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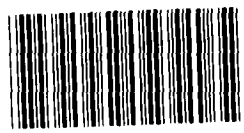
General Accounting Office

EPA Implementation Of Selected Aspects Of The Toxic Substances Control Act

After reviewing the law and legislative history, GAO determined that the Environmental Protection Agency (EPA) does have the authority to negotiate voluntary agreements with the chemical industry for needed health and environmental effects tests for chemical substances in lieu of issuing administrative rules formally requiring such testing. Although the voluntary approach is in the early stages, EPA believes test information could be available 12 to 18 months earlier than otherwise.

This report also provides information on (1) EPA'S criteria for assessing chemical risks, (2) the regulation of asbestos by EPA and other Federal agencies, (3) EPA's proposed exemption of small chemical manufacturers from certain reporting and recordkeeping requirements, and (4) EPA's requirement for information reporting on 250 chemicals.



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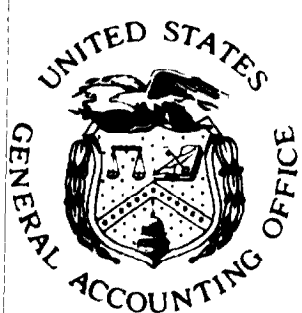

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RESOURCES, COMMUNITY,
AND ECONOMIC DEVELOPMENT
DIVISION

B-209343

Chairman and Ranking Minority Member,
Senate Committee on Environment
and Public Works, and
Selected Senators
United States Senate

This report is in response to your August 9, 1982, letter in which you asked us to assess the Environmental Protection Agency's (EPA's) authority to negotiate voluntary agreements with the chemical industry to perform health and environmental effects tests of chemical substances in lieu of issuing administrative rules to require such testing pursuant to section 4 of the Toxic Substances Control Act (TSCA). You also asked us to identify whether opportunities are provided under this alternative approach for public participation.

Based on our analysis of TSCA and its legislative history, we believe the EPA Administrator may negotiate voluntary testing agreements and, in appropriate instances, accept them in lieu of section 4 test rules. Also, the process designed by EPA for negotiating testing agreements with industry provides the opportunity for public participation at four different points in the process.

In addition, as agreed with the committee office, we are providing requested information on selected aspects of EPA's implementation of TSCA in appendixes I through IV, as follows.

Appendix I: EPA Criteria for Assessing Chemical Risks

Appendix II: Actions of EPA and Other Federal Agencies to Regulate Asbestos

Appendix III: Proposed Small Chemical Manufacturer Exemption From TSCA Reporting and Recordkeeping Requirements

Appendix IV: EPA's Final Rule Requiring Information To Be Reported on Approximately 250 Chemicals

OBJECTIVES, SCOPE, AND METHODOLOGY

The objective of our review was to determine if EPA has the authority to negotiate voluntary testing agreements with the chemical industry for needed human and environmental tests for chemical substances in lieu of formal rulemaking procedures. We also sought

information on EPA implementation of certain other aspects of TSCA relating to risk assessment, asbestos, small chemical manufacturer exemptions, and chemical information reporting requirements.

In reaching our opinion regarding EPA's authority for negotiating testing agreements, we reviewed TSCA and its legislative history; reports of views opposing EPA's action to negotiate voluntary testing agreements; and appropriate proposed and final rules and their supporting documents. We also discussed the issue with EPA officials from the Office of Toxic Substances and the Office of General Counsel and considered their views.

The information presented in appendixes I through IV is based on discussions with officials from EPA's Office of Toxic Substances and our review of various EPA reports, documents, and records pertinent to the matters discussed, such as EPA's proposed and final rules and their supporting documents. As agreed with the committee office, we did not independently verify much of the information presented in appendixes I, III, and IV.

Our work, conducted from August to November 1982, was done in accordance with generally accepted government audit standards.

EPA AUTHORITY TO NEGOTIATE VOLUNTARY TESTING

Under TSCA, EPA has been given the authority to gather certain kinds of basic information on chemicals, to identify harmful substances, and when necessary, to control those substances whose risk of injury to public health and the environment outweighs their benefits to society and the economy.

Section 4 of TSCA authorizes the EPA Administrator to require, through administrative rulemaking, that manufacturers conduct tests to determine the health and environmental effects that might result from the manufacture, processing, sale, use, or disposal of their products. Such testing allows EPA to develop data on health and environmental effects where there is insufficient data and experience and which are relevant to determining whether the chemical substances present an unreasonable risk of injury to health or the environment.

The Interagency Testing Committee (ITC), established by TSCA, is composed of representatives from eight Federal departments, agencies, and the Council on Environmental Quality. Its purpose is to recommend chemicals which should be given priority consideration for testing. The ITC may designate a priority list which may include no more than 50 chemicals at one time. EPA is required to respond to each designation within 12 months, either by initiating

rulemaking to require testing of each listed chemical substance or by issuing notice of EPA's decision and rationale for not initiating rulemaking.

At a March 1982 meeting with the Administrator's Toxic Substances Advisory Committee (composed of representatives from chemical manufacturers, processors, and users and environmental, health, and public interest organizations), EPA announced it would seek to negotiate a voluntary test program with industry, where possible, in lieu of issuing a test rule, although test rules would remain an appropriate mechanism in some circumstances. Appendix V is a chart, prepared by EPA, outlining the steps and time frames of the negotiated testing agreement and the formal test rulemaking approaches. (On August 23, 1982, we provided your committee office with a detailed description of the section 4 negotiated testing process and a schedule of EPA chemical testing actions.)

The Director of the Assessment Division and other officials of the Office of Toxic Substances, who are responsible for implementing TSCA, told us that voluntary negotiated testing agreements outside of the formal rulemaking process reduce the amount of time it takes to get health and environmental effects data. They said a voluntary negotiated testing agreement can lead to testing of a priority chemical within 18 months from receipt of an ITC testing recommendation, whereas it takes at least 2-1/2 to 3 years to develop a final test rule for testing to commence. EPA has already begun to receive test data from the testing programs negotiated in late 1981 and early 1982. These officials said that had these chemicals gone through formal rulemaking, data would not have become available until sometime in 1984 at the earliest. They also said that fewer EPA resources would be required to develop a negotiated agreement than to acquire the same data through a formal rule.

Officials of EPA's Office of Toxic Substances said that negotiating an agreement lends itself to a cooperative and harmonious rather than an adversarial relationship among all parties. They also said that if a testing agreement cannot be reached or if industry fails to perform the tests as agreed, EPA can still promulgate a test rule to require the necessary testing.

EPA takes the position that issuance of a test rule to require health and environmental effects testing by manufacturers is not necessary under section 4 when voluntary testing by the manufacturers either has been agreed to or is ongoing. EPA argues that a finding by the Administrator under section 4(a) that testing of a priority chemical substance is necessary does not mandate the agency to undertake a rulemaking if the goal of developing the data can be met another way. Hence, EPA maintains that where industry voluntarily agrees, within TSCA's 12-month deadline, to

an adequate test program for a chemical substance, a legally sufficient reason exists not to pursue a section 4 test rule.

We believe EPA's interpretation of its authority to negotiate agreements with industry for the voluntary testing of priority chemical substances is reasonable. To compel testing under section 4, where otherwise acceptable voluntary testing is planned, would in our opinion be an inefficient use of EPA's resources and inconsistent with the Congress' desire to avoid duplicative and unnecessary testing. Accordingly, we do not believe that TSCA compels the promulgation of a section 4 test rule where adequate test data may be developed under a voluntary testing agreement. We believe implied authority exists for EPA to negotiate voluntary testing agreements because the agreements are reasonably consistent with the significant purposes of section 4--to ensure that industry at its own expense develops adequate data to assess a chemical substance's or mixture's risk to health or the environment.

A major shortcoming of the negotiated testing agreement is that the agreement, unlike a test rule, is not enforceable. For example, a test rule for an existing chemical specifies a period within which prescribed testing is to be completed and test results submitted. Failure to comply with a deadline or other provision of a test rule is a violation of TSCA subject to civil penalty. Failure to comply with provisions of a negotiated test agreement is not subject to TSCA penalties which apply only to a test rule. Also, the negotiated agreements have not contained any provision for penalties.

EPA's Chief of the Test Rules Development Branch, Office of Toxic Substances, told us that the agreements are voluntary and not enforceable. However, he said that EPA can issue a test rule if an agreement is not lived up to. He believes that industry will make every effort to comply with the agreement because industry supports the concept. He said that EPA intends to make the test results available to the public, publish them in the Federal Register, and establish a specific schedule for test completion as part of negotiated testing agreements.

Appendix VI provides additional information on the legal aspects of voluntary negotiated testing agreements under TSCA.

PUBLIC PARTICIPATION IN THE NEGOTIATED TESTING PROCESS

The negotiated testing process, as described by EPA, provides the opportunity for the public to review and comment on EPA's proposed actions at four distinct points in the process, as follows:

--Following publication of the ITC report recommending chemicals for priority testing.

--During EPA's assessment of the adequacy of available test data before EPA makes its decision as to whether additional chemical testing may be necessary, the public may comment and submit information to EPA on the need for tests.

--Following EPA's initial decision that additional testing is necessary. At that time the public has the opportunity to comment on the range and scope of additional testing that may be needed. This is generally done before the negotiations with industry are initiated.

--Following publication of EPA's proposed acceptance of the test program that is agreed to by the industry. At this point the public is given the opportunity to comment on the adequacy of the test program as negotiated. After a public comment period, EPA publishes a final acceptance, responding to comments and indicating a schedule for receipt of test data.

The Administrator's Toxic Substances Advisory Committee supported the negotiated test agreement process in March 1982 but warned that public input during the negotiation and development of a testing program will be very difficult to achieve within the tight time frames.

At your request, we did not take the time to obtain written agency comments, but the matters covered in the report were discussed with agency officials. Their comments are included in the report where appropriate.

As arranged with the committee office, we plan no further distribution of this report until 15 days from the date of its issuance. At that time we will send copies to interested parties and make copies available to others upon request.

J. Dexter Peach
Director

LIST OF ADDRESSEES FOR GAO REPORT ON EPA IMPLEMENTATION OF THE TOXIC SUBSTANCES CONTROL ACT

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

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

The Honorable Max Baucus
Member, Committee on Environment
and Public Works
United States Senate

The Honorable Slade Gorton
Member, Committee on Environment
and Public Works
United States Senate

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ABBREVIATIONS

EPA	Environmental Protection Agency
GAO	General Accounting Office
ITC	Interagency Testing Committee
TSCA	Toxic Substances Control Act

EPA CRITERIA FOR ASSESSING CHEMICAL RISKS

TSCA authorizes the EPA Administrator to regulate any chemical in commerce which the Administrator determines to present an unreasonable risk to health or the environment. The Administrator can regulate any part of a chemical's life cycle from production through distribution, use, and disposal. However, TSCA directs that the Administrator, in assessing whether the risks posed by a chemical are unreasonable, should consider:

--Hazard: the effects of the chemical substances on health and the environment.

--Exposure: the magnitude of the exposure of human beings and environment to the chemical substance.

--Risk: the attendant risks of specific hazards given the exposures.

--Benefits: the benefits of the chemical substance for various uses, the availability of substitutes for such uses, and the reasonably ascertainable economic consequences of alternative regulatory actions after consideration of the effect on the national economy, small business, technological innovation, the environment, and public health.

Because TSCA does not specify what would constitute unreasonable risk, the determination of unreasonable risk in any particular case is left to the EPA Administrator's judgment. The Administrator must weigh the magnitude of risks as contrasted with the benefits of a chemical and the consequences of a given regulatory action. If the risks are judged to pose a greater burden than the benefits of a continued specific chemical usage, the risks are termed unreasonable. TSCA requires EPA to control those risks by the least burdensome means to the point where the risks from chemical exposure are no longer unreasonable; that is, they are now acceptable. Because each chemical has its own distinct risks and benefits, the evaluation of a chemical's "unreasonable risk" will depend on the chemical's own unique set of risk and benefit factors. Therefore, EPA must make judgments about unreasonable risk on a case-by-case basis.

A science advisor to the EPA Assistant Administrant for Pesticides and Toxic Substances, the Director of the Assessment Division, and other officials of the Office of Toxic Substances said that there were no categorical criteria or triggers for determining carcinogenicity, mutagenicity, teratogenicity, and toxicity of a chemical. To assess carcinogenicity, EPA relies on general guidelines it developed in 1976 which are basically consistent with recommendations from international and national scientific bodies, such as the International Agency for Research on Cancer. These recommendations take a "weight-of-the-evidence" approach applied in a case-by-case manner.

ACTIONS OF EPA AND OTHER FEDERAL AGENCIES TO REGULATE ASBESTOS

The following sections describe EPA's regulation of asbestos in schools; summarize our recent report on EPA efforts--"Asbestos in Schools: A Dilemma," GAO/CED-82-114, dated August 31, 1982; and identify other Federal regulations of asbestos.

EPA's regulation of asbestos in schools

The Federal Government conducts three major activities directed toward alleviating asbestos hazards in schools. EPA has operated a voluntary technical assistance program since March 1979 to help State and school officials identify and correct asbestos hazards. Also, since June 1980, the Department of Education has been charged with administering the Asbestos School Hazard Detection and Control Act. This act requires that the Department of Education establish procedures for detecting and controlling asbestos in coordination with EPA, provide financial assistance to help schools detect and abate asbestos, and impose recordkeeping and reporting requirements on the States. Most recently, in May 1982, EPA issued a rule under TSCA requiring schools to inspect for asbestos and notify employees and parent-teacher groups of the presence of asbestos.

Our August report evaluated Federal efforts to control asbestos hazards in schools. A copy of this report was previously provided to your office. In general, the report reveals that:

--EPA's technical assistance program was a limited success. Many schools have not been inspected for asbestos, and the quality of inspections that were done is questionable. Also, the program did not provide definitive criteria for determining asbestos hazards and appropriate control actions. Thus, it is uncertain whether corrective actions taken by schools using program guidance were sufficient or even necessary.

--The Asbestos School Hazard Detection and Control Act of 1980 has had little impact, chiefly because the grant and loan program for detecting and abating asbestos was never funded.

--EPA's Inspection and Notification Rule will do little to alleviate the varied local and State responses to asbestos hazards. Although the rule requires schools to inspect for asbestos, no specific guidance exists for determining when asbestos is hazardous and what control actions are most appropriate.

Other Federal regulation of asbestos

EPA, as well as numerous other Federal agencies, is involved in a wide variety of asbestos regulation, in addition to the asbestos in schools situation.

EPA, the Occupational Safety and Health Administration (OSHA), the Mine Safety and Health Administration (MSHA), the Food and Drug Administration (FDA), the Consumer Product Safety Commission (CPSC), and the Department of Transportation (DOT) have all issued rules regulating asbestos. Many of these agencies are also conducting rulemaking proceedings to further control exposures to asbestos. Currently, about 20 separate rules and regulations control asbestos exposures. Some of these are discussed below.

--Under the Clean Air Act, EPA has established emissions standards for asbestos for milling, spraying, manufacturing, demolition, renovation, and waste disposal. Also, under the Federal Water Pollution Control Act, EPA has established effluent limitations and new source and pretreatment standards for asbestos manufacturing. Most recently, EPA issued rules under TSCA requiring asbestos producers, importers, and processors to report information on commercial and industrial uses of asbestos and requiring manufacturers and processors of asbestos to submit lists and copies of unpublished health and safety studies. These rules are intended to provide a data base for identifying unreasonable exposure risks and to develop initiatives to protect public health.

--OSHA has promulgated numerous asbestos exposure workplace standards.

--MSHA has established standards regulating exposure to asbestos dust in coal mines, metal and nonmetallic mines, and sand, gravel, and crushed stone operations.

--FDA has published regulations restricting the use of asbestos filters in the manufacture of drugs for injection and has banned an asbestos filtration technique used in producing food grade salt.

--CPSC has banned numerous asbestos products, including patching compounds used to join or repair interior walls and ceilings, artificial fireplace embers, and general use garments.

--DOT has regulated the generation of airborne concentrations of asbestos that may result from the packaging and handling of asbestos fiber shipments in commercial transportation.

In May 1982, EPA proposed establishing a Federal Asbestos Task Force of representatives from EPA, OSHA, CPSC, and other agencies, as appropriate. The task force held its first meeting on August 13, 1982. The task force is intended to provide a multi-agency forum to agree upon a unified Federal approach to the regulation of asbestos and to coordinate future actions by participating agencies. Through the cooperative efforts of the task force, the participating agencies hope to increase the cost effectiveness of regulatory activities by eliminating duplicative efforts.

APPENDIX III

PROPOSED SMALL CHEMICAL MANUFACTURER EXEMPTION FROM TSCA REPORTING AND RECORDKEEPING REQUIREMENTS

On June 23, 1982, EPA proposed a rule which would exempt small manufacturers from most TSCA section 8(a) reporting and recordkeeping requirements. Section 8(a) authorizes the Administrator to require manufacturers and processors, other than small manufacturers or processors, to collect and report information on a chemical's estimated production volume, use, by-products, any existing data on the environmental and health effects of such substance, the number of individuals exposed, and the manner of disposal. These requirements are intended to provide EPA with information to assess chemical risks. Section 8(a)(3) of TSCA requires the Administrator to issue a rule prescribing standards for determining which small manufacturers would be exempt from most TSCA reporting requirements. The legislative record indicates that a small manufacturer exemption standard was needed to balance the need for risk-related information with the need to minimize the reporting and recordkeeping burden on small manufacturers. However, TSCA also gives the Administrator the authority, in certain circumstances, to override the exemption and require small manufacturers to report on specific chemicals.

The proposed exemption standard applies to small chemical manufacturers only. The Director of the Assessment Division and other officials from the Office of Toxic Substances said that they have not yet developed general exemption standards for small chemical processors because of the large number and diversity of processors. Therefore, until the rule is final, EPA defines small manufacturers and processors of individual chemicals on a rule-by-rule basis.

A manufacturer must meet either of the following standards to qualify as a small manufacturer:

1. Total annual sales (combined with parent company sales) of less than $30 million and annual production volume of a particular chemical at any individual site not greater than 100,000 pounds; or

2. Total annual sales (combined with parent company sales) of less than $3 million, regardless of quantity produced.

Under the first standard, a manufacturer's exemption status is determined on an individual chemical and plant site basis. A manufacturer having total sales of less than $30 million, but producing over 100,000 pounds of a chemical at a single plant site, is not exempt for that chemical and that site. However, if the same manufacturer produces less than 100,000 pounds of a chemical at a single site, it need not report on that chemical at that site.

Thus, a manufacturer with sales of less than $30 million need report only on chemicals whose plant site production volume is greater than 100,000 pounds. According to the proposed rule, the combination of the two standards would exempt 36 percent of all firms that manufacture chemicals and 12 percent of the total number of manufacturing sites.

Table I

Estimated Number of Exempt Small Manufacturers (note a)
(Based on the small manufacturer exemption standard)

	Firms		Sites	
	Number	Percent	Number	Percent
Small size	272	36	365	12
Other	483	64	2,679	88
Total	755	100	3,044	100

a/These figures do not represent an absolute measurement of the effect of the proposed exemption standards on the chemical industry. Rather, they represent the estimated impact of the standards. EPA selected a sample set of 1,459 chemicals likely to be subject to future section 8(a) reporting rules. Approximately 755 companies, representing 3,044 manufacturing plant sites, reported on these chemicals for the 1979 Chemical Substance Inventory. Using this representative data base, EPA examined the approximate impact of various exemption standards on the industry. These firms and sites are a sample of the approximately 5,000 U.S. chemical manufacturing firms and 8,000 plant sites (a firm may have more than one site).

In the second standard, firms with less than $3 million in total annual sales will qualify for an exemption regardless of the volume of individual chemicals produced. Approximately 8.4 percent of all manufacturing plant sites will be exempt under this standard.

The small manufacturer exemption will apply only to future reporting requirements under section 8(a) of TSCA and not to other TSCA requirements such as premanufacture reviews, tests, and regulatory controls. EPA officials believe that small manufacturer exemptions generally will not prevent or hinder their ability to obtain needed reporting of exposure-related information on specific chemicals because the Administrator has the discretionary authority to modify or eliminate the small manufacturer exemption in those few cases where critical information may be held by a small manufacturer. The Administrator also has the authority to

APPENDIX III

require reporting and recordkeeping even from small manufacturers of chemical substances that are subject to a rule proposed or promulgated under other sections of TSCA.

In your letter, you asked whether or not Life Sciences, Inc. (former manufacturer of kepone), Michigan Chemical Co. (former manufacturer of PBB's), and Crystal Chemical Company (producer of herbicides with a site on the Superfund list) would qualify as small manufacturers under EPA's definition. Using EPA's proposed criteria, Life Sciences, Inc., would not qualify as a small manufacturer. EPA's Office of Toxic Substances provided us with information which indicated that the firm probably produces more than 100,000 pounds of kepone per year. However, because kepone is used as a pesticide, Life Sciences would not be subject to TSCA reporting requirements in any case.

Michigan Chemical Co. produced close to 5 million pounds of PBB's in 1974. This greatly exceeds the 100,000-pound criterion set by EPA. In addition, because of PBB's toxicity, EPA has promulgated a small manufacturer definition and rule applicable to that chemical alone. The small manufacturer standard for PBB's is total annual sales of less than $500,000, except that no manufacturer is classified as "small" if annual PBB production at one site is greater than 10,000 pounds. PBB's were manufactured between 1970 and 1977.

As of June 1, 1982, Crystal Chemical Company reported sales of $1,750,000. Because it is a manufacturer with a single location, it could be classified as a small manufacturer. However, because Crystal Chemical Company manufactures herbicides, and herbicide manufacturers are not subject to TSCA, reporting requirements would not apply to this manufacturer.

EPA's FINAL RULE REQUIRING INFORMATION TO BE REPORTED ON APPROXIMATELY 250 CHEMICALS

Under section 8(a), EPA is authorized to promulgate rules prescribing recordkeeping and reporting requirements for manufacturers of specified chemical substances. Information required by section 8(a) rules includes (1) chemical identity and molecular structures, (2) categories of use, (3) amounts manufactured or processed for each use, (4) a description of by-products, (5) existing data on health and environmental effects, (6) number of individuals exposed, and (7) method of its disposal.

EPA issued a final section 8(a) rule on June 22, 1982, requiring information on approximately 250 chemicals. The purpose of the section 8(a) rule is to obtain production, use, and exposure data on selected chemicals from chemical manufacturers and importers. When it was issued as a proposed rule on February 29, 1980, the rule called for information on 2,226 chemicals, but in its final form the number of chemicals for which data is being requested has been reduced to approximately 250. EPA officials said that the final section 8(a) rule requiring information on 250 chemicals was based on an Office of Toxic Substances policy decision to focus its efforts on those chemicals which had been designated as priority chemicals for evaluation due to their possible risk to health and the environment. EPA decided not to require reports on other chemicals, at this time, for the purpose of general information gathering.

Consequently, EPA's final rule is limited to chemicals that are considered to pose the greatest potential for risk to health and environment--chemicals recommended for testing by the Interagency Testing Committee (ITC) (approximately 217 chemicals) and certain chemicals (33 chemicals) for which EPA received section 8(e) notifications of substantial risk. 1/

EPA's Chief of the Test Rules Development Branch said that EPA did not evaluate each of the 2,226 chemicals to determine whether it should be on the final list. Instead, EPA came up with the final 250 chemicals by listing the ITC-designated chemicals and the chemicals from TSCA section 8(e) notifications of substantial risk. The Chief said that eliminating the approximately 2,000 chemicals from the request for data on production volumes, processes, and human exposure does not mean that EPA has determined

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1/Under section 8(e), persons who obtain information which reasonably supports the conclusion that a substance presents substantial risk of injury to human health or the environment must notify EPA immediately.

that they are not hazardous, only that EPA has decided to delay any requests for data on these chemicals to some future date and concentrate its efforts on those chemicals that, based on best available information, pose the greater potential risk.

The basis for chemicals being included in the rule as initially proposed included factors such as high production volume, high exposure potential, toxicity, and structural similarity to a toxic substance. Most of the 2,226 chemicals consisted of high production volume chemicals and ITC-reviewed chemicals. According to the Chief of the Test Rules Development Branch, most high production volume chemicals were deleted from the final rule.

Impact of final rule on industry

EPA estimated that about 450 plant sites will submit a total of 1,300 reports. The plant sites represent about 330 companies. The companies will submit a two-page "Manufacturer's Report--Preliminary Assessment Information" form which identifies

--where a chemical is made;

--in what quantities it is made;

--how many workers are potentially exposed during manufacture, processing, and use at the manufacturing plant site;

--what likely environmental releases exist; and

--what quantities are used in various categories of uses both by the manufacturer and as the chemical moves into commerce.

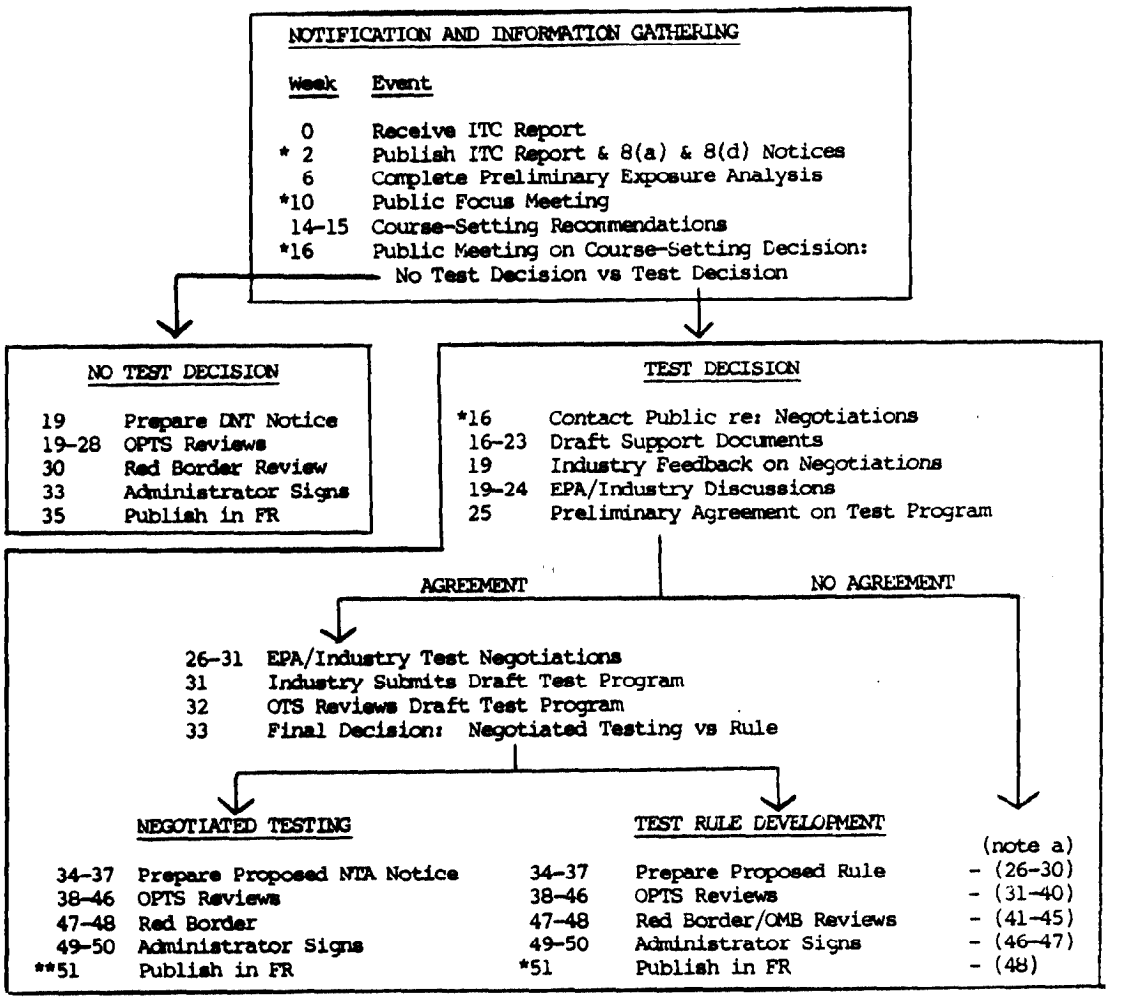
Proposed EPA rule on additional chemicals

In addition to the final section 8(a) rule for the 250 chemicals, EPA issued on June 22, 1982, a proposed rule on 50 additional chemicals for manufacturer reports of preliminary assessment information. These are chemicals that the ITC has designated as candidates for testing in its fifth through ninth reports.

As part of this proposed rule, EPA also proposed supplementary processor reports on the 300 chemicals subject to manufacturer reporting, when customer-use information submitted by the manufacturer is inadequate. In this supplementary or second round of reporting, processors would report on chemical substances that are marketed by manufacturers who reported unknown customer uses for more than 20 percent of the total quantity manufactured and imported.

EPA is also proposing an amendment to the final section 8(a) rule on manufacturer reporting requirements that would automatically require manufacturers to report on ITC-designated chemicals within 60 days after they are designated as priority chemicals by the ITC.

CHART OF VOLUNTARY NEGOTIATED TESTING AGREEMENT PROCESS AND MILESTONES



ITC - Interagency Testing Committee
DNT - Decision Not To Test
OPTS - Office of Pesticides and Toxic Substances
NTA - Negotiated Test Agreement
OTS - Office of Toxic Substances
OMB - Office of Management and Budget
FR - Federal Register
* - Points in the process when public comment is solicited.
** - Publication of a proposed acceptance of a negotiated test program. Following public comment, a final acceptance is published.

a/These are milestones for developing a test rule when a decision is made at week 25 not to negotiate a testing agreement.

Source: EPA.

APPENDIX VI

ANALYSIS OF TSCA AND THE BASIS FOR EPA's AUTHORITY TO NEGOTIATE VOLUNTARY TESTING AGREEMENTS FOR CHEMICALS PLACED ON THE ITC PRIORITY LIST

I.

Under section 4(a) of the Toxic Substances Control Act (TSCA), 15 U.S.C. §2603(a) (1976), the Administrator of the Environmental Protection Agency (EPA) is authorized to compel testing of chemical substances or mixtures where certain specified conditions are met.[1]

---

[1] Section 4(a)'s operative language, insofar as pertinent here, reads as follows:

> "If the Administrator finds that--
>
> "(1)(A)(i) the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or that any combination of such activities, may present an unreasonable risk of injury to health or the environment,
>
> "(ii) there are insufficient data and experience upon which the effects of such manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and
>
> "(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data; or
>
> "(B)(i) a chemical substance or mixture is or will be produced in substantial quantities, and (I) it enters or may reasonably be anticipated to enter the environment in substantial quantities or (II) there is or may be significant or substantial human exposure to such substance or mixture,

APPENDIX VI

Section 4(e) of TSCA establishes an eight-member interagency advisory committee to advise the Administrator concerning testing priorities. 15 U.S.C. §2603(e) (1976).

[1] (cont'd)

"(ii) there are insufficient data and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and

"(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data; and

"(2) in the case of a mixture, the effects which the mixture's manufacture, distribution in commerce, processsing, use, or disposal or any combination of such activities may have on health or the environment may not be reasonably and more efficiently determined or predicted by testing the chemical substances which comprise the mixture;

the Administrator shall by rule require that testing be conducted on such substance or mixture to develop data with respect to the health and environmental effects for which there is an insufficiency of data and experience and which are relevant to a determination that the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture, or that any combination of such activities, does or does not present an unreasonable risk of injury to health or the environment."

In recommending that the Administrator give a chemical substance or mixture priority consideration for the promulgation of a test rule under section 4(a), the interagency advisory committee, commonly known as the Interagency Testing Committee (ITC), must take into consideration "all relevant factors," including eight statutorily enumerated factors. 15 U.S.C. §2603(e)(1)(A). The ITC's priority list may not exceed 50 chemicals or classes of chemicals at any one time. Id. The ITC is directed to designate chemicals on the list which it believes merit a section 4(a) rulemaking within 12 months. Id.

The ITC's recommendations are not binding on the Administrator; the final decision to initiate a section 4 test rule proceeding remains with the Administrator. 15 U.S.C. §2603(e)(1)(A); H.R. Rep. No. 94-1679 at 62 (1976). However, should the Administrator decide not to initiate a rulemaking in accordance with the ITC's recommendation, the reasons therefor must be divulged:

> "* * * Within the 12-month period beginning on the date of the first inclusion on the list of a chemical substance or mixture designated by the committee under subparagraph (A) the Administrator shall with respect to such chemical substance or mixture either initiate a rulemaking proceeding under subsection (a) of this section or if such a proceeding is not initiated within such period, publish in the Federal Register the Administrator's reason for not initiating such a proceeding." 15 U.S.C. §2603(e)(1)(B) (emphasis added).[2]

There are various regulatory options available if the Administrator determines as a result of the testing that the chemical poses an unreasonable risk. These options include

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2 Although section 4(e) does not specify the range of legally acceptable "reasons for not initiating [a subsection (a)] proceeding," the Senate report accompanying S. 3149 explains that it is "expected that the Administrator's statement in the Federal Register will be specific and will explain in some detail why the conditions for testing under subsection (a) are absent." S. Rep. No. 94-698 at 17 (1976).

requiring labeling with respect to its use or prohibiting its manufacture or distribution. See generally, 15 U.S.C. §2605 (1976).

II.

There is no express authority granted the Administrator to negotiate voluntary testing agreements in lieu of initiating a section 4(a) rulemaking. However, we conclude that neither section 4(a) nor 4(e) compels the promulgation of a test rule proceeding where adequate test data may be developed pursuant to voluntary testing agreements. We further conclude that since voluntary testing agreements are consistent with the signficant purposes of section 4, implied authority exists for EPA to negotiate such agreements.

III.

The National Resources Defense Council charges that "[S]ection 4 establishes the comprehensive and exclusive scheme under which Congress envisioned testing would be conducted for chemicals meeting the criteria listed in subsection (a)."[3] Thus, according to the Council, where the specified criteria of subsection 4(a)(1)(A) or (B) are met, Congress intended that EPA compel testing by rule for chemicals designated by the ITC for priority consideration under section 4(e). The Council asserts that the fact that EPA negotiates and later accepts a voluntary testing agreement indicates that the criteria of subsection 4(a)(1)(A) or (B) are met, and, in particular, that "testing is necessary" within the contemplation of subsection 4(a)(1)(A)(iii) and (B)(iii).[4]

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3 Comments of the Natural Resources Defense Council, Inc., on Voluntary Testing Programs For the Alkyl Phthalates and the Chlorinated Paraffins: A Critical Review of their Legal and Scientific Adequacy Under Section 4 of [TSCA] at 8 (October 20, 1981).

4 Id. at 9, 11.

EPA rejects this argument, asserting instead that its scheme for negotiating voluntary testing agreements with industry representatives "is consistent with section 4." 47 Fed. Reg. 335 (January 5, 1982). EPA argues that simply because the Administrator could make the section 4(a) findings with respect to a priority chemical substance does not "mandate the Agency to undertake a rulemaking if the goal of developing data can be met another way."[5] Furthermore, EPA views the section 4(a)(1)(A)(iii) and (B)(iii) "testing is necessary" finding as ambiguous. According to EPA, a test rule is clearly not necessary, and indeed would be a misallocation of EPA's resources where otherwise acceptable industry testing is either on-going[6] or planned.[7] Under EPA's construction of subsection 4(a)(1)(A)(iii) and (B)(iii), the statutory criterion is not the necessity of testing per se, but the necessity of testing pursuant to a test rule.[8] Hence, where the affected industry agrees to a voluntary testing program within section 4(e)'s 12-month deadline, EPA believes that a legally sufficient reason exists not to pursue a section 4(a) test rule.

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5 EPA's legal position on this issue is taken mainly from the Federal Register notice of EPA's decision not to pursue a section 4(a) test rule for alkyl phthalates or benyl butyl phthalate and the more detailed response to NRDC's legal comments placed by EPA in the public record for this decision. See 47 Fed. Reg. 335 (January 5, 1982).

6 Chloromethane and Chlorinated Benzenes Proposed Test Rule, 45 Fed. Reg. 48524, 48530 (July 30, 1980) ("Where EPA has been able to conclude that the on-going study is likely to meet its needs, there is no need to require additional testing.") See also Benzidine-, O-Toldine- and O-Diamisidine - Based Dyes Response to the Interagency Testing Committee, 46 Fed. Reg. 55004 (November 4, 1981).

7 Acrylamide: Response to the Interagency Testing Committee, 45 Fed. Reg. 48510 (July 18, 1980) ("* * * Dow Chemical Company plans to conduct oncogenicity testing. Thus, EPA believes that, as a matter of priorities and resource allocations, the Agency should not develop a test rule for acrylamide to resolve remaining issues about its toxicity but instead should seek data on chemicals for which the need for data is greater.")

8 See also 45 Fed. Reg. at 48530.

IV.

It is clear that section 4 of TSCA responds to the failure of chemical manufacturers and processors to voluntarily test chemical substances or mixtures prior to marketing. See H.R. Rep. No. 94-1341 at 5 (1976). It is equally clear that the phrase "shall by rule require [testing]" emphasizes the mandatory nature of the Administrator's duty under section 4(a). However, the Adminstrator's duty to initiate a rulemaking proceeding is conditioned on his ability to make the requisite findings specified in section 4(a) as to the need for testing. Absent those findings, testing may not be required. Here the issue is the construction of the section 4(a)(1)(A)(iii) and (B)(iii) findings.

As we discussed above, EPA argues that it is the necessity of testing pursuant to a section 4(a) rule which is the statutory standard, not simply the necessity of testing per se. We do not believe EPA's construction of subsection 4(a)(1)(A)(iii) and (B)(iii) is unreasonable. Indeed, to construe subsection 4(a)(1)(A)(iii) and (B)(iii) otherwise would require the Administrator to initiate test rule proceedings even where otherwise acceptable testing is on-going or planned. If the need to test is obviated by the fact that otherwise acceptable testing is planned, we perceive no more reason to pursue a test rule pursuant to section 4(a) where EPA has negotiated the planned testing with the affected industry. Moreover, EPA retains the option to pursue a section 4(a) test rule at a later date should the planned testing not proceed in an acceptable or timely fashion.

In our review of this issue, we have extended to EPA's construction of section 4(a)(1)(A)(iii) and (B)(iii) the deference typically extended an agency's interpretation of a statute it is charged to administer. See, e.g., Udall v. Tallman, 380 U.S. 1, 16 (1965). In our view, such deference is warranted because of EPA's needs to adjust "an intricate and unfathomable system of regulation" in a realistic and pragmatic manner to administrative practicalities. See Dow Chemical Company v. EPA, 605 F.2d 673, 676 (3d Cir. 1979).

Deference, however, should not be extended to an agency interpretation which is clearly inconsistent with the intent of Congress. Morton v. Ruiz, 415 U.S. 199, 237 (1974); Espinoza v. Farah Mfg. Co., 414 U.S. 86, 94 (1973). We do

not believe such is the case here. Our examination of TSCA's legislative history indicates that Congress did not specifically focus on this issue. Although, as noted earlier, section 4 results from Congress' concern with the chemical industry's failure to adequately test chemical substances, the legislative history of section 4 lacks any indication that Congress intended to discourage voluntary testing or to require duplicative testing, resulting in unnecessary red tape and expense for industry and government alike. The very purpose of subsections 4(a)(1)(A)(ii) and (iii) and (B)(ii) and (iii) is to avoid duplicative and redundant testing. H.R. Rep. No. 94-1341 at 18 (1976). And, voluntary test agreements are consistent with the primary purpose of section 4--to ensure that industry at its own expense develops adequate data to assess a chemical substance or mixture's risk to health or the environment.[9]

The National Resources Defense Council also argues that EPA's negotiated test scheme will not trigger other provisions of TSCA keyed to a section 4 test rule, thereby frustrating Congress' intent in enacting these provisions.[10] This argument, like the Council's earlier argument, rests on the proposition that section 4(a) is the exclusive scheme for testing chemicals meeting section 4(a)'s criteria.

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9 Section 2(b)(1) and (2), 15 U.S.C. §2601, expresses the policy of the United States that

> "(1) adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such data should be the responsibility of those who manufacture and those who process such chemical substances and mixtures, [and]
>
> "(2) adequate authority should exist to regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment, and to take action with respect to chemical substances and mixtures which are imminent hazards."

10 See NRDC's Comments at 11, cited n. 3 above.

APPENDIX VI

For the reasons discussed earlier, we have rejected the Council's basic assumption in favor of what we believe is a more reasonable construction of section 4. Since, under the rationale adopted here, voluntary testing may obviate the need for a section 4(a) test rule and since EPA's acceptance of a voluntary testing proposal is not inconsistent with Congress' purpose in enacting section 4, we do not believe it is correct to say that such agreements "frustrate" Congress' intent in enacting those other regulatory provisions keyed to section 4.

It is of course true that a voluntary testing agreement does avoid regulatory requirements that otherwise would be triggered by a section 4(a) test rule. For example, a test rule for existing chemicals must include a specification of the period within which test data must be submitted. 15 U.S.C. §2603(b)(1)(C). Failure to comply with such deadline or other provision of a test rule is a violation of section 15, 15 U.S.C. §2614, subject to a civil penalty in an amount not to exceed $25,000 for each day the violation continues, 15 U.S.C. §2615(a).[11] Health and safety studies for chemicals "for which testing is required under [section 4]"

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11 Although the voluntary testing agreements may appear at first glance to contain the essential prerequisites of a contract--offer, acceptance and adequate consideration--what is lacking and which would defeat the formation of a legally enforceable contract is any apparent intention either by EPA or industry to create a legally binding contract. See Corbin on Contracts §34 (1963). An examination of the Chemical Manufacturers Association proposal to voluntarily test phthalate esters for health and environmental effects states that it "is intended to be wholly voluntary." Phthalate Esters-Voluntary Test Program Under Section 4 of the Toxic Substances Control Act, vol. 1, at p. 2, dated September 30, 1981, submitted by the Chemical Manufacturers Association to the Environmental Protection Agency. Similarly, EPA apparently views the agreements as merely voluntary. See 46 Fed. Reg. 53775 (October 30, 1981). Nonetheless, EPA administratively could structure the negotiation process and the negotiated agreement to effectuate many of TSCA's test rule requirements.

are available for public disclosure unless such data discloses manufacturing processes or a mixture's specific formulation. 15 U.S.C. §2613(b). Where a chemical substance or mixture is manufactured or processed solely for export to a foreign country, the Administrator must furnish the foreign country notice of the availability of the test data developed under section 4. 15 U.S.C. §2611(b). And test rules are judicially reviewable pursuant to section 19, 15 U.S.C. §2618, and enforceable pursuant to section 20, 15 U.S.C. §2619.[12]

Congress retains the authority to prohibit EPA's use of voluntary testing agreements in lieu of a section 4(a) rulemaking, either in whole or in part. For example, Congress could amend section 4(e) to make the ITC's recommendations mandatory on the Administrator, EPA, yet permit EPA to retain flexibility to negotiate test agreements for less sensitive chemical substances or mixtures. Alternatively, Congress could incorporate a regulatory negotiation process into section 4 of TSCA. The process could be fashioned along the lines discussed in the recent recommendation of the Administrative Conference. See Administrative Conference of the United States, Procedures for Negotiating Proposed Regulations, Recommendation 82-4 (June 18, 1982).

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12 Other TSCA requirements keyed to a section 4 test rule include section 5(b)(1), 15 U.S.C. §2604(b)(1) (submission of test rule data with section 5 premanufacture notice), and section 18(a)(2)(A), 15 U.S.C. §2617(a)(2)(A) (preemption of state testing requirements).

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