| Terrestrial organisms effects: Short-term toxicity to plants | | | | • | | • |
| Transport/Distribution between environmental compartments | | | | | • | |
| **Total tests for environmental effects/fate** | **3** | **7** | **9** | **16** | **7** | **21** |

Source: GAO analysis of U.S. TSCA New Chemicals and HPV Programs and EU REACH regulation.

Note: Not all of the tests/data requirements listed necessarily have to be conducted. In some cases, certain tests are not appropriate for the chemical in question or it is not technically feasible to carry them out. In other cases, required information may be replaced by other information, adapted in another way, or inferred from other information.

[a]Under REACH, for chemicals produced in the one to ten ton range, only chemicals that are likely to be classified as carcinogenic, mutagenic, or toxic for reproduction will require human health and environmental effects data. All chemicals in this range will require physical/chemical properties and any available human health and environmental effects data.

[b]EPA may require human health or environmental hazard testing through a TSCA Section 5(e) Consent Order either based on risk criteria or exposure criteria under EPA's TSCA Section 5(e) Exposure Based Policy for chemicals produced at 100 tons or more. However, not all tests under this policy are required for all chemicals produced at 100 tons or above. Chemicals that meet human exposure criteria may require some or all of the health effects tests listed by EPA; chemicals that meet substantial environmental release criterion (exposure criteria) may require some or all of the environmental effects tests listed by EPA; chemicals that meet the drinking water, ground water, total release to environment media, or total release to surface water exposure-based policy criteria may require some or all of the environmental fate tests listed by EPA.

[c]For the 100 ton level and the 1,000 ton level, the chemical company should submit a testing proposal if they do not already possess the required information. Since tests might be costly and might involve testing on vertebrate animals, the necessity for and the quality of the testing proposal will be checked by the European Chemicals Agency, in coordination with the Member States, in the evaluation process.

[d]The HPV Challenge Program is a voluntary program aimed at developing and making publicly available screening level health and environmental effects information on chemicals manufactured in or imported into the United States in quantities of one million pounds or more per year. Health and environmental effects tests are based on the Organization for Economic Cooperation and Development's (OECD) Screening Information Data Sets. The OECD is a forum where the governments of 30 countries work together to address economic, social, and environmental issues and is recognized as the largest and most reliable source of comparable statistical, economic, and social data. The Screening Information Data Sets is the OECD's program under which data on HPV chemicals are collected and shared.

[e]Once a company begins production of a chemical, it is placed on the TSCA Inventory and is classified as an existing chemical.

[f]For the HPV Challenge Program, only one of the three tests of oral route, inhalation, or dermal route are required. For REACH, the oral route test is the only one required at one ton or above and all three (oral, inhalation, and dermal) are required at 10 tons or above.

[g]These tests may be required at production volumes of 1 million pounds (about 454 tons) or more.

[h]Three biotic degradation tests are specified: simulation testing on ultimate degradation in surface water; soil simulation testing (for substances with a high potential for adsorption to soil); and sediment simulation testing (for substances with a high potential for adsorption to sediment). The choice of the appropriate test(s) depends on the results of the chemical safety assessment.

# Appendix V: Comments from the Environmental Protection Agency

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUL - 2 2007

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Mr. John Stephenson
Director, Natural Resources and Environment
General Accounting Office
441 G St, N.W.
Washington, D.C. 20548

Dear Mr. Stephenson:

Thank you for the opportunity to review and comment on the proposed draft Government Accountability Office (GAO) report entitled "*Chemical Regulation: Comparison of U.S. and Recently Enacted European Union Approaches to Protect Against the Risks of Toxic Chemicals*" (GAO-07-825). The report is intended to provide a comparison of the chemical control approaches used by the U.S. under the Toxic Substances Control Act (TSCA) and the newly enacted, but not yet implemented, European Union (EU) Registration, Evaluation, and Authorization of Chemicals (REACH) legislation.

For more than 30 years, TSCA has provided the American public with the assurance that industrial chemicals are manufactured, imported, and used safely in this country. TSCA provides EPA with the tools necessary to ensure that both public health and the environment are protected from the adverse effects of new and existing industrial chemicals, including the ability to effectively address nanotechnology and emerging chemicals of concern. TSCA provides EPA with authority to review and manage risks from new chemicals prior to introduction into commerce; collect health and safety data as well as production, use, and exposure information on industrial chemicals in commerce; require testing on new or existing chemicals; ban or take other risk mitigation actions on new or existing chemicals of concern; manage "legacy" chemicals such as PCBs, asbestos, and mercury; and enforce compliance with its rules and requirements.

Over the years, EPA has successfully used TSCA to:

- Review and take appropriate action on more than 46,000 new chemicals.
  - Approximately ten percent of these were subject to various restrictions and/or requirements for additional testing under TSCA sections 5(e) and 5(a)(2).
  - More than 1700 have been withdrawn in the face of Agency action.
  - 10,000 new chemicals have been approved for manufacture and use subject to the terms of the exemption filing.
  - 20,000 new chemicals have gone into production and been added to the TSCA Inventory, for a total of 82,000 chemicals currently on the Inventory.

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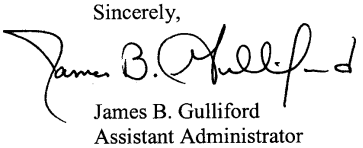
- Control or otherwise regulate 178 existing and over 4,000 new chemicals.
- Serve as the regulatory backstop to a highly successful voluntary program to collect health and safety data on 2200 High Production Volume (HPV) chemicals, which cover more than 93% of the production volume EPA tracks on the TSCA Inventory.
- Collect more than 50,000 health and environmental studies on existing chemicals using TSCA section 8(d).
- Regularly collect updated production, exposure and use information on thousands of higher volume existing chemicals under the TSCA section 8(a) Inventory Update Rule.
- Receive and assess over 16,000 substantial risk submissions from the chemical industry since 1977 (average rate of 800 per year).
- Instigate the phase out of chemicals of concern such as perfluorooctane sulfonate (PFOS), penta and octa brominated dipheny ethers (BDEs), polybrominated biphenyls, benzidene dyes, etc.
- Seek commitments from national and international chemical manufacturers to reduce releases and work toward the elimination of sources of exposure to perfluorooctanoic acid (PFOA), PFOA precursors, and higher homologues.
- Provide critical information on chemicals to Federal, State and local governments, the emergency planning community, a wide array of stakeholders, the public, and the international community, while effectively securing and managing Confidential Business Information.

We are extremely proud of these accomplishments and are moving aggressively with current efforts to develop screening hazard /risk characterizations on the HPV chemicals and to begin to assess lower-volume existing chemicals. These activities will help us identify and take needed next steps, including regulatory and voluntary measures, to obtain more detailed toxicity or exposure information, identify safer substitutes, or identify and initiate risk mitigation steps, as necessary. Because of the head start provided by the HPV Challenge information and the Inventory Update Rule reporting, this approach will result in risk management and testing decisions on these chemicals over the next several years, ahead of the schedules associated with the REACH registration process. Additionally, as the REACH effort progresses, EPA is committed to considering any data generated for that effort which would further inform our regulatory decisions.

These accomplishments, successes, and on-going activities are examples of a proven, fully implemented statute that has withstood the test of time. By contrast, REACH is not yet in force and there is no practical experience with any aspect of its implementation. While it is possible to compare the differences in approaches, such as the scope of requirements on industry, EPA believes that it is not yet possible to evaluate or compare the effectiveness of the different chemical management approaches and requirements of TSCA and REACH.

Again, thank you for the opportunity to review and comment on the report GAO-07-825, "*Chemical Regulation: Comparison of U.S. and Recently Enacted European Union Approaches to Protect Against the Risks of Toxic Chemicals.*" Our technical and editorial comments are enclosed. We look forward to continuing to work with GAO and the Congress on our efforts to ensure that the Agency meets TSCA's primary purpose that chemicals, as manufactured, processed, and used, do not present unreasonable risks to human health and the environment.

Sincerely,



James B. Gulliford
Assistant Administrator

Enclosure

# Appendix VI: GAO Contact and Staff Acknowledgments

## GAO Contact

John B. Stephenson, (202) 512-3841

## Staff Acknowledgments

In addition to the individual named above, David Bennett, John Delicath, Richard Johnson, Valerie Kasindi, Ed Kratzer, and Tyra Thompson made key contributions to this report.

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