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CHEMICAL REGULATION

Actions Are Needed to Improve the Effectiveness of EPA's Chemical Review Program

Statement of John B. Stephenson,
Director, Natural Resources and Environment

August 2, 2006

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Highlights

Highlights of GAO-06-1032T, testimony before the Committee on Environment and Public Works, U.S. Senate

Why GAO Did This Study

Chemicals play an important role in everyday life, but some may be harmful to human health and the environment. Chemicals are used to produce items widely used throughout society, such as cleansers and plastics as well as industrial solvents and additives. However, some chemicals, such as lead and mercury, are highly toxic at certain doses and need to be regulated because of health and safety concerns. 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.

This testimony is based on GAO's June 2005 report, *Chemical Regulation: Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program* (GAO-05-458). GAO's report describes EPA's efforts to (1) assess chemicals used in commerce, (2) control the use of chemicals not yet in commerce, and (3) publicly disclose information provided by chemical companies under TSCA. GAO recommended that the Congress consider providing EPA additional authorities under TSCA to improve EPA's ability to assess chemical risks, and that the EPA Administrator take several actions to improve EPA's management of its chemical review program. EPA did not disagree with our findings and is currently implementing some of our recommendations.

www.gao.gov/cgi-bin/getrpt?GAO-06-1032T.

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

What GAO Found

EPA's authority under TSCA to obtain the data needed to assess existing chemicals does not facilitate its review process because the costly and time-consuming burden of obtaining the data is on EPA, rather than chemical companies. Consequently, EPA has used its authorities to require testing of fewer than 200 of the 62,000 chemicals in commerce when EPA began reviewing chemicals under TSCA in 1979. To obtain more data on existing chemicals, EPA implemented its High Production Volume Challenge Program, under which chemical companies voluntarily provide test data on about 2,800 chemicals produced or imported in amounts of 1 million pounds or more a year. While the purpose of the program is laudable, several problems remain, including that the chemical industry has not agreed to provide test data for over 200 chemicals with high production volumes. Moreover, after obtaining test data, EPA is required under TSCA's provisions to determine that a chemical poses an unreasonable risk before EPA can act to regulate its production or use. EPA officials say the act's legal standards for demonstrating unreasonable risk are so high that they have generally discouraged EPA from using its authorities to ban or restrict the manufacture or use of existing chemicals. Since Congress enacted TSCA in 1976, EPA has issued regulations to ban or limit the production of only five existing chemicals or groups of chemicals.

EPA's reviews of new chemicals provide only limited assurance that health and environmental risks are identified because TSCA does not require companies to test chemicals before they notify EPA of their intent to manufacture the chemicals. Because of a general lack of data on new chemicals, EPA has developed methods to predict their potential exposure and toxicity levels by using scientific models to compare the new chemicals with chemicals that have similar molecular structures and for which toxicity information is available. However, the use of these models can be problematic because the models are not always accurate in predicting chemical properties and EPA's evaluation of general health effects of the chemicals is contingent upon the availability of information on chemicals with similar molecular structures. Additionally, the estimates of a chemical's production volume and anticipated uses, which EPA uses to assess exposure, can change substantially after EPA completes its review. Despite these limitations, EPA's reviews have resulted in some action being taken to reduce the risks of over 3,600 new chemicals.

EPA's ability to provide the public with information on chemical production and risk is generally limited by the confidential business information provisions of TSCA. As a result, state agencies and foreign governments interested in obtaining this data for important purposes are denied access to the information. Recently, chemical companies have expressed interest in working with EPA to identify ways of enabling the agency to share confidential information with other organizations, provided that appropriate safeguards are adopted to prevent the unauthorized use of the information.

Mr. Chairman and Members of the Committee:

I am pleased to appear today before the Senate Committee on Environment and Public Works, to discuss our work on the Environmental Protection Agency's (EPA) implementation of the Toxic Substances Control Act (TSCA). Tens of thousands of chemicals are currently in commercial use in the United States and, on average, over 700 new chemicals are introduced into commerce each year. Although these chemicals are an integral component in the production of important goods and services, some may be toxic and may adversely affect human health and/or the environment. It was in this context, that the Congress passed TSCA in 1976, authorizing EPA to obtain manufacturer information on the risks of chemicals and to control those that EPA determines will pose an unreasonable risk.

TSCA addresses those chemicals manufactured, imported, processed, distributed in commerce, used, or disposed of in the United States, but excludes certain substances including pesticides regulated under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and food additives, drugs, and cosmetics regulated under the Federal Food, Drug, and Cosmetic Act (FFDCA). TSCA authorizes EPA to review those chemicals already in commerce – what are referred to as existing chemicals — and to assess chemicals before they enter commerce – so-called new chemicals. EPA lists chemicals currently in commerce in 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, approximately 20,000 new chemicals were added to the inventory and are now in use as existing chemicals.

Prior to the passage of TSCA, chemical substances generally entered the marketplace without review or controls. Without government intervention, and often with little or no knowledge of their potential adverse health and environmental impacts, some of these chemicals were produced and used in high volumes. Earlier legislation on clean water and air had primarily addressed releases of chemicals into the environment. In contrast, TSCA authorized EPA to control the entire life cycle of chemicals from their production and distribution to their use and disposal—including options for the outright banning of chemical substances to mandating requirements for chemical testing or product labeling. Now, chemical companies are required to submit to EPA, 90 days before beginning to manufacture a new chemical, a premanufacture notice containing information including the chemical's identity, categories of uses, estimated

production volumes, and any test data possessed by the chemical company.

My testimony today, which is based on our June 2005 report, *Chemical Regulation: Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program*,[1] describes EPA's efforts to (1) assess existing chemicals used in commerce, (2) control the risks of new chemicals not yet in commerce, and (3) publicly disclose information provided by chemical companies under TSCA.

In summary, EPA does not routinely assess the human health and environmental risks of existing chemicals and faces challenges in obtaining the information necessary to do so. TSCA's authorities for collecting data on existing chemicals do not facilitate EPA's review process because they generally place the costly and time-consuming burden of obtaining data on EPA, rather than requiring chemical companies to develop and submit such data to EPA. Consequently, EPA has used its authorities to require testing for fewer than 200 of the 62,000 chemicals in commerce when EPA began reviewing chemicals under TSCA in 1979. Recognizing the need for additional information on existing chemicals, in the late 1990s EPA implemented its High Production Volume (HPV) Challenge Program, under which chemical companies have begun to voluntarily provide test data on about 2,800 chemicals produced or imported in amounts of 1 million pounds or more a year. While the HPV Challenge Program is a laudable effort to develop data on these chemicals, several problems remain, including that the chemical industry has not agreed to provide testing for over 200 chemicals originally identified in the HPV Challenge Program and that even with the test data provided under the program, EPA would need to demonstrate that the chemicals pose unreasonable risks in order to control their production or use under TSCA. While TSCA does not define what risk is unreasonable, according to EPA officials the standard has been difficult to meet. In order to withstand judicial scrutiny, a TSCA rule must be supported by substantial evidence in the rulemaking record. In this regard, EPA officials say the act's legal standards are so high that they have generally discouraged EPA from using its authorities to ban or restrict the manufacture or use of chemicals. Since Congress enacted TSCA in 1976, EPA has issued regulations under the act

[1] 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.: June 13, 2005).

to ban or limit the production of only five existing chemicals or groups of chemicals.

EPA's reviews of new chemicals can provide only limited assurance that health and environmental risks are identified before the chemicals enter commerce because TSCA does not require chemical companies to test new chemicals before notifying EPA of their intent to manufacture a chemical. Furthermore, chemical companies generally do not voluntarily perform such testing. Because of a general lack of data, EPA has developed sophisticated methods to predict the potential exposure and toxicity levels of new chemicals by using scientific models to compare them with chemicals with similar molecular structures for which toxicity information is available. However, the use of these models can present weaknesses in the assessment because the models are not always accurate in predicting physical chemical properties and the evaluation of general health effects is contingent on the availability of information on chemicals with similar molecular structures. Additionally, chemical company estimates of a chemical's production volume and anticipated uses provided in the premanufacture notices that EPA uses to assess exposure, can change substantially after EPA completes its review and manufacturing begins. However, these estimates do not have to be amended by companies unless EPA promulgates a rule determining that a use of a chemical constitutes a significant new use, which EPA has done for only a small percentage of new chemicals. Despite limitations in the information available on new chemicals, EPA's reviews have resulted in some action being taken to reduce the risks of over 3,600 new chemicals submitted for review.

EPA's ability to provide the public with information on chemical production and risk has also been hindered by strict confidential business information provisions of TSCA. TSCA generally prohibits the disclosure of confidential business information and, according to EPA officials, about 95 percent of the premanufacture notices for new chemicals contain some information that is claimed as confidential. While EPA has the authority to evaluate the appropriateness of confidentiality claims, these efforts are time and resource-intensive, and the agency does not have the resources to challenge a significant number of claims. 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. Chemical companies recently 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 our June 2005 report, we recommended that the Congress consider providing EPA additional authorities under TSCA to improve its ability to assess chemical risks, such as providing the EPA Administrator the authority to require chemical companies develop test data when production volumes reach certain levels. We also recommended that the EPA Administrator take several actions to improve EPA's management of its chemical program, including revising its regulations to require that companies reassert confidentiality claims under TSCA within a certain time period after the information is initially claimed as confidential. EPA did not disagree with the report's findings and is in the process of implementing several of our recommendations. For example, EPA is currently launching a pilot project to review claims of confidentiality for data on certain older chemicals.

EPA Has Limited Information on the Health and Environmental Risks of Existing Chemicals and Has Issued Few Regulations Controlling Such Chemicals

Because chemical companies are generally not required to develop and submit toxicity information to EPA, when the agency decides to review existing chemicals, it generally has only limited information on the risks that the chemicals pose to human health and the environment. Furthermore, EPA's authority under TSCA to require industry testing that would provide the information to review the chemicals is difficult to use, according to EPA officials. EPA has used its authority to require testing for fewer than 200 of the 62,000 chemicals in commerce when EPA began reviewing chemicals under TSCA in 1979. Furthermore, EPA has rarely banned, limited the production, or restricted the use of existing chemicals. Since 1998, EPA has focused its efforts on obtaining information on existing chemicals through voluntary programs, such as the HPV Challenge Program. This program is intended to provide basic data on the characteristics of about 2,800 chemicals produced in excess of 1 million pounds a year.

EPA Has Limited Toxicity and Exposure Data with Which to Review Existing Chemicals

EPA's toxicity and exposure data on existing chemicals is often incomplete and TSCA's authority to require testing in support of the agency's review process is difficult to use. While TSCA authorizes the review of existing chemicals, it generally provides no specific requirement, time frame, or methodology for doing so. Chemical companies are not required to develop and submit toxicity information to EPA unless the agency promulgates a testing rule, thus placing the burden for obtaining data on EPA. In addition, if chemical company testing shows that a

chemical is not toxic, there is generally no standing requirement that the chemical companies submit this data to EPA. Consequently, when EPA decides to review existing chemicals, it generally has only limited information on the risks of injury the chemicals pose to human health and the environment.

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. For example, there are currently over 200 high-production-volume chemicals for which chemical companies have not agreed to provide the minimal test data that EPA believes are needed to initially assess their risks. Furthermore, many additional chemicals are likely to be added to become high production chemicals because the specific chemicals used in commerce are constantly changing, as are their production volumes. Chemical industry representatives told us that TSCA provides EPA with adequate authority to issue rules requiring companies to provide EPA with any test and exposure data possessed by the companies, and that EPA could use such authority to obtain company information on existing chemicals of concern. EPA could then use that information to determine whether additional rules should be issued to require companies to perform additional testing of the chemicals.

However, EPA officials told us that it is time-consuming, costly, and inefficient for the agency to use a 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 fewer than 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,[2] 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, and in our in June 2005 report, 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.

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

Even when EPA has toxicity and exposure information on existing chemicals, the agency stated that it has had difficulty demonstrating that harmful chemicals pose an unreasonable risk and that they should be banned or have limits placed on their production or use. Indeed, EPA has rarely banned, limited the production, or restricted the use of existing chemicals. Since the Congress enacted TSCA in 1976, EPA has issued regulations under the act to ban or limit the production or restrict the use of only five existing chemicals or chemical classes. For an additional 173 existing chemicals, EPA has required chemical companies to submit notices of any significant new uses of the chemical, providing EPA the opportunity to review the risks posed by the new use.

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

EPA Implemented a Voluntary Program to Collect More Industry Data on Existing Chemicals

Facing difficulties obtaining information on existing chemicals, EPA took steps to address this shortcoming with the implementation of the HPV Challenge Program in 1998. According to EPA, the lack of information on existing chemicals and the relative difficulty of requiring testing under TSCA on the scale that would be necessary for the thousands of chemicals produced at high volumes, has led EPA, in cooperation with chemical companies, environmental groups, and other interested parties, to implement a voluntary program to obtain test data on high-production-volume chemicals from chemical companies. The HPV Challenge Program focuses on obtaining chemical company "sponsors" to voluntarily provide data on the approximately 2,800 chemicals that chemical companies reported in 1990, that they produced at a high volume—generally over 1 million pounds.

Through this program, sponsors develop a minimum set of data on the chemicals, either by gathering available information, using models to predict the chemicals' properties, or conducting testing of the chemicals. EPA plans to use the data collected under the program to prioritize high-production chemicals for further assessment, but it has not yet adopted a methodology for prioritizing the chemicals or for determining those that require additional information. In our June 2005 report, we recommended that EPA develop and implement such a methodology for using information collected through the HVP Challenge Program to prioritize chemicals for further review and to identify and obtain additional information needed to assess their risks. At EPA's request, a federal advisory group has proposed a methodology for prioritizing the HPV Challenge Program chemicals, and EPA anticipates that the agency will implement the proposal during 2006.

Nonetheless, other problems exist in the HPV Challenge Program. Chemical companies have not volunteered to provide data on all the chemicals currently in the HPV Program. In addition, despite the fact that companies may begin raising the production volumes of other chemicals, EPA has no mechanism for placing these chemicals on the HPV Challenge Program list once they are produced in greater volume. We believe that action to implement our previously mentioned recommendation that the Congress consider giving EPA additional authority to require chemical testing could ameliorate such problems.

EPA Lacks Sufficient Data to Ensure That the Potential Health and Environmental Risks of New Chemicals Are Identified

EPA's review of new chemicals provides only limited assurance that health and environmental risks are identified because the agency has limited information with which to review them. In the absence of chemical test data, EPA largely relies on scientific models that do not always accurately determine chemicals' properties or the full extent of their adverse effects. Further, information that companies provide in the premanufacture notices that EPA uses to assess potential exposures to new chemicals are estimates that can change substantially once manufacturing begins. Despite limitations in the information available on new chemicals, EPA's reviews have resulted in some action being taken to reduce the risks of over 3,600 new chemicals submitted for review.

EPA Has Limited Information on New Chemicals and Relies on Modeling Tools to Assess the Health and Environmental Risks of 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. During a review of a new chemical, EPA evaluates risks by conducting a chemical analysis, searching the scientific literature, reviewing agency files (including files of related chemicals that have already been assessed by EPA), analyzing toxicity data on structurally similar chemicals, calculating potential releases of and exposures to the chemical, and identifying the chemical's potential uses. On the basis of this review, EPA makes a decision to (1) take no action; (2) require controls on the use, manufacture, processing, distribution in commerce, or disposal of the chemical pending development of test data; or (3) ban or otherwise regulate the chemical pending the receipt and evaluation of test studies performed by the chemical's manufacturer. Because EPA generally does not have sufficient data on a chemical's properties and effects when reviewing a new chemical, EPA uses a method known as structure activity relationships analysis to screen and evaluate a chemical's toxicity. This method, also referred to as the nearest analogue approach, involves using models to compare new chemicals with chemicals with similar molecular structures for which test data on health and environmental effects are available.

EPA officials told us that, while the overall accuracy of the models has not been validated for regulatory purposes, they are effective as screening tools that allow EPA to focus its attention on the chemicals of greatest concern—chemicals about which little is known other than that they are structurally related to known harmful chemicals. By applying approaches

that make conservative predictions, EPA believes that it is more likely to identify a false positive (where a chemical is determined to be of concern, but on further analysis is found to be of low concern) than a false negative (where a chemical is initially viewed as a low concern though on further analysis is actually of higher concern). According to EPA, only about 20 percent of the premanufacture notices received annually go through the agency's more detailed full-review process after they have been initially screened. That is, according to EPA officials, the majority of new chemicals submitted for review can be screened out as not requiring further review because (1) EPA determines on the basis of its screening models that a chemical has low potential to harm human health or the environment or (2) on the basis of other information, such as the anticipated uses, exposures, and releases of the chemicals, only limited potential risks to people and the environment are expected. In addition, using these models, EPA identifies for possible regulatory action, those chemicals belonging to certain chemical categories that based on its prior experience in reviewing new chemicals are likely to pose potential risks such that testing or controls are needed. In our June 2005 report, we recommended that the EPA Administrator develop a strategy for improving and validating, for regulatory purposes, the models that EPA uses to assess and predict the risks of chemicals and to inform regulatory decisions on the production, use, and disposal of the chemicals.

Estimates of Exposures and Other Information Provided in Premanufacturing Notices Can Change after Manufacturing Begins

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. To address this potential, TSCA authorizes EPA to promulgate a rule specifying that a particular use of a chemical would be a significant new use. 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.

EPA Reviews of New Chemicals Have Resulted in Some Control Actions

When EPA's assessment of a new chemical identifies health and safety problems, EPA can issue a proposed rule to prevent chemical companies from manufacturing or distributing the chemical in commerce, or to otherwise restrict the chemical's production or use, if the agency believes the new chemical may present an unreasonable risk before EPA can regulate the chemical under the relevant provisions of TSCA. Despite limitations in the information available on new chemicals, EPA's reviews have resulted in some action being taken to reduce the risks of over 3,600 new chemicals that chemical companies have submitted for review. These actions ranged from chemical companies voluntarily withdrawing their notices of intent to manufacture new chemicals, chemical companies entering into consent orders with EPA to produce a chemical under specified conditions, and EPA promulgating significant new use rules requiring chemical companies to notify EPA of their intent to manufacture or process a chemical for new uses.

For over 1,700 chemicals, companies withdrew their premanufacture notices, sometimes after EPA indicated that the agency planned to initiate the process for placing controls on the chemical, such as requiring testing or prohibiting the production or certain uses of the chemical. EPA officials told us that after EPA screens a chemical or performs a more detailed analysis of it, chemical companies often drop their plans to market a new chemical when the chemical's niche in the marketplace is uncertain and EPA requests that the company develop and submit test data.

For over 1,300 chemicals, EPA has issued orders requiring chemical companies to implement workplace controls or practices during manufacturing (pending the development of information), and/or perform toxicity testing when the chemical's production volumes reached certain levels. EPA may issue these proposed orders to control the production, distribution, use, or disposal of a new chemical when there is insufficient information available to reasonably evaluate the human health or environmental effects of a chemical and when the chemical (1) may present an unreasonable risk to human health or the environment or (2) 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. While TSCA does not authorize EPA to require that chemical companies develop this information, the act does allow EPA to control the manufacturing and processing of the chemical until EPA has sufficient data to determine if the chemical will pose a risk.

For over 570 new chemicals submitted for review, EPA required chemical companies to submit premanufacture 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 had begun.

EPA's Ability to Share Data Collected Under TSCA Is Limited

EPA's ability to make publicly available the information that it collects under TSCA is limited. Chemical companies may claim the information they provide to EPA under TSCA as confidential business information. While EPA believes that some claims of confidential business information may be unwarranted, challenging the claims is resource-intensive.

When companies submit information to EPA through premanufacture notices, many claim a large portion of the information as confidential. According to EPA, about 95 percent of premanufacture notices contain some information that chemical companies claim as confidential. Under EPA regulations, information that is claimed as confidential shall generally be treated as such if no statute specifically requires disclosure. Exceptions include if the information is required to be released by some other federal law or court order, if the company voluntarily withdraws its confidential claim, or if the EPA Office of General Counsel makes a final administrative determination that the information does not meet the regulatory criteria substantiating a legal right to the claim. EPA has not performed any recent studies of the appropriateness of confidentiality claims, although a 1992 EPA study indicated that problems with inappropriate claims were extensive. That 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, they have no data on the number of inappropriate claims.

EPA officials told us that the agency does not have the resources necessary to investigate and, where appropriate, challenge claims that it believes 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, confidentiality claims relating to health and safety studies performed by the chemical companies involving chemicals currently 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 when 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. For example, on the basis of a study performed by the state of Illinois with the cooperation of chemical companies and EPA, Illinois regulators found that toxicity information submitted under TSCA was useful in identifying chemical substances that should be included in contingency plans in order to alert emergency response and planning personnel to the presence of highly toxic substances at facilities. Additionally, the availability of this information could assist the states with environmental monitoring and enforcement. For instance, using TSCA data, Illinois regulators identified potential violations of state environmental regulations, such as cases where companies had submitted information to EPA under TSCA but failed to submit such information to the states as required.

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.

TSCA's provisions are in contrast to those of some foreign governments' environmental laws, such as Canada, which authorizes its environmental agency to share confidential business information with other governments under agreements or arrangements where the government undertakes to keep the information confidential. Chemical industry representatives told us that the industry also sees benefits in allowing EPA to share information with other countries in order to harmonize chemical assessments among developed countries and improve chemical risk assessment methods by allowing cooperation on improving models used to predict chemical toxicity. The chemical industry is concerned, however, that confidential information be protected from inappropriate disclosure. These chemical industry representatives told us that some countries currently do not have adequate procedures for protecting confidential business information. However, they suggested that the policies and procedures EPA currently uses to protect confidential information are appropriate. Accordingly, they said that the chemical industry would not object to TSCA revisions allowing EPA to share confidential information

with foreign countries and organizations, provided that such revisions contain specific reference to safeguards that EPA would establish and enforce to ensure that those receiving the information have stringent policies and procedures to protect it.

Our June 2005 report included two recommendations for addressing the problems we identified related to the confidential business information provisions of TSCA. We recommended that EPA revise its regulations to require companies to reassert claims of confidentiality within a certain period after the information is initially claimed as confidential. We also 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. EPA did not disagree with the report's findings and is in the process of implementing several of our recommendations. For example, EPA is currently launching a pilot project to review claims of confidentiality for data on certain older chemicals.

Concluding Observations

Mr. Chairman, EPA's efforts to encourage companies to voluntarily provide data on existing chemicals is commendable. However, the fundamental and historical problems the agency has experienced with utilizing its authorities under TSCA continue to limit EPA's ability to manage its chemical review program and assess chemical risks. In this respect, EPA faces considerable difficulties using its authorities to require testing of existing chemicals, which prevents the agency from reviewing substantially more chemicals in less time than it could if it had the authority to require chemical companies to provide test data on chemicals once they have reached a substantial production volume. Moreover, EPA's ability to provide the public with information on chemical production and risks is hampered by the strict confidential business information provisions of TSCA. While protecting such information is a legitimate concern, TSCA currently prohibits EPA from disclosing much data for important purposes such as assisting state agencies in carrying out their environmental management responsibilities and foreign governments in harmonizing international chemical assessment approaches—a goal generally shared by these governments and the chemical industry. We believe the actions that we have recommended to both the Congress and EPA would go a long way in addressing the challenges EPA faces in exercising its authorities under TSCA.

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

Contacts and Acknowledgments

For further information about this testimony, please contact me Mr. John B. Stephenson at (202) 512-3841. David Bennett, John Delicath, Tyra DiPalma-Vigil, Richard Johnson, Valerie Kasindi, and Ed Kratzer made key contributions to this statement.

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