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Report to Congressional Requesters

June 2005

CHEMICAL REGULATION

Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program

GAO-05-458

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Highlights

Highlights of GAO-05-458, a report to congressional requesters

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, including consumer products such as cleansers, paints, plastics, and fuels, 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.

GAO reviewed EPA's efforts to (1) control the risks of new chemicals not yet in commerce, (2) assess the risks of existing chemicals used in commerce, and (3) publicly disclose information provided by chemical companies under TSCA.

What GAO Recommends

GAO recommends that the Congress consider providing EPA additional authorities under TSCA to improve its ability to assess chemical risks and that the EPA Administrator take several actions to improve EPA's management of its chemical program. EPA did not disagree with GAO's recommendations but provided substantive comments.

www.gao.gov/cgi-bin/getrpt?GAO-05-458.

To view the full product, including the scope and methodology, click on the link above. For more information, contact John Stephenson at (202) 512-6225 or stephensonj@gao.gov.

What GAO Found

EPA's reviews of new chemicals provide limited assurance that health and environmental risks are identified before the chemicals enter commerce. Chemical companies are not required by TSCA, absent a test rule, to test new chemicals before they are submitted for EPA's review, and companies generally do not voluntarily perform such testing. Given limited test data, EPA predicts new chemicals' toxicity by using models that compare the new chemicals with chemicals of similar molecular structures that have previously been tested. However, the use of the models does not ensure that chemicals' risks are fully assessed before they enter commerce because the models are not always accurate in predicting chemical properties and toxicity, especially in connection with general health effects. Nevertheless, given the lack of test data and health and safety information available to the agency, EPA believes the models are generally useful as screening tools for identifying potentially harmful chemicals and, in conjunction with other information, such as the anticipated potential uses and exposures of the new chemicals, provide a reasonable basis for reviewing new chemicals. The agency recognizes, however, that obtaining additional information would improve the predictive capabilities of its models.

EPA does not routinely assess the risks of all existing chemicals and EPA 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. Partly because of a lack of information on existing chemicals, EPA, in partnership with industry and environmental groups, initiated the High Production Volume (HPV) Challenge Program in 1998, under which chemical companies began voluntarily providing information on the basic properties of chemicals produced in large amounts. It is unclear whether the program will produce sufficient information for EPA to determine chemicals' risks to human health and the environment.

EPA has limited ability to publicly share the information it receives from chemical companies under TSCA. TSCA prohibits the disclosure of confidential business information, and chemical companies claim much of the data submitted as confidential. While EPA has the authority to evaluate the appropriateness of these confidentiality claims, EPA states that it does not have the resources to challenge large numbers of claims. State environmental agencies and others are interested in obtaining confidential business information for use in various activities, such as developing contingency plans to alert emergency response personnel of 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.

Contents

Abbreviations

ACC	American Chemistry Council
CCT	comfort cooling towers
CEPA	Canadian Environmental Protection Act
EPA	Environmental Protection Agency
EC	European Commission
EU	European Union
FFDCA	Federal Food Drug and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
HPV	High Production Volume
ITC	Interagency Testing Committee
IUR	Inventory Update Rule
NPPTAC	National Pollution Prevention and Toxics Advisory Committee
OECD	Organization for Economic Co-operation and Development
PCBs	polychlorinated biphenyls
PMN	pre-manufacture notice
PPA	Pollution Prevention Act
REACH	Registration, Evaluation and Authorization of Chemicals
SAR	structure activity relationships
SNUR	significant new use rule
SOCMA	Synthetic Organic Chemical Manufacturers Association
TCCD	tetrachlorodibenzo-p-dioxin
TSCA	Toxic Substances Control Act
VCCEP	Voluntary Children's Chemical Evaluation Program

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United States Government Accountability Office
Washington, D.C. 20548

June 13, 2005

The Honorable James M. Jeffords
Ranking Minority Member,
Committee on Environment and Public Works
United States Senate

The Honorable Frank R. Lautenberg
United States Senate

The Honorable Patrick Leahy
United States Senate

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. Many of these chemicals play an important role in people's everyday lives. Consumers use products containing or made from chemicals ranging from cleansers and paints to plastics and fuels. In a wide variety of other products and industrial processes, companies use chemicals as solvents and additives. Although chemicals are important in producing goods and services, some may adversely affect human health and the environment. For example, 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. Materials that contained asbestos were used widely for fireproofing, thermal and acoustical insulation, and decoration in building construction and renovation before the adverse effects of it were known.

In 1976, the Congress passed the Toxic Substances Control Act (TSCA) to provide the Environmental Protection Agency (EPA) with the authority to obtain more information on chemicals and regulate those chemicals that pose an unreasonable risk to human health or the environment. TSCA addresses those chemicals manufactured, imported, processed, distributed in commerce, used, or disposed of in the United States, but excludes certain substances including, among other things, pesticides that are regulated under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); and food; food additives; drugs; cosmetics or devices that are regulated under the Federal Food, Drug and Cosmetic Act (FFDCA).

TSCA authorizes EPA to assess chemicals before they enter commerce (new chemicals) and review those chemicals already in commerce (existing chemicals). EPA lists chemicals 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, EPA has reviewed more than 40,000 substances as new chemical submissions, of which, approximately 20,000 were added to the inventory after chemical companies began manufacturing them.

EPA has developed programs to assess, test, and manage identified potential risks from new and existing chemicals. To assess risks, EPA evaluates a chemical's potential exposure levels and adverse effects on human health and the environment. For new chemicals, TSCA generally requires a company to notify EPA at least 90 days before manufacturing a new chemical by submitting a premanufacture notice. These notices are to provide information on the chemical's identity, production process, anticipated production volume, intended uses, potential exposure and release levels, disposal, byproducts, test data possessed or controlled by the chemical company, and a description of any other data concerning the chemical's environmental or health effects known to or reasonably ascertainable by the chemical company.

Information on chemical risks that EPA collects under TSCA is not always available to state and local governments and 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.

In response to your request, we reviewed EPA's efforts to (1) control the risks of new chemicals not yet in commerce, (2) assess existing chemicals used in commerce, and (3) publicly disclose information provided by chemical companies under TSCA. In addressing these issues we also obtained information on some of EPA's voluntary chemical control programs designed to complement TSCA and on the chemical control programs of Canada and the European Union (EU). In addition, we identified some legislative options that we have noted in the past could strengthen EPA's ability to assess and regulate chemicals under TSCA. This information is presented in appendixes I, II, and III, respectively.

To review the extent to which EPA has assessed the risks of new and existing chemicals and has made information obtained under TSCA public, we identified and analyzed EPA's policies and guidelines on how the chemical review and control programs for new and existing chemicals

work, including the handling of confidential information, and determined what actions EPA has taken to control chemicals. We also gathered documentation on EPA's voluntary programs. These efforts were augmented by interviews with EPA officials and representatives of the American Chemistry Council (a national chemical manufacturers association), Environmental Defense (a national, nonprofit, environmental advocacy organization), and the Synthetic Organic Chemical Manufacturer's Association (a national, specialty chemical manufacturer's association). We also obtained and reviewed studies conducted by EPA on the usefulness of confidential business information to states. To identify potential options to strengthen EPA's ability to assess and regulate chemical risks under TSCA, we (1) interviewed officials at EPA, the American Chemistry Council, Environmental Defense, EPA's National Pollution Prevention and Toxics Advisory Committee, and the Synthetic Organic Chemical Manufacturer's Association; (2) reviewed pertinent literature, including prior GAO reports, case law, and congressional hearings on TSCA; (3) attended various public meetings and conferences sponsored by EPA and others; and (4) discussed chemical laws in Canada and the EU with their representatives. A detailed description of our scope and methodology is presented in appendix IV. We performed our work between July 2004 and April 2005 in accordance with generally accepted government auditing standards.

Results in Brief

While TSCA authorizes EPA to promulgate rules requiring testing of chemicals if EPA has made certain findings, TSCA does not require chemical companies to test new chemicals for toxicity and to gauge exposure levels before they are submitted for EPA's review and, according to EPA officials, chemical companies typically do not voluntarily perform such testing. In the absence of such data, EPA predicts potential exposure levels and toxicity of new chemicals by using scientific models and by comparing them with chemicals with similar molecular structures (analogues) for which toxicity information is available. However, the use of the 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 suitable analogues. Nevertheless, given the lack of test data in general, and health and safety test data in particular available to the agency, EPA believes that the models are generally useful as screening tools for identifying potentially harmful chemicals and, in conjunction with other information chemical companies provide in premanufacture notices, such as the chemicals' estimated production volume and anticipated uses,

provide for a reasonable review of new chemicals. By enabling EPA to screen chemicals for certain properties and characteristics, the models allow the agency to perform more detailed reviews of those chemicals that have properties and characteristics generally identified as posing potential risks to people and the environment. EPA believes that, based on limited validation studies, its models are more likely to identify a false positive (where a chemical is determined to be of concern) than a false negative (where a chemical is initially identified as a low concern though on further analysis is actually of higher concern. EPA recognizes, however, that obtaining additional information from chemical companies could provide additional insight into chemical toxicities and improve the predictive capabilities of its models. Furthermore, the estimates of a chemicals' production volume and anticipated uses provided in the premanufacture notice, which EPA uses to assess exposure, can change substantially after EPA completes its review and manufacturing begins. 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, in which case a significant new use notice would be required. EPA does this for only a small percentage of new chemicals. However, the risk of exposure, and thus the risk of injury to human health or the environment, may increase when chemical companies increase production levels or expand the uses of a chemical.

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. In this regard, TSCA authorizes EPA to require chemical companies to develop test data only when the agency finds 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. 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. In the late 1990s, in cooperation with chemical companies and environmental groups, 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. However, the chemical industry has not agreed to provide testing for 300 chemicals

originally identified in the HPV Challenge Program, and EPA believes that some of the chemicals produced in lesser quantities might potentially warrant testing. Furthermore, even with the test data provided under the HPV Challenge Program, EPA would need to demonstrate that 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.

EPA has limited ability to publicly share the information it receives under TSCA. TSCA generally prohibits disclosing to nonfederal officials trade secrets and privileged or confidential commercial or financial information protected under the Freedom of Information Act. In addition, TSCA authorizes chemical companies to claim data as confidential business information. According to EPA officials, about 95 percent of the premanufacture notices for new chemicals submitted by chemical companies contain some information that is claimed as confidential. Under EPA's regulations, information that is claimed as confidential business information shall generally be treated as such. Exceptions include if the information is required to be released by some federal law or order of a court, if the company submitter voluntarily withdraws its claim of confidentiality, or if EPA makes an administrative determination that the information does not meet the regulatory criteria substantiating a legal right to the claim. While TSCA confidential business information can be provided to federal officials and contractors, it generally cannot be provided to other organizations responsible for assessing chemical risks, enforcing chemical control laws, and performing other environmental activities, including state regulatory agencies and foreign governments. However, some state environmental regulators believe that toxicity information submitted under TSCA would be useful in managing their environmental risk programs, including developing contingency plans to alert emergency response personnel to the presence of highly toxic substances at manufacturing facilities. While EPA has the authority to evaluate the appropriateness of confidentiality claims and can deny companies' claims of confidentiality if they are found to be illegitimate, these efforts are time and resource-intensive, and the agency does not have the resources to challenge a significant large number of claims. EPA has considered various changes in its regulations for TSCA confidentiality claims, such as revising the regulations to require chemical companies to more fully substantiate their claims. In addition, the EPA Office of General Counsel led a comprehensive review of EPA's agency wide confidential

business information regulations, which are referred to in the TSCA confidential business information regulations, but this did not lead to any amendments to the general agency-wide regulations.

In order to improve EPA's ability to assess the health and environmental risks of chemicals, we are recommending that the Congress consider amending TSCA to provide EPA additional authorities. We are also making several recommendations to improve EPA's management of its chemical review program.

Background

In the last several decades, the Congress has passed legislation to increase federal agencies' ability to determine 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, soil, 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. These laws were generally enacted in or before the early 1970s. 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 more information on chemicals and regulate those chemicals that pose an unreasonable risk to human health or the environment.[1]

TSCA provides 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 commerce or otherwise regulating them, such as by placing restrictions on those already in the marketplace. While other environmental and occupational health laws generally only control 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

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

production and distribution to their use and disposal. However, the act does not apply to certain substances such as nuclear material, firearms and ammunition, pesticides, food, food additives, tobacco, drugs, and cosmetics.

TSCA's role in ensuring that chemicals in commerce do not present an unreasonable risk of injury to health or the environment is established in six major sections of the act, as shown in table 1.

Table 1: TSCA's Major Sections for Chemical Data Collection and Control

Section	Purpose
4	Chemical testing
5	New chemical review and control and Significant new use rules
6	Chemical regulation
8	Industry reporting of chemical data
9	TSCA's relationship to other laws
14	Disclosure of chemical data

Source: GAO analysis of TSCA.

Under section 4, EPA can promulgate rules to require chemical companies to test potentially harmful chemicals for their health and environmental effects. To require testing, EPA must find that a chemical (1) may present an unreasonable risk of injury to human health or the environment or (2) 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 or may reasonably be anticipated to enter the environment in substantial quantities. (For the remainder of this report, we will refer to parts (a) and (b) of this second finding in abbreviated form as a finding "that there is or may be substantial human or environmental exposure to the chemical"). 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.

Section 5 requires chemical companies to notify EPA at least 90 days before beginning to manufacture a new chemical or before manufacturing or processing 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.

Section 6 requires EPA to apply regulatory requirements to chemicals for which EPA finds a reasonable basis exists 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, disposal or use, or requires warning labels be placed on the chemical. Under TSCA, EPA must choose the least burdensome requirement that will adequately protect against the risk. In promulgating a rule, EPA must consider and publish a statement regarding: the effects of the chemical on health and the environment and the magnitude of human and environmental exposure; the benefits of the chemical for various uses and the availability of substitutes for those uses; and 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. If another law would sufficiently eliminate or reduce the risk of injury to health or the environment, then EPA may not promulgate a TSCA rule unless it finds that it is in the public interest to do so, considering all relevant aspects of the risk, a comparison of the estimated costs of compliance under TSCA and the other law and the relative efficiency of actions under TSCA and the other law to protect against risk of injury.

Section 8 requires EPA to promulgate rules under which chemical companies must 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. In addition, section 8 provides EPA with the authority 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.

Section 9 establishes TSCA's relationship to other laws. The section includes a mechanism for EPA to alert other federal agencies of a possible need to take action if EPA has a reasonable basis to conclude that an unreasonable chemical risk may be prevented or sufficiently reduced by action under a federal law not administered by EPA. Section 9 also requires EPA to use authorities under other laws that it administers if its Administrator finds that a risk to health or the environment could be eliminated or sufficiently reduced under those laws, or unless EPA determines that it is in the public interest to protect against such risks under TSCA.

Section 14 details when EPA may disclose chemical information obtained by the agency under TSCA. Chemical companies can claim certain information, such as data disclosing chemical processes, as confidential business information. EPA generally must protect confidential business information against public disclosure unless necessary to protect against an unreasonable risk of injury to health or the environment. Other federal agencies and federal contractors can obtain access to this confidential business information in order to carry out their responsibilities. EPA may also disclose certain data from health and safety studies.

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

While TSCA authorizes EPA to promulgate rules requiring chemical companies to conduct tests on chemicals and submit the resulting data to EPA, TSCA does not require chemical companies to test new chemicals for their toxicity and exposures before they are submitted for EPA's review and, according to EPA officials, chemical companies typically do not voluntarily perform such testing. In the absence of chemical test data, EPA largely relies on scientific models to screen new chemicals. However, use of the models can present weaknesses in an assessment because models do not always accurately determine the chemicals' properties and the full extent of their adverse effects, especially with regard to their general health effects. Nevertheless, EPA believes that the models are useful as basic screening tools where actual test data on health and environmental effects information is not available from chemical companies. EPA believes that the models are an effective tool that, in conjunction with other factors, such as premanufacture notice information on the anticipated production levels and uses of a chemical, supplies a reasonable basis for either dropping the chemical from further review or subjecting it to more detailed review and possible controls. EPA routinely updates database sources for models with new data received through premanufacture notice submissions, required testing from consent orders, substantial risk submissions, and voluntary testing. EPA acknowledges, however, that future efforts to obtain additional test data could enhance the models' usefulness by providing a more robust database for their further development and validation for regulatory purposes.

Furthermore, the information in premanufacture notices that EPA uses to assess potential exposures to new chemicals, such as production volume and anticipated uses, are estimates that can change substantially once EPA completes its review and manufacturing begins. Although TSCA authorizes EPA to require a manufacturer to submit a new notice under certain conditions, the agency must first, after consideration of relevant statutory factors, promulgate a significant new use rule in which it identifies significant new uses or activities for which a new notice is required.

EPA Has Limited Information on New Chemicals and Relies on Modeling Tools to Assess the Health and Environmental Risks of New Chemicals

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) under section 5(e) of TSCA, 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 (SAR) 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 applies models where actual test data in general, and health and environmental effects test data in particular, are not available. EPA officials said that the models make conservative predictions that the agency believes result in erring on the side of protecting human health and the environment in screening chemicals. EPA's own attempts to determine the strength of these models shows them to be highly accurate in predicting some chemical characteristics, but less accurate for other characteristics. For example, in 1993, EPA and the EU jointly conducted a study to compare EPA's predictions of individual physical and chemical properties or health or environmental effects with those identified by the EU based on test data submitted with EU notifications.[2] The joint evaluation showed that the accuracy of EPA's predictions varied, depending on the effect or the property being compared. For example, the study concluded that EPA methods are likely to identify those substances that are not readily biodegradable—in other words, slowly degrading chemicals. However, the

[2]Because the study was used for context purposes, we did not assess its reliability.

study concluded that EPA methods do not appear to work as well in identifying chemicals that readily degrade as determined by the EU's "ready biodegration" base set test. The model performance is explained by recognizing that EPA's model does not focus on ready biodegration but rather on ultimate biodegredation. Since the 1993 study, EPA and others have conducted studies on selected aspects of some of its models, such as a 2001 study conducted by PPG Industries on the accuracy of aquatic toxicity predictions for different types of polymers. This study showed mixed results in that the models proved to be highly accurate for predicting the toxicity of the chemicals tested on rainbow trout, but were in error for about 25 percent of the cases in which the models' results were compared with actual test data for determining the chemicals' effects on the growth of aquatic algae, an important environmental end point.[3]

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 potential for low toxicity to human health or 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

[3]J. Chun, V. Nabholz, and M. Wilson. 2001. "Comparison of measured aquatic toxicity data with EPA, OPPT SAR Predictions." Poster presentations by J. Chun, PPG Industries at the March 2001 meeting of the Society of Toxicology in San Francisco, Calif., and the November 2002 meeting of the Society of Environmental Toxicology and Chemistry.

new chemicals, are likely to pose potential risks such that testing or controls are needed.

EPA officials told us that while they take efforts to improve and validate their models for regulatory purposes where opportunities arise (e.g., models are subjected to peer review when significant modifications are introduced in their design or structure), they do not have a specific program to do so. EPA officials stated that they routinely use test data to improve the models as it becomes available but TSCA does not require companies to routinely conduct tests and submit such data to the agency. Unless EPA requires testing under section 4 of TSCA, TSCA only requires chemical companies to provide notice to EPA of information the companies obtain that reasonably supports the conclusion that the chemical presents a substantial risk of injury to health or the environment. Under section 4 of TSCA, EPA may promulgate a rule requiring companies to conduct tests and submit test data but may do so only if it first determines 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. EPA officials said that chemical companies may have test data that shows that a chemical has low toxicity. These officials also said that such data would be useful for helping to improve the accuracy of their models. EPA has authority under section 8 of TSCA to promulgate rules requiring companies to submit any existing test data concerning the environmental and health effects of a chemical or copies of any health and safety studies conducted or initiated by, or otherwise known by, the chemical company.

EPA officials told us that other efforts are under way to validate these models for regulatory purposes. Organization for Economic Co-operation Development (OECD) member countries are undertaking collaborative efforts to develop and harmonize SAR methods for assessing chemical hazards. However, EPA is hampered in its ability to provide supporting test data to aid OECD as part of this effort because confidentiality provisions in TSCA do not allow EPA to share confidential business information submitted by chemical companies with foreign governments. EPA officials said that international efforts to validate SAR models for regulatory purposes and to move toward harmonized international chemical assessments would be improved if EPA had the ability to share this information under appropriate procedures to protect confidentiality. TSCA's provisions are in contrast to those of the Canadian Environmental Protection Act (CEPA), for example, which authorizes the Canadian

Minister of the Environment 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 countries to share information in order to harmonize chemical assessments among developed countries and improve chemical risk assessment methods by allowing countries to cooperate in improving models used to predict chemical toxicity. The chemical industry is concerned, however, that the confidential information shared be protected from inappropriate disclosure. These chemical industry representatives told us that some countries currently do not have stringent enough 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. In this regard, chemical industry representatives stated that such policies and procedures should include provisions such as requiring that those who handle confidential information be briefed on the importance of not disclosing the information to those without the proper clearance and keeping such information in locked storage.

EPA officials told us that, in addition to assisting international efforts to enhance modeling tools and harmonize international chemical assessments, the ability to share confidential business information with foreign governments would be beneficial for developing a strategy to identify the resources needed to develop and validate new models for regulatory purposes—a measure that is especially important given the continuing central role of scientific models in EPA's assessment program for new chemicals. These officials also suggested that it would be productive to explore regulatory and voluntary approaches that could be used to obtain additional information from chemical companies on chemical properties and characteristics, including "negative" studies—i.e., evidence that a chemical is not harmful. According to EPA, such information is useful for understanding the chemical and thus for developing and validating models for regulatory purposes. Under TSCA, companies submitting a premanufacture notice must, at the same time, submit data such as anticipated production volume, manufacturing

process, and any test data in their possession and a description of any other reasonably ascertainable data concerning the environmental and health effects of the chemical. If EPA feels it needs more information on these chemicals, it could explore promulgating a test rule under section 4 or issuing a proposed order pending the development of information under section 5(e). In addition, as noted above, EPA has authority under section 8 of TSCA to promulgate rules requiring companies to submit any existing test data concerning the environmental and health effects of a chemical or copies of any health and safety studies conducted or initiated by, or otherwise known by, the chemical company.

Chemical industry representatives with whom we spoke told us that they see much merit in working toward a strategy that would give EPA data that could help the agency improve its models. They believe that it is to everyone's benefit to have approaches that produce models that are useful for identifying both safe and problematic chemicals. This is especially true for enabling industry to make timely decisions--especially for chemicals having short life spans and requiring quick production decisions essential to innovation. These chemical industry representatives also said that a comprehensive strategy for improving models would be particularly beneficial to developing countries lacking extensive experience in manufacturing chemicals because it would enable them to speed their progress toward developing chemicals that are safe and effective.

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

Chemical companies are generally required to submit to EPA, 90 days before beginning to manufacture a new chemical, a premanufacture notice containing information including the chemical's identity, its production process, categories of uses, estimated production volumes, potential exposure levels and releases, any test data in the possession or control of the chemical company, and a description of any other data concerning the environmental or health effects known to or reasonably ascertainable by the chemical company. 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 the premanufacture notice do not have to be amended once manufacturing begins. That is, once EPA completes its review and production begins, absent any requirement imposed by EPA such as a significant new use rule, 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 such a rule specifying that a particular use of a chemical would be a "significant new use." The manufacturers, importers, and processors of the chemical for that use would then be required 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 Numerous Control Actions

When EPA's assessment of new chemicals 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 section 6 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 3,500 of the 32,000 new chemicals that chemical companies have submitted for review.[4] 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 certain chemicals for new uses prior to manufacturing or processing the chemicals for such uses.

For over 1,600 chemicals, companies withdrew their premanufacture notices, sometimes after EPA officials 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 screened the chemical or performed 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.

[4]These chemicals reviewed do not include EPA's review of the chemicals manufactured by companies that EPA has exempted from the premanufacture notice requirements: 717 Test Marketing Exemption Applications; 7,888 Low Volume Exemptions; 35 Low Release/Low Exposure Exemptions; and 2,530 Polymer Exemptions. EPA may exempt a chemical company from the premanufacture notice 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.

According to an EPA official, companies may be uncertain that they will recoup the costs of testing and prefer instead to withdraw their premanufacture notice.

For over 1,200 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 EPA 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) 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. Under section 5 of TSCA, EPA cannot require that chemical companies develop this information, but TSCA authorizes 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 about 570 of the 32,000 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. 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 premanufacture notice.

Finally, in 1984, EPA issued proposed rules that were effective upon publication to impose certain controls on four new chemicals the agency determined would pose an unreasonable risk to human health or the environment.[5] The rules—which remain in effect today—prohibit adding any nitrosating agent, including nitrites, to metal working fluids that contain these substances. According to EPA, adding nitrites or other nitrosating agents to the substances causes the formation of a substance

[5]EPA has limited the uses of four new chemicals: (1) mixed mono and diamides of an organic acid, (2) triethanolamine salts of a substituted organic acid, (3) triethanolanime salt of tricarboxylic acid, and (4) tricarboxylic acid.

known to cause cancer in laboratory animals. See appendix V for more information on the rules issued to control these four chemicals.

EPA Does Not Routinely Assess Existing Chemicals, Has Limited Information on Their Health and Environmental Risks, and Has Issued Few Regulations Controlling Such Chemicals

TSCA authorizes but does not specifically require EPA to review the risks of existing chemicals. Further, EPA cannot require chemical companies to test the safety of existing chemicals and provide the resulting test data to the agency, unless EPA first determines on the basis of risk or production and exposure information that the chemicals warrant such testing. 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, according to EPA, in part because it is costly and labor-intensive for EPA to require the development of toxicity and exposure data, the agency has performed internal reviews of only an estimated 2 percent of the chemicals that were in the TSCA inventory when EPA began chemical reviews in 1979. Additionally, EPA has rarely banned, limited the production, or restricted the use of existing chemicals. Only five chemical substances or groups of chemical substances have been regulated under section 6, and the last final action EPA took to control existing chemicals under section 6 was published in 1990. Since 1998, EPA has focused its efforts on obtaining information on existing chemicals through voluntary programs, such as the HPV Challenge Program. This program will provide basic data on the characteristics of about 2,800 chemicals produced in excess of 1 million pounds a year. However, while EPA has received recommendations from the NPPTAC on a process for screening these chemicals, the agency has not yet implemented guidelines for reviewing the data so that the chemicals can be prioritized and more detailed information can be obtained to further assess their risks to human health and the environment. Canada and the EU have recently taken action—passing legislation and proposing a new regulation, respectively—to further regulate or assess existing chemicals. When implemented, these actions may require U.S. chemical companies to submit information on some chemicals manufactured or processed in or exported to Canada and the EU. EPA has authority under section 8 of TSCA to require that copies of such data for chemicals manufactured or processed by chemical companies in the United States be made available to EPA.

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

According to EPA officials, EPA's toxicity and exposure data on existing chemicals is often incomplete and TSCA's authority to require testing is difficult to use in support of the agency's review process. While TSCA authorizes the review of existing chemicals, it generally provides no specific requirement, time frame, or methodology for doing so.[6] Instead, EPA conducts initial reviews after it receives information from the public or chemical companies that a chemical may pose a risk. For example, if a chemical company voluntarily tests a chemical or otherwise obtains information about a chemical that reasonably supports the conclusion that the chemical presents a substantial risk[7] to human health or the environment, TSCA requires that the chemical company immediately notify EPA about this information. EPA then reviews the information to determine the need for additional testing or risk management. However, chemical companies are not required to develop and submit toxicity information to EPA unless EPA promulgates a testing rule, thus placing the burden for obtaining or requiring industry development of data on the agency. 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.[8] 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. Facing difficulties obtaining such information, as noted above, EPA has made little progress in reviewing existing chemicals since EPA began reviewing chemicals under TSCA in 1979.[9]

The limited amount of information available to EPA on existing chemicals' toxicity was illustrated in a 1998 EPA report of publicly available data on 2,863 high-production-volume chemicals produced and/or imported at over

[6]TSCA does contain specific provisions regarding review of polychlorinated biphenyls.

[7]EPA guidance states that manufacturers are to consider (1) the seriousness of the adverse effect and (2) the probability of the effect's occurrence in determining if information qualifies as substantial risk information. This information need not establish conclusively that a substantial risk exists.

[8]If the company must submit a notice as the result of a significant new use rule, then TSCA would require the company to submit this information.

[9]As discussed later in this section of the report, however, EPA took steps to address this shortcoming with the implementation of the HPV Challenge Program in 1989.

1 million pounds per year in 1990.[10] For each of these chemicals, EPA examined the readily available data corresponding to six basic end points that have been internationally agreed to as necessary for a screening level assessment of a chemical's toxicity and environmental fate. EPA estimated that only about 7 percent of the 2,863 chemicals had information on all six basic end points, 50 percent had information for one to five of the end points, and 43 percent had no information for any of the end points. According to EPA officials, the agency has access to even less information for chemicals not considered high-production-volume chemicals.

Furthermore, EPA has limited information on how existing chemicals are used and how they come into contact with people or the environment. To gather more exposure information, in 2003, EPA amended its TSCA Inventory Update Rule (IUR), which is primarily used to gather certain information on chemicals produced at more than a basic threshold volume in the year reported.[11] Among other things, EPA raised the basic production volume reporting threshold from 10,000 to 25,000 pounds, required chemical companies producing or importing chemicals at a site at or above this threshold to report the number of workers reasonably likely to be exposed to the chemical at each site, and added 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.[12]

Nevertheless, TSCA does provide EPA with the authority to obtain information needed to assess chemicals by issuing rules under section 4 of

[10]The 2,863 HPV chemicals included in the study consist of a subset of chemicals found in the United States. They are defined by production within the United States of a volume of 1 million pounds or more per year and the legal definitions established in TSCA. This study represents EPA's most recent study to assess the number of publicly available data for these HPV chemicals.

[11]Section 8(b) of TSCA requires EPA to compile, keep current, and publish a list of each chemical manufactured or processed in the United States. EPA promulgates inventory update rules under section 8(a) of TSCA, which requires EPA to promulgate rules under which chemical companies are required to maintain certain records and submit certain reports to EPA.

[12]EPA also added inorganic chemicals for which basic information at a 25,000-pound threshold will be provided in 2006. Inorganics are exempted from additional use and processing information at the 300,000-pound threshold in the 2006 reporting cycle. This information will be required for higher volume inorganic chemicals in the next IUR reporting cycle.

TSCA requiring chemical companies to test chemicals and submit the test data to EPA. However, because promulgating test rules to obtain test data on chemicals can be time consuming, EPA has negotiated agreements with chemical companies to conduct testing. In 1979, EPA instituted a process to negotiate with chemical companies and reach voluntary agreements to test the safety of certain chemicals. However, in 1984, the United States District Court for the Southern District of New York found that EPA had failed to discharge its obligations under TSCA by negotiating such voluntary agreements instead of initiating rulemaking with respect to chemicals designated for testing by the Interagency Testing[13] Committee (ITC) under section 4(e) of TSCA.[14] The court determined that EPA had made *de facto* findings that testing of the ITC-designated chemicals was necessary. The court noted that the very negotiation and acceptance of voluntary testing agreements demonstrated EPA's belief that additional data on the particular chemicals at issue needed to be developed. Upon making such findings, the court stated that it is EPA's duty under TSCA to make the mandatory choice between initiating rulemaking proceedings or publishing its reasons for not doing so and that EPA had not done this. The court found no support either in TSCA or "on some vague assertion of agency discretion" for EPA's use of the negotiated testing agreements instead of rulemaking proceedings. The court also found that, in addition to violating the test rule promulgation process set forth in TSCA, EPA's failure to use the rulemaking process bypassed several other important provisions within the statutory framework of TSCA. The court stated that it was not EPA's prerogative to "substitute for this intricate framework a number of haphazard and informal purported equivalents" and that negotiated testing programs without rulemaking cannot be sanctioned under TSCA.

In order to address the concerns raised by the court, EPA promulgated a rule in 1986, revising its procedures and providing for its current use of enforceable consent agreements, which EPA believes bind the companies signing them to perform the testing they agree to perform.[15] EPA regulations state that when EPA believes testing is necessary, it will explore whether a consent agreement can be negotiated that satisfies those testing

[13]The ITC is an independent advisory committee to EPA created to identify chemicals regulated by TSCA 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.

[14]*Natural Resources Defense Council v. EPA*, 595 F. Supp. 1255 (S.D.N.Y. 1984).

[15]51 Fed. Reg. 23706 (June 30, 1986).

needs.[16] The regulations further require EPA to publish a notice in the *Federal Register* when it decides to initiate negotiations.[17] EPA will meet with manufacturers, processors, and other interested parties (those responding to EPA's *Federal Register* notice) to attempt negotiation of a consent agreement. All negotiating meetings are open to the public, and EPA is to prepare meeting minutes and make them—as well as testing proposals, correspondence, and other relevant material—available to the public. When EPA prepares a draft consent agreement, it is circulated for comment to all interested parties, who have 4 weeks to submit comments or written objections. Where consensus exists on the draft consent agreement, as determined under the criteria listed in EPA's regulations,[18] the draft will be circulated to EPA management and interested parties for final approval and signature. EPA will then publish another *Federal Register* notice summarizing the consent agreement and listing the name of the chemical to be tested in its regulations.

According to EPA, these agreements allow greater flexibility in the design of the testing program because test methods can be negotiated. The relationship between EPA and the chemical industry is typically nonadversarial, and it usually takes less than a year for testing to begin on chemicals subject to enforceable consent agreements. According to EPA, negotiating these agreements is generally less costly and time-consuming than promulgating test rules because EPA does not have to determine that (1) a chemical poses or may pose an unreasonable risk or (2) a significant or substantial potential may exist for human exposure to the chemical. However, chemical companies must be willing to participate in such negotiations. EPA has entered into consent agreements with chemical companies to develop tests for about 60 chemicals. EPA officials told us that, for an additional 250 chemicals, EPA issued formal decisions not to test. In a number of these cases, EPA had initiated the process to either require testing or to negotiate consent agreements but prior to finalizing the rules or agreements chemical companies or other organizations had met EPA's need for the data.

While it appears that EPA's enforceable consent procedures have been a good mechanism for acquiring needed test data, as the United States

[16]40 C.F.R. § 790.22(b).

[17]40 C.F.R. §§ 790.22(b), 790.28(b).

[18]40 C.F.R. § 790.24.

District Court for the Southern District of New York noted, "[i]t is not an agency's prerogative to alter a statutory scheme even if its assertion is as good or better than the congressional one." In this regard, it is not clear whether EPA's current use of enforceable consent agreements would fare better than its previous use of voluntary agreements if challenged in court. EPA's regulations require enforceable consent agreements to address many of the provisions of TSCA triggered by test rules that the court found were lacking in EPA's earlier voluntary agreements. However, some important differences remain between the TSCA framework for testing rules and EPA's regulations for enforceable consent agreements. First, the enforceable consent agreement regulations would not account for some of the TSCA provisions that would be triggered by a test rule. For example, the regulations do not require the submission of test data along with the premanufacture notices for new chemicals. The regulations also neither preempt state or local testing rules, as a TSCA test rule would, nor do they have the same reporting and recordkeeping requirements. Second, unlike a testing rule, which would trigger TSCA requirements for all manufacturers and processors of a particular chemical, the consent agreement would generally only trigger such requirements for those manufacturers and processors that sign the agreement. While EPA regulations state that any person exporting or intending to export a chemical that is the subject of an enforceable consent agreement must notify EPA, it is unclear how EPA would enforce this provision if the person had not signed the agreement. Despite EPA's attempts to incorporate a number of the test rule-triggered TSCA provisions into its enforceable consent agreements, its efforts may still fall short. Like EPA's earlier use of voluntary agreements, its use of enforceable consent agreements is not explicitly authorized under TSCA, and, if a court determined that EPA's use of enforceable consent agreements equated to a *de facto* finding that testing was necessary, a court could again find that EPA lacked discretion to require testing other than through promulgation of a test rule.

EPA officials believe that the agency's revised procedures address the court's findings, and that, while TSCA does not specifically authorize the use of consent agreements to obtain test data, a sound legal basis exists for invoking TSCA's enforcement provisions against chemical companies that violate such agreements. Representatives of the American Chemistry Council (ACC) also told us that they have always considered the consent agreements to be enforceable and binding on the chemical companies signing them. Bolstering these views somewhat is the fact that EPA has been using the enforceable consent agreement process since establishing it by rule in 1986—nearly two decades ago. Nevertheless, an EPA legal

memorandum states that although EPA could reasonably take the position that it is authorized to enter into enforceable consent agreements requiring testing—ultimately concluding that enforceable consent agreements could be enforced by EPA and would be upheld by the courts—"the matter is not free from doubt." EPA officials have stated that revising TSCA to explicitly provide authority to enter enforceable consent agreements would be beneficial for clarifying when EPA has authority to enter into such agreements. Chemical industry representatives agreed with EPA that explicit authorization could be useful.

Finally, according to EPA, the lack of information on existing chemicals and the relative difficulty in requiring testing under TSCA on such a large scale as would be required for the more than 2,000 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 information on the chemicals, either by gathering available data, using models to predict the chemicals' properties, or conducting testing of the chemicals.[19]

EPA plans to use the data collected under the HPV Challenge Program to prioritize high-production chemicals for further assessment. However, EPA has not yet adopted a methodology for prioritizing the chemicals or determining those that require additional information. At EPA's request in 2005, a federal advisory group has proposed a methodology for prioritizing the HPV Challenge Program chemicals. EPA anticipates implementing the recommendation and beginning screening in early 2006.

While EPA will soon be collecting limited exposure information on chemicals produced at or above 25,000 pounds per year, the agency does

[19]Animal welfare groups filed a lawsuit alleging that EPA violated TSCA by developing and implementing the HPV Challenge Program, rather than promulgating formal test rules. The United States District Court held that EPA's use of the HPV Challenge Program was not in violation of TSCA and that EPA was not required to initiate rulemaking. *Physicians Committee for Responsible Medicine v. Leavitt*, 331 F. Supp. 2d 204 (S.D.N.Y. 2004). This case is currently on appeal.

not regularly collect exposure information on lower volume chemicals. EPA officials stated, based on the success of the HPV Challenge Program, there may be promise in a future effort to develop an appropriate level of information for lower volume chemicals, although given the demands of current efforts by EPA, industry, and others on HPV chemicals, no steps have been taken in this regard. Furthermore, EPA has no voluntary or test rule program in place for obtaining test data on chemicals that are currently produced in low volumes but which may be produced at high volumes in the future. While chemical industry organizations have said that they will voluntarily provide a basic set of test data on certain high-production-volume chemicals that are not part of the HPV Challenge Program, it is unclear that their efforts will produce information sufficient for EPA to make determinations of a chemical's risk to human health or the environment or provide the information in a timely manner.

EPA officials told us that, in cases where chemical companies do not voluntarily provide needed test data and health and safety studies in a complete and timely manner, requiring testing of existing chemicals of concern is the only practical way to ensure that needed information is obtained by the agency. For example, there are currently over 300 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 this number in the future because the specific chemicals used in commerce are constantly changing, as are their production volumes. Chemical industry representatives told us that TSCA (under section 8) 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 under section 4 of TSCA 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 section 8 of TSCA (which can take months or years to develop) to obtain exposure data or available test date that the chemical industry does not voluntarily provide to EPA and then (2) issuing additional rules under section 4 of TSCA requiring companies to perform specific tests necessary to ensure the safety of the chemicals tested. They also said that EPA's authority to issue rules requiring chemical companies to conduct tests on

existing chemicals under section 4 of TSCA has been difficult to use because of the findings the agency must first make before EPA can require testing. Section 4 of 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.

For example, if EPA wanted to issue a test rule on the basis of a chemical's production volume, it would still need to make the other requisite findings. In this regard, according to EPA officials, obtaining exposure information needed for rulemaking is particularly difficult. To fully assess human exposure to a chemical, EPA needs to know how many workers, consumers and others are exposed; whether the exposure occurs through inhalation or other means, such as skin absorption; and the amount and duration of the exposure. For environmental exposure, EPA needs to know such things as whether the chemical is being released in the air, water or land; how much is being released; and the extent of the area affected. Another important factor in environmental exposure is chemical fate, that is, how the chemical acts and is ultimately disposed of in the environment. EPA must rely on its estimates for most of this information because actual measurements of exposure in the environment, workplace, and home, for the thousands of chemicals in use are not practicable because of the monitoring equipment and staff resources that would be required.

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 under section 4 of TSCA 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 185 of the approximately 82,000 chemicals in the TSCA inventory. Because EPA has used section 4 so sparingly, it has not continued to maintain information on the cost of implementing test rules. However, in our October 1994 report on TSCA, we noted that EPA officials told us that issuing a rule under section 4 can cost between about $68,500 and $234,000.

Given the difficulties involved in requiring testing, EPA officials do not believe that TSCA's authorities under section 4 provide an effective means for testing a large number of chemicals. They believe that EPA could review substantially more chemicals in less time if they had authority to require chemical companies to conduct testing and provide test data on

chemicals once they reach a substantial production volume, assuming EPA has also determined that testing is necessary in order to obtain these data.

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. 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 five existing chemicals or chemical classes. The five chemicals or chemical classes are polychlorinated biphenyls (PCB), fully halogenated chlorofluoroalkanes, dioxin, asbestos, and hexavalent chromium. (See app. V for additional information on these five chemicals). In addition, for 160 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.

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, 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.

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. According to EPA, it has found it difficult to meet all of these requirements for rulemaking.

Finally, 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."[20] 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 by substantial evidence that EPA is promulgating the least burdensome requirement.

EPA's 1989 asbestos rule illustrates the evidentiary requirements that TSCA places on EPA to control existing chemicals. In 1979, EPA began exploring rulemaking under TSCA to reduce the risks posed by exposure to asbestos. Based upon its review of over 100 studies of the health risks of asbestos as well as public comments on the proposed rule, EPA concluded that asbestos was a potential carcinogen at all levels of exposure. In 1989, EPA promulgated a rule under TSCA section 6 prohibiting the future manufacture, importation, processing, and distribution of asbestos in almost all products.[21] 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.[22]

[20]15 U.S.C. § 2618(c)(1).

[21]54 Fed. Reg. 29460 (July 12, 1989).

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

In its ruling, 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 health or the environment. EPA had not calculated the risk levels for intermediate levels of regulation, as 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, 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. Since the court's 1989 decision, EPA has only exercised its authority to ban or limit the production or use of an existing chemical once (for hexavalent chromium). However, EPA officials said that they had started the process for promulgating the rule for hexavalent chromium years prior to the asbestos decision.

As the court noted, TSCA is not a zero-risk statute. EPA generally is required to choose the least burdensome regulatory action and the Congress has indicated its intent that EPA carry out TSCA "in a reasonable and prudent manner [after considering] the environmental, economic, and social impact of any action."[23] While concerns about the potential economic and social impacts of EPA's regulations are legitimate, according to EPA officials, requiring EPA to satisfy before taking regulatory action that the regulation uses the least burdensome approach to mitigate unreasonable risks and that its rulemaking is supported by substantial evidence has proven difficult for EPA to meet.

Canada and the EU Are Moving Toward Greater Control of Existing Chemicals

Canada and the EU have recently taken action to prioritize and review existing chemicals. The Canadian legislation (CEPA), enacted in 1999, requires the Minister of the Environment and the Minister of Health to compile, and from time to time amend, a Priority Substances List specifying those substances that the ministers believe should be given priority for assessing whether they are toxic or capable of becoming toxic. Within 7 years of the act, the ministers are to categorize existing chemicals for the

[23] 15 U.S.C. § 2601(c).

purpose of identifying substances that, in their opinion, and on the basis of available information, (1) may present to individuals in Canada the greatest potential for exposure or (2) are persistent or bioaccumulative in accordance with the regulations, and inherently toxic to human beings or to nonhuman organisms, as determined by laboratory or other studies. The ministers shall then conduct screening assessments for such chemicals. The EU is currently considering a proposed regulation that, among other things, would require chemical companies to register and submit information on chemicals produced or imported in volumes of 1 metric ton or more per year, and would require submission of a chemical safety report documenting an assessment of chemicals manufactured or processed in quantities of 10 metric tons or more per year.

Under CEPA and the proposed EU regulation, U.S. chemical companies may be required to provide information on some existing chemicals that are manufactured or processed in, or exported to, Canada and the EU. Under current EPA regulations, these U.S. chemical companies generally would not be required to submit the same information to EPA, although section 8 of TSCA provides the EPA Administrator authority to promulgate rules requiring chemical companies to submit such existing information on chemicals manufactured in or imported into the United States. While EPA officials told us that they are aware of the agency's authority to require the submission of at least some of the types of information that U.S. chemical companies may be required to submit to Canada and the EU, they have not decided whether or when to use such authority. For example, these officials said that while the concept of obtaining copies of the information that U.S. chemical companies submit to foreign countries has merit, they might be able to obtain the information through voluntary arrangements with the foreign governments. Furthermore, EPA officials told us that any requirement for chemical companies to provide EPA a copy of the information they submit to Canada and the EU would have to meet the requirements under the Paperwork Reduction Act of 1995. Under this act, federal agencies must, among other things, conduct a review of the proposed information collection and obtain Office of Management and Budget approval before requesting most types of information from the public.

EPA officials acknowledged that exchanging information through voluntary arrangements with foreign governments would have limitations, such as EPA's inability to provide other countries with confidential business information. EPA officials also acknowledged that requiring copies of the submissions directly from the companies would produce a

substantial amount of information that EPA could use to improve its models for assessing and predicting chemical risks. They told us that, given the recency of the Canadian chemical control changes and the pending nature of the EU regulation, EPA has not assessed all options or decided on a preferred approach for obtaining the data that U.S. chemical companies may be required to submit to foreign governments. EPA officials told us that the agency does not currently have a strategy or milestones for identifying resource needs and making decisions regarding future agency efforts to obtain such data.

Chemical industry representatives told us that the industry would have no objections to EPA using its authority to require that chemical companies submit to EPA the same information that they provide to Canada, the EU, or other foreign governments. They indicated that few additional costs would be incurred by providing this information, but that companies could face additional burdens depending on the specific requirements governing the submission of data. For example, it would be easier for the chemical companies to provide the information periodically, such as annually, rather than concurrently along with the submissions to foreign governments.

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 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, such as state health and environmental officials and foreign governments.[24] However, some state officials believe this information would be useful for informing and managing their environmental risk programs. While EPA believes that some claims of confidential business information may be unwarranted, challenging the claims is resource-intensive. Lacking the resources needed to challenge claims on a wide basis, EPA identified several possible changes aimed at discouraging the submission of unwarranted claims of confidential business information under TSCA, but few were adopted.

[24]EPA can disclose certain health and safety data, as well as information that it determines is necessary to disclose in order to protect health or the environment from an unreasonable risk.

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 order of a court, if the company submitter 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. 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 potential risks from harmful chemicals. For example, on the basis of a study[25] 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 dialogues with chemical companies about reducing chemical risks, preventing accidents, and limiting chemical exposures.

EPA has not performed any recent studies of the appropriateness of confidentiality claims, although a 1992 EPA study indicated that problems

[25]Illinois EPA TSCA CBI Evaluation Final Report (May 31, 1996).

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, they have no data on the number of inappropriate claims.

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.

During the early 1990s, the EPA Office of General Counsel led an agency wide review of EPA's confidential business information regulations, but this review did not lead to substantial changes. Subsequent to this effort, EPA developed a plan involving various voluntary and regulatory measures to reduce industry's use of TSCA confidentiality claims. These measures included exploring ways to make confidential information available to states, having senior corporate officials certify that the information claimed as confidential meets applicable statutory and regulatory requirements, and requiring companies to reassert their claims at a future date when confidentiality may no longer be necessary. While most of these changes were not implemented, EPA officials said they did make some changes to TSCA confidential business information regulations as a result of this review such as requiring up-front substantiation requirements for claiming plant site identity as confidential. EPA serves as an intermediary between chemical companies and state agencies that wish to have access to TSCA confidential information and, according to EPA, in recent years, state agencies have not been very aggressive in requesting such information. EPA believes, based on informal discussions with state officials, that obtaining such information may no longer be a high priority of the states, although the agency has not fully analyzed this issue. In addition, EPA officials said that chemical companies had expressed concerns about the costs of changing confidentiality procedures and have suggested that providing this information to states could increase the risk that some confidential information could be revealed to competitors.

However, as noted previously, chemical industry representatives told us that chemical companies would not object to revising TSCA to enable states to obtain access to the confidential business information that companies provide to EPA—provided that adequate safeguards exist to ensure that the information would be used only for legitimate reasons and would be protected from inappropriate disclosures. EPA would need to ensure that the states receiving confidential information have policies and procedures similar to those that EPA uses to protect confidential information from improper disclosures. For example, when EPA provides confidential TSCA information to other federal agencies as permitted under the act, EPA ensures that the agencies have policies and procedures for protecting the information. In this regard, among other things, the agencies provide security briefings to those handling the confidential information, take steps to prevent the information from being stored on electronic systems open to the Internet, and require that such information is kept locked away when not in use.

Chemical company representatives also told us that, in principle, they have no concerns about revising TSCA or EPA regulations to require that confidentiality claims be reasserted at a future date. They said that chemical companies make bona fide claims at the time the information is submitted to EPA, but this information may not need to be kept confidential after a certain date because confidentiality may no longer be necessary in order to protect trade secrets. However, EPA has no mechanism for determining when information no longer needs to be protected as confidential. Chemical company representatives said that companies sometimes choose to inform EPA that the information is no longer confidential, but neither TSCA nor EPA regulations require them to do so. Chemical industry representatives said that a requirement to reassert claims of confidentially at some later date would not be disruptive to the industry if the effective date of the requirement occurred after a considerable period had passed, such as 5 years or more after the information was initially claimed as confidential.

Conclusions

While TSCA allows EPA to require the testing of existing chemicals through the rulemaking process, EPA has found it difficult and costly to make the findings necessary to promulgate rules, including findings that a chemical may pose unreasonable risks or that the chemical will be produced in substantial quantities, and that there is or may be substantial human or environmental exposure to the chemical. Consequently, to obtain the test information needed on existing chemicals, EPA relies extensively on the

chemical industry to perform specific tests of certain chemicals under (1) consent agreements negotiated with chemical companies and (2) voluntary industry efforts under the HPV Challenge Program. Although the agency believes that the negotiated agreements are enforceable and consistent with EPA's authority under TSCA section 4, the enforceable consent agreements have never been tested in court, and EPA believes that explicit reference to the agreements in TSCA would be beneficial.

Chemical companies have begun voluntarily providing some test data that EPA needs to assess chemical risks through the HPV program. However, in cases where the industry does not agree to voluntarily perform testing in an adequate and timely manner, EPA believes that requiring such testing is the only practical way to ensure that testing is performed. In this regard, while the chemical industry believes that EPA can use its existing authority under TSCA to promulgate testing rules and require testing as needed on a case-by-case basis, EPA notes its relative lack of experience in promulgating large multichemical test rules and that the testing authorities may prove difficult to implement on a large number of chemicals. For example, EPA has pointed out that, despite notable voluntary efforts regarding high-production-volume chemicals, (1) chemical companies have not agreed to test 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. Furthermore, although the chemical industry may be willing to take action even before EPA has the evidence required for rulemaking under TSCA, the industry is nonetheless large and diverse, and it is uncertain that all companies will always take action voluntarily.

While the protection of confidential business information is obviously a legitimate concern, TSCA currently prohibits EPA from disclosing much of this data for useful and important purposes such as providing complete information to state environmental management agencies and assisting international efforts to develop and validate, for regulatory purposes, SAR models or to harmonize chemical assessment approaches by sharing information with foreign governments—a goal generally shared by government and industry. Both EPA and the chemical industry believe that revising TSCA to allow the sharing of such information would be beneficial and appropriate provided that EPA ensures that recipients have in place policies and procedures designed to prevent inappropriate disclosures of

the information. In addition, EPA and the chemical industry agree that the need to protect industry data often diminishes over time, and thus it would be appropriate to revise TSCA regulations to require companies to periodically reassert the confidentiality of business information.

Largely because of limitations in the amounts and types of test data provided with new chemical notifications, over the past decades EPA has moved toward innovative approaches to assessing new chemicals and to obtaining test data needed to assess chemicals. Most notably, these approaches include the development and extensive use of models to assess new chemicals and voluntary chemical testing approaches to obtain test data needed to assess some existing chemicals. While of many of EPA's models have not been validated for regulatory purposes, EPA believes that they are useful screening tools that have supported EPA's actions to control the production or use of about 3,500 of the more than 32,000 new chemicals reviewed under TSCA. Nonetheless, EPA recognizes that, given the central role that these models play in the chemical review process, the agency needs a multifaceted strategy for improving the models, which includes obtaining additional information on chemical properties necessary to further develop and validate the models for regulatory purposes.

Likewise, EPA is encouraged by the early results of the HPV voluntary chemical testing program for existing chemicals, which has already produced substantial amounts of basic test data. The agency has moved toward, but has not yet implemented, a methodology necessary for using the data to prioritize chemicals for further review and identify the specific additional data needed to determine whether and what controls should be placed on their production or use. The impact of EPA's programs could be substantially enhanced as a result of additional information that companies may be required to provide to Canada and the EU. By promulgating a rule requiring U.S. companies and their subsidiaries to submit to EPA the same information that they submit to foreign governments, the agency could acquire substantial additional basic test data and health and safety studies, at little, if any, additional cost to the chemical companies.

Matters for Congressional Consideration

To improve EPA's ability to assess the health and environmental risks of chemicals, the Congress should consider amending TSCA to

- provide explicit authority for EPA to enter into enforceable consent agreements under which chemical companies are required to conduct testing;

- 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 substantial production volume and the necessity for testing; and

- 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.

Recommendations for Executive Action

To improve EPA's management of its chemical review program, we recommend the EPA Administrator

- develop and implement a methodology for using information collected through the HPV Challenge Program to prioritize chemicals for further review and to identify and obtain additional information needed to assess their risks;

- promulgate a rule under section 8 of TSCA requiring chemical companies to submit to EPA copies of any health and safety studies, as well as other information concerning the environmental and health effects of chemicals, that they submit to foreign governments on chemicals that the companies manufacture or process in, or import to, the United States;

- 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; and

- 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.

Agency Comments and Our Evaluation

We provided EPA a draft of this report for its review and comment. EPA did not disagree with the report's findings and recommendations. EPA, however, offered two substantive comments. Regarding our

recommendation to the Administrator to promulgate a Section 8 rule to obtain data submitted by chemical manufacturers to foreign governments, EPA commented that, while such a reporting rule may bring useful information, other targeted approaches for collecting information which are directed at EPA's domestic priorities, rather than foreign government mandates, may be more prudent. We believe that having access to the information submitted to foreign governments would provide EPA with an important source of information that would be useful for assessing the risks of existing chemicals and improving the models that EPA uses to assess new chemicals. EPA could tailor this rule more narrowly, however, if it saw good reason to do so, such as to avoid duplication of information it already possesses. Regarding the matter for Congressional consideration that Congress consider amending TSCA to explicitly recognize enforceable consent agreements, EPA stated that it believes that there is currently strong legal authority for these agreements. As we noted in our report, TSCA does not explicitly authorize EPA to enter into these agreements and a court could find that EPA lacked discretion to require testing other than through promulgation of a test rule. EPA's comments are reproduced in appendix VI.

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) 512-6225 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 VII.

John B. Stephenson
Director, Natural Resources
and Environment

EPA's Voluntary Programs

The Environmental Protection Agency (EPA) has initiated voluntary programs to help gather data to assess chemical risks and to promote the use of more environmentally safe chemicals. The following information does not offer an exhaustive account of EPA's voluntary programs but rather a discussion of three specific programs that are designed to complement EPA's efforts to assess and control chemicals under the Toxic Substances Control Act (TSCA) and to encourage pollution prevention under the Pollution Prevention Act (PPA).

High Production Volume Challenge Program

In response to several studies that showed that there were relatively few U.S. High-Production-Volume (HPV) chemicals for which an internationally agreed upon set of hazard screening data was available to the public, EPA, in cooperation with industry, environmental groups, and other interested parties, officially launched the HPV Challenge Program in late 1998. The program was created to ensure that a baseline set of data on approximately 2,800 high-production-volume-chemicals would be made available to the public. HPV chemicals are manufactured or imported in amounts equal to or greater than 1 million pounds per year and were identified for this program through data reported under TSCA Inventory Update Rule (IUR).[1] Under the HPV Challenge Program, EPA invited chemical companies to voluntarily sponsor the approximately 2,800 chemicals. As part of their commitment to the HPV Challenge Program, sponsors submit data summaries of existing information along with a test plan that proposes a strategy to fill data gaps for either individual chemicals or for a category of chemicals. Sponsors could fill data gaps by (1) using existing scientifically adequate data, (2) using an estimation technique such as Structured Activity Analyses (SAR), or (3) proposing new testing. Testing will only be conducted when there are inadequate existing data or when other approaches, such as SAR, are not adequate to meet the need. EPA requested that companies perform a self-assessment on the quality of information they are providing to EPA.

EPA officials believe that the early results of the HPV Challenge Program are promising. Nonetheless, several problems remain. While chemical companies collectively have agreed to sponsor, or provide data for, most of

[1]IUR requires certain manufacturers and importers of chemical substances included on the TSCA inventory to report, among other things, current data on the production volume of these substances. The HPV program generally uses information from the 1990 IUR reporting period to determine HPV chemicals.

the chemicals that are produced at a high-production-volume, about 300 chemicals, called, "orphans," have not been sponsored by any chemical company. EPA has issued a proposed rule under section 4 of TSCA requiring chemical companies to conduct tests on and provide data for 37 orphan chemicals in 2000, but has not yet finalized these rules.[2] According to EPA officials, due in part to the difficulty and cost in developing and issuing such rules, EPA has not determined how to proceed on obtaining data on the remaining orphan chemicals. EPA officials do not know if they can make the findings necessary to issue test rules for the additional unsponsored chemicals. In addition, since 1990, other chemicals are produced at or above the high-production-volume threshold. Although EPA has not developed a plan to address these new HPV chemicals, several chemical associations have announced a joint initiative to extend industry's work to chemicals that meet the HPV threshold as of 2002 and to provide use and exposure information for chemicals sponsored through EPA's and industry's programs. Finally, while the HPV Challenge Program looks promising in that, if successful, it will provide EPA and the public with information not previously available on the properties of chemicals produced at large volumes in the United States, this program may not provide enough information for EPA to use in making risk assessment decisions. While the data in the HPV Challenge Program may help EPA prioritize chemicals of concern, the data may not present 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.

Voluntary Children's Chemical Evaluation Program

The Voluntary Children's Chemical Evaluation Program (VCCEP) is a pilot program developed by EPA to ensure that there is adequate publicly available toxicity and exposure information to assess the potential risks to children posed by 23 specific chemicals. The pilot VCCEP was announced in a *Federal Register* notice in December 2000.[3] EPA is running a pilot of the VCCEP in order to gain insight into how best to design and implement the program in order to effectively provide the agency and the public with the means to understand the potential health risk to children associated with certain chemical exposures. EPA intends the pilot to be the means of identifying efficiencies that can be implemented in future VCCEPs. EPA

[2]65 Fed. Reg. 81658 (Dec. 26, 2000).

[3]65 Fed. Reg. 81700 (Dec. 26, 2000).

asked companies that produce and/or import 23 specific chemicals to volunteer to sponsor their chemical in the first phase of a pilot of the VCCEP. Chemical companies have volunteered to sponsor 20 of the 23 chemicals in the VCCEP.

Chemical companies volunteering to sponsor a chemical under the program make chemical-specific public commitments to make certain hazard, exposure, and risk assessment data and analyses publicly available. EPA is pursuing a three-tiered approach for gathering information, with Tier 3 conducting more detailed toxicology and exposure studies than Tier 2, and Tier 2 conducting more detailed toxicology and exposure studies than Tier 1. After the submission of Tier 1 information and its review by a 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 to assess a chemical's risk to children, 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 for determining if 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 six assessments on chemicals to EPA and the consultation group. EPA officials believe that they will collect Tier I data for all 20 sponsored chemicals within the next 4 to 5 years. According to EPA officials, as of December 2004, three assessments are in the peer consultation stage, and industry has indicated that three or four assessments will be ready for peer consultation in 2005. Although EPA has not currently assessed the effectiveness of VCCEP, it plans to have an interim evaluation in 2005, and a final evaluation in 2007.

Sustainable Futures

In December 2002, EPA announced the Sustainable Futures Program, a voluntary program designed to help industry develop new chemicals that are sustainable economically and environmentally.[4] Industry participants in the program are offered (1) hands on training on some of EPA's chemical

[4]67 Fed. Reg. 76282 (Dec. 11, 2002).

risk screening models, (2) regulatory relief in the form of expedited review, (3) small business assistance, (4) technical assistance, and (5) public recognition. In Sustainable Futures, EPA has sought to reduce the likelihood of harmful new chemicals entering into commerce by making its screening tools available to chemical companies. EPA provides companies training for and access to the same chemical risk screening models that EPA uses in screening and evaluating the risks of new chemicals. Use of these tools may enhance companies' ability to identify concerns and halt or redirect work on a potentially risky chemical early in the research and development phase. This approach can save a company the resources it might otherwise invest in a chemical that ultimately may encounter problems during EPA's review process for new chemicals. By getting early feedback on the potential hazards of a new chemical, a company can reduce regulatory uncertainty, lower development and production costs, and make production decisions that consider a broader array of factors other than the potential profitability of a new chemical. Additionally, by using these screening tools, companies may choose not to produce chemicals that could be regulated by EPA, thus, potentially reducing EPA's regulatory burden.

Canadian and EU Chemical Legislation

Canada and the European Union (EU) have inventories of chemicals already in the marketplace and require chemical companies to notify regulators about the manufacture or importation of new chemicals. Officials we spoke with identified several notable aspects of the Canadian and EU chemical legislation that differ from the Toxic Substances Control Act (TSCA). First, in the EU, chemical companies must notify regulators prior to marketing new chemicals, which is after production has already begun. Second, Canadian law requires chemical companies to conduct testing of new chemicals based on production or import volume, while EU legislation requires testing based on marketed volume. Finally, the EU is considering changes to its basic chemical legislation that would require chemical companies to submit testing information on existing, as well as new, chemicals. A chart generally describing some of the provisions of TSCA and chemical control legislation in the EU and Canada, along with the proposed EU Registration, Evaluation and Authorization of Chemicals (REACH) regulation, is provided in table 2.

Canadian and EU Processes for Assessing the Health and Environmental Risks of Chemicals

Canadian Environmental Protection Act (CEPA) regulations and EU legislation require chemical companies to submit certain test data on new chemicals before they enter commerce. Canada defines new chemicals as those chemicals that are not on Canada's Domestic Substances List—a list of all known substances that were in commercial use in Canada between January 1, 1984, and December 31, 1986, were manufactured in or imported into Canada by any person in a quantity of 100 kilograms or more in any calendar year during that period, or that have subsequently been fully notified and assessed under CEPA. Under CEPA regulations, chemical companies must submit certain information and test data to the government when production or importation volumes reach specified levels. The information required for new chemicals differs depending on whether the new chemical is listed on the Non-Domestic Substances List—a list that is based on the TSCA Chemical Substances Inventory. Chemicals that are on the Non-Domestic Substances List are subject to notification requirements at higher volume thresholds than are applicable to other new chemicals and are exempt from certain information submission requirements. In addition, the requirements to submit test data for low volume chemicals are less extensive and complex than those for high volume chemicals. According to Canadian officials, a new chemical is generally not added to the existing chemical inventory until a certain level of production or import has been reached, and specified testing for that level has been performed without conditions being placed on the chemical's manufacture or import.

The EU currently maintains a separate inventory for new chemicals, which are subject to additional testing and review before they are marketed in volumes starting at 10 kilograms. Existing chemicals are not subject to the same testing requirements. However, under the proposed EU REACH chemical regulation, according to officials, this distinction between new and existing chemicals would largely be eliminated. All chemical companies would generally be required to register substances they produce or import in volumes of 1 metric ton or more per year. REACH would require chemical companies to gather and submit information on the properties of their substances and where necessary perform tests to generate health and safety data. For all substances subject to registration manufactured or imported by the registrant in quantities of 10 metric tons or more per year, REACH would require submission of a chemical safety report, documenting a chemical safety assessment including, among other things, human health and environmental health hazard assessments. Substances would not be allowed to be manufactured or imported in the European community unless they met the registration requirements. Thus, according to EU officials, REACH would reverse the burden of proof that is now placed on public authorities to manage the risks and uses of particular existing chemicals.

Confidentiality Claims

CEPA and EU legislation allow chemical companies to make confidentiality claims. However, according to officials we spoke with, these countries place some greater restrictions than TSCA does on the types of data that may be claimed as confidential.

In Canada, information that companies request be treated as confidential is not to be disclosed except in certain circumstances. The Minister of the Environment may disclose certain information upon giving 24 hours notice to the company, if (a) the disclosure is in the interest of public health, public safety or the protection of the environment and (b) the public interest in the disclosure (1) outweighs in importance any material financial loss or prejudice to the competitive position of the person who provided the information or on whose behalf it was provided and (2) any damage to the privacy, reputation or human dignity of any individual that may result from disclosure. However, CEPA maintains certain protections for information protected under Canada's Privacy Act, Access to Information Act, and Hazardous Materials Information Review Act.

EU legislation also allows chemical companies to make confidentiality claims. However, according to an EU official we spoke with, the EU places

some greater restrictions on the types of data that may be claimed as confidential than TSCA does. In the EU, a company may indicate that information is commercially sensitive and that disclosure may be harmful to the company industrially and commercially and, therefore, that the company wishes to keep the information secret from all persons other than the competent authorities and the European Commission. Secrecy, however, shall not apply to

- the trade name of the substance,
- certain physicochemical data concerning the substance,
- possible ways of rendering the substance harmless,
- the interpretation of the toxicological and ecotoxicological tests and the name of the body responsible for the tests, and
- certain recommended methods and precautions and emergency measures.

The authority receiving the information is to decide on its own responsibility what information is covered by commercial and industrial secrecy. The company can go to court and appeal the authority's decision.

Under REACH, as currently proposed, one of the objectives of the new system for the management of industrial chemicals would be to make information on chemicals more widely available. Whenever a request for access to documents held by the proposed European Chemicals Agency is made, the agency would be required to inform the registrant of the chemical or other party concerned of the request. That party would have 30 days to submit a declaration identifying information considered to be commercially sensitive and disclosure of which might harm the party commercially that the party wishes to be kept confidential. The agency would consider the information and decide whether to accept the declaration. The party could appeal this decision. The following information would be among the types of information that would not be treated as confidential:

- the trade name(s) of the substance; physicochemical data concerning the substance and on pathways and environmental fate,
- the result of each toxicological and ecotoxicological study,

- if essential to classification and labeling, the degree of purity of the substance and the identity of impurities and/or additives which are known to be dangerous,
- guidance on safe use, and
- information contained in the safety data sheet (except for the name of the company or otherwise accepted as confidential in REACH).

The following information would be treated as confidential, even if the company did not claim it as confidential:

- details of the full composition of a preparation,
- the precise use, function, or application of a substance or preparation,
- the precise tonnage of the substance or preparation manufactured or placed on the market, and
- links between a manufacturer or importer and his downstream users.

However, in exceptional cases where there are immediate risks to human health, safety or the environment, REACH would authorize the proposed European Chemicals Agency to disclose this information.

Table 2: Regulation of Chemicals in the United States, Canada, and European Union

	United States	Canada	European Union	
Name of chemical legislation	Toxic Substances Control Act	Canadian Environmental Protection Act, 1999 (CEPA)	Current EU chemical legislation[a]	EU proposed Regulation Registration, Evaluation, and Authorisation of Chemicals (REACH)[b]
Approximate number of chemicals in commerce when legislation was passed	62,000[c]	23,000[d]	100,000[e]	Not applicable[f]
Notifications requirement	Companies notify EPA of new chemicals by Premanufacture Notice (PMN).	According to a Canadian official, companies must notify the government of a new chemical that is not on the Non-Domestic Substances List (NDSL) before it exceeds a quantity of 20 kilograms per year.[g]	Companies notify the EU about new chemicals once the marketing level reaches 10 kilograms.	Companies would generally be required to register chemicals with a new European Chemicals Agency once production or import reaches 1 metric ton (2,204.6 lbs).
Testing requirement	No specific tests are required for registration of new chemicals.	Tiered testing levels for new chemicals based on production and importation volume.	Tiered testing levels for new chemicals based on production volume.	According to an EU official, testing would be required only when there is insufficient information available and other sources of information are not appropriate.
Risk assessment	Public authorities perform a 90-day risk assessment on new chemicals. Public authorities concentrate risk assessment efforts on high-volume existing chemicals.	According to officials, public authorities are responsible for performing risk assessments on new and existing chemicals, but industry will provide the majority of the test data.	Public authorities perform risk assessments on existing chemicals. Industry provides testing and risk information on new chemicals.	Manufacturers and importers would be responsible for using knowledge on properties of the substances they manufacture or import to ensure responsible and well-informed management of the risks those substances may present. For all substances subject to registration that are manufactured or imported at a level of more than 10 metric tons per year, a chemical safety assessment would be required.

Source: GAO.

Note: This table is not meant for purposes of legal comparison but only to provide some basic information about the countries' regulation of chemicals.

[a]The current EU chemical legislation consists of 4 major pieces of legislation with adaptations to technical progress over the years: Council Directive 67/548/EEC: "Classification, Packaging and Labeling of Dangerous Substances", Council Directive 76/769/EEC: "Marketing and Restrictions", Council Regulation 793/93: "Existing Substances Evaluation", and Council Directive 88/379/EEC as replaced by 99/45/EC: "Preparations" as well as a number of other directives.

[b]The EU is currently considering a proposal known as REACH. COM 2003 0644 (03), Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a

European Chemicals Agency and amending Directive 1999/45/EC and Regulation (EC) {on Persistent Organic Pollutants} Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Council Directive 67/548/EEC in order to adapt it to Regulation (EC) of the European Parliament and of the Council concerning the registration, evaluation, authorisation and restriction of chemicals. An EU representative estimates that the earliest possible implementation of REACH, if adopted, is 2006 with the first registrations arriving in 2009.

[c]Since EPA began its review program for new chemicals, approximately 20,000 new chemicals have been added to the list of chemicals in commerce.

[d]Because the data from Canada was used for context purposes, we did not assess the reliability of the data.

[e]Because the data from the EU was used for context purposes, we did not assess the reliability of the data.

[f]If the REACH regulation is passed, an EU representative estimates that over 30,000 chemicals currently in commerce or production in the EU will qualify as existing chemicals because their production or import exceeds 1 metric ton (2,204.6 lbs) per producer, or importer per year. At this time, the proposed regulation has not been passed.

[g]According to a Canadian official, a revised notification regulation is expected to be finalized in the summer of 2005. Once the New Substances Notification Regulation is published and enforced, the volume thresholds will be under 100 kilograms per year for a new chemical that is not on the Non-Domestic Substances List. For chemicals that are listed on the NDSL, the notification level will be 1,000 kilogram per year. The Non-domestic Substances List (NDSL) specifies substances that are not on the Domestic Substances List but are in commercial use in the United States. The Domestic Substances List (DSL) is the sole basis for determining whether a substance is new for the purposes of the Canadian Environmental Protection Act, 1999 (CEPA, 1999). The DSL contains 23,000 substances that were existing substances at the time CEPA, 1999 was enacted.

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 the Environmental Protection Agency's (EPA) ability under the Toxic Substances Control Act (TSCA) to assess chemicals and control those found to be harmful. These options are those that we previously identified in an earlier GAO report[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.

Options to Reduce EPA's Evidentiary Burden to Take Action under TSCA

The Congress could amend TSCA to reduce the evidentiary burden that EPA must meet to take regulatory action under the act by (1) amending the unreasonable risk standard that EPA must meet to regulate existing chemicals under section 6 of TSCA, (2) amending the 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, or (3) amending the requirement that EPA must choose the least burdensome regulatory requirement.

Currently, under TSCA section 6, EPA may only regulate existing chemicals if it finds 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."[2] Several options are available to amend this standard. For example:

- The Congress could authorize EPA to regulate existing chemicals when it identifies "significant," rather than "unreasonable," risks of injury to health or the environment. "Significant risk" is the standard under TSCA section 4(f) by which EPA is to identify chemicals for priority review. EPA officials view the term "significant risk" as a very high threshold for action. However, they believe that demonstrating significant risk would be less demanding than demonstrating unreasonable risk. While "significant risk" implies a finding that the risks are substantial or serious, EPA believes that a finding of "unreasonable" risk requires an

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

[2]15 U.S.C. § 2605(a).

extensive cost-benefit analysis. When reviewing EPA's asbestos rule, the United States Court of Appeals for the Fifth Circuit 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.[3]

- The Congress could amend TSCA to require that EPA demonstrate that a chemical "may present" an unreasonable risk, rather than requiring a demonstration that a chemical "presents or will present" an unreasonable risk. Such a change would still require EPA to develop documentation of evidence supporting its assessment, although to a lesser extent than is currently required under TSCA.

In addition, TSCA currently requires a court to hold unlawful and set aside a TSCA rule if it finds that the rule is not supported by substantial evidence in the rulemaking record.[4] 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.[5] The Congress could amend the standard for judicial review to instead reflect a rational basis test to prevent arbitrary and capricious administrative decisions.

Finally, TSCA currently requires that EPA choose the least burdensome requirement when regulating existing chemicals. As we noted earlier, in its ruling that EPA had failed to muster substantial evidence to justify its asbestos ban, the United States. Court of Appeals for the Fifth Circuit 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 health or the environment. EPA had not calculated the risk levels for intermediate levels of regulation, as it

[3]The Supreme Court has stated that the Congress, in a number of statutes has used the phrase "unreasonable risk" to "signify a generalized balancing of costs and benefits." American Textile *Manufacturers Inst. v. Donovan*, 452 U.S. 490, 512 (1981).

[4]42 U.S.C. § 2618(c)(1)(B)(i).

[5]See *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1213-14 (5th Cir. 1991); *Environmental Defense Fund v. EPA*, 636 F.2d 1267, 1277 (D.C. Cir. 1980).

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, beginning with the least burdensome, and the costs and benefits of each option. Congressional testimony has indicated that, under this court decision, the process "is not merely onerous; it may well be impossible."[6] The Congress could amend or repeal this requirement.

Options for Requiring Chemical Companies to Provide Additional Information on New Chemicals

TSCA could be revised to require companies to test their chemicals and submit the results to EPA with their premanufacture notices. Currently, such a step is only required 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 EU, testing requirements for low-volume chemicals are less extensive and complex than for those for high-volume chemicals.

Another option would be to provide EPA with greater authority to require testing targeted to those areas in which EPA's structure activity relationship (SAR) analysis does 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 SAR 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 production or environmental release levels.

[6]Statement of Lisa Heinzerling, Professor of Law, Georgetown University Law Center before the Committee on House Energy and Commerce, Subcommittee on Environment and Hazardous Materials (July 13, 2004). David Monsma, Toxics Project, referred to this standard in his July 13, 1994, testimony as an "arduous standard" and stated that "TSCA can be restored to a functional state by articulating, as a general purpose of the Act, its pollution prevention purposes and by removing the regulatory trap created by the" least burdensome alternative" language.

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.

Options for Requiring the Systematic Testing of Existing Chemicals

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 the HPV Challenge Program to EPA, for example, as a condition of manufacture or import above some specified volume.

Options for Reducing Risks through Chemical Use Reduction

Given the thousands of chemicals in use and the many ways that exposures and releases to the environment can occur, TSCA's chemical-by-chemical approach means that the act is unlikely to address more than the most serious chemical risks. The process of collecting information on chemical effects and exposures to support regulatory actions under TSCA is a resource intensive and time-consuming process. A different approach would be to set goals for reducing the use of toxic chemicals overall. Under this approach, legislation could establish national goals for reductions in the use of toxic chemicals and provide EPA with various tools, such as pollution taxes and other economic incentives to encourage chemical companies to engage in risk reduction activities. This approach differs from a command-and-control approach in which the regulator specifies how pollution must be reduced or what pollution control technology must be used. An approach employing economic incentives gives companies more flexibility in choosing how to reduce pollution and could lead to more

cost-effective solutions to pollution problems. An approach employing economic incentives can take several forms, including systems under which firms can buy and sell emission reduction credits and pollution taxes. A pollution tax is a tax on the emissions of a pollutant or on harmful products or substances. Such a tax would have to be carefully designed and implemented to be effective in achieving environmental and economic benefits.

Because of their inherently greater flexibility, market-based incentives may be both a less costly and a more effective means of controlling pollution. More chemicals could also be addressed under TSCA if the Congress were to amend TSCA to expand the types of circumstances under which EPA could take action under the act to specifically include situations in which (1) it identifies pollution prevention opportunities, such as when safer chemical substitutes can be shown to exist at a reasonable cost, or (2) the use of a toxic chemical cannot be shown to pose a current problem, but its continued use could be a long-term problem because it persists in the environment or accumulates in plant or animal tissue. To better support EPA's pollution prevention initiatives, TSCA could also be amended to expand the range of regulatory control options available to EPA to reduce chemical risks. Such additional options could include the authority to require the use of safer chemical substitutes or manufacturing processes that result in less exposure or fewer environmental releases.

Scope and Methodology

Our objectives were to review the Environmental Protection Agency's (EPA) efforts to (1) control the risks of new chemicals not yet in commerce, (2) assess existing chemicals used in commerce, and (3) publicly disclose information provided by chemical companies under the Toxic Substances Control Act (TSCA). In addressing these issues we also obtained information on EPA's voluntary chemical control programs that complement TSCA, the chemical control programs of Canada and the European Union (EU), and identified some legislative options that GAO and others have previously noted could strengthen EPA's authority to assess and regulate chemicals under TSCA.

To review the extent to which EPA has assessed the risks of new and existing chemicals and has made information obtained under TSCA public, 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 and representatives of the American Chemistry Council (a national chemical manufacturers association), Environmental Defense (a national, nonprofit, environmental advocacy organization), and the Synthetic Organic Chemical Manufacturer's Association (a national, specialty chemical manufacturer's association). We also obtained and reviewed documentation provide to EPA by the states on the usefulness of confidential business information to states. We interviewed several EPA officials to assess the reliability of data related to assessment and control of new chemicals. We determined the data were sufficiently reliable for the purposes of this report.

To understand efforts EPA has taken to assess and control the risks of new and existing chemicals, we identified several voluntary programs designed to promote environmentally safer chemicals and to gather information to assess the risks of chemicals, in particular, EPA's Sustainable Futures Program, Voluntary Children's Chemical Evaluation Program (VCCEP), and the High Production Volume (HPV) Challenge Program. We selected Sustainable Futures because it is a risk assessment tool used to complement EPA's other pollution prevention programs. Sustainable Futures represents a pollution prevention program that impacts manufacturer's chemical decision-making process for chemicals not yet in commerce; while other pollution prevention programs focus on chemicals already in commerce. We selected the HPV Challenge Program and VCCEP because they represent significant data collection efforts to provide

information for EPA's assessment of existing chemicals. To enhance our understanding, we interviewed EPA officials and representatives at American Chemistry Council, Environmental Defense, and the Synthetic Organic Chemical Manufacturer's Association; we also attended EPA's National Toxic and Pollution Prevention Advisory Committee meetings. Finally, we obtained and reviewed agency documents related to these programs.

To understand other chemical control regulation, we collected documentation and interviewed individuals knowledgeable about (1) the Toxic Substances Control Act and (2) foreign chemical control laws or proposed legislation: (a) the Canadian Environmental Protection Act 1999 and (b) the European Union's Chemical Directives and proposed Registration, Evaluation and Authorization of Chemicals. The EU and Canada were chosen because they have recently taken action to revise their chemical legislation. In 1999, Canada revised its chemical control law and in 2003, the EU proposed a new regulation. The EU and Canada were also selected because they have characteristics that are similar to those of the United States: Canada and the EU member countries are industrialized nations and have extensive experience with the review and control of chemical substances. In addition, Canada and the EU produce a considerable amount of chemicals. Furthermore, EPA officials and chemical industry representatives recommended these countries for comparison with TSCA. For each of the countries, we obtained laws, technical literature, and government documents that describe their chemical control programs. We also interviewed foreign officials responsible for implementing the chemical substances control laws in Canada and for representing the European Commission in the United States. Our descriptions of these countries' laws are based on interviews with government officials and written materials they provided.

To identify potential options to strengthen EPA's ability to assess and regulate chemical risks under TSCA, we (1) interviewed officials at EPA, the American Chemistry Council, Environmental Defense, EPA's National Toxic and Pollution Prevention Advisory Committee, and the Synthetic Organic Chemical Manufacturer's Association; (2) reviewed pertinent literature, including prior GAO reports and congressional hearings on TSCA; (3) attended various public meetings and conferences sponsored by EPA and others; and (4) reviewed chemical legislation in Canada and and proposed legislation in the EU. This report does not discuss all possible options for revising TSCA. Those options that are discussed were selected because they have been identified as addressing constraints in EPA's

authority under the act. Our selection of these options reflects (1) our knowledge of EPA's implementation of TSCA obtained during this and previous reviews of the agency's toxics programs, (2) foreign countries' approaches to reviewing and controlling harmful chemicals, and (3) views provided by U.S. government officials and representatives of the chemical industry and environmental groups.

Our review was performed between June 2004 and April 2005 in accordance with generally accepted government auditing standards.

Regulations Promulgated under Section 6 of TSCA

The Environmental Protection Agency (EPA) has promulgated rules under section 6 of the Toxic Substances Control Act (TSCA) to place restrictions on five existing chemicals or chemical categories and four new chemicals. The five existing chemicals/chemical categories are polychlorinated biphenyls (PCB), fully halogenated chlorofluoroalkanes, dioxin, asbestos and hexavalent chromium. The four new chemicals are all used in metal working fluids that, when combined with nitrites, could cause the formation of a cancer causing substance. EPA's rules for the four new chemicals were immediately effective, unlike EPA's rules for existing chemicals, which required a comment period.

Existing Chemicals

Polychlorinated Biphenyls

Because the Congress believed that PCBs posed a significant risk to public health and the environment, section 6(e) of TSCA prohibited the manufacture, processing, distribution in commerce, or use of PCBs other than in a totally enclosed manner after January 1, 1978, unless otherwise authorized by EPA rule. Under TSCA, EPA may, by rule, authorize the manufacture, processing, distribution in commerce or use of any PCB in a manner other than a totally enclosed manner if EPA finds that it will not present an unreasonable risk of injury to health or the environment. EPA was also required by July 1977 to promulgate rules to (1) prescribe methods for PCB disposal and (2) require PCBs to be marked with clear and adequate warnings and instructions with respect to their processing, distribution in commerce, use, or disposal. EPA has issued various rules to implement these statutory requirements and provide for some exemptions to the PCB prohibitions. About 50 percent of PCBs were used in electrical, heat transfer, and hydraulic equipment. PCBs were also used in numerous other applications, including plasticizers and fire retardants. Approximately half of the PCBs manufactured were disposed of or released into the environment prior to EPA promulgating rules for the disposal requirements under TSCA. PCBs are toxic and very persistent in the environment. When released into the environment, they decompose very slowly and can accumulate in plants, animals, and human tissue. Laboratory tests show that they cause cancer in rats and mice and that they have adverse effects on fish and wildlife.

Fully Halogenated Chlorofluoroalkanes

In 1978, EPA banned nonessential uses of fully halogenated chlorofluoroalkanes as propellants in aerosol spray containers. EPA took this action because of concerns that these chemicals were destroying the

upper atmosphere's ozone layer, which shields the earth from ultraviolet radiation. Increased exposure to ultraviolet radiation has been linked to increased skin cancer. Depletion of the ozone layer is also thought to lead to climate changes and other adverse effects. Chlorofluorocarbons, halons, and other fully halogenated chlorofluoroalkanes have been relied upon for applications including air conditioning, refrigeration, fire suppression, insulation, and solvent cleaning. According to EPA officials, in advance of its obligations under the Montreal Protocol, the United States began phasing out production of the most potent ozone depleting chemicals in 1994 and is now gradually phasing out hydrofluorocarbon production as well. According to EPA officials, other industrialized countries have followed the U.S. lead, and developing countries with assistance from the Multilateral Fund are now complying with the protocol phase out requirements. The regulation of fully halogenated chlorofluoroalkanes was eliminated in 1995 by an EPA final rule because EPA had banned such chlorofluorocarbons propellants under the Clean Air Act, making the TSCA rule obsolete.[1]

Dioxin

In 1980, EPA promulgated a rule prohibiting Vertac Chemical Company and others from removing for disposal certain wastes containing 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) stored at Vertac's Jacksonville, Arkansas, facility.[2] The rule also required any persons planning to dispose of TCCD contaminated wastes to notify EPA 60 days before their intended disposal. TCDD, one of the most toxic of the about 75 dioxins in existence and an animal carcinogen, is a contaminant or waste product formed during the manufacture of certain substances. EPA concluded that it was likely to result in adverse human health effects. This TSCA action was superseded by a 1985 Resource Conservation and Recovery Act regulation.[3]

Asbestos

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 containing materials were used widely for fireproofing, thermal and acoustical insulation, and decoration in building construction and renovation before the adverse effects of asbestos were known. Asbestos also has numerous other applications, for example,

[1]60 Fed. Reg. 31917 (June 19, 1995).

[2]45 Fed. Reg. 32676 (May 19, 1980).

[3]50 Fed. Reg. 2003 (Jan. 14, 1985).

in friction products such as brake linings. After initially regulating asbestos under the Clean Air Act in the early 1970s, EPA issued a final rule under TSCA to ban the manufacturing, importing, and processing of nearly all asbestos products in July 1989.[4] The rule was to begin phasing out asbestos-containing products in August 1990, and complete the phaseout by 1997. EPA's rule was challenged in federal court by asbestos product manufacturers, and in October 1991, the United States Court of Appeals for the Fifth Circuit vacated most of the rule—the rule continued to apply to asbestos products no longer in commerce—and remanded it to the agency for further consideration.

Hexavalent Chromium

In 1990, EPA banned the use of hexavalent chromium-based water treatment chemicals in comfort cooling towers (CCT) and the distribution of them in commerce for use in CCTs on the basis of health risks associated with human exposure to air emissions.[5] According to EPA, hexavalent chromium was being released from a large number of unidentified cooling towers. At the time, hexavalent chromium was a known human carcinogen. EPA could have issued an emissions standard under the Clean Air Act. However, the agency believed that regulation under TSCA would be more efficient and effective because the act could be used to regulate use and distribution of hexavalent chromium-based water treatment chemicals.

New Chemicals

EPA issued proposed rules to impose certain controls on four new chemicals: (1) mixed mono and diamides of an organic acid,[6] (2) triethanolamine salts of a substituted organic acid,[7] (3) triethanolanime salt of tricarboxylic acid, and (4) tricarboxylic acid.[8] The agency determined these chemicals would pose an unreasonable risk to human health or the

[4]EPA first regulated asbestos in the early 1970s as a hazardous air pollutant under the Clean Air Act by prescribing, among other things, work practices to prevent or minimize the release of asbestos into the air during the demolition or renovation of buildings containing asbestos. In 1982, EPA issued a rule requiring all public and private elementary and secondary schools to inspect for friable (easily crumbled into powder) asbestos-containing materials.

[5]55 Fed. Reg. 222 (Jan. 3, 1990).

[6]49 Fed. Reg. 36846 (Sep. 20, 1984).

[7]49 Fed. Reg. 24658 (Sep. 20, 1984).

[8]49 Fed. Reg. 2762 (Jan. 23, 1984).

environment. According to EPA, adding nitrites or other nitrosating agents to the substances causes the formation of a substance known to cause cancer in laboratory animals. EPA promulgated the rules regulating these chemicals in 1984 to prohibit adding any nitrosating agent, including nitrites, to metal working fluids that contain these substances. EPA promulgated the rules under TSCA section 5(f). Under this section of TSCA, if EPA determines that there is a reasonable basis to conclude that the manufacturing, processing, distribution in commerce, or disposal of a new chemical presents or will present an unreasonable risk of injury to health or the environment before EPA can promulgate a rule under TSCA section 6, EPA may limit the amount or impose other restrictions via an immediately effective proposed rule. The restrictions on these chemicals remain in place today.

Comments From the Environmental Protection Agency

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

MAY 26 2005

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Mr. John Stephenson
Director
Natural Resources and Environment
Government Accountability Office
Washington, DC 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: Actions Needed to Improve EPA's Ability to Assess Health Risks and Manage its Chemical Review Program"* (GAO-05-458). The Report examines the Environmental Protection Agency's (EPA's) efforts to (1) control the risks of new chemicals not yet in commerce, (2) assess the risks of existing chemicals used in commerce, and (3) publicly disclose information provided by chemical companies under the Toxics Substances Control Act (TSCA).

EPA is proud of the progress that we have made in protecting human health and the environment. There are over 82,000 chemicals currently on the TSCA inventory and approximately 1,500 new chemical notices are reviewed each year in EPA's New Chemicals Program. To date, TSCA authority has provided the Agency the ability to review more than 40,000 new chemicals prior to introduction into the marketplace and we have restricted or otherwise regulated over 1,600 of these chemicals while a similar number have been withdrawn by the manufacturer, often in the face of EPA action. In addition, the Agency has issued rules requiring Agency review of significant new uses of more than 700 chemicals. The Agency utilizes a variety of tools including modeling, voluntary and innovative approaches, international coordination, and information gathering and dissemination to ensure that we have the ability to make informed decisions and that there is transparency for a wide range of stakeholders and the public.

The Agency also works to target chemical data development and information collection and appreciates GAO's recognition of the need to balance this against external expectations and regulated community burdens. We also appreciate GAO bringing these considerations into the dialogue at various points throughout the report. This balance is, in part, evidenced by the interviews your staff conducted with the American Chemistry Council, Environmental Defense, the Synthetic Organic Chemical Manufacturers Association and members of EPA's National Pollution Prevention and Toxics Advisory Committee. GAO recognizes EPA's "numerous control actions" resulting from reviews of new chemicals and efforts under the High Production

Volume Chemicals Challenge Program to aggressively obtain data on a key set of chemicals on the TSCA Inventory. EPA's "numerous control actions" speak to the range of traditional and innovative approaches applied by the Agency in the chemical review program.

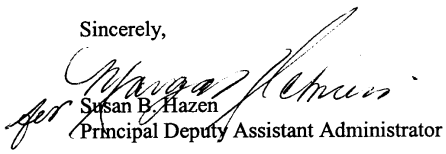
While EPA appreciates the observations and suggestions for the chemicals management program, there are two substantive comments that we would like to provide. Technical and editorial comments are provided in the enclosed Appendices.

- EPA has concerns regarding GAO's recommendation to the Administrator to promulgate a Section 8 rule to obtain data submitted to foreign governments. The Report recommends a rule that would require chemical companies to submit to EPA copies of any health and safety studies and related information that the companies submit to foreign governments on chemicals manufactured, processed, or imported in the United States. The recommendation suggests a potentially broad-ranging information collection. While such a reporting rule may bring useful information, other more targeted approaches for collecting information which are directed at EPA's domestic priorities, rather than foreign government mandates, may be more prudent.

- In another recommendation for Congressional consideration, GAO recommends that TSCA be amended to explicitly recognize enforceable consent agreements (ECAs). As we have stated throughout the discussions on this report, EPA believes that there is currently strong legal authority for ECAs under which chemical companies are required to conduct testing.

Thank you for this opportunity to review and comment on the report GAO-05-458, *"Chemical Regulation: Actions Needed to Improve EPA's Ability to Assess Health Risks and Manage its Chemical Review Program."* We look forward to continuing to work with the General Accountability Office and Congress on our efforts to ensure chemical safety and protection of human health and the environment.

Sincerely,



Susan B. Hazen
Principal Deputy Assistant Administrator

Enclosures

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Staff Acknowledgments

In addition to the individual named above, David Bennett, John Delicath, Richard Frankel, Ed Kratzer, Malissa Livingston, Jean McSween, Marcella Phelps, and Amy Webbink made key contributions to this report.

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