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CHEMICAL REGULATION

**Options for Enhancing the
Effectiveness of the Toxic
Substances Control Act**

Statement of John Stephenson, Director
Natural Resources and the Environment



GAO

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Highlights of [GAO-09-428T](#), a testimony before the Subcommittee on Commerce, Trade, and Consumer Protection, Committee on Energy and Commerce, House of Representatives

Why GAO Did This Study

Congress passed the Toxic Substances Control Act (TSCA) in 1976, authorizing the Environmental Protection Agency (EPA) to obtain information on the risks of industrial chemicals and to control those that EPA determines pose an unreasonable risk. However, EPA does not have sufficient chemical assessment information to determine whether it should establish controls to limit public exposure to many chemicals that may pose substantial health risks. In reports on TSCA, GAO has recommended statutory changes to, among other things, provide EPA with additional authorities to obtain health and safety information from the chemical industry and to shift more of the burden to chemical companies for demonstrating the safety of their chemicals. The most important recommendations aimed at providing EPA with the information needed to support its assessments of industrial chemicals have not been implemented—a key factor leading GAO in January 2009 to add transforming EPA's process for assessing and controlling toxic chemicals to its list of high-risk areas warranting attention by Congress and the executive branch.

This testimony, which is based on prior GAO work, addresses EPA's implementation of TSCA and options for (1) obtaining information on the risks posed by chemicals to human health and the environment, (2) controlling these risks, and (3) publicly disclosing information provided by chemical companies under TSCA.

To view the full product, including the scope and methodology, click on [GAO-09-428T](#). For more information, contact John B. Stephenson at (202) 512-3841 or stephensonj@gao.gov.

CHEMICAL REGULATION

Options for Enhancing the Effectiveness of the Toxic Substances Control Act

What GAO Found

TSCA generally places the burden of obtaining data on existing chemicals on EPA, rather than on the companies that produce the chemicals. For example, the act requires EPA to demonstrate certain health or environmental risks before it can require companies to further test their chemicals. As a result, EPA does not routinely assess the risks of the roughly 80,000 industrial chemicals in use. Moreover, TSCA does not require chemical companies to test the approximately 700 new chemicals introduced into commerce annually for their toxicity, and companies generally do not voluntarily perform such testing. Further, the procedures EPA must follow in obtaining test data from companies can take years to complete. In contrast, the European Union's chemical control legislation generally places the burden on companies to provide health effects data on the chemicals they produce. Giving EPA more authority to obtain data from the companies producing chemicals, as GAO has in the past recommended that Congress consider, remains a viable option for improving the effectiveness of TSCA.

While TSCA authorizes EPA to issue regulations that may, among other things, ban existing toxic chemicals or place limits on their production or use, the statutory requirements EPA must meet present a legal threshold that has proven difficult for EPA and discourages the agency from using these authorities. For example, EPA must demonstrate "unreasonable risk," which EPA believes requires it to conduct extensive cost-benefit analyses to ban or limit chemical production. Since 1976, EPA has issued regulations to control only five existing chemicals determined to present an unreasonable risk. Further, its 1989 regulation phasing out most uses of asbestos was vacated by a federal appeals court in 1991 because it was not based on "substantial evidence." In contrast, the European Union and a number of other countries have largely banned asbestos, a known human carcinogen that can cause lung cancer and other diseases. GAO has previously recommended that Congress amend TSCA to reduce the evidentiary burden EPA must meet to control toxic substances and continues to believe such change warrants consideration.

EPA has a limited ability to provide the public with information on chemical production and risk because of TSCA's prohibitions on the disclosure of confidential business information. About 95 percent of the notices companies have provided to EPA on new chemicals contain some information claimed as confidential. Evaluating the appropriateness of confidentiality claims is time- and resource-intensive, and EPA does not challenge most claims. State environmental agencies and others have said that information claimed as confidential would help them in such activities as developing contingency plans to alert emergency response personnel to the presence of highly toxic substances at manufacturing facilities. The European Union's chemical control legislation generally provides greater public access to the chemical information it receives, and GAO has previously recommended that Congress consider providing EPA additional authorities to make more chemical information publicly available.

Mr. Chairman and Members of the Subcommittee:

I am pleased to appear today before the Subcommittee on Commerce, Trade, and Consumer Protection, House Committee on Energy and Commerce, to discuss our work on the need to improve the Toxic Substances Control Act (TSCA). As you know, tens of thousands of chemicals are currently in commercial use in the United States and hundreds of new chemicals are introduced into commerce each year—some of which may be toxic and adversely affect human health or the environment. The Congress passed TSCA in 1976 to enable the Environmental Protection Agency (EPA) to obtain information on the risks of commercially used chemicals and to control those that EPA determines may pose unreasonable risks. However, TSCA generally places the burden of obtaining information about the roughly 80,000 chemicals already on the U.S. market on EPA, rather than on the companies that produce the chemicals. The act requires EPA to demonstrate certain health or environmental risks before it can require companies to further test their chemicals. As a result, EPA does not routinely assess the risks of the industrial chemicals that are already in use. Further, for the approximately 700 new chemicals introduced into commerce annually, chemical companies are required to provide EPA with certain information in “premanufacture notices,” and EPA can ban or limit a chemical’s use if it finds, among other things, that this information is insufficient to allow evaluation of the chemical’s health and environmental effects. Although 85 percent of the notices lack any health or safety test data, EPA does not often use its authority to obtain more information.

In previous reports on TSCA, we have recommended both statutory and regulatory changes to, among other things, strengthen EPA’s authority to obtain additional information from the chemical industry, shift more of the burden to chemical companies for demonstrating the safety of their chemicals, and enhance the public’s understanding of the risks of chemicals to which they may be exposed. In part because the most important recommendations aimed at providing EPA with the information needed to support its assessments of industrial chemicals have not been implemented, in January 2009, we added transforming EPA’s processes for assessing and controlling toxic chemicals to our list of areas at “high-risk” for waste, fraud, abuse and mismanagement or in need of broad-based transformation.¹

¹*High Risk Series: An Update*. [GAO-09-271](#). Washington, D.C.: Jan. 22, 2009.

My testimony today is largely based on our prior work involving TSCA that identified the challenges associated with implementing the act and some of the legislative options available to address these challenges. Specifically, my statement addresses EPA's implementation of TSCA and options for (1) obtaining information on the risks posed by chemicals to human health and the environment, (2) controlling these risks, and (3) publicly disclosing information provided by chemical companies under TSCA. In addition, my testimony will also highlight the results of our 2007 report assessing the key differences between the approach to chemical regulation under TSCA and the chemical control policy the European Union adopted in 2006 under legislation known as Registration, Evaluation and Authorization of Chemicals (REACH). (See Related GAO Products following this statement.)

In summary, EPA lacks adequate scientific information on the toxicity of many chemicals in the environment. TSCA generally places the burden of obtaining data on chemicals on EPA, rather than on the companies that produce the chemicals. This approach requires that EPA demonstrate certain health or environmental risks before it can require companies to further test their chemicals. As a result, EPA has only limited information on the health and environmental risks posed by these chemicals. In previous reports on TSCA, we have identified for Congressional consideration statutory changes to strengthen EPA's authority to obtain information from the chemical industry. In our view, these changes remain viable options for improving the effectiveness of TSCA and thereby enhancing EPA's ability to protect public health and the environment.

While TSCA authorizes EPA to issue regulations that may, among other things, ban existing toxic chemicals or place limits on their production or use, the statutory requirements EPA must meet to do so present a legal threshold that has proven difficult for EPA and discouraged agency action. For example, EPA has long concluded that asbestos is a known human carcinogen that can cause lung cancer and other diseases. Although EPA spent 10 years developing a rule to phase out the use of nearly all products containing asbestos under its TSCA authority, a federal appeals court largely vacated the rule because it was not based on "substantial evidence." In contrast to the United States, the European Union and a number of other countries have essentially banned asbestos and asbestos-containing products. Since EPA's asbestos rule was rejected in 1991, the agency has not completed any actions to ban or limit toxic chemicals under section 6. The options for enhancing the effectiveness of TSCA that we have identified in prior reports include amendments to reduce the

evidentiary burden that EPA must meet to enable EPA to better protect the public health and the environment.

EPA's ability to provide the public with information on chemical production and risk has been hindered by strict confidential business information provisions of TSCA, which generally prohibits the disclosure of confidential business information. State environmental agencies and others have expressed interest in obtaining information claimed as confidential business information for use in various activities, such as developing contingency plans to alert emergency response personnel to the presence of highly toxic substances at manufacturing facilities. In previous reports, we have identified options for statutory changes to improve EPA's ability to make more chemical information publicly available.

Background

The Toxic Substances Control Act was enacted in 1976 to provide EPA with the authority, upon making certain determinations, to collect information about the hazards posed by chemical substances and to take action to control unreasonable risks by either preventing dangerous chemicals from making their way into use or placing restrictions on those already in commerce. TSCA authorizes EPA to review chemicals already in commerce (existing chemicals) and chemicals yet to enter commerce (new chemicals). EPA lists chemicals in commerce in the TSCA inventory. Of the over 83,000 chemicals currently in the TSCA inventory, about 62,000 were already in commerce when EPA began reviewing chemicals in 1979. Since then, over 21,000 new chemicals were added to the inventory and are now in use as existing chemicals. To assess risks, EPA examines a chemical's toxicity or potential adverse effects and the amount of human and environmental exposures. TSCA generally requires the industry to notify EPA at least 90 days before producing or importing a new chemical. These notices contain information, such as the chemical's molecular structure and intended uses that EPA uses to evaluate the chemical's potential risks. TSCA also authorizes EPA to promulgate rules to require manufacturers to perform tests on chemicals in certain circumstances or provide other data, such as production volumes, on existing chemicals. In addition, TSCA requires chemical companies to report to EPA any data that reasonably support a conclusion that a chemical presents a substantial risk. If EPA finds that a chemical's risks are unreasonable, it can prohibit or limit its production, processing, distribution, use, and disposal or take other action, such as requiring warning labels on the substance. While TSCA authorizes EPA to release chemical information obtained by the agency under the act, TSCA provides that certain

information, such as data disclosing chemical processes, can be claimed as confidential business information by chemical manufacturers and processors. EPA generally must protect such information against public disclosure unless such disclosure is necessary to protect against an unreasonable risk of injury to health or the environment.

Like the United States, the European Union has laws and regulations governing the manufacturing and use of chemicals. However, the EU has recently revised its chemical control policy through legislation known as Registration, Evaluation and Authorization of Chemicals (REACH). REACH went into effect in June 2007, but full implementation of all the provisions of REACH will be phased in over an 11-year period. 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 manufacturer can demonstrate that the risks from a use of the chemical can be adequately controlled or that the socioeconomic benefits outweigh the risks and that there are no suitable alternatives. 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, or use such substances that do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary principle. 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.

EPA Lacks Adequate Information on Potential Health and Environmental Risks of Toxic Chemicals

While TSCA authorizes EPA to review existing chemicals, it generally provides no specific requirement, time frame, or methodology for doing so. Significantly, chemical companies are not required to develop and submit toxicity information to EPA on existing chemicals unless the agency finds that a chemical may present an unreasonable risk of injury to human health or the environment or is or will be produced in substantial quantities and that either (a) there is or may be significant or substantial human exposure to the chemical or (b) the chemical enters the environment in substantial quantities. EPA must also determine there are insufficient data to reasonably determine the effects on health or the environment and that testing is necessary to develop such data before it can require a company to test its chemicals for harmful effects. This

structure places the burden on EPA to demonstrate a need for data on a chemical's toxicity rather than on a company to demonstrate that a chemical is safe. As a result, EPA does not routinely assess the risks of the roughly 80,000 industrial chemicals in use.

EPA has begun to rely on voluntary programs for data, such as the High Production Volume Challenge program, where companies voluntarily agree to provide EPA certain data on high-production volume chemicals. However, these programs may not provide EPA with complete data in a timely manner. For example, there are currently over 200 high-production-volume chemicals for which chemical companies have not voluntarily agreed to provide the minimal test data that EPA believes are needed to initially assess their risks. EPA officials told us that in cases where chemical companies do not voluntarily provide test data and health and safety studies in a complete and timely manner, requiring the testing of existing chemicals of concern—those chemicals for which some suspicion of harm exists—is the only practical way to ensure that the agency obtains the needed information. Furthermore, many additional chemicals are likely to become high production chemicals because the specific chemicals used in commerce are constantly changing, as are their production volumes.

However, EPA officials told us that it is time-consuming, costly, and inefficient for the agency to use TSCA's two-step process of (1) issuing rules under TSCA (which can take months or years to develop) to obtain exposure data or available test data that the chemical industry does not voluntarily provide to EPA and then (2) issuing additional rules requiring companies to perform specific tests necessary to ensure the safety of the chemicals tested. Officials also said that EPA's authority under TSCA to issue rules requiring chemical companies to conduct tests on existing chemicals has been difficult to use because the agency must first make certain findings before it can require testing. Specifically, TSCA requires EPA to find that current data is insufficient; testing is necessary; and that either (1) the chemical may present an unreasonable risk or (2) that 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.

Once EPA has made the required findings, the agency can issue a proposed rule for public comment, consider the comments it receives, and promulgate a final rule ordering chemical testing. EPA officials told us that finalizing rules can take from 2 to 10 years and require the expenditure of substantial resources. Given the time and resources required, the agency has issued rules requiring testing for only about 200 chemicals. Because

EPA has used authority to issue rules to require testing so sparingly, it has not continued to maintain information on the cost of implementing these rules. However, in our October 1994 report on TSCA, we noted that EPA officials told us that issuing such a rule can cost hundreds of thousands of dollars. Given the difficulties involved in requiring testing, EPA officials do not believe that TSCA provides an effective means for testing a large number of existing chemicals. They believe that EPA could review substantially more chemicals in less time if they had the authority to require chemical companies to conduct testing and provide test data on chemicals once they reach a substantial production volume, assuming EPA had first determined that these data cannot be obtained without testing. We have long held a similar view based on our reviews involving TSCA. For example, in our June 2005 report,² we recommended that the Congress consider giving EPA the authority to require chemical manufacturers and processors to develop test data based on substantial production volume and the necessity for testing. We continue to believe that providing EPA with more authority to obtain test data from companies would enhance the effectiveness of TSCA.

In contrast with TSCA's provisions for obtaining information on chemicals, we found that REACH, the legislation through which the European Union has recently revised its chemical control policy, requires chemical companies to develop more information than TSCA on the effects of chemicals on human health and the environment. REACH generally requires that chemical companies provide to, and in some cases develop for, government regulators information on chemicals' effects on human health and the environment, while TSCA generally does not. For example, under REACH, chemical companies provide information on chemicals' properties and health and environmental effects for 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.

²GAO, *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.: June 13, 2005

Regarding new chemicals, TSCA generally requires chemical companies to notify EPA of their intent to manufacture or import new chemicals and to provide any available test data. Yet EPA estimates that most premanufacture notices do not include test data of any type, and only about 15 percent include health or safety test data. Chemical companies do not have an incentive to conduct these tests because they may take over a year to complete, and some tests may cost hundreds of thousands of dollars. Because EPA generally does not have sufficient data on a chemical's properties and effects when reviewing a new chemical, EPA uses models to compare new chemicals with chemicals with similar molecular structures for which test data on health and environmental effects are available.

EPA bases its exposure estimates for new chemicals on information contained in premanufacture notices. However, the anticipated production volume, uses, exposure levels, and release estimates outlined in these notices generally do not have to be amended once manufacturing begins. That is, once EPA completes its review and production begins, chemical companies are not required under TSCA to limit the production of a chemical or its uses to those specified in the premanufacture notice or to submit another premanufacture notice if changes occur. However, the potential risk of injury to human health or the environment may increase when chemical companies increase production levels or expand the uses of a chemical. TSCA addresses expanded uses of chemicals by authorizing EPA to promulgate a rule specifying that a particular use of a chemical would be a significant new use. However, EPA has infrequently issued such rules, which require manufacturers, importers, and processors of the chemical for the new use to notify EPA at least 90 days before beginning manufacturing or processing the chemical for that use.

An option that could make TSCA more effective would be to revise the act to require companies to test their chemicals and submit the results to EPA with their premanufacture notices. Currently, such a step is required only if EPA makes the necessary findings and promulgates a testing rule. A major drawback to testing is its cost to chemical companies, possibly resulting in a reduced willingness to perform chemical research and innovation. To ameliorate such costs, or to delay them until the new chemicals are produced in large enough quantity to offset the cost of testing, requirements for testing could be based on production volume. For example, in Canada and the European Union, testing requirements for low-volume chemicals are less extensive and complex than for those for high-volume chemicals. Congress could give EPA, in addition to its current authorities under section 4 of TSCA, the authority to require chemical

substance manufacturers and processors to develop test data based on, for example, substantial production volume and the necessity for testing.

Another option would be to provide EPA with greater authority to require testing targeted to those areas in which EPA's analysis models do not adequately predict toxicity. For example, EPA could be authorized to require such testing if it finds that it cannot be confident of the results of its analysis (e.g., when it does not have sufficient toxicity data on chemicals with molecular structures similar to those of the new chemicals submitted by chemical companies.) Under such an option, EPA could establish a minimal set of tests for new chemicals to be submitted at the time a chemical company submits a premanufacture notice for the chemical for EPA's review. Additional and more complex and costly testing could be required as the new chemical's potential risks increase, based on, for example, production or environmental release levels.

According to some chemical companies, the cost of initial testing could be reduced by amending TSCA to require EPA to review new chemicals before they are marketed, rather than before they are manufactured. In this regard, 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. Thus, requiring companies to conduct tests and submit the resulting test data only for chemicals that are actually marketed would be substantially less expensive than requiring them to test all new chemicals submitted for EPA's review.

Likewise, TSCA's chemical review provisions could be strengthened by requiring the systematic review of existing chemicals. In requiring that EPA review premanufacture notices within 90 days, TSCA established a firm requirement for reviewing new chemicals, but the act contains no similar requirement for existing chemicals unless EPA determines by rule that they are being put to a significant new use. TSCA could be amended to establish a time frame for the review of existing chemicals, putting existing chemicals on a more equal footing with new chemicals. However, because of the large number of existing chemicals, EPA would need the flexibility to identify which chemicals should be given priority. TSCA could be amended to require individual chemical companies or the industry as a whole to compile and submit chemical data, such as that included in EPA's High Production Volume (HPV) Challenge Program, for example, as a condition of manufacture or import above some specified volume.

TSCA's Regulatory Framework Impedes EPA's Efforts to Control Toxic Chemicals

While TSCA authorizes EPA to issue regulations that may, among other things, ban existing toxic chemicals or place limits on their production or use, the statutory requirements EPA must meet to do so present a legal threshold that has proven to be difficult for EPA. Specifically, in order to regulate an existing chemical under section 6 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. EPA officials believe that demonstrating an unreasonable risk is a more stringent requirement than demonstrating, for example, a significant risk, and that a finding of unreasonable risk requires an extensive cost-benefit analysis. In addition, before regulating a chemical under section 6, the EPA Administrator must consider and publish a statement regarding

- 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.

Moreover, while TSCA offers EPA a range of control options when regulating existing chemicals—ban or restrict a chemical's production, processing, distribution in commerce, or disposal or use, or require warning labels on the chemicals—EPA is required to choose the least burdensome requirement that will be adequately protective. For example, if EPA finds that it can adequately manage the unreasonable risk of a chemical by requiring chemical companies to place warning labels on the chemical, EPA may not ban or otherwise restrict the use of that chemical. EPA must also develop substantial evidence in the rulemaking 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 rulemaking record.” As several courts have noted, the substantial evidence standard is more rigorous than the arbitrary and capricious standard normally applied to rulemaking under the Administrative Procedure Act. Further, according to EPA officials, 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

substantial evidence that EPA is promulgating the least burdensome requirement.

EPA has had difficulty demonstrating that harmful chemicals pose an unreasonable risk and consequently should be banned or have limits placed on their production or use. In fact, since Congress passed TSCA nearly 33 years ago, EPA has issued regulations under the act to ban or limit or restrict the production or use of only five existing chemicals or chemical classes.³ Significantly, in 1991, EPA's 1989 regulation broadly banning asbestos was largely vacated by a federal appeals court decision that cited EPA's failure to meet statutory requirements.⁴ In contrast to the United States, the European Union, as well as a number of other countries, has banned all, or almost all, asbestos and asbestos-containing products.

Asbestos, which refers to several minerals that typically separate into very tiny fibers, is a known human carcinogen that can cause lung cancer and other diseases if inhaled. Asbestos has been used widely in products such as fireproofing, thermal insulation, and friction products, including brake linings. EPA invested 10 years in exploring the need for the asbestos ban and in developing the regulation. Based on its review of over 100 studies of the health risks of asbestos as well as public comments on the proposed rule, EPA determined that asbestos is a potential carcinogen at all levels of exposure—that is, that it had no known safe exposure level. EPA's 1989 rule under TSCA section 6 prohibited the future manufacture, importation, processing, and distribution of asbestos in almost all products. In response, some manufacturers of asbestos products filed suit against EPA arguing, in part, 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 chemical companies, concluding that EPA had failed to muster substantial evidence to justify its asbestos ban and returning parts of the rule to EPA for reconsideration.

Specifically, the court concluded that EPA did not present sufficient evidence to justify the ban on asbestos because it did not consider all necessary evidence and failed to show that the control action it chose was the least burdensome regulation required to adequately protect human

³EPA has placed controls on four new chemicals under section 5(f).

⁴The court vacated most of the rule but continued the rule's ban on asbestos products no longer in commerce.

health or the environment. EPA had not calculated the risk levels for intermediate levels of regulation because it believed there was no asbestos exposure level for which the risk of injury or death was zero. As articulated by the court, the proper course of action for EPA, after an initial showing of product danger, would have been to consider each regulatory option listed in TSCA, beginning with the least burdensome, and the costs and benefits of each option. The court further criticized EPA's ban of 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. In addition, the court stated that in evaluating what risks are unreasonable, EPA must consider the costs of any proposed actions; moreover, the court noted that TSCA's requirement that EPA impose the least burdensome regulation reinforces the view that EPA must balance the costs of its regulations against their benefits. After completing the 1989 asbestos rule, EPA has completed only one regulation to ban or limit the production or use of an existing chemical (for hexavalent chromium in 1990). Further, EPA has not completed any actions to ban or limit toxic chemicals under section 6 since the court rejected its asbestos rule in 1991.

With EPA's limited actions to control toxic chemicals under TSCA, state and federal actions have established controls for some toxic chemicals. For example, a California statute enacted in 2007 prohibits the manufacture, sale, or distribution of certain toys and child care articles after January 1, 2009, if the products contain concentrations of phthalates exceeding 0.1 percent.⁵ In 2008, Congress took similar action. California has also enacted limits on formaldehyde in pressed wood. In response to a petition asking EPA to use section 6 of TSCA to adopt the California formaldehyde regulation, EPA recently issued an advance notice of proposed rulemaking suggesting several regulatory options the agency could pursue under its TSCA section 6 authority to limit exposure to formaldehyde. However, because of the legal hurdles the agency would face in regulating formaldehyde under TSCA, some stakeholders have recommended that EPA pursue legislation to control formaldehyde.

In our previous reports on TSCA, we identified a number of options that could strengthen EPA's ability to regulate harmful chemicals under TSCA

⁵This statute, as well as restrictions in place by the European Union, covers several phthalates, including dibutyl phthalate. In 2000, the Department of Health and Human Services' National Toxicology Program concluded that dibutyl phthalate may adversely affect human reproduction or development if exposures are sufficiently high.

and enhance EPA's ability to protect public health and the environment. Potential changes to TSCA include reducing the evidentiary burden that EPA must meet to take regulatory action under the act by amending the (1) unreasonable risk standard that EPA must meet to regulate existing chemicals under section 6 of TSCA, (2) standard for judicial review that currently requires a court to hold a TSCA rule unlawful and set it aside unless it is supported by substantial evidence in the rulemaking record, and (3) requirement that EPA choose the least burdensome regulatory requirement. We have previously recommended that the Congress amend TSCA to reduce the evidentiary burden that EPA must meet.⁶

Alternatively, the European Union's recently enacted chemical control legislation, REACH, represents a regulatory model that differs from the TSCA framework in key ways. For example, 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. In addition, 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, the 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. This process substantially differs from TSCA's section 6 requirements as discussed above.

⁶GAO, *Toxic Substances Control Act: Legislative Changes Could Make the Act More Effective*. [GAO/RCED-94-103](#). Washington, D.C.: September 26, 1994

EPA's Ability to Share Information Under TSCA's Confidential Business Information Provisions Are Limited

EPA's ability to make publicly available the information that it collects under TSCA is limited. Chemical companies may claim some of the information they provide to EPA under TSCA as confidential business information. EPA is required under the act to protect trade secrets and privileged or confidential commercial or financial information against unauthorized disclosures, and this information generally cannot be shared with others, including state health and environmental officials and foreign governments. However, some state officials believe this information would be useful for informing and managing their environmental risk programs. Furthermore, while EPA believes that some claims of confidential business information may be unwarranted, challenging the claims is resource-intensive.

EPA has not performed any recent studies of the appropriateness of confidentiality claims, but a 1992 EPA study indicated that 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. While EPA may suspect that some chemical companies' confidentiality claims are unwarranted, the agency does not have data on the number of inappropriate claims. According to EPA, about 95 percent of premanufacture notices contain some information that chemical companies claim as confidential. EPA officials also told us that the agency does not have the resources that would be needed to investigate and, as appropriate, challenge claims to determine the number that are inappropriate. Consequently, 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 the chemical companies involving chemicals currently used in commerce. The EPA official responsible for initiating challenges to confidentiality claims told us that EPA challenges about 14 such claims each year and that the chemical companies withdraw nearly all of the claims challenged.

Officials who have various responsibilities for protecting public health and the environment from the dangers posed by chemicals believe that having access to confidential TSCA information would allow them to examine information on chemical properties and processes that they currently do not possess and could enable them to better control the risks of potentially harmful chemicals. Likewise, the general public may also find information provided under TSCA useful. Individual citizens or community groups may have a specific interest in information on the risks of chemicals that are produced or used in nearby facilities. For example,

neighborhood organizations can use such information to engage in dialogue with chemical companies about reducing chemical risks, preventing accidents, and limiting chemical exposures.

While both TSCA and REACH have provisions to protect information claimed by chemical companies as confidential, REACH requires greater public disclosure of certain information, such as basic chemical properties. Furthermore, REACH places greater restrictions on the kinds of information chemical companies may claim as confidential. For example, REACH includes a provision for public access to basic chemical information, including brief profiles of hazardous properties and authorized uses. The European Union's approach to public's access to information combines 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. 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 certain conditions are met.

In previous reports, we recommended that the Congress consider providing EPA additional authorities under TSCA to improve its ability to make more chemical information publicly available. For example, in our June 2005 report,⁷ we recommended that the Congress consider amending TSCA to authorize EPA to share with the states and foreign governments the confidential business information that chemical companies provide to EPA, 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. In our September 1994 report,⁸ we recommended that the Congress consider limiting the length of time for which information may be claimed as confidential without resubstantiation of the need for confidentiality.

⁷GAO, *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.: June 13, 2005.

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

Mr. Chairman, this concludes my prepared statement. I would be happy to respond to any questions that you or Members of the Subcommittee may have.

Contacts and Acknowledgments

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