United States General Accounting Office

GAO

Report to Congressional Requesters

September 1994

TOXIC SUBSTANCES CONTROL ACT

Legislative Changes Could Make the Act More Effective

GAO/RCED-94-103

GAO

United States
General Accounting Office
Washington, D.C. 20548

Resources, Community, and
Economic Development Division

B-256039

September 26, 1994

The Honorable Harry M. Reid
Chairman, Subcommittee on Toxic
Substances, Research and Development
Committee on Environment and Public Works
United States Senate

The Honorable Mike Synar
Chairman, Environment, Energy,
and Natural Resources Subcommittee
Committee on Government Operations
House of Representatives

As requested, this report discusses the Environmental Protection Agency's (EPA) efforts under the Toxic Substances Control Act to assess the risks of chemicals, control those found to be harmful, and make information on chemical risks publicly available. The report also contains options for revising the act to improve EPA's efforts in each of these areas.

As arranged with your offices, unless you publicly announce its contents earlier, we will make no further distribution of this report until 30 days after the date of this letter. At that time, we will send copies to the appropriate congressional committees; the Administrator, EPA; and the Director, Office of Management and Budget. We will also make copies available to other interested parties on request.

This work was performed under the direction of Peter F. Guerrero, Director, Environmental Protection Issues, who can be reached at (202) 512-6111 if you or your staff have any questions. Other major contributors to this report are listed in appendix IV.

Keith O. Fultz
Assistant Comptroller General

Executive Summary

Purpose

Thousands of chemicals are in commercial use. Although these chemicals are important in producing goods and services, they are often toxic and can have adverse health and environmental effects. The Congress passed the Toxic Substances Control Act (TSCA) in 1976 to enable the Environmental Protection Agency (EPA) to obtain more information on chemicals and to control those that pose an unreasonable risk.

Concerned that EPA has been slow to implement TSCA, Senate and House Subcommittee Chairmen with responsibilities for overseeing the act asked GAO to review the agency's progress and identify changes to make the act more effective. Specifically, the Chairmen asked GAO to review EPA's efforts to (1) assess chemicals under TSCA, (2) control those found to be harmful, and (3) make TSCA's information on chemical risks publicly available by reducing the amount of information that the industry claims as confidential.

Background

TSCA authorizes EPA to review chemicals before and after they enter commerce. To assess risks, EPA examines a chemical's toxicity or potential adverse effects and the amount of human and environmental exposures. If EPA finds that a chemical's risks are unreasonable, it can prohibit or limit its production, distribution, use, and disposal or take other action, such as requiring warning labels on the substance.

TSCA requires the industry to notify EPA at least 90 days before producing or importing a new chemical. These notices contain information, such as the chemical's molecular structure and anticipated uses, that EPA uses to evaluate the chemical's potential risks. TSCA also authorizes EPA to require manufacturers to perform tests or provide other data, such as production volumes, on existing chemicals. In addition, TSCA requires the industry to report to EPA any data that reasonably support a conclusion that a chemical presents a substantial risk.

Of about 72,000 substances in EPA's inventory of TSCA chemicals, 62,000 were already in commerce when EPA began to review new chemicals in 1979. EPA reviewed the remaining 10,000 substances as new chemicals and added them to the inventory when their manufacture began.

Results in Brief

TSCA's unique authorities to limit the manufacture, distribution, and use of toxic chemicals could be important tools in a comprehensive program for these chemicals. However, the act's legal standards are so high that they

have usually discouraged EPA from using these authorities. In addition, EPA has generally interpreted TSCA as giving preference to dealing with chemical risks under other laws. As a result, EPA has issued regulations to control only nine chemicals in almost 18 years.[1]

Although EPA has reviewed new chemicals in a timely manner, its process does not ensure that their potential risks are fully assessed before they enter commerce. EPA usually has few if any test data, and it predicts chemicals' potential effects with mixed results. In addition, the data that EPA uses to assess exposure may change substantially after manufacture begins. For existing chemicals, the burden is essentially on EPA to compile the data, which is time-consuming and costly. As a result, EPA has reviewed the risks of about 2 percent of the 62,000 chemicals that were already in commerce when the agency began to review new chemicals.

TSCA's provisions on confidential business information are difficult for EPA to implement. The chemical information collected under TSCA can be useful to others, such as state environmental officials. However, EPA cannot disseminate much of the information because industry claims that it is confidential. EPA believes that many claims are not necessary to protect trade secrets. The agency has successfully challenged the validity of some claims, but it does not have the resources to challenge a significant portion.

Principal Findings

EPA Regulates Few Chemicals Under TSCA

EPA has issued regulations to control four new and five existing chemicals determined to present an unreasonable risk. TSCA does not define what risk is unreasonable. However, according to EPA officials, the threshold is very high in that the agency must present substantial evidence that the benefits to society of implementing the controls outweigh the costs. This standard is especially difficult for major controls or restrictions because the costs can be extensive and the full range of benefits may be difficult to document. Although EPA had considerable evidence of serious health problems and spent several years developing a rule to phase out the use of nearly all products containing asbestos, the Fifth Circuit Court of Appeals decided in 1991 that the agency had issued the rule on the basis of insufficient evidence.

[1]EPA can impose temporary controls on new chemicals pending the development of sufficient information on their effects and has done so for a small percentage of chemicals.

EPA's interpretation that TSCA gives preference to dealing with chemical risks under other laws, such as the Clean Air and Occupational Safety and Health acts, has been controversial within and outside the agency. While these laws can limit environmental releases and certain exposures, they do not offer TSCA's flexibility to ban or restrict chemicals' production, distribution, use, and disposal. Some EPA staff, Members of Congress, and environmental groups believe that EPA should pursue more chemical regulations under TSCA.

EPA Has Not Fully Assessed Chemical Risks

TSCA does not require routine testing of chemicals, and industry performs limited tests on new chemicals. Because test data are generally insufficient, EPA uses a method known as structure activity relationships analysis to predict health and environmental effects by comparing new chemicals with chemicals of similar molecular structures that have been tested. However, a 1993 study comparing EPA's predictions with the results of testing required for new chemicals in the European Union showed that EPA's predictions were not always accurate, especially for such aspects as the chemicals' physical properties. These properties, such as vapor pressure, are important factors in how much exposure occurs during a chemical's manufacture and use.

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 manufacture begins. Although TSCA authorizes EPA to require a manufacturer to submit a new notice under these conditions, the agency must promulgate a rule in which it identifies the new uses or activities that may pose health or environmental hazards.

EPA has reviewed the risks of about 1,200 existing chemicals. At the current rate of about 100 chemicals per year, EPA will need many years to review just the higher-priority chemicals. According to EPA, over 16,000 chemicals are potentially of some concern because of their production volume and chemical structure. In addition, the reviews that have been conducted may already be or may become outdated as production expands and new uses develop for the chemicals reviewed.

TSCA authorizes EPA to issue rules to require testing if the agency finds that chemicals may present an unreasonable risk or may result in significant human or environmental exposure. However, EPA must expend considerable time and resources to obtain chemical information from the

industry. According to EPA, promulgating a test rule for a chemical can take as long as 24 to 30 months and cost about $68,500 to $234,000.

Large Amounts of TSCA's Data Are Claimed as Confidential

A 1992 study by a consulting firm found that more than 90 percent of the premanufacture notices that the firm reviewed contained information claimed as confidential. Although EPA officials recognize that some of these claims are needed to protect trade secrets, they believe, on the basis of the 1992 study and their experience with the data, that the claims are excessive. Under certain conditions, federal officials can obtain access to confidential information, but state health and environmental officials cannot.

To discourage excessive confidentiality claims, EPA is considering various actions, including revisions to its regulations to require substantiation of claims. Currently, the burden is on EPA to perform a series of labor-intensive steps to declassify data that it believes should not be treated as confidential.

Matters for Congressional Consideration

The Congress could strengthen EPA's ability to regulate chemicals by allowing TSCA to be used in preference to other environmental laws, when appropriate, and establishing a framework for taking action that is less burdensome for EPA. The Congress could also improve EPA's ability to conduct chemical reviews by requiring industry to submit additional data on new chemicals and shifting to industry some of the burden for compiling data on existing chemicals. To increase the dissemination of TSCA data, the Congress could give the states access to confidential data and limit confidentiality claims. GAO also presents options for the Congress to consider in reauthorizing TSCA in these areas.

Agency Comments

GAO discussed the facts in this report with EPA officials, including the Director of the Chemical Control Division, Office of Pollution Prevention and Toxics, who generally agreed with the report's accuracy. These officials acknowledged that TSCA's effectiveness has been limited and that changes to the act's provisions could strengthen EPA's ability to control harmful chemicals, assess chemical risks, and increase the dissemination of TSCA data on chemical hazards. The EPA officials also suggested changes to clarify and update information on the agency's implementation of TSCA, and GAO made changes as appropriate. As requested, GAO did not obtain written comments on the draft report.

Contents

Abbreviations

CFC	chlorofluorocarbon
EPA	Environmental Protection Agency
GAO	General Accounting Office
OSHA	Occupational Health and Safety Administration
PCB	polychlorinated biphenyl
RCRA	Resource Conservation and Recovery Act
SAR	structure activity relationships
TCDD	2,3,7,8-tetrachlorodibenzo-p-dioxin
TSCA	Tosic Substances Control Act

Introduction

Thousands of chemicals are in commercial use in the United States, and chemical manufacturers introduce many new chemicals into the marketplace each year. Although these chemicals are important in producing many American goods and services, they are often toxic and can have adverse effects on human health and the environment if significant levels of exposure to them occur.

The Toxic Substances Control Act (TSCA) was enacted in October 1976 to provide a safeguard against the introduction of additional contaminants into the environment and to address the risks posed by existing chemicals. Under TSCA, the Environmental Protection Agency (EPA) may require chemical manufacturers and processors to test potentially harmful chemicals for the purpose of assessing their health and environmental effects. If a chemical poses an unreasonable risk to health or the environment, EPA can take action to control its manufacturing, processing, distribution, use, and/or disposal. These controls can range from banning the chemical to requiring warning labels on the chemical or products containing the chemical when they are sold.

Chemicals Are Important but Present Potential Dangers

More than 7 million recognized chemicals are in existence, and approximately 80,000 of them are in common use worldwide. Over 72,000 chemicals have been produced for commercial use in the United States and are listed in the TSCA inventory of chemicals. In addition, about a thousand new chemicals are developed and added to the inventory each year.

Chemicals play an important role in people's lives. In performing common household activities, consumers use products containing chemicals, such as cleaning detergents, soaps, and paints. In producing a wide variety of other products and industrial processes, industries use chemicals as solvents, resins, and additives. Also, the production of chemicals makes a significant contribution to the national economy. The chemical industry, one of the largest industries in the United States, has a work force of about 850,000, almost 5 percent of all U.S. manufacturing workers. Ten percent of U.S. scientists and engineers work for chemical companies, a reflection of the industry's high technology products and capital-intensive, complex manufacturing processes. In 1991, more than 178 billion pounds of synthetic organic chemicals were produced, representing $85 billion in chemical sales.

While the production of chemicals generates many benefits to consumers and the national economy, the health and environmental risks associated with chemicals are not always known. For many chemicals, there is little knowledge of the ill-effects they might cause to people and the environment exposed to them. Human exposure to some chemicals can contribute directly to health problems, such as cancers, birth defects, respiratory disorders, and other acute and chronic diseases. Also, chemicals released into the environment have been responsible for problems such as contaminated drinking water supplies, contaminated fish, air pollution, hazardous waste dumps, and other adverse impacts on environmental quality.

The Federal Government's Important Role in Protecting Against Harmful Chemicals

Federal laws have been enacted over the years to determine the health and environmental hazards associated with toxic chemicals and to address these problems. These laws, such as the Clean Air Act, the Clean Water Act, the Resource Conservation and Recovery Act, the Federal Food, Drug and Cosmetic Act, and the Federal Insecticide, Fungicide, and Rodenticide Act, are designed to control hazardous chemicals that may be present in food, drugs, and pesticides and in the air, water, and soil. 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 at home.

These laws were generally enacted or substantially amended in the early 1970s. Despite their existence, problems with toxic chemicals continued to occur. In addition, the Congress became increasingly concerned about the long-term effects of substantial amounts of chemicals entering the environment. TSCA was enacted to authorize EPA to collect information about the hazards posed by chemical substances and to take action to control unreasonable risks by either preventing dangerous chemicals from making their way into use or placing restrictions on those already in commerce. Under the act, EPA can control the entire life cycle of chemicals from their production, distribution in commerce, and use to their disposal. Other environmental and occupational health laws generally control only disposal or release to the environment, or exposures in the workplace.

TSCA applies to new (not yet in commerce) and existing (currently in the marketplace) "industrial" chemicals. The act does not apply to eight categories of chemical products—pesticides, tobacco, nuclear material, firearms and ammunition, food, food additives, drugs, and cosmetics—that are regulated under other laws.

TSCA's Major Provisions

TSCA's primary purpose of ensuring that chemicals in commerce do not present an unreasonable risk of injury to health or the environment is carried out through six major sections of the act, as shown in table 1.1.

Table 1.1: TSCA's Major Sections for Chemical Data Collection and Control

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

Under section 4, EPA can promulgate rules to require chemical manufacturers and processors to test potentially harmful chemicals for their health and environmental effects. To require testing, EPA must determine that the chemical may present an unreasonable risk or that substantial exposure may exist.

Section 5 requires industry to notify EPA at least 90 days before beginning to manufacture or process a new chemical. EPA generally has these 90 days to review the chemical information in the notification and identify the chemical's potential risks. If the chemical will present an unreasonable risk, EPA must act to protect against the risk. If insufficient data exist and an unreasonable risk may be present, EPA can impose temporary controls or restrictions until sufficient data are developed.

Section 6 requires EPA to take actions against chemicals for which a reasonable basis exists to conclude that the chemicals present or will present an unreasonable risk to health or the environment. To adequately protect against a chemical's risk, EPA can take a range of actions that include banning or restricting the chemical's production, processing, distribution, or use and requiring warning labels on the chemical.

Section 8 directs chemical manufacturers and processors to maintain records and to 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, chemical manufacturers, processors, and distributors are required to submit lists or copies of

certain health and safety studies to EPA and to report to EPA information which indicates that a chemical presents a substantial risk.

Section 9 sets out TSCA's relationship to other laws. If EPA determines, in its discretion, that an unreasonable chemical risk may be prevented or sufficiently reduced by action under a federal law not administered by EPA, it must refer information on the chemical's risk to the agency administering the other law. That agency must initiate action to regulate the chemical or publish in the Federal Register why no action is needed. The section also directs EPA to use other laws it administers to protect against unreasonable risks, unless EPA determines that it is in the public interest to protect against such risks under TSCA.

Section 14 authorizes EPA to release chemical information obtained by the agency under the act. Certain information, such as data disclosing chemical processes, can be claimed as confidential business information by chemical manufacturers and processors. EPA must protect such information against disclosure unless public disclosure is necessary to protect against an unreasonable risk.

EPA's Organization and Resources for Implementing TSCA

The primary responsibility for implementing TSCA resides with EPA's Office of Pollution Prevention and Toxics, formerly the Office of Toxic Substances. Nearly all program activities are carried out by EPA headquarters staff. EPA's regional offices have some enforcement responsibilities.

The Office's TSCA activities center around two principal programs: new chemicals and existing chemicals. The new chemicals program implements TSCA section 5, whereas the existing chemicals program implements the section 4 testing, section 6 chemical control, and section 8 information-gathering provisions. Section 14 governs the disclosure of information collected from industry under both programs.

One of EPA's first task's under the act was to compile an inventory of chemicals already in U.S. commerce. This initial inventory, which EPA published in July 1979 and then in revised form in July 1980, contained about 62,000 chemicals. EPA's new chemical program began with publishing the initial inventory. Any chemicals not on the inventory were to be considered new substances under TSCA and subject to the section 5 premanufacture notification requirements. EPA adds new chemicals to the inventory when it completes its review of the premanufacture notices and

is informed that manufacture or import of the chemicals has begun. About 10,000 chemicals have been added to the inventory since 1979, bringing the total to over 72,000 chemicals. Chemicals on the inventory are referred to as existing chemicals.

The Office of Pollution Prevention and Toxics' fiscal year 1994 budget for implementing TSCA is about $67.9 million. Of this amount, about $14.3 million is for new chemicals and $53.6 million is for existing chemicals. Although the amount for existing chemicals appears substantially larger than that for new chemicals, about $5.7 million is for chemical testing and $31.4 million is to carry out congressionally mandated activities related to the control of three chemicals: asbestos, lead, and polychlorinated biphenyls (PCBs).

EPA's regulatory control actions for new and existing chemicals are discussed in chapter 2. EPA's programs for the review of the risks of new and existing chemicals are discussed in chapters 3 and 4, respectively. Chapter 5 discusses EPA's implementation of TSCA's confidential business information provisions.

Objectives, Scope, and Methodology

Citing concerns about EPA's implementation of TSCA, the Chairman, Subcommittee on Toxic Substances, Research and Development, Senate Committee on Environment and Public Works, and the Chairman, Subcommittee on Environment, Energy, and Natural Resources, House Committee on Government Operations, requested that we review EPA's efforts to (1) control chemicals under TSCA, (2) assess the risks of chemicals before and after they enter commerce, and (3) reduce the amount of information collected under TSCA that cannot be disseminated because industry claims that it is confidential. The Chairmen also requested that we identify ways to make TSCA more effective in these areas.

To review EPA's progress in evaluating the risks of chemicals and controlling those harmful to human health or the environment, we determined the results of EPA's reviews for about 1,500 new chemicals from January 1990 to May 1993. In addition, we determined the number of existing chemicals reviewed by EPA for the various types and levels of review conducted by the agency and examined EPA's files for selected chemicals. We also identified EPA's requirements, policies, and guidelines on how the new and existing chemical review and control programs work and determined the extent of actions taken by EPA to control new and

existing chemicals. These efforts were augmented by interviews with officials of EPA and the Occupational Safety and Health Administration and representatives of the Chemical Manufacturers Association and the Environmental Defense Fund.

To identify potential regulatory changes to make TSCA more effective, we (1) interviewed officials from EPA's Office of Pollution Prevention and Toxics, the Interagency Testing Committee, the Chemical Manufacturers Association—which represents companies that account for over 90 percent of the U.S. bulk chemical production—and the Environmental Defense Fund; (2) reviewed literature and congressional hearings on TSCA and attended various public meetings and conferences sponsored by EPA and others, such as the American Chemical Society; (3) reviewed written comments submitted to us by representatives of the Chemical Manufacturers Association; and (4) compared EPA's new and existing chemical programs with programs implemented in three other countries—Canada, Germany, and Sweden.

These countries were chosen to help us identify potential changes to TSCA because each country has recently revised its chemical control laws and taken other actions to improve its chemical review and control programs. These countries were also selected because they have important characteristics that are similar to those of the United States: All are industrialized nations and have extensive experience with the review and control of chemical substances. In addition, Canada and Germany produce a considerable amount of chemicals.

For each of the foreign countries we reviewed, we obtained national laws, technical literature, and government documents that describe the country's chemical control programs. We also interviewed the foreign officials responsible for implementing the chemical substances control laws in the three countries. We limited our data collection efforts in these countries to the national level, recognizing that there may be significant differences across provinces. We further interviewed representatives from the Canadian Chemical Producers' Association, the German Institute for Applied Ecology (Oko-Institut), the German Chemical Industry Association, the Association of Swedish Chemical Industries, and the Swedish Society for the Conservation of Nature to obtain views on their respective countries' chemical control programs. Finally, we interviewed officials of the Commission of the European Union and of the European Center for Ecotoxicology and Toxicology of Chemicals in Brussels, Belgium, to obtain their views on reviewing and controlling new and

existing chemicals. Our descriptions of these countries' laws are based on interviews with government officials and written materials they provided.

This report does not discuss all possible options for revising TSCA. Those options that are discussed were selected because they address major constraints to EPA's implementation of 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 September 1992 and July 1994 in accordance with generally accepted government auditing standards.

TSCA's Regulatory Control Authorities Are Seldom Used

Because issuing regulations under TSCA is so difficult, this course of action is generally not a viable alternative when EPA is considering how best to deal with toxic chemical concerns. In the almost 18 years since TSCA was enacted, EPA has issued regulations under the act to control only nine chemicals—five existing chemicals and four new ones. The agency has been more successful in entering into individual agreements with manufacturers of new chemicals to take certain actions, such as to implement workplace practices, pending the development of additional data. New-chemical manufacturers have also voluntarily conducted certain toxicity tests or withdrawn their plans to manufacture the chemicals when EPA has indicated plans to require these controls. EPA does not have similar authority for existing chemicals but has begun to encourage industry's voluntary actions to reduce the risks of these chemicals.

EPA has issued only a few regulations under TSCA because the act's legal standards are very high, and the burden of proof is essentially on EPA. In addition, consensus does not exist in the Congress and the environmental community on whether the act is intended to have a greater role in addressing toxic chemicals. Some in the Congress and in the environmental community believe that TSCA is a comprehensive or umbrella law; their belief is based on the fact that the act deals exclusively with industrial chemicals and provides EPA with authorities to control chemicals throughout their life cycle, from production to use and disposal. However, some EPA officials and industry representatives believe that the act's purpose is generally limited to filling gaps in other health and environmental laws. The act does not clearly articulate what EPA is to achieve through the use of its regulatory authorities.

EPA Has Controlled Few Chemicals Under TSCA

EPA seldom uses TSCA to regulate existing chemicals. In addition, nearly all of the actions for new chemicals have been temporary controls or voluntary actions by individual chemical manufacturers, primarily to address occupational or worker exposure.

EPA Has Placed Controls on Five Existing Chemicals

Since the enactment of TSCA in 1976, EPA has issued regulations under the act to control five existing chemicals: (1) polychlorinated biphenyls (PCB), (2) chlorofluorocarbons (CFC), (3) dioxin, (4) asbestos, and (5) hexavalent chromium. Even this small number of chemicals does not fully indicate EPA's reluctance to use TSCA's regulatory authorities because the act itself required EPA to regulate PCBs. In addition, EPA attempted to refer asbestos to the Occupational Safety and Health Administration for action until the

Congress and public interest groups objected. Furthermore, EPA's Office of Air and Radiation requested that the Office of Pollution Prevention and Toxics regulate hexavalent chromium under TSCA because substantially more resources would be needed to enforce a Clean Air Act regulation. Officials in the Office of Pollution Prevention and Toxics told us that a ban under TSCA was a better approach than EPA's having to issue and monitor compliance with an emissions standard for hexavalent chromium under the Clean Air Act.

The regulations for two of the chemicals were comprehensive. The PCB rules, as required in the act, address manufacture, distribution, use, and disposal. A 1989 asbestos rule would have phased out most uses, but the rule was overturned by a 1991 court decision.[1] On the other hand, the CFC rule banned the substance's use in aerosol spray cans—other uses were phased out later under the Clean Air Act. Under the dioxin rule, EPA prevented land disposal of one kind of dioxin by one manufacturer (other companies were required to notify EPA if they intend to dispose of this substance). In addition, the hexavalent chromium rule covered only its use in commercial cooling towers, not industrial ones. (The TSCA regulations for these five chemicals are discussed in more detail in app. I.)

A Small Percentage of New Chemicals Has Been Controlled

Of the 23,971 new chemicals reviewed, some action to reduce risks were taken on 2,431, or about 10 percent of the chemicals. In addition to issuing regulations to impose certain controls on 4 chemicals, EPA entered into agreements or consent orders with manufacturers of 626 chemicals to implement temporary workplace practices or controls during manufacture and/or to perform toxicity testing when the chemicals' production volumes reached certain levels. For 827 chemicals, the manufacturers voluntarily agreed to perform toxicity testing before EPA completed its reviews. For the remaining 974 chemicals, the manufacturers or processors withdrew the premanufacture notices after EPA had indicated its plans to require testing or controls.

In the four cases involving rule-making, EPA determined that the chemicals presented an unreasonable risk of injury to health or the environment and promulgated rules to protect against the risks. These chemicals—(1) mixed mono and diamides of an organic acid, (2) triethanolamine salts, (3) triethanolamine salt of tricarboxylic acid, and (4) tricarboxylic acid—are ingredients in metalworking fluid. The rules, promulgated in 1984, prohibit adding any nitrosating agent, including nitrites, to

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

metalworking fluid that contains these substances. According to EPA, the addition of nitrites or other nitrosating agents to the substances leads to the formation of a substance known to cause cancer in laboratory animals.

In the cases of the consent orders for 626 chemicals, EPA determined that insufficient data existed to assess the chemicals' health and environmental effects and that an unreasonable risk may be present. Under its section 5 authority, EPA cannot require that these data be developed, but it is authorized to control human and environmental exposures to the substances until sufficient data are available. Consent orders allow limited manufacture, processing, distribution in commerce, use, and disposal of chemicals until the data are developed. In return, the firms agree in writing to implement workplace practices or controls to eliminate or reduce exposures to the chemicals. Examples of these controls are requirements for employees' use of protective equipment, such as gloves when skin contact is a concern, and implementation of worker training programs on how to handle the chemicals. Consent orders may also involve certain restrictions, such as a prohibition or limitation on a chemical's release to water, or certain tests that must be performed when a chemical reaches a designated production volume. According to EPA, this production volume level is set at the point at which the agency estimates that profits from a chemical will support the cost of testing.

In the 827 cases in which manufacturers voluntarily agreed to develop certain toxicity data before EPA completed its review, EPA determined that sufficient toxicity information was not available to evaluate the chemicals' effects and anticipated that health or environmental exposures could not be controlled through the routine workplace practices or controls normally incorporated into consent orders. EPA recommended additional testing and evaluation of the results before allowing the chemicals to be produced or imported. According to EPA, voluntary testing may be the best option available to the manufacturer if releases or exposures cannot be controlled pending testing or if the requested testing is relatively cheap and not very time-consuming. The only other alternative is to withdraw the premanufacture notice.

In the 974 cases in which premanufacture notices were withdrawn from the review process, the manufacturers decided not to proceed with plans to market the chemicals in the face of EPA's plans to require testing, impose controls, or prohibit production or use. EPA officials told us that manufacturers often drop plans to market a new chemical when the chemical's niche in the marketplace is uncertain and EPA informs them that

toxicity data will be needed for the agency to complete its evaluation of the chemical's risks. This testing can cost from a few hundred to thousands of dollars to perform.

TSCA's Regulatory Framework Ensures That EPA Will Control Few Chemicals

Although TSCA appears to give EPA broad authority to control harmful chemicals, several key provisions and their interpretation or implementation by the agency and the courts have worked together to discourage chemical control actions under the act. The legal standards for taking action and the burden of proof placed on EPA by the act make it extremely difficult for the agency to use this authority. In addition, the act encourages EPA to use other environmental laws to control chemical risks or to refer concerns to other federal agencies with health and safety responsibilities.

EPA Must Meet High Legal Standards to Take Control Actions

Under section 6 of TSCA, the existence of an unreasonable risk of injury to human health or the environment is the trigger for controlling an existing chemical. To make an unreasonable risk determination, the act requires EPA to consider more than whether the chemical is toxic or harmful to humans, animals, plants, and other organisms. The agency is to also determine the magnitude of human and environmental exposures to the chemical. Once it determines the extent of the risks presented by the chemical, EPA must determine whether these risks are unreasonable. According to EPA officials, the agency must, in effect, perform a cost-benefit analysis, considering the economic and societal costs of placing controls on the chemical. EPA must take into account the benefits provided by the various uses of the chemical, the availability of substitutes, and the reasonably ascertainable economic consequences of regulating the chemical after considering the effects of such regulation on the national economy, small business, technological innovation, the environment, and public health.

Section 5 of TSCA contains standards for imposing controls on the production, distribution, use, and disposal of new chemicals. If EPA determines that a new chemical presents an unreasonable risk, the agency must impose controls to protect against the risk. In the event that EPA does not have sufficient information to make a determination of risk, the agency has the authority under section 5 to impose controls to limit exposures to the chemical until sufficient data are developed. In the latter case, EPA can impose these controls if it can demonstrate that the chemical may present an unreasonable risk or that substantial human exposure may occur.

According to EPA officials, it is less difficult to demonstrate that a chemical may present rather than actually presents an unreasonable risk.

The reason for these requirements lies in congressional concern about the cost to industry and the economic impact of EPA's actions. TSCA provides EPA with such sweeping authority to impose controls, including bans or limits on production and restrictions on the use of harmful chemicals, that a single action could have substantial economic consequences. The requirements also reflect an underlying philosophy of the statute that manufacturers and processors have the right to produce and market chemicals and that before EPA can take any legal action to restrict this right, it must demonstrate that the risks outweigh both the costs to industry and the lost benefits of the unrestricted use of the chemical.

While concerns about the potential impact of EPA's regulations on industry are legitimate, the requirement for a finding of unreasonable risk has proven difficult for EPA to implement. TSCA does not define "unreasonable risk" and provides little guidance on what level of risk should be considered unreasonable under the act. In a June 1991 report, we cited three cases in which EPA had determined, on the basis of test results, that the chemicals—cyclohexanone, ethylhexanoic acid, and octylphenol—were dangerous but took no regulatory action.[2] We reported, for example, that over 839,000 workers were exposed to cyclohexanone and that test data had shown that the chemical adversely affected the development of embryos and fetuses in laboratory test animals. According to EPA officials, these chemicals' risks were not such that they constituted a significant risk for priority review under TSCA section 4(f) or an unreasonable risk for control under section 6.[3] EPA officials told us the agency uses a "high threshold of risk" to assess whether a chemical poses significant or unreasonable risks.

Given the recognized dangers of cyclohexanone, ethylhexanoic acid, and octylphenol and the fact that EPA had no criteria and methodology to guide its managers in determining when chemicals present a significant or unreasonable risk, our 1991 report questioned the basis for EPA's failure to take regulatory action on the chemicals. We recommended that EPA

[2]Toxic Substances: EPA's Chemical Testing Program Has Not Resolved Safety Concerns (GAO/RCED-91-136, June 19, 1991).

[3]Section 4(f) of TSCA is a priority review provision that requires EPA to initiate appropriate control action or publish a Federal Register notice that the risk is not unreasonable within 180 days (plus a 90-day extension) after receipt of test data or any other information which indicates that there may be a reasonable basis to conclude that a chemical presents, or will present, a significant risk of serious or widespread harm to human beings from cancer, gene mutations, or birth defects.

establish criteria and a methodology for determining when chemicals present risks that would trigger implementation of TSCA's regulatory provisions. We further recommended that the criteria and methodology include definitions of significant and unreasonable risk and quantitative and qualitative measures to determine when such risks are present. EPA officials told us that they do not believe that the agency can develop overall criteria and must determine significant or unreasonable risk for each individual case because each circumstance is so different. We continue to believe that some criteria or guidelines are needed to provide for the agency's consistent and systematic implementation of TSCA's regulatory provisions.

A major difficulty in making an unreasonable risk finding is the level of evidence that the act requires. EPA must develop "substantial evidence" through rule-making sufficient to withstand judicial review. This requirement, together with the unreasonable risk requirement, imposes a burden of legal proof that is greater than in the Administrative Procedure Act, which requires only that an agency's actions not be arbitrary and capricious.[4] The burden is on EPA to obtain the necessary evidence to (1) prove that the use of a particular chemical will cause great harm that cannot be alleviated in a less costly manner and (2) demonstrate that the agency has considered whether less harmful, economically viable substitutes are readily available.

Even if EPA had the substantial resources needed to develop this evidence, the outcome would not be assured. In current state-of-the-art risk assessments, some uncertainty and some basis for a legal challenge almost always exist. Furthermore, the costs to the economy of regulating a chemical are usually much more easily documented than the risks of the chemical or the benefits associated with controlling it, according to EPA officials.

The court decision on EPA's 1989 asbestos rule illustrates the substantial burden that TSCA places on EPA. As discussed above, the rule prohibited the future manufacture, importation, processing, and distribution of asbestos in almost all products. Some of the manufacturers of these asbestos products filed suit against EPA, arguing that the rule was not promulgated on the basis of substantial evidence. In October 1991, the U.S. Court of

[4]The Administrative Procedure Act, among other things, sets procedures and standards for federal agencies' rule-makings. Agencies are to adhere to these procedures and standards unless the law under which a particular rule-making is taking place sets different procedures or standards.

Appeals for the Fifth Circuit agreed with the manufacturers and sent the rule back to EPA for further consideration.[5]

In its ruling, the court concluded that the burden is on EPA to justify that the products it bans present an unreasonable risk and that EPA did not present sufficient evidence to justify the ban on asbestos. In reaching this conclusion, the court found that EPA did not consider all necessary evidence and failed to show that the control action it chose was the least burdensome reasonable regulation. As articulated by the court, the proper course of action for EPA would have been to consider the costs and benefits of each regulatory option available under section 6, starting with the less restrictive options, such as product labeling, and working up through a partial ban to a complete ban. The court further criticized EPA's ban of products for which no substitutes are currently available because TSCA explicitly requires the agency to consider the benefits of the substance for various uses and the availability of various substitutes for those uses. Thus, EPA would need to analyze each product or use of a chemical, which can number up to a hundred or more.

The court's decision on the asbestos rule is especially revealing about section 6 because EPA spent 10 years preparing the rule. In addition, asbestos is generally regarded as one of the substances for which EPA has the most scientific evidence or documentation of substantial adverse health effects. As a result of the court decision, EPA finds itself faced with the need to commit even more resources to any effort to regulate under section 6 and the possibility that the effort may not end in regulation. Officials of EPA's Office of Pollution Prevention and Toxics told us that with the court decision in the asbestos case, EPA most likely will not attempt to issue regulations under section 6 for comprehensive bans or restrictions on chemicals.

TSCA's Relationship to Other Laws Limits Its Use

Section 9 of TSCA generally requires that other environmental laws be used to address the risk posed by a chemical, if the EPA Administrator determines that such laws can eliminate or sufficiently reduce the chemical's risk. EPA has usually interpreted this section to mean that TSCA should be used primarily to fill gaps in the authorities of other laws. As a result, the Office of Pollution Prevention and Toxics has referred essentially all risks identified for existing chemicals to other EPA offices or agencies for action under these other laws. (New chemicals are dealt with under TSCA because the act is the only federal legislation that can address

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

concerns about industrial-use chemicals before they are manufactured and enter commerce.)

TSCA contains little guidance on section 9 and does not clearly articulate what EPA is expected to achieve through the use of the act's regulatory authorities. Some controversy has occurred when EPA has referred chemicals to other agencies rather than take control action, and the Congress has at times expressed concern about how little EPA has achieved under TSCA. The center of this debate is whether TSCA is a comprehensive toxics law or is a gap-filling act, as it has usually been viewed by EPA.

EPA Has Generally Used TSCA to Fill Gaps in Other Laws

According to EPA officials, TSCA's relationship to other laws has been controversial within the agency. EPA does not have a written policy or guidance on when it should exercise its discretion to use TSCA or to refer a chemical for action under these other laws. However, a 1985 legal opinion by the agency concluded that section 9 of the act states a preference for the other laws to be used to control chemical risks. In addition, various staff members in the Office of Pollution Prevention and Toxics told us that under section 9, they must refer chemical concerns to other offices or agencies for action if either an existing regulation could be revised or a new regulation could be promulgated under the authorities of the other acts to address the concerns. On the other hand, other office representatives told us that they believe that TSCA is more than a gap-filler. These officials agreed, however, that TSCA's role and relationship to other environmental laws are unsettled issues.

Because these other laws collectively cover the major sources of toxic chemical exposure, Office of Pollution Prevention and Toxics officials have identified very few chemical risks that could not be addressed, at least to some extent, under the authorities of other laws. (As shown in app. II, virtually all risk concerns—human health, environmental, worker, and consumer—associated with the industrial use of chemicals are covered by other laws.) As a result, nearly all chemical risks that EPA officials believe should be controlled are referred to the EPA offices or other agencies responsible for implementing those laws.

The five existing chemicals that EPA regulated under TSCA also could have been addressed under other legislation. EPA's Office of Air requested that hexavalent chromium in cooling towers be controlled under TSCA because a TSCA regulation could be enforced with fewer resources than a Clean Air

Act regulation. Likewise, the dioxin chemical could have been regulated under the Resource Conservation and Recovery Act, but EPA decided to use TSCA because a rule under the act would become effective immediately and the reporting requirement would cover all facilities.

By far the largest number of chemicals that EPA has controlled under TSCA are new chemicals, and EPA usually takes these actions to address concerns about workers' exposure. The Director of the Office of Pollution Prevention and Toxics told us that it is understandable that most control actions under TSCA are directed at new chemicals and worker protection because no other statute or agency program addresses worker exposure concerns before the chemicals are on the market and in the workplace.

EPA Formally Refers Few Chemical Concerns to Other Agencies

For chemicals referred to other agencies, section 9 of TSCA requires that these agencies respond to EPA's concerns. EPA is to submit to the other agency a report describing the risk, the activity or activities that present the risk, and the information on which the report is based. EPA is to publish the report in the Federal Register. The other agency is to determine if action under the law it administers can prevent or sufficiently reduce the risk and to issue an order declaring whether the activity or activities cited in the report present such risk. The agency is to respond to EPA within the time specified in EPA's report (the specified time cannot be less than 90 days). The agency must also submit a detailed statement of its findings and conclusions and publish them in the Federal Register.

EPA has referred four chemicals to other agencies under the formal process established by section 9. Three referrals were to the Occupational Safety and Health Administration (OSHA) for 4,4'-Methylene dianiline in 1985, 1,3,-Butadiene in 1985, and glycol ethers in 1986, all because of potential adverse health effects from exposure in the workplace. EPA also referred dioxin in bleached wood pulp and paper products to the Food and Drug Administration in 1990 because of concerns about exposure to dioxin in paper materials used to package food. According to EPA officials, the process of formally referring chemicals to other agencies has not been very effective for two reasons. First, EPA has difficulty meeting the unreasonable risk standard contained in the section, and the term "unreasonable risk" is not relevant to agencies, such as OSHA, whose legislation does not contain this standard. Second, EPA does not find it easy to influence the agendas of other agencies that have their own priorities.

EPA has also informed OSHA through Federal Register notices of its concerns about four other chemicals under a provision of section 9 that requires the Administrator to consult and coordinate with other agencies to obtain maximum enforcement of the act with the least burden of duplicative requirements. For these chemicals, EPA did not determine that the risks were unreasonable, and OSHA was not required to either formally rebut the finding or to report on actions to control the exposure. EPA believed that these chemicals—toluenediamine, p-Dichlorobenzene, 4,4'-Methylene bis chloroaniline, and formaldehyde—presented a significant risk to workers but not an unreasonable risk considering other factors, such as the cost of regulation and the availability of suitable substitutes. In 16 additional cases, EPA officials informally referred or made known their concerns about chemicals to other agencies. According to EPA officials, it is also general practice to share risk assessments related to occupational issues with OSHA and the National Institute for Occupational Safety and Health.

TSCA does not establish a formal mechanism for the Office of Pollution Prevention and Toxics to use when it refers chemical risks to other offices within EPA. The act also does not require the other offices to formally report on the actions they plan to take to address the risks. Although EPA did not have information on the number of these referrals, our discussions with EPA officials and review of selected chemical files indicate that these referrals are more numerous than formal referrals.

Some Believe EPA Should Use TSCA as Comprehensive Legislation

The intent of Section 9 and its effect on TSCA's role in environmental protection has been a source of contention. The first attempt to use section 9 referrals to other agencies was in February 1985, when EPA announced its intention to abandon its efforts to regulate asbestos and to refer the substance to the Occupational Safety and Health Administration. This announcement caused a public controversy in which the Congress and environmental groups charged that EPA and the Office of Management and Budget were subverting the regulatory process. In March 1985, EPA suspended the referral process and continued with its efforts to issue the 1989 asbestos rule.

Before and during the debate on the attempted asbestos referral, various offices within EPA, the Office of Management and Budget, and the Congress expressed various positions on the proper use of section 9 for coordinating interagency regulatory action. The major point of contention was whether TSCA should be an "umbrella" statute aimed at regulating all

unreasonable chemical risks or a gap-filler essentially addressing only those risks that cannot be controlled under other laws.

This contention over TSCA's role has continued as congressional oversight and authorization subcommittees have recently criticized EPA's lack of progress in controlling potentially harmful chemicals. For example, the Chairman of the Subcommittee on Toxic Substances, Research and Development, Senate Committee on Environment and Public Works, introduced a bill, the Lead Exposure Reduction Act of 1993, in April 1993 because EPA had not taken action to reduce the levels of lead in the environment, including restrictions on the continuing uses of certain lead-containing products.

A central aspect of this debate is that TSCA contains authorities to eliminate or restrict the production or use of toxic chemicals, whereas other health and environmental laws generally accept the production and use of the chemicals and provide for limits on exposures or discharges to the environment. For example, environmental laws generally provide for standards governing the amount of pollution that can be emitted or discharged by a single source (performance standards) or standards governing pollution abatement technology and practices that companies must adopt (technology standards).

In addition, these other laws have been slow to address toxics. Few of the chemicals used in commerce have been regulated under the laws. (See app. III for a description of the status of regulation of toxics under four of these laws: the Clean Water, Clean Air, Safe Drinking Water, and Occupational Safety and Health Acts.) Billions of pounds of toxic chemicals are released to the environment each year, and workers and consumers are exposed to chemicals that may put them at risk.[6]

Recognizing the need for a more comprehensive approach to addressing toxics, the Office of Pollution Prevention and Toxics is working to establish a program that focuses on pollution prevention and other strategies, such as promoting the design, development, and application of safer chemicals, processes, and technologies, to reduce toxic exposures,

[6]For example, the Toxics Release Inventory reported that manufacturing facilities in 1992 (the latest available data) released about 3.2 billion pounds of toxics into the environment and sent an additional 4.4 billion pounds off-site for treatment, disposal, energy recovery, and recycling. The inventory reports on releases of about 300 chemicals and 20 chemical categories.

releases, and risks.[7] Although TSCA's regulatory control authorities can approach toxic chemical concerns at the front-end by providing for controls or restrictions on chemical production, processing, distribution, and use, the office's approach is to seek voluntary actions by industry to reduce toxic releases or take other risk reduction actions. EPA officials believe that voluntary actions will take less time and fewer office resources than promulgating regulations under TSCA. In addition, they believe that the approach has the advantage that industry, which should have the most knowledge about the operations or circumstances generating the risk, identifies and plans the specific actions that it will take. According to EPA, industry has taken voluntary actions, such as labeling, testing, and undertaking an emissions reduction program, on 12 chemicals or groups of chemicals.

Other Countries Have Different Approaches to Regulating Chemicals

Although the other countries that we visited during our review—Canada, Germany, and Sweden—consider economic impacts in their regulatory decision-making process, none of them used the unreasonable risk standard. For example, the Canadian Environmental Protection Act of 1988 authorizes the government to control chemicals that are "toxic." The act defines a substance as toxic if it is entering or may enter the environment in a quantity or concentration or under a condition having or that may have an immediate or long-term harmful effect on the environment, health, or human life. A chemical is also defined as toxic if it is entering or may enter the environment in a quantity or concentration or under conditions constituting or that may constitute a danger to the environment on which human life depends. Canadian officials, who are familiar with TSCA, told us that they believe it is easier to control chemicals under their toxic standard than under the United States' unreasonable risk standard. According to Canadian officials, some type of control is likely for chemicals found toxic. The type of control will depend on such factors as the extent and type of risks and economic impacts.

In Germany, the major focus of the chemical control law is to classify and label chemical products on the basis of their toxicity. In addition to determining the labeling of a chemical, classification is the starting point for risk assessment. The classifications also influence legislation concerned with aspects of risk management, such as worker protection.

[7]EPA, on an agencywide basis, is also placing an increasing emphasis on pollution prevention. Citing the difficulty of achieving substantially greater reductions in environmental releases through the technology-based, end-of-the-pipe type of controls on which EPA's major programs are based, the agency's pollution prevention efforts focus on actions taken up-front, or during manufacturing and processing, to avoid or reduce the generation of toxic wastes.

The risk assessments can result in additional testing or the imposition of certain controls on the chemical, such as use restrictions. Bans or major restrictions on chemicals are rare because of the complex process established for taking these actions.

In Sweden, the major focus is also on the classification and labeling of chemicals on the basis of their toxicity. Certain mandatory controls are established for each classification category. Use restrictions may also apply, depending on the chemical's classification. Sweden's chemical control law also requires industry to substitute less hazardous chemicals for more hazardous ones.

Although the Swedish government has banned or severely restricted only a few chemicals, it has established a list of 13 undesirable chemicals that it wants to eliminate or significantly reduce by the year 2000.[8] These chemicals have been identified for complete bans or severe restrictions on use because they are considered to have sufficiently hazardous properties in combination with widespread use to warrant such action. According to Swedish officials, the phaseout of chemicals by the government cannot be avoided when the chemical industry does not follow through with its responsibility under the act to substitute for hazardous chemicals.

Options for Strengthening TSCA's Chemical Control Authorities

TSCA's regulatory provisions could be strengthened by revising the act to clarify its role and relationship to other laws and to reduce EPA's regulatory burden. Additional legislative changes would be needed if TSCA is to be a comprehensive toxics statute.

Clarifying TSCA's Role and Relationship to Other Laws

The overlap among TSCA and EPA's other environmental laws demonstrates the need for the Congress to establish clear expectations for EPA's use of TSCA's regulatory authorities. If EPA is to limit use of the act to filling gaps in other legislation, the act requires little change. The Congress could revise the act to define what gaps the act should fill or what circumstances are in the public interest and would invoke TSCA's authorities.

If TSCA is to be an umbrella act, the Congress could simply revise the act to eliminate its provisions on its relationship to other laws. EPA would then have the option to pursue risk reductions through restrictions on chemical

[8]The 13 chemical substances that Sweden plans to phase out are lead, mercury, cadmium, organic tin or organotin compounds, methylene chloride, trichloroethylene, tetrachlorethylene, creosote, arsenic, brominated flame retardants, phthalates, nonylphenolethoxylates, and chlorinated paraffins.

production, distribution, and use or through limits on releases or exposures, depending on which would be the most cost-effective. EPA's efforts to address toxic chemical concerns or risks could be carried out either through a strategy of actions under other environmental and health and safety laws, through its own authorities, or both. TSCA, with its authorities to control chemical production, distribution, and use, would be on an even footing with other environmental laws that prescribe performance and technology standards limiting the amount of environmental releases or exposures. An alternative would be to revise these provisions to explicitly provide for EPA to select the most cost-effective course of action using TSCA and/or one or more of the other laws.

Reducing EPA's Regulatory Burden

To ensure that EPA is not discouraged from taking chemical control actions under TSCA, the Congress could revise the act in two ways. First, it could change the unreasonable risk standard and the requirement that EPA use the least burdensome regulation adequate to regulate a substance. Second, it could revise the act's requirement that EPA develop substantial evidence to support a regulation.

One way to change the risk standard would be to authorize EPA to take control actions when it identifies significant rather than unreasonable risks. EPA could then make a judgment on whether the chemical's toxicity and exposures constitute significant risks of harm to health or the environment. EPA officials view the term "significant risk," as they use it in section 4(f) of TSCA to identify chemicals for priority review, as a very high threshold for action. However, they expect 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 extensive cost-benefit analysis.

For those chemicals that pose a significant risk, EPA would determine the most cost-effective actions to adequately reduce the risks. The costs and benefits of the contemplated regulations would not be factors in deciding whether to reduce risks; they would be considerations in selecting a specific course of action to deal with the risks. This two-step process for taking regulatory action would be similar to the Canadian process.

EPA's burden of proof could be reduced by changing the requirement in TSCA that EPA have "substantial evidence" to a requirement similar to the

"arbitrary and capricious" standard in the Administrative Procedure Act. Alternatively, requiring that EPA demonstrate that a chemical may present an unreasonable risk could require less documentation than requiring the agency to demonstrate that the chemical presents or will present an unreasonable risk.

Broadening TSCA's Impact

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 and risk-based approach means that the act is unlikely to address more than the most serious chemical risks, even if EPA's regulatory burden is reduced. The process of collecting information on chemical effects and exposures to support TSCA's regulations 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 achieve these goals. In a February 1993 report, we concluded that because of their inherently greater flexibility, market-based incentives can be both a less costly and more effective means of controlling pollution.[9]

More chemicals could also be addressed under TSCA, if the act's goal or purpose were to achieve reductions in exposures to and environmental releases of toxic chemicals. EPA then would not have to document the risks associated with each use of each chemical and show that they are unreasonable or significant; rather, it could show that a chemical is toxic to humans and/or the environment, exposures or releases to the environment occur or are likely to occur in substantial amounts, and opportunities exist to reasonably reduce exposures and releases. To implement this goal, changes could be made in the act to expand the types of circumstances under which EPA could take action under TSCA 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.

[9]Environmental Protection: Implications of Using Pollution Taxes to Supplement Regulation (GAO/RCED-93-13, Feb. 17, 1993).

To better support EPA's pollution prevention initiatives, TSCA could also be revised to expand the range of regulatory control options available to EPA to reduce chemical risks. These 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.

Conclusions

Although TSCA contains some unique regulatory authorities, EPA has seldom used them because the act's legal standards are so high. In addition, EPA officials responsible for implementing TSCA do not believe that the act gives them a clear mandate or directive to control more than a few chemicals. Consequently, TSCA has not had a major role in EPA's efforts to protect human health and the environment from the potential adverse effects of toxic chemicals.

EPA instead plans to continue to rely primarily on standards under other laws aimed at limiting exposures to or releases of toxic chemicals, on voluntary risk reduction, and on pollution prevention initiatives. Although we recognize that EPA has made progress in these areas, we believe that controls or restrictions on production, distribution, and use should be viable alternatives for EPA when it considers how to effectively deal with the adverse effects of toxic chemicals.

Despite their achievements, the various environmental, health, and safety programs have been slow to deal with toxic chemicals, and EPA's emphasis on voluntary industry actions is relatively new. Voluntary efforts may provide faster results than rule-making under TSCA, and industry, when presented with concerns, may be willing to take action even before EPA has the evidence or documentation required for rule-making under TSCA. However, the chemical industry is large and diverse, and it is uncertain that all firms will always act responsibly or agree with the concerns raised by EPA and its efforts to obtain voluntary action, especially when it may involve more expensive controls or reduced production of an important chemical product. In addition, strong regulatory authorities can ensure a "fair playing field" when all companies are not willing to cooperate in voluntary action and by their presence encourage industry to develop solutions on their own. For these reasons, effective and viable regulatory authorities are essential whether TSCA is to be a supplemental or umbrella act.

Even if TSCA's regulatory authorities are made easier to use, the act is unlikely to address more than the most serious chemical risks. TSCA's

approach, as well as that of the other environmental laws, is to address concerns on a chemical-by-chemical basis. Given the large number of chemicals in use, this approach is resource-intensive and time-consuming, and major reductions in toxic releases to the environment are difficult to achieve.

Matters for Congressional Consideration

In some cases, banning, restricting, or placing other controls on production, distribution in commerce, use, or disposal may be the most cost-effective way to deal with toxic chemicals. TSCA contains authorities to take these actions, but because of high legal standards and uncertainty about the act's role and relationship to other laws, these authorities are too difficult to use. Consequently, these types of actions are not viable alternatives when EPA is considering how to address chemical risks.

In its deliberations on reauthorizing TSCA, the Congress may wish to consider changes to allow the act to be used in preference to other environmental laws, when appropriate, and reduce EPA's burden of proof in using the act's regulatory authority, as discussed earlier in this chapter. In addition, to supplement TSCA's chemical-by-chemical and risk-based approach, the Congress may wish to consider establishing overall goals for reductions in the use of toxic chemicals and provide EPA with tools, such as market-based incentives, to achieve these goals.

EPA's New Chemical Review Process Does Not Fully Assess Health and Environmental Risks

EPA's new chemical review process has enabled the agency to review over 20,000 substances in a timely manner. However, the reviews do not ensure that the potential human health and environmental risks of new chemicals are fully identified because EPA has limited data on their toxic effects and exposures.

TSCA does not require industry to test new chemicals for their toxicity, and industry generally does not voluntarily perform this testing. Thus, EPA must predict toxicity by comparing new chemicals to other chemicals with similar molecular structures and for which toxic effects are known. However, its prediction method has been questioned in the scientific community, and a recent EPA study has confirmed that the method does not always produce accurate results.

EPA must also predict exposure to new chemicals on the basis of the limited information contained in premanufacture notifications. Notifications are not binding, and once EPA completes its reviews and production begins, manufacturers are not required under TSCA to limit chemical production levels or uses to their estimates in the notifications. Increased production or use of the chemicals in different ways can significantly increase exposure and risks. Although TSCA authorizes EPA to require the industry to submit additional notifications for significant new uses or production increases, the agency has made limited use of these authorities because applying them on an individual chemical basis is a resource-intensive process.

EPA's New Chemical Review Process

From the start of the new chemical review program in 1979 through September 1993, EPA reviewed a total of about 24,000 new chemical submissions, an annual average of about 1,700 notifications over this period.[1] In more recent years, the number of notices has increased—EPA estimates that it will review 2,500 notifications in 1994. In nearly all cases, the agency has performed its review within the 90 days TSCA requires.[2]

Despite the increase in the number of notifications, EPA's budget for new chemical review has not substantially changed. For example, the new chemical review budget was $13.7 million in fiscal year 1984 to review

[1]Included in this total is EPA's review and approval of about 5,000 applications for exemption from premanufacture notification reporting requirements. Under the authority contained in section 5 of TSCA, EPA has limited the reporting of relatively low risk substances, such as chemicals that are to be produced in volumes less than 1,000 kilograms per year or manufactured in small quantities solely for research and development.

[2]EPA, for good cause, can extend the premanufacture notice review period for an additional 90 days.

fewer than 1,300 notifications and $15 million in fiscal year 1993 to review an estimated 2,500 notifications. In more recent years, the agency's resources for new chemical review have declined. For example, much of the detailed work involved in developing toxicity and exposure assessments is performed under contracts, for which funding decreased from $8.6 million in fiscal year 1988 to about $5 million in fiscal year 1993.

According to EPA officials, the agency has dealt with an increasing workload by making the program more efficient and focusing its review process on the substances of greatest concern. These substances are those about which little is known other than that they are structurally related to known harmful chemicals. According to EPA, about 5 percent of the premanufacture notices received annually go through the agency's more detailed or full review process. In the process's earlier stages, those chemicals are screened out that EPA (1) anticipates will have a limited amount of exposure or (2) using preliminary structure activity relationships analyses, estimates will have few, if any, adverse human health or environmental effects. In addition, substances in certain chemical categories are identified for possible regulatory action without undergoing a full review.

During a full review, EPA evaluates the chemical's risks by conducting a chemistry analysis, searching the scientific literature and agency files for and analyzing toxicity data on structurally similar chemicals, calculating potential releases of and exposures to the chemical, and identifying potential new uses of the chemical. On the basis of this review, EPA makes a decision to either take no action, require controls on the use, manufacture, or disposal of the chemical, or ban the chemical pending the receipt and evaluation of test studies performed by the chemical's manufacturer or processor.

EPA Usually Does Not Have Test Data When Reviewing New Chemicals

To assess chemicals' risks, EPA needs to know the chemicals' toxic or adverse human health and environmental effects. Potential health effects that may be considered include skin and eye irritation, blood effects, cancer, birth defects, and harm to the central nervous system. Consideration of potential environmental effects include those on aquatic life, such as fish and algae. Another major consideration is chemical fate, that is, the characteristics of a chemical, such as its ability to be absorbed in water, and its ultimate disposition in the environment.

EPA officials told us, however, that the agency frequently lacks comprehensive toxicity data when reviewing new chemicals. Although TSCA does not require manufacturers to test new chemicals, they are to submit with premanufacture notices the results of the testing that has been done. According to EPA, less than half of all premanufacture notices contain any toxicity data.

EPA's Performance in Predicting Toxicity for New Chemicals Is Mixed

Because comprehensive test data are generally not available when reviewing new chemicals, EPA uses structure activity relationships (SAR) analysis to identify potential chemical hazards. In SAR analysis, EPA scientists' predictions of the characteristics and potential effects of a new chemical are based on the known characteristics and effects of chemicals with structures whose key parts are similar to those of the new chemical. According to EPA officials, the SAR technique is used for each new chemical under review.

The U.S.-European Union's Project to Compare SAR Predictions With Test Results

In 1993, EPA completed a study with the European Union (formerly the European Community), whose member countries require certain toxicity testing before new chemicals are reviewed and go on the market. For 144 chemicals, the European Commission (the executive arm of the European Union) sent EPA information similar to that which is generally contained in premanufacture notices. EPA then used this information in SAR analysis to predict the toxic properties of the chemicals and carry out preliminary hazard assessments. The physical properties and hazards that EPA identified for the individual chemicals were then compared with those identified by the European Union using test data. EPA wanted to determine how well its SAR approach worked in identifying chemicals' toxic effects, and the European Union wanted to determine whether SAR could be used as a substitute for testing to avoid costs and the destruction of laboratory animals.

The comparisons of EPA's predictions of individual chemical properties or effects with the actual test results showed that SAR's accuracy varied, depending on the effect or property being compared. For example, the SAR predictions were correct for only 50 percent and 63 percent of the chemicals when predicting their boiling point and vapor pressure, respectively. On the other hand, the accuracy rate for biodegradation[3] was 93 percent.

[3]Biodegradation refers to the capability of chemicals, under normal conditions, to be broken down in the environment by the action of living things, especially microorganisms.

The U.S. Perspective on the Study Results

The EPA officials' overall conclusion from the study was that the SAR approach to screening new chemicals is useful and effective in identifying chemicals that may be toxic and in need of further scrutiny to determine whether to regulate them. However, according to the officials, the SAR approach appears to have limitations in predicting physical chemical properties under some circumstances and in predicting the exact type and level of toxicity of the chemical, especially in connection with general systemic (health) effects.

EPA officials further concluded that although the SAR approach has largely been successful in identifying chemicals of concern, the process could be improved by selectively incorporating specific testing schemes into the process. The officials said that results of this testing would provide insight into chemical toxicities and improve SAR's predictive capabilities. According to the officials, the testing would provide a richer data base upon which to base predictions.

The European Union's Perspective on the Study Results

The European Union officials concluded that the study identified a number of possibilities for making greater use of SAR as part of the testing package for new chemicals. According to the officials, the SAR approach performed extremely well in predicting biodegradation and acute toxicity to fish and daphnia. On the other hand, the officials said that given the relatively low cost of tests for physical chemical properties, the results of this study did not constitute a persuasive argument for introducing SAR as an alternative for testing. The officials stated that of the physical chemical properties, SAR performed best in predicting water solubility, but even with this property SAR could not be used with confidence for all chemical groups.

For health effects, the European Union officials did not believe that the SAR approach was sufficiently developed for estimating eye and skin irritation or sensitization. On the other hand, the officials believed that SAR was relatively successful in assessing acute lethal toxicity. The officials also noted that although SAR tended to underestimate the severity of the effects, it provides an excellent additional tool to decide about further testing for subchronic, repeated dose toxicity. In addition, the officials stated that the study results suggest that SAR could usefully be incorporated into a battery of approaches for evaluating the mutagenic potential of a new chemical.

Example of Potential Impact of Inaccurate SAR Predictions

In 1990, EPA received a premanufacture notification for a new chemical generically described as dialkyldialkoxysilane. On the basis of SAR analysis, EPA identified potential adverse health effects (skin and eye irritation and liver and lung toxicity) and environmental effects (toxicity to aquatic organisms at low concentrations) for the chemical. EPA, however, did not make an unreasonable risk finding and did not impose regulatory controls because exposures and releases of the chemical were expected to be low.

In 1991, EPA received another premanufacture notification for the same chemical from a different manufacturer. Because the submitter of the earlier premanufacture notification had not yet commenced production and the chemical was not yet on the TSCA inventory, EPA decided to evaluate the second notification as a new chemical. The second notification contained the results of several toxicity tests for the chemical; EPA found, on the basis of these tests, that potential inhalation exposure considerably increased because the actual vapor pressure of the chemical was 100 times greater than had been previously predicted using SAR analysis. On the basis of the new data, EPA found that the chemical posed an unreasonable risk and proposed regulations to control new uses of the chemical.

An official in EPA's new chemical review program told us that in the vast majority of cases, a second notification would not be sent before production of the chemical had begun and that the second notification would not result in a new chemical review of the chemical. The official also pointed out that most notifications do not contain test data and that had such data not been available for dialkyldialkoxysilane, EPA would not have identified and acted upon the unreasonable risk presented by exposure to the chemical.

SAR Depends on the Availability of Test Data on Similar Chemicals

Without adequate test data on chemicals with similar molecular structures, SAR analysis does not have a reliable basis for predicting the toxicity of new chemicals. For example, an EPA official who participated in the project with the European Commission told us that the SAR approach had some difficulty in predicting systemic toxicity because of a lack of test data on similar chemicals. Situations also arise in which EPA must review new chemicals with molecular structures not similar to any chemical for which it has health and environmental effects data. An official in EPA's new chemical review program told us that he was not comfortable using SAR analysis to predict the hazards posed by such chemicals but that no other

option exists since EPA cannot require chemical manufacturers to conduct tests of new chemicals before the agency's review.

Uncertainty in EPA's Exposure Estimates May Limit Regulation

EPA's exposure assessments for new chemicals are based on information contained in premanufacture notices. This information generally includes data on how the manufacturer anticipates that the chemical will be used and estimates of production volumes, chemical releases, and number of employees in contact with the chemical at the company's plants. These estimates are not binding and do not have to be amended once manufacturing begins, unless EPA promulgates a rule specifically to require the reporting of new uses or significant increases in production or releases.

Chemical manufacturers can also modify the information in premanufacture notices during EPA's 90-day new-chemical review process. EPA officials told us that manufacturers have, when informed that EPA had targeted one of their chemicals for regulation, amended exposure information. The officials believe that the manufacturers made some of these changes to avoid regulatory control of their chemicals.

At our request, EPA officials provided us with examples of exposure data changes, including reductions in production volumes and environmental releases and revisions in predicted uses of the chemicals resulting in lower levels of expected exposure. For example, when informed of EPA's determination that uncontrolled release of a new chemical to surface waters could present an unreasonable risk to aquatic organisms, the company informed the agency of a revised manufacturing process that would result in a tenfold reduction in predicted water releases. In another case, EPA determined that production of the new chemical in substantial quantities could potentially cause significant human exposure to the substance. The manufacturer then submitted new information indicating that the chemical would have a narrower use than originally identified and would be processed using a system that would prevent releases of the chemical outside of the production process. As a result of the manufacturers' reported changes in these cases, EPA could not support its initial concerns about the chemicals and could take no regulatory action.

EPA Makes Limited Use of TSCA's Authorities to Obtain Additional Data

Although TSCA authorizes EPA to control chemicals pending development of needed test data and to require chemical manufacturers to notify EPA of significant new uses that develop after manufacture begins,[4] the agency uses these authorities for only a small percentage of new chemicals. Using these authorities is difficult because EPA must take these actions on a chemical-by-chemical basis, which can require considerable resources.

EPA Requires Additional Testing for a Small Percentage of Chemicals

If EPA determines that a new chemical may present an unreasonable risk or may result in significant exposure but that insufficient data exist to adequately assess the chemical's health and environmental effects, TSCA section 5(e) authorizes EPA to control exposure to the substance until sufficient data are available. If EPA believes that the manufacturer can control exposure to the chemical through routine workplace practices or controls, it will enter into an agreement or consent order with the manufacturer to allow production under these controls until test data are developed. The manufacturer can perform the testing and seek to have the controls removed, or it can choose to forgo the testing and continue the controls. In some consent orders, manufacturers have agreed to perform certain testing when the production volume reaches a designated level. If EPA anticipates that routine workplace practices or controls will not adequately reduce exposure, the manufacturer cannot begin production until it performs the additional testing and EPA evaluates the results.

For about 6 percent of the new chemicals reviewed, the manufacturers or processors either agreed to manufacture the chemicals with controls on exposure pending the development of test data or provided additional information during EPA's review process.[5] In about one-third of these cases, EPA would not allow manufacture to begin until the necessary testing had been performed. According to EPA, this 2 percent of chemicals reviewed accounted for 80 percent of the test data obtained through its new-chemical review process.

In 1988, EPA implemented a policy aimed at increasing the amount of testing performed on high-volume new chemicals by making use of its section 5(e) authority. This policy calls for basic toxicity testing for new chemicals with planned annual production volumes of 100,000 kilograms

[4]The term "new uses" refers not only to additional applications of a chemical, but also to significant increases in the projected volume of production or a significant change in the type, magnitude, or duration of human or environmental exposure.

[5]EPA made section 5(e) findings for these chemicals and for an additional 4 percent of premanufacture notices that the submitters later withdrew.

or more, if EPA believes that substantial or significant human exposures or substantial environmental releases will occur. From October 1989 through March 1993, EPA issued 54 orders under the policy, about 1 percent of about 7,200 premanufacture notices it received during this period.

EPA Has Issued Significant New Use Rules for a Small Portion of Chemicals

TSCA section 5(a)(2) rules requiring that manufacturers or processors submit premanufacture notices for significant new uses of chemicals provide EPA with the opportunity to obtain additional exposure data and reassess the risks posed by new chemicals. However, according to EPA officials, to issue one of these rules, the agency generally must show that (1) a reason exists to be concerned about the chemical's toxicity and (2) the potential exists for uses, other than those contained in the premanufacture notice, that could lead to higher exposure.

In July 1989, EPA issued a rule to establish an expedited process for issuing significant new use rules. The process enables EPA to more quickly issue these rules for chemicals for which the agency has entered into section 5(e) consent orders and for chemicals that may present human health and environmental hazards, if exposures or releases are substantially different from those in the premanufacture notice. However, the burden is still on EPA to identify future uses and to support the need for the additional reporting on a chemical-by-chemical basis. From October 1989 through March 1993, EPA issued significant new use rules for 382 of the approximately 7,200 new chemicals reviewed. EPA issued a total of 12 rules before fiscal year 1990.

Other Countries Place More of the Burden on Industry

Two of the countries that we visited, Canada and Germany, also review new chemicals before they enter commerce—at the premanufacture stage in Canada and at the premarketing stage in Germany. However, unlike the U.S. practice, these countries require manufacturers to perform certain tests and submit the results to the government at the beginning of the review process. Sweden's Act on Chemical Products places the main responsibility on manufacturers to assess the risks of both new and existing chemicals and provide adequate information on their effects to chemical users. Sweden plans to implement requirements similar to those of Germany in 1995, when it joins the European Union.

Germany and other European Union countries maintain a separate inventory for new chemicals, and chemicals on this inventory are subject to additional testing and review when the annual amount marketed

reaches certain levels. In addition, a new manufacturer has to notify the government before marketing the chemical, even though the chemical may have been marketed by the original manufacturer for several years.

In Canada, requirements for additional testing are also triggered as production or import volumes increase. A new chemical is generally added to the existing chemicals inventory only after 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. Until the chemical is placed on the inventory, anyone planning to produce the chemical must notify the government. In Sweden, a new manufacturer of a chemical product generally has to notify the government that it is manufacturing the product.

Options for Revising TSCA

Various options exist for revising TSCA to enhance EPA's ability to obtain the information it needs to assess the potential risks of new chemicals and to take control actions to protect against those risks. We discuss below some options to address the problems that we noted in TSCA.

Increasing the Availability of Toxicity Data for New Chemicals

To help ensure that EPA has sufficient information on toxic effects when reviewing new chemicals, manufacturers could be required to test their chemicals and submit the results to EPA with their premanufacture notifications. The major drawback to testing is its cost to the chemical industry, which representatives of the Chemical Manufacturers Association believe could reduce chemical research and innovation. For example, Canadian officials told us that testing a chemical in that country can cost up to $130,000, and a representative of the Swedish chemical industry told us that the government's planned testing requirement will cost about $188,000 per chemical.

To reduce these costs or to delay them until the chemicals are produced in larger quantities, Canada and Germany require testing based on production volume. The testing requirements for low volume chemicals are less extensive and complex than those for high volume chemicals.

As an option, testing could be targeted to those areas in which EPA's SAR analysis does not accurately predict toxicity. TSCA could be amended to authorize EPA to establish a set of tests for new chemical reviews. Some tests could be required with the premanufacture notifications; more complex and costlier tests could be required on the basis of a chemical's

production or environmental release levels. According to EPA officials, the tests needed would not be as comprehensive as those in Germany and Canada because SAR analysis works well for characterizing some toxic effects. They also said that testing could result in more accurate SAR analysis because the testing would provide more toxicity information on which to base future SAR analysis.

On the basis of the results of the EPA/European Union study, SAR analysis is generally not reliable for predicting physical chemical properties. Testing for these properties is not very costly. For example, according to EPA, testing to determine a chemical's boiling point can range from about $420 to $560. The cost to determine vapor pressure can range from about $1,790 to $2,520.

Revising TSCA to require EPA to review new chemicals before they are marketed rather than before they are manufactured would reduce the costs of initial testing. According to EPA, about half of the premanufacture notices that the agency reviews are for chemicals that never enter the marketplace. Thus, a requirement that certain initial test results be submitted with notifications would apply to far fewer new chemicals.

Another option for increasing the availability of toxicity data for new chemicals would be to enable EPA to require certain testing without going through rule-making. 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 because it does not have sufficient toxicity data on chemicals with structures similar to the new chemicals submitted by manufacturers.

Improving EPA's Assessments of Exposures to New Chemicals

To provide additional assurances that new chemicals do not result in harmful use, TSCA could be revised to require manufacturers to submit additional premanufacture notices or comparable data when production volumes or uses change significantly from the estimates in the previous premanufacture notices. This requirement could be implemented in various ways. One way would be to make statements in premanufacture notices concerning projected production levels and uses binding on manufacturers. Under this approach, the manufacturer or processor submitting the notice would be required to submit additional notices for significant increases in production volume or new uses. In addition, other firms that decide to manufacture or process the chemical would also have to submit premanufacture notices of their plans. Currently, once EPA's review of a premanufacture notice has been completed and the agency is

notified that manufacture has begun, the chemical is added to the TSCA inventory of chemicals. At that point, any manufacturer can produce the chemical in any amount and for any use without notifying EPA, unless EPA has promulgated a significant new use rule.

Making premanufacture notices binding would provide EPA with up-to-date exposure information without the burden of issuing a large number of significant new use rules. This approach would also encourage chemical manufacturers and processors to pay more attention to their production volume and use estimates and would provide an opportunity for EPA to reassess the risks of new chemicals as their production increases and uses expand.

Under this approach, manufacturers would be required to submit new notices to EPA, if production volumes, releases, and exposures increased significantly or if the manufacturing process or the use of the chemical changed significantly from those in the original premanufacture notice. The burden of identifying when new notices are needed would be shifted to the industry, and EPA would not have to expend the time and resources to issue significant new use rules. On the other hand, industry would have some additional costs to prepare new notices. The number of new notices would largely depend on how EPA defines a "significant" change and how many new chemicals become commercial successes. Of the over 20,000 premanufacture notices reviewed, about 10,000 chemicals entered commerce. According to EPA officials, only about 2,000 of these chemicals attained any significance in the marketplace.

Conclusions

Although TSCA recognizes that the best time to assess the risks posed by chemicals is before the production and use of the substances begin, the act's authorities for obtaining the information on which EPA can base these assessments are ineffective. TSCA does not require routine testing of new chemicals, and the chemical industry provides little test data with its premanufacture notifications. In addition, the EPA/European Union study showed that EPA's use of SAR analysis to determine potential toxicity posed by new chemicals often does not accurately determine the chemicals' properties and the full extent of their adverse effects.

Concerns also exist about whether the data submitted in premanufacture notifications accurately reflect actual exposures once production and use of new chemicals begin. The production and exposure information submitted in premanufacture notices is not binding under TSCA and may

not reflect actual conditions once the chemical commences production and its marketing expands. Given these limitations in TSCA's new-chemical review program, we do not believe that EPA can be assured that it identifies the potential risks posed by the chemicals.

Matters for Congressional Consideration

In its deliberations on reauthorizing TSCA, the Congress may wish to consider revising the act to place more of the burden on industry to demonstrate that new chemicals are safe. Some of the burden could be shifted by requiring industry to test new chemicals and to notify EPA of significant increases in production, releases, and exposures or of significant changes in manufacturing processes and uses after new chemicals enter commerce.

Without Changes, EPA Will Not Review the Risks of Many Existing Chemicals

EPA has made little progress in reviewing the risks of existing chemicals. EPA's information on chemical effects and exposures is often scarce, incomplete, or outdated, and TSCA's data-gathering authorities are difficult to use and not very effective in supporting EPA's review process. As a result, the reviews are generally lengthy and resource-intensive. Because of competing priorities, EPA has made limited resources available for review of existing chemicals.

EPA Has Been Slow to Assess Existing Chemicals' Risks

Under its existing chemicals program, EPA has reviewed the risks of about 1,200 substances. This amount represents only about 2 percent of the approximately 62,000 chemicals in the TSCA inventory that were already in commerce when EPA began its new-chemical review program in 1979 and were not reviewed as new substances. Although EPA reviewed the other 10,000 chemicals in the inventory as new chemicals, it generally has not reviewed them after their production began and they were placed on the inventory. In total, EPA has reviewed about 16 percent of the inventory, either as new chemicals or existing ones.

However, even this small percentage overstates EPA's progress in fully identifying chemical risks. First, EPA's reviews often do not include all uses of individual existing chemicals. For example, EPA is clustering some chemicals by use, such as chemicals used in paint stripping. This approach enables EPA to review more chemicals and compare their relative risks and trade-offs. On the other hand, EPA does not examine other uses for the chemicals that may pose risks.

EPA's progress may also be overstated because many of the completed reviews may be outdated. Production volumes may have increased and new uses may have developed since EPA conducted the reviews. In addition, the toxicity information that EPA had available at the time of the reviews may not have included all the potential toxic effects of the chemicals.

According to EPA, the existing chemical review process typically takes from 12 to 16 weeks and requires about 100 staff hours. During this process, nearly all the burden is on EPA to compile and analyze the available data on a chemical. The agency must search its files and public data bases for information on the chemical's effects, physical properties, production volumes, manufacturing processes, uses, releases to the environment, and other data, such as the number of workers exposed to the chemical. Because limited information is generally available, EPA uses

various computer models to estimate or project certain data, such as the amounts and types of environmental releases. A chemical can have various potential health and environmental effects that EPA needs to consider in evaluating its risks. In addition, chemicals often have several uses—as many as 100, or even more, if they have been on the market for a long time. The agency has to also consider a chemical's individual uses because use largely determines the amount of exposure.

Of about $53.6 million for existing chemicals in fiscal year 1994, about $11.2 million was allocated for chemical review and associated risk management activities. The remainder went primarily to chemical testing and carrying out congressionally mandated activities related to the control of asbestos, lead, and PCBs.

With its current level of resources and review process, EPA is reviewing about 100 existing chemicals per year. At this rate, it would take over a century and a half just to cover the approximately 16,000 chemicals in the inventory that EPA believes are of higher priority because of their production levels and chemical structures.

TSCA Provides Limited Information to Support EPA's Chemical Reviews

The completeness and quality of EPA's reviews are dependent on the information that the agency has on the chemicals' potential toxic effects and the amounts and types of exposures that occur. TSCA authorizes EPA to require manufacturers and processors to conduct toxicity testing and to provide exposure-related information on their chemicals. However, EPA rarely uses these authorities because they are costly and time-consuming to use. As a result, EPA generally has to rely on (1) limited and sometimes outdated information in its files and in publicly available data bases and (2) computer modeling to project or estimate key information, such as environmental releases.

Little Chemical Testing Is Done Under TSCA

Industry voluntarily conducts some chemical tests. In addition, other federal agencies, such as the Department of Health and Human Services' National Toxicology Program, have chemical testing programs. Universities and other organizations may also test chemicals for their effects.

However, few test data are available for many chemicals. A 1984 study by the National Research Council is the most comprehensive analysis of the availability of test data. The Council sampled the entire TSCA inventory and

then determined what test data on health effects (the analysis did not include environmental effects) were available for the sample. According to the analysis, no health toxicity information was available for almost 80 percent of the chemicals. A 1989 analysis by EPA staff of about 1,300 substances on the Organization for Economic Cooperation and Development's list of international high volume chemicals showed that many of them did not have the major types of health and environmental toxicity information. Only acute (effects of a single exposure) or general toxicity data were found for more than half of the chemicals. Less than one-fourth of them had any reproductive or developmental toxicity data. Aquatic toxicity data were found for 41 percent. (According to EPA officials, the analysis did not determine the data's validity or reliability, only whether data were available.) A more recent analysis performed by the Organization for Economic Cooperation and Development identified about 500 of over 1,300 high volume international chemicals as having potential health or environmental concerns but having few test data publicly available to assist in evaluating their risks. According to the Director of EPA's Office of Pollution Prevention and Toxics, little is known about the effects of many chemicals used in commerce.

As of May 1994, EPA had issued only 30 test rules covering 121 chemicals. In addition, EPA has entered into negotiated test agreements or consent agreements to test 59 more chemicals, and industry has voluntarily agreed to test 230 chemicals. According to EPA officials, the agency has not used its authority to require more testing, largely because it must undergo a lengthy and costly rule-making process. EPA must demonstrate that it needs the test results, issue a proposed rule for public comment, consider the comments it receives, and issue the final rule. According to EPA officials, this process can take as long as 24 to 30 months and cost between about $68,500 and $234,000.

EPA Has Limited Exposure Data

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 whether the chemical is being released to 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 it acts and its ultimate disposition in the environment.

Actual measurements of exposure in the environment, workplace, and home, on an extensive basis, for the thousands of chemicals in use are not practicable because of the monitoring equipment and staff resources required. Consequently, EPA estimates the types and amounts of exposure on the basis of a chemical's physical properties, how it is used, the industrial processes for producing and processing it, production volumes, and the type and amount of releases to the environment.

However, the basic data that EPA needs to develop its estimates are often not available, and EPA must rely on models or other analytical techniques. According to EPA officials, sufficient data on exposures rarely exist to permit full analysis of a chemical, and the agency has little assurance that its exposure assessments are accurate and complete.

Chemical Use and Release Data

The amount of exposure to a chemical can vary substantially depending on its use. For example, only workers are potentially exposed to chemicals that are used solely for industrial purposes, whereas both workers and consumers can be exposed to chemicals used in household products. However, TSCA does not require routine reporting of chemical use information, and EPA receives very little of this information under its current industry reporting rules.

EPA is planning to revise its TSCA Inventory Update Rule to add reporting requirements for information on chemical use.[1] According to EPA officials, the current rule collects some key information, such as production volumes, needed to identify chemicals of concern, but additional information on use is essential to determine possible exposure routes and scenarios and identify potentially safer substitute chemicals. EPA is also considering broadening the scope of industries that have to report and increasing the reporting frequency from every 4 years to every 2 years. The chemical industry has expressed concern about the additional reporting burden and cost of these changes; its specific concerns are how much information it must report on each chemical and whether EPA will require it to report on all chemicals.

Even with additional information provided under an expanded inventory update rule, EPA will lack key data on "downstream" chemical uses. Manufacturers produce certain chemicals and often sell to processors,

[1]The rule requires chemical manufacturers and importers to provide updated information for the TSCA inventory every 4 years. This information includes chemical identity, plant sites, and production volumes. Two updates have taken place, the first in 1986 and the other in 1990. The next scheduled update is 1994.

who prepare these chemicals or mixtures for distribution in commerce. The processors' customers may then buy the chemicals for use as solvents, lubricants, or various other purposes.

According to EPA officials, manufacturers generally know how the processors use chemicals, and processors generally know their customers' major uses. However, a processor's customer may use a chemical for a purpose that the processor is not aware of or even sell some of the chemical to another firm for a different purpose. EPA officials said that some chemicals have many uses, some of which may surprise the manufacturer or processor. According to EPA officials, these downstream uses can be important factors in assessing exposure, but TSCA does not provide EPA with the authority to collect information from these users.

Another important factor in assessing exposure is the release of a chemical to the environment during its manufacture, processing, distribution, use, and disposal. Such releases are a potential source of exposure for plants, animals, and people living near industrial and disposal sites. In assessing the extent of this exposure, EPA considers the quantity released; whether the releases were to the air, water, or land; the chemical's migration through the air, water, and soil; the time required for it to biodegrade or break down in the environment; and whether it accumulates in the tissue of animals or plants.

However, according to the head of the EPA office responsible for developing exposure estimates, few release data are available for chemicals not included in the Toxics Release Inventory, which contains estimates of annual releases to the air, water, and land for about 300 chemicals. Many other potentially harmful chemicals are produced in large quantities. For example, over 16,000 nonpolymer existing chemicals are produced in amounts of 10,000 pounds or more annually. To obtain some indication of the types and amounts of releases for chemicals not in the inventory, EPA develops estimates on the basis of where and how the chemicals are manufactured and how much is produced, but it acknowledges that the accuracy of these estimates is uncertain.

Worker and Consumer Exposure Data

The extent of worker exposure is especially important in assessing a chemical's risks because workers are often in contact with the substance. The key information needed is the number of exposed workers and the concentration and duration of the exposure.

EPA's major source of data on the number of workers exposed is the National Occupational Exposure Survey. This survey, which the National Institute for Occupational Safety and Health conducted in the early 1980s, contains estimates of the number of workers exposed nationally to over 10,000 chemicals. It also contains data such as the number of sites at which a chemical is manufactured or used. Although EPA officials recognize that the survey is old and probably outdated, it is often the only available data on the number of workers exposed to a particular chemical. According to National Institute for Occupational Safety and Health and EPA officials, funds are not available to update worker exposure information.

Because the survey does not provide the needed information and little is available elsewhere, EPA generally estimates how exposure occurs and its duration. These estimates are made on the basis of information that the agency can compile on the chemical's physical properties, its uses, and the industrial operations or procedures involved in manufacturing, processing, and using the chemical.

EPA's files on 2-Mercaptobensothiazole, a chemical primarily used to produce rubber, inhibit corrosion, and act as a fungicide, illustrate some of the agency's difficulty in obtaining worker exposure data. EPA's late 1991 and early 1992 review of this chemical found only outdated information on the number of workers exposed and no data on how long exposure occurs. An occupational hazard survey conducted by the National Institute for Occupational Safety and Health from 1972 to 1974 resulted in an estimate that as many as 558,893 workers may be exposed to the chemical. On the other hand, the National Occupational Exposure Survey estimated that only 2,398 workers were exposed. EPA officials did not know the reason for the difference in the two estimates but speculated that (1) the hazard survey may have included all of the workers in the industries using the chemical and (2) the exposure survey may have included only those workers in direct contact with the chemical. The number of exposed workers was important because test results on the chemical indicated possible adverse effects on the fetuses of pregnant women who are exposed to the chemical.

Consumers may also be exposed to potentially toxic chemicals through skin contact or inhalation of the fumes of products containing these substances. When reviewing a chemical, EPA often does not have information on all of its uses, including as an ingredient in household products. Even if EPA is aware of consumers' use of a chemical, it does not have good information on the number of people using the products or the

frequency and duration of their use. According to an EPA official, the agency needs much better information on consumers' exposure to assess the risks of chemicals but does not believe that extensive monitoring of consumers' exposure to products is practicable.

To obtain the information that it needs, EPA is considering estimating human exposures to chemicals in consumer products on the basis of measurements of the concentrations of product residue on indoor and outdoor sources. However, industry representatives have expressed concerns about the cost and complexity of such an effort. For example, assessing consumers' exposure to a single chemical may involve making measurements for its use in various consumer products.

Other Countries Have Major Initiatives Under Way

The other countries that we visited—Canada, Germany, and Sweden—have recently established systematic processes for reviewing existing chemicals. Recognizing that it was not feasible to immediately review all of the chemicals in commerce, the Canadian Environmental Protection Act of 1988 required the development of Priorities Substances Lists. The government is to periodically develop a list of high priority chemicals for assessment. Each chemical on the list is to be assessed and the results made available to the public within 5 years. The government's goal is to comprehensively assess and report on 100 priority substances of greatest concern by the year 2000.

Germany is implementing a 1993 European Union regulation that requires the member countries to participate in a systematic review process for existing chemicals. On the basis of information submitted by chemical manufacturers and importers, the European Union plans to periodically develop priority lists of chemicals for member countries to review, with the initial focus on high volume chemicals. The Union plans for its members to assess up to 50 chemicals—and possibly more—each year.

In addition to a requirement that manufacturers and importers assess the risks of their own chemicals, the Swedish government has implemented a project to develop a systematic process for identifying chemicals with properties and patterns of use that make them potential candidates for general restrictions on their use. During the pilot project, the government started with a list of about 2,000 high volume or environmentally hazardous chemicals. This list was narrowed down to about 200 chemicals on the basis of their environmental hazards and production volumes. After

eliminating low-volume, regulated, and unregistered substances, the government identified 41 chemicals for review.

These countries place more of the burden on industry for the review of chemical risks. Sweden's Act on Chemical Products makes manufacturers and importers primarily responsible for determining chemical risks. In Canada and Germany, the government is responsible for assessing chemical risks. However, it is easier for the government to obtain chemical information from industry. In Germany, the European Union regulation being implemented requires industry to compile and report the data needed to review the risks of existing chemicals. On the other hand, in Canada, the government is responsible for compiling available chemical information. However, under the Canadian Environmental Protection Act, the government can collect additional information on a chemical by informing manufacturers and importers of the needed data through a notice in the Canada Gazette, which is similar to the Federal Register in the United States. The government can also write letters to the manufacturers or importers to demand that they submit the needed data by a certain date.

Options to Strengthen TSCA's Provisions on Reviewing Existing Chemicals

TSCA's chemical review provisions can be strengthened by requiring the systematic review of existing chemicals and expanding EPA's information-gathering authorities. A requirement for systematic review would ensure that EPA's risk assessments of existing chemicals receive sufficient agency priority and resources. The expanded information-gathering authorities would enable the agency to obtain more of the data it needs to perform these reviews.

Systematic Review of Existing Chemicals

In providing for EPA to 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. Accordingly, EPA's priority has been to comply with the statutory requirement for new chemicals. EPA's Office of Pollution Prevention and Toxics has increased its emphasis on existing chemicals but has not been able to obtain additional resources for this purpose because of competing needs for limited resources.

TSCA could be revised to establish a goal for the review of existing chemicals. Such a goal could focus EPA's and the chemical industry's attention on completing these reviews and put existing chemicals on more

of an equal footing with new chemicals. Because of limited resources and the large and growing number of existing chemicals, a goal to review all existing chemicals within the near future would be impracticable. Even the 16,000 chemicals that EPA considers of potential concern because of their production volumes and chemical structures could take many years to review. EPA would need the flexibility to identify those chemicals most in need of review and give them priority. TSCA could be revised to set out a systematic review process for EPA to implement or to require EPA to establish and carry out such a process.

TSCA's Information-Gathering Authorities

Approaches similar to those of Germany and Canada would be two basic options for improving TSCA's information-gathering powers. Under one option, EPA would still rely largely on its files and publicly available data bases as the major sources of information for its reviews. EPA would have authority to demand, without undergoing costly and time-consuming rule-making, that industry provide certain additional information that EPA needs to complete its reviews. To limit the potential reporting burden on industry, this authority could be limited to filling specific data needs on those chemicals scheduled for review during a specific period.

The other option would be to place on industry more of the burden for existing chemical reviews. The industry could be required to compile and submit essential chemical data to EPA, as is done for new chemicals in submitting premanufacture notices. EPA would specify the reporting form and the information to be contained in these "manufacture notices." Manufacturers or importers could individually submit the required data or they could collectively submit it for an individual chemical.

The industry's costs to prepare the notices could be reduced by requiring this reporting for only those chemicals scheduled to undergo EPA's review in the short term. The agency could notify the industry of chemicals that it will assess during a certain period and require that the notices be submitted by a particular date. Because more data are available to review and EPA generally has to consider more uses and potential pathways of exposure for existing chemicals, the review period probably would need to be longer than the 90 days for new chemicals.

Conclusions

Very little is known about the risks of many of the chemicals to which workers, consumers, the general public, and plant and animal life are potentially exposed. EPA has been slow to assess the risks of existing

chemicals, and for those that have been assessed, frequent gaps in the data raise questions about the completeness of the reviews.

The burden is essentially on EPA in reviewing existing chemicals, and several factors have contributed to EPA's slow progress. These include limited resources, a greater emphasis on new chemicals, and the difficulty in using TSCA's data-gathering authorities. Although these authorities would appear to provide EPA with the tools to obtain the data it needs, the act's restrictions on EPA, such as the requirement that EPA promulgate a rule to obtain data on a chemical, have made using the authorities time-consuming and costly. EPA's experience in implementing the act has shown that the restrictions place a heavy burden on the agency, given available resources.

The countries that we visited have initiatives under way to systematically review existing chemicals. These initiatives illustrate potential options for revising TSCA to enable EPA to make better progress in the agency's efforts to review existing chemicals. We believe that a substantial increase in the number of these reviews is unlikely unless TSCA is changed to give such reviews more emphasis and to place more responsibility on industry to compile the information needed to assess chemical risks.

Matters for Congressional Consideration

To put existing chemicals on a more equal footing with new chemicals, the Congress could consider revising TSCA to set specific deadlines or targets for the review of existing chemicals. These deadlines or targets would provide for EPA to establish priorities to review those chemicals that, on the basis of their toxicity, production volumes, and potential exposure, present the highest risk to health and the environment.

The Congress could also consider revising TSCA to shift to the industry more of the burden for the review of existing chemicals. If more of this responsibility were shared by the industry, EPA could review more chemicals with its current level of resources. In deciding how much burden to shift, the major consideration for the Congress is to what extent is providing the data to show that chemicals are safe a cost of doing business for the chemical industry. As discussed in this chapter, the burden could be shifted in various ways and to varying extents.

TSCA's Provisions on Confidential Business Information Need to Be Revised

A key component of EPA's strategy to revitalize its toxics program is to disseminate information on toxic chemicals to educate the public on chemical risks and involve them in environmental decision-making. Nonetheless, recognizing the need to protect against the disclosure of trade secrets or other proprietary data to competitors, TSCA allows companies to designate the information submitted to EPA as confidential if it meets certain criteria. Other federal agencies and federal contractors can obtain access to this confidential business information if they can demonstrate that they need it to carry out their responsibilities and they can protect the information against unauthorized release.

According to the industry, a large amount of the TSCA data it submits to EPA is confidential business information. While EPA considers many of the confidentiality claims to be legitimate, it does not believe that others meet the criteria established in the act. EPA further believes that the resources necessary to protect the information designated as confidential discourages other federal agencies with health and safety responsibilities from obtaining it. In addition, the confidentiality designation limits the dissemination and usefulness of the data because many interested groups are not allowed access to the data, including private organizations and public, state, and local groups responsible for health and environmental issues.

EPA is currently reviewing confidentiality claims and thus far has been successful when it has challenged their appropriateness. However, this effort is resource-intensive, and EPA has challenged only a small percentage of the claims. EPA is also implementing various voluntary and regulatory measures to reduce claims.

Confidentiality Claims Limit Data's Usefulness and Are Costly

EPA believes that public release of important environmental data gives everyone the ability to participate in the broader national effort to address chemical issues. EPA's Toxic Release Inventory illustrates the ability of information to dramatically promote and empower initiatives by the toxics community. Toxic Release Inventory data have helped industry to identify problems and target actions and have given the public an opportunity to learn about problems and become involved in their solutions.

Information on toxic substances is available in numerous trade publications and scientific literature, and nonconfidential TSCA data are available through several sources, such as the National Technical Information Service, the National Library of Medicine, and the TSCA

hotline. The confidential TSCA data, however, are available only through the companies that submit them. TSCA's data also provide the only available comprehensive view of what is known about the flow and environmental effects of commercial chemicals.

Consequently, the data are of great value to various government officials and to scientists and researchers in general. Providing state government officials with access to TSCA's confidential data could enable them to control potential risks from chemicals subject to TSCA reporting, using their authorities under state laws. The scientific community could review risk assessment decisions made by EPA or test EPA's hazard and risk predictions if it had the confidential TSCA information to perform the tasks. In addition, federal agencies, such as the Occupational Safety and Health Administration, could also use the information for promulgating worker protection standards.

TSCA's confidential data is available upon request to staff in various EPA offices and to other federal agencies. However, most EPA offices are generally not familiar with the data available under TSCA, and even those that are aware of the data do not attempt to use them because of the difficulties associated with obtaining security clearances and handling confidential data. Federal officials outside of EPA also limit their requests for confidential data because they are required to give the information the same level of protection afforded by EPA. In addition, confidentiality claims make it difficult for federal officials to know that the data exist within EPA.

State and local governments and public groups, such as environmental organizations and unions, would like to obtain access to the confidential business information submitted to EPA to protect the health and safety of the public. However, TSCA does not provide for disclosure of such information to them.

Safeguarding confidential information also imposes significant costs on EPA. Staff discussions on chemicals must be held in secure areas, documents can be reviewed only in secure environments, meeting notes themselves become confidential documents and must be logged and guarded under lock and key, and computers must have their memories and permanent storage media erased after processing confidential data. In addition, all staff working with or accessing confidential documents must have appropriate security clearances. The protection that EPA provides for TSCA's confidential data is equivalent to that provided to information deemed "secret" for national security purposes. Since EPA does not

account for many of these costs separately, it cannot quantify how much these requirements cost the agency.

Many Claims Are Inappropriate

EPA initiated its Confidential Business Information Review and Challenge Program in August 1990 to review confidentiality claims in TSCA filings and, when appropriate, to challenge the claims. By September 1992, industry had voluntarily amended and withdrawn over 600 claims after EPA's inquiries. On the basis of their experience with TSCA data, EPA officials believe that the problem with inappropriate claims is extensive. They plan to continue to review claims but do not expect to increase their efforts because of limited resources.

Concerned about how often its challenge program identified inappropriate confidentiality claims, EPA retained the Hampshire Research Associates, Inc., in 1992 to study how EPA's policies on confidential information have affected the implementation of TSCA. The study examined the confidential business information claims made, the validity of the claims, and the impact of inappropriate claims on the usefulness to the public of TSCA data.

The Hampshire Study found that many of the claims submitted under TSCA were not appropriate, particularly for health and safety data. For example, the study noted that between September 1990 and May 1991, EPA reviewed 351 health and safety studies submitted by chemical companies and challenged 77, or 22 percent. In each of these cases, the submitter amended the claim when challenged.

EPA is concerned about the industry's confidentiality claims over information on the identity of chemicals in health and safety studies. TSCA mandates the availability of health and safety data, with protection given for proprietary information. Although EPA takes a broad view of what is a health and safety study and believes the legislative history supports this position, it is difficult for the agency to prevent the chemical industry from making confidentiality claims for data that relate to health and safety, given that the statute does not actually define the term. Consequently, EPA believes that it would be helpful if TSCA were revised to clarify that data submitted under the statute be made available to the public if the data relate to a chemical's effects on public health and safety.

The Hampshire study also pointed out that information already publicly available was submitted to EPA as confidential business information. For example, information contained elsewhere in newspaper articles and

corporate annual reports was submitted as was publicly available information from EPA's Toxics Release Inventory, a system that contains nationwide information on toxic chemicals emitted into the air, ground, and water by manufacturing facilities. In one case, a submitter provided EPA with a final draft study of the effects of working with particular chemicals for prolonged periods, a study that had already been provided to union representatives of the submitter's employees. Despite the fact that all of the relevant information had already been made public, the submitter claimed the company's name, the union's name, plant sites, and chemical identities as confidential information. Following discussions with EPA, the submitter agreed to drop all confidentiality claims for the information submitted.

The Hampshire study also compared data collected under TSCA with similar data collected under the Emergency Planning and Community Right-to-Know Act of 1986. This act required thousands of industrial facilities, starting in 1988, to report annually to EPA and to states the estimated quantities of hundreds of toxic chemicals emitted directly into the environment or transported to waste treatment, storage, or disposal locations.The study shows that under the Emergency Planning and Community Right-to-Know Act, confidentiality claims are much more restrictive. Under this act, industry can make claims only for chemical identity, a top corporate official must sign the claims, a company must submit information to substantiate a trade secret claim, and EPA can levy penalties on corporate officials making false trade secret claims under the act. None of these conditions applies for claims under TSCA. The Hampshire study pointed out that industry is far more likely, because of the more liberal requirements of TSCA, to claim as confidential information the data collected under TSCA than nearly identical data reported under the Emergency Planning and Community Right-to-Know Act.

EPA invited all interested parties to discuss the points raised in the Hampshire study and to identify ways to improve EPA's existing confidential business information policies under TSCA. EPA held its first public meeting in October 1992, and subsequent meetings have been held among a variety of states, environmental groups, and the regulated community.

All 12 chemical industry commentators were skeptical of the points and conclusions raised in the study. They said that the purpose of TSCA information is to provide EPA with a factual basis for chemical regulation,

not to provide a basis for disseminating data on the chemicals to other interested organizations.

The industry commentators were also concerned about the protection of confidential information on new chemicals submitted for EPA's review before they are manufactured. One commentator observed that requiring the disclosure of identity for these chemical substances could provide a company's competitors with critical information on research direction and on the timing and developmental progress of new products. Such information can affect the marketability of new chemical products. EPA responded by saying that it is aware of the sensitivity of information on the new-chemicals process and that for this reason, the focus of EPA's effort to disseminate toxics information has been on those chemicals that have already gone through the new-chemicals review process and may be legally used in commerce.

Although the chemical industry was critical of the report, most of the chemical industry commentators accepted the study's basic finding that the chemical industry does make improper confidentiality claims and needs to address such claims. The industry commentators stated that EPA could use its workshops, newsletters, and question-and-answer bulletins to inform the industry of EPA's confidential business information policy. In addition, some commentators were amenable to a change in the TSCA process to provide for holding information confidential for only a specific period, provided that the chemical industry is given an opportunity to justify extending the period, as circumstances warrant. For example, a chemical company could furnish comments in response to an EPA request that the company resubstantiate a claim by a specific date. If the company did not submit such comments, EPA would automatically declassify the information previously submitted on the chemical.

EPA Is Considering Alternatives to Reduce Inappropriate Claims

Using study recommendations and meeting results, EPA published in the Federal Register, dated June 4, 1993, the notice of a public meeting to obtain comments on confidential business information policies and certain proposed EPA actions that would change confidential business information requirements. After considering comments on the proposed actions, EPA announced in a July 6, 1994, Federal Register notice the availability of its final action plan.

EPA's plan includes various voluntary and regulatory measures to reduce confidentiality claims. One of the voluntary measures is the development

of educational programs to apprise industry of EPA's policy on confidentiality claims and procedures. In addition, the Chemical Manufacturers Association has offered to implement educational programs for its members and the regulated chemical community. The Chemical Manufacturers Association presented a course on the subject in December 1993 and in February and June 1994. EPA is also planning to prepare instructional papers clearly identifying the types of confidentiality claims that it will not accept.

Other measures of EPA's reform program include:

- Exploring how to make TSCA's confidential information available to the states. This project is under way and is supported by the Chemical Manufacturers Association and the Forum on State and Tribal Toxics Action.
- Having the regulated community voluntarily review old submissions of claims on a periodic basis to weed out unnecessary ones.
- Continuing to review claims and challenging those that appear to be inappropriate.

EPA is also considering changes to its regulations to require (1) industry to substantiate claims at the time of submission, (2) senior corporate officials to sign claims to ensure that the information claimed as confidential meets statutory and regulatory requirements, and (3) submitters to resubstantiate claims at a future date when confidentiality may no longer be required. According to EPA, the agency has already begun to implement many of the measures in its plan and expects to achieve significant progress by January 1995.

Authorities to Claim Confidentiality Are More Restrictive in Countries Visited

The other countries that we visited also allow industry to make confidentiality claims. However, these countries generally specify more types of data that cannot be claimed as confidential. In addition, they generally have more requirements for substantiating or justifying confidentiality claims.

While health and safety studies are the only type of information on which TSCA restricts confidentiality claims, Canada generally does not allow claims on data such as chemical uses and safe handling procedures. Exposure data are confidential in Germany, but it generally does not allow claims for information such as the chemical's trade name, physical chemical properties, precautionary and emergency measures, and

evaluations of toxicological tests. Sweden is more restrictive in that it generally limits claims to chemical identity and some business aspects, such as the volume of production. (Although these types of data would appear to provide the public with information on the potential dangers of chemicals without revealing proprietary information, some U.S. industry representatives have expressed concern that the information could, in some cases, reveal trade secrets.)

Upon making confidentiality claims in Sweden, chemical manufacturers must submit evidence substantiating that disclosure of the data would adversely affect business. In Germany, chemical manufacturers must indicate the information that is commercially sensitive and provide evidence that its disclosure might cause the company industrial or commercial harm. Canada also requires some substantiation of claims but not the extent of justification required in Sweden and Germany.

Conclusions

EPA needs a process that will both protect legitimate confidential business information claims under TSCA and discourage the chemical industry from filing inappropriate claims. EPA is concerned that the health and safety data that should be available to the public is now being claimed by industry as confidential business information. While EPA currently reviews a limited number of confidentiality claims for appropriateness, this process is very resource-intensive and would be difficult to expand, given EPA's limited resources.

TSCA does not permit the sharing of confidential business information with states. If state governments could be provided with access to this information, it would enable them to control potential risks from chemicals subject to TSCA reporting, using their state authorities. This would provide the public with another line of defense to protect health and the environment.

Canada, Germany, and Sweden also recognize the need to protect trade secrets. However, they place more restrictions than the United States does on the types of information that can be claimed as confidential.

Administrative initiatives planned by EPA include educating the chemical industry on confidential business information policies and procedures and having the chemical industry periodically review old claims to weed out those that have expired. Although EPA plans to pursue these and other changes administratively, we believe that legislation may be needed,

especially for some of them, such as making confidential business information available to states.

Matters for Congressional Consideration

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

- clarify that health and safety data cannot be claimed as confidential business information,
- require substantiation of confidentiality claims at the time that the claims are submitted to EPA,
- limit the length of time for which information may be claimed as confidential without resubstantiation of the need for confidentiality,
- establish penalties for the false filing of confidentiality claims, and
- authorize states to have access to confidential business information when they can demonstrate to EPA that they have a legitimate need for the information and can adequately protect it against unauthorized disclosure.

Regulations Promulgated Under Section 6 of the Toxic Substances Control Act

Polychlorinated Biphenyls (PCB)	Because the Congress believed that PCBs posed a significant risk to public health and the environment, TSCA specifically prohibits the manufacture, processing, distribution in commerce, and use of all PCBs in other than a totally enclosed system, unless authorized by EPA, and requires their proper disposal. PCBs, which have been used primarily in electrical equipment, 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. EPA has issued various rules to implement these requirements.
Chlorofluorocarbons (CFC)	In 1978, EPA banned nonessential uses of CFCs as propellants in aerosol spray containers. EPA took this action because of a concern 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. CFCs have numerous other uses, ranging from solvents to air conditioning. Litigation for EPA to act on these other uses and international concern about ozone depletion led to an international agreement in late 1988 to freeze production of five major CFCs at 1986 levels and cut production levels up to 50 percent by 1999. EPA issued a final rule under the Clean Air Act in August 1988 that allocates production quotas to current producers on the basis of their 1986 production levels.
Dioxin	In 1980, EPA promulgated a rule prohibiting Vertac Chemical Company from disposing of its wastes containing 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) stored at its Jacksonville, Arkansas, facility. The rule also required that any other persons planning to dispose of TCDD-containing wastes notify EPA 60 days before their intended disposal. TCDD, 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 is likely to result in adverse human health effects.
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. 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, in friction products such as brake linings. In July 1989, EPA issued a final rule to ban the manufacturing, importing, and processing of nearly all asbestos products. The rule was to begin phasing out asbestos-containing products in August 1990 and complete the phaseout by 1997. EPA was challenged in federal court by asbestos manufacturers, and in October 1991 the Fifth Circuit Court of Appeals 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. 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.

Hexavalent Chromium

In 1990, EPA banned the use of hexavalent-chromium-based water treatment chemicals in commercial cooling towers on the basis of health risks associated with human exposure to air emissions. Hexavalent chromium is a known human carcinogen that is also widely used in industrial cooling towers. 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. According to EPA, hexavalent chromium was being released from a large number of unidentified cooling towers.

Other Major Laws That Can Address Industrial Chemical Concerns

Law	Regulated action
Clean Air Act of 1963, as amended	Protect and enhance air quality to promote public health and welfare.
Federal Water Pollution Control Act of 1956, as amended (Clean Water Act)	Restore and maintain the chemical, physical, and biological integrity of the nation's waters.
Safe Drinking Water Act of 1974, as amended	Protect the quality of all sources of drinking water.
Resource Conservation and Recovery Act of 1976, as amended (RCRA)	Regulate the generation, transportation, treatment, shortage, and disposal of hazardous wastes.
Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended (Superfund)	Finance cleanup measures for releases of hazardous substances and leaking hazardous waste dumps.
Marine Protection, Research, and Sanctuaries Act of 1972, as amended	Regulate the dumping of materials into oceans and prevent or strictly limit the dumping of material that adversely affects human health or the marine environment.
Occupational Safety and Health Act of 1970, as amended	Develop and enforce mandatory job safety and health standards to ensure as far as possible that employees have safe and healthful working conditions.
Consumer Product Safety Act of 1972, as amended	Protect the public against unreasonable risks of injury associated with consumer products.

Status of Regulation of Toxic Chemicals Under Selected Laws

The following narratives summarize the status of toxic chemical regulation under the Clean Water, Clean Air, Safe Drinking Water, and Occupational Safety and Health Acts.

Clean Water Act

In July 1991, we reported that excessive levels of toxic pollutants getting into the nation's rivers, lakes, and streams is a serious water quality problem.[1] Under the Clean Water Act, the principal tools for controlling toxic water pollution are numeric discharge limits in permits issued to facilities discharging wastes to surface waters. These permit limits are largely based on national effluent guidelines and criteria documents developed by EPA.

We also reported that these national standards control only a limited number of toxic discharges. EPA was slow to revise existing national effluent guidelines and to develop new ones. Specifically, some existing guidelines did not reflect the latest advances in treatment technologies available to eliminate toxic and nonconventional discharges, and many categories of industries discharging toxics were not covered by such guidelines. EPA was also slow to develop and revise criteria documents. According to EPA officials, the lack of resources hampered their efforts to issue more timely criteria documents.

Our recent update of EPA's progress in developing criteria documents showed that only a few of them had been developed or updated since our 1991 report. For a list of 126 priority toxic pollutants, EPA, as of September 30, 1993, had issued human health criteria documents for 91 of the chemicals and aquatic life criteria documents for only 26 of them. Aquatic life criteria documents for 12 of the priority pollutants had been revised, whereas none of the human health criteria documents had been revised. Human health and aquatic life criteria documents had also been issued for eight nonpriority pollutants. EPA was in the process of developing criteria documents for 12 additional priority pollutants and 11 nonpriority ones and revising the criteria documents for 1 priority and 2 nonpriority pollutants.

Clean Air Act

Section 112 of the Clean Air Act authorized EPA to establish standards to regulate emissions of hazardous air pollutants. However, by 1990 EPA had promulgated standards for only seven substances. Dissatisfied with this

[1]Water Pollution: Stronger Efforts Needed by EPA to Control Toxic Water Pollution (GAO/RCED-91-154, July 19, 1991).

slow pace, the Congress established a list of 189 toxic pollutants in the Clean Air Act Amendments of 1990 and directed EPA to impose standards with a new two-phase strategy. For the first phase, the amendments set out a schedule for promulgation of standards for all 189 of the pollutants by November 2000. As the second phase of control, after these standards have been met, certain facilities may be subject to further regulation in situations in which EPA determines that additional standards are required to protect health and the environment.

EPA is already behind in meeting the schedule set by the 1990 amendments. The agency's first deadline was to promulgate 40 standards by November 15, 1992. It did not promulgate its first standard until September 1993 and did not plan to issue the remaining standards until February 1994, nearly 15 months behind schedule.

Safe Drinking Water Act

Chemicals can enter drinking water supplies as a consequence of surface or ground water contamination in conjunction with chemical production, use, or disposal. The Safe Drinking Water Act, enacted in 1974, required EPA to, among other things, establish standards or treatment techniques for drinking water contaminants that could adversely affect human health. By the mid-1980s, EPA had regulated only 23 contaminants. Concerned about drinking water quality and frustrated with the pace at which EPA was developing regulations, the Congress amended the act in 1986 to require EPA to regulate 83 specific contaminants by 1989, plus an additional 25 contaminants every 3 years thereafter.

A September 1993 EPA report to the Congress stated that 76 of the 83 contaminants had been regulated and the remaining 7 were in process. According to the report, EPA will regulate an estimated total of 112 contaminants by 1995. Although the report noted that other contaminants could be a problem in some locations and at some wells (over 77,000 industrial, pesticide, food, and drug chemicals are released to the environment to some extent), EPA said that a continuing stream of these regulations would add considerably to the regulatory burden on states and drinking water systems and detract from implementation of the priority contaminants among the first 112 standards. EPA estimated that the annual state funding shortfall for implementing federal drinking water requirements is approximately $162 million.

Occupational Safety and Health Act

A key responsibility of the Occupational Safety and Health Administration (OSHA) under the Occupational Safety and Health Act is to issue safety and

health standards for the workplace. However, employees continue to be exposed to many hazardous work practices, conditions, and substances because of delays by OSHA in issuing these standards. Since 1971, OSHA has promulgated fewer than 30 health and 40 safety standards, and it routinely takes up to 10 years from the time the agency recognizes the need to regulate until the regulation becomes final. One attempt by OSHA to speed up the process was successfully challenged in court. OSHA had updated the permissible exposure limits for over 400 substances in one rule-making effort that took less than 2 years. However, the court ruled that OSHA could not change permissible exposure levels for multiple substances without providing substantial evidence in support of each change.

Major Contributors to This Report

Resources, Community, and Economic Development Division, Washington, D.C.	Bernice Steinhardt, Associate Director, (202) 512-6501 Edward A. Kratzer, Project Director Raymond H. Smith, Jr., Project Manager Donald E. Pless, Senior Evaluator Frank J. Gross, Senior Evaluator
Philadelphia Regional Office	Denise R. Dias, Senior Evaluator Victoria A. Snyder, Evaluator

Ordering Information

The first copy of each GAO report and testimony is free. Additional copies are $2 each. Orders should be sent to the following address, accompanied by a check or money order made out to the Superintendent of Documents, when necessary. Orders for 100 or more copies to be mailed to a single address are discounted 25 percent.

Orders by mail:

U.S. General Accounting Office
P.O. Box 6015
Gaithersburg, MD 20884-6015

or visit:

Room 1100
700 4th St. NW (corner of 4th and G Sts. NW)
U.S. General Accounting Office
Washington, DC

Orders may also be placed by calling (202) 512-6000 or by using fax number (301) 258-4066, or TDD (301) 413-0006.

Each day, GAO issues a list of newly available reports and testimony. To receive facsimile copies of the daily list or any list from the past 30 days, please call (301) 258-4097 using a touchtone phone. A recorded menu will provide information on how to obtain these lists.

PRINTED ON RECYCLED PAPER

United States
General Accounting Office
Washington, D.C. 20548-0001

Bulk Mail
Postage & Fees Paid
GAO
Permit No. G100

Official Business
Penalty for Private Use $300

Address Correction Requested