REPORT BY THE

Comptroller General

OF THE UNITED STATES

EPA's Efforts To Identify And Control Harmful Chemicals In Use

The Toxic Substances Control Act of 1976 gave the Environmental Protection Agency (EPA) the responsibility for identifying, assessing, and controlling unreasonable risks to health or the environment from the manufacture, processing, distribution, use, or disposal of the 60,000 existing chemicals now in commerce, To date, EPA has acted to control four existing chemicals and has conducted priority reviews of two other chemicals. In addition, EPA has identified 22 other chemicals that it has determined need testing for certain health and environmental effects. However, EPA has not yet finalized the rules requiring chemical firms to conduct the needed testing of these chemicals

Since 1982, EPA has taken several actions which strengthened its existing chemicals program. Also, the President's fiscal year 1985 budget includes proposed increases for the program. Although these actions may help achieve the act's objective, GAO believes that additional emphasis is needed to ensure that (1) testing begins for the 22 chemicals that EPA has already determined require testing and (2) priority review is given to chemicals that present or will present a significant risk of serious or widespread harm from cancer, birth defects, or gene mutations. This report includes a recommendation to EPA and matters for the Congress' consideration in addressing these areas.

GAO/RCED-84-100
JUNE 13, 1984

COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON D C 20548

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The Honorable Robert T. Stafford
Chairman, Committee on Environment
and Public Works
United States Senate

The Honorable Jennings Randolph
Ranking Minority Member,
Committee on Environment and
Public Works
United States Senate

The Honorable James J. Florio
Chairman, Subcommittee on Commerce,
Transportation and Tourism
Committee on Energy and Commerce
House of Representatives

This report on the Environmental Protection Agency's efforts to implement the Toxic Substances Control Act and its mandate to identify, assess, and control existing chemicals which present an unreasonable risk to health or the environment, is in response to a December 21, 1982, letter from the Chairman and Ranking Minority Member of the Senate Committee on Environment and Public Works and, later, the Chairman, House Subcommittee on Commerce, Transportation, and Tourism, Committee on Energy and Commerce.

As arranged with your offices, unless you publicly release its contents earlier, we will make this report available to other interested parties 30 days after the issue date. At that time, we will send copies to the Administrator, Environmental Protection Agency; the Director, Office of Management and Budget; the Chairman, Council on Environmental Quality; and other interested parties upon request.

Charles A. Bowsher

Comptroller General
of the United States

D I G E S T

Today, nearly 60,000 chemicals are in use in the United States and about 1,000 new chemicals are proposed each year for manufacture. Under the Toxic Substances Control Act of 1976, the Environmental Protection Agency (EPA) is responsible for identifying, assessing, and controlling unreasonable risks to health or the environment from the manufacture, processing, distribution, use, or disposal of new and existing chemicals--those currently in commerce. This report focuses on EPA's efforts to review and control existing chemicals; another GAO report addresses EPA's program to review new chemicals.[1] (See pp. 3 to 8.)

The Chairman and the Ranking Minority Member of the Senate Committee on Environment and Public Works in December 1982 and, later, the Chairman of the House Subcommittee on Commerce, Transportation, and Tourism, Committee on Energy and Commerce, requested GAO to review EPA's current progress in implementing the existing chemicals program. (See pp. 9 to 10.)

EXISTING CHEMICALS PROGRAM A LOW PRIORITY, BUT IMPROVEMENTS BEGUN

Since 1982, EPA has begun to make progress in implementing the existing chemicals program by establishing a process for identifying, assessing, and controlling existing chemical hazards. Although these improvements should help EPA meet the act's objective, the existing chemicals program has been a low priority in relation to other activities required by the act.

From fiscal years 1981 through 1983, there had been a downward trend in EPA funding for this program. The program received $23 million for

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[1]Assessment of New Chemical Regulation Under the Toxic Substances Control Act (GAO/RCED-84-84).

fiscal year 1984, a 33 percent decline from fiscal year 1981 funding and a 2 percent increase from fiscal year 1983. EPA stated that it has focused its efforts and resources on meeting certain requirements of the act having time-related deadlines, such as the 90-day review of new chemicals being introduced into the market and the act's mandate to regulate polychlorinated biphenyls, known as PCBs. (See pp. 17 to 19.)

Until 1982, EPA had not established a comprehensive strategy, process, or organization for reviewing unreasonable risks from existing chemicals. Previous GAO and EPA studies have concluded that until 1982, the program had no clear sense of direction and had organizational and staffing problems (see p. 8). However, during 1982 and 1983, EPA began to make progress in implementing the existing chemicals program by establishing a process for identifying, assessing, and controlling existing chemical hazards; developing a plan for implementing the program; and establishing an existing chemicals task force to develop, monitor, and manage the program. (See pp. 20 to 22.)

Since the act's passage 7 years ago, EPA has regulated four existing chemicals. EPA has identified 60 existing chemicals, through its new assessment process, that may present an unreasonable risk and need to be evaluated to determine what, if any, regulatory controls are needed.[2] EPA stated that resource constraints will result in only a few of these chemicals being considered for regulatory control action each year.

Recognizing these problems, the President's fiscal year 1985 budget reverses the downward

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[2]The act regulates chemical substances that present unreasonable risks to health or the environment. However, the act's criteria--"may present," "presents," or "will present" an "unreasonable risk" or "significant risk"--and the level of evidence needed for EPA to implement the act vary depending on the regulatory activity involved, such as the testing of chemicals, chemical recordkeeping and reporting, and the controlling of chemicals.

trend in EPA funding by proposing resource increases of $4.9 million, a 21 percent increase from fiscal year 1984, for the existing chemicals program. Although the proposed resource increases could help accomplish the act's objectives, it remains to be seen whether the resources are adequate or to what extent they will address the risks of toxic chemicals. (See pp. 19 to 26.)

NO TESTING HAS BEEN REQUIRED FOR CHEMICALS THAT EPA DETERMINED NEEDED TESTING

The act authorizes EPA to require manufacturers to test a chemical to determine its health and environmental effects if it is suspected of presenting an unreasonable risk of injury to health or the environment and if there are insufficient data to evaluate its toxicity, cancer-causing potential, or environmental effects. The act established a committee, known as the Interagency Testing Committee,[3] to recommend chemicals for testing. EPA is required to initiate rulemaking proceedings within 1 year from the Committee's recommendation to require testing or to publish its reasons for not doing so. (See p. 29.)

Through December 1983, the Committee recommended 72 chemicals for testing. In the Committee's judgment, these chemicals should be tested because certain of their health or environmental effects are not well-defined. (See p. 31.) Depending on the test results, some of these 72 chemicals could be added to the 60 chemicals that EPA is currently reviewing to determine if any regulatory controls are needed.

As of December 1983, EPA determined that 41 of the 72 Committee-recommended chemicals needed to be tested and 31 either did not require testing or were under review. EPA decided not to require testing of certain chemicals because they were already being tested by

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[3]The Committee, made up of members from eight federal agencies including EPA, is charged with identifying and recommending to EPA high-priority chemicals that need to be tested for health and/or environmental effects.

other federal agencies or industry; their manufacture, import, or exposures were limited; or adequate data already existed to characterize their health and environmental effects. (See p. 33.)

Of the 41 chemicals that needed testing, EPA determined that 22 chemicals would be mandatorily tested under EPA regulations. Another 19 chemicals would be tested through negotiated, voluntary testing agreements between EPA and chemical firms. Implied authority exists under the act for EPA to negotiate voluntary testing agreements. (See pp. 32 to 36.)

Initially, EPA did not meet the act's mandate to initiate chemical test rulemaking proceedings (or publish reasons for not doing so) within the 1-year deadline. According to EPA, limited resources prevented it from meeting the act's deadline. As a result, an environmental group sued EPA and, in January 1981, a court order put EPA on a 3-year schedule to address the backlogged chemicals. By the end of 1983, EPA had cleared up the backlog and met deadlines for chemicals recommended by the Committee since the 1981 court order. (See p. 31.)

Between July 1980 and December 1983, EPA had proposed test rules requiring industry to test 22 chemicals, but none of these rules has become final. As a result, chemical manufacturers have not yet been required to test any of these chemicals. EPA stated that the delays in finalizing these rules were caused by limited resources being shifted to meet both the court-ordered schedule for reviewing backlogged chemicals and the deadlines for reviewing 21 additional chemicals recommended by the Committee since the 1981 court order. Six of the proposed rules are over 2 years old. (See pp. 33 to 34.)

Although the act does not include any deadline for issuing a final test rule, GAO believes that EPA should follow through by finalizing proposed test rulemakings within a reasonable period of time to ensure that chemical tests are started and conducted and that results on a chemical's health and environmental effects are obtained. An EPA official stated that 12 to 18 months is a reasonable time to finalize

proposed rules. Such test results are necessary for EPA to begin assessing chemicals for risk-reduction actions. (See p. 41.)

To save resources and start testing sooner, in 1982 EPA began to emphasize negotiated, voluntary testing with chemical manufacturers rather than require mandatory testing. Under this voluntary approach, and in most cases, test studies have been initiated and data have been received by EPA from 12 to 18 months sooner than would occur under a test rule. (See pp. 34 to 36.)

EPA recognizes that not all chemicals are appropriate for voluntary, negotiated testing agreements. Such factors as the number of manufacturers of a specific chemical or the complexity of testing may preclude this approach. (See p. 35.)

Recommendation to the Administrator, EPA

To ensure that chemical tests are started and conducted and that results on a chemical's health and environmental effects are obtained, GAO recommends that the Administrator, EPA, finalize proposed test rulemaking within a reasonable time, such as a goal of 12 to 18 months after proposal. If EPA is not able to finalize test rules in a reasonable time, it should inform the Congress of the delay, the reasons, and suggested solutions, such as negotiated testing agreements, additional resources, or legislative changes. (See p. 42.)

PRIORITY REVIEWS INITIATED FOR TWO CHEMICALS

Because the Congress was concerned about risks of cancer, gene mutations, and birth defects from chemicals, the act requires EPA to give priority to reviewing chemicals which involve these risks. Upon receiving information from any source indicating that a reasonable basis exists to conclude that a chemical presents or will present a significant risk of serious or widespread harm from cancer, birth defects, or gene mutations, section 4(f) of the act requires EPA to assess the chemical's risk within 180 days. (See p. 13.)

EPA has received information on hundreds of known or highly-suspected cancer-causing

chemicals which could be potential candidates for section 4(f) review. It has designated and assessed two such chemicals for the 180-day priority review. (See p. 15.)

The act does not specify what kinds of or how much information is needed for a chemical to be designated for priority review; rather, it allows EPA to determine the information needed. EPA has interpreted the act to require substantial amounts of data before a chemical can be designated for priority review. EPA has stated that both biological effects data and information on the extent of human exposure to these chemicals are needed before the 180-day review requirement of section 4(f) applies.

Once a chemical is designated for priority review, the act requires EPA to either initiate regulatory action or publish its reason why the risk is not unreasonable. (See p. 13.) According to EPA, a constraint of section 4(f) is that it does not give EPA a third option of determining that further information-gathering may be needed. EPA stated that once a chemical is designated for priority review, the 180-day limit for review may not be sufficient time to gather the necessary exposure data to make a reasonable assessment of a chemical's risk. (See pp. 13 to 15.)

Environmental organizations such as the Conservation Foundation and the Natural Resources Defense Council, however, disagree with EPA's interpretation of section 4(f) because that interpretation calls for more data than they believe the act intended. The Defense Council has filed a suit against EPA claiming that sufficient data on the chemical formaldehyde currently exists for EPA to designate it for priority review. EPA is now reconsidering designating formaldehyde for priority review. (See p. 16.)

The act's legislative history gives no guidance in implementing the section 4(f) priority-review provision, such as how much data are needed; also, the act gives EPA the discretion to determine what constitutes a significant risk of serious or widespread harm from cancer, birth defects, or gene mutations. (See p. 13.)

Matters for consideration by the Congress

If the Congress is satisfied with EPA's implementation of the act's section 4(f) priority-review provision, then no further congressional action may be needed.[4] However, if the Congress believes that EPA should use this provision more frequently, it may want to consider alternatives for increasing the number of chemicals considered for priority review. Among some possible alternatives, the Congress could:

--Require EPA to designate chemicals which, according to a group of federal research and regulatory agencies, are known to cause cancer, gene mutations, or birth defects. One such possible source could be the National Toxicology Program of the Department of Health and Human Services, which publishes an annual review of carcinogens. Under this option, EPA's review of the chemicals listed would be mandatory.

--Establish an advisory group of representatives from federal research and regulatory agencies to recommend chemicals for EPA to consider for priority review. Under this option, EPA could be required either to initiate priority review under section 4(f) or publish its reasons for not doing so.

--Provide EPA the authority to gather additional information, if deemed necessary, to properly assess a chemical's risk during the section 4(f) review. Under this option, the 180-day period could be suspended while the information is obtained. EPA could be required to specify, and publish in the Federal Register, what data are needed and how and when they will be obtained. The Congress may also want to provide EPA with authority to obtain these data on a priority basis.

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[4]As noted above, litigation was recently brought against EPA alleging that EPA had sufficient information requiring it to designate formaldehyde for section 4(f) priority review. The outcome of this litigation may affect EPA's implementation approach.

--Require EPA to include in its annual reports to the President and the Congress the chemicals it considered for priority review, its decisions, and the related reasons for the decisions.

The alternatives listed are not intended to be all-inclusive. Also, combinations of these or other alternatives could be adopted. Although these alternatives could require additional resources, GAO did not review the resource implications. In considering these alternatives, the appropriate congressional committees may wish to request information on these implications from EPA. (See p. 27 to 28.)

AGENCY COMMENTS

GAO did not obtain agency comments on the report. However, issues in the report were discussed with responsible agency officials.

Contents

ABBREVIATIONS

EPA	Environmental Protection Agency
GAO	General Accounting Office
ITC	Interagency Testing Committee
MBOCA	4,4'-methylenebis (2-chlorobenzenamine)
MDA	4,4'-methylenedianiline
OTS	Office of Toxic Substances
PCB	polychlorinated biphenyls
TDA	toluenediamines
TSCA	Toxic Substances Control Act

CHAPTER 1

INTRODUCTION

Today, thousands of chemicals are in use in the United States and many new chemical substances are introduced every year. Countless benefits are derived from chemical production and use; however, many chemicals if not properly controlled can present real and potential hazards to human health and the environment. Although several federal statutes govern the regulation of some chemicals and their uses, none of these laws provide comprehensive authority to regulate toxic chemicals throughout their entire life cycles. Recognizing the need to close the gaps in existing legislation, as well as review the risks of chemicals for possible regulatory control before and after they have entered the marketplace, the Congress enacted the Toxic Substances Control Act (TSCA) of 1976 which provides authorities to regulate most chemicals throughout their entire life cycles.

TSCA, which became effective on January 1, 1977, gives the Administrator of the Environmental Protection Agency (EPA) broad regulatory authority over the thousands of chemical substances that are currently in commerce. Under TSCA, EPA is given authority to identify potentially harmful chemical substances and require industry to keep records, submit reports, and conduct tests on chemicals of concern. The act also allows EPA to take appropriate control actions when chemicals are found to present an unreasonable risk to human health or the environment. Such control actions may include regulating the manufacturing, processing, commercial distribution, use, or disposal of chemical substances and can range from attaching warning labels to chemical products to banning the production and use of a particular chemical or mixture.

CHEMICAL HAZARDS AND FEDERAL REGULATORY EFFORTS

There are over five million identified chemical entities. More than 60,000 of these are estimated to be currently manufactured in or imported into the United States, and as many as 1,000 notices of new chemicals are submitted by industry to EPA every year. In 1982 the production of the top 50 inorganic and organic chemicals approximated 316 billion pounds and 150 billion pounds, respectively, totaling 466 billion pounds. Combined chemical sales of the top 50 chemical producers totaled $100.6 billion in 1982.

Chemicals and the chemical industry are linked to almost every segment of the U.S. economy. Chemicals are used by other industries as feedstocks (raw chemical materials), solvents, resins, additives, and as other processing aids for a wide variety of products and industrial processes. The chemical industry also provides consumer products directly, such as detergents, soaps, paints, and a variety of plastic and synthetic fiber products.

Chemical hazards

While the production of chemicals generates many benefits to consumers and the national economy, many chemicals if not properly controlled can present hazards to human health and the environment. Human exposure to some chemicals can contribute directly to a number of 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, fish kills, air pollution, hazardous waste dumps, and other adverse impacts on environmental quality.

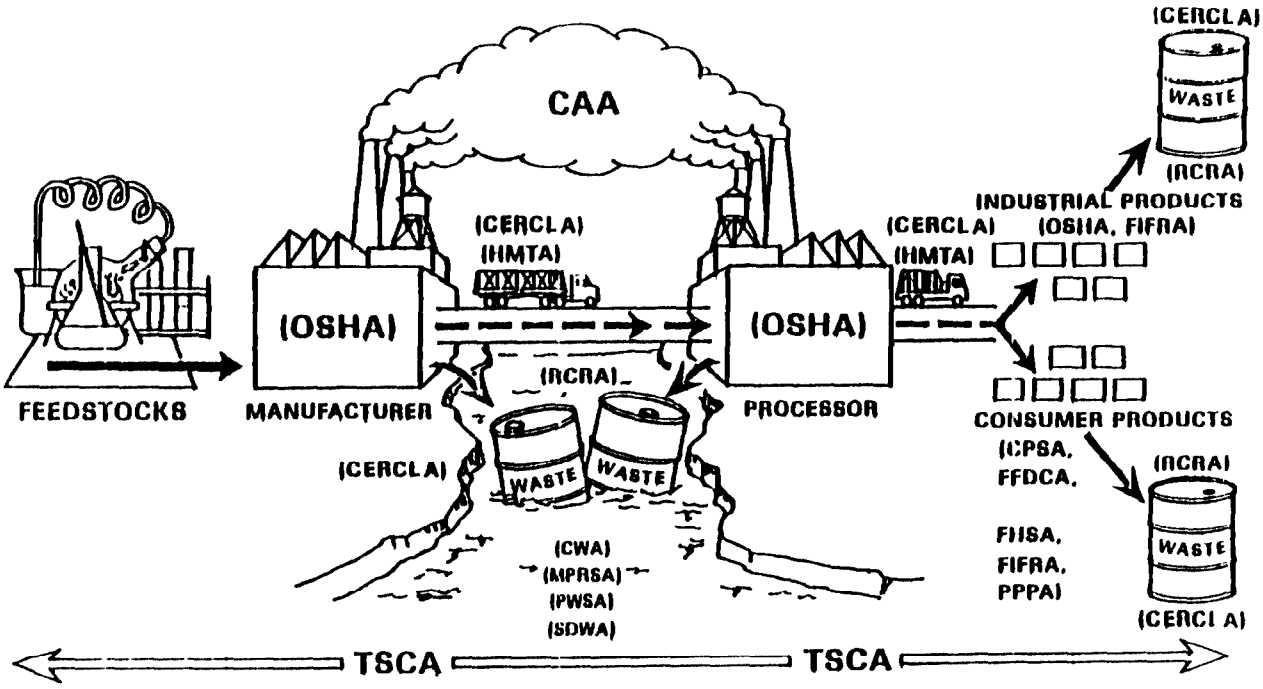
Evidence is strong that exposure to some chemicals can contribute to and cause various health problems and types of environmental damage and contamination. But for many more chemicals, not enough scientific data are available to assess their risks. Considering the many thousands of chemicals currently in commerce, relatively few have been tested for health and environmental effects. Even when chemicals have been tested, often the results are inconclusive because of the uncertainty associated with the existing scientific methods used to predict health and environmental effects.

Federal regulatory efforts

Many federal laws have been enacted over the years to address the serious health and environmental problems associated with hazardous chemicals. In general, these laws have tried to control hazardous chemicals which may be present in the workplace and in various types of products (pesticides, foods, drugs, and other consumer products), or are emitted into the environment through particular environmental media (air, water, and soil). However, many gaps existed in these laws which allowed certain chemicals, chemical products, and exposure paths to go unregulated or which precluded regulatory action until a chemical had already caused some harm to health or the environment.

In response to this situation, the Congress enacted TSCA, which provided authorities to close the gaps in existing legislation, as well as provide comprehensive regulatory authority over the entire life cycles of chemicals. The following diagram illustrates the coverage provided by the various federal laws over the course of a chemical's life cycle.

LEGISLATIVE AUTHORITIES AFFECTING THE LIFE CYCLE OF A CHEMICAL



CAA	- CLEAN AIR ACT	HMTA	- HAZARDOUS MATERIALS TRANSPORTATION ACT
CPSA	- CONSUMER PRODUCT SAFETY ACT	MPRSA	- MARINE PROTECTION, RESEARCH & SANCTUARIES ACT
CWA	- CLEAN WATER ACT	OSHA	- OCCUPATIONAL SAFETY & HEALTH ACT
FFDCA	- FED FOOD, DRUG, & COSMETIC ACT	PPPA	- POISON PREVENTION PACKAGING ACT
FHSA	- FED HAZARDOUS SUBSTANCES ACT	PWSA	- PORTS & WATERWAYS SAFETY ACT
FIFRA	- FED INSECTICIDE, FUNGICIDE, & RODENTICIDE ACT	RCRA	- RESOURCE CONSERVATION & RECOVERY ACT
CERCLA	- COMPREHENSIVE ENVIRONMENTAL RESPONSE, COMPENSATION & LIABILITY ACT	SDWA	- SAFE DRINKING WATER ACT
		TSCA	- TOXICS SUBSTANCES CONTROL ACT

KEY

SOURCE: EPA.

TSCA applies to all chemical substances except pesticides, tobacco, nuclear materials, firearms and ammunition, food, food additives, drugs, and cosmetics, which are covered by other laws administered by EPA and other federal agencies. The act provides authorities to regulate both existing and new chemicals that fall within its jurisdiction.

TSCA PROVISIONS FOR THE REVIEW OF NEW CHEMICALS

In enacting TSCA, the Congress recognized that the best time to identify hazardous chemicals and prevent unreasonable risks to human health and the environment is before they become widely used in commerce. In order to achieve this objective, the Congress established notification requirements with which manufacturers of new chemicals must comply.

Under Section 5 of TSCA, any person who intends to manufacture or process a new chemical substance, with certain exemptions, in the United States must submit a notice called a premanufacture notification to EPA at least 90 days before

beginning manufacture. This provision of the act allows EPA to review and evaluate the potential risks of new substances and control risks before they can cause harm to human health or the environment.

EPA is required to review the notification and assess whether or not the new substance either presents or may present an unreasonable risk to health or the environment. EPA has 90 days within which to conduct its review. However, the Agency for good cause may extend the review period for 90 more days. If the Administrator determines that the new substance presents an unreasonable risk, EPA is required under section 5(f) to take control actions to protect against that risk. Such control actions can include limiting or prohibiting the manufacture, processing, or distribution of the substance. If it is determined that there are insufficient data to assess the substance's effect on health and the environment and that an unreasonable risk may be present, the Administrator is authorized under section 5(e) to control human and environmental exposure to the substance until sufficient data are developed for assessing health and environmental effects.

REGULATING EXISTING CHEMICALS UNDER TSCA

TSCA contains provisions not only for reviewing all new chemical substances that are about to enter commerce, but also for regulating existing chemicals. One of EPA's initial tasks under TSCA was to compile an inventory of all chemical substances manufactured, processed, or imported in the United States. TSCA also requires EPA to add to the inventory of existing chemicals newly manufactured chemicals that have been reviewed under the premanufacture notification program of section 5. All chemicals not listed on the inventory are subject to the premanufacture notification requirements for new chemicals. All chemicals listed on the inventory are classified as existing chemicals. Under TSCA, EPA is given broad authorities to require testing, gather information, and control risks from any of the over 60,000 existing chemicals currently in commerce.

In this report, we use the term "existing chemicals program" to cover all TSCA activities dealing with existing chemicals, including the chemical testing program under section 4 of the act, the regulation of hazardous chemicals under section 6, and the reporting and information-gathering activities under section 8. A brief description of these TSCA sections follows.

Testing chemicals

Under section 4,[1] EPA may require the manufacturers or processors of potentially harmful chemicals to test the chemicals for health and environmental effects. To require testing, EPA must find that (1) the chemical may present an unreasonable risk or there may be substantial human or environmental exposure to the chemical, (2) data and experience are insufficient for determining or predicting the chemical's effects, and (3) testing is necessary to develop such data.

TSCA also established a priority-setting mechanism to ensure that chemicals are systematically identified and evaluated for testing decisions. TSCA section 4(e) set up a committee, known as the Interagency Testing Committee (ITC), composed of representatives from eight federal agencies concerned with health and the environment, to recommend chemical substances and mixtures for priority EPA consideration as to whether testing is needed. The ITC can also recommend to EPA the nature of the tests to be conducted on the recommended chemicals. TSCA specifies that the ITC consider the following factors in making its recommendations: production volume, environmental release, occupational exposure, general population exposure, similarity to known hazardous substance, existence of available data on health or environmental effects, extent to which additional testing may fill data gaps, and the availability of facilities and personnel. The ITC is also to give priority attention to substances which are known or suspected of causing or contributing to cancers, gene mutations, or birth defects.

The ITC recommendations are presented in the form of a priority list of chemical substances. The total number of chemicals on the list may not, at any time, exceed 50. TSCA gives EPA 1 year to review the available information on these chemicals and either to initiate rulemaking to require testing of the chemical, or to publish its reasons for not doing so. The ITC deals only with the testing needs of existing chemicals.

The ITC is made up of representatives of eight statutory member organizations. There are also representatives of six nonstatutory, liaison organizations who are nonvoting but active and full participants in the ITC review and chemical selection process. The statutory member organizations are the Council on Environmental Quality, the Department of Commerce, the Environmental Protection Agency, the National Cancer Institute, the National Institute of Environmental Health Sciences, the National Institute for Occupational Safety and Health, the National Science Foundation, and the Occupational Safety and

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[1]EPA's administration of several aspects of Section 4 of TSCA has been challenged in federal district court. GAO takes no position on the merits of this pending action. NRDC v. EPA, 83 Civ. 8844 (S.D.N.Y.).

Health Administration. The liaison, nonvoting organizations are the Consumer Product Safety Commission, the Department of Agriculture, the Department of Defense, the Department of the Interior, the Food and Drug Administration, and the National Toxicology Program of the Department of Health and Human Services.

Information gathering

Section 8 of the act authorizes EPA to issue rules requiring manufacturers and processors to maintain records and to submit such information necessary for the effective enforcement of the act. This information can include the name of the chemical, its chemical identity, its uses, estimates of production levels, description of byproducts, data on adverse health and environmental effects, and number of workers exposed to the chemical. Exemptions are provided for small manufacturers and processors as well as those manufacturing and processing mixtures or small quantities of a chemical used solely for research or analysis.

This section of TSCA also provides that

--the Administrator must publish a list of all existing chemicals and add to that list all new chemical substances that commence manufacture and

--persons who manufacture, process, or distribute chemicals in commerce must

(1) keep records of significant adverse reactions to health or the environment that are allegedly caused by a chemical substance or mixture;

(2) submit lists or copies of health and safety studies to EPA when required by rule by the Administrator; and

(3) report to EPA information which indicates that a chemical presents a substantial risk of injury to health or the environment, in the absence of actual knowledge that the Administrator has already been adequately informed.

Chemical control

Section 6 requires EPA to take action against chemical substances or mixtures for which a reasonable basis exists to conclude that the manufacture, processing, distribution in commerce, use, or disposal of such chemical substances or mixtures, or any combination of such activities, presents or will present an unreasonable risk of injury to health or the environment. Actions which may be taken range from a complete ban to a simple labeling requirement. The control requirements imposed must not place an undue burden on industry; at the same time, they must provide an adequate margin of protection against the unreasonable risk.

Also, TSCA Section 6(e) specifically requires the regulation of polychlorinated biphenyls (PCBs). EPA must issue labeling and disposal regulations for PCBs and prohibit their manufacture, processing, distribution in commerce, and use, other than in a totally enclosed manner.

Determining unreasonable risk

The existence of an unreasonable risk to human health or the environment is the trigger mechanism for control action under Section 6 of TSCA. TSCA provides EPA with discretion in determining unreasonable risk. In deciding on an appropriate action for reducing or eliminating unreasonable risks, the EPA Administrator shall consider the costs and benefits of its regulations; however, the act does not require formal, quantitative cost-benefit analysis.

The act requires that before regulating a chemical, EPA consider the following factors in assessing unreasonable risk:

--The chemical's effects on health and the environment and the magnitude of human and environmental exposure to it.

--The benefits provided by various uses of the chemical.

--The availability of substitutes for the chemical for such uses.

--Reasonably ascertainable economic consequences of regulating the chemical after consideration of the effects of such regulation on the national economy, small business, technological innovation, the environment, and public health.

The level of proof for establishing the degree of risk varies under the different TSCA sections. For example, in order to require testing of a chemical, EPA must find that (1) the chemical may present an unreasonable risk or that the chemical is produced in substantial quantities which may result in substantial exposure, (2) lack of information makes it impossible to determine if the chemical may present an unreasonable risk, and (3) testing is needed to develop the data. To take regulatory action, EPA must make an explicit finding that a reasonable basis exists to conclude that a chemical presents or will present an unreasonable risk.

Relationship to other federal laws

The Administrator may determine that an unreasonable risk presented by a chemical may be prevented or reduced by action under a federal law not administered by EPA. If so, the Administrator will request the agency administering the other law to determine whether the risk exists and if the agency's action would sufficiently reduce the risk. If the agency finds no risk or

takes action directed at the risk, EPA may not take any regulatory action directed at the same risk.

TSCA also directs the Administrator to use other laws administered by EPA to protect against unreasonable risks unless the Administrator determines that it is in the public interest to protect against such risks under TSCA.

Prior GAO reviews

We have issued four reports on certain aspects of TSCA. These reports have addressed EPA's efforts to implement the legislative requirements of the act, EPA's regulatory action on specific chemicals, and EPA's use of voluntary testing agreements.

Our initial work concerning TSCA resulted in the report we issued on October 28, 1980, entitled EPA Is Slow to Carry Out Its Responsibility to Control Harmful Chemicals (CED-81-1). The objective of that work was to determine the status of EPA's efforts to implement TSCA and to identify major issues confronting EPA in implementing the major program requirements concerning the screening of new chemicals, information reporting, testing, and control of existing chemicals. The report concluded that EPA had made limited progress in identifying and controlling existing chemicals and in developing a program to control new chemicals because there was no clear sense of direction to guide the program and because of organizational and staffing problems. Some of these problems included the absence of a clearly articulated plan of action, the prolonged search for an assistant administrator to head the program, and an unorganized and understaffed office.

Since this initial report, we have issued reports on EPA's efforts under TSCA to regulate two specific toxic substances--PCBs and asbestos. In our December 30, 1981, report entitled EPA Slow in Controlling PCBs (CED-82-21), we reported that (1) EPA has made limited progress in implementing the legislative mandate to control PCBs, (2) EPA has little assurance that industry is complying with its regulation, and (3) EPA's enforcement program lacked overall direction and did not encourage quick compliance. In our report issued on August 31, 1982, entitled Asbestos in Schools: a Dilemma (GAO/CED-82-114), we reviewed EPA's efforts to address the health risks associated with asbestos-containing materials in schools. We reported that EPA's rule requiring that all schools be inspected for asbestos and that parents and teachers be notified if asbestos is present, puts school officials in a serious dilemma because EPA has not provided school officials with specific criteria about when the asbestos poses a problem and what control actions are most appropriate. As a result, schools may either overreact and spend money needlessly on unnecessary asbestos abatement action, or underreact and expose school occupants to hazardous asbestos conditions.

Our most recent report entitled EPA Implementation of Selected Aspects of the Toxic Substances Control Act

(GAO/RCED-83-62) was issued on December 7, 1982. The report presented our conclusion that EPA has the authority to use negotiated testing agreements with the chemical industry to obtain needed health and environmental effects tests for chemical substances in lieu of issuing administrative rules formally requiring such testing.

OBJECTIVES, SCOPE, AND METHODOLOGY

On December 21, 1982, the Senate Committee on Environment and Public Works asked us to update our 1980 study by reviewing and reporting on EPA's actions and progress in carrying out its responsibilities under TSCA. Subsequently, the House Subcommittee on Commerce, Transportation and Tourism, Committee on Energy and Commerce, expressed its interest in our work. In our further discussions with both Committee offices, they agreed that this review would be conducted for both Committees and that our report should be issued jointly to both the Senate Committee and the House Subcommittee. This report covers EPA's performance regarding existing chemicals. EPA's performance regarding new chemicals is covered in a companion report, Assessment of New Chemical Regulation Under the Toxic Substances Control Act (GAO/RCED-84-84).

The Committees asked us to evaluate EPA's actions and progress in identifying the hazards associated with existing chemicals and protecting the public and environment from those existing chemicals that pose an unreasonable risk. More specifically, we were asked to

- --identify how EPA is using and plans to use the authority it was provided under TSCA to require chemical manufacturers to report information and conduct tests of chemicals that may present an unreasonable risk to health or the environment;

- --assess EPA's efforts in complying with the legislative requirements for responding to the Interagency Testing Committee's recommendations for chemical testing and court-ordered chemical reviews;

- --address EPA's efforts relative to "significant risk notifications" under TSCA Section 8(e), and citizens' petitions for EPA action on specific chemicals under section 21; and

- --analyze EPA's decisionmaking process for regulation of existing chemicals in terms of how "unreasonable risk" is determined and how health and environmental risks are weighed against the economic costs of regulatory action.

To identify how EPA has used and plans to use TSCA authorities to require the chemical industry to report information on chemicals that may present an unreasonable risk, we reviewed

proposed and final information-gathering rules issued under section 8 of the act, including industry's submission of section 8(e) notices of substantial risk, as well as supporting materials, reports, documents, plans, and internal memorandums. Our review of these documents was augmented by discussion with former and present EPA personnel and officials associated with EPA's existing chemicals program, as well as other EPA officials in the Offices of the General Counsel, and Policy and Resource Management. We also discussed EPA's use of section 8 authorities with representatives of the chemical trade associations, the Chemical Manufacturers Association, the Synthetic Organic Chemical Manufacturers Association, and several chemical firms. We also reviewed publications of or had discussions with representatives from environmental groups, including the Conservation Foundation, the Natural Resources Defense Council, and the Environmental Defense Fund.

In order to assess EPA's efforts in using the testing authorities provided for in Section 4 of TSCA, we reviewed proposed testing rules (no final rules have been promulgated) and supporting documents, as well as voluntary testing agreements that EPA has negotiated with chemical firms. We also had discussions with EPA personnel responsible for test rule development and obtained the views of industry and various environmental groups on negotiated testing agreements. We met with members of the Interagency Testing Committee and attended several of their meetings. We also observed ITC expert panels review and score hundreds of chemicals for further ITC consideration of the chemicals' health and environmental effects testing needs. We attended a meeting of the Administrator's Toxic Substances Advisory Committee and talked with current and past chairpersons.

In order to evaluate EPA's progress in using chemical control authorities under Section 6 of TSCA as well analyze how EPA determines "unreasonable risk," we reviewed proposed and final rules issued under section 6 and support documents. We discussed chemical control and "unreasonable risk" with EPA officials responsible for the program and met with various industry and environmental group representatives.

We were assisted in our work by two consultants, George S. Dominguez of Springborn Regulatory Services, Inc., Enfield, Connecticut, and Steven D. Jellinek of SCJ Incorporated, Washington, D.C. They reviewed our study plans, advised us on issues, and reviewed and commented on our draft report.

We discussed the matters contained in the report with EPA officials responsible for the existing chemicals program. Their comments have been incorporated in the report where appropriate. Our review was conducted from January 1983 through December 1983 at EPA headquarters in Washington, D.C., in accordance with generally accepted government auditing standards, except that as requested by the Chairmen's offices we did not obtain official agency comments on the report.

CHAPTER 2

EXISTING CHEMICALS PROGRAM A LOW PRIORITY, BUT IMPROVEMENTS BEGUN

In October 1980, we reviewed EPA's implementation of the Toxic Substances Control Act of 1976 and concluded that the Agency was slow to carry out its responsibility to control harmful chemicals. Although actions had been taken to control three chemicals, no chemicals had been tested and basic data were lacking on most of the existing chemicals. We concluded that several factors contributed to this slow progress, including a lack of a clear sense of direction to guide the program and organizational and staffing problems. (See p. 8.)

Since our 1980 review, EPA had acted to control one additional existing chemical and had initiated priority reviews of two chemicals. The act's priority review provision requires EPA, within a certain time, to either initiate appropriate regulatory action to prevent or reduce the risk or publish its reasons that the risk is not unreasonable.

Although we did not determine if more chemicals need to be controlled or subjected to priority review, EPA has identified 60 chemicals that need to be evaluated for regulatory control because of potential unreasonable risks and has received information on hundreds of chemicals which may be potential candidates for priority review. EPA's ability to do more has been constrained for several reasons:

--The act's priority-review provision to assess certain chemical risks has been used twice because it is resource-intensive and EPA has interpreted it to require substantial amounts of supporting data on hand before a chemical can be designated for priority review.

--The existing chemicals program had limited resources and a low priority in relation to other activities required by TSCA.

--Until 1982, no comprehensive process existed to identify and evaluate unreasonable risks from existing chemicals.

However, since our 1980 review, EPA has made progress in building a foundation for the existing chemicals program. EPA has adopted a system for identifying, assessing, and controlling existing chemical hazards which, if properly implemented, should help accomplish the objectives of the act. EPA developed a plan for implementing the existing chemicals program and established an existing chemicals task force to develop, monitor, and manage the program. EPA screened over 3,000 chemicals, identified 60 chemicals for further analysis, and put 8 in some stage of regulatory development. Also, EPA announced in February 1984 that its fiscal

year 1985 budget included proposed resource increases for the existing chemicals program. Although these actions strengthen EPA's existing chemicals program, the extent of their impact on the program's effectiveness remains to be seen.

EPA HAS PLACED CONTROLS ON FOUR EXISTING CHEMICALS

Since enactment of TSCA in 1976, EPA has taken actions to control four existing chemicals--polychlorinated biphenyls (PCBs), chlorofluorocarbons, dioxin, and asbestos. EPA issued its first PCB rule in May 1979, the chlorofluorocarbons rule in March 1978, the dioxin rule in May 1980, and the asbestos-in-school rule in May 1982. Each of these chemical control actions is briefly discussed below.

Polychlorinated biphenyls. Polychlorinated biphenyls, known as PCBs, are the only toxic substances that the Congress specifically directed EPA to address because it believed that the chemical and toxicological properties of PCBs posed a significant risk to public health and the environment. PCBs are used primarily in electrical equipment. PCBs are very stable and when released into the environment, do not decompose. Furthermore, they are toxic and very persistent. TSCA prohibits the manufacture, processing, distribution in commerce, and use of all PCBs in other than a totally enclosed system, unless authorized by the Administrator, and requires proper disposal of PCBs. EPA has issued regulations implementing these provisions and has published over 40 Federal Register notices dealing with the control of PCBs under TSCA.

Chlorofluorocarbons. In 1978, EPA banned nonessential uses of chlorofluorocarbons as aerosol propellants. This action was taken because chlorofluorocarbons may deplete the stratospheric ozone layer, which could lead to an increase in skin cancer, climate changes, and other adverse effects.

Dioxin. On May 19, 1980, EPA promulgated a rule under Section 6 of TSCA prohibiting Vertac Chemical Company from disposing of its wastes containing 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) (one of 75 dioxins) stored at its Jacksonville, Arkansas, facility. The rule also requires that any other persons planning to dispose of TCDD-containing wastes notify EPA 60 days prior to their intended disposal. TCDD, the most toxic of the dioxins 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. EPA is transferring TCDD-contaminated waste disposal responsibility to the Office of Solid Waste under the Resource, Conservation, and Recovery Act. EPA has proposed a waste-disposal rule under this act to include TCDD-contaminated wastes and other hazardous wastes. EPA expects this rule to be final by early summer 1984, whereupon the TSCA rule on TCDD will be revoked.

Asbestos. In May 1982, EPA issued a rule requiring all public and private elementary and secondary schools to inspect for friable (easily crumbled into powder) asbestos by June 28, 1983. Asbestos is a known human carcinogen. Asbestos-containing materials have been used widely for fireproofing, thermal and acoustical insulation, and decoration in building construction and renovation. EPA is conducting a compliance survey to determine the extent to which schools complied with the asbestos-in-schools rule. In an August 31, 1982, report, Asbestos in Schools: A Dilemma (GAO/CED-82-114), we concluded that federal programs do not ensure "that school occupants are being adequately protected or that abatement actions being taken are necessary." As discussed on page 24, EPA is considering a ban on certain asbestos uses and a production limit on others.

EPA REVIEWED TWO CHEMICALS UNDER TSCA's PRIORITY REVIEW PROVISION

Although EPA has the discretion to determine what is an unreasonable risk, TSCA Section 4(f) specifies that EPA initiate appropriate action for certain chemical risks. Section 4(f) is a priority-review provision which requires EPA to initiate appropriate control actions or publish a Federal Register notice that the risk is not unreasonable within 180 days (including a 90-day extension) after receipt of test data or 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.

EPA has designated two chemicals for priority review under section 4(f). EPA used the section 4(f) provision for the first time in 1983 when it initiated a 180-day review of the chemical 4,4'-methylenedianiline (MDA). In December 1983, EPA designated a second chemical, 1,3-butadiene, for priority review. On May 20, 1982, the EPA Assistant Administrator for Pesticides and Toxic Substances testified before the House Subcommittee on Investigations and Oversight, Committee on Science and Technology, and said that under section 4(f) of the act, substantial amounts of supporting data on hand are necessary before a chemical can be designated for priority review. EPA's interpretation of section 4(f) has been questioned by environmentalists in recent years, especially EPA's decision on formaldehyde (see discussion on p. 16). The Natural Resources Defense Council, for example, has stated that sufficient data on formaldehyde currently exist for EPA to designate it for priority review.

Section 4(f): criteria unclear and resource-intensive

The act and the legislative history do not define the key terms of section 4(f)--"significant risk," "serious," and "widespread." Also, there is no reference in the legislative history to the specific purpose or motivation underlying the section 4(f)

provision. EPA's Office of General Counsel stated, in an October 31, 1980, memorandum, that:

> "The dearth of explicit Congressional discussion on the purposes of Section 4(f) is matched by the almost total lack of explanation of the terms used in the section and of possible problems that might be encountered in its implementation. This paucity of legislative history generally hampers legal analysis of Section 4(f)."

Further, by not defining the probability of harm which is considered significant and by not providing any guidance on how grave a problem must be to be characterized as either "serious" or "widespread," the Congress left EPA to implement the concept and to exercise discretion in applying these standards.

EPA's draft internal procedures for designating a chemical for priority review state that the criterion for a section 4(f) designation should be more than simply a potential for "unreasonable risk" and, in fact, should be one that is an especially serious one, either in terms of the number of persons at risk or the likelihood of injury.

The section 4(f) language is not specific as to the level of evidence--that is, how much or what specific kinds of data are needed to designate a chemical for priority review. According to the act, the 180-day review begins on the date of the receipt of data or information which indicates that there may be a reasonable basis to conclude that a risk meets section 4(f) criteria. EPA procedures state that both valid biological effects data and exposure information are necessary elements for a decision on the significance of risk. The procedures also state that the clock starts on the date when EPA first has sufficient data of each kind to measure against section 4(f) criteria and reach a conclusion. If data are missing and must be obtained, the clock does not start until the data are gathered or generated.

According to May 1982 testimony of the Assistant Administrator for Pesticides and Toxic Substances, a substantial amount of data in hand is necessary before section 4(f) can be invoked. Section 4(f) designation requires EPA to initiate regulatory action to prevent or reduce the risk or to publish its reasons that the risk is not unreasonable. He stated that section 4(f) does not give EPA the option of determining that further investigation might be needed, for example, to obtain exposure data.

The Acting Director of the Office of Toxic Substances told us that a section 4(f) action requires tremendous resources because of the need to concentrate risk analyses in a very short 180-day period. According to the Director of the Existing Chemical Assessment Division, a risk assessment cannot be realistically done within 180 days, including a 90-day extension. In fact, according to the Director, EPA has little incentive to initiate a

section 4(f) review based on one piece of information because the act does not facilitate EPA's ability to obtain other necessary risk assessment data any sooner than if EPA did not initiate the section 4(f) action. For example, simply designating a chemical for high-priority consideration under section 4(f) does not automatically trigger other TSCA information-gathering authorities. EPA must develop, propose, obtain public comments, and then issue a rule if it wants to obtain additional data on the chemical. The Chief of the Risk Management Branch said it may take 18 months before any data are received by EPA as a result of any information-gathering rule.

According to the Director, Existing Chemical Assessment Division, section 4(f) puts EPA in the position of deciding within 180 days whether or not a significant risk is present, when often EPA does not have the necessary exposure data to make a reasonable decision. A former Assistant Administrator for Pesticides and Toxic Substances also told us that section 4(f) is difficult to implement because it requires a risk assessment decision within 180 days when all the data may not be readily available.

According to the Chief, Risk Management Branch, there are hundreds of chemicals with known, valid biological effects data (such as carcinogenicity) that could be potential candidates for section 4(f) review if EPA also had the needed exposure information to make the significant risk decision required under section 4(f). For example, a source of information that EPA reviews for possible section 4(f) consideration is the test studies supported by the National Toxicology Program of the Department of Health and Human Services.[1] The 1982 Third Annual Report on Carcinogens, prepared by the National Toxicology Program, lists 117 known or reasonably anticipated to be human carcinogens. According to the Director of the Existing Chemical Assessment Division, consideration of this list of carcinogens alone is insufficient to designate the chemical for priority review because in many cases the exposure data on the chemical are missing or incomplete.

EPA has used section 4(f) priority review twice

As of December 1983, EPA had identified four chemicals that may have warranted priority consideration under section 4(f). However, for two of these chemicals, di(2-ethylhexyl)phthalate (DEHP) and formaldehyde, EPA concluded in February 1982 that available evidence did not warrant priority review under section 4(f).

The third chemical, 4,4'-methylenedianiline (MDA), a potential carcinogen, is used in making other chemicals and

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[1]The National Toxicology Program of the Department of Health and Human Services coordinates and manages the Department's activities in toxicology testing. Part of its responsibility is to prepare an annual report on carcinogens, which is done with the participation of nine federal research or regulatory agencies, including EPA.

plastics. As many as 12,000 to 13,000 workers may be exposed to it in the workplace. At least five firms manufacture MDA, and an estimated 200 to 400 million pounds were produced in 1982 in the United States. EPA concluded that current data on MDA met the section 4(f) threshold and on April 27, 1983, announced plans to initiate a 180-day review of the chemical under section 4(f). Data from the National Toxicology Program indicate that MDA is an animal carcinogen. On September 20, 1983, and within the 180-day review period, EPA and the Occupational Safety and Health Administration published a joint notice of their intent to determine and implement means to control exposures to MDA. This action on MDA was the first time EPA had initiated and completed a 180-day priority review of a chemical under section 4(f).

In the fourth case, EPA announced on December 20, 1983, that it was initiating a section 4(f) priority review of the chemical 1,3-butadiene--a substance used in the manufacture of synthetic rubber, plastics, and latexes--to determine if it should be regulated. Butadiene causes cancer in laboratory mice and rats. EPA stated that significant risk of serious harm may occur during the production of synthetic rubber from the chemical.

Environmental groups such as the Natural Resources Defense Council and the Conservation Foundation, however, disagree with EPA's interpretation of section 4(f) because the Agency is too restrictive, that is, requiring more data in order to designate chemicals for priority review than the groups believe was intended by section 4(f) of the act. This disagreement is demonstrated in the agency's handling of formaldehyde.

A controversy arose in 1982 on whether EPA should or should not have considered formaldehyde for a priority 180-day review under TSCA's Section 4(f). In February 1982, EPA decided not to consider formaldehyde a priority chemical for action under section 4(f) because it did not meet the criteria for priority review. On July 18, 1983, the Natural Resources Defense Council and the American Public Health Association filed a suit in U.S. District Court for the District of Columbia challenging EPA's failure to act on formaldehyde as a priority candidate for regulation. The plaintiffs claim, among other things, that EPA's decision not to designate formaldehyde for priority consideration, after the agency had received information showing that the chemical caused cancer in laboratory animals and that human exposure was widespread, was "arbitrary, capricious, and not in conformity with law." As of April 15, 1984, the case was still pending before the court.

On November 18, 1983, EPA announced that it was rescinding its February 1982 decision that formaldehyde did not meet the criteria for priority review under section 4(f). Accordingly, EPA is soliciting public comments to assist it in determining whether formaldehyde meets the criteria for section 4(f) priority review. An EPA decision is expected in May 1984. We did not review EPA's 1982 decision not to consider formaldehyde a priority chemical for

action under section 4(f) because of the congressional investigations and hearings and the ongoing lawsuit.

EXISTING CHEMICALS PROGRAM IS A LOW PRIORITY

EPA has the discretion to conclude whether a chemical requires regulation under section 6 and to determine the time frame it will follow. One reason that more has not been done under this section is that because EPA has focused its efforts and resources on attempting to meet certain deadlines set by TSCA--primarily, the 90-day review of new chemicals submitted under section 5 premanufacture notice requirements, the 12-month EPA mandatory response to the Interagency Testing Committee (ITC) recommendations of chemicals for testing, and TSCA's mandate to regulate PCBs.

EPA's existing chemicals program received declining amounts of resources in fiscal years 1981 through 1983. The toxic substances program, of which the existing chemicals program is a part, is one of EPA's newest programs with a fiscal year 1984 budget of $67 million.[2] According to a Congressional Budget Office analysis, the fiscal year 1984 $67 million budget request for toxic substances represents a 9 percent decrease in real terms from the fiscal year 1983 level. Compared with 1981, 1984 funding for the entire toxics program is 39 percent lower in real terms, and the related full-time staff has decreased by 15 percent.

The Office of Toxic Substances, which has the primary responsibility for implementing TSCA, had $39.7 million in fiscal year 1984 for the following programs:

	(millions)
New Chemicals	$13.7
Existing Chemicals	10.7
Chemical Testing	12.6
Toxic Substances Integration	2.7
	$39.7

The existing chemicals program, as used in this report, includes existing chemicals and chemical testing totaling $23.3 million for fiscal year 1984. This figure is a 33 percent decrease from the $34.8 million funded in fiscal year 1981 and about a 2 percent increase from the $22.9 million in fiscal year 1983. Of the $23.3 million in the existing chemicals program (including chemical testing), $12.6 is for chemical testing which

[2]The toxic substances program includes the following components: abatement and control, enforcement, and research and development. This report does not cover the enforcement and research and development components.

serves to identify future candidates for existing chemical control evaluation and $1.7 million is for testing guideline development, review, and update. Together, this $14.3 million does not contribute to the evaluation of the current 60 chemical candidates in the existing chemical review process. This leaves approximately $9 million for EPA to address other existing chemicals, including the current 60 chemicals being reviewed.

Although more funds are available for the existing chemicals program (including the chemical testing program) than the new chemicals program, the Director, Existing Chemical Assessment Division, stated that resources for the existing chemicals program are limited and inadequate. With present resources, he said that EPA expects to initiate reviews in its existing chemical process of about 60 chemicals during fiscal year 1984. This contrasts with the over 60,000 existing chemicals on the TSCA inventory and the projection of approximately 1,450 new chemicals for which premanufacture notifications will be submitted in fiscal year 1984 and which the act requires EPA to review. The number of new chemicals that EPA reviews is externally determined by the number of new chemical premanufacture notifications submitted by the chemical industry for EPA's review.

He explained that a reason for the fewer number of existing chemicals reviewed each year is that assessing existing chemicals requires more resources (time, staff, and analyses) than new chemicals because (1) there generally are more data to obtain and review on an existing chemical than on a new chemical and (2) differences in the findings required by the act necessitates a more rigorous analysis of existing chemicals that are being considered for regulation under section 6 than for new chemicals controlled under section 5(e). Existing chemicals are already in commerce, and the burden is on EPA to obtain and assess more health and environmental effects and exposure data on these chemicals. Data on new chemicals, on the other hand, are generally limited and submitted by industry in the premanufacture notification package.

According to a former EPA Assistant Administrator for Pesticides and Toxic Substances, EPA made a strategic decision to give low priority to section 6 regulatory actions in the first 3 years of administering TSCA. EPA's position was that most existing substances for which information on exposure and health/environmental effects was already available, were either adequately controlled under other federal laws or were capable of being controlled; resources devoted to section 6 would therefore materially detract from and delay efforts to use TSCA's unique authorities to review new chemicals and to develop data on existing chemicals. Also, EPA's emphasis on new chemicals, testing, and information development would produce a larger and more pervasive impact on decisionmaking in the industry.

The Acting Director, Office of Toxic Substances, told us that the limited resources available for TSCA are out of balance when

one considers the tasks that could be done under TSCA. According to the Director, Chemical Control Division, only a few existing chemical hazards can be considered for control action each year, partly because of limited resources and the use of those resources for mandatory TSCA activities. He said, however, that as EPA completes some of the mandatory activities, it will be in a better position to identify and control additional chemical hazards. According to an October 1983 briefing document on the existing chemicals program, the Office of Toxic Substances concluded that it has "more chemicals identified for evaluation and potential control than the program can currently handle."

Recent EPA budget increases for the existing chemicals program

On February 1, 1984, EPA announced that the President's fiscal year 1985 budget includes proposed increases for the risk management of existing chemicals and for the chemical testing program. An increase of $3 million and 22 workyears will be used to undertake risk management actions and assess data received from EPA's testing program. In addition, increases of $1.9 million and 7 workyears will be used for the chemical testing program to support efforts to finalize testing actions proposed in previous years. This total of $4.9 million is a 21 percent increase over the fiscal year 1984 budget.

EPA HAD NO FORMAL REVIEW PROCESS BEFORE 1982

Until 1982, EPA had not established a comprehensive strategy, process, or organization for reviewing unreasonable risks from existing chemicals. Previous GAO and EPA studies have concluded that until 1982 the program had organizational and staffing problems and no clear sense of direction.

TSCA implementation problems identified in 1980 GAO report

On October 28, 1980, we issued a report to the Congress, EPA Is Slow to Carry Out Its Responsibility to Control Harmful Chemicals (CED-81-1). We said that although actions had been taken to control three chemicals, no chemicals had been tested and basic data were lacking on most of the chemicals in commerce. We reported that several factors contributed to this slow progress, including

--delays and problems in starting up and developing a new organizational structure,

--delays in hiring senior management staff,

--no clear strategic plan to guide program implementation, and

--a relatively low EPA priority for controlling existing chemicals.

We reported that EPA had been slow to collect basic information on chemicals. During the first years of implementation, EPA had emphasized other TSCA mandates and had placed less emphasis on assessing the potential risks of existing chemicals and controlling those found to present an unreasonable risk.

EPA recognizes implementation problems

In January 1982, EPA's Office of Toxic Substances released a report entitled Priorities for OTS Operations which identified "problems that have led to a sense that the OTS existing chemicals program is misdirected and accomplishing little." Some of the problems were

--inadequately defined objectives for the existing chemicals program efforts;

--inadequate communication and coordination of efforts with other offices and agencies, industry, and other outside groups; and

--no approved process for conducting existing chemicals evaluations and control efforts.

The report also pointed out that the lack of an established process for identifying, evaluating, and responding to existing chemical problems had hampered the existing chemicals program. The roles and responsibilities of various divisions and branches of the Office of Toxic Substances in dealing with existing chemical problems had been confused, and each problem or project had been handled largely in an ad hoc manner. The following section describes some of the corrective actions and improvements EPA initiated.

EPA ESTABLISHES A PROCESS FOR IDENTIFYING, ASSESSING, AND CONTROLLING EXISTING CHEMICAL HAZARDS

Since January 1982, the Office of Toxic Substances has made progress in building a foundation for the existing chemicals program by establishing a process for identifying, assessing, and controlling existing chemical hazards; developing a plan for implementing the program; and establishing an existing chemicals task force to develop, monitor, and manage the program.

A step-by-step evaluation process is used for identifying chemicals in commerce for appropriate risk reduction action. Chemicals go through the same type of evaluation although they may enter or leave at different stages, depending on the amounts and types of data available. Only after a serious risk is determined

to exist, based on hazard and/or exposure analyses, is the chemical assessed for the appropriate type of risk control.

Chemicals for evaluation come from four general categories:

First Priority--chemicals that emerge from the TSCA testing program (see ch. 3), or from other government or industry-sponsored testing programs.

Second Priority--chemicals for which there is information, such as reported under TSCA (see ch. 4), that reasonably supports a conclusion of significant risk.

Third Priority--chemicals that are the subject of citizens' petitions for action, as provided for under TSCA (see app. I for EPA responses to citizens' petitions).

Fourth Priority--chemicals already in commerce that are identified, in the course of EPA review of premanufacture notices on new chemicals, as possible problems.

Once identified, these chemicals proceed through an evaluation process which becomes progressively more detailed regarding the information and assessment required. EPA's evaluation begins with an entry review to determine if a chemical has properties that may result in significant risks. After a determination has been made that a chemical has such properties, the process concentrates on hazard and exposure questions to verify and characterize the risk. Questions considered during the evaluation are:

--Is there a verified and significant risk or an exposure that would require testing?

--If so, how should the risk be addressed?

--What is the nature of the effects?

--What are acceptable exposure limits?

--What are cost-effective ways of controlling exposure?

The latter phases of the process address questions concerning methods and costs of reducing risks where appropriate. To answer these questions, the evaluation process establishes a series of evidence thresholds to confirm the validity of the risk. If the data do not meet these evidence thresholds, the chemical is dropped from further evaluations. The information needed for the evaluation is collected incrementally, with available information used first to help define and focus any additional information-gathering efforts. EPA has stated that this results in more effective and cost-efficient data collection and analysis and also more rapid and focused decisionmaking.

According to the existing chemicals program guidance document, the program focuses on specific effects of concern, rather than on a more general study of a chemical's characteristics. The program emphasizes negotiation and information exchange among EPA, industry, and the public to reduce risks. For example, if EPA receives test data from negotiated testing, health and safety studies, and notices from the chemical industry of substantial risks, including voluntary risk reduction action, that information is made available to the public and other agencies so that they can make their own risk assessment or take appropriate risk-reduction action. In addition to encouraging early, nonregulatory action, EPA plans to require risk reduction measures whenever necessary or appropriate.

One of the problems with the existing chemicals program was the lack of an internal structure to review, set priorities, and efficiently assess problems with chemicals in commerce under TSCA's jurisdiction. EPA recognized this, and in September 1982 the Director, Office of Toxic Substances, established the Existing Chemicals Task Force to develop and implement a process for reviewing and assessing chemicals in commerce.[3] The task force was set up to develop, oversee, and manage projects to define specific existing chemical problems, the need for detailed evaluation, and possible risk-reduction actions.

To carry out this objective, the task force develops a workplan outlining a strategy for each specific chemical review and identifying what needs to be done, when, and by whom. At the end of each assessment, task force decision documents are prepared for the Director and division directors of the Office of Toxic Substances, who make a decision which is forwarded to the Assistant Administrator for Pesticides and Toxic Substances.

The review process is identifying chemicals that may need control

EPA's new system for identifying, assessing, and controlling existing chemical hazards has identified 60 chemicals which may need further evaluation or controls to reduce risk. EPA's preferred method for achieving such risk reduction is through encouraging voluntary control measures by industry and the public. Although EPA is making progress, it is too early to judge the effectiveness of its new process or the appropriateness of voluntary controls and negotiated rulemaking because few such actions have been taken.

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[3]A reorganization effective October 30, 1983, permanently established the task force as the Risk Management Branch within the Existing Chemical Assessment Division, Office of Toxic Substances.

Current existing chemical program activities

The TSCA inventory contains over 60,000 existing chemicals. EPA could not provide an exact number of existing chemicals screened; however, it estimates that over 3,000 screens have been done as of October 1983. (A "screen" is defined as an EPA review of a report or published document on the health or environmental effects of one or more chemicals.)

Of the estimated 3,000 screens, 80 chemicals have been or are being reviewed by the task force as of October 31, 1983. The remainder of the existing chemicals were dropped from further consideration because the chemical's toxicity was low, exposure was low or controlled, or the chemical was being evaluated or controlled by another EPA office or federal agency. The task force review of the 80 chemicals has resulted in 20 being dropped from active review because of low exposure or toxicity concern; 52 have been targeted for further analysis and preliminary decisions within 12 months; and 8 have been recommended for regulatory consideration. In addition to MDA, formaldehyde, 1,3-butadiene, and asbestos, which were discussed earlier, EPA is considering regulatory action on 4,4'-methylenebis (2-chloroaniline) (MBOCA), glycol ethers, toluenediamines (TDA), and nitrosamines in cutting fluids.

On May 23, 1983, EPA announced that it proposed to regulate MBOCA, an industrial curing agent used in the manufacture of polyurethane plastics. EPA based its decision in part on the fact that MBOCA has been demonstrated to be a confirmed animal carcinogen and that it is not being considered for regulation by the Occupational Safety and Health Administration.

EPA's position is that the risk from exposure to MBOCA may be unreasonable, and it will explore a range of regulatory options including a complete or partial ban. As part of its announcement, EPA is soliciting public comments on whether the manufacture, processing, use, or distribution in commerce of MBOCA should be subject to control. This proposed action marks the first section 6 action on an existing chemical other than the four chemicals discussed on page 12.

The Acting Director of the Office of Toxic Substances told us that while MBOCA may not be the most hazardous substance, it is an appropriate chemical for consideration under section 6. The Acting Director said that adequate information exists on MBOCA to initiate action now, rather than wait until information on a more hazardous chemical is developed and action is taken. The Acting Director also told us that TSCA's broad regulatory authority under section 6 should be used more often to reduce chemical risks.

EPA is acting or considering action on several other chemicals:

--Glycol ethers are solvents used in making surface coatings for industrial, general trade, and consumer use. EPA is considering proposing a section 6 rule on glycol ethers to control risks from fetal and reproductive effects.

--Toluenediamines (TDAs) are large-volume chemicals used in making polyurethane foam and dyes. One of the members of the TDA chemical category is a known animal carcinogen.

--1,3-Butadiene is a high production volume chemical (3 billion pounds per year) used in the manufacture of synthetic rubber, plastics, and latexes. EPA has designated this chemical for priority review under section 4(f) because of data on its carcinogenic effect and exposure.

--Metalworking fluids are used as lubricants and coolants in the cutting and grinding of metals. EPA is considering issuing a chemical advisory (see below) because it is concerned about the presence of nitrosamines, known carcinogens, in metalworking fluids.

--Asbestos is a known human carcinogen. EPA is developing a proposed ban on certain asbestos uses and limiting the production of others. EPA plans to ban asbestos used in cement pipe and fittings, saturated and unsaturated roofing felt, flooring felt, sheet vinyl flooring, and floor tile.

EPA initiates use of a voluntary control option: chemical advisories

On December 30, 1983, EPA approved for distribution its first "chemical advisory," which is a voluntary approach to chemical control. The advisory is a way to convey information about a specific chemical hazard and to encourage voluntary action on the part of a manufacturer, processor, or user of a chemical of concern. EPA plans to issue advisories in conjunction with rules or where risk can be reduced by informing people about the nature of the hazard. However, according to the Acting Administrator for Pesticides and Toxic Substances, the chemical advisory will not be a substitute for rulemaking.

The first advisory is on used motor oil and is being sent to service station workers, engine mechanics, and anyone who handles motor oil. It will advise workers to avoid skin contact with used oil and remove any oil on their skin promptly. This advisory is based on a study showing that mice developed skin tumors after repeated applications of oil on their skins. The advisory on used motor oil was stimulated in part by a substantial risk notice on a widely used oil additive submitted by the American Petroleum Institute to EPA as required under Section 8(e) of TSCA. Another advisory is being considered on the presence of nitrosamines in metalworking fluids. EPA estimates that advisories will be prepared for 2 or 3 chemicals a year.

The Natural Resources Defense Council has commented that the advisories are worthwhile as an advance notice of, or as an adjunct to, required labeling and posting. More information and explanation can be included in the advisory than would normally be contained in brief warning labels and posters. However, the Council warns that advisories should not be issued in place of formal actions, such as labeling, banning, limiting production, and other rulemaking measures.

EPA's efforts to negotiate rulemaking

In January 1983, EPA's Associate Administrator for Policy and Resource Management announced plans to initiate a demonstration project for negotiating environmental regulations. According to the Associate Administrator, negotiating a regulation with the interested parties has the "potential to produce substantially superior rules, acceptable to a wide range of interests, more quickly, and without the need for litigation." The EPA Administrator has indicated that one of his high priority projects is the negotiated rulemaking demonstration project being designed by the Office of Policy, Planning, and Evaluation. One of the demonstration projects selected involves the chemical category toluenediamines, of which one member is a known animal carcinogen. TDAs are used in making polyurethane foam and dyes. The Office of Toxic Substances has been evaluating TDAs for both section 4 testing and section 6 control option. EPA estimates that negotiating control of TDAs under TSCA Section 6 and foregoing chemical testing could save between $3 and $5 million--the estimate for conducting various proposed testing schemes of the chemical. The negotiations would bring in labor, environmental, industrial, EPA, and Occupational Safety and Health Administration interests.

According to EPA, some of the objectives of the regulatory negotiation demonstration project will be to

--negotiate regulations involving all interested parties to produce a consensus on the regulation that EPA will publish as its notice of proposed rulemaking;

--determine whether negotiation has the potential to reduce the time, cost, and unpredictability now associated with some adversarial rulemaking; and

--build support for possible expansion of negotiation in EPA rulemaking and continued investigation of this and other alternatives.

EPA recognizes that negotiated rulemaking is not appropriate in all cases. The Associate Administrator for Policy and Resource Management cited several factors relevant to the negotiability of a regulation, including some agreement about the technical basis for the rule; a reasonable number of related issues about which some parties agree; and the participation of parties having a genuine interest in producing a consensus notice of proposed rulemaking.

In embarking upon this demonstration project, EPA also recognizes some of the potential problems that may not be conducive to speedy dispute resolution. For example, according to EPA, under current law, the Federal Advisory Committee Act would probably apply to the kind of negotiations which it is proposing. Under this act, groups involved with negotiations would be subject to the procedural requirements applicable to an advisory committee, such as obtaining an Office of Management and Budget-approved charter and holding open, public meetings.

CONCLUSIONS

Since the enactment of TSCA in 1976, EPA has taken control actions on four chemicals and has initiated priority reviews of two chemicals. Although we did not determine if more chemicals need to be controlled or subject to priority review, EPA has identified 60 chemicals that need to be evaluated for regulatory control, has identified 8 of these chemicals for regulatory consideration because of potential unreasonable risks, and has received information on hundreds of chemicals which may be potential candidates for priority review. EPA's ability to do more has been constrained for several reasons:

- --limited resources and low priority in relation to the mandatory activities required by TSCA;
- --the lack of a comprehensive process, until 1982, for identifying, evaluating, and controlling unreasonable risks from existing chemicals; and
- --limited use of TSCA's Section 4(f) priority-review provision because EPA views it as resource-intensive and has interpreted it to require substantial amounts of supporting data on hand before a chemical must be designated for priority review.

However, EPA has made progress in implementing TSCA's objectives for controlling unreasonable risks from existing chemicals. In 1982 and 1983, EPA took several actions to improve its implementation of the existing chemicals program. It adopted a new system for identifying, assessing, and controlling existing chemicals which, if properly implemented, should help accomplish the act's objectives. It also set up an existing chemicals task force to develop, manage, and monitor the progress of the Agency's risk assessment of an existing chemical as it moves through the process. EPA developed a plan, outlining its priorities and strategy for carrying out its responsibilities for the existing chemicals program. The new process has identified at least eight chemicals which EPA is considering for risk-reduction action.

Although these actions may strengthen EPA's existing chemicals program, the extent of their impact on the program's effectiveness remains to be seen. EPA, however, has recently proposed additional resources for the existing chemicals program.

The President's fiscal year 1985 budget reverses a downward trend in EPA funding by including proposed increases of $4.9 million and 29 workyears for the existing chemicals program, including chemical testing.

Finally, section 4(f) of TSCA requires that if EPA receives information indicating 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, EPA shall, within 180 days of receipt of such information, either initiate action to regulate the chemical or publish its finding that the risk is not unreasonable. EPA stated that hundreds of chemicals with known biological effects could be potential candidates for section 4(f) review. It has designated and assessed two such chemicals for the 180-day priority review.

The act does not specify what kinds of or how much information is needed for a chemical to be designated for priority review; rather, it allows EPA discretion in determining the information needed. EPA has interpreted the act to require substantial amounts of data before a chemical can be designated for priority review. EPA has stated that both biological effects data and information on the extent of human exposure for these chemicals are needed before the 180-day review requirement of section 4(f) applies. Also, according to EPA, once a chemical is designated for priority review, the 180-day limit (including the 90-day extension) for review may not be sufficient time to gather the necessary data to make a reasonable assessment of a chemical's risk. Once a chemical has been designated for priority review under section 4(f), the act does not give EPA the option of determining that further information-gathering may be needed after the 180-day (and a 90-day extension) period.

Environmental organizations such as the Conservation Foundation and the Natural Resources Defense Council, however, disagree with EPA's interpretation of section 4(f) because it is too restrictive--requiring more data than they believe the act intended. The Defense Council has filed a suit against EPA claiming that sufficient data on the chemical formaldehyde currently exist for EPA to designate it for priority review under section 4(f). EPA is now reconsidering designating formaldehyde for priority review.

MATTER FOR CONSIDERATION BY THE CONGRESS

The Congress gave EPA the discretion to determine whether a chemical presents or will present a significant risk of serious or widespread harm to human beings from cancer, gene mutations, or birth defects and should be designated for priority review. If the Congress is satisfied with EPA's implementation of section

4(f), then no further congressional action may be needed.[4] However, if the Congress believes that EPA should use this provision more frequently, it may want to consider alternatives for increasing the number of chemicals considered for priority review. Among some possible alternatives, the Congress could:

--Require EPA to designate chemicals which, according to a group of federal research and regulatory agencies, are known to cause cancer, gene mutations, or birth defects. One such possible source could be the National Toxicology Program of the Department of Health and Human Services, which publishes an annual review of carcinogens. Under this option, EPA's review of the chemicals listed would be mandatory.

--Establish an advisory group of representatives from federal research and regulatory agencies to recommend chemicals for EPA to consider for priority review. Under this option, EPA could be required either to initiate priority review under section 4(f) or publish its reasons for not doing so.

--Provide EPA the authority to gather additional information, if deemed necessary, to properly assess a chemical's risk during the section 4(f) review. Under this option, the 180-day period could be suspended while the information is obtained. EPA could be required to specify, and publish in the Federal Register, what data are needed and how and when they will be obtained. The Congress may also want to provide EPA with authority to obtain these data on a priority basis.

--Require EPA to include in its annual reports to the President and the Congress the chemicals it considered for priority review, its decisions, and the related reasons for the decisions.

The alternatives listed are not intended to be all-inclusive. Combinations of these or other alternatives could also be adopted. Although these alternatives could require additional resources, we did not review the resource implications. In considering these alternatives, the appropriate congressional committees may wish to request information on these implications from EPA.

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[4]As noted earlier, litigation was recently brought against EPA alleging that EPA has sufficient information requiring it to designate formaldehyde for section 4(f) priority review. The outcome of this litigation might affect EPA's implementation approach.

CHAPTER 3

PROGRESS AND PROBLEMS IN INITIATING CHEMICAL TESTING

One of TSCA's major goals is to induce development of test data by chemical manufacturers and processors for those existing chemicals that are not well characterized as to their potential health and environmental effects. EPA does not conduct chemical testing under Section 4 of TSCA, but EPA may, through the promulgation of section 4 rules, require the manufacturers or processors of potentially harmful chemicals to test them. The act also established an interagency advisory committee, commonly known as the Interagency Testing Committee (ITC), composed of representatives from eight federal agencies, to continually identify and recommend to the Administrator chemicals which should be given priority consideration for testing to determine their hazards to human health and the environment (see p. 5). TSCA requires that EPA evaluate the chemicals recommended by the ITC and, within 1 year, that it either initiate rulemaking to require testing or publish in the Federal Register its reasons for not doing so.[1]

Between October 1977 and November 1983, the ITC submitted 13 reports to EPA, designating 72 chemicals for testing consideration by EPA. EPA did not meet TSCA's 1-year deadline for responding to chemicals listed in the first five ITC reports. However, faced with a January 1981 court order, EPA took action to meet the court-ordered schedule for responding to backlogged ITC chemicals by either proposing a rule to require testing, negotiating a voluntary testing agreement with chemical firms, or deciding not to require testing. EPA has also taken similar actions to meet the statutory deadline for additional ITC chemicals recommended subsequent to the 1981 court order.

Of the 72 chemicals ITC recommended for testing, EPA has responded to 63 chemicals and determined that 22 chemicals required testing by rule; 19 would be tested under negotiated voluntary testing agreements; and 22 did not require testing. Although EPA has proposed test rules for those chemicals it determined needed testing, these rules have not been finalized. Six rules were proposed over 2 years ago. According to EPA, these proposals have not been finalized because employees were shifted

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[1]In this report, we use the term "ITC recommendations" to refer to those chemicals designated by the ITC for an EPA response within a 1-year deadline. This is not to be confused with the ITC terminology where "ITC designations" are those chemicals to which EPA must respond to within 1 year and where "ITC recommendations" are those chemicals which do not have a deadline. Our report does not cover ITC recommendations that do not have deadlines. Only two such recommendations have been made since the ITC was established.

to develop additional proposed test rules on other backlogged ITC-recommended chemicals.

Since 1982, EPA has been emphasizing negotiated, voluntary testing by industry. In most cases, this approach has been providing EPA with test data sooner than would be the case under a test rule. However, a disadvantage of this voluntary approach is its lack of enforceability. EPA is unable to ensure that a chemical manufacturer will comply with the agreement to initiate tests and submit data on time.

Because EPA's testing program has been aimed at responding to ITC-recommended chemicals, it has not used its authority to require needed testing of other chemicals. EPA expects to begin reviewing the testing needs of these other chemicals now that it has completed its responses to the backlogged ITC-recommended chemicals.

In addition to its test rulemaking responsibilities, EPA is also required to issue test standards. In our October 1980 report,[2] we reported that EPA had not done this. Since then, it has issued test guidelines and regulations for good laboratory practices and has audited test facilities.

EPA RESPONSES TO ITC RECOMMENDATIONS OF CHEMICALS FOR TESTING

Since 1977, the ITC has recommended 72 chemicals to EPA for testing. Initially, EPA was unable to meet TSCA's mandate to respond within the 1-year deadline by either initiating rulemaking proceedings or publishing reasons for not doing so. In response to a lawsuit by the Natural Resources Defense Council, an environmental group, and the resulting court order, EPA has been responding to the backlog of ITC-recommended chemicals and chemicals recommended by the ITC subsequent to the court order. As of December 31, 1983, EPA responded to 63 of the 72 chemicals ITC recommended for testing, and determined that 22 required testing under EPA regulations, 22 did not need testing, and for 19 others EPA would negotiate testing agreements with industry. The nine most recently ITC-recommended chemicals are still under EPA study. Although EPA has proposed 22 test rules, none have become final although 6 were proposed over 2 years ago. The primary reason cited by EPA for not finalizing any test rules is that limited resources were shifted to develop proposed test rules on backlogged ITC chemicals.

ITC-recommended chemicals for priority testing

As established by TSCA, the Interagency Testing Committee serves as a priority-setting body to ensure that chemicals are

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[2]EPA Is Slow to Carry Out Its Responsibility to Control Harmful Chemicals (CED-81-1; Oct. 28, 1980).

systematically identified and evaluated for testing, particularly chemicals suspected of causing cancer, gene mutations, and birth defects. Since ITC's inception in 1977, the ITC has submitted 13 reports to EPA, recommending 72 chemicals or chemical categories for priority testing.

ITC report number	Date of report	Number of chemicals and chemical categories
1	October 1977	10
2	April 1978	8
3	October 1978	3
4	April 1979	12
5	November 1979	5
6	April 1980	1
7	October 1980	3
8	April 1981	3
9	October 1981	3
10	May 1982	4
11	November 1982	11
12	May 1983	5
13	November 1983	4
Total		72

The 13 reports were published in the Federal Register along with reasons for recommending testing. The ITC considered whether the chemicals needed testing for cancer, gene mutations, birth defects, other chronic effects, environmental effects, and epidemiology. Reasons for recommending testing of a chemical typically involve a high production volume for the chemical, a high release rate into the environment, widespread human exposure in the workplace and/or from consumer products, biological activity or known acute toxic effects of the chemical, inconclusive but suggestive previous test results, inability to extrapolate adequately from previous tests, lack of any prior testing, or structural similarity to chemicals known or suspected to be harmful.

Initial delays in responding to ITC-recommended chemicals

EPA is legislatively required within 1 year from receiving ITC testing recommendations to review the available information on the chemical and either initiate rulemaking to require testing or publish in the Federal Register reasons for not doing so. Initially, the chemical testing program got off to a slow start, and EPA did not meet the first five statutory deadlines for responding to ITC-designated chemicals. As a result, EPA was sued in 1979 by the Natural Resources Defense Council for failure to respond to ITC-recommended chemicals within the 1-year statutory deadline.

The result of the suit was a court order in January 1981 putting EPA on a 3-year schedule to respond to the backlog of chemicals from ITC reports 1 through 6. The court ordered EPA to take action on 11 chemicals in calendar year 1981; 13 chemicals in calendar year 1982; and 13 chemicals in calendar year 1983. By the end of calendar year 1983, EPA had responded to all 37 backlogged chemicals.[3] During these years of responding to the backlog, EPA was also able to respond within the statutory 1-year deadline to 24 additional chemicals recommended by ITC in its seventh through eleventh reports, issued between October 1980 and November 1982.

The Chief of the Test Rules Development Branch identified a number of problems that hampered EPA's efforts to obtain information on ITC-recommended chemicals. Such problems included limited staff resources, difficulties in gaining access to relevant industry information which is confidential or proprietary, and difficulties in establishing and maintaining appropriate contacts with other agencies.

EPA testing decisions

Upon receiving ITC's recommendation for consideration of a chemical for testing, EPA makes one of three decisions: (1) require testing under a section 4 rule, (2) decide not to require testing under a section 4 test rule because a negotiated testing agreement is being reached with the participating manufacturer(s), or (3) decide testing is not necessary.

As of December 1983, EPA had not issued any final section 4 test rules requiring chemical manufacturers to test any of the 72 ITC-recommended chemicals. The following is EPA's response, as of December 1983:

[3]In the court-ordered schedule, the three chemicals chloromethane, chlorinated benzene (mono- and di-), and chlorinated benzene (tri-, tetra-, and penta-) were counted as one. Elsewhere in this report, we counted these chemicals separately.

EPA decisions to require testing (proposed rules)	22	
EPA decisions not to require testing	22	
EPA decisions not to require testing because of negotiated testing agreements	19	
Number of ITC chemicals responded to by EPA		63[a]
ITC chemicals being reviewed by EPA:		
ITC's 12th report (EPA response due May 1984)	5	
ITC's 13th report (EPA response due November 1984)	4	
		9
Number of ITC chemicals		72

[a]For several chemicals, EPA made multiple decisions on the same chemical. For purposes of this report, we counted a multiple decision as one decision in favor of either testing under a proposed rule or under a negotiated agreement, in that order.

EPA decided not to require testing of 41 chemicals recommended for testing by the ITC. Nineteen of these decisions were because voluntary testing agreements had been negotiated between EPA and the participating chemical manufacturers.

EPA decided not to require testing of 22 chemicals because they were already being tested by the National Toxicology Program, the National Cancer Institute, or industry; their manufacture, import, or exposures were limited; or adequate data already existed to characterize their health and environmental effects.

EPA has promulgated no final test rules

Over 6 years after ITC recommended its first chemical for testing and 3 years after EPA proposed its first test rule, EPA has not issued a final section 4 test rule requiring chemical manufacturers to test a chemical that may present an unreasonable risk. The deadline under TSCA Section 4(e) requires EPA to respond to ITC recommendations within 1 year by either initiating rulemaking proceedings or publishing reasons for not doing so. The act does not have any deadline for EPA to promulgate final regulations after they have been proposed.

Of the 22 proposed test rules which had been issued as of December 1983, 2 rules are over 3 years old and 4 are over 2 years old. The other 16 proposed test rules were proposed in 1982 and 1983. Below is a list of the six oldest proposed rules.

Chemical or category	Date published in Federal Register
Chloromethane	July 18, 1980
Chlorinated benzenes	July 18, 1980
Dichloromethane	June 5, 1981
Nitrobenzene	June 5, 1981
1,1,1- Trichloroethane	June 5, 1981
Fluoroalkenes	Oct. 30, 1981

According to the Chief of the Test Rules Development Branch, the reason for the delays in issuing final test rules for these chemicals is that resources were shifted to meet a January 1981 court-ordered schedule for EPA to respond to the backlog of ITC-recommended chemicals. As a result, personnel were not available to carry out the tasks of finalizing proposed test rules, such as obtaining and addressing public comments, reviewing additional data received by EPA after announcement of a proposed rule, and making appropriate changes to the proposed rule. In addition to resource constraints, the Branch Chief told us that some delays in issuing some of the specific test rules were the result of some flaws discovered in data used to support a proposed rule; new data received by EPA after announcement of a proposed rule; and EPA's decision to negotiate a testing agreement for one of the chemicals instead of issuing a test rule.

The Branch Chief told us that issuing a final rule should be fairly simple and less time- and resource-intensive compared with the more difficult task of developing a proposed test rule. He said that 12 to 18 months is a reasonable amount of time to promulgate a final test rule after it has been proposed. During fiscal year 1984, EPA plans to issue its first final test rule on the chemical 1,1,1-trichloroethane in September 1984. Also, EPA has issued or plans to issue final negotiated testing agreements on 6 chemicals.

NEGOTIATED TESTING CAN HASTEN DATA, BUT LACKS ENFORCEABILITY

Since 1982, EPA has emphasized negotiating voluntary testing programs with industry instead of issuing test rules. EPA has taken the position that this approach uses fewer resources, takes less time, and gets test data sooner than a test rule. However, EPA recently experienced long delays in receiving test data from a voluntary testing program involving chlorinated paraffins. These delays illustrate a disadvantage of the negotiated testing approach--the lack of enforceability of these agreements.

EPA's negotiated testing program objectives

As of December 1983, EPA had proposed test rules for 22 ITC-recommended chemicals but had not issued any final rules. Partly because of the amount of time and resources required to promulgate test rules and the importance of developing needed test

data sooner, EPA adopted a policy, in certain cases, to negotiate voluntary testing agreements with chemical manufacturers in lieu of test rules. Although negotiated testing agreements are not legally binding and enforceable, they have the advantage of potentially providing needed test data sooner than would be the case under a test rule.

In our December 7, 1982, report, EPA Implementation of Selected Aspects of the Toxic Substances Control Act (GAO/RCED-83-62), we expressed our opinion that, under TSCA,

> "implied authority exists for EPA to negotiate voluntary testing agreements because the agreements are reasonably consistent with the significant purposes of section 4, to ensure that industry at its own expense develops adequate data to assess a chemical substance's or mixture's risk to health or the environment."

We also said that

> "to compel testing under section 4, where otherwise acceptable voluntary testing is planned, would . . . be an inefficient use of EPA's resources and inconsistent with the Congress' desire to avoid duplicative and unnecessary testing."

In testimony before the Congress, EPA's Acting Assistant Administrator for Pesticides and Toxic Substances said:

> "I would like to emphasize that while we see negotiated testing agreements as an effective way to speed receipt of test data, we do not believe that all chemicals are appropriate for negotiation. Certain general factors, such as multiple manufacturers or the magnitude of testing needed or complex issues which prevent agreement, all may tip the scale toward rulemaking. In responding to the original court schedule for addressing the backlog, the Agency picked the easiest ITC chemicals first. Many of those lent themselves well to the negotiated process. However, many of the remaining chemicals do not."[4]

The Chief of the Test Rules Development Branch said that negotiating a voluntary test program uses fewer EPA resources and takes less time than promulgating test rules. Negotiating a testing agreement takes 47 staff-weeks compared with an EPA-estimated 81 staff-weeks for issuing a final test rule. Also, developing and publishing a final negotiated testing agreement takes 93 weeks (about 2 years) compared with an estimated 158 weeks (over 3 years) to develop and publish a final test rule.

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[4]July 27, 1983, hearings before the Subcommittee on Toxic Substances and Environmental Oversight, Senate Committee on Environment and Public Works.

Negotiated testing agreements have saved time. In 1982, OTS received 124 test studies as a result of testing agreements on three ITC-recommended chemicals under the negotiated testing program. Under test rules, according to the Chief of the Test Rules Development Branch, these studies probably would not have been completed until 1984. OTS also received another 125 studies on eight chemicals in 1983 and anticipates receiving another 200 studies in 1984, all from negotiated testing agreements.

A representative of the Chemical Manufacturers Association testified that negotiated testing programs are more flexible and efficient than promulgating test rules and are advantageous to both industry and EPA. The Association has taken the position that testing conducted on a negotiated basis begins sooner and requires fewer industry and EPA resources than testing commenced after rulemaking. Also, the negotiation process occurs in a less formal, nonadversarial atmosphere which is more conducive to resolving complex scientific issues.

Delays in receipt of negotiated test data on chlorinated paraffins

EPA has stated that needed chemical tests can be initiated and test results received much faster under negotiated testing programs than under test rules. However, EPA became concerned about delays experienced in data submission of the chlorinated paraffins testing program in the spring of 1983. Program officials estimated delays of 18 to 24 months between original and revised test schedules for some of the more than 80 tests being conducted by an international consortium of chlorinated paraffin manufacturers.

EPA efforts to require testing of chlorinated paraffins (primarily used as flame retardants) started in early 1977 prior to the October 1977 ITC recommendation that the chemical category be tested for certain biological and environmental effects. These chemicals were part of the first chemical category being tested under a negotiated testing program. The consortium proposed a testing program which was accepted by EPA in late 1981 in lieu of requiring testing regulations. Chlorinated paraffins are one of the few chemical categories being tested by an international consortium of manufacturers. Over 80 tests are involved, making the chlorinated paraffins test program one of the more involved negotiated test programs.

Between January and July 1983, a series of events occurred that indicated potential problems in meeting test schedules. The consortium made some fundamental changes in the sequence of two tests that affected the test schedule for several other tests and did not notify EPA of the changes. The testing program did not require notification of such interim changes. The consortium ran into technical difficulties in conducting several studies and did not notify EPA of this fact; it was under no obligation to do so. The consortium did not meet some of the test deadlines. In May

1983,. EPA staff conducted a laboratory inspection and study audit at the test facility and found that some raw test data existed and had been available at the testing contractor for several months, although the data had not been written up into a report at the time of the audit. Upon EPA's subsequent request for the raw data, the consortium refused to provide EPA with the test data on the basis that the consortium had not had a chance to review the data. A revised schedule was worked out and all the scheduled reports were forwarded to EPA by the end of December 1983.

According to EPA, these problems were generally due to the lack of specific commitments in the voluntary testing agreement between EPA and the consortium and the failure of the consortium to notify EPA about a significant change in the sequence of tests. EPA has requested that the consortium submit monthly status reports. EPA told the consortium to initiate all tests/testing sequences by May 15, 1983, which it has done. EPA has accepted the consortium's revised test schedule. On July 18, 1983, EPA sent a letter to the consortium reminding it that the individual corporate members of the consortium were subject to a statutory reporting obligation under TSCA Section 8(e) to submit information which provides reasonable support for a conclusion of substantial risk of injury to health or the environment. On September 8, 1983, the consortium submitted to EPA a section 8(e) notification of substantial risk, informing the agency of significant environmental effects from two consortium studies on chlorinated paraffins. EPA is reviewing these and related studies to determine whether there is a hazard and what the appropriate EPA response should be. According to the manager of the Existing Chemicals Task Force, the information provided on this section 8(e) notice is one of the first significant notices of an environmental effect that EPA has received from the chemical industry.

As a result of the experience with the chlorinated paraffins negotiated test program, EPA has revised its Guide For the Preparation of a Testing Program Proposal and has incorporated these revisions into other negotiated testing agreements. Specific revisions included addressing

--quarterly reporting requirements;

--commitments on interaction between EPA and chemical manufacturers or consortia; and

--definitions and commitments on test schedules, such as beginning and ending test dates, and final report submission dates.

Negotiated testing agreements are not enforceable

Although EPA has the authority to negotiate testing agreements with industry in lieu of issuing test rules, these

agreements are voluntary and therefore are not enforceable. If companies deviate from the terms of the negotiated agreement or the schedule for data submissions, EPA said it will move to expedite rulemaking as soon as evidence is received that a company does not intend to live up to the terms of the agreement.

The Chemical Manufacturers Association has stated that industry has important incentives to ensure that negotiated test programs are performed.

> "Some critics have questioned whether industry will abide by negotiated agreements. However, these agreements represent a written, public commitment by the firms involved to conduct testing. Failure to honor such commitments would detract from their credibility and jeopardize their relationships with EPA, customers, and the public. Accordingly, the chemical industry has important incentives to insure that negotiated test programs are fully performed."[5]

The Test Rules Development Branch explored several ways of increasing the enforceability of the agreements. Enforceability options identified by EPA include treating a negotiated testing agreement as a contract; requiring test sponsors to post performance bonds; requiring test sponsors to pay a noncompliance penalty; and treating negotiated agreements as a test rule for the purpose of invoking TSCA's administrative and judicial sanctions. However, EPA recognized that these options raise several legal questions, including whether EPA has the authority under TSCA or other federal laws to implement these options. Another option that EPA considered was whether, after significant noncompliance occurs, EPA should propose and promulgate a test rule not limited to the negotiated testing agreement.

Although EPA has reviewed the various options for making the agreements enforceable, it has not decided that making negotiated testing agreements enforceable is a necessary and desirable goal. The Chief of the Test Rules Development Branch said that it has always been the Office of Toxic Substances' policy to initiate formal rulemaking if significant noncompliance occurs. He said that the agency would probably focus on efforts to expedite test rulemaking in the case of noncompliance with a negotiated testing agreement. One such effort would be to promulgate the negotiated testing agreement as a test rule.

In addition to the enforceability issue, other concerns have been raised by the Natural Resources Defense Council. In an August 2, 1983, letter to EPA, the Council expressed its objections to negotiated testing programs based on several legal and procedural deficiencies, such as no guarantee of public access

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[5]Hearing of the House Energy and Commerce Subcommittee on Commerce, Transportation, and Tourism, April 21, 1983.

to the test data; absence of a judicial review; and the fact that other TSCA sections cannot be implemented because they can be used only upon certain actions, such as a section 4 test rule.

Because of EPA's reliance on negotiated testing agreements to obtain chemical effects data and recent experience in delays of the chlorinated paraffins testing program, EPA needs to implement some kind of enforcement or compliance mechanism to ensure that the negotiated testing program works and to sufficiently warn the chemical industry as a whole of the importance of their stated commitments to a negotiated testing program and the integrity of the program. We did not evaluate the advantages and disadvantages of the various options because EPA was still in the process of identifying and considering the various alternatives for enforcing negotiated testing agreements.

EPA IS NOT IDENTIFYING ADDITIONAL TESTING NEEDS

EPA's chemical testing program and activities have been aimed at responding to ITC-recommended chemicals for priority consideration. Although TSCA also gives EPA the authority to require testing of other non-ITC-recommended chemicals, the agency has not proposed a test rule for such chemicals. The Chief of the Test Rules Development Branch said that its limited resources are used to address ITC chemicals by assessing their testing needs, developing proposed test rules, and negotiating voluntary testing agreements. He said that when the backlog of ITC chemicals is eliminated by the end of 1983, EPA will be better able to begin identifying testing needs of non-ITC-recommended chemicals.

In his July 27, 1983, testimony before the Subcommittee on Toxic Substances and Environmental Oversight, Senate Committee on Environment and Public Works, the Acting Assistant Administrator for Pesticides and Toxic Substances said that

> ". . . because we [Office of Toxic Substances] were addressing both backlog and current ITC chemical designations, we have not been in the position to use information from other TSCA provisions to decide chemical testing needs. Areas where we can get high priority chemicals for testing consideration include: substances with significant human exposure which have been identified through monitoring activities or by others as important; classes of substances identified as potential concerns in the new chemical review process; and chemicals for which exposure currently is not enough to warrant testing but which might if production increased. An example of this latter category are ITC chemicals where the Office of Toxic Substances has decided not to require testing because of low production or highly limited exposure and release. A possible alternative response to no testing in such cases is to develop 'triggered' testing rules that would take effect only when production volume, exposure, or release criteria contained in the rule were exceeded."

According to the Acting Chief of the Test Rules Development Branch, there are about 12 chemicals or chemical categories from the above areas where the Office of Toxic Substances can get high priority chemicals for testing considerations. However, he said that efforts to address these chemicals are dependent on available resources and their use on the mandatory TSCA and court-ordered activities.

EPA HAS COMPLETED OTHER ACTIVITIES UNDER TSCA SECTION 4 TESTING AUTHORITY

While EPA's major activities under TSCA's Section 4 testing authority involve both proposing test rules and negotiating voluntary testing for chemicals, the agency has also been issuing test methodology guidelines and regulations on good laboratory practices for chemical manufacturers and test facilities to follow when conducting tests; reviewing and disseminating test data received under the negotiated testing program; and inspecting test sponsors or private testing laboratories and auditing test studies conducted under negotiated testing programs. In our October 1980 report, we reported that EPA had issued no final health or environmental test standards as required by the statute. Since our 1980 report EPA has

- --developed and issued 88 test guidelines (not requirements) covering 108 test methodologies for testing a chemical's health and environmental effects, as well as physical, chemical, and other characteristics;

- --issued Good Laboratory Practice regulations effective on December 29, 1983, as authorized by TSCA to ensure that adequate and reliable test data are developed; and

- --conducted audits of 13 test facilities during fiscal year 1983.

CONCLUSIONS

Since 1977, the ITC has recommended 72 chemicals for testing. Although TSCA requires EPA, within 1 year, to either initiate test rulemaking proceedings or publish its reasons for not testing these chemicals, EPA has had problems meeting some of the early deadlines. Faced with a court order, EPA has been able to meet the court-ordered schedule for responding to the backlog. EPA has also been able to respond within the statutory deadlines to additional chemicals ITC recommended for testing after the court order.

As of December 1983, EPA had determined that of the 72 chemicals ITC recommended for testing, 22 required testing under EPA regulations, 22 did not need testing, and 19 were candidates for or were under negotiated testing agreements. Although EPA has proposed test rules for 22 chemicals, no test information has resulted because the proposed rules have not yet been finalized.

Six of the 22 rules were proposed over 2 years ago. Although neither the act nor its legislative history mentions a specific time period for EPA to finalize a proposed test rule, we believe that to meet one of the purposes of the act--to protect human health and the environment--EPA needs to follow through by finalizing proposed test rulemaking for those chemicals which were recommended for testing by the ITC as early as 1977. The primary reason EPA cited for not finalizing these test proposals was that its limited resources were shifted to develop additional proposed test rules on backlogged ITC-recommended chemicals and current ITC recommendations.

To get testing started sooner and to save EPA resources, EPA began, in 1982, to emphasize negotiated, voluntary testing rather than require such testing by rule. Testing delays have occurred under this approach, but in most cases, test studies have been initiated and data have been received by EPA from 12 to 18 months sooner than would occur under a test rule.

Although the negotiated testing program is initiating certain chemical testing sooner than would occur under test rules, we do not know whether it will prove to be an effective substitute for required testing under TSCA's Section 4 authority. One of the problems with this approach is the lack of enforceability; as a result, EPA is unable to ensure that a manufacturer will comply with the agreement, start testing, and submit test data on time. Because of EPA's reliance on negotiated testing agreements and its recent experience with delays in the chlorinated paraffins testing program, we believe EPA needs to develop a compliance strategy to ensure that the negotiated testing program works in a timely and responsive manner and to sufficiently warn the chemical industry of the importance of its stated commitments to a negotiated testing program and the integrity of the program. EPA is in the process of identifying and considering various alternatives for enforcing negotiated testing agreements.

In addition to the chemicals that the ITC has recommended for testing, EPA has stated that other priority chemicals also need testing. However, because EPA has been addressing both the backlogged and current ITC chemicals, it has been unable to initiate test proposals for other chemicals. EPA expects to begin proposing testing of these other chemicals now that it has responded to the backlogged ITC-recommended chemicals.

Recently, EPA announced plans to provide additional needed resources for the chemical testing program. On February 1, 1984, EPA announced that the President's fiscal year 1985 budget includes proposed increases of $1.9 million and 7 work-years for the chemical testing program to support efforts to finalize testing actions proposed in previous years. These proposed resource increases will also be used to expand the test data audit program to keep pace with increases in ongoing test studies.

We recognize that in the current period of budget constraints, it is difficult to seek additional staff and funds for the existing chemicals program, but we believe that these proposed increases will help to accomplish one of the objectives of TSCA--the development of adequate data on the effects of chemicals on health and the environment.

RECOMMENDATION TO THE ADMINISTRATOR, EPA

The act requires EPA to respond, within 1 year, to ITC testing recommendations by either initiating a rulemaking proceeding or publishing its reasons for not doing so. The act does not require that testing rules be finalized within a certain time. However, we believe that EPA should follow through by finalizing, within a reasonable period of time (such as a goal of 12 to 18 months), regulatory actions necessary to ensure that chemical tests are started and conducted and that results on a chemical's health and environmental effects are obtained. Such information is necessary to begin assessing chemicals for risk-reduction actions.

Therefore, we recommend that the Administrator, EPA, issue final test rules within a reasonable time, such as a goal of 12 to 18 months after proposal, for test rules that have been developed. If EPA is not able to finalize test rules in a reasonable time, it should inform the Congress of the delay, the reasons, and suggested solutions, such as negotiated testing agreements, additional resources, or legislative changes.

CHAPTER 4

STATUS OF EPA's PLANS AND USE OF INFORMATION-GATHERING AUTHORITIES

TSCA authorizes EPA to obtain from industry information on a chemical's production level, use, exposure potential, and health and environmental effects. Our October 1980 report pointed out that EPA had been slow to collect basic information on existing chemicals. This occurred because this activity was assigned a lower priority in relation to other TSCA activities, was understaffed, and encountered difficulty in resolving basic program questions. Since then, EPA has made some progress in gathering these data. However, a number of problems remain.

Although EPA has maintained an inventory of existing chemicals as required by the act, the production-related data on these chemicals are outdated. These data are important in screening and characterizing exposures associated with potentially hazardous chemicals. EPA has stated that it recognizes the importance of updating this information and is considering various options to do so.

EPA delayed requiring industry to maintain records of significant adverse reactions to health or the environment alleged to have been caused by a chemical. Although it has been working on the requirement since 1977, it only issued rules implementing this requirement in August 1983. EPA delayed implementation because it determined that time and resources should be spent on implementing other important TSCA provisions first. As a result of these delays, EPA estimates it will take 2 or 3 years more before industry develops an adequate data base which can be used in EPA's chemical assessment process.

In addition, EPA plans to make little use of its authority to require industry to report production-related data and health and safety studies. EPA determined that the rulemaking process is too lengthy and costly and intends to gather the needed data through rulemaking only when it cannot obtain the necesary data itself or obtain them through voluntary submissions by industry. We were unable to assess the reasonableness of EPA's proposed course of action, since it could not provide us with data comparing the cost of obtaining information through rulemaking with the cost of obtaining similar data itself or by voluntary submissions.

SOME PROGRESS MADE IN USING SECTION 8 AUTHORITIES

The basic information-gathering provisions in Section 8 of TSCA gave EPA the authority to obtain the necessary data needed to make prudent risk assessment and chemical control decisions. There are five major authorities under section 8. Briefly, EPA

--may require the industry to report data on a particular chemical's production characteristics, including its identity, use, production volume, and other information relating to human and environmental exposure to a chemical (section 8(a));

--must compile, keep current, and publish an inventory of existing chemical substances in commerce (section 8(b));

--must promulgate rules requiring chemical manufacturers and processors to keep records of significant adverse reactions to health or the environment alleged to have been caused by a chemical; such records may be inspected and must be reported to the Administrator upon request (section 8(c));

--may require the industry to report lists and copies of known health and safety studies relating to a particular chemical substance (section 8(d)); and

--must be notified by chemical manufacturers if the manufacturers obtain information that a chemical may present a substantial risk of injury to health and the environment (section 8(e)).

In our October 1980 report on the status of TSCA implementation, we reported that EPA had implemented only two of the five authorities provided for in section 8. EPA had compiled an inventory of chemical substances found in commerce with corresponding production range and manufacturing site information (section 8(b)). EPA had also been evaluating notifications of substantial risk which were automatically required to be reported by industry when TSCA became effective (section 8(e)). However, at that time, EPA had not issued reporting rules to obtain information on the production characteristics (secion 8(a)), or existing health and safety studies (section 8(d)), associated with a particular chemical substance. EPA had also not promulgated a rule defining for industry the recordkeeping requirements for allegations of significant adverse reactions (section 8(c)).

Since our October 1980 report, EPA has continued to add the identities of new chemicals entering commerce onto the existing chemical substances inventory and has been evaluating notices of substantial risk. EPA has taken the following actions under section 8:

--Issued its first major final reporting rule in June 1982, requiring industry to submit information on the production, uses, and exposures of 250 chemicals (section 8(a)). This rule has been amended to include an additional 46 ITC chemicals recommended for testing, as well as to require automatic reporting for all future chemicals recommended by the ITC. Other chemical-specific rules have been issued for polybrominated biphenyls (PBBs), tris (2,3-dibromopropyl) phosphate (Tris) in October 1980, and asbestos in July 1982.

--Added 953 new chemicals to the existing chemical substances inventory, as of August 1983, that have gone through premanufacturing review requirements and have subsequently been manufactured.

--Issued final recordkeeping rules in August 1983, requiring industry to maintain records of significant adverse reactions to health or the environment alleged to have been caused by a chemical (section 8(c)).

--Issued a final rule in September 1982 requiring industry to submit lists and copies of health and safety studies on particular ITC-recommended chemicals (section 8(d)). This rule also requires automatic reporting for all future chemicals recommended by the ITC.

--Reviewed about 500 section 8(e) notices of substantial risk. In addition, it has received and evaluated approximately 250 related submissions that, though not formal 8(e) notices, are relevant to EPA's review of existing chemicals. Many of these notices have been the impetus for the priority review of certain chemicals under the existing chemicals review process.

While EPA has made progress in obtaining information on existing chemicals, problems remain.

CHEMICAL INVENTORY PRODUCTION DATA ARE OUT OF DATE

EPA has published an inventory of chemical substances manufactured, imported, and processed in the United States for commercial purposes, as required by Section 8(b) of TSCA. The Agency has also added to that inventory all new chemical substances that have been introduced into commerce since its initial publication. However, the production-related data attached to the specific chemical listings on the inventory are out of date. These data reflect only the state of chemical production as it existed in 1977, the year data were collected for inclusion on the inventory. Not only are these production data out of date, but such data have never been collected for the 953 new chemicals that had been added to the inventory as of August 1983. According to the Acting Director of OTS, these types of production-related data can be helpful in screening and characterizing the exposure risks associated with potentially hazardous chemicals. Although, EPA has not updated these data, it is planning to gather the information.

Status of the chemical substances inventory

Under Section 8(b) of TSCA, EPA is required to compile, keep current, and publish an inventory of chemical substances manufactured, imported, or processed in the United States. The primary intent of the inventory is to establish a base list of

existing chemicals in commerce so that EPA and industry can determine what chemicals are new and thus must go through the premanufacturing review process for new chemicals. TSCA also requires that all new chemicals that have gone through the pre-manufacturing review process must be added to the inventory once manufacture has commenced.

To develop the inventory, EPA initially proposed a reporting rule in March 1977, which required manufacturers, importers, and processors to report only the identity of chemicals in commerce. However, after reviewing comments received on the proposal, EPA decided to repropose the rule and expand its scope, using section 8(a) authority, to include the submission of information necessary to develop a profile of the production characteristics of the chemical industry.

In December 1977, EPA issued a final two-phase inventory reporting rule using authorities contained in Section 8 of TSCA. During the first phase, manufacturers and importers reported the identity of all chemicals manufactured or imported since January 1975. With certain exceptions for small firms, they also reported where the chemical was produced, in what quantities, and whether it was distributed beyond the production site. An initial inventory of over 43,000 chemicals was published on June 1, 1979.

In the second phase, after the publication of the initial inventory, chemical processors and importers of chemical substances reported additional chemical substances, not previously reported, that were processed, used, or imported for commerical purposes as part of a mixture or article. A revised inventory was published on July 28, 1980, bringing the total number of chemicals on the inventory to 55,103.

Since the publication of the revised inventory in July 1980, the number of chemical substances listed on the inventory had increased to 61,434 as of August 26, 1983. Part of this increase represents 953 new chemicals. The remaining increase of 5,378 chemicals is due to EPA's adding chemicals that were submitted during the original reporting period; either these reports contained incomplete data or were not evaluated by EPA in time to be included in the original inventory.

Production-related information has not been updated since the inventory was first compiled, neither for the chemicals originally listed nor for any chemicals subsequently added to the inventory. Although the inventory of chemical substances may still be valid, the data concerning production volume, plant location, and distribution are 6 years old and do not reflect the current production characteristics of these chemicals. For example, a 1983 EPA estimate of a sample of chemicals on the inventory indicated that 58 percent of plant sites had reported significant changes in production volume and 41 percent of sites reported a change in location or existence of plant sites.

EPA needs current production data on existing chemicals

In 1980, both OTS' Management Support Division and the Assessment Division conducted an inventory user survey to determine the need for updating the inventory. In general, both surveys concluded that the availability of more current information on the inventory would be of great utility to most users.

The inventory production volume and manufacturing site data have been useful to the Office of Toxic Substances, other EPA offices, EPA regions, and the ITC in carrying out their activities by providing broad production range and plant location information that can be used as an initial indicator of a chemical's exposure potential. These EPA offices have also used the manufacturing site data to identify manufacturers of particular chemicals and plant sites in order to help set priorities for enforcement-related activities. Also, the ITC has used inventory data to screen for exposure information for chemicals needing priority testing.

OTS' Management Support Division issued a report in September 1982 (revised January 1983), based on a survey of inventory users, concerning whether and how the TSCA inventory data base should be updated. According to this report:

> "The growing outdatedness of the Inventory data has increasingly become a major problem for OTS in discharging its responsibilities mandated by TSCA. For example, when OTS [begins to investigate potentially hazardous substances, it is] important to determine who produces them, where, and in what quantities. The inventory should provide such basic information. Unfortunately, this rather unique resource cannot now be relied upon for information accurate enough to use reliably in the assessment process."

OTS has recently made a decision to study the feasibility of updating a portion of the inventory. Under an OTS draft plan, manufacturers and importers must all initially report production-type information on existing chemicals selected for reporting. Thereafter, annual update reports would be required only when significant changes occurred in a chemical's production characteristics. OTS has established an EPA-wide work group to study how the inventory should be updated, and the work group is currently in the process of determining those chemicals needing updating and defining the reporting criteria. Though it is too soon to tell exactly how the inventory will be updated and what the scope of the update will be, OTS expects to issue a proposed rule in the fall of 1984 and issue a final rule in the fall of 1985.

EPA DELAYED IMPLEMENTING RECORDKEEPING REQUIREMENTS FOR SIGNIFICANT ADVERSE REACTIONS

Under section 8(c), manufacturers, processors, and distributors of chemical substances must maintain records of significant adverse human or environmental reactions which are alleged to have been caused by an existing chemical. Records relating to the health of employees must be kept for 30 years, and records of other adverse reactions (e.g., consumer injury, environmental damage) must be kept for 5 years. EPA may, upon request, inspect and obtain copies of these records.

However, before these recordkeeping requirements are effective, section 8(c) requires the Administrator to determine by rule the records of significant adverse reactions to health and the environment which must be kept. EPA has only recently, in August 1983, issued a final rule implementing this section. EPA cited higher TSCA priorities as the reason why this section was not implemented sooner. Because of this delay, industry has not been required to develop this data base which, according the Chief of OTS' Chemical Screening Branch, could be useful in screening and characterizing potential risks associated with chemical substances. Such records can:

--Create a historical record of significant adverse reactions alleged to have been caused by a substance or mixture. EPA can examine such records whenever a chemical is discovered to present possible risks to human health or the environment.

--Provide a means to identify previously unknown chemical hazards and to reveal patterns of adverse effects that might otherwise either not be noticed or go undetected for long periods of time.

Implementing recordkeeping requirements not a high EPA priority

Although records of significant adverse reactions could be useful to EPA, the promulgation of section 8(c) provisions has not been a high EPA priority in relation to the other information-gathering authorities of the act. According to the Director of OTS' Assessment Division, EPA believed that other important TSCA authorities should be implemented first, such as test rule development and rules to obtain production data and health and safety studies, before spending the time and resources needed to implement this provision.

While EPA has been working on a regulation implementing section 8(c) since 1977, it did not issue a proposed rule until July 1980. Since that time, according to the OTS official responsible for the rulemaking effort, OTS has spent considerable time responding to over 160 public comments on the proposal. Also, internal organizational changes within OTS further delayed final promulgation of the rule.

A final rule implementing 8(c) recordkeeping provisions was promulgated in August 1983. This rule requires industry to keep records of significant adverse rections; it makes no provisions for automatically reporting significant data. However, EPA expects that an accumulation of 8(c) reports on a chemical may result in industry's automatically reporting to EPA under section 8(e) notification of substantial risk requirements.

After section 8(c) recordkeeping requirements have been in place long enough for a meaningful data base to develop, EPA will still need to develop procedures and criteria for calling up these data. OTS plans to implement a records inspection program within a year, for enforcement purposes, and to determine the types and volume of records being recorded. According to the Chief of OTS' Risk Management Branch, EPA must inspect the characteristics of data being kept before it considers either (1) issuing a rule for the automatic reporting of significant data or (2) promulgating notice to industry requiring the forwarding of such data on particular chemicals of interest.

Because of the delays in developing recordkeeping requirements for allegations of significant adverse reactions, industry has not been required to develop this important data base that could be used in supporting EPA's chemical assessment and control activities. According to the Chief of OTS' Risk Management Branch, such a data base could take 2 to 3 more years for industry to develop, beyond the 7 years that have passed since TSCA's enactment, before it can be very useful in supporting OTS activities.

EPA PLANS LITTLE USE OF ITS REPORTING AUTHORITIES TO GATHER PRODUCTION DATA AND HEALTH AND SAFETY STUDIES

EPA is authorized under two TSCA sections to promulgate rules requiring manufacturers and processors to submit (1) reports on production-related data for existing chemicals (section 8(a)) and (2) lists and/or copies of health and safety studies conducted, known, or reasonably ascertainable on any chemical (section 8(d)). Such information, according to the Chief of OTS' Risk Management Branch, can be helpful to EPA in further characterizing the risks associated with specific chemicals under evaluation for testing or potential regulatory control. Although EPA has used these authorities for mostly ITC-recommended chemicals, it does not currently plan to use these authorities for many other chemicals actively being assessed in its existing chemicals review process. EPA contends that it is often cheaper and more timely to obtain the necessary data itself, or through voluntary industry submissions, rather than obtaining such data through rulemaking. Because EPA has not developed cost comparisons, we did not evaluate the appropriateness of this approach.

Status of EPA's use of reporting authorities under section 8(a)

According to EPA, data on a chemical's use, production level, by-products, adverse health and environmental effects, number of workers exposed, and methods of disposal, which can be required under section 8(a), can be useful in carrying out its chemical testing and risk control responsibilities. The most important use of these types of data is in screening and developing exposure profiles of chemical substances of concern. For instance, chemicals of high toxicity but with no exposure potential present little hazard to health or the environment; conversely, chemicals of low toxicity but high exposure may present unreasonable risks. Thus, the development of exposure data is extremely important in determining which chemicals present health and environmental hazards.

In October 1980, we reported that except for the data reported on the chemical substances inventory, EPA had not issued any rules using section 8(a) authority to develop production and exposure-related information on priority chemicals. Since our last report, EPA has made some progress in requesting, obtaining, and evaluating such data on a number of chemicals of priority concern.

EPA has issued the following rules under section 8(a):

--In October 1980, an 8(a) rule was issued requiring industry to notify EPA of any manufacture or importation of polybrominated biphenyls and tris (2,3-dibromoprophyl) phosphate. Although industry had voluntarily agreed to cease manufacture and importation of these substances, due to evidence that they presented risks to human health, EPA wanted to confirm that there are no significant sources of these substances to ensure that EPA has the opportunity to investigate the circumstances of any resumption of production. To date EPA has received no reports.

--In July 1982, an 8(a) rule was issued to help EPA regulate asbestos; it required reports by asbestos manufacturers, importers, and processors. The information sought included data on quantities of asbestos used in making products, employee exposure, and waste disposal and pollution control equipment. EPA has received data under this rule and is currently evaluating the information to help support its ongoing investigation of potential asbestos hazards.

However, EPA's major effort to date in implementing section 8(a) is its preliminary assessment rule issued in June 1982 requiring exposure-related information on approximately 250 chemicals. These include 217 chemicals that the ITC had

identified for test rule development[1] and 33 chemicals that had been identified through section 8(e) as being of substantial risk. The purpose of the section 8(a) rule was to obtain production, use, and exposure data on these selected priority chemicals that OTS was evaluating for possible test rule development or potential regulatory control.

As discussed on page 46, EPA also has used its section 8(a) authority to compile certain broad production-related data for the chemical substances inventory to identify a chemical's broad production ranges, plant site location, and whether the chemical was distributed beyond the production site. According to the Director of OTS' Assessment Division, such information would be of little use in any in-depth assessment of these chemicals' exposure potential. The 8(a) preliminary assessment rule required manufacturers to submit more detailed information, including where a chemical is made, in what quantities, potential worker exposure, likely environmental releases, and categories of use.

Under this preliminary assessment rule requesting information on 250 chemicals, EPA has received 767 reports. Such information has been used by OTS' Test Rules Development Branch in evaluating ITC-recommended chemicals and been evaluated by OTS' existing chemicals task force in determining whether chemicals reported under section 8(e) deserve further assessment under the existing chemicals review process. Of those 33 section 8(e) identified chemicals subject to the section 8(a) rule, 29 have been dropped from review and 4 were still under active review as of October 1983.

The 8(a) preliminary assessment information rule was designed to be a model rule that could be amended to include other chemicals of priority concern in the future. EPA has amended this rule to

--add 46 more chemicals to the original 8(a) rule that were identified by the ITC in its sixth through ninth reports (May 19, 1983) and

--require automatic 8(a) preliminary assessment information reporting on all future ITC chemical lists, beginning with ITC's tenth report.

When the 8(a) preliminary assessment information rule was first proposed in February 1980, the rule called for information to be submitted on 2,226 chemicals. Included in this number were chemicals identified through (1) industry's submissions of 8(e)

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[1]The rule requires reporting of chemicals designated for testing by ITC in its first through fourth reports. Though ITC had recommended only 33 chemicals in those reports, the 217 chemicals included in the 8(a) rule constitute subcategories of chemicals recommended by ITC.

notices of substantial risk, (2) ITC-recommended chemicals needing priority testing, (3) chemicals of high production volume, exposure potential, and toxicity, and (4) chemicals whose structure was similar to known toxic substances. EPA stated in the proposal that these chemicals were chosen for the purpose of screening and ranking to find those deserving further investigation and that the 2,226 chemicals were ones for which EPA had reason to believe there is or may be significant toxicity or exposure.

However, when EPA issued its final preliminary assessment information rule in June 1982, it eliminated approximately 2,000 chemicals from its reporting requirements. The major reason for eliminating these chemicals was "primarily in order to reduce the reporting burden," as stated in the Agency's responses to individual comments on the proposed rule. EPA estimated that implementing the proposed rule would cost industry approximately $6 million, but the final rule, which applies to only about 250 chemicals, would have an impact of only about $760,000 on industry.

As we reported in a December 7, 1982 report, EPA Implementation of Selected Aspects of the Toxic Substances Control Act (GAO/RCED-83-62), EPA, in its efforts to reduce the reporting burden of the rule, decided to eliminate those chemicals that were included on the list merely for the purpose of general information gathering. Those chemicals eliminated were generally those that were of interest because of their high production volume levels and exposure potential. EPA decided to limit its final rule to chemicals that are known to pose some risk potential to health and environment and have been identified through other TSCA mechanisms, such as chemicals recommended for testing by the ITC (217 chemicals) and certain chemicals (33 chemicals) for which EPA received section 8(e) notifications of substantial risk.

The 250 chemical substances subject to the final rule do not necessarily represent the greatest potential chemical risks, but they are risks for which enough preliminary toxicity data exists, along with sufficient exposure data, that OTS will be able to characterize the substance for possible chemical control. OTS officials have stated that eliminating the approximately 2,000 chemicals from the final information gathering rule does not mean that EPA has determined that they are not hazardous, only that EPA has decided to delay any requests for data on these and other chemicals to some future date and concentrate its efforts on those chemicals that, based on best available information, pose the greater potential risk or would result in a near-term EPA response.

Status of EPA's use of section 8(d) authority

Though EPA issued a final 8(d) rule in July 1978 requesting studies on the first 10 substances ITC recommended for priority testing, EPA revoked the rule subsequent to a lawsuit filed by a

chemical company challenging the scope of EPA's statutory authority. Despite the fact that EPA revoked the rule, the Court of Appeals sustained EPA's interpretation of its information-gathering authority.

Since that court ruling, and since our October 1980 report, EPA has issued final rules to obtain health and safety studies under section 8(d) for ITC-recommended chemicals. In September 1982, EPA issued a section 8(d) rule requiring health and safety studies on the 38 chemical substances and categories recommended by ITC in its first through fifth reports, as well as certain categories of asbestos. This rule also contained provisions requiring automatic section 8(d) reporting on all future chemicals recommended for testing by the ITC. Since promulgation of this reporting rule, EPA has amended it to include subsequent ITC-recommended chemicals. Over 4,000 studies to date have been reported, processed, and evaluated from the first two section 8(d) rules and are being actively used in the development of test rules for ITC chemicals.

EPA views rulemaking under these authorities as lengthy and costly

Under its existing chemical review process, as of October 1983, EPA is currently evaluating approximately 60 chemical substances. These chemicals have been chosen for active review because they are suspected of presenting an unreasonable risk to human health or the environment. Of these 60, 5 have been subject to a section 8(a) rule to obtain production-related data and 1 to a section 8(d) rule to obtain health and safety studies. The five chemicals subject to 8(a) reporting were originally identified through section 8(e) substantial risk notifications and were subject to reporting under the first 8(a) rule requiring data on 250 chemicals. The one chemical with section 8(d) data was originally an ITC-recommended chemical and thus subject to automatic 8(d) reporting requirements.

Although the Acting Director of OTS, the Director of OTS' Existing Chemical Assessment Division, and the Chief of OTS' Risk Management Branch have all stated that production data and health and safety studies would be useful in the assessment of these chemicals, EPA plans to obtain such data from section 8(a) and 8(d) rulemaking only infrequently. When asked why EPA has previously gone through rulemaking to obtain section 8(a) and 8(d) data on certain chemicals in the past, but does not plan to regularly obtain similar data on those chemicals currently being assessed under the existing chemicals review process, these officials responded that the rulemaking experiences of promulgating those rules have led them to the conclusion that it is often an inefficient use of OTS resources to obtain such data through rulemaking. These officials stated that the rulemaking procedures that are required to add chemicals to 8(a) and 8(d) rules are both lengthy and costly and that EPA can obtain enough adequate data to make prudent assessment decisions through its own

search of existing data bases, the development of its own data, or the voluntary submission of needed data from industry. EPA was not able to identify the specific costs to the Agency of obtaining such data on its own compared to the cost of obtaining similar data through rulemaking. Though EPA has not ruled out the possibility of amending the section 8 rules to include additional chemicals in the future, it intends to do this only in limited instances where EPA cannot develop the necessary data itself.

CONCLUSIONS

In October 1980, we reported that EPA had been slow to collect basic information on existing chemicals and had not implemented or used many of the authorities contained in TSCA's Section 8 information-gathering authorities. While EPA had made some progress in using these information-gathering authorities, problems remained.

EPA has maintained a list of existing chemical substances found in commerce as required by chemical inventory provisions of section 8(b). However, the production-related data on these chemicals are outdated. EPA recognizes the need to update these data and has convened a work group to study several proposals to accomplish this. Although it is too soon to tell exactly how the inventory will be updated, the head of the work group said that he expects EPA to issue a proposed rule in the fall of 1984, and a final one in the fall of 1985. Until this update occurs, EPA will not be able to rely upon the accuracy of the inventory information for screening and characterizing the exposure risks associated with potentially hazardous chemicals.

EPA's implementation of TSCA's Section 8(c) requirement that industry record allegations of significant adverse reactions had been delayed. EPA has only recently issued a final rule implementing this section, in August 1983. EPA officials cited higher TSCA priorities, complexities of rulemaking, and internal organizational changes as reasons why the final rule was delayed. Because of these delays, industry has not been required to develop this data base that could be used in supporting EPA's chemical assessment and control activities. In addition, 2 or 3 more years may be required before an adequate data base is developed to support EPA activities.

Although EPA has issued rules requiring industry to report production data and health and safety studies using TSCA authorities contained in sections 8(a) and 8(d), it plans little use of these authorities in the future for other than ITC chemicals recommended for testing. Such information can be helpful to EPA to further characterize chemicals actively being assessed in its existing chemicals review process, but EPA believes that obtaining such information through rulemaking is lengthy and costly. EPA contends it can often obtain the needed data cheaper and in a more timely manner itself or through voluntary industry submissions. As a result, it plans to require

rulemaking to gather these data in only limited instances where EPA cannot readily develop the data itself. EPA was unable to provide us with figures comparing the cost of obtaining such data through rulemaking with the cost of obtaining similar data itself or voluntarily. Because of this we were unable to make a reasoned assessment of EPA's proposed course of action.

EPA DISPOSITION OF TSCA SECTION 21 CITIZENS' PETITIONS

(As of September 20, 1983)

	Petitioner/date	Petitioner's request	EPA disposition/Federal Register notice
1.	Manufacturing Chemists Assoc. Sept. 12, 1978	Repeal or amend the health and safety reporting regulations promulgated under section 8(d).	Denial because the major points lack the substantive merit and/or timeliness to warrant repeal or amendment of the section 8(d) rule. (43 FR 56274, Dec. 4, 1978)
2.	New Jersey Governor Brendan T. Byrne Sept. 18, 1978	Initiate a rulemaking under section 6, to control asbestos emissions from sprayed material that have been applied in school buildings.	Granted because EPA will initiate rulemaking to regulate asbestos containing material in schools. (44 FR 27257, May 9, 1979) (44 FR 40900, July 13, 1979)
3.	Environmental Defense Fund Dec. 21, 1978	Control, under section 6, asbestos emissions from spray-on material applied in public school buildings.	Granted because EPA will initiate rulemaking to regulate asbestos containing material in schools. (44 FR 20290, April 4, 1979) (44 FR 40900, Julv 13, 1979)
4.	State of North Carolina Feb. 6, 1979	Modify the PCB regulation to provide EPA Regional Administrator discretion to approve additional disposal methods for soil and debris contaminated with PCBs.	Denial because there are no known environmentally acceptable disposal alternative to EPA-approved methods. (44 FR 40132, July 9, 1979)
5.	Glenn Scott June 21, 1979	Initiate a proceeding for the issuance of a rule to prohibit the manufacture and distribution of asbestos cement water pipes.	Granted because EPA plans to investigate asbestos cement pipe as part of an ongoing regulatory development program. (44 FR 60155, Oct. 18, 1979)

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	Petitioner/date	Petitioner's request	EPA disposition/Federal Register notice
6.	Chemical Manufacturers Assoc. March 17, 1980	Augment the rulemaking record for Preliminary Assessment Information Rule; place in the rulemaking record certain detailed information on 2,200 chemicals for which the Agency is soliciting basic data for preliminary assessment purposes; and grant an extension of the comment period following this augmentation.	Denial because request is not a petition, but a request to augment the rulemaking record. EPA will clarify the record where appropriate. (45 FR 28172, April 28, 1980)
7.	Walter Fitzpatrick May 5, 1980	Initiate a proceeding for the issuance of a rule to prohibit the manufacture and distribution of nitrilotriacetic acid.	Denial because the projected exposure and health risks are low. (45 FR 72778, Nov. 3, 1980)
8.	Glenn Scott April 26, 1980	Prohibit the manufacture of 2-naphthalenamine.	Denial because the substance is not manufactured, imported, or processed in the U.S. and it has been removed from the TSCA inventory, thus making it subject to section 5 premanufacture notification requirements. (46 FR 36244, July 14, 1981)
9.	John Scoggins Floor Sweep Co. and Tak-Less Floor Sweep Co. April 28, 1980	Amend the PCB prohibition rule to allow PCBs in concentrations as high as 10 parts per million in floor sweep compounds.	Denial because use of PCBs in dust control agents would result in rapid and direct entry of PCBs into the environment. (45 FR 80320, Dec. 4, 1980)
10.	Thomas L. Rush Aug. 26, 1980	Ban the manufacture, distribution, possession, or use of alpha-chloroacetophenone for use in tear gas, thermal grenades or foggers.	Denial because the benefits outweigh the small potential for serious health injuries. (47 FR 333, Jan. 5, 1982)
11.	EOI, Inc. Aug. 7, 1981	Add to, modify, and delete certain provisions of PCB manufacturing, processing, distribution in commerce, and use prohibitions.	Denial of 6 specific recommendations to amend the PCB regulations because EPA clarification can be accomplished without amending the regulation. (47 FR 2379, Jan. 15, 1982)

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	Petitioner/date	Petitioner's request	EPA disposition/Federal Register notice
12.	Ronald W. Wood April 26, 1982	Initiate rulemaking to prohibit the distribution of alkylnitrites in consumer products.	Denial based on the Consumer Product Safety Commission's prior assessment and decision that banning the chemical's use in consumer products is not warranted. (47 FR 32779, July 29, 1982)
13.	Dow Chemical May 13, 1982	Amend the PCB regulations to exclude monochloro biphenyls.	Denial because the issue of by-products and inadvertent PCBs will be the subject of EPA proposed rules. (47 FR 37258, Aug. 25, 1982)
14.	General Electric Company July 14, 1982	Amend the PCB regulations to exclude monochloro biphenyls and dichloro biphenyls.	Denial because the issue of by-products and inadvertent PCBs will be the subject of EPA proposed rules. (47 FR 46723, Oct. 20, 1982)
15.	MET Electrical Testing Co. Inc. Jan. 13, 1983	Amend the PCB regulations to create a new regulatory classification for transformers that contain less than 250 ppm PCBs.	Denial because no substantive issues were identified. (48 FR 16884, April 20, 1983)
16.	Environmental Congress of Mid-Michigan and the Foresight Society March 16, 1983	Initiate certain investigations and enforcement actions related to dioxin and furan pollution in central Michigan.	Denial of a portion of the petition requesting action under section 6(b) to obtain quality control information from Dow Chemical Co., because the action is essentially being pursued under other authorities. EPA outlined ongoing and planned activities which attempt to address the environmental problems mentioned. (48 FR 33739, July 25, 1983) (48 FR 35168, Aug. 3, 1983)
17.	Citizens Clinic for Accountable Government April 20, 1983	Supplemental petition that requested same action from EPA as the above petition from the Environmental Congress of Mid-Michigan and the Foresight Society.	Denial (same as item 16 above). (48 FR 33739, July 25, 1983) (48 FR 35168, Aug. 3, 1983)

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