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

June 1991

TOXIC SUBSTANCES

EPA's Chemical Testing Program Has Not Resolved Safety Concerns

RELEASED

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Resources, Community, and
Economic Development Division

B-243540

June 19, 1991

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

Dear Mr. Chairman:

As requested, we are reporting on the Environmental Protection Agency's (EPA) performance in reviewing and acting on test results received under the chemical testing program established by section 4 of the Toxic Substances Control Act of 1976. This report contains recommendations aimed at improving the timeliness and quality of the chemical review process. In a supplemental report and in testimony, we will soon provide you with additional information on (1) the current status of EPA's reviews of each of the 22 chemicals discussed in this report and (2) EPA's recent programmatic changes to the chemical testing program.

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

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

Sincerely yours,

J. Dexter Peach
Assistant Comptroller General

Executive Summary

Purpose

Americans are exposed to over 60,000 chemicals used in products for homes, offices, and industries. While many of these chemicals are known to be harmless, the effects that thousands of chemicals have on human health or the environment are questionable. The Toxic Substances Control Act (TSCA) of 1976 authorizes the Environmental Protection Agency (EPA) to require industry to test potentially harmful chemicals and to regulate or ban the use of chemicals found to be dangerous to human health or the environment.

In an April 1990 report[1] to the Chairman, Environment, Energy, and Natural Resources Subcommittee, House Committee on Government Operations, GAO noted that EPA has made slow progress in identifying chemicals for testing since the passage of TSCA. The Chairman requested GAO to follow up on that report by reviewing (1) EPA's actions upon receipt of test data, including the criteria that EPA uses in deciding whether to take regulatory action under TSCA, (2) management controls over the chemical review process, and (3) how EPA disseminates the results of chemical testing.

Background

The Congress enacted TSCA to provide a safeguard against the introduction of additional contaminants into the environment and to address the risks posed by existing chemicals. Under TSCA, EPA may require chemical manufacturers and processors to test potentially harmful chemicals for the purpose of assessing their health and environmental effects. If a chemical poses a significant risk of harm from cancer, gene mutations, birth defects, or unreasonable risk to health or the environment, TSCA authorizes EPA to regulate the use of the harmful chemical through such actions as banning the chemical or requiring warning labels on the chemical or products containing the chemical when they are sold. In addition to using its regulatory authority under TSCA, EPA can take other actions such as issuing advisories to warn the public of chemical dangers.

Results in Brief

EPA has made little progress in developing information on the safety of the thousands of chemicals that affect our daily lives and has not taken action to regulate, or warn the public about, chemicals found to be harmful. Since TSCA was enacted in 1976, EPA has received health and environmental results on only 22 chemicals and assessed the test results for 13 of these chemicals. Although EPA has determined that three of the

[1]Toxic Substances: EPA's Chemical Testing Program Has Made Little Progress (GAO/RCED-90-112, Apr. 25, 1990).

chemicals are dangerous, it has not taken regulatory action because it does not believe the chemicals present a significant or unreasonable risk. Given that EPA has no criteria or methodology for determining significant or unreasonable risk, GAO questions the basis for EPA's failure to take regulatory action regarding the chemicals. Even from a non-regulatory standpoint, GAO found that EPA has not been timely in issuing warnings to the public on the three harmful chemicals or transmitting test results on these chemicals to other regulatory agencies.

In addition, management control weaknesses and inattention to resolving testing problems in a timely manner have added years to the assessment of chemical safety concerns. EPA has several actions underway to improve management control over the chemical testing process, including the development of a management information system to monitor the status of chemicals being tested.

After EPA completes its evaluation of industries' chemical test results, it makes them available to the public at its headquarters location but does not make the results available to scientific journals and data bases. Such journals and data bases require peer review of test results, and TSCA testing is not peer-reviewed. Therefore, the scientific community and the public do not have easy access to the data and cannot fully benefit from the test results. EPA is currently exploring ways to more broadly disseminate the results, including peer review of test data.

Principal Findings

EPA Lacks Criteria for Regulatory Decisions

In evaluating chemical industry test data on 13 of the 22 chemicals, EPA determined that 3 are harmful to human health or the environment. EPA's risk assessment showed that two of these chemicals cause birth defects and that industry workers are exposed to the chemicals beyond safe levels. One of the chemicals, used primarily in the manufacturing of nylon, affects an estimated 839,000 workers. The other chemical, used primarily in oil-based paints, affects an estimated 400 workers, and its effect on consumers is uncertain. A third chemical, used primarily in marine paints, although not harmful to human health, was shown to be highly toxic to fish and aquatic organisms.

Although EPA acknowledges that the three chemicals are dangerous, it has not taken regulatory action to reduce the chemicals' harmful effects

because, in EPA's judgment, they posed no significant or unreasonable risk. Given the recognized danger of the chemicals and the fact that EPA has no criteria and methodology to guide its managers in determining when chemicals present a significant or unreasonable risk, GAO questions the basis for EPA's failure to take regulatory action regarding these chemicals. In light of GAO's findings, EPA officials are currently reconsidering whether such criteria and methodology should be established.

Management Improvements Needed for Timely Resolution of Chemical Testing Problems

GAO found that EPA is not taking timely action in completing its assessment of industry's test data and in resolving chemical safety concerns, where warranted, through means other than regulatory action, such as through issuing advisories to affected workers or sending test results to other federal agencies concerned with chemical safety issues. Although EPA's current guidance calls for completing evaluations of industry test data within a 5-month period, GAO's analysis shows that EPA took an average of 2 years to evaluate test data for the 13 chemicals whose evaluations were completed.

The reasons for delays in completing test data evaluations are not apparent from EPA's documentation on the chemicals. GAO's review, however, identified a general lack of timely management monitoring, control, and attention to resolving problems with test data. For example, when EPA scientists and a private contractor hired by EPA reviewed test data for a group of chemicals used primarily as industrial solvents, all agreed that the submitted test data were not adequate to address the chemical's effects on the nervous system. Nevertheless, after 2 years, EPA has not addressed these technical concerns. In recognition of management control problems in the chemical testing program, EPA has initiated a number of actions, including hiring a contractor to establish a management information system capable of tracking the status of chemicals in the program.

TSCA Test Results Are Not Readily Available to Others

By not publishing the results of industry's testing of chemicals in use, EPA has not fully informed the scientific community and the public about the effects that potentially dangerous chemicals have on human health and the environment. Information on test data is also needed to avoid duplication of testing among the various regulatory agencies and research organizations.

EPA makes industry summaries of test studies available in a central location at its headquarters. However, EPA's reviews of the industry test

results and EPA's risk assessments, including human and environmental exposures to the chemicals, are not available in the EPA files. A more effective approach to making the results known to other parties would be to publish them in scientific journals and computerized data bases. EPA is aware of the benefits of publishing test data, but TSCA testing results do not receive peer review, a requirement of the major scientific data bases. Consequently, EPA is currently exploring ways to more broadly disseminate the results, including peer reviews of test data.

Recommendations

To ensure timely and effective response to chemical test results, GAO recommends that the Administrator of EPA establish and implement criteria and a methodology for determining when chemicals present risks that would trigger implementation of TSCA regulatory provisions. GAO also recommends that the Administrator implement an information system to track the status of chemicals being tested and identify ways to make TSCA test results more readily available to other regulatory agencies, researchers, and other interested parties.

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.

Contents

Abbreviations

EPA	Environmental Protection Agency
GAO	General Accounting Office
OSHA	Occupational Safety and Health Administration
TSCA	Toxic Substances Control Act

Introduction

Americans are exposed to chemicals every day of their lives through products for our homes, businesses, and industry. In 1990, the Environmental Protection Agency's (EPA) inventory of existing chemicals showed that U.S. industries produced or imported more than 60,000 chemicals. While some chemicals in the inventory are known to be harmless, the effects that thousands of other chemicals have on human health or the environment are questionable. Some chemicals such as asbestos and polychlorinated biphenyls were in use for years before they were found to cause tumors, birth defects, or cancers.

The Congress enacted the Toxic Substances Control Act (TSCA) in October 1976 to provide a safeguard against the introduction of additional contaminants to the environment and to address the risks posed by existing chemicals. The act requires EPA to identify and regulate hazardous chemicals that were not being addressed by other federal legislation. TSCA does not apply to eight categories of chemical products regulated under other laws. These categories are pesticides, tobacco, nuclear material, firearms and ammunition, food, food additives, drugs, and cosmetics.

In an April 1990 report to the Chairman, Environment, Energy, and Natural Resources Subcommittee, House Committee on Government Operations,[1] we noted that EPA has made slow progress in identifying chemicals for testing since the passage of TSCA. This review is a follow-up to that report in that it discusses EPA's actions upon receipt of test data.

EPA's Section 4 Chemical Testing Program

Under section 4 of TSCA, EPA can require chemical manufacturers and processors to test potentially harmful chemicals already in use to develop data on their health and environmental effects. Section 4 established the Interagency Testing Committee and authorized it to semiannually recommend to EPA chemicals that should be given priority consideration for testing. The Committee consists of representatives from eight statutory 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

[1]Toxic Substances: EPA's Chemical Testing Program Has Made Little Progress (GAO/RCED-90-112, Apr. 25, 1990).

Department of Commerce. At the Committee's invitation, representatives from 10 other federal entities also assist in chemical reviews.

Section 4 requires EPA to respond to the Interagency Testing Committee's recommendations within 1 year by initiating rulemaking to require testing or explaining in the Federal Register its reasons for not doing so. As of September 1990, EPA had required the chemical industry to test 151 chemicals, 76 of which were recommended by the Committee. Recommendations for section 4 testing also come from a number of other sources, including units within EPA and other government agencies, industry, and interested parties outside of government. As of September 1990, EPA required industry to test 68 chemicals recommended from sources other than the Interagency Testing Committee.

To require industry to conduct chemical testing, EPA must first determine that (1) the chemical may present an unreasonable health or environmental risk, or that there is or may be substantial human or environmental exposure to the chemical, (2) current data on the chemical are insufficient for determining the chemical's effects, and (3) testing is necessary to develop adequate data. When EPA makes such a determination, it notifies industry of testing requirements by publishing proposed test rules in the Federal Register. If industry agrees with EPA on the need for and scope of testing requirements, EPA may initiate testing by issuing an enforceable agreement between EPA and industry called a consent order. If agreement with industry cannot be reached, EPA publishes final test rules in the Federal Register ordering industry to perform the tests. In issuing consent orders or test rules in the Federal Register, EPA must specify the chemical to be tested, test standards, and schedules for the submission of data to EPA.

EPA may require three basic types of testing by test rules. Human health tests attempt to identify impacts on human organisms through testing performed on laboratory animals. Such testing includes acute and chronic adverse health effects; the incidence of gene mutations, cancer, and birth defects; and toxic effects on the central nervous system. Environmental testing primarily focuses on the chemical's effects on aquatic life. Such testing includes acute and chronic adverse effects on marine animals. Chemical fate testing is the third type of testing that may be required by test rules. Such testing involves assessing the chemical's characteristics, such as its ability to be absorbed in water. Any one or combination of the three types of testing may be required by a test rule for a chemical.

How the Chemical Testing Program Review Process Works

Companies manufacturing or processing chemicals in the United States are responsible for conducting tests and submitting test data to EPA. EPA's Office of Toxic Substances has the primary responsibility for the technical evaluation of test data. This office determines whether the data are complete and reliable, whether the test standards specified in the final test rule or consent order have been met, and whether the testing laboratory followed appropriate testing procedures. The office also determines whether test data indicate a cause for concern or a need for further testing.

After technical evaluation, the office assesses the risk that chemicals pose to human health and the environment. Risk assessment translates laboratory test results, which identify animal responses to various dose levels, to expected responses in humans or the environment at given exposures to the chemicals.

EPA circulates summaries of TSCA test results and technical evaluations of data among managers of the Office of Toxic Substances' divisions, including an exposure evaluation division, an economics and technology division, and an existing chemical assessment division. With input from their managers, the division directors hold risk management meetings to discuss chemical test results and possible courses of action, such as taking regulatory action to ban the chemical, referring test results for the consideration of other government agencies, or not taking any action on the chemical.

TSCA Provisions for Regulating Chemicals

TSCA sections 4(f), 6, and 9 provide for regulating chemicals that may be harmful to human health and the environment. Section 4(f) deals with chemicals that may present significant risks, while sections 6 and 9 deal with chemicals that present unreasonable risks.

- Section 4(f) is a priority review provision which requires EPA to take action when it receives test data or any other information which indicates that there may be a reasonable basis to conclude that a chemical presents, or will present, a significant risk of serious or widespread harm to human beings from cancer, gene mutations, or birth defects. EPA must, within 180 days following its receipt of the data, either initiate action to prevent or reduce the chemical's risk, or publish in the Federal Register a finding that such risk is not unreasonable.
- Section 6 requires EPA to take actions against chemicals for which a reasonable basis exists to conclude that the chemical presents or will present an unreasonable risk of injury to health or the environment. EPA

must use one or more of a range of specified actions, to the extent necessary to protect adequately against such risk using the least burdensome requirements. The actions which may be taken include banning the use of the chemical, or requiring warning labels on the chemical or products containing the chemical when they are sold.

- Section 9(a) provides that if EPA has a reasonable basis to conclude that a chemical presents or will present an unreasonable risk of injury to health or the environment, and determines, in its discretion, that the risk may be prevented or reduced by action under a federal law not administered by EPA, it must refer information on the chemical to the agency administering the other law. The receiving agency must initiate action to regulate the chemical or publish a notice in the Federal Register as to why no action is needed. 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.
- Section 9(b) directs EPA to use other laws administered by it to protect against unreasonable risks to health or the environment associated with a chemical, unless the EPA determines that it is in the public interest to protect against such risks under TSCA.

In addition to regulating chemicals under TSCA or taking action under section 9, EPA can issue advisories warning the public of chemical dangers or can informally send test results to other federal agencies having public safety responsibilities, such as the Occupational Safety and Health Administration. Informal referrals to other federal agencies do not require action on the part of the agencies.

Objectives, Scope, and Methodology

The Chairman, Environment, Energy, and Natural Resources Subcommittee, House Committee on Government Operations, asked us to review EPA's program for testing existing chemicals, including (1) the criteria EPA employed in deciding whether and what action to take under TSCA, (2) management controls over the chemical review process, and (3) how EPA disseminates testing results.

Our review focused on examining EPA's evaluation of and action taken in response to the test results for the 22 chemicals for which EPA had received complete test results as of June 1990. These chemicals and examples of their uses are listed in appendix I. As such, we did not examine EPA's performance with regard to all chemicals for which testing was in process under the section 4 program.

To determine the regulatory options that were available to EPA and the limitations on their use, we reviewed TSCA, EPA's implementing regulations, and internal EPA policies and procedures. We also interviewed EPA officials and scientists involved in the existing chemical testing program and determined their decision-making process for taking actions under TSCA.

To determine the criteria EPA used to decide whether to take regulatory action, we reviewed EPA's case files for each of the 22 chemicals and discussed the test results, EPA's evaluations, and actions taken with EPA project officers responsible for the particular chemical and with officials responsible for directing and managing the section 4 testing program.

To determine management control over the chemical testing review process, we identified EPA requirements, policies, and procedures relating to how the process is to work and compared them with the results of our review of the case files. We discussed with testing program officials the differences between how the process is to work and how it worked in the case of specific chemicals. For each of the 13 chemicals for which EPA had completed its evaluations as of December 31, 1990, we documented how long it took from the time a chemical was recommended for testing to completion of EPA's review of the final test results. These time frames, which are based on a review of Federal Register notices and EPA files, are shown in appendix II.

To determine how TSCA test results are disseminated, we reviewed EPA procedures for making test results and EPA's evaluations of them available for public use. We also interviewed responsible EPA officials to obtain an understanding of the process. To obtain another agency's perspective on the issues of testing, using TSCA test data, and disseminating test results, we interviewed officials of the National Institute of Environmental Health Sciences, a part of the National Toxicology Program administered by the National Institutes of Health. The National Institute of Environmental Health Sciences is a member of the Interagency Testing Committee; it administers a chemical testing program which principally focuses on carcinogenicity issues.

To obtain a broader perspective on which to review EPA's actions with regard to evaluating test results, we interviewed officials and scientists of EPA's Health Effects Research Laboratory located in Research Triangle Park, North Carolina, under the Assistant Administrator for Research and Development. This laboratory assists the Office of Toxic Substances in designing and developing guidelines for chemical toxicity

tests. We also discussed EPA's chemical testing process and its evaluations of specific chemicals with representatives of a large chemical manufacturer and the Chemical Manufacturers Association. The Chemical Manufacturers Association represents industry in numerous chemical testing programs.

We conducted our work between June 1990 and March 1991 in accordance with generally accepted government auditing standards. We discussed with EPA officials the factual information in the report, and their comments have been incorporated as appropriate. However, as requested, we did not obtain official agency comments on a draft of this report.

EPA Needs Criteria for Determining Risk and Better Management Control to Resolve Chemical Safety Concerns

After reviewing TSCA test data in early 1987 and late 1988, Office of Toxic Substances managers determined that three chemicals were potentially hazardous to human health or the environment. Data showed that two chemicals cause birth defects in laboratory test animals and that industry workers are exposed to the chemicals beyond safe levels. Another chemical was shown to be highly toxic to aquatic organisms in amounts emitted in industry wastewater discharges. Nonetheless, up to 4 years has elapsed since EPA first reviewed the test results, and EPA has not yet taken action to either regulate these chemicals or to communicate the test results to other regulatory agencies, the public, or industry.

The Director of the Existing Chemical Assessment Division in EPA's Office of Toxic Substances told us that EPA decided not to initiate regulatory action against the three chemicals because it does not consider them to pose a significant risk of harm from cancer, gene mutations, or birth defects or unreasonable risk to human health or the environment. Such a determination of significant or unreasonable risk is required by TSCA as a basis for EPA to take regulatory action. However, our review shows that EPA has not developed criteria or methodology for determining significant or unreasonable risk. The Director told us that the Office of Toxic Substances has informally set an extremely high standard for making such a determination and that the chemical testing program has never found an existing chemical to present such risks.

EPA files also revealed numerous instances in which the Office of Toxic Substances failed to take timely action in assessing test results and in resolving testing problems. This has resulted in unnecessary delays in reaching a decision on whether these chemicals are potentially hazardous. EPA's untimeliness was caused by a general lack of management control and attention geared to resolving outstanding problems.

EPA officials recognize that changes are needed to make the chemical testing program more effective, and EPA has several initiatives under way to "revitalize" the program. In order to ensure that the results of the testing program are used, EPA has decided that before it requires industry to test chemicals, it will identify regulatory agencies such as the Occupational Safety and Health Administration (OSHA) that will have a particular need for the test data. Agency officials believe that this change will result in more focused testing, relieve EPA of regulatory burdens, and enable EPA to devote its limited resources to getting more chemicals tested. Such a policy change, however, does not relieve EPA of its regulatory responsibilities under TSCA.

No Criteria Exist for Determining Significant or Unreasonable Risk

Chemicals considered to present significant risk of harm from cancer, gene mutations, or birth defects or unreasonable risks to health and the environment may be regulated by EPA under TSCA in a number of ways. For example, when EPA finds that test results show that a chemical presents an unreasonable risk, it may require warning labels on products using the chemical (section 6) or it may refer the test results to another federal agency empowered to regulate the chemical under another federal law (section 9(a)). When test results show that a chemical presents a significant risk of serious or widespread harm from cancer, gene mutation, or birth defects, TSCA requires EPA to initiate action to prevent or reduce the risk within 180 days after it receives the test data or publish a notice in the Federal Register that the risk is not unreasonable (section 4(f)).

In explaining to us why EPA has never used these authorities in the chemical testing program, the Director of the Office of Toxic Substances' Existing Chemical Assessment Division said that EPA uses a "high threshold" of risk in assessing whether a chemical imposes significant or unreasonable risks. He told us, however, that EPA has not defined the meaning of the terms "significant" or "unreasonable" for the purpose of implementing TSCA.

In 1985, the Existing Chemical Assessment Division prepared a draft document that contained criteria and methodology for determining significant risk. The draft document was to provide EPA managers with the agency's interpretation of the role of TSCA's section 4(f) and the criteria for identifying the chemical risks that invoke it. While the document did not provide a qualitative and quantitative method for ranking chemicals according to their potential risk, it did discuss the information needed about both the toxicity of a chemical and human exposure to it in order to make a judgment about the risk it may cause. The document pointed out that decision makers, by necessity, would have to make judgments involving scientific uncertainties that are inherent in chemical risk assessments. The Existing Chemical Assessment Division intended to revise the criteria and methodology as needed, on the basis of advances in science and experience gained.

An example of the application of the criteria was their intended use in making decisions about the degree of concern for birth defects. The criteria call for the computation of a ratio between the highest administered dose level that did not produce a birth defect (the no-observed-effect level) and the expected human exposure. Thus, if testing showed

that 10,000 parts per million was the no-observed-effect level in a laboratory test animal and EPA found that consumers or workers were exposed to the chemical at 1 part per million, the ratio would be 10,000/1. The criteria state that large ratios, like 10,000/1, signify a negligible level of concern while low ratios, approaching 1/1, will be interpreted as indicating a significant risk of serious harm.

The Director of the Existing Chemical Assessment Division told us that EPA never implemented the draft 1985 criteria for making a determination of significant risk and has never drafted criteria for unreasonable risk. He declined to specify any reason for not doing so, other than that EPA's practice is to rely on the professional judgment of its managers to determine when a chemical presents such risks. The Deputy Director of the Office of Toxic Substances told us that EPA is currently reconsidering whether to establish criteria and methodology for both significant and unreasonable risk.

EPA Has Not Acted on Chemical Safety Concerns

Despite deciding that three chemicals were dangerous to human health and the environment, EPA did not take timely actions to reduce the chemicals' safety concerns. Test data indicate that two of the chemicals cause birth defects and that a third chemical is very toxic to fish and aquatic organisms. (App. III shows the results of EPA's evaluation of the 13 chemicals for which EPA, as of December 1990, had completed its evaluations of industry's test results.) The following narrative describes the three chemicals which EPA considered dangerous—cyclohexanone, ethylhexanoic acid, and octylphenol.

Cyclohexanone

Cyclohexanone is used primarily in the manufacturing of nylon and is also used as a solvent for resins, lacquers, dyes, and pesticide formulations. Because the chemical loses its identity in the finished product, it is not considered a threat to consumers. According to EPA estimates, over 839,000 workers may be exposed to the chemical. The existing OSHA worker air standard for cyclohexanone is 50 parts per million. However, TSCA test data showed that air concentrations of over 6.5 parts per million could be harmful.

Test data on the chemical, received by EPA in May 1984, showed that it adversely affected the development of embryos and fetuses in laboratory test animals. The data also indicated that OSHA's current workplace

safety standard was set too high. Nonetheless, the Office of Toxic Substances did not evaluate this data until 1988, when it had received additional test data on other potential effects of the chemical. In its technical review of test data in May 1988, EPA scientists stated:

"Given the past history of the application of Section 6 of TSCA, it is unlikely that the [cyclohexanone test] data will drive any formal regulatory action . . . However, the data do support concern for developmental and reproductive effects from exposure to cyclohexanone. At the very least this information should be communicated to the affected industry, workers, consumers, and relevant regulatory agencies...The alternative is to bury the information into EPA files where it is unlikely to have any impact on the exposed community-analogous to the disposition of the Ark in the movie 'Raiders of the Lost Ark.'"

EPA managers met to evaluate the risks of cyclohexanone in May 1988, 4 years after EPA received test data showing the chemical caused birth defects. The managers decided to prepare an advisory to warn workers of the dangers of cyclohexanone, but the advisory was never prepared. In March 1989, EPA managers discussed referring the test data to OSHA, but a decision to refer or not to refer was never made. The chemical's project manager told us that responsibilities for writing an advisory or making a referral were not assigned to any EPA manager and that no one followed up to ensure action was taken.

According to EPA's records, in November 1990, Office of Toxic Substances directors decided to send summaries of the test data to OSHA, the Consumer Products Safety Commission, and the American Council of Government Industrial Hygienists. The Deputy Director of the Existing Chemical Assessment Division told us that EPA expects that the test data summaries on cyclohexanone will influence OSHA to revise its workplace standard to reduce worker exposure to the chemical. As of March 1991, the summaries had not been sent.

Ethylhexanoic Acid

Ethylhexanoic acid is used in the manufacturing process for oil-based paints, inks, varnishes, and synthetic greases. Test data that EPA received in June 1988 showed that the chemical can cause birth defects and that exposure to the chemical beyond 0.1 milligrams per kilogram of body weight is not safe. EPA estimates that workers could be exposed to the chemical at the daily rate of 60 milligrams per kilogram of body weight. No OSHA workplace safety standard exists governing worker exposure to the chemical, and EPA estimates that about 400 workers are exposed to the chemical. EPA is not certain whether the chemical poses a threat to consumers.

In addition to TSCA testing, EPA's Health Effects Research Laboratory also conducted a test of the reproductive effects of ethylhexanoic acid. The laboratory tested 11 chemicals that had a similar chemical structure to valproic acid, a chemical known to cause birth defects. The tests showed that ethylhexanoic acid was the only chemical that produced effects that were identical to valproic acid. The laboratory's tests on pregnant rats showed that the chemical caused deaths of both pregnant mothers and fetuses, and many of the surviving pups had deformities. The director of the developmental toxicology program of the laboratory said that the prominent effect of valproic acid in humans is a condition known as spina bifida, a lack of closing of the spine.

EPA branch managers agreed in November 1988 to draft a chemical advisory warning workers of the dangers of the chemical and to further study the potential threat the chemical poses to consumers. Despite these agreements, no further action was taken until August 1990, 21 months later. EPA's project manager for the chemical said that the November 1988 agreements were not carried out because the chemical was lost in EPA's paperwork. The Deputy Director of the Existing Chemical Assessment Division confirmed that, because EPA did not follow up on the November 1988 agreements, no action was taken to draft an advisory or perform further study of the chemical for a period of nearly 2 years.

In August 1990, EPA decided that further study of the threat to consumers was not needed and that the test results would be referred to the ONE committee, an interagency coordinating committee comprising representatives from OSHA, National Institute of Occupational Safety and Health, and EPA. As of March 1991, EPA had not yet discussed the chemical's test results with the ONE committee.

The Director of EPA's Existing Chemical Assessment Division told us that the chemical will be referred to the ONE committee because a representative of OSHA sits on the committee. He said that EPA hopes that the OSHA representative will decide to initiate action to establish an OSHA workplace standard for ethylhexanoic acid.

Octylphenol

In addition to the two chemicals for which test data indicated potentially harmful effects to workers exposed to them, EPA's Chemical Testing Program has shown that the chemical 4-(1,1,3,3,-tetramethylbutyl) phenol, also known as octylphenol, is very toxic to

fish and aquatic organisms. Octylphenol is a chemical used in marine paints, adhesives, and varnishes.

EPA reviewed industry's test data on octylphenol in January 1987. Based on these data, EPA's Office of Water, in February 1987, noted that existing data are sufficient for the office to issue a water quality advisory to the public warning of the chemical's danger to aquatic organisms. However, later in February 1987, the Office of Water also requested that the Office of Toxic Substances have industry perform an additional test to determine the chemical's effects on saltwater organisms. Industry sponsors refused to voluntarily do the saltwater organism testing on octylphenol because they were beginning a TSCA testing program, which included saltwater testing, on a similar chemical compound. EPA decided to wait for the saltwater test results of the new chemical, rather than requiring industry to perform the saltwater tests for octylphenol. However, in discussions with EPA scientists in the Health and Environmental Review Division, we were told that, because the two chemicals have different chemical structures, test results of the chemical being tested by industry cannot be applied to octylphenol.

We discussed octylphenol test results, and the EPA scientists' statements that results of the similar chemical being tested cannot be applied to octylphenol, with Office of Water officials in November 1990. We found that the office had suspended activity on octylphenol, pending the outcome of the test results on the similar chemical compound. However, in January 1991, Office of Water officials told us that they had reconsidered octylphenol since our November 1990 discussion and believed that existing data on the chemical were sufficient for EPA to issue an advisory. We were told that an advisory on octylphenol will be issued by the end of 1991, nearly 5 years after industry submitted test results warning of the chemical's danger.

Management Control Needed for the Chemical Review Process

At the time EPA was evaluating the 22 chemicals included in our review, it had not established any goals or milestones for the timely completion of chemical test result evaluation. Although we could not measure EPA's performance against such goals or milestones, we were able to identify numerous unnecessary delays that occurred in EPA's evaluations of test results. These delays occurred because EPA did not make timely decisions on test results or testing problems that were encountered.

As of December 1990, EPA had completed its evaluations of 13 of the 22 chemicals included in our review. An average of 7.7 years elapsed from

the time the Interagency Testing Committee recommended the 13 chemicals for testing until EPA completed its evaluation of industry's test results. (App. II shows testing and review time frames for each of the 13 chemicals.) The scope of our review encompassed the phase of the chemical testing and review process that occurs when EPA receives the test results from industry. An average of 2.0 years elapsed during this phase for the 13 chemicals. In addition, over 2 years have already elapsed for three of the nine chemicals that EPA is currently evaluating.

Preliminary evaluations of the nine chemicals currently being analyzed show that three can cause adverse health effects, three can cause adverse environmental effects, one can cause both adverse health and environmental effects, and two appear to have no adverse effects. EPA's evaluations of test data are essential to understanding the risks of the chemicals because the evaluations include data on whether human beings or the environment are exposed to the chemicals at levels which are harmful to them. (App. IV shows the results of EPA's preliminary evaluations of these chemicals.)

We found that testing problems were delaying five of the nine chemicals currently being analyzed. The following examples illustrate EPA's difficulties in making timely decisions to resolve testing problems. Each of the three chemicals discussed below has been under evaluation by EPA for more than 2 years since industry submitted final test data to EPA.

- In December 1988, both EPA and a private contractor hired by EPA reviewed an inhalation neurotoxicity study for C-9 aromatic hydrocarbons and concluded that it was not possible to make scientifically valid conclusions based on the study data. The chemicals are used as solvents and plasticizers and are also used in gasoline blending. EPA did not have an estimate of the number of people exposed to the chemicals, but pointed out that the number would be large due to the substantial number of service station attendants and consumers that use self-service gasoline stations. EPA's technical reviewer noted that at least six neurotoxicologists have reviewed the data, and all are in agreement that the data are not adequate to address the chemical's neurotoxicity potential. Nevertheless, after 2 years, EPA has not yet addressed these technical concerns.
- In May 1988, EPA noted that the results of a 90-day subchronic dust inhalation study for bisphenol A confirmed earlier findings of adverse health effects. Bisphenol A is used primarily in the manufacture of resins, and EPA estimates that 33,000 workers in the chemical industry may be exposed to the chemical. The study noted, however, that the

long-term effects are not known. In July 1988, EPA sent the study results to the National Institute for Occupational Safety and Health and asked the Institute for its advice on the need for further testing and any regulatory concerns that the Institute may have for this chemical. Officials of EPA's Office of Toxic Substances told us that more than 2 years later, a reply has not been received and EPA has not followed up on the matter. Our inquiry to the National Institute for Occupational Safety and Health revealed that the Institute lost track of EPA's inquiry.

- In August 1985, managers in EPA's Office of Toxic Substances decided that while industry test results for isophorone were negative, data from the National Toxicology Program[1] showed positive results that isophorone was carcinogenic. Isophorone is used primarily in the formulation of lacquers, and EPA estimates that over a million workers are potentially exposed to the chemical. Because of concern about the chemical, EPA decided to conduct a risk assessment and obtain additional test data from industry. These agreements were never carried out. Over 5 years later, in January 1991, EPA managers reevaluated the data and decided that a risk assessment and additional test data were not needed, but that the test results should be referred to several other federal regulatory entities for their scrutiny.

The fundamental causes of the above and similar delays were not apparent from EPA's documentation on the chemicals, other than that there was a general lack of management control and attention to resolving outstanding problems in a timely fashion. In the opinion of the Deputy Director of EPA's Existing Chemical Assessment Division, delays have occurred in chemical test result evaluations because EPA does not have an adequate information system for tracking chemical testing matters. To illustrate, the Deputy Director said that in preparing for congressional hearings in the summer of 1990, he could not get a consistent answer on the number of chemicals being tested in the program. He also said that the division has had great difficulty in responding to the inquiries we raised during our review of the status of chemicals tested in the program and to questions raised by a contractor hired in the fall of 1990 to review the organizational structure of the Office of Toxic Substances.

[1]The National Toxicology Program was established under the Department of Health and Human Services to coordinate the Department's activities in characterizing the toxicity of chemicals. It is composed of the National Institutes of Health's National Institute of Environmental Health Sciences, the Center for Disease Control's National Institute for Occupational Safety and Health, and the Food and Drug Administration's National Center for Toxicological Research.

In recognition of management control problems in the chemical testing program, the deputy director said that the division has initiated a number of actions. In the summer of 1990, EPA hired a contractor to research and report on the status of chemicals being tested under the program. In the fall of 1990, a management consulting firm was hired to identify problems in the program's management and suggest remedies. And in March 1991, EPA hired a contractor to establish a management information system capable of tracking the status of chemicals in the program.

In addition, EPA has recently developed informal guidance for its managers to use in evaluating chemicals. This guidance establishes a goal of 5 months for completing EPA's evaluation of industry test results, a goal which, if met, would reduce the average evaluation period by 19 months.

EPA's New Approach to Testing Existing Chemicals

EPA has acknowledged that only a limited number of the many thousands of chemicals that could be tested have undergone the testing necessary to obtain test data needed for regulatory decisions. In a December 21, 1990, report to the President, the Administrator of EPA identified the lack of effectiveness and productivity in chemical testing as a material weakness in the agency. To address this weakness, EPA is revitalizing its chemical testing program by instituting a series of actions to encourage testing of all chemicals for which testing is needed. These actions include (1) encouraging voluntary testing on the part of industry, (2) enlisting greater numbers of chemical industry testing operations through international cooperative testing efforts through the Organization for Economic Cooperation and Development, and (3) implementing multi-chemical rules that will more efficiently and more rapidly put the chemical industry on notice as to the chemicals in which EPA has an interest.

Office of Toxic Substances officials also told us that as part of its efforts to improve the chemical testing program, in the future EPA will pursue a policy of requiring chemical testing only when a "client" exists and identifies a specific interest in the test results. In accordance with this policy, EPA is considering requesting that the Interagency Testing Committee recommend for testing only chemicals for which there is a client, such as OSHA or another federal agency. As discussed in chapter 1, most chemicals tested under EPA's program have been recommended for testing by the Committee.

Office of Toxic Substances officials told us that industry often has perceived chemical testing recommended by the Interagency Testing Committee as being basic research-oriented and that the new policy will produce greater program results because future testing will focus on client concerns, such as cancer testing, instead of on a broad range of health and environmental effects testing. These officials told us that because the policy will identify a client who is willing to take action on the test results, EPA will be relieved of the need to spend resources on activities such as determining whether to send test results to another regulatory agency for possible action or whether to issue advisories to affected workers.

Conclusions

EPA has not implemented TSCA's regulatory authorities to limit or prevent the use of three chemicals that the Office of Toxic Substances has found to be harmful to human health or the environment on the basis of industry test data submitted to EPA. Given the recognized danger of the chemicals and the fact that EPA has no criteria and methodology to guide its managers in determining when chemicals present a significant or unreasonable risk, we question the basis for EPA's failure to take regulatory action regarding these chemicals.

In making determinations on risk, EPA relies on the professional judgment of its managers in the Office of Toxic Substances. We believe that such judgments should be guided by quantitative and qualitative criteria that can be consistently and systematically applied by the Office of Toxic Substances for each potentially harmful chemical that is assessed. Because the science of risk assessment is still evolving, the criteria and methodology will need to be periodically revised in view of advances in science and in view of EPA's experience gained in applying TSCA's regulatory authorities.

We also found that EPA is not taking timely action in completing its assessment of industry's test data and in resolving chemical safety concerns, where warranted, through means other than regulatory action, such as through issuing advisories to affected workers or sending test results to other federal regulatory agencies concerned with chemical safety issues. For several of the 22 chemicals we reviewed, years were lost in taking action because of inadequate management control and inattention to resolving outstanding problems in a timely manner. We believe that EPA is now taking appropriate steps to address this problem by developing guidance for evaluating chemicals within a specific period. We also noted that EPA is considering a management information

system to monitor the status of chemicals being tested, a function we believe is much needed on the basis of the results of our review.

EPA also has recently adopted a policy of not having industry perform chemical testing unless it or the Interagency Testing Committee identifies a client, such as another federal regulatory agency, that agrees to use TSCA test results. EPA believes that under this policy, it will be free to identify and test greater numbers of potentially harmful chemicals without having to spend its limited resources on regulatory actions. Even with more effective targeting of chemicals to be tested, EPA remains responsible under TSCA for determining the significance or unreasonableness of risk from exposure to harmful chemicals. To do so effectively, as stated above, we believe that EPA needs to take action to develop criteria for determining whether risk is significant or unreasonable and to implement controls to ensure that chemical review functions progress in a timely manner.

Recommendations

To ensure that EPA meets it responsibilities under TSCA to identify chemicals that present a significant risk of harm from cancer, gene mutation, or birth defects or unreasonable risk to human health or the environment, we recommend that the Administrator of EPA establish criteria and methodology for determining when chemicals present risks that would trigger implementation of TSCA regulatory provisions. The criteria and methodology should include definitions of significant and unreasonable risk and quantitative and qualitative measures to determine when such risks are present.

We also recommend that the Administrator provide for improved accountability and control over the chemical review process by implementing an information system to monitor the status of the chemicals being tested. Such a system should provide information on the current status and milestones for each chemical tested in the program; the types of tests performed, time frames for future actions required, and the test results; summaries of EPA reviews of test results; and the final disposition of the chemical.

EPA Needs to Publish TSCA Test Results

TSCA test results can be useful to research institutions and to other federal and state regulatory agencies in carrying out their responsibilities for identifying hazardous chemicals and protecting workers, consumers, and the environment against their adverse effects. EPA does not publish these test results in scientific journals and data bases, but relies instead primarily on making the studies available for review at its headquarters location. This method of making the results available, however, does not provide easy access to the data for the wide range of potential users. In addition, the dockets do not contain EPA's evaluation of the results and, in some cases, not all of the studies could be found by researchers in need of them. EPA currently is exploring ways to have its test results published.

TSCA Test Results Can Be Useful to Others

The regulatory agencies and research institutions working to identify harmful chemicals need to be aware of and have access to the results of TSCA's industry testing and EPA's evaluations. Although testing requirements vary by chemical, they are generally extensive and may cost industry thousands of dollars to conduct. Thus, adequate distribution of the results is important to avoid costly duplication of effort in research.

EPA has completed its evaluations of test data on 13 chemicals under the chemical testing program. Before this testing was done, the effects of these chemicals on human health and the environment were unknown.

The American people are exposed to many thousands of chemicals through their use in a wide variety of industrial and consumer products, as well as those naturally occurring in food. Various federal regulatory agencies, such as EPA, the Food and Drug Administration, and OSHA, and their counterparts at the state and local levels, have various responsibilities to protect consumers, workers, the general public, and the environment from the adverse effects of harmful chemicals. The health effects of most chemicals are generally unknown or in question.

The Interagency Testing Committee and National Institute for Environmental Health Sciences officials told us that TSCA test results would be useful to federal and state regulatory agencies. Committee officials said, for example, that New York's state water control board would be very interested in the test results for the chemical 2-chlorotoluene—1 of the 22 chemicals for which testing under TSCA has been completed. Several inconclusive studies had shown that the chemical may be toxic to aquatic organisms, and up to 100 pounds of the chemical were being released into the Niagara River each day. Committee officials said that

even though industry testing showed that the chemical was not dangerous in the amounts presently emitted, the test results would be of interest because they could alleviate concerns about whether the releases are damaging the environment and show the levels at which the chemical could be dangerous in the future.

TSCA test results can also be useful to other research organizations to avoid duplication of effort and to reduce costs. For example, the National Toxicology Program, within the Department of Health and Human Services, conducts testing of chemicals to determine their toxicity. The program's purpose is to strengthen the science base in toxicology and coordinate research and testing activities providing information on potentially toxic chemicals for the use of health regulatory and research agencies and others. The Department views the program's role in research and testing of toxic chemicals as a logical extension of the Public Health Service's responsibility for safeguarding the public's health and preventing unnecessary exposure to hazards. Thus, chemicals tested under TSCA may also be of interest to the program. An example is the chemical methyl ethyl ketone, which the program is interested in testing as part of its assistance in reviewing toxic waste cleanup under the Superfund program, and for which EPA has already tested under TSCA.

TSCA testing results can be useful to manufacturers if they currently use the chemical or decide to do so at a later date. Industry's testing under TSCA is usually conducted under the auspices of a panel of test sponsors or by an individual manufacturer that has its own research capability. However, the testing is done primarily for EPA, and there is no requirement for distributing results beyond that. Because results are not published, those interested later in using the chemical may not be aware that testing was done.

EPA's Distribution of Test Results Is Limited

TSCA test results are not readily accessible to researchers, other regulatory agencies, or the interested public. EPA relies on notices in the Federal Register, and summaries of test results in the chemical dockets located at EPA headquarters, as its means of distributing test results. However, the dockets are not always complete, and researchers are not always aware of EPA's completed chemical testing programs because the results are not published in scientific journals or data bases. Our review disclosed that poor dissemination of research resulted in an apparent

costly duplication of research because another federal agency was unaware that EPA had recently completed a similar test on the same chemical. We also found that EPA officials were concerned that industry was publishing information indicating that testing showed that a chemical produced no effect when in fact EPA's interpretation was that the test results produced an adverse effect.

EPA publishes a Receipt of Data notice in the Federal Register when it receives test data on a chemical. It makes test results available to the public by putting copies of abstracts of the studies in the chemical dockets located at EPA headquarters for review during business hours. EPA publishes an index of unpublished technical information that it receives from chemical manufacturers and processors under provisions of TSCA. This index identifies the existence of technical information submissions, including test results from the chemical testing program, but does not contain abstracts of the test data.

In addition, EPA may send the test results to another federal agency, such as the National Toxicology Program if it is aware of a particular interest or need for the data on a chemical. EPA also may send the results to another agency, such as OSHA, if it believes the agency needs to take action to protect consumers, workers, or others from the chemical's dangers revealed by the testing.

TSCA test results are not published in scientific journals or data bases, such as the National Library of Medicine's "TOXLINE," which compiles toxicology studies from research institutions around the world. The Director of EPA's Existing Chemical Assessment Division told us that TOXLINE and similar data bases require peer review of test data for publication, and TSCA test results are not peer reviewed. The National Toxicology Program's test results are peer reviewed and are included in TOXLINE.

EPA's current method of making test results available is not always effective. For example, EPA completed its evaluation of test data for methyl ethyl ketone in 1986. Agency records indicate that the test results were to be transferred to the National Toxicology Program, which needed to know the toxicity of methyl ethyl ketone as part of its reviews of toxic waste clean-up efforts. However, National Toxicology Program officials told us that EPA had never sent them the test data that they had requested on the chemical. EPA's Deputy Director of the Existing Chemical Assessment Division told us that this was another

example of poor internal controls caused by a lack of an adequate management information system.

In 1988, while waiting for the testing data, the National Toxicology Program started research on a phase of methyl ethyl ketone testing which they presumed was not covered in the TSCA testing program. Unknown to the National Toxicology Program, similar testing of methyl ethyl ketone had also been performed under the TSCA program. The project officer responsible for the testing at the National Toxicology Program told us that the testing, which was carried out at a cost of about $500,000, may not have been necessary had EPA published the results.

EPA's reliance on the chemical dockets as the primary means to make test results available to interested parties does not provide the same type of easy access as computerized data bases. Reliance on the dockets is also a problem in that references to them may not be complete. For example, the contractor hired by the Office of Toxic Substances to assess the status of chemicals being tested in the program could not locate through the index of technical information submissions 46 of the 147 studies performed for the chemicals.

The docket also does not contain EPA's assessments of test results, which include EPA's evaluations of test data and EPA's risk assessments. Office of Toxic Substances' scientists told us that test data evaluations and risk assessments are vital to an understanding of TSCA test results. They said reviewers of chemical test results should know, for example, if data are compromised by inadequate laboratory procedures. They also pointed out that, in order to properly understand the risks of chemicals, test results need to be related to human and environmental exposure to the chemicals, information included in EPA's risk assessments but not included in the dockets available to the public.

For example, in April 1989, the acting chief of the chemical testing branch in the Office of Toxic Substances called for the preparation of a chemical advisory on ethylhexanoic acid, which the Office of Toxic Substances managers earlier agreed to prepare. The acting chief noted that industry sources have been notifying the public that ethylhexanoic acid testing showed no adverse developmental affects in laboratory test animals, whereas EPA found that the data clearly indicated adverse developmental effects in the test animals. He stated that "the public is receiving a biased interpretation of the data from industry."

Industry officials, however, told us that in their opinion the testing laboratory had found no adverse health effects associated with ethylhexanoic acid. The industry officials said they requested a meeting to discuss

EPA concerns, but EPA never responded. They also said that EPA informed them that all pertinent records on the chemical were in the EPA docket, which is maintained at EPA headquarters in Washington, D.C. Industry officials said, however, that from their review of the docket, they were not able to determine that EPA had evaluated the industry test data. EPA officials explained to us that the dockets are intended to contain all material that EPA uses to evaluate test data but not the results of EPA's evaluation.

EPA officials are aware that current procedures for making test results available are limited. They said that they are exploring ways to obtain broader dissemination of the results. According to the officials, they are in the process of identifying scientific journals or publications that do not require submitted test data to be peer reviewed. The Deputy Director of the Existing Chemical Assessment Division told us that the division is planning to develop, by the summer of 1991, a proposal to require industry to obtain peer review of TSCA test results, making them acceptable for publication in the major scientific data bases.

Conclusions

Various federal and state regulatory agencies and research organizations share with EPA the responsibility to identify hazardous chemicals and to protect people and the environment from their harmful effects. TSCA test results, however, are not readily accessible. We believe that when testing is done on any of the thousands of chemicals for which health and environmental effects have been unknown or are in question, the results need to be made readily available to these other agencies and organizations so that they can take appropriate action, including the avoidance of duplicate testing. TSCA test results, however, are not readily accessible. Even when the test results show no harmful effects or show that a chemical is not hazardous at current exposure levels, this information can be important to many interested parties and should be communicated through publication of test results and EPA's risk assessments.

Recommendation

We recommend that the Administrator of EPA identify and implement additional ways to make TSCA test results readily available to federal and state regulatory agencies, research organizations, and other interested parties. Establishing peer reviews of chemical test results so that they can be included in major scientific data bases is an option that should be explored.

Examples of Use for 22 Chemicals With Complete Test Results

Chemical	Examples of Use
Acetonitrile	Industrial solvent; drug and pesticide manufacturing.
Antimony Trioxide	Flame retardant in plastics and textiles.
C-9 Aromatic Hydrocarbons	Solvents and placticizers; used in gasoline blending.
Biphenyl	Used in dye carrier and heat transfer fluid production.
Bisphenol A	Manufacturing of polycarbonate, epoxy, and phenoxy resins.
2-Chlorotoluene	Herbicide carrier; paint stripper; general cleaner.
Cumene	Manufacturing of liquid detergents; aviation fuel additive.
Cyclohexanone	Used in nylon manufacturing, and as a solvent for resins, lacquers, dyes, and pesticide formulations.
3,4 Dichlorobenzotrifloride	Herbicide manufacturing.
1,2 Dichloropropane	Manufacturing of dry cleaning fluid; furniture finish removers.
2-Ethylhexanoic Acid	Salts of the chemical are used in oil-based paint driers, inks, varnishes, and synthetic greases.
Hydroquinone	Photographic developer; bleach.
Isophorone	Solvent used in lacquers and surface coatings.
Metal Napthenates	Paint and ink driers.
Methyl Ethyl Ketone	Solvents for industrial coatings and adhesives.
Methyl Isobutyl Ketone	Solvents, fixatives, and adhesives.
Octylphenol	Marine paints, adhesives, varnishes.
Oleylamine	Additive in petroleum lubricants.
2-Phenoxyethanol	Solvent in paint removers; dye carrier.
Propylene Oxide	Solvent in printing inks; urethane plastic manufacturing.
Tetrabromobisphenol A	Flame retardant for plastics, paper, textiles.
Tris Trimellitate	High-temperature insulation materials.

Testing Time Frames for the 13 Completed Chemicals (In Years)

Chemical	Nomination-test rule[a]	Test rule- test receipt[b]	Test receipt-EPA review[c]
Acetonitrile	4.3	.7	5.8
Biphenyl	5.0	1.8	0.4
2-Chlorotoluene	1.0	3.0	0.5
Cyclohexanone	4.6	2.9	1.9
2-Ethylhexanoic Acid	2.4	1.6	2.2
Methyl Ethyl Ketone	4.3	1.1	1.3
Methyl Isobutyl Ketone	4.3	1.1	1.3
Hydroquinone	7.5	2.5	.4
Metal Napthenates	1.0	1.2	4.2
Octylphenol	1.6	3.6	0.6
2-Phenoxyethanol	1.0	3.4	2.4
Propylene Oxide	10.1	0.2	2.9
Tris Trimellitate	1.5	2.5	1.5
Average	3.7	2.0	2.0

[a]Time required to issue a test rule after the Interagency Testing Committee recommended the chemical for testing.

[b]Time required to receive test results after the test rule was issued.

[c]Time required to assess the test data after receiving the final test results from the chemical industry.

EPA's Evaluation of Test Results for 13 Completed Chemicals

Chemical	Test results		Harmful effects	
	Positive	Negative	Health	Environmental
Acetonitrile		X		
Biphenyl		X		
2-Chlorotoluene		X		
Cyclohexanone	X		X	
2-Ethylhexanoic Acid	X		X	
Methyl Ethyl Ketone		X		
Methyl Isobutyl Ketone		X		
Hydroquinone		X		
Metal Napthenates		X		
Octylphenol	X			X
2-Phenoxyethanol		X		
Propylene Oxide		X		
Tris Trimellitate		X		

EPA's Preliminary Evaluations of Test Results for Nine Chemicals Being Assessed

Chemical	Test results[a]		Potential effects	
	Positive	Negative	Health	Environmental
Antimony Trioxide	X		X	X
Bisphenol A	X		X	
C-9 Aromatic Hydrocarbons[b]				
Cumene	X			X
3,4 Dichlorobenzotrifluoride[b]				
1,2 Dichloropropane[b]				
Isophorone	X		X	
Oleylamine	X		X	
Tetrabromobisphenol A	X			X

[a]Although these chemicals may have tested positive for health or environmental effects, a risk assessment is essential to interpreting the test results. The risk assessment process determines if human beings or the environment are exposed to a chemical at levels that are dangerous to them. For example, laboratory testing may show that a chemical produces positive adverse health effects in laboratory animals at relatively high doses. The risk assessment, however, may find that humans are exposed to the chemical at levels that are not harmful to them.

[b]Test results do not clearly indicate either positive or negative effects.

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