United States General Accounting Office

GAO

Report to the Chairman, Environment, Energy, and Natural Resources Subcommittee, Committee on Government Operations, House of Representatives

April 1990

TOXIC SUBSTANCES

EPA's Chemical Testing Program Has Made Little Progress

GAO/RCED-90-112

GAO

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

Resources, Community, and
Economic Development Division

B-232917

April 25, 1990

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

Dear Mr. Chairman:

As you requested, we evaluated the Interagency Testing Committee's and Environmental Protection Agency's (EPA) implementation of the chemical testing program set forth under section 4 of the Toxic Substances Control Act of 1976. This report contains recommendations and matters for congressional consideration aimed at improving the progress of the chemical testing program.

As arranged with your office, unless you publicly release its contents earlier, we plan no further distribution of this report until 30 days after the date of this letter. At that time, we will send copies of the report to the appropriate congressional committees; the Administrator, EPA; and the Director, Office of Management and Budget.

This work was performed under the direction of Richard L. Hembra, Director, Environmental Protection Issues, (202) 275-6111. Other major contributors to this report are listed in appendix I.

Sincerely yours,

J. Dexter Peach
Assistant Comptroller General

neither ITC nor EPA has produced a list of those that do not require testing. Moreover, EPA has compiled complete test data for only six chemicals since the enactment of TSCA and has not finished assessing any of them. The testing program has made little progress primarily because EPA was slow to get started, but other problems remain, which, if not corrected, will further limit progress. These problems are as follows:

- ITC lacks crucial data it needs to make recommendations. In addition, its efforts may have been hampered by its members' poor attendance at monthly meetings.
- After proposing test rules, EPA continues to take an average of more than 2 years to make them final, which is more than the 12- to 18-month time frame GAO recommended in 1984.
- More importantly, the testing program lacks overall objectives and a strategy for achieving them.

Principal Findings

ITC Lacks Data and Has Poor Member Participation

ITC has designated 386 chemicals for testing since it began making recommendations in 1977, or an average of about 32 chemicals per year. ITC's efforts have been hampered by a lack of data it needs to justify recommendations. Throughout its chemical review efforts, ITC has had to use outdated production data because current data were not available. In addition, ITC has had difficulty obtaining exposure data because they are generally not readily available from chemical manufacturers and processors unless specifically requested.

ITC's progress may also have been impeded by its members' poor attendance at monthly meetings. Members provide the expertise needed to review chemicals and must vote on which chemicals to recommend for testing. In a survey of ITC's monthly meetings held between January 1986 and April 1989, GAO found that the average attendance was about 61 percent.

EPA Continues to Be Slow in Issuing Final Test Rules

As of the end of fiscal year 1989, EPA had required testing for about 39 percent of the 386 chemicals that ITC had designated. It has made preliminary decisions to require testing for about 36 percent of the chemicals and has decided not to test about 25 percent. As GAO discussed in a June 1984 report entitled EPA's Efforts to Identify and Control Harmful

pace at which it plans to address these chemicals. As a result, EPA officials are unclear about the program's direction and priorities. The agency itself has reported that the absence of explicit written documentation concerning such matters as program direction has contributed significantly to the lack of productivity and the misdirection of EPA's overall chemical review efforts under TSCA, including the testing program.

Recommendations

To improve the progress of the chemical testing program, we recommend that the Administrator of EPA do the following:

- Exercise EPA's data-gathering authority on ITC's behalf under TSCA to obtain the data that ITC needs to make recommendations.
- Work with ITC to improve its member participation.
- Place a high priority on issuing final test rules by ensuring that adequate staff resources are devoted to completing test rules within a reasonable time, such as the 12- to 18-month time frame that GAO recommended in 1984.
- Develop overall objectives for the testing program and a strategy for achieving the objectives. These should identify, among other things, the universe of chemicals EPA needs to address and the pace at which it plans to address these chemicals.

Matters for Congressional Consideration

To ensure that the chemical testing program achieves what the Congress intended, the Congress may want to require EPA to develop a comprehensive plan setting forth objectives, a strategy, and time frames, and submit the plan to the Congress for approval.

Agency Comments

GAO discussed the matters in this report with EPA officials, who generally agreed with our findings and conclusions. However, as requested, GAO did not obtain official agency comments on a draft of this report.

Executive Summary

Purpose

More than 60,000 chemicals are in commerce in the United States. Some of these, such as polychlorinated biphenyls (PCBs) and asbestos, have been shown to cause tumors, birth defects, or cancer. Other chemicals may be just as harmful, but adequate data do not exist to make that determination. Section 4 of the Toxic Substances Control Act (TSCA) authorized the Environmental Protection Agency (EPA) to require industry to test potentially harmful chemicals for the purpose of developing data on their health and environmental effects. Section 4 also created the Interagency Testing Committee (ITC) to recommend to EPA chemicals that should receive priority attention for testing.

Concerned about the lack of progress, the Chairman, Environment, Energy, and Natural Resources Subcommittee, House Committee on Government Operations, asked GAO to evaluate ITC's and EPA's implementation of the chemical testing program set forth under section 4 of TSCA.

Background

The Congress enacted TSCA in October 1976 to provide comprehensive regulatory authority over chemicals that were not covered by existing legislation. The act applies to all chemicals except those in eight product categories that are covered by other laws: pesticides, tobacco, nuclear material, firearms and ammunition, food, food additives, drugs, and cosmetics.

One important section of TSCA—section 4—authorized EPA to require chemical manufacturers and processors to test potentially harmful chemicals. EPA must show that existing data are insufficient to determine whether the chemicals in fact have toxic consequences and that testing is needed to make that determination. Section 4 also created ITC, which is composed of representatives from eight federal agencies involved in environmental and health issues. ITC must report semiannually to EPA and include a list of no more than 50 chemicals designated for testing. EPA must respond to these chemical designations within 1 year by proposing a test rule or explaining its reasons for not doing so in the Federal Register. TSCA established no time requirements for EPA in issuing a final test rule.

Results in Brief

The chemical testing program has made little progress. It has identified for testing less than 1 percent of the more than 60,000 chemicals in the TSCA inventory. Although not all 60,000 chemicals may need to be tested,

Chemicals in Use (GAO/RCED-84-100, June 13, 1984), EPA was slow to implement the chemical testing program. GAO also noted that EPA, at that time, had issued no final test rules and was taking too long (over 3 years) to make a proposed rule final. GAO recommended that, after proposing test rules, EPA make them final within a reasonable time, such as 12 to 18 months.

Although EPA is now generally meeting the 1-year statutory deadline for responding to ITC, the agency continues to be slow in issuing final test rules. EPA took an average of more than 27 months in completing 12 of the 15 test rules it proposed in response to chemical designations ITC had made since GAO's 1984 report. It met the 12- to 18-month time frame for only 1 of the 12 rules. EPA has not completed the remaining three proposed rules; two of these are over 2 years old. In addition, as of the end of fiscal year 1989, EPA still needed to complete four rules that it initiated before June 1984.

GAO believes that issuing final test rules is as important as issuing proposed rules. Until a final rule is issued, testing does not begin and industry does not develop the data needed to determine the health and environmental effects of potentially harmful chemicals. Since EPA has been slow to issue final rules, the health and environmental effects of thousands of chemicals remain unknown. Chemicals that have not yet been tested include aryl phosphates and glycidol and its derivatives, which are suspected of causing cancer or gene mutations or have the potential for widespread environmental and human exposure. These chemicals are used as plasticizers, in hydraulic fluids, in lubricants, or in epoxy glues. While EPA initiated test rules for them in 1983, it still has not issued final rules to begin their testing.

Testing Program Lacks Overall Objectives and Strategy

GAO believes that federal agencies need to establish objectives and strategies for adequate internal control of their programs. Objectives and strategies provide, among other things, focus, direction, and a perspective on the magnitude of the tasks that a program faces. They also help to identify priorities and resource needs.

EPA has established various policies and procedures for implementing the chemical testing program. However, it has not developed overall objectives for the program or a strategy for achieving them. In particular, it has not identified which of the 60,000 chemicals in TSCA's inventory most likely need testing and which do not. Nor has it identified the

Contents

Executive Summary		2
Chapter 1 Introduction		8
	TSCA and Section 4 Chemical Testing Provisions	8
	The Chemical Testing Program and Chemical Review Procedures	9
	Objectives, Scope, and Methodology	11
Chapter 2 Insufficient Data and Poor Member Participation Impede ITC's Progress		13
	Status of ITC's Chemical Recommendations	13
	ITC Has Had Difficulties Obtaining Current Production and Exposure Data	14
	Participation by ITC Members Is Poor	15
	Conclusions	16
	Recommendations	16
Chapter 3 EPA Continues to Be Slow in Issuing Final Test Rules		17
	Status of EPA's Responses to ITC's Recommendations	17
	EPA Was Initially Slow to Respond to ITC's Recommendations and Issue Final Test Rules	18
	EPA Is Generally Meeting 1-Year Deadline but Is Still Slow to Issue Final Test Rules	19
	Conclusions	21
	Recommendation	22
Chapter 4 Chemical Testing Program Lacks Overall Objectives and a Strategy		23
	Importance of Establishing Overall Program Objectives and a Strategy for Achieving Them	23
	EPA's Policies and Procedures Do Not Identify Overall Program Objectives or Strategy	23
	Conclusions	24
	Recommendation	25
	Matters for Consideration by the Congress	25
Appendix		
	Appendix I: Major Contributors to This Report	26

Tables

Table 1.1: Steps in ITC's and EPA's Chemical Review Procedures 11
Table 3.1: EPA's Responses to ITC's Recommendations 17
Table 3.2: EPA's Initial Responses to Recommendations Made After June 1984 19
Table 3.3: Length of Time EPA Took to Complete Test Rules for Chemicals Recommended Since June 1984 20

Figure

Figure 2.1: Number of Chemicals Recommended by ITC 14

Abbreviations

ECAD	Existing Chemical Assessment Division
EPA	Environmental Protection Agency
GAO	General Accounting Office
ITC	Interagency Testing Committee
OTS	Office Of Toxic Substances
PCBs	polychlorinated biphenyls
TSCA	Toxic Substances Control Act

Introduction

More than 60,000 chemicals are in commerce in the United States. Although laws existed before 1976 to control hazardous chemicals in food, drugs, air, water, and soil, they did not address all chemicals. Consequently, chemical substances—such as polychlorinated biphenyls, commonly known as PCBs, and asbestos—went unregulated. PCBs and asbestos have been shown to cause tumors, birth defects, or cancer.

Recognizing the need for legislation to address chemicals not covered by existing legislation, the Congress passed the Toxic Substances Control Act (TSCA) in October 1976. One important section of TSCA—section 4—authorized the Environmental Protection Agency (EPA) to require chemical manufacturers and processors to test chemicals in commerce that may be harmful. Section 4 also created the Interagency Testing Committee (ITC) to recommend to EPA chemicals that should receive priority attention.

TSCA and Section 4 Chemical Testing Provisions

The primary purpose of TSCA is to ensure that chemicals in commerce do not present an "unreasonable risk of injury to health or the environment." TSCA authorized EPA to gather and assess information on the effects of chemicals and regulate those found to present unreasonable risks. TSCA does not apply to eight product categories that are covered by other laws: pesticides, tobacco, nuclear material, firearms and ammunition, food, food additives, drugs, and cosmetics.

One of EPA's initial tasks under TSCA was to compile an inventory of all chemical substances that the nation manufactures, processes, or imports. All chemicals listed in the TSCA inventory are classified as "existing chemicals" or "chemicals in commerce." All chemicals not listed in the inventory are new chemicals and are subject to premanufacture notification requirements established under another section of TSCA. (This report does not address new chemicals.) The inventory, first published in 1979 and periodically updated, contains more than 60,000 chemicals in commerce.

Section 4 of TSCA authorized EPA to require chemical manufacturers and processors to test potentially harmful chemicals in commerce for the purpose of developing data on their health and environmental effects. To require testing, EPA must determine that (1) the chemical may present an unreasonable risk (e.g., because it is structurally similar to another chemical that is known to be harmful), or it is produced in substantial quantities (e.g., more than 1 million pounds produced annually) and may result in substantial or significant human exposure (e.g., over

1,000 individuals) or environmental release; (2) the data are insufficient for determining the chemical's effects; and (3) testing is necessary to develop adequate data. EPA must notify companies of testing requirements by publishing test rules in the Federal Register. In issuing a test rule, EPA must specify the chemical to be tested, test standards, and schedules for submission of data.

Section 4 also established the Interagency Testing Committee (ITC) and authorized it to semiannually recommend to EPA chemicals that should be given priority consideration for testing. ITC was to consist of representatives from eight federal entities involved in environmental and health issues: EPA, the Department of Labor, the Council on Environmental Quality, the National Institute for Occupational Safety and Health, the National Institute of Environmental Health Sciences, the National Cancer Institute, the National Science Foundation, and the Department of Commerce. No individual representative may serve as an ITC member for more than 4 years. In identifying chemicals for recommendation, ITC must consider, among other things, production and exposure levels and give priority consideration to those that might cause cancer, gene mutations, or birth defects. ITC must report semiannually to EPA and include a list of no more than 50 chemicals designated for testing.

Section 4 requires EPA to respond to ITC's chemical designations within 1 year by proposing a test rule or explaining its reasons for not doing so in the Federal Register. It established no time requirements for EPA in issuing a final test rule.

The Chemical Testing Program and Chemical Review Procedures

To implement section 4 of TSCA, EPA established the chemical testing program shortly after TSCA was enacted. The program encompasses ITC's and EPA's chemical review activities.

To carry out its responsibilities, ITC has developed a chemical review procedure that consists of two major phases: an initial screening and an in-depth review. The purpose of the screening process is to identify chemicals that could be harmful, such as (1) those that are produced in large quantities (e.g., more than 1 million pounds) and thus have the potential for widespread human exposure or environmental release and (2) those that are structurally similar to chemicals already found to be harmful. ITC convenes experts in the fields of toxicology and environmental chemistry for this task. Chemicals not identified by the experts are deferred until additional data indicate a need for further review.

In the in-depth review phase, ITC representatives evaluate in detail the potentially harmful chemicals identified in the initial screening. In addition to the statutory members, representatives from various agencies have been invited by ITC to assist it in its in-depth chemical review: the Agency for Toxic Substances and Disease Registry, the Consumer Product Safety Commission, the Department of Agriculture, the Department of Defense, the Department of the Interior's Fish and Wildlife Service, the Food and Drug Administration, the National Library of Medicine, and the National Toxicology Program. These "liaison" members are not mandated by TSCA and therefore cannot vote on which chemicals to recommend, but they may otherwise fully participate in ITC's chemical review.

The statutory and liaison members meet monthly to decide which chemicals are of most concern and should be recommended to EPA. In making the chemical recommendations, they consider a number of factors, such as the quantities manufactured, the number of individuals exposed to the chemical, the extent of environmental release, and the kind of testing that is needed. ITC assumes that the greater the production of a chemical and level of exposure, the greater the potential for harm. The members also review available studies on the chemicals under consideration to determine whether they may cause cancer, birth defects, or gene mutations.

After receiving ITC's recommendations, EPA reviews the chemicals to determine whether they meet the criteria set forth under section 4 for testing. If the criteria are met, EPA decides what test data are needed; if the criteria cannot be met, EPA makes a decision not to test. According to the chief of the testing program, in determining what test data are needed, EPA primarily looks for chemical effects in three areas: (1) human health, (2) environment, and (3) chemical fate. Testing for human health effects includes testing for acute and chronic effects, gene mutations, cancer, birth defects, and neurotoxicity. Environmental testing primarily focuses on the chemical's effects on aquatic life. Testing for chemical fate involves assessing the chemical's characteristics, such as its ability to be absorbed in water.

Table 1.1 summarizes the basic steps by which ITC and EPA review chemicals for testing.

Table 1.1: Steps in ITC's and EPA's Chemical Review Procedures

ITC	Reviews available data on chemicals in TSCA's inventory, including data on production and exposure levels and chemical properties to identify a more manageable subset of chemicals for in-depth review.
	Reviews in depth chemicals of concern.
	Recommends chemicals for priority testing in a report to EPA.
EPA	Receives and publishes ITC's report and issues notices to industry to submit information, such as available health and safety studies, on the chemicals recommended.
	Invites and responds to public comments on ITC's recommendations and holds public meetings.
	Reviews information submitted by industry and the public and decides whether to test.
	Issues proposed test rule and responds to public and industry comments.
	Issues final test rule.[a]

[a]In a few cases, when EPA reached a consensus among affected chemical manufacturers and/or processors and interested parties on the required testing, EPA issued a consent agreement instead of a test rule because it believed this approach used fewer resources, took less time, and obtained test data sooner than a test rule. However, according to the chief of the chemical testing program, for the most part, EPA has proceeded with rulemaking because of difficulties in getting agreement from all parties.

Companies generally take about 2 to 5 years to complete the testing. EPA officials then assess the data and make a final decision about the chemical's disposition. They may decide, for example, to forward it to another TSCA program for further review and possible regulation, or they may decide to take no further action.

Objectives, Scope, and Methodology

On August 8, 1988, the Chairman, Subcommittee on Environment, Energy, and Natural Resources, House Committee on Government Operations, requested GAO to assist the Subcommittee in its comprehensive review of EPA's implementation of TSCA. As agreed with the Chairman's office, we evaluated the chemical testing program, focusing on ITC's efforts in making recommendations and EPA's efforts in responding to ITC's recommendations. We determined whether ITC's and EPA's policies and criteria are consistent with section 4 provisions; whether ITC and EPA are following their policies and criteria as prescribed; what the status of the chemical testing program is; and whether any problems hamper the program's progress and what can be done to solve them.

To determine whether ITC's and EPA's policies and criteria are consistent with section 4 provisions, we reviewed relevant Federal Register notices,

policy pamphlets, and procedural manuals; ITC's chemical recommendation reports; EPA's annual TSCA reports; and other pertinent information. We discussed ITC's and EPA's policies and criteria with ITC members, EPA officials,[2] and EPA's legal counsel involved with TSCA. Furthermore, we compared the prescribed policies and criteria with the provisions in section 4.

To determine whether ITC and EPA are following their prescribed policies and criteria, we examined ITC's and EPA's chemical review procedures. We also discussed with ITC members and EPA officials their views on the procedures for implementing section 4 requirements.

To determine the status of the chemical testing program, we identified the number of chemicals ITC recommended, the number of recommendations EPA responded to, the number of chemicals EPA issued test rules for, and the number it decided not to test. We also identified the results of the program, such as the number of chemicals for which test data have been received and the number of final decisions EPA has made on those chemicals. However, we did not determine the validity of EPA's decisions to test or not test.

To determine whether any problems hamper the program's progress and what can be done to solve them, we assessed the adequacy of the data ITC and EPA use, their criteria for reviewing chemicals, and their objectives and strategies for implementing the chemical testing program. We also obtained views about the program from ITC members, EPA officials, the Environmental Defense Fund, and the Chemical Manufacturers Association to identify any concerns they might have.

We conducted our work between May and November of 1989 in accordance with generally accepted government auditing standards. We discussed with EPA officials the factual information in the report. However, as requested by the Chairman, Subcommittee on Environment, Energy, and Natural Resources, House Committee on Government Operations, we did not obtain written agency comments on a draft of this report.

[2]The EPA officials we talked to included those in the Office of Toxic Substances (OTS) under the Assistant Administrator for Pesticides and Toxic Substances, which is responsible for implementing all TSCA provisions; the Existing Chemical Assessment Division (ECAD) under OTS, which is responsible for addressing existing chemicals under TSCA; and the Test Rules Development Branch under ECAD, which has the lead responsibility for the chemical testing program.

Insufficient Data and Poor Member Participation Impede ITC's Progress

To recommend chemicals to EPA for testing, ITC needs data on their production and exposure levels. In addition to being legislatively required to consider such data, ITC needs the information to determine the chemicals' potential harm to humans and the environment and to determine whether the chemicals should be given priority for testing. Since TSCA was enacted, however, ITC has had problems obtaining current production and exposure data. According to ITC's executive secretary, these problems have impeded ITC's progress in recommending chemicals.

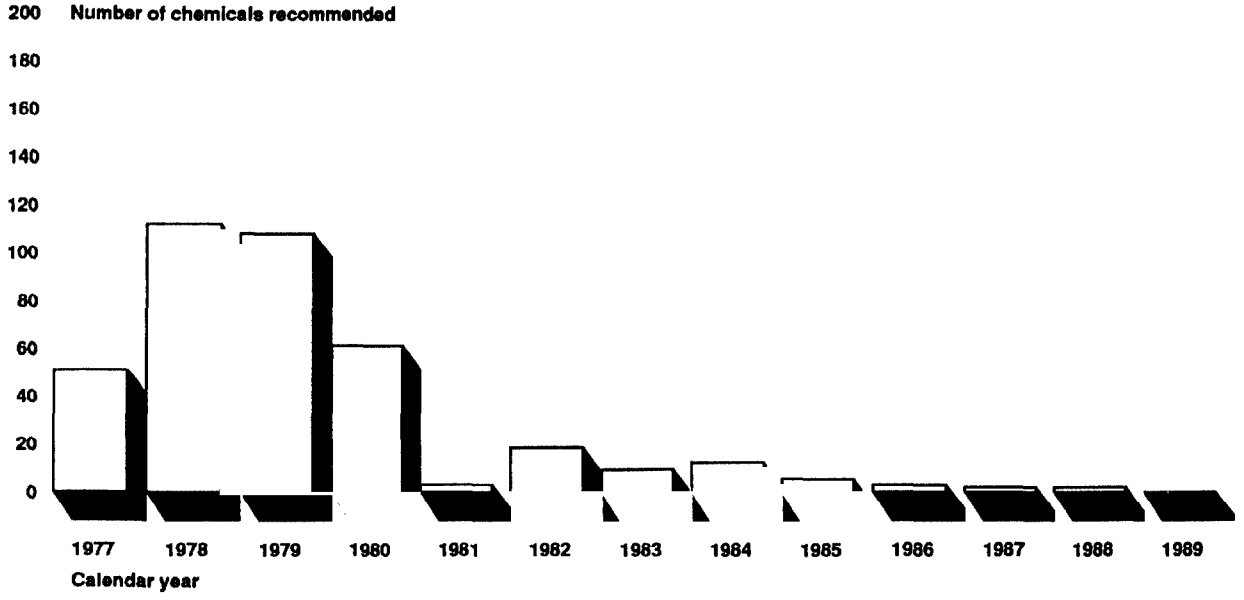
ITC also suffers from poor member participation. ITC members are needed at monthly meetings to review chemicals, provide valuable input on chemicals under consideration, and vote on which chemicals should be recommended for testing. We found that the average rate of attendance at ITC's monthly meetings held between January 1986 and April 1989 was about 61 percent. This poor attendance may have further slowed the chemical review process and limited the number of chemical recommendations ITC could make.

Status of ITC's Chemical Recommendations

Since October 1977, when ITC issued its first report to EPA, ITC has recommended 386 chemicals for testing.[1] This represents an average of approximately 32 chemicals recommended per year and less than 1 percent of the more than 60,000 chemicals in TSCA's inventory. As figure 2.1 illustrates, most of the chemicals were recommended in the first 4 years.

[1] In this report, we use the term "ITC recommendations" to refer to chemicals ITC designates for an EPA response within 1 year.

Figure 2.1: Number of Chemicals Recommended by ITC



Note: Data obtained as of the end of fiscal year 1989.

After 1980, the number of chemical recommendations dropped significantly because, in general, ITC stopped recommending categories of chemicals. EPA informed ITC in 1982 that it could not count categories as one recommendation, since they often contained large numbers of chemicals and thus could circumvent the statutory 50-chemical limit. However, the number of recommendations may also have dropped after 1980 because ITC had difficulty obtaining production and exposure data.

ITC Has Had Difficulties Obtaining Current Production and Exposure Data

ITC has had to use outdated production data because of problems in obtaining current data. Before 1979, ITC was able to obtain only limited production data on chemicals from whatever existing chemical databases were available because complete data for the more than 60,000 chemicals in the TSCA inventory did not exist. In 1979, EPA issued its first TSCA inventory, which included production data that ITC subsequently used. However, ITC found that production levels for a number of chemicals had changed significantly since the data were obtained; consequently, it could not rely on the 1979 inventory data. EPA has since updated the TSCA inventory data, but according to an EPA official responsible for the inventory, the update was limited to data on chemicals produced in 1985.

In addition, ITC has had difficulty obtaining adequate exposure data. In general, such data are not readily available from chemical manufacturers and processors unless specifically requested. In 1980, EPA and ITC identified 2,226 chemicals that they believed might be harmful. To help ITC obtain current exposure data for its in-depth review, EPA proposed a rule under section 8 of TSCA requiring chemical manufacturers to submit this information. (Section 8 authorizes EPA to require manufacturers and processors to maintain records and submit any information EPA needs to effectively enforce the act.) However, in the final rule, issued under section 8 in 1982, EPA required data for only 250 chemicals. EPA reduced the number, in part, because of the reporting burden on industry.

According to ITC's executive secretary, because ITC was limited by the reduced number of chemicals covered in the final rule, it chose to obtain additional needed information on its own by researching whatever was available in published literature. In this way, ITC obtained data on an additional 250 chemicals. However, as of the end of our audit work in November 1989, ITC still did not have exposure information for more than 1,700 chemicals. According to one former ITC representative, all 1,700 chemicals still need to be reviewed and need exposure data.

According to the ITC chairman, the lack of current production and exposure data has prevented ITC from making more recommendations in recent years. He believes this continues to be a problem.

Participation by ITC Members Is Poor

In addition to having data problems, ITC has problems with member participation. As stated in chapter 1, ITC consists of representatives from eight federal entities involved in environmental and health issues and liaison representatives from another eight agencies, who, at ITC's invitation, assist in the in-depth chemical reviews. ITC relies on both its statutory members and its liaison members to review potentially harmful chemicals identified through the screening process and to provide valuable input at ITC's monthly meetings, where chemicals are discussed and statutory members vote on which chemicals to recommend to EPA.

Between January 1986 and April 1989, attendance by statutory members at ITC's monthly meetings averaged about 61 percent. Attendance by liaison members averaged even less—54 percent. We found that reviews of chemicals had to be postponed several times because members were not present to provide the needed input. According to a former ITC executive secretary, attendance at the monthly meetings has been a problem because ITC representatives have other responsibilities.

Conclusions

ITC's review of chemicals has been hampered by the lack of current production data. In addition, although EPA has obtained some data for ITC under a section 8 rule, ITC still lacks exposure data for approximately 1,700 chemicals that were identified as early as 1980 as chemicals of concern. ITC's executive secretary believes that the lack of current production and exposure data has impeded ITC's progress in reviewing chemicals.

The lack of a full commitment from ITC members may have further slowed ITC's chemical review process and limited the number of chemical recommendations ITC could make. We believe that since EPA is ultimately responsible for implementing the chemical testing program and since the program's success depends, in part, on ITC's member participation, EPA needs to work with ITC to improve its member participation and, thus, the progress of the chemical testing program.

Recommendations

We recommend that the Administrator of EPA exercise EPA's data-gathering authority on ITC's behalf under section 8 of TSCA to obtain the data that ITC needs to make recommendations. This can be done in phases so that industry is not overburdened. We also recommend that the Administrator work with ITC to improve its member participation.

EPA Continues to Be Slow in Issuing Final Test Rules

As we reported in June 1984, EPA was initially slow in responding to ITC's recommendations and issuing final test rules, and we recommended that EPA make test rules final within a reasonable time, such as 12 to 18 months.[1] Since our 1984 report, EPA has continued to be slow in issuing final test rules, taking an average of more than 2 years. The delays may have been partly due to recent high staff turnover. More significantly, though, EPA is concentrating its efforts on issuing proposed rules, rather than final rules, to ensure that the agency is responding to ITC's recommendations within the 1-year statutory deadline. Until a final test rule is issued, testing does not begin and industry is not developing the data needed to determine the health and environmental effects of potentially harmful chemicals. These delays, if not corrected, will continue to limit EPA's progress in implementing the testing program.

Status of EPA's Responses to ITC's Recommendations

EPA has responded to all of ITC's chemical designations. As of the end of fiscal year 1989, ITC had recommended 386 chemicals. EPA required testing for approximately 39 percent of the 386 recommended chemicals, made preliminary decisions to test about 36 percent, and decided not to test about 25 percent (see table 3.1). EPA decided not to test 98 chemicals (all of which were recommended before December 1984) for a combination of reasons: they were already being tested by the National Toxicology Program, the National Cancer Institute, or industry; their production or exposure levels were limited; and/or adequate data already existed to characterize their health and environmental effects.

Table 3.1: EPA's Responses to ITC's Recommendations

EPA's response	Number of chemicals	Percent of total
Testing required	151[a]	39
Preliminary decision to require testing	137	36
Decision not to require testing	98	25
Total	**386**	**100**

[a]For several chemicals or categories of chemicals, EPA made multiple decisions, requiring certain types of testing but not others or testing of a few but not all chemicals in a category. For the purposes of this report, we counted a multiple decision as one decision in favor of testing for the chemical or the entire category of chemicals.

[1] EPA's Efforts to Identify and Control Harmful Chemicals in Use (GAO/RCED-84-100, June 13, 1984).

EPA Was Initially Slow to Respond to ITC's Recommendations and Issue Final Test Rules

As we reported in June 1984, the chemical testing program had a slow start. EPA did not respond to any of ITC's recommendations until 1980, more than 2 years after ITC began making recommendations. As a result, the Natural Resources Defense Council sued the agency for failure to respond within the 1-year statutory deadline. The outcome of the suit was a court order in January 1981 putting EPA on a 3-year schedule to respond to ITC's recommendations. By the end of calendar year 1983, EPA had responded to the backlog of more than 300 chemicals and had begun to respond within the statutory 1-year deadline to new recommendations.

As we also noted in the 1984 report, EPA had not at that time issued any final rules requiring manufacturers or processors to test chemicals. This was over 6 years after ITC had recommended its first chemical for testing and over 3 years after EPA had proposed its first test rule. According to the Chief of the Test Rules Development Branch at that time, the primary reason for the delays was that resources were shifted to meet the January 1981 court-ordered schedule and personnel were not available to carry out the tasks of completing proposed test rules. Such tasks included obtaining and addressing public comments, reviewing additional data EPA received after announcing a proposed rule, and making appropriate changes to the proposed rule. The Branch Chief also told us that issuing a final rule was fairly simple and that 12 to 18 months was a reasonable amount of time to make a test rule final. Accordingly, we recommended that EPA complete test rules within a reasonable time, such as 12 to 18 months.

EPA Is Generally Meeting 1-Year Deadline but Is Still Slow to Issue Final Test Rules

EPA is now generally meeting the 1-year statutory deadline. Since our June 1984 report, ITC designated 19 chemicals for testing. EPA generally met the 1-year requirement for all but one, for which EPA took about 13 months to respond (see table 3.2).

Table 3.2: EPA's Initial Responses to Recommendations Made After June 1984

Chemical recommended by ITC	Date recommended	Date of EPA's response	Elapsed time (days)
Anthraquinone	11/29/84	11/06/85	342
2-Chloro-1,3-butadiene	11/29/84	08/26/85	270
Cumene	11/29/84	11/06/85	342
Mercaptobenzothiazole	11/29/84	11/06/85	342
Octamethylcyclotetrasiloxane	11/29/84	10/30/85	335
Pentabromoethylbenzene	11/29/84	11/13/85	349
Sodium N-methyl-N-oleoyltaurine	11/29/84	11/06/85	342
Methylcyclopentane	05/21/85	05/15/86	359
Tetrabromobisphenol A	05/21/85	05/15/86	359
Triethylene glycol monomethyl ether	05/21/85	05/15/86	359
Triethylene glycol monoethyl ether	05/21/85	05/15/86	359
Triethylene glycol monobutyl ether	05/21/85	05/15/86	359
Cyclohexane	05/19/86	05/20/87	366
2,6-Di-tert-butyl phenol	05/19/86	06/25/87	402
Tributyl phosphate	11/14/86	11/12/87	363
Isopropanol	05/20/87	03/16/88	301
Methyl tert-butyl ether	05/20/87	03/31/88	316
1,6-Hexamethylene diisocyanate	05/20/88	05/17/89	362
Crotonaldehyde	11/16/88	11/09/89	358

However, EPA continues to take an average of more than 2 years to complete its test rules. For the 19 chemicals ITC designated for testing since June 1984, EPA issued 15 proposed rules.[2] EPA took an average of more than 27 months to complete 12 of these 15 test rules and met the 12- to 18-month time frame for only 1 of the 12 rules (see table 3.3). EPA has

[2]EPA decided not to test two of the remaining four chemicals recommended (2-chloro-1,3-butadiene and sodium N-methyl-N-oleoyltaurine) and proceeded with consent agreements for the other two (methyl tert-butyl ether and crotonaldehyde).

not completed the remaining three proposed rules; two of these are over 2 years old.

Table 3.3: Length of Time EPA Took to Complete Test Rules for Chemicals Recommended Since June 1984

Chemical recommended by ITC	Date of proposed rule	Date of completion	Elapsed time (months)
Anthraquinone	11/06/85	06/04/87	18+
Cumene	11/06/85	07/27/88	32+
Mercaptobenzothiazole	11/06/85	09/07/88	34+
Octamethylcyclotetrasiloxane	10/30/85	01/10/89[a]	38+
Pentabromoethylbenzene	11/13/85	11/22/88[b]	36+
Methylcyclopentane	05/15/86	02/05/88	20+
Tetrabromobisphenol A	05/15/86	07/06/87	13+
Triethylene glycol monomethyl ether	05/15/86	04/03/89[c]	34+
Triethylene glycol monoethyl ether	05/15/86	04/03/89[c]	34+
Triethylene glycol monobutyl ether	05/15/86	04/03/89[c]	34+
Cyclohexane	05/20/87	[d]	
2,6-Di-tert-butylphenol	06/25/87	[d]	
Tributyl phosphate	11/12/87	08/14/89	21+
Isopropanol	03/16/88	10/23/89	19+
1,6-Hexamethylene diisocyanate	05/17/89	[d]	

[a]EPA reached a consent agreement for this chemical.

[b]EPA withdrew the proposed rule for this chemical because it was undergoing review under the "significant new use rule" for new chemicals. EPA proposed this new use rule in 1987 as a follow-up tool to require manufacturers of existing chemicals that have a significant new use, such as substantially increased production, to comply with TSCA's premanufacture notice requirements.

[c]EPA decided on a combination of consent agreement and final rule for these three chemicals.

[d]EPA had not completed rules for these chemicals as of the end of our audit work.

Furthermore, as of the end of fiscal year 1989, EPA still needed to complete four rules that it had initiated before June 1984. These rules were for the following chemicals or groups of chemicals: aryl phosphates, glycidol and its derivatives, phenylenediamines,[3] and methylolurea.

Because EPA was initially slow to respond to ITC's recommendations and continues to be slow in issuing final test rules, it did not issue its first final test rules until December 1985, more than 8 years after ITC began making recommendations and 9 years after TSCA was enacted. Since it

[3]EPA issued a final test rule for phenylenediamines in November 1989.

takes about 2 to 5 years to develop test data, EPA did not begin receiving complete test data until May 1988. According to EPA officials, as of the end of fiscal year 1989, EPA had received complete test data for only six chemicals and had not finished assessing any of them for possible further action.

According to the Chief of the Test Rules Development Branch at the time of our review, EPA has continued to be slow in issuing final test rules because of recent high staff turnover. He stated that in fiscal year 1988, 6 of the Branch's 20 professional staff members, or 30 percent, left the testing program; in fiscal year 1989, 8 additional members, or 40 percent, left. As a result, the completion of rules had to be postponed until experienced staff members were available to work on them. The Branch Chief acknowledged that under normal circumstances 12 to 18 months would be a reasonable time for making a proposed test rule final.

Also, the Branch Chief noted that EPA is placing a high priority on issuing proposed rules, rather than final rules, to ensure that it is responding to ITC's recommendations within the 1-year statutory deadline. However, we believe that issuing final test rules is as important as issuing proposed rules. Until a final rule is issued, testing does not begin and the data needed to determine the health and environmental effects of potentially harmful chemicals are not being developed. Because EPA is slow to issue test rules, the health and environmental effects of thousands of chemicals remain unknown. For example, aryl phosphates and glycidol and its derivatives still have not been tested. Aryl phosphates (used as plasticizers, in hydraulic fluids, and in lubricants) are produced in quantities exceeding millions of pounds per year and have the potential for substantial human exposure and environmental release. Glycidol and its derivatives (used in epoxy glues) are produced in quantities exceeding 1,000 pounds per year and have exposure estimates of over 100,000 workers; they are suspected of causing cancer and gene mutations. ITC recommended aryl phosphates and glycidol and its derivatives for testing more than 10 years ago. EPA initiated test rules for these chemicals in 1983, but has still not issued final rules.

Conclusions

EPA was initially slow to implement the chemical testing program. It did not finish addressing the backlog of ITC-recommended chemicals and begin meeting the 1-year statutory deadline for responding to ITC's recommendations until the end of calendar year 1983. Although EPA is now generally meeting the 1-year statutory deadline for responding to ITC's

recommendations, it continues to be slow in issuing final test rules. GAO recommended in 1984 that EPA issue a test rule within 12 to 18 months after proposing it; however, since then, the agency has continued to take an average of more than 2 years to make its proposed rules final and has still not made final some test rules it initiated before 1984.

While EPA blames high staff turnover for this problem, it is also placing a higher priority on issuing proposed test rules than on issuing final rules. By doing so, EPA continues to be slow to begin the testing needed to determine the health and environmental effects of potentially harmful chemicals.

Recommendation

We recommend that the Administrator of EPA place a high priority on issuing final test rules by ensuring that adequate staff resources are devoted to completing test rules within a reasonable time, such as the 12- to 18-month time frame we recommended in 1984.

Chemical Testing Program Lacks Overall Objectives and a Strategy

GAO believes that objectives and strategies are needed for adequate internal control of federal programs. Although EPA has established various policies and procedures for implementing the chemical testing program, it has not established any overall objectives or a strategy for achieving those objectives. In particular, it has not identified the universe of chemicals that it needs to address or the pace at which it plans to address these chemicals. Without these matters defined, EPA officials are unclear about the chemical testing program's direction and priorities.

Importance of Establishing Overall Program Objectives and a Strategy for Achieving Them

Overall objectives and a strategy for achieving them are key elements in any federal program. They provide focus and direction and help establish priorities. In addition, they provide the agency a perspective on the magnitude of the tasks it faces and help identify resource needs. They can also provide timing for expected results and benchmarks for measuring program performance. Furthermore, specified objectives and a strategy can provide the Congress with a sense of what can be achieved with the level of resources committed.

In GAO's Standards for Internal Controls in the Federal Government, we pointed out the importance of having objectives and strategies. The report presents the Comptroller General's internal control standards, which executive agencies are to follow in establishing and maintaining systems of internal control, as required by the Federal Managers' Financial Integrity Act of 1982. Internal controls are the combination of policies and procedures managers use to help ensure that their agencies, programs, or functions are effective and efficient. The report specifically identifies objectives and strategies as internal control standards.

EPA's Policies and Procedures Do Not Identify Overall Program Objectives or Strategy

In implementing the chemical testing program, EPA has developed various policies and procedures that basically reiterate and further define the requirements cited in section 4 of TSCA. For example, in 1980 EPA issued a proposed statement of policy and procedures for implementing the testing program. It stated that "EPA has two primary objectives: (1) to require testing of selected high priority chemicals to determine reliably whether or not such substances pose an unreasonable risk to health or the environment; and (2) to make such testing requirements as efficient and cost effective as possible."

In implementing the testing program, EPA also developed the Project Managers Handbook. This handbook describes the project manager's

role in EPA's test-rulemaking process. For example, it supplies specific language that project managers should use in the Federal Register notices and illustrates how to assess the adequacy of chemical studies in determining whether a test rule should be issued.

However, EPA's policies and procedures do not identify overall objectives for the chemical testing program. Such objectives would define the universe of chemicals EPA needs to address (i.e., the portion of the 60,000 chemicals in TSCA's inventory that most likely need testing and those that do not) and the pace at which EPA plans to address these chemicals.

According to the Chief of the Test Rules Development Branch at the time of our review, EPA has essentially relied on ITC to identify chemicals for testing and has not developed a program plan that identifies the program's overall objectives and a strategy for achieving them. The Branch Chief responded that to do so would draw staff away from the development of test rules.

Without overall objectives and a strategy defined, EPA officials are unclear about the direction and priorities of the chemical testing program. Officials are uncertain about whether the testing program's goal is to gather a little information on as many chemicals as possible or to require more extensive testing for a few chemicals more highly suspected of posing an unreasonable risk.

In a 1988 draft report entitled Existing Chemical Review Program: Operations Manual, EPA identified its own lack of clear direction in its overall review of existing chemicals under TSCA, which includes the chemical testing program. The draft report discussed the differences among staff and management about the goals of EPA's chemical review efforts. The potential goals suggested were: (1) gather and compile chemical data, (2) develop chemical information management and dispersion systems, (3) identify chemicals that need to be regulated, and (4) reduce the risk of chemicals through all available mechanisms. The report stated that the absence of explicit written documentation concerning such matters as program direction has contributed significantly to the lack of productivity and misdirection of EPA's overall review of existing chemicals.

Conclusions

EPA has developed various policies and procedures in implementing the chemical testing program. However, it has not established overall objectives for the chemical testing program and a strategy for achieving those objectives. In particular, EPA has not established the universe of

chemicals that EPA needs to address or the pace at which EPA plans to address these chemicals.

We believe that EPA needs to establish overall objectives and a strategy for the chemical testing program. They are needed not only to ensure adequate internal control but also to provide clear and consistent direction and priorities for the program staff. Clear direction is important to ensure the most efficient and effective use of staff time, especially when staff turnover is high, as in the chemical testing program.

There are still other benefits to having overall program objectives and a strategy. They can provide a perspective on the magnitude of the tasks ahead, timing for expected results, and benchmarks for measuring progress. They can also help identify resource needs.

Recommendation

We recommend that the Administrator of EPA develop overall objectives for the chemical testing program and a strategy for achieving those objectives. These should identify, among other things, the universe of chemicals EPA needs to address and the pace at which it plans to address these chemicals.

Matters for Consideration by the Congress

To ensure that the chemical testing program achieves what the Congress intended, the Congress may want to require EPA to develop a comprehensive plan setting forth objectives, a strategy, and time frames, and submit the plan to the Congress for approval.

Major Contributors to This Report

Resources, Community, and Economic Development Division, Washington, D.C.	Peter F. Guerrero, Associate Director, (202) 252-0600 J. Kevin Donohue, Assistant Director Irene P. Chu, Evaluator-in-Charge Peter J. Espada, Evaluator Charles T. Egan, Evaluator Sharon E. Butler, Writer-Editor

Requests for copies of GAO reports should be sent to:

U.S. General Accounting Office
Post Office Box 6015
Gaithersburg, Maryland 20877

Telephone 202-275-6241

The first five copies of each report are free. Additional copies are $2.00 each.

There is a 25% discount on orders for 100 or more copies mailed to a single address.

Orders must be prepaid by cash or by check or money order made out to the Superintendent of Documents.

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

Official Business
Penalty for Private Use $300

First-Class Mail
Postage & Fees Paid
GAO
Permit No. G100