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EPA

Toxic Substances Control Act (TSCA)

Report to Congress for Fiscal Year 1985

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Abbreviations

AAP	Asbestos Action Program
ANPR	Advance Notice of Proposed Rulemaking
ASHAA	Asbestos School Hazard Abatement Act
CAIR	Comprehensive Assessment Information Rule
CHIP	Chemical Hazard Information Profile
CMA	Chemical Manufacturers Association
CPSC	Consumer Product Safety Commission
EDF	Environmental Defense Fund
EPA	U.S. Environmental Protection Agency
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
GLP	Good Laboratory Practice
HESAP	Health and Environmental Studies Audit Program
IPCS	International Program on Chemical Safety
IRPTC	International Register of Potentially Toxic Chemicals
ITC	Interagency Testing Committee
NBN	National Blood Network
NHATS	National Human Adipose Tissue Survey
NIOSH	National Institute for Occupational Safety and Health
NRDC	Natural Resources Defense Council
NTA	Negotiated Testing Agreement
NWF	National Wildlife Federation
OECD	Organization for Economic Cooperation and Development
OPTS	Office of Pesticides and Toxic Substances
OSHA	Occupational Safety and Health Administration
OSW	Office of Solid Waste
OTS	Office of Toxic Substances
PAIR	Preliminary Assessment Information Rule
PMN	Premanufacture notification
RCRA	Resource Conservation and Recovery Act
SEIU	Service Employees International Union
SNUR	Significant New Use Rule
TSCA	Toxic Substances Control Act
UNEP	United Nations Environment Program
WHO	World Health Organization

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Introduction

This eighth annual report to Congress summarizes the Environmental Protection Agency's (EPA) activities and accomplishments under the Toxic Substances Control Act (TSCA) during Fiscal Year 1985 (see Appendix A). It fulfills the Congressional reporting requirements of TSCA sections 9(d), 28(c), and 30 (see Appendix B). Highlights of significant Agency progress during the year are presented in the next section of this report.

The Toxic Substances Control Act, which took effect on January 1, 1977, charged EPA with protecting human health and the environment from unreasonable risks of injury from toxic chemicals. The Office of Toxic Substances (OTS) under the direction of the EPA Assistant Administrator for the Office of Pesticides and Toxic Substances (OPTS) is responsible for implementing mandatory and discretionary provisions of the Act.

The Act gives EPA broad authority to gather information on chemicals subject to TSCA from manufacturers, importers, processors, and other persons to identify potential hazards to health and the environment. The law enables EPA to require companies to test chemicals where necessary to obtain data needed to evaluate their risks. It further requires companies to submit to EPA certain specified information on all new chemicals before they begin manufacture.Under TSCA, the Agency may select from a broad range of regulatory control actions. These range from hazard-warning labels to complete bans on manufacture or use of substances that present unreasonable risks. TSCA's regulatory authority covers manufacturing, processing, distribution in commerce, use, and disposal. To achieve a balanced regulatory approach, however, the Act requires careful evaluation of the risks posed by a substance weighed against the benefits provided by the particular chemicals or classes of chemicals and the costs of regulation. To ensure compliance with regulations, TSCA authorizes both civil and criminal penalties for violations. When TSCA is not the most appropriate mechanism for a given exposure/risk situation associated with a particular chemical, the Act provides procedures for referral to other Federal agencies for action.

EPA now has a variety of programs to implement the Act. Recordkeeping and reporting rules have been promulgated and data are being collected on a number of chemical substances. Models have been developed to determine the extent and methods of exposure to various toxic substances, and surveys have been made to determine current levels of exposures. Test rules and other approaches to require industry testing where existing data are inadequate have been developed and are providing valuable toxicity information to support risk evaluations. Laboratory inspections and data audits ensure the quality and integrity of data received from industry as a result of chemical testing. The Agency also has developed specific strategies and tools to enforce TSCA regulations.

This eighth year of operation under TSCA finds EPA continuing to improve and refine its programs to protect human health and the environment from unreasonable risks.

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Highlights

In FY 1985, EPA undertook a number of new initiatives to improve and refine its regulatory processes and took actions to address several significant hazards to human health and the environment.

The Agency initiated a broader approach to gathering information, and proposed a rule under TSCA section 8(d) for the first time to acquire health and safety studies from industry for use by another program. A model rule is being developed for standardized comprehensive reporting on existing chemicals under section 8(a). The Agency also conducted broad-based monitoring to identify candidates for further attention and evaluation. Risk evaluations were undertaken based on reviews of data on groups of chemicals, related by common function, market application, or chemical structure. The Agency, with participation by the public and industry, developed more efficient methods and mechanisms for implementing TSCA's testing provisions.

The Agency issued a comprehensive air toxics strategy in FY 1985, and prepared criteria, an illustrative list of substances, chemical specific profiles and guidance to local communities for evaluating and responding to accidental releases, for release to state and local governments.

Improved Information Collection

In FY 1985, EPA began developing a Comprehensive Assessment Information Rule (CAIR) under section 8(a) of TSCA, to consolidate into a model rule a wide range of reporting provisions and questions. Reporting requirements for a particular chemical can be specified by identifying from the entire list of standard questions only those that are needed by the users. Individual chemicals can be added to the rule as the need arises with a minimum of new rule development. This is expected to reduce duplicative efforts and industry reporting burden.

Broad-based, as well as chemical-specific, monitoring has been conducted to identify substances of potential concern. A new analytical protocol was developed in FY 1985 for use in the National Human Adipose Tissue Survey (NHATS). It improves the utility of survey data to detect TSCA-related chemicals in human tissue. EPA exposure teams also generated data to support risk evaluation on several existing chemicals.

Under the authority of section 8(a), on March 12, 1985, the Agency proposed an Inventory Update rule (50 FR 9944) to require manufacturers/importers of chemical substances to report current production volume and plant site data on a critical portion of the more than 63,000 chemicals included on the TSCA Chemical Inventory. The proposed rule represents the first update of the Inventory's production data since 1977. It would cover substances both originally reported for the Inventory as well as those PMN substances subsequently added. The rule would allow the Agency to obtain actual production data on newly manufactured substances. The rule would require both initial and recurring reporting — an updating mechanism not a part of the original Inventory Reporting Rule. It also would require every manufacturer, unless exempt, to report.

Under the authority of section 8(d), EPA proposed a rule (50 FR 40874) to require manufacturers, importers, and processors of certain chemical substances to submit lists and copies of pertinent unpublished health and safety studies to assist the Office of Solid Waste in developing health-based disposal standards. This marks the first time that OTS has proposed to use TSCA to collect information for another EPA program.

New Risk Evaluation Strategies

In FY 1985, OTS initiated a pilot study to develop an alternative to the current priority setting mechanisms for both new and existing chemicals. The strategy involves a "clustering" approach aimed at grouping chemicals into categories by common function, market application, structure or other similarity. This new approach will (1) promote consistent analysis of chemicals that substitute for each other in use, (2) focus resources on chemicals that pose the greatest aggregate risk, and (3) reduce repetitive analyses and rulemaking.

In the test rules program, a use-based clustering approach is being considered. This approach will permit a broad view of use/industry groups that incur large collective burdens over time while at the same time allowing EPA to focus resources in a cost-effective manner.

In FY 1985, EPA began using this new approach involving review of groups of new and existing chemicals. Toxicity concerns are being evaluated for groups of chemicals with common chemical structures rather than one at a time. Under this approach, evaluation and regulatory strategies are simultaneously conducted for both new and existing members of selected chemical categories. In FY 1985, OTS identified eleven chemical categories and evaluated six for future regulatory action.

Streamlining Test Rulemaking

In FY 1985, the Agency developed two alternative approaches to accelerate testing under section 4. On May 17, 1985, EPA amended its rulemaking procedures for test rules by adopting a new single-phase process. By means of this approach, EPA will propose appropriate test guidelines as the required test standard in the initial notice of proposed rulemaking. The final rule may then promulgate as the test standard the previously proposed test guidelines, a modified version, other suitable guidelines, an alternative submitted by commenters, or a modification of an alternative methodology. This approach should shorten rulemaking and expedite testing. It also reduces the industry burden to prepare and submit test protocols for approval.

A series of public meetings was held in which industry, an environmental group, and the Agency jointly developed a new approach of using enforceable consent agreements as an alternative to test rules, when consensus can be reached on testing requirements. Such agreements may expedite the initiation of testing, while providing safeguards equivalent to those under test rules.

Risk Management Actions

In FY 1985, EPA continued to implement the TSCA section 6(e) prohibitions on polychlorinated biphenyls (PCBs). A proposed and final rule addressed fire-related risks associated with continued use of PCB transformers. The final rule requires registration of PCB transformers with fire departments and building owners by December 1, 1985, requires immediate reporting of all fire-related incidents involving PCB transformers to the National Response Center, requires removal of certain PCB transformers in or near public buildings and places additional restrictions on continued use of others. EPA continued to promote industry participation in developing safe PCB disposal methods through review and approval procedures for disposal permits. In addition to high temperature incineration, EPA has granted nationwide permits for chemical dechlorination, and solvent extraction. Regional permits have been granted for thermal and biological treatment processes. Seven applications were received during FY 1985, and three nationwide final permits issued.

Asbestos continued to be a high EPA priority concern, with special emphasis on abatement of asbestos hazards in schools. In June, EPA offered $45 million in grants and loans to school districts to assist in asbestos hazard abatement in 340 schools. Awards were distributed to 47 states, the Northern Marianas and the Bureau of Indian Affairs' schools. EPA also opened three Federally-financed asbestos information centers in the greater Atlanta, Boston,

and Kansas City areas. These centers offer courses to a wide audience on proper identification and control of asbestos-containing materials in buildings. In July, EPA published an immediately effective rule to protect state and local public employees who take part in asbestos abatement projects. The Asbestos Abatement Projects Rule establishes a permissible exposure level and requires use of certain work practices during asbestos abatement.

A major risk evaluation and management action during FY 1985 addressed risks from toxic air pollutants. In June 1985, EPA released a comprehensive air toxics strategy, calling for control of hazards from both routine and sudden accidental releases. An Agency-wide working group prepared criteria and an initial list identifying acutely toxic substances that could cause serious human health effects from short-term exposures. In addition, the Agency developed chemical-specific profiles for each of the listed chemicals, including first aid information. This information is intended to assist the public to prepare for and respond to accidental toxic releases. Site-specific guidance was also prepared for use by local communities to evaluate the risks posed in their communities by chemicals meeting the evaluation criteria. This information will be available in early FY 1986.

The Agency announced a decision to initiate a priority review under TSCA section 4(f) for risks of human cancer from certain exposure to methylene chloride. Methylene chloride, also known as dichloromethane, is a non-flammable, colorless, volatile liquid with an ether-like odor, used widely as a degreaser, aerosal propellant, and solvent. Early in FY 1986, an Advance Notice of Proposed Rulemaking will announce that EPA intends to conduct an interagency comprehensive and integrated regulatory investigation on this chemical.

In July, EPA referred a report on 4,4'-methylenedianiline (4,4'-MDA) to the Occupational Safety and Health Administration (OSHA) for regulatory consideration. EPA asked OSHA to make findings as to the risk from 4,4'-MDA and OSHA's authority to prevent or reduce that risk. Because the major exposures to 4,4'-MDA occur in the workplace, EPA, submitting a report under section 9(a) for the first time, gave OSHA the first opportunity to regulate exposures to the chemical. EPA will refer another report on 1,3-butadiene to OSHA based on EPA's conclusion that exposure to the chemical presents an unreasonable risk of cancer to workers. The report will be published in the *Federal Register* in early FY 1986.

The Agency implemented two final rules during FY 1985 to exempt from the premanufacture notification (PMN) process certain chemicals that would not present

unreasonable risks to health or the environment. One exemption rule is applicable to certain polymers; the other is applicable to chemicals that are produced in small amounts. Under these rules, eligible polymers and low-volume chemicals will undergo an abbreviated 21-day premanufacture notice review.

In support of the Office of Solid Waste and the 1984 Amendments to the Resource Conservation and Recovery Act, concerning underground storage tanks, OTS conducted a statistically-based national survey of motor fuel tanks to assess the magnitude of the leaking tank problem. The survey is providing a broad range of national and regional statistics which will be used to determine if the problem warrants Federal or State regulation.

Biotechnology

Early in FY 1985 (December 31, 1984), EPA published a proposed policy statement which described how the Agency would apply TSCA and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to new commercial products of biotechnology. This statement was published in a joint *Federal Register* notice with the White House Office of Science and Technology Policy, the Food and Drug Administration, and the U.S. Department of Agriculture. After review and consideration of the comments received, the Agency plans to issue a final statement of policy on biotechnology early in 1986, again in coordination with other Federal regulatory agencies. Throughout FY 1985, the Agency has continued to work with the other Federal agencies to coordinate Federal biotechnology activities. The Agency has also continued to support scientific conferences on biotechnology, and to work with the Organization for Economic Cooperation and Development (OECD) to harmonize international approaches to biotechnology.

International Activities

EPA continued to play an active role in FY 1985 in international programs. EPA led an Organization for Economic Cooperation and Development effort to develop a Chemical Information Switchboard designed to increase member stateaccess to unpublished information on chemicals. The pilot Switchboard, with five countries besides the U.S. participating, began operation on July 1, 1985. The Agency also participated in OECD chemical program efforts involvinghazard assessment, good laboratory practices, and confidentiality of data. During FY 1985, EPA was active on the OECD Test Guidelines Updating Panel, reviewing new guidelines in genetic toxicology and considering proposals to revise an acute (eye irritation) toxicology guideline. In response to the Bhopal, India tragedy, OTS participated in a United

Nations' International Program on Chemical Safety (IPCS) effort for a more effective international reaction to such accidents.

Enforcement

In FY 1985, EPA continued to enforce the provisions of TSCA through inspections and by issuing civil and criminal actions where violations were identified. In FY 1985, EPA inspections focused on PCBs (1,616 inspections), and asbestos-in-schools (2,014 inspections). In addition, the Agency conducted 586 inspections of chemical substances imports, 336 inspections on new chemicals, 494 inspections for compliance with reporting and recordkeeping under TSCA section 8, and 20 inspections of laboratories for compliance with Good Laboratory Practices (GLPs).

In the enforcement area, 733 civil complaints were issued. The majority of these were for asbestos-in-schools (443) and PCB (253) violations. In FY1985, the Agency issued the first complaints for violations of TSCA section 8(a) (8), for TSCA section 13 import requirements (12), and TSCA section 4 (3).

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New Chemicals

Program Status

EPA reviews new chemicals prior to manufacture or import as required by section 5 of TSCA. New chemicals are defined as those that are not listed on the TSCA Chemical Substances Inventory. This inventory of existing chemicals is EPA's comprehensive list of chemical substances in commerce. Manufacturers are required by section 5(a) to provide the Agency with a premanufacture notification (PMN) ninety days in advance of manufacture or import of a new chemical. EPA reviews and evaluates the potential risk posed by the product and makes a determination whether controls are appropriate, whether additional data are needed, or whether production and use should be prohibited.

Regulations under section 5 also require a manufacturer to submit a Notice of Commencement of Manufacture after an EPA review of the PMN is completed and prior to the actual start of manufacture. This notice is given when the manufacturer actually begins producing the substance. It is at this point that a new chemical is added to the TSCA Chemical Substances Inventory. TSCA also authorizes EPA to track new chemicals that might be of concern if their uses change, or if production volume increases significantly after initial PMN review. Significant new use rules (SNURs) provide a mechanism to accomplish this task.

The New Chemicals Program provides for the review and control of new chemicals to prevent large scale distribution before a new substance's effects on health or the environment are fully known. In addition, the program includes (1) follow-up activities to ensure that risks are limited during commercialization; and (2) special exemptions from the PMN process of chemicals that are found to not present an unreasonable risk.

With the standardized procedures and submission form required by the final PMN rule, which became effective in October 1983, the PMN program has evolved into a very effective mechanism for identifying problems and managing risks. The Agency can now consistently and efficiently review the large number of PMN submissions it receives.

PMN Actions

Since the establishment of TSCA, EPA has received an increasing number of PMNs to review. In FY 1985, EPA received 1,478 PMNs, bringing the total received since inception of the program to 5,679. Most of the new chemicals reviewed under this program did not require regulatory action. Wherever necessary, however, the Agency took appropriate action according to several regulatory options available under section 5 of TSCA. The Agency issued 37 section 5(e) orders controlling exposure to 45 chemicals during FY 1985, bringing the total of PMN chemicals affected by 5(e) orders since inception of the program in 1979 to 218. In addition, 33 PMNs were withdrawn by their submitters in FY 1985, in anticipation of EPA action under section 5(e) or 5(f). Table 1 summarizes new chemical actions.

Increased Testing

The Agency continued to make a concerted effort in 1985 to increase the quantity and quality of toxicity data on PMN chemicals suspected of presenting unreasonable risks. EPA has taken several approaches under section 5(e) to obtain such data where the PMN revealed the need.

The Agency asks for testing before production begins if the testing can be done quickly and without unreasonable expense. EPA also asks for preproduction testing if the potential risk cannot be adequately controlled pending availability of the data. However, if the potential risk can be controlled (e.g., by restricting use of the chemical, or by requiring protective equipment for workers handling the chemical), EPA issues "delayed trigger" testing orders (under section 5(e)). Such orders require submission of test data only when total production of the chemical reaches a predetermined volume. Using these approaches, necessary data are obtained to support evaluation of new chemicals, adverse impact on industry innovation is limited, and public health and the environment are protected from unreasonable risk.

Category Evaluations

In FY 1985, EPA initiated an approach to the evaluation and assessment of chemical categories. Individual chemicals which can be grouped together because of structure or use similarities, will be evaluated and assessed as a category, not as individual chemicals. In such evaluations, the Agency looks at both existing and new members of the category, and strategies which address both are then developed. Among other advantages, this approach minimizes unintended "new chemical bias" by simultaneously evaluating and developing strategies for both new and existing members of selected chemical categories. EPA expects evaluation and regulation will be more efficient and effective when groups of comparable

Table 1 **Summary of New Chemical Actions**
October 1, 1984-September 30, 1985

	No. of PMN Actions in FY'85	Aggregated Total Since Beginning (mid-1979)
Submissions of Bona Fide Intent to Manufacture	571	2,088
Valid PMNs Received	1,478	5,679[a]
PMNs Requiring No Further Action	1,094	4,546
Voluntary Testing in Response to EPA Concerns	14	92
Voluntary Control Actions by Submitters	7	44
PMNs Voluntarily Withdrawn in Light of EPA Concern	33	92
PMNs Subject to section 5(e) Consent Orders*	45	218[a]
PMNs Unilateral section 5(e) Orders*	1	15
PMNs Subject to section 5(f) Rules	0	4
Number of Chemicals for which Commencement of Manufacture Notices Were Received	750**	2,580
New Chemicals Subject to Proposed Significant New Use Rules	19***	42
New Chemicals Subject to Final Significant New Use Rule	12***	14
Valid Test Market Exemptions		
Received	66	379
Granted	39	315
Granted with Modifications	9	19
Withdrawn	16	34
Denied	0	9
Polymer Exemptions	150	150
Granted	131	131
Withdrawn	19	19
Low Volume Exemptions	93	93
Granted	89	89
Withdrawn	4	4

[a]Includes 106 synfuels.

*A consent 5(e) order is issued by EPA with the agreement of the PMN submitter. A unilateral 5(e) order is issued by EPA without the agreement of the PMN submitter.

**This number includes PMNs received in previous fiscal years for which commencement of manufacture notices were received in FY 1985.

***This number includes chemicals which were the subjects of PMNs received in previous fiscal years but for which proposed or final rules were not published until FY 1985.

chemicals are dealt with by category, rather than on a one-by-one basis, as has traditionally been done.

In FY 1985, OTS identified 11 chemical categories based on structural similarities, and selected six for further evaluation. For each of the six, a preliminary strategy has been developed to characterize the toxicity, exposure and risk, and to develop regulations as needed. FY 1986 plans call for implementing some elements of the strategies for two of the categories by drafting regulations; three will undergo further evaluation; and one category has been determined to be inappropriate for further consideration. Categories may be based on chemical structure, use, physical-chemical properties, exposure, or other common elements or combinations of elements.

Exemptions

EPA is authorized to exempt chemicals from the PMN process if the Agency finds that such chemicals will not present an unreasonable risk of injury to health or the environment (section 5(h)(4)). In 1985, EPA implemented two final rules to exempt certain chemicals from full notice and review requirements. One rule applied to polymers with a number average molecular weight greater than 1,000 grams per mole, and polyesters manufactured solely from a list of approved reactants. This rule became effective in January 1985. The second rule exempted chemicals that are produced in small amounts (i.e., less than 1,000 kg/yr). This rule was implemented in June 1985. Under both exemption rules, eligible polymers and low volume chemicals are now subject to a shortened, 21-day review period, and to abbreviated notice requirements. The Agency has been reviewing an average of 15 polymer and 20 low-volume exemption notices per month.

Biotechnology

Early in FY 1985 (December 1984), EPA published a proposed policy statement clarifying the applicability of TSCA and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to new microorganisms produced through biotechnology and used commercially. With this statement, the Agency committed to protecting human health and the environment while not inhibiting the development of beneficial biotechnological products and uses. During FY 1985, EPA has continued to analyze policy options and refine its program for reviewing biotechnological products under TSCA.

EPA's proposed policy statement was published on December 31, 1984, in a joint *Federal Register* notice with the Office of Science and Technology Policy, the Food and Drug Administration, and the Department of Agriculture. The major issue in the TSCA portion was the applicability

of TSCA section 5 PMN authority to biotechnology products. The Agency proposed an approach and requested comments. There were 71 comments from 68 different respondents received by the close of the comment period on April 15, 1985. These comments are being analyzed by the Agency for use in developing its next statement of policy on biotechnology, which is expected to be issued in early 1986 in coordination with the other Federal regulatory agencies.

The Agency continued to participate during FY 1985 in the Working Group on Biotechnology, established by the Cabinet Council on Natural Resources and the Environment. This group discusses major Federal interagency issues in biotechnology and develops a coordinated position on them.

EPA has contributed to the planning of a number of scientific conferences on biotechnology during FY 1985, all aimed at developing better information on which to base regulatory decisions in this important area. For example, EPA participated in the planning and conduct of a cross disciplinary symposium on "Engineered Organisms in the Environment: Scientific Issues," held June 10-13 in Philadelphia. The Agency also helped to fund and organize a scientific workshop on physical and biological containment of organisms, held October 1-4 at Shackelton Point, N.Y., as well as many other similar workshops and conferences held throughout the year.

In the international area, EPA participated as a member of the U.S. delegation to the Organization for Economic Cooperation and Development (OECD) Working Group on Safety and Regulation of Biotechnology. This group is producing a report on health and safety considerations associated with commercial applications of genetically engineered organisms. The report is being developed as a step toward harmonization of international approaches to biotechnology. It includes sections on large-scale commercial and environmental use of the products of biotechnology.

The Agency continues to be active in formulating, implementing and assessing the research program in biotechnology that is being conducted by its Office of Research and Development. The research is designed to increase the body of knowledge available to support risk assessments for biotechnology products.

Follow-up Program

An important aspect of both the premanufacture review program and the existing chemicals program is the policy to continue to monitor both new and existing chemicals that may be of concern if their uses change, or production volumes significantly increase from those estimated during

their initial review. EPA uses several regulatory authorities including its significant new use rule authority under section 5(a) to accomplish this purpose. Significant new use rules (SNURs) are also used to extend the terms and conditions of section 5(e) orders to other manufacturers and processors of the same chemical who otherwise could make or process the chemical without the restrictions placed on the original submitter.

EPA must be notified at least 90 days in advance of the date any person begins to manufacture or process a chemical for a significant new use. EPA then reviews this notice to see if the new use might present an unreasonable risk. All new and existing chemical regulatory authorities are available if needed.

EPA proposed 10 SNURs covering 19 new chemicals in FY 1985 and promulgated 7 SNURs covering 12 chemicals to regulate the manufacture, import, or processing of a chemical subject to a SNUR (see Appendix A).

In addition to the SNURs on new chemicals, EPA also proposed two SNURs on two existing chemicals, using section 5 authority.

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Existing Chemicals

Program Status

The OTS Existing Chemicals Program goal is to reduce unreasonable risks of injury to health or the environment from chemicals already in commerce. Specifically, the objectives of this program are: (1) to identify risks to the public health and environment; (2) to evaluate those risks; and (3) to ensure that risks are addressed and appropriate risk management actions taken under TSCA or other relevant authority. TSCA addresses all phases of a chemical's life cycle, including manufacture, processing, distribution, use, and disposal.

EPA identifies potential risks, using TSCA section 8 authorities to gather information about the toxicity of particular chemicals and the extent to which people and the environment are exposed to them. TSCA section 4 authorizes EPA to require testing by manufacturers and processors of designated chemicals where necessary to obtain needed data.

The Agency evaluates and determines the actual character of the risks by analyzing the gathered data. A risk assessment on a given chemical is made based on exposure and health and environmental effects data.

From the available information and the risk assessment, a decision is made regarding the need for risk management actions. Alternative risk management actions are identified and evaluated, considering effectiveness and cost factors. The Agency focuses its efforts on the potential risks of greatest concern. Finally, EPA implements the appropriate risk management actions. Provisions of section 5 (i.e., significant new use rules), as well as nonregulatory tools (such as chemical advisories) can be used to monitor or warn of situations which raise some concern, but are not suitable for immediate regulation. EPA can control unreasonable risks through regulatory action under the authority of section 5 or 6 or require immediate elimination of any imminent hazards under section 7. When TSCA is not the most appropriate mechanism for a given exposure/risk situation associated with a chemical of concern, section 9 governs the procedures for referral to other Federal agencies for action.

Only those chemicals for which unreasonable risks are identified will be addressed in all phases of the program described above. Chemicals found to not pose unreasonable risks are dropped from further evaluation;

and resources are reprogrammed toward evaluation of other more potentially hazardous chemicals.

During FY 1985, 83 chemicals were subjected to the Existing Chemicals Program review process. Of that number, 21 were dropped, 11 were referred for risk management, 7 were referred for information gathering, and 48 are undergoing further evaluation. (A summary of existing chemical program activities is provided in Table 2.)

Table 2 **Summary of Existing Chemical Actions**

	# In FY 1985
Risk Identification	
Testing Studies Received under Section 4 (see Appendix C)	102
Section 8(a) Preliminary Assessment Reports Received	201
Section 8(d) Health and Safety Studies Received	549
Section 8(e) Substantial Risk Notification Program:	439
- Initial 8(e) Submissions	37
- Supplemental/Followup 8(e) Submissions	99
- "For Your Information" (FYI) Submissions	303
Chemical Hazard Information Profiles (see Appendix E)	16
Substitute Hazard Profiles (see Appendix E)	23
Section 21 Petitions Received (see Appendix F)	2
National Toxicology Program Studies Reviewed (see Appendix D)	16
Risk Evaluation	
- Dropped from further evaluation	21
- Continued assessment	48
- Referred for risk management	11
- Section 4(f) designations	1
- Referred for information gathering	7
Risk Management	
Proposed and final rules under section 6(e)	5
Chemical Advisories	2
Significant new use rules proposed	2
Section 9 Referral	1

Risk Identification

Section 8 of TSCA authorizes EPA to require reporting and recordkeeping on chemical substances and mixtures. Section 8(a) authorizes EPA to promulgate rules requiring manufacturers, importers, and processors to maintain records and report certain information to the Agency. Under section 8(a), there is a Preliminary Assessment Information Rule (PAIR) which requires manufacturers of listed chemicals to report general production, use and

exposure information. These data are especially important to the Agency's review of chemicals designatediby the Interagency Testing Committee (ITC) for priority testing consideration. Under section 8(c), manufacturers and certain processors must maintain records alleged "significant adverse reactions." This information must be provided to EPA upon request. Section 8(d) requires certain manufacturers, processors, and distributors to submit lists of actual unpublished health and safety studies to EPA. Section 8(e) requires that EPA be notified when there is new information which reasonably supports the conclusion that a chemical substance or mixture presents a "substantial risk" to health or environment. Such notification must be given to the Agency immediately upon discovery. The Agency also receives a large number of "For Your Information" submissions related to chemical toxicity and exposure. This information may be submitted by institutions which do not have a section 8(e) reporting responsibility (e.g., trade associations, academic institutions) or by companies in cases where the information does not meet section 8(e) criteria. Another source of data on existing chemicals risks is the National Toxicology Program, from which test data are received and routinely reviewed.

In FY 1985, the existing chemicals program received and reviewed a substantial amount of data on existing chemicals (see Table 2). During the fiscal year, section 8(a) and 8(d) rules were amended to require reporting on 15 additional chemicals. Section 8(a) and section 8(d) rules resulted in submission by the chemical industry of 750 studies and reports on existing chemicals. Under the section 8(e) substantial risk notification program, EPA received 37 initial reports, 99 supplements related to previous section 8(e) initial reports, and 303 "For Your Information" (FYI) submissions, totalling 439 for FY 1985. A total of 102 completed test studies required under section 4 were received from industry (see Appendix C). Sixteen National Toxicology Program studies were also received and reviewed by OTS (see Appendix D).

Section 8(d) Rule for Office of Solid Waste (OSW)

EPA proposed a rule under section 8(d) of TSCA (50 FR 40874) that will require manufacturers, importers, and processors of 33 listed chemical substances to submit to EPA lists and copies of unpublished health and safety studies on those substances. The 33 substances listed in the proposed rule were nominated by the Office of Solid Waste, which requires the information in order to develop health-based standards for the disposal of solid waste. The health-based standards are needed to meet certain land disposal restrictions provisions of the Hazardous and Solid Waste Amendments of 1984. This rulemaking marks the

first time that OTS has specifically developed a rule under TSCA authority to collect information needed for another EPA program.

TSCA Chemical Inventory Update Rule

On March 12, 1985, the Agency issued a proposed section 8(a) rule (50 FR 9944) that would require manufacturers/importers of chemical substances to report current production volume and plant site data on a critical portion of the more than 63,000 chemicals included on the TSCA Chemical Inventory. The proposed rule represents the first update of the Inventory's production data since 1977. The rule would cover substances both originally reported for the Inventory as well as those PMN substances subsequently added. This will allow the Agency to obtain actual production data on newly manufactured substances as well as update information on chemicals already listed. The rule would require both initial and recurring reporting, a self-correcting mechanism that was not included in the original inventory reporting rule. This rule would require every manufacturer, unless exempt, to report. Exempt persons and/or substances include small manufacturers who satisfy specific criteria; persons who manufacture or import chemical substances in limited circumstances or through coincidental manufacture; and substances that include polymers, inorganics, microorganisms, naturally occurring chemical substances, and substances with an annual site-specific production volume of less than 10,000 pounds.

A reportable substance under this rule is essentially any non-polymeric synthetic organic chemical substance with an annual site-specific production volume of 10,000 pounds or more. For each of the reportable substances, every manufacturer/importer subject to this rule will be required to submit current data every four years, for as long as this rule is in effect. A final rule is expected to be promulgated by the end of the calendar year. Initial reporting under this rule would begin early in 1986.

Comprehensive Assessment Information Rule (CAIR)

In an effort to improve and simplify data gathering procedures under section 8(a) for existing chemicals, EPA is developing a Comprehensive Assessment Information Rule (CAIR). It is designed to consolidate a comprehensive list of reporting provisions and questions into a model rule. A standard list of questions will be established from which specific reporting requirements for various chemicals may be selected. Reporting would be required on only those data elements, from the entire list of questions, that are of primary interest to the users of the data. The rule would be used to obtain information needed by EPA and other Federal agencies to support assessment

and regulation of chemical substances and mixtures. Chemical specific rules would still be promulgated in certain cases where the CAIR questions cannot obtain the required information.

Under this rule, reporting requirements on individual chemicals could then be developed quickly by simply adding the chemicals to the rule. The requirements could be tailored to meet specific data needs by specifying the questions to be answered. The rule is expected to reduce duplicative effort within EPA and the Government as well as industry reporting burdens.

Chemical Hazard Information Profiles (CHIPs)

In FY 1985, EPA prepared Chemical Hazard Information Profile (CHIP) documents for 16 chemicals (see Appendix E). CHIP candidates are selected from chemcials reviewed in the risk identification phase of the existing chemical review process. They are brief summaries of readily available information concerning the health and environmental effects and exposure potential of a chemical. Information-gathering for a CHIP consists primarily of a search of secondary literature sources including computerized data bases, abstracts, government reports, scientific review documents, and reference works. During CHIP preparation, EPA also solicits information from companies, other government agencies and other institutions involved in chemical risk assessment.

There also were 23 Substitute Hazard Profiles prepared in FY 1985 (see Appendix E). As part of the overall risk identification and evaluation process, potential substitutes for a chemical being considered for risk management are identified. Substitute Hazard Profiles, similar in content and format to CHIPs, are preliminary risk identification documents prepared to ensure that any TSCA regulatory action will not encourage the substitution of even more hazardous chemicals for the chemical being considered for risk reduction action.

Section 21 Petitions

Section 21 of TSCA is a means by which any citizen may request EPA to initiate action. Under this section, any person may petition the EPA Administrator to initiate a proceeding for issuing, amending, or repealing a rule under various sections of the Act. EPA may either grant or deny the petition. If it is granted, EPA must promptly commence an appropriate proceeding under section 4, 5, 6, or 8 of the Act. Denials must be published in the *Federal Register* with the reasons for the denial. If EPA denies the petition or fails to act within 90 days, the petitioner may begin a civil action in a U.S.District Court. Two petitions were received in FY 1985; action was also taken on two previously submitted petitions (see

Appendix F). During this fiscal year, one petition was granted. Another petition submitted by the Environmental Defense Fund and the National Wildlife Federation was partially granted, resulting in a regulatory investigation of dioxins and furans. Regulatory actions under sections 4 and 8 are being considered. Guidance for preparing citizens' petitions under section 21 was developed in FY 1985. Petitioners' use of this guidance will assist the Agency to properly evaluate citizens' petitions within the 90-day review mandated by the statute. This guidance will also assist petitioners in effectively presenting their cases to EPA with the most pertinent available support. The guidance will be published in early FY 1986.

Monitoring

Another EPA program supporting regulatory decisionmaking on existing chemicals is OTS' chemical-specific and broad-based monitoring activities. Chemical-specific studies are conducted to obtain data on levels of human and environmental exposure to specific substances of concern. Broadbased studies serve to identify substances of potential concern. These studies help EPA plan future TSCA ambient monitoring programs, identify candidates for testing (under section 4) or for regulatory controls under other TSCA authorities, and evaluate the effectiveness of TSCA actions in protecting human health and the environment.

In FY 1985, a new analytical protocol was developed and implemented for use in the National Human Adipose Tissue Survey (NHATS). This survey, in 1984, produced the first human exposure-based chemical list for OTS review to identify potential unreasonable risks. The new protocol improves the utility of the survey data to detect TSCA related chemicals in human tissue. In addition, the NHATS survey design was modified in 1985 to allow statistically valid human exposure estimates to be made for each EPA Region as well as for the usual U.S. Census Divisions.

Chemical exposure support activities generated data used for seven existing chemicals. Those actions included occupational monitoring of exposure to acrylamide, needed for a risk assessment; laboratory analysis of consumer products containing glycol ethers, subject of possible TSCA regulatory action; experiments to measure exposure-reduction potential of several methods for transfer of dry 4,4'-methylenebis(2-chloroaniline) (MBOCA), a demonstrated animal carcinogen used in the manufacture of certain polyurethane elastomeric articles; a survey, air and water monitoring, and multiple dermal absorption tests for 4,4'-methylenedianiline, subject of a TSCA section 9 referral to the Occupational Safety and

Health Administration (OSHA); a comprehensive preliminary exposure assessment on methylene chloride, in support of a TSCA section 4(f) priority review regulatory decision; an interagency field survey with the National Institute for Occupational Safety and Health (NIOSH) of the entire monomer and polymer industry for 1,3-butadiene, the subject of a TSCA section 9 referral; and initiation of a field study in the textile industry to assess exposure to dyes, a persistent concern to both workers and the environment.

Underground Storage Tanks

In FY 1985, OTS conducted the National Survey of Underground Motor Fuel Storage Tanks, in support of the Office of Solid Waste and the 1984 Amendment to the Resources Conservation and Recovery Act (RCRA). The purpose of the survey was to attempt to extrapolate the magnitude of the leaking tank problem and provide statistics for determining appropriate Federal or State regulation.

The Agency's immediate concern with leaking tanks is groundwater contamination. Half of the population of the U.S. depends on groundwater from community or private wells for their water supplies. There is a growing body of data showing that motor fuels are contaminating groundwater, and that leaking underground motor fuel storage tanks are the source of this contamination. Once groundwater is contaminated, it is very difficult and costly to purify the water for human consumption or agricultural use.

Designed and field tested in 1984, the survey is providing a broad range of unbiased national and regional statistics on underground tanks and tank leakage. The survey is based on a scientific sample of approximately 900 establishments with approximately 2,500 tanks. The survey includes on-site interviews of tank owners or operators, collection and analysis of tank-productivity data, and physical tightness testing of more than 500 of the 2,500 tanks. All field operations were completed in FY 1985, and a final report will be available in early 1986.

Risk Evaluation

Major risk evaluation activities in FY 1985 focused on a section 4(f) priority review of methylene chloride and a regulatory investigation of formaldehyde. The Agency prepared risk assessment documents on six potentially hazardous chemicals. A major toxic air pollution strategy was released by the Agency, with substantial OTS efforts in the area of sudden accidental releases.

Methylene Chloride

In March 1985, EPA received bioassay data which showed that methylene chloride was carcinogenic in two species of laboratory animals. On May 14, 1985 (50 FR 20126) EPA, under section 4(f) of TSCA, announced that certain exposures to methylene chloride may present a significant risk of serious or widespread harm to humans from cancer. Methylene chloride is a high-volume chemical with a variety of uses such as a solvent, aerosol propellant, and degreaser, among other applications. In early FY 1986, the Agency published an Advance Notice of Proposed Rulemaking (ANPR), announcing EPA's plans to conduct a comprehensive interagency regulatory investigation of exposures to methylene chloride.

Formaldehyde

In May 1984, EPA announced a high-priority review (under section 4(f)) of formaldehyde exposure of the two largest exposed populations to this chemical: permanent-press apparel manufacturing workers and residents of mobile and conventional houses built with urea-formaldehyde construction products. The ongoing regulatory investigation during FY 1985 has evaluated the carcinogenic and noncarcinogenic risks of exposure, the economic costs of possible control options, and the appropriateness of further EPA action to reduce the risk versus action by other Federal agencies. Selection of risk management options is continuing.

Risk Assessments

Six risk assessment documents were prepared in FY 1985. They addressed 1,3-butadiene, a monomer used in manufacturing rubber and other polymer products; 4,4'-methylenedianiline, used primarily as an intermediate in the manufacture of other chemicals and plastics; formaldehyde, used in both apparel and wood products; methylene chloride, a solvent with many commercial and industrial uses; chlorinated paraffins, used as additives to metalworking fluids, plasticizers, and flame retardants; and cutting fluids, used as lubricants on machine-shop cutting tools. In addition, the results of a risk assessment on glycol ethers provided the basis for an Environmental Health Criteria document prepared by the World Health Organization (WHO). Such WHO documents are used for assisting member nations to establish worldwide standards for subject substances.

Toxic Air Pollutants Strategy

A major EPA risk evaluation initiative during FY 1985 addressed risks from toxic air pollutants. This year has seen a number of significant releases of acutely hazardous chemicals into the atmosphere, most notably that which occurred in Bhopal, India, in December 1984. In June 1985, the Agency released a comprehensive air toxics

strategy. The strategy calls for controlling hazards from both routine releases and sudden, accidental releases.

For routine releases, EPA will continue to use authorities under the Clean Air Act. The Agency is enhancing Federal support so states can improve their capability to deal with air toxics within their own borders.

For sudden, accidental releases, the strategy calls for improving emergency preparedness and response at all levels of government to prepare for and respond to accidental toxic releases. OTS headed an Agency-wide working group that developed criteria and an initial list of acutely toxic substances. The purpose of the criteria and the list is to identify those chemicals that are able to cause serious human health effects from short-term exposures. Exposure through the air is of most concern because of the inability of exposed individuals to avoid contact with the chemical. The working group also prepared site-specific guidance to be used by local communities to evaluate the risks posed in their community by the chemicals meeting the criteria. These activities are being coordinated with the activities of the Office of Solid Waste to develop guidance for organizing a community to evaluate the risks of significant hazardous releases and emergency preparedness and response plans.

Risk Management

Risk management activities in FY 1985 resulted in TSCA section 6 actions or section 9 referrals on polychlorinated biphenyls, asbestos abatement, 4,4'-methylenedianiline, and 1,3-butadiene. The Agency also developed section 5 significant new use rules (SNURs) to monitor the future manufacture of several existing chemicals, including 4,4'-methylenebis(2-chlorobenzenamine) (MBOCA), methyl n-butyl ketone (MBK), and hexachloronorbornadiene (HexBCH). Descriptions of some of the more significant FY 1985 activities are presented below.

Polychlorinated Biphenyls

In FY 1985, EPA continued to implement the TSCA section 6(e) prohibitions on polychlorinated biphenyls (PCBs) by issuing 2 notices of proposed rulemaking, 2 final rules and one final action by rule.

The proposed PCB Transformer Fires Rule (49 FR 39966) and the final PCB Transformer Fires Rule (50 FR 29170) addressed the fire-related risks associated with the continued use of PCB Transformers. The final rule places restrictions and conditions on the continued use of PCB containing transformers to reduce the frequency of fire related incidents, as well as the risks in the event of a fire involving this equipment. In compliance with a court ordered deadline, EPA issued a final rule (49 FR 44634) modifying the definition of "totally enclosed

manner" to more accurately reflect the Agency's framework for assessing PCB exposure. On August 29, 1985, EPA issued a proposed rule responding to petitions for exemption from the prohibitions on PCBs (50 FR 35182) and a notice of denial on a petition for exemption (50 FR 35192). On April 4, the Agency issued a proposed rule incorporating by reference certain American Society for Testing and Materials test methods to be used to meet particular PCB testing requirements (50 FR 13393).

In support of the PCB Transformer Fires Rule, the Agency conducted a study on the formation of polychlorinated dibenzodioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs) as combustion by-products of PCB dielectric fluids. That study also looked at the combustion by-products of substitute dielectric fluids.

In March 1983, EPA issued a procedural amendment to the PCB rule, entrusting the Office of Pesticides and Toxic Substances with the authority to review and issue nationwide approval for various types of processes for safely disposing of PCBs. The nature of a nationwide approval is to allow PCB disposal facilities to be used in more than one region, eliminating duplication of effort in the 10 regional offices and unifying the Agency's approach to PCB disposal. These types of processes approved at the national level extend beyond high temperature incineration. As EPA's PCB regulations have evolved, so has industry's innovativeness. Nationwide permits have been granted for alternative methods of PCB destruction. These methods include chemical dechlorination and solvent extraction. Regional permits have been granted for thermal and biological treatment processes.

EPA continues to promote industry participation in the development of PCB destruction methods with the objective of attaining safe handling of these toxic chemicals. Accomplishments to date in FY 1985 include issuing 4 research and development (R&D) permits, 7 demonstration permits, and 8 nationwide disposal permits.

Table 3 Actions on Nationwide PCB Disposal Permits FY 1985

Applications Received:	9
R&D Permits Issued:	4
Permit Deficiency Letters:	11
Demonstration Permits Issued:	7
Nationwide Final Permits Issued:	8

Asbestos

Asbestos continued to be a high priority concern for EPA in FY 1985. A new office, the Asbestos Action Program (AAP), was created to administer the Asbestos School Hazard Abatement Act (ASHAA) of FY 1984, and provide technical assistance in supporting school abatement projects. In support of ASHAA, EPA produced a state application packet for Federal monies. The ASHAA established a loan and grant program to support abatement programs in schools with the most serious asbestos problems and demonstrated financial need. The application packet requested information from school districts, detailing the condition of public and private school buildings and finances within the individual school districts.

In June 1985, EPA awarded $45 million in grants and loans to school districts to assist in the abatement of asbestos hazards in 340 schools. Approximately 5,000 schools had applied for funds under the ASHAA administered by EPA. The awards were distributed to 47 states, the Northern Marianas, and Bureau of Indian Affairs' schools.

As part of the nationwide drive to provide information and training on the identification and abatement of potential asbestos hazards, EPA opened three Federally-financed asbestos information centers. They are located in the greater Atlanta, Boston, and Kansas City areas. The centers train people in proper asbestos identification and abatement techniques. Funds for the first centers were awarded to Georgia Tech, Tufts University, and the University of Kansas. EPA is considering whether to open additional centers.

Since 1979, EPA has provided technical assistance on asbestos abatement to school officials and building owners and managers. In FY 1985, the Agency completed a number of informational guidance documents to help educate the public about asbestos in buildings and how to reduce the hazard. Several publications were completed and distributed publicly in FY 1985. In July, 1985, the Agency completed the revision of the EPA 1982 asbestos guidance document. The newly revised document is entitled "Guidance for Controlling Asbestos-Containing Materials in Buildings." The 1985 edition provides more comprehensive instruction for the treatment of asbestos-containing materials. The information presented in the new version was compiled by a panel of national experts in asbestos identification and control.

To complement the new guidance document, OTS coordinated with EPA's Office of Research and Development (Environmental Monitoring Systems Laboratory, Research Triangle Park) to coproduce

"Measuring Airborne Asbestos Following an Abatement Action." The document presents specific guidance on the determination of the acceptable completion of an abatement project. A panel of national experts met and discussed the issues involved in deciding whether a worksite is "clean" following an abatement activity.

A third publication, "Asbestos in Buildings: Guidance for for Service and Maintenance Personnel," was completed and has been made available. The manual provides custodial workers information on practices to minimize unnecessary exposure to asbestos during normal service and maintenance activities.

The survey, "Asbestos in Buildings: A National Survey of Asbestos-Containing Friable Materials," was published in FY 1985 as a result of a national survey conducted in FY 1984 to determine the extent of asbestos-containing friable materials in schools. Asbestos technical bulletins comprise another source of information. Bulletins produced in 1985 include "Evaluating Compliance with the Asbestos-In-Schools Identification and Notification Rule" and "Use of Asbestos-Containing Friable Materials and Vinyl-Asbestos Floor Tiles in Public and Commercial Buildings." A bulletin on the handling of asbestos-containing pipe wrap will be distributed in the Spring of 1986.

Another form of EPA assistance is to encourage states to establish contractor certification programs. This program provides grants to states for the purpose of developing and carrying out certification programs and giving technical assistance. Eleven states received funding in FY 1985, and an additional fifteen states are expected to be funded in FY 1986. For FY 1986, contractors who conduct asbestos abatement work under the Asbestos School Hazard Abatement Act (ASHAA) either must be state certified or must have attended an EPA-approved training course.

EPA awarded a grant to the Maryland Department of Health and Mental Hygiene to develop a model asbestos abatement contractor certification program based on Maryland's existing program. Maryland prepared "Recommended Guidelines for Asbestos Abatement Contractor Licensing Programs" in April 1985. EPA distributed this model state regulation to all of the states and sponsored three model workshops on this document in Atlanta, San Francisco, and Boston between April 24, 1985 and June 21, 1985. State officials and the public were invited to the workshops. In addition, EPA has developed and made available to the states a model training program for abatement contractors. This program was presented to 18 states on July 8, 1985.

On July 12, 1985, EPA proposed the Asbestos Abatement Projects Rule under section 6 of TSCA to protect state and local public employees who take part in asbestos abatement projects but are not protected by OSHA regulations. The rule, which is similar to the current OSHA asbestos standard, establishes a permissible exposure level and requires use of certain work practices during asbestos abatement. The rule, under section 6(d) of TSCA, was immediately effective upon publication, and will be made final after a public comment period in FY 1986.

During FY 1985, the Agency reviewed appropriateness of action under TSCA to control risks associated with the commercial manufacture and use of asbestos. The Agency expects to decide on a course of action early in FY 1986.

4,4'-Methylene-dianiline (4,4'-MDA)

In July 1985, EPA referred 4,4'-MDA to the Occupational Safety and Health Administration (OSHA) for regulatory consideration, based on the conclusion that this chemical presents an unreasonable risk of cancer to workers. The report describing this referral, issued under the authority of section 9(a) (July 5, 1985 (50 FR 27674)) was the first use of section 9 of TSCA. In exercising its referral authority under section 9(a), EPA gave OSHA the first opportunity to regulate workplace exposures to 4,4'-MDA.

About 98 percent of the 400 million pounds of 4,4'-MDA produced in the United States each year is used to make methylene diphenylene isocyanate (MDI), which is used, in turn, to make polyurethane foams and elastomers. The chemical is also used to make products such as epoxy resins, wire coatings, and dyes. Workers can be exposed to 4,4'-MDA either by breathing it or by absorbing it through the skin. Approximately 600 workers are exposed to the chemical during its manufacture and conversion to MDI; several thousand are exposed to non-MDI applications.

1,3-Butadiene

EPA will refer the chemical, 1,3-butadiene, to OSHA, under the authority of section 9(a) of TSCA, for regulatory consideration. This referral is based on EPA's conclusion that exposure to the chemical presents an unreasonable risk of cancer to workers. The report describing the referral will be published in the *Federal Register* early in FY 1986. 1,3-Butadiene is an industrial chemical produced at a rate of about 3 billion pounds per year in the U.S. and is predominantly used as a monomer in the production of various types of synthetic rubbers, plastic, and resins. 1,3-Butadiene is a gas at ambient temperatures, and there is a significant potential for human exposure via inhalation of this chemical at the workplace. Worker exposure may occur during manufacture of the monomer,

during processing into polymers, and during fabrication of various products (e.g., tires) from the polymers.

The Agency has reviewed a number of surveys of air concentrations of 1,3-butadiene to which workers are exposed in plants that produce the monomer and in plants that process it into various polymers. The data compiled from various sources indicate that from 500 to 700 workers in monomer production plants and from 4,800 to 7,500 workers in polymerization plants are exposed to 1,3-butadiene.

EPA, in a joint effort with the National Institute for Occupational Safety and Health (NIOSH), is currently assessing other occupational exposures to 1,3-butadiene, such as in rubber tire manufacturing plants.

Glycol Ethers

In FY 1984, EPA initiated a regulatory investigation under section 6 to explore the need for, and feasibility of risk management regulations for 2-ethoxyethanol, 2-methoxyethanol and their acetates (glycol ethers). Studies indicate that the subject glycol ethers produce adverse reproductive and developmental effects in animals at low doses.

The Agency is considering referrals under section 9 to either the Consumer Product Safety Commission and/or the Occupational Safety and Health Administration, for those agencies' consideration of possible new control measures and/or controls pursuant to section 6 of TSCA. A proposed section 6 rule and/or section 9 referral is expected to be published during FY 1986.

Metalworking Fluids

In FY 1984, EPA initiated a regulatory investigation of nitrosamines in metalworking fluids. Adding inorganic nitrite corrosion inhibitors to metalworking fluids containing amines results in the formation of nitrosamines, particularly n-nitrosodiethanolamine (NDELA). Studies indicate that NDELA is a potent animal carcinogen at relatively low doses.

As a result of the investigation, EPA is concerned that the intentional addition of inorganic nitrites to water-containing metalworking fluids may present an unreasonable risk of cancer to workers. The Agency is evaluating whether TSCA or the OSHA Act is the appropriate regulatory authority. A proposed section 6 rule or section 9 referral is expected to be published in the spring of FY 1986.

4,4'-Methylenebis-(2-chlorobenzenamine) (MBOCA)

On April 26, 1985, EPA proposed a significant new use rule (50 FR 16519) under section 5 of TSCA applicable to any person intending to manufacture MBOCA in the U.S. It would require prior EPA review of any such planned manufacture. MBOCA, a demonstrated animal carcinogen,

is used as a curing agent in the manufacture of certain polyurethane elastomeric articles. Significant human exposure to this chemical can occur in manufacturing facilities predominantly through dermal contact with MBOCA dust. MBOCA is not now manufactured in the U.S.; no OSHA standard exists for the chemical. EPA is exploring regulatory options managing the risks associated with commercial use of this chemical.

1,2,3,4,7,7-Hexachloronorbornadiene (Hex-BCH)

On February 22, 1985, EPA proposed an information gathering rule for Hex-BCH (50 FR 7351). This rule would require manufacturers, importers, and processors of isodrin or endrin to submit a section 8(a) report to EPA. All other manufacturers, importers, and processors of Hex-BCH would be required to submit a section 5(a) significant new use notice. These reports and notices would allow EPA to monitor the volume of Hex-BCH manufactured, imported, and processed, the number of individuals exposed to Hex-BCH, and the method of its environmental release or disposal. EPA would evaluate the reported information to determine if further regulatory action is needed.

Methyl *n*-Butyl Ketone (MBK)

EPA drafted a proposed significant new use rule under section 5 of TSCA applicable to manufacturers, importers, and processors of MBK. This chemical is not currently being manufactured, imported, or processed in the United States. It has been used as a lacquer thinner, varnish remover, and solvent. It is a known human neurotoxicant, with effects noted in workers at facilities using MBK, as well as in consumers exposed to the substance.

Chemical Advisories

Chemical Advisories provide information to the public about toxic effects of chemicals of concern, routes of exposure, and alternative methods of reducing risks. They are written by EPA's Office of Toxic Substances after consultation with interested parties which include companies, public interest groups, and other agencies. They are designed to be used where an increased awareness of potential risk is likely to lead to meaningful precautions, and are addressed and distributed to individuals or organizations for whom the information is most useful. Chemical Advisories are intended to encourage voluntary risk-reduction actions by individuals or organizations in instances where regulatory control is not appropriate or as interim measures while regulatory action is pursued.

In FY 1985, two Chemical Advisories (non-regulatory informational documents) were issued. They addressed hazards from *p-tert*-butyl benzoic acid, and 4,4'-methylenebis(2-chloroaniline) (MBOCA). Another

Chemical Advisory on burning used oil in space heating equipment is currently under external review by other interested agencies and is expected to be issued early in FY 1986.

Manufacturers, processors, and importers who handle p-tert-butyl benzoic acid and derivatives were advised to minimize worker exposure to these chemicals. They have been shown in laboratory tests to cause testicular effects in rats and are suspected of causing these effects in humans. Tests also indicate that these chemicals may also damage the liver and kidney and cause central nervous system effects. EPA recommended that workplace exposures be monitored, airborne concentrations be controlled at the source by enclosing the operation or process and using local exhaust ventilation, and the use of protective equipment or clothing by workers where direct contact with the chemicals cannot be avoided.

For 4,4'-methylenebis(2-chloroaniline), also known as MBOCA, manufacturers of polyurethane products who use this chemical were advised to minimize worker exposures to it. MBOCA has been demonstrated to cause cancer in laboratory animals. Workers can be exposed to MBOCA primarily through skin contact and, to a lesser extent, through inhalation or ingestion of MBOCA dust particles. Engineering controls were recommended, such as enclosing processes that use MBOCA and replacing manual transfer of the substance with automated systems. Other suggested controls included consideration of a glove box installation or the use of a specialized ventilation hood.

Another Chemical Advisory addresses the problem of potential exposure to lead and other combustion products from improperly vented oil burners. The concern is for small workplaces where used motor oils containing lead are burned as fuel in heaters. The Advisory will be distributed in early FY 1986 to complement a proposed rule by the Office of Solid Waste under the Resource Conservation and Recovery Act (RCRA). When final, that rule will ban burning used oil in unvented space heaters. Prior to publication of the final rule, the Advisory will alert those people who burn used oil of the hazard, along with notifying them of the planned regulation.

5

Chemical Testing

Program Status

Section 4 of TSCA gives EPA the authority to require by rule that manufacturers and processors of chemicals test for certain health and/or environmental effects. A test rule specifies the chemical to be tested, health and environmental effects for which testing is required, test standards, schedules for submission of the test data, and who is responsible for conducting the testing. The Agency requires testing where existing data are insufficient to determine or predict effects. Data obtained through testing are used by EPA and others to determine whether and how to regulate or control potentially hazardous substances.

An Interagency Testing Committee (ITC) was established by section 4 to review available data on chemicals in commerce and to recommend chemicals for priority testing consideration by EPA. From these recommendations, the ITC designates those chemicals to which the EPA should respond within 12 months. The ITC can also recommend chemicals without designating them. The ITC's list of designations is limited to 50 chemical substances and mixtures at any one time. Under the Act, the Committee must consider revising its list, and report to the EPA at least every six months. TSCA requires EPA to respond to chemical designations within one year by either initiating rulemaking to require testing of each designated chemical, or by determining there is no need to test and publishing the reasons for not testing.

As part of developing test rules, EPA is required annually to develop and review test standards and guidelines for a wide variety of health and environmental effects. EPA develops generic test guidelines which then become the basis for chemical-specific test standards cited in the rules (47 FR 13012). These EPA guidelines and certain Organization for Economic Cooperation and Development (OECD) guidelines were published in the *Federal Register* (50 FR 39252 and 50 FR 39472, respectively) and subsequently will be codified in the *Code of Federal Regulations*. As each new guideline is developed, scientists from other EPA program offices review the guidelines to ensure that they are consistent and reflect the most current and valid testing practices. It is then submitted to peerreview by scientists and experts from outside the Agency in the academic community,

State and Federal agencies, public interest groups, and industry. In addition, an annual review of the published guidelines is carried out and, where warranted, the guidelines are updated.

In FY 1985, EPA took a total of 21 ITC-related actions. Eight of these were responses to new ITC designations, 11 were post-initial response determinations, and 2 were actions on chemicals recommended, but not designated by the ITC. These produced 10 decisions not to test; 2 ANPRs; 6 proposed rules; and 3 final rules. Table 4 shows FY 1985 actions taken on ITC designated and recommended chemicals.

During FY 1985, EPA developed four new, and updated two testing guidelines for publication. Thirty-eight chemical specific test standards were produced in support of proposed test rules.

Table 4 Responses to Interagency Testing Committee (ITC) Designations

Date	Chemical	Action	ITC List
11/19/84	2-(2-Butoxyethoxy)-ethyl Acetate	Advance Notice of Proposed Rulemaking; expands scope of Rulemaking to include diethylene glycol butyl ether, defines testing EPA is considering for both chemicals, and seeks public comment on EPA's plan to propose a test rule for these two chemicals.	13
11/19/84	Ethylene Bis-(oxyethylene) Diacetate	Decision Not to Test; sufficient data are available to determine or predict the effects on human health under under current conditions of manufacture and use.	13
11/19/84	1,2,3,4,7,7-Hexachloro-norbornadiene	Decision Not to Test; the present limited manufacture and controlled disposal of this chemical is not expected to cause substantial or significant human exposure or present an unreasonable risk to human health or the environment.	13
11/19/84	Oleylamine	Notice of Proposed Rulemaking; to perform testing for health effects including developmental toxicity, dermal subchronic toxicity, and mutagenicity.	13
12/28/84	Chlorobenzenes	Decision Not to Test; to withdraw structural teratogenicity and subchronic effects testing of monochlorobenzene, ortho-dichlorobenzene, para-dichlorobenzene and 1,2,4-trichlorobenzene; and oncogenicity and reproductive effects testing of pentachlorobenzene, based on sufficient availability of data to reasonably predict low risk at anticipated exposure levels.	1
01/30/85	Phenylenediamines	Decision Not to Test; 34 of 47 PDA category members were not believed to warrant testing because of low, or no, production.	6

Date	Chemical	Action	ITC List
05/03/85	Isopropyl Biphenyl/ Diisopropyl Biphenyl	Decision Not to Test; based on limited exposure to these chemicals during their manufacture, processing, and use, there is neither significant human exposure to them nor reason to believe that there may be an unreasonable risk to human health or the environment.	14
05/17/85	Bisphenol A	Notice of Proposed Rulemaking; to perform health and environmental effects testing including inhalation subchronic toxicity, and acute and chronic aquatic toxicity testing.	14
05/07/85	Chloromethane	Decision Not to Test; to withdraw oncogenicity and structural teratogenicity testing. Notice also discusses availability of information on chloromethane's reproductive and mutagenic potential.	1
05/08/852	1,2-Dibromo-4-(1,2-dibromoethyl) Cyclohexane	Decision Not to Test; sufficient available data indicate that few people are exposed and then at very low levels.	14
05/17/85	2-Ethylhexanoic Acid	Notice of Proposed Rulemaking; to perform health effects testing including pharmaco-kinetic studies, subchronic toxicity and developmental toxicity tests.	14
05/17/85	Ethyltoluene/Trimethyl-benzene (C_9 fraction)	Notice of Final Rulemaking; to test the C_9 aromatic hydrocarbon fraction for neurotoxicity, mutagenicity, developmental toxicity, reproductive effects, and oncogenicity.	10
05/23/85	Diethylenetriamine	Notice of Proposed Rulemaking; to conduct chronic oncogenicity bioassays.	8
05/23/86	Diethylenetriamine	Notice of Final Rulemaking; to perform testing including oral subchronic toxicity, dermal absorption, chemical fate and mutagenicity.	8
08/07/85	1,1,1-Trichloroethane	Notice of Proposed Rulemaking; to propose that the protocols and schedule submitted by an industry consortium be adopted as the test standards to be used to test this chemical for developmentally toxic effects.	2
09/06/85	Benzyl Butyl Phthalate	Notice of Proposed Rulemaking; to require certain environmental fate and effects testing.	7
09/06/85	Alkyl Epoxides	Decision Not to Test; existing information on health effects does not suggest an unreasonable risk at expected exposure levels.	1
09/12/85	Biphenyl	Notice of Final Rulemaking; to perform testing for environmental effects and chemical fate according to protocols submitted to and approved by EPA.	10
10/03/85	2-Chlorotoluene	Decision Not to Test; data received from a Negotiated Testing Agreement were adequate to support determination that this chemical does not pose risk to health and the environment.	8
11/19/84	Diethylene Glycol Butyl Ether	Advance Notice of Proposed Rulemaking; EPA proposes to include this non-designated chemical with the Advance Notice of Proposed Rulemaking for ITC designated chemical 2-(2-Butoxyethoxy)ethyl acetate, and defines the testing EPA is considering to propose.	13
07/22/85	Carbofuran Intermediates	Decision Not to Test; EPA does not believe there is a basis to find that these substances may present unreasonable risk to the environment.	11

Streamlining Test Rulemaking

In order to accelerate the testing of chemicals recommended or designated by the ITC, the Agency had developed the approach of negotiating testing agreements (NTAs) with industry, where possible. This system was pursued in lieu of the more lengthy regulatory test rulemaking process. In August 1984, however, in a suit brought by the Natural Resources Defense Council (NRDC) (NRDC vs. US EPA, 595 F. Supp. 1255, S.D.N.Y. 1984), a U.S. District Court issued a decision which found that NTAs were not sanctioned under TSCA. Accordingly, EPA has since reevaluated its section 4 testing program to find other approaches to streamlining its rulemaking process for testing.

Single-Phase Rulemaking

On May 17, 1985, EPA amended its procedural rule describing a two-phase rulemaking process used to develop certain test rules under section 4(a) of TSCA. Under the previous two-phase process, the first phase states testing requirements and solicits proposed test study plans; the second phase adopts a final test study program and specifies the schedule for submission of data. Testing can not begin until the second phase is promulgated. The amended rule establishes an alternative single-phase rulemaking process that the Agency will use in most cases to expedite the development of test rules and to grant exemptions from those test rules. Under the single-phase process, EPA will propose the pertinent test guidelines or other suitable test guidelines as the required test standard in the initial notice of proposed rulemaking. The Agency will also propose time frames for the submission of the test data in the initial notice. In the final rule, EPA may promulgate as the test standard either the previously proposed test guidelines, a modified version, an alternative methodology submitted by commenters, or a modification of an alternative methodology.

This single-phase approach offers a number of advantages over the two-phase approach. First, the Agency believes that the single-phase approach will shorten the rulemaking period and expedite initiation of the required testing. Secondly, this process will eliminate the requirement for industry to submit test protocols for approval, while allowing commenters to submit alternative test methodologies during the comment period. Thus, it preserves the flexibility of the two-phase process, but at reduced administrative cost.

EPA will use the two-phase process, however, when no well-accepted test methodology is available for inclusion in the proposed test rule. Under such circumstances, the two-phase process is expected to be the more expeditious route to developing a final rule.

Use-Based Cluster Analysis

A pilot study was initiated in FY 1985 on an alternative priority-setting strategy associated with test rule development activities. The strategy involves a "use-based clustering" approach, which refers to a way of grouping chemicals based on common function and market application characteristics. In general, use-based cluster approaches would accomplish three things: (1) promote consistent analysis of chemicals that substitute for each other in use, (2) focus resources on chemical uses that pose the greatest aggregate risk, and (3) reduce repetition of analysis and regulatory initiatives, while permitting a broad view of use/industry groups that incur large collective burdens over time. Application of this strategy to the test rules process would ensure that the chemical selection and data development process for section 4 is better integrated with risk assessment and risk management activities in the OTS existing chemicals program. Two chemicals were selected from the ITC's 15th and 16th reports for the pilot study. A preliminary analysis was made to identify substitutes for the designated chemicals in those uses where exposure is significant. Chemical screening is currently proceeding.

Quality of Data

In addition to test rulemaking, guidelines, and chemical-specific standards, EPA pursues a rigorous program to ensure the quality of data received as a result of chemical testing. In FY 1984, the Agency promulgated Good Laboratory Practices (GLP) standards (48 FR 53922-53944, November 29, 1983). These established procedures for conducting health effects and environmental effects testing under TSCA; and requirements for facility operation, maintenance of equipment and recordkeeping.

To ensure compliance with these GLP standards and with testing requirements under TSCA and FIFRA, EPA's Office of Compliance Monitoring within the Office of Pesticides and Toxic Substances is responsible for conducting laboratory inspections and auditing completed test studies. Inspection staffs are drawn from EPA headquarters, Regional Offices, and from the Food and Drug Administration (FDA). OTS provides scientific and technical support to the Office of Compliance Monitoring through its Health and Environmental Studies Audit Program (HESAP). HESAP staff participate in laboratory inspections and review test data resulting from ongoing industry testing and test rules. Inspection and study audit reports from EPA Regional Offices and the FDA are received and reviewed and regulatory actions recommended as appropriate.

In FY 1985, 20 laboratory inspections were conducted and 122 test studies were audited. See Chapter 6 for specifics on compliance and enforcement actions.

6

Compliance and Enforcement

EPA has developed specific strategies to enforce regulations under TSCA. These strategies identify and rank possible violations, identify the available tools for compliance monitoring, specify how these tools are to be used, and provide a formula to determine the application of inspection resources. Where inspections uncover violations of TSCA requirements, EPA levies civil penalties and, as appropriate, criminal penalties, as authorized by section 16 of TSCA.

Program Actions

During FY 1985, EPA developed and issued a compliance monitoring strategy for the section 6 Asbestos Abatement Projects Rule. EPA also developed and issued an enforcement response policy for TSCA Good Laboratory Practices (GLP), and revised the enforcement response policies for TSCA sections 5 and 8(a), and the section 6 asbestos-in-schools rule.

EPA continued its five cooperative enforcement agreement programs to monitor compliance with the PCB regulations in the States of Connecticut, Maryland, Michigan, and Ohio and to conduct compliance monitoring activities concerning the presence of asbestos-in-schools in the State of California. During FY 1985, these States conducted 463 PCB compliance inspections and 133 asbestos-in-schools inspections at local education agencies.

During the latter part of FY 1985, EPA entered into cooperative enforcement agreements with 10 additional States to initiate 4 PCB and 8 asbestos-in-schools compliance inspection programs.

Compliance Actions

During FY 1985, EPA conducted a broad range of inspections for TSCA requirements. The EPA along with 4 state agencies cooperating under the terms of enforcement grants-in-aid conducted 2,079 PCB compliance monitoring inspections. In addition, the Agency, operating under a cooperative agreement with the American Association of Retired Persons and the State of California, conducted 2,147 asbestos-in-schools inspections. The Agency also initiated the initial inspections under the Asbestos Abatement Projects Rule and conducted 5 inspections in that area in FY 1985.

During FY 1985, the Agency also monitored compliance with TSCA sections 4, 5, 8, and 13 requirements. EPA

inspected 20 laboratories conducting testing under TSCA to determine if the laboratories were in compliance with GLP requirements. During these inspections EPA conducted 122 audits of health and environmental tests to determine if testing had been conducted according to test protocols, and if reports accurately reflected study findings. EPA also conducted over 800 inspections to determine compliance with sections 5 and 8 requirements. The Agency conducted a total of 586 inspections to determine compliance with chemical import requirements. In addition, the Agency also conducted 14 inspections to monitor compliance with the ban on nonessential aerosol uses of chlorofluorocarbons, and conducted 6 compliance inspections for the section 6 dioxin rule (45 FR 32686).

Civil Enforcement Actions

Fiscal Year 1985 saw unprecedented enforcement activity under the Toxic Substances Control Act. The largest civil administrative penalty in the history of EPA was collected this year. In addition, for the first time, full scale environmental audits were included in Agency case settlements. Among the most significant TSCA civil administrative actions in 1985 were the following:

Chemical Waste Management — Emelle, Alabama. This case represents one of the most comprehensive enforcement actions ever undertaken by EPA. The violations at this facility included illegal storage and disposal of PCB-contaminated oil. The settlement included an enforceable schedule for compliance activities, the first comprehensive environmental audit included in an Agency consent agreement, a hydrogeologic study of groundwater, and payment of a cash penalty of $600,000.

Diamond Shamrock Corporation — Greens Bayou, Texas. This enforcement action addressed violations which included the illegal disposal of PCB-contaminated waste at an unpermitted facility. The settlement, negotiated by EPA Region 6 personnel, required environmental management improvements, the development of new operating procedures for handling and disposing of PCBs, payment of an $800,000 cash penalty, and assessment of stipulated penalties for non-compliance with the terms of the consent agreement.

Diamond Shamrock Chemicals Corporation — Irving, Texas. In this action, Diamond Shamrock was charged with violations of TSCA section 5 premanufacture notification requirements for new chemicals. Under the terms of this settlement, the company paid a civil penalty of $900,000, the highest single penalty ever collected under TSCA section 5, and agreed to perform

comprehensive TSCA compliance audits at 43 of its facilities nationwide.

Chemical Waste Management — Vickery, Ohio. This settlement, negotiated by EPA Region 5 staff, concerned TSCA and RCRA violations. These violations included the illegal sale and distribution in commerce of over 6,000,000 gallons of PCB-contaminated waste oils. The settlement required the suspension of additional waste receipts at the facility for a period of 10 months, construction of a toxic chemical waste landfill, implementation of a comprehensive groundwater monitoring program, an environmental management audit, and the payment of a civil penalty in the sum of $2,500,000. This is the largest civil administrative penalty ever collected in the history of EPA.

Commonwealth Edison Corporation — Chicago, Illinois. This settlement, negotiated in January, 1985, by Region 5 staff, settled an administrative penalty action involving improperly disposed of PCBs, which have been spilled from polemounted electrical capacitors. Edison decontaminated each spill site, demonstrated the cleanup levels through verification sampling and analysis, and paid a civil penalty of $80,000, the largest penalty ever paid by an electrical utility.

In addition to the above enforcement actions brought in FY 1985, the Agency also undertook four enforcement initiatives in areas of high priority to the toxics program.

In June, EPA simultaneously filed six civil administrative complaints under TSCA's PMN requirements seeking penalties ranging from $6,000 to $3.7 million. The simultaneous filings of these actions by Headquarters and by Region 5 were intended to promote the visibility of the Agency's chemical assessment program.

A similar effort followed in July with respect to TSCA reporting requirements. As part of a Headquarters-coordinated effort, EPA regional personnel filed administrative cases assessing civil penalties totaling $160,000 against seven companies for reporting violations.

Six of these cases concern major violations of the reporting requirements with respect to commercial and industrial uses of asbestos. These were the first such cases ever brought by EPA concerning asbestos reporting under TSCA. A seventh case involved failure to file a required report on an imported chemical.

The Agency followed with two additional enforcement initiatives in September 1985, both undertaken by Region 2 attorneys. First, the Region filed three civil administrative actions under TSCA seeking total penalties

of $75,000. Section 4, a test rule, requires manufacturers to submit notices of intent to test shipments of certain chemicals or to submit an application for exemption from the test rule at the time of manufacture. These cases represented the first EPA enforcement actions ever taken under TSCA section 4.

Also in September, Region 2 filed twelve administrative complaints seeking total penalties of $90,000 for failure to comply with the import certification requirements of TSCA. This provision requires a chemical importer to either certify the compliance of shipments with TSCA requirements, or to declare that shipments are exempt from TSCA requirements. These were the first enforcement actions to be taken by the Agency for import violations.

As a result of stepped up asbestos-in-schools inspections, the Agency issued 443 civil complaints for alleged violations of section 6 asbestos-in-schools requirements. The Agency also issued 253 civil complaints this fiscal year as a result of PCB inspections. For the first time under TSCA, 8 civil complaints were issued to violators of section 8(a), 12 civil complaints to violators of section 13, and 3 civil complaints were issued for violations of section 4. In addition, EPA issued 1 civil complaint for alleged violation of section 3(e) and 13 civil complaints for violations of section 5. Figures for each EPA Regional Office and Headquarters appear in Table 5.

Table 5 **Administrative Civil Actions Taken Under Section 16 of TSCA, Complaints Issued, Cases Completed, and Amounts Assessed** (by Regions)*

Region	Total No. Complaints Issued FY'79-85	No. Complaints Issued FY'85	Total No. Cases Completed FY'79-85	No. Cases Completed In FY'85**	Total No. of Cases Pending	Total Civil Penalties Collected ($) In FY'85	Total Penalties (In $) Collected FY'79-85
1	79	50	41	23	38	92,609	350,231
2	240	98	156	68	84	79,365	1,773,785
3	132	51	94	48	38	114,650	541,135
4	150	83	114	79	36	70,150	391,672
5	453	167	314	130	139	2,630,050	4,434,389
6	158	44	104	20	54	71,550	1,344,465
7	185	102	120	60	65	139,175	388,655
8	130	55	79	26	51	8,900	401,515
9	85	32	52	21	33	100,750	501,125
10	82	45	43	23	39	38,490	149,140
HQ.	23	6	17	7	6	900,000	1,794,750
TOTAL	1,717	733	1,134	505	583	4,245,689	12,070,862

*All actions taken involved alleged violations of sections 4, 5, 6, 8, and 13.
**Includes cases carried over from FY 1980 - FY 1984.

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Litigation

Environmental Defense Fund, Inc. v. Environmental Protection Agency (No. 791580, D.C. Cir.)

In 1979, the Environmental Defense Fund (EDF) petitioned for review of EPA's regulations under TSCA sections 6(e)(2) and (3) governing the manufacture, processing, distribution, and use of polychlorinated biphenyls (PCBs). A decision largely in EDF's favor was issued on October 30, 1980. This decision and its aftermath were described in reports for previous years. As a result of the Court's orders in this case, EPA has issued three additional PCB rules. In August 1982, EPA issued a regulation affecting the use of PCBs in electrical equipment; in October 1982, the Agency issued a rule providing an exclusion from the statutory ban for PCBs produced in closed manufacturing processes or discharged into wastes that are disposed of in an acceptable manner; finally, in July 1984, EPA issued a regulation affecting other PCBs inadvertently generated in chemical manufacturing processes. These rules, in turn, have generated other litigation and other regulation. The development for fiscal year 1985 in this case and related rulemakings are described below.

Last year's report discussed the litigation and progress in settlement negotiations involving the August 1982, electrical equipment rule. Early in FY 1984, EPA entered into two separate agreements whereby parties who had filed petitions for review agreed to dismiss their suits if the Agency would conduct two additional PCB rulemaking proceedings within agreed upon time limits. EPA has completed both rules. In November 1984, EPA issued a regulation amending the PCB rule by modifying the definition of "significant exposure" and presenting the Agency's current framework for assessing PCB exposures. EPA also issued a regulation in July 1985, amending the PCB rule by placing restrictions and conditions on the use of PCB transformers. The July 1985 rule has generated another lawsuit. A petition for review was filed by Mississippi Power Company in the Fifth Circuit.

A petition for review of the October 1982 rule was filed by the Chemical Manufacturers Association (CMA) in December 1982. By agreement of the parties, approved by the Court, this petition was stayed pending further PCB rulemaking. No further action has been taken on this petition to date.

In late September 1984, petitions for review of the July 1984 rule were filed by the American Die Casting Institute and Outboard Marine Corporation in the Seventh Circuit, and by the American Paper Institute and Fort Howard Paper Company in the D.C. Circuit. The Seventh Circuit petition has since been transferred to the D.C. Circuit where the Court consolidated both cases. Settlement discussions are proceeding.

Madison Metropolitan Sewerage District vs. Environmental Protection Agency, (No. 85 Civ. 4605 W.D. Wisconsin)

On May 23, 1985, plaintiffs in this case challenged the refusal of the Region 5 Administrator to authorize immediate disposal of PCB contaminated municipal sludge on agricultural lands. Under the PCB regulations (40 CFR 761.60(a)(5)), EPA can approve an alternative disposal method for disposing of municipal sewage if certain findings are made. Plaintiffs contend that EPA's denial of its application was: (1) arbitrary, capricious, an abuse of discretion and not in accordance with law; and (2) unsupported by substantial evidence in the record.

On July 24, 1985, EPA filed a motion to dismiss the complaint on the grounds that plaintiff failed to exhaust administrative remedies and for lack of jurisdiction. The court issued a decision in EPA's favor on September 13, 1985.

N.O.C., Inc., t/a Noble Oil Company v. Administrator, (No. 85-3175 3rd Cir.)

Noble Oil Company seeks review of a final order by the Administrator assessing a civil penalty of $40,000 for three separate violations of the regulations concerning disposal, marking, and storage of PCBs.

Respondent argues, among other things, that: (1) the PCB regulations were unenforceable because they were invalidated by the D.C. Circuit in 1979; (2) the Administrator's decision is not supported by substantial evidence; and (3) the Administrator abused his discretion by assessing the $40,000 civil penalty against Noble for 3 separate violations.

Briefs have been filed and oral arguments are expected during fiscal year 1986.

Service Employees International Union (SEIU) v. Ruckelshaus, (No. 84-2790, D.D.C.)

SEIU brought this action in September 1984 to require EPA to issue Federal regulations setting standards for determining when an asbestos hazard requiring correction exists in schools and other public and commercial buildings, requirements for abatement activities where such hazards exist, and standards for performing abatement activities, including standards for the protection of persons performing abatement.

In early proceedings SEIU asked the Court for a preliminary injunction, arguing that EPA had a mandatory duty to issue such rules based on promises made by the Agency in response to citizens' petitions. Alternatively, SEIU argued that EPA had failed to complete rulemaking actions on asbestos hazards in a reasonable time.

On November 16, 1984, the Court denied the preliminary injunction because EPA was "actively pursuing new approaches for asbestos abatement," and because EPA has in place a voluntary/regulatory asbestos program. Further, the Court determined that deference to EPA was appropriate, citing EPA's assurances that it would shortly issue a final decision on the most feasible asbestos regulatory approach.

November 30, 1984, EPA issued a final decision with respect to certain parts of SEIU's request, stating that it would not issue regulations governing decisions affecting asbestos abatement activities because such decisions are best made at the local level and the Agency's current program and planned improvements should adequately deal with the problem. EPA, however, continued with rulemaking efforts related to protection of workers conducting abatement activities and protection of building occupants during abatement. Activities in this areas are discussed elsewhere in this report.

SEIU amended its complaint, asking the Court to reverse EPA's decision not to issue some of the regulations requested, claiming that EPA's program is not adequate to deal with the asbestos hazard in schools and other buildings.

By the end of FY 1985, SEIU and EPA had filed written arguments supporting their respective positions. A hearing before the Court on pending motions has been scheduled for early FY 1986.

Natural Resources Defense Council (NRDC) and National Wildlife Federation (NWF) v. Thomas (No. 85-0973, D.D.C)

Plaintiffs brought this action after EPA had denied, in part, their citizens' petition to issue comprehensive regulations under TSCA on certain isomers of the chemicals known as dioxins. These are substances chemically similar in structure to 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) and which, according to plaintiffs, may present risks similar to TCDD.

By the end of FY 1985 a schedule for the filing of motions was established.

Polaroid Corporation v. United States Environmental Protection Agency and William M. Ruckelshaus (No. 84-3134-K, D. Mass.)

In October 1984, Polaroid Corporation (Polaroid) challenged EPA's disclosure and handling of information submitted by Polaroid under TSCA which had been claimed as confidential business information under section 14 of TSCA and EPA's confidentiality regulations in 40 CFR Part 2. Polaroid challenged EPA making disclosures of such confidential business information to certain EPA contractors and subcontractors, other Federal agencies, and certain arms of Congress and challenged the adequacy of EPA's security and handling of such information. Further, Polaroid alleged that some of EPA's actions violated the settlement of a previous Polaroid suit involving confidentiality issues in 1978 (*Polaroid Corp. v. Costle* 78-1133S, D. Mass.). Polaroid sought declarative and injunctive relief.

Polaroid requested and was granted expedited discovery which focused primarily on EPA's physical handling and security of confidential business information under the procedures in EPA's "TSCA Confidential Business Information Security Manual" and the related manual "Contractor Requirements for the Control and Security of TSCA Confidential Business Information." In January 1985, Polaroid unsuccessfully sought a temporary restraining order which would have severely constrained EPA's review of certain premanufacture notices submitted by Polaroid under section 5 of TSCA.

After further discovery, EPA and Polaroid entered settlement negotiations which resulted in the District Court entering a Consent Order. The Consent Order addresses two areas. First, EPA was in the process,

separate from this litigation, of making certain refinements of its security procedures for handling and protecting TSCA confidential business information, including revisions of its security manuals. With respect to those refinements, EPA agreed to report to the Court when they were completed. Second, EPA and Polaroid identified certain additional refinements in the course of settlement discussions which EPA concluded would be worthwhile to make. The Consent Order commits EPA to making those additional refinements and reporting to the Court when they are completed.

Several of the requirements of the Court Order have already been met, and EPA anticipates that the remaining requirements will be met by the end of FY 1986.

Chemical Manufacturers Association v. Environmental Protection Agency (No. 84-1569, D.C. Cir.)

On November 19, 1984, the Chemical Manufacturers Association (CMA) filed a petition for review of the first significant new use rule EPA promulgated under section 5(a)(2) of TSCA. The rule was promulgated on September 5, 1984 (49 FR 35011) and related to two chemical substances which were the subject of premanufacture notices under section 5 of TSCA. The rule also included general procedural provisions that will be applicable to all significant new use rules. In the course of informal discussions, CMA indicated that it was concerned about some of these procedural provisions. EPA indicated that it was willing to undertake further rulemaking on these provisions which was likely to meet these concerns. Accordingly, CMA agreed to defer briefing until EPA proposed revisons to these procedural provisions. The proposal of these revisions is likely to occur during the first half of FY 1986.

Citizens for a Better Environment, et al., v. Lee M. Thomas (No. 85 C 08000, N. Ill.)

In September 1985, two public interest groups challenged EPA's decision that had denied a petition these same groups had filed in April 1985, pursuant to section 21 of TSCA. The April 1985 petition had requested that EPA identify business entities in the southeast area of Chicago which were releasing 11 named chemical substances into the environment. The petitioners also requested that EPA initiate rulemaking under TSCA section 4(a) to require these businesses to conduct a wide ranging set of testing

on the identified chemical substances — including testing of the substances for cumulative and antagonistic effects.

The Agency denied the section 21 petition, in part, because there are no available test standards for studying the cumulative effects of chemical substances. In addition, EPA's denial notice indicated that health effects data on the individual identified substances were adequate for regulatory assessment. Finally, the notice stated that the Illinois EPA had already identified 44 businesses in southeast Chicago which emit pollutants into the air, and that EPA was conducting a variety of environmental investigations in southeast Chicago.

Plaintiffs' complaint asks the Court to order the Agency to take the actions (described above) which EPA had declined to take in responding to the plaintiffs' TSCA section 21 petition.

8

International Activities

During FY 1985, EPA continued its international activities to promote coordinated approaches to evaluating and controlling toxic substances. These international activities include the exchange of information and expertise. By sharing its technical expertise and its broad experience in chemical review and control, EPA provides a valuable contribution to the several international programs.

One of its most important international efforts is participation in the Chemicals Group and Management Committee of the Organization for Economic Cooperation and Development (OECD). The OECD, a 24-member international organization composed of the world's major industrialized nations, was founded to promote development of and prevent barriers to international trade. Due to a proliferation of national chemical laws during the 1970s, the OECD membership recognized the potential for chemical trade barriers and established a program in 1977 to develop harmonized approaches to the review, evaluation and control of toxic substances.

During FY 1985, EPA continued to play an active role in the Chemicals Group and Management Committee. Several important initiatives were launched and the first steps were taken toward defining the framework for Chemicals Group and Management Committee activities into the next decade. In the area of existing chemicals, member states agreed in October 1984 to establish, on a trial basis, a Chemicals Information Switchboard, designed to increase member state access to unpublished information on chemicals. The Switchboard pilot, with six countries including the United States, began operation on July 1 and, since that time, has received 11 queries and has initiated 4. This could become an important mechanism for international information sharing on chemicals.

Three early efforts in the Chemicals Program involved hazard assessment, good laboratory practice (GLP) and confidentiality of data. During the past year, important new ground was broken for future work in these important areas. With respect to hazard assessment, member states convened in a special expert meeting in March 1985 and arrived at a general consensus that work in environmental exposure assessment should be started as a first priority. The first workshop dealing with environmental exposure assessment will convene in Vienna, Austria, in early 1986.

In the area of good laboratory practice, the Chemicals Group and Management Committee moved forward during the past year on the basis of 1981 and 1983 GLP recommendations. A meeting of GLP experts convened in February 1985 and agreed on major components of a work program in this area. Member states later agreed that information exchange was the most important program element. Accordingly, it was decided to establish a regular forum for national GLP administrators and experts to exchange information and experience. The U.S. is ready to conclude bilateral agreements on GLPs with several countries and believes that these efforts could serve as a model for other OECD member state agreements.

An expert group on confidentiality of data will convene later this year in London to begin work on developing model agreements for the exchange of confidential information. This work will be based on three earlier recommendations in this area concerning: principles to govern the exchange of confidential information between governments; a list of generally considered non-confidential data; and measures for protecting proprietary data.

Increasingly, EPA's attention and efforts will focus on preparations for the third meeting of the Chemical Group at High Level (called HLM). These HLMs occur periodically to review work in the Chemicals Program and, more importantly, to give guidance for the nature and direction of future work.

Ongoing Chemicals Program activities of importance to OTS are the Test Guidelines Updating Panel and the Complementary Information Exchange Procedure. During the past year in the Updating Panel, several new guidelines in genetic toxicology were reviewed for incorporation into the OECD Test Guidelines; and revisions were proposed to an acute (eye irritation) toxicology guideline. Ongoing, and increasing, concern for animal welfare prompted the Secretariat to offer to host an OECD meeting on this issue, scheduled for early spring 1986. Participants will consider primarily revisions to existing acute toxicity guidelines, particularly the LD_{50} guideline.

The Complementary Information Exchange Procedure was established in 1978 to provide member states early notice of regulatory plans or actions. The U.S. has historically sent more information through this system than other member countries. However, as more and more countries have legislation or regulatory action to report, the system is being utilized to an increasing degree.

EPA also participates in several programs of the United Nations, such as the United Nations Environment Program

(UNEP), International Register of Potentially Toxic Chemicals (IRPTC) and the World Health Organization (WHO) International Program on Chemical Safety (IPCS). The basic objective of the IRPTC is promoting more efficient use of national and international resources in the evaluation of chemicals. EPA supports IRPTC by providing scientific and regulatory information on chemicals, and by responding to chemical inquiries relayed through IRPTC headquarters in Geneva.

In January, UNEP convened experts for the second time to develop a UN-wide scheme for the exchange of information related to banned or severely restricted chemicals in international trade. The scheme, which closely resembles EPA's existing export notification procedures, was adopted on a provisional basis in May.

The IPCS was established in response to a recognized need for a collaborative international approach to evaluate the effects of chemicals on health and the environment. Member state experts work within the IPCS to develop assessment documents on chemicals, set exposure guidelines, coordinate testing when appropriate, and promote technical cooperation and training. EPA was a co-sponsor, and chairman, of an international symposium on hexachlorobenzene, which took place in Lyon, France in June 1985, and also has assumed lead responsibility for an assessment document on glycol ethers. In response to the Bhopal tragedy, IPCS launched an effort for more effective international response to such accidents. OTS is participating in the first steps of this effort, which include projects on reactive intermediates and identification of national emergency response mechanisms and reporting of incidents.

In addition to these multilateral international activities, OTS engaged in bilateral activities with other governments or organizations. Most recently, OTS had bilateral consultations with the Commission of the European Communities in Brussels. Agreement was reached for future cooperation in the areas of existing chemicals, biotechnology, hazard assessment and investigation of formaldehyde.

Appendix A

Major FY 1985 TSCA Actions

Section of Law	Description	Date
4(a)	For listing of testing decisions see Table 4	
4(b)	Testing Guidelines Published -Partition Coefficient (n-Octanol/Water)-Generator Column Method -Acute Oral Toxicity: Bobwhite and Mallard -Marine Fish Early-Life Stage Test -Neurotoxic Esterase (NTE) Assay for Evaluation of Neurotoxic Potential of Organophosphorous Substances	09/27/85
4(f)	Methylene chloride; Initiation of Accelerated Review	05/14/85
	Designation of Certain Chemicals for Priority Attention; Notice of Availability of Guidelines	07/16/85
5(a)	[(Dinitrophenyl)azo]-[2,4-diamino-5-methoxybenzene] derivatives (Proposed Significant New Use Rule) (2 chemicals)	10/25/84
	Derivative of tetrachloroethylene (Final Significant New Use Rule)	10/25/84
	Dicarboxylic acid monoester (Final Significant New Use Rule)	10/26/84
	1,2-Benzenediamine,4-ethoxy, sulfate (Final Significant New Use Rule)	10/26/84
	Substituted polyglycidyl benzenamine (Final Significant New Use Rule)	10/31/84
	Isopropylamine, distillation residues; ethylamine, distillation residues (Final Significant New Use Rule) (2 chemicals)	11/26/84
	Disubstituted diaminoanisole (Proposed Significant New Use Rule)	12/07/84
	Alkyl glycol/ether acrylic acid derivative (Proposed Significant New Use Rule)	12/24/84
	Benzophenonetetracarboxylic acid dimethyl ester, reaction product with methylenedianiline and substituted pyridine	12/27/84
	Benzophenonetetracarboxylic acid dimethyl ester, reaction product with methylenedianiline and alkylenediamine; and benzophenonetetracarboxylic acid dimethyl ester, reaction product with methylenedianiline, alkylenediamine and substituted pyridine (Proposed Significant New Use Rule) (2 chemicals)	
	Substituted 2-phenoxypyridine Substituted methylpyridine (Final Significant New Use Rule) (5 chemicals)	12/28/84
	Benzoic acid, 3,3'-methylenebis(6-amino-di-2-pro-penyl) ester (Proposed Significant New Use Rule)	1/02/85
	Methylphenol, bis(substituted alkyl) (Proposed Significant New Use Rule)	03/21/85
	Substituted tetrafluoroalkene/Disubstituted tetrafluoroalkene (Proposed Significant New Use Rule) (3 chemicals)	03/21/85
	Acrylate and methacrylate chemicals (Proposed Significant New Use Rule) (6 chemicals)	03/27/85
	Disubstituted diaminoanisole (Final Significant New Use Rule)	08/26/85
	Halogenated-*N*-(2-propenyl)-*N*-(substituted phenyl) acetamide (Proposed Significant New Use Rule)	08/26/85
	Poly(oxy-1,4-butanediyl)-alpha-(1-oxo-2-propenyl)-omega-[(1-oxo-2-propenyl)oxy)] (Proposed Significant New Use Rule)	08/26/86
	Hexachloronorbornadiene (Proposed Significant New Use Rule on an Existing Chemical)	02/22/86
	4,4'-Methylenebis(2-chlorobenzenamine) (Proposed Significant New Use Rule on an Existing Chemical)	04/26/85

Section of Law	Description	Date
5(e)	Consent Order; Substituted aliphatic acid halide; substituted hydroxylamine—requires the use of impervious gloves and protective clothing by workers when handling either substance, as well as the use of respirators when workers are exposed to vapors of substituted aliphatic acid halide pending development of information. Wastes resulting from production of substituted aliphatic acid halide must be incinerated. Wastes resulting from production of substituted hydroxylamine must be treated so that content is less than 10 ppm prior to discharge.	10/12/84
	Consent Order; Unsaturated aminoalkyl ester salt, unsaturated amino ester salt—requires the Company to inform workers of the hazard and provide labeling; requires workers to wear protective clothing, gloves and goggles, pending development of information. In addition, controls on use, commercial distribution, wastes and discharge, will be implemented. The same controls are also required of contract manufacturers.	10/30/84
	Consent Order with Testing Trigger; Substituted aryl olefin, Substituted alkyl arene—restricts the PMN substance to a maximum production volume pending 90-day subchronic testing to address the health effects.	11/15/84
	Consent Order: Poly[1-oxo-1,6-hexanediyl)]-alpha-hydro-omega-hydroxy-, ester with 3-hydroxy-2,2-dimethylpropyl-3-hydroxy-2,2-dimethyl propanoate(2:1), di-2-propanoate; Poly[oxy(1-oxo-1,6-hexanediyl)]-alpha-(1-oxo-2-propenyl)-omega-[(tetrahydro-2-furanyl)methoxy]; Poly[oxy(1-oxo1,6-hexanediyl)]-alpha-hydro -omega-hydroxy-, ester with 2,2'-[oxybis(methylene)]bis[2-(hydroxymethyl)-1, 3-propanediol]2-propenoate, 2-propanoate; 2-Propenoic acid, [2-[1,1-dimethyl-2-[(1-oxo-2-propenyl)oxy]ethyl]-5-ethyl-1,3-dioxane-5-yl]methyl ester; (Imported)—requires the use of protective equipment in the form of impervious gloves, safety goggles and protective clothing pending development of information. In addition, the importer will only sell to those who will process and use these substances in the same place.	12/04/84
	Consent Order; Phosphonium salt—requires workers to wear protective equipment.	12/10/84
	Consent Order; Disubstituted nitrobenzene — requires workers to wear protective equipment in the form of impervious gloves, goggles and protective clothing when handling this substance pending development of information.	12/27/84
	Consent Order; Substituted aminobenzoic acid ester— requires protective equipment in the form of impervious gloves, goggles, and protective clothing pending development of information.	12/27/84
	Consent Order; Polyaromatic urethane poly (unsaturated)ester—requires appropriate protective equipment, notification letters, and labeling pending development of information. Distribution of the PMN substance is also limited.	01/15/85
	Consent Order; Polyfunctional aziridine—requires protective equipment in the form of impervious gloves, goggles, protective clothing and respirators for workers pending development of information.	01/28/85
	Consent Order; *N*-Dimethylthiocarbamylthio-*N'*-phenyl urea—requires workers to wear gloves, protective clothing, and chemical safety goggles pending development of information.	2/01/85
	Consent Order; Methylammonium *N*-methyldithiocarbamate—requires protective equipment pending development of information.	02/09/85

tion law	Description	Date
	Consent Order with Testing Trigger; C_{6-8} Carboxylic acid—includes a production volume trigger, at which time the Company must submit developmental toxicity data. The Order also requires gloves, notification letters, labels, a Material Safety Data Sheet (MSDS) and standard teratology testing to address teratogenicity concerns.	02/14/85
	Consent Order; Epoxy ester—requires impervious gloves, protective clothing and chemical safety goggles for workers pending development of information.	02/16/85
	Consent Order; Polychlorofluoro aromatic alkylated hydrocarbon—requires the use of impervious gloves, a Material Safety Data Sheet (MSDS) and a label that limits worker exposure pending development of information.	03/01/85
	Consent Order; 6-Nitro-2(3H)-benzoxazolone—requires workers to wear protective equipment in the form of impervious gloves.	03/12/85
	Consent Order; 3-Alkyl-2-(2-anilino)vinyl thiazolinium salt—requires the use of safety goggles, impervious gloves, and chemical respirators; labeling, a notification letter with disposal and first aid procedures, and certain restrictions on manufacture and distribution of the chemical pending development of information.	04/09/85
	Consent Order; N-N'-Bis(2-(2-(3-alkyl)vinyl)-1,4-phenylenediamine double salt—requires the use of goggles, gloves, chemical respirators, labeling, a notification letter with disposal and first aid procedures, and certain restrictions on manufacture and distribution of the chemical pending development of information.	04/09/85
	Consent Order; Polyurethane—limits worker exposure and requires impervious gloves, safety goggles, protective clothing and respirators pending development of information.	04/16/85
	Consent Order with Testing Trigger: Alkyl ester—requires protective gloves and labeling to control worker exposure and a testing trigger for a 90-day oral or inhalation subchronic study.	04/20/85
	Consent Order; Polyurethane polymer—requires dermal protection, warning labels, a letter, and Material Safety Data Sheet (MSDS) notifying users of the requirements of the Order and the hazard concerns pending development of information.	04/27/85
	Consent Order; Alkylated diphenyl oxide—requires chemical safety goggles, impervious gloves and protective clothing to control worker exposure, pending a Chernoff screening test.	05/02/85
	Consent Order; Urethane acrylate—requires the use of protective equipment in the form of impervious gloves, safety goggles and protective clothing pending development of information.	06/11/85
	Consent Order with Testing Trigger; Alkyltrialkoxysilane—requires chemical safety goggles, impervious gloves, respirators, protective clothing and includes a testing trigger involving a 28-day repeated dose inhalation study.	06/18/85
	Consent Order; (1) Brominated arylamine—requires protective equipment for potentially exposed workers. In addition, the Order restricts the physical form in which the PMN substance may be distributed; (2) with Testing Trigger; Brominated aromatic—requires protective equipment for potentially exposed workers. The Order also includes a testing trigger involving a 90-day subchronic study, and restricts the physical form in which some of the PMN substances will be distributed; and (3) with Testing Trigger; Brominated arylamine amino—requires protective equipment for potentially exposed workers. The Order includes a testing trigger involving a 90-day subchronic study.	06/21/85
	Consent Order with Testing Trigger; Brominated arylcarbonate—requires protective equipment for potentially exposed workers. The Order includes a testing trigger involving a 90-day subchronic study and a second generation reproductive study. In addition, the physical form in which the PMN substance will be distributed is restricted.	06/21/85

Section of Law	Description	Date
	Consent Order; Carboxylated alkane diol—requires personal protective equipment to be worn to prevent exposure to the potential oncogen pending development of information.	6/22/85
	Consent Order; Methyl vinyl sulfone—requires protective equipment for workers in the form of impervious gloves, safety goggles, and protective clothing pending development of information.	06/25/85
	Consent Order; Polysubstituted polyol—This is the first Consent Order requiring processors to become co-signers of a PMN and the Order, subject to its terms. These measures allow increased distribution of the PMN substance pending the development of a Significant New Use Rule (SNUR).	07/02/85
	Consent Order; Polymer of hydroxyethyl acrylate, 4,4'-diphenylmethane diisocyanate, and polymethylene polyphenyl isocyanate—requires use of gloves, protective clothing over exposed body areas, chemical safety goggles, respirators during spray operations, employee safety training program, labeling, and recordkeeping pending development of information.	07/07/85
	Consent Order; Acrylic ester—requires use of NIOSH-approved respirators, protective clothing, chemical safety goggles, impervious gloves, workers safety training programs, written warnings, and recordkeeping.	07/12/85
	Consent Order; Functionally modified urethane—requires use of gloves, safety goggles and protective clothing, a respirator if spray application is used, employee safety training programs, labeling and recordkeeping pending development of information.	07/17/85
	Consent Order with Testing Trigger; Polymer of hydroxyethyl acrylate and polyisocyanate—requires gloves, goggles, protective clothing and a respirator pending development of information.	07/24/85
	Consent Order with Testing Trigger; Trisubstituted phenol—requires gloves, goggles, protective clothing and a respirator pending development of information.	07/27/85
	Consent Order with Testing Trigger; Ester modified phenolic resin—requires gloves, goggles, protective clothing and a respirator pending development of information.	08/09/85
	Consent Order; Benzenedisulfonic acid, Chlorotriazinylamino/dimethylphenylazo/sulfonaphthaleneazo (Imported)—prohibits manufacture in the U.S., limits quantity of PMN substances that can be imported, limits quantity sold to each customer each year to no more than two persons who discharge effluent wastes directly or indirectly into the same stream or river, and requires recordkeeping.	09/01/85
	Consent Order; Polymer of substituted aryl olefin; protective equipment in the form of impervious gloves, goggles and protective equipment and respirators.	09/06/85
	Consent Order; Vinyl epoxy ester—requires protective equipment in the form of impervious gloves, goggles and protective clothing.	09/09/85
5(h)(3)	Premanufacture Notification; Proposed Revisions of Regulation (Proposed Rule)	12/27/84
5(h)(4)	Premanufacture Notification Exemptions; Exemptions of Polymers (Final Rule)	11/21/84
	Premanufacture Notification Exemptions; Exemption for Chemical Substances Manufactured in quantities of 1,000 kg or Less Per Year (Final Rule)	04/26/85
6(d)	Asbestos Abatement Projects (Immediately Effective Proposed Rule)	07/12/85
6(e)	PCBs: Modification of Definition of Totally Enclosed Manner for PCB Activities (Final Rule)	11/08/84
	PCBs: PCBs in Electrical Transformers (Final Rule)	07/17/85
	PCBs: Proposed Incorporation by Reference Revision (Proposed Rule)	04/04/85

Section of Law	Description	Date
	PCBs: Response to Exemption Petitions (22) (Proposed Rule)	08/29/85
	PCBs: Response to Ward Transformer Company Petition for Exemption (Denial) (Final Rule)	08/29/85
8(a)	Preliminary Assessment Information; Amendment to Include 3,4-Dichlorobenzotrifluoride from the 14th ITC List (Proposed Rule)	11/05/84
	Reporting & Recordkeeping Requirements; Small Manufacturer Exemption Standards (Final Rule)	11/16/84
	Chemical Information Rule; Additional Automatic Reporting; Amendment to the Preliminary Assessment Rule (Proposed Rule)	11/19/84
	Preliminary Assessment Information; Amendment to Add Seven Chemicals from the 15th ITC List (Final Rule)	11/28/84
	Hexachloronorbornadiene; Proposed Submission of Notice of Manufacture, Import, or Processing and Determination of Significant New Use (Proposed Rule)	02/22/85
	Partial Updating of TSCA Inventory Data Base; Production and Site Reports (Proposed Rule)	03/12/85
	Preliminary Assessment Information; Amendment to include 3,4-Dichlorobenzotrifluoride from the 14th ITC List (Final Rule)	03/25/85
	Preliminary Assessment Information; Amendment to include Urea-Formaldehyde Resins (Final Rule)	05/03/85
	Preliminary Assessment Information; Amendment to include Five Chemicals from the 16th ITC List (Final Rule)	05/21/85
	Chemical Information Rules; Additional Automatic Reporting (Final Rule)	08/28/85
8(b)	Chemical Substance Inventory; Intent to Remove 106 Incorrectly Reported Chemical Substances from the TSCA Inventory (Proposed Rule)	05/07/85
8(c)	Records & Reports of Allegation of Significant Adverse Reactions to Health or Environment; Clarification of Persons Subject to the Rule (Proposed Rule)	12/24/84
8(d)	Health & Safety Data Reporting; Amendment to include 3,4-dichlorobenzotrifluoride from the 14th ITC List (Proposed Rule)	11/05/84
	Health & Safety Data Reporting; Submission of Lists and Copies of Health & Safety Studies (Proposed Rule)	11/19/84
	Health & Safety Data Reporting; Amendment to add Seven Chemicals from the 15th ITC List (Final Rule)	11/28/84
	Health & Safety Data Reporting; Amendment to add 3,4-dichlorobenzotrifluoride from the 14th ITC List (Final Rule)	03/25/85
	Health & Safety Data Reporting; Establishment of Termination Date (Final Rule)	04/25/85
	Health & Safety Data Reporting; Amendment to include Urea-Formaldehyde Resins (Final Rule)	05/03/85
	Health & Safety Data Reporting; Amendment to add Five Chemicals from the 16th ITC List (Final Rule)	05/21/85
	Submission of List and Copies of Health & Safety Studies on Vinyl Acetate (Proposed Rule)	08/08/85
	Health & Safety Data Reporting; Submission of Lists and Copies of Studies (Final Rule)	08/28/85
	Health & Safety Data Reporting Period Termination (sunset provision on 200 chemicals temporarily suspended) (Interim Final Rule)	09/30/85
	Health & Safety Data Reporting Period Terminations (removal of 7 chemicals from list) (Final Rule)	09/30/85
	Health & Safety Data Reporting; lengthening sunset provision on 250 chemicals (Proposed Rule)	09/30/85

Section of Law	Description	Date
	Submission of Lists of Copies of Health and Safety Studies in Certain Substances Subject to the 1984 RCRA Amendments (33 chemicals) (Proposed Rule)	10/07/85
9(a)	4,4'-Methylenedianiline; Decision to Report to the Occupational Safety and Health Administration	07/05/85
12(b)	Notification of Chemical Export; Applicability of Final Test Rule (Statement of Clarification)	11/19/84
21	Denial of Citizens' Petition to Eliminate or Reduce Disposal and Emissions of Toxic Substances into Environment of Southeast Chicago from Multiple Polluting Sources.	10/31/84
	Granted petition by the Natural Resources Defense Council, Inc., that EPA Ban Use of Asbestos in Original Equipment and Replacement Brakes for On-Road Cars and Trucks.	12/19/84
	Partial Grant of Environmental Defense Fund and National Wildlife Federation Citizens' Petition that EPA initiate multimedia investigations and research on dioxins and dibenzofurans. That EPA commence regulatory action was denied.	01/30/85
	Denial of Citizens for a Better Environment and Irondalers Against the Chemical Threat Citizens' petition that EPA issue a rule under section 4 requiring the scientific testing of certain toxic chemical substances and mixtures identified as pollutants in Southeast Chicago.	07/26/85
	Chemical Advisories	
	Notice of Potential Risk, *p-tert*-Butyl Benzoic Acid and Derivatives	03/85
	Notice of Potential Risk, 4,4'-Methylenebis(2-chloroaniline)	06/85

Appendix B

Summary Guide to Information Required by Congress

Sections 30, 28(c), and 9(d) of TSCA require that certain information be reported each year to the President and Congress. To assist readers in locating this information, a summary of each pertinent TSCA action and reference to a more detailed explanation found within this report are given here.

Section 30. This section contains the basic requirement for the Annual Report as follows:

(1) Testing. In FY 1985, EPA published 10 decisions not to test, 2 ANPR's, 6 notices of proposed rulemaking, and 3 final rules (see Table 4).

(2) Premanufacture Notices (PMNs). EPA received 1,478 PMN's during FY 1985 which brought the total received since the program's beginning in mid-1979, to 5,679. (None of these chemicals were subject to rulemaking under section 4.) In FY 1985, 21 cases underwent voluntary testing or control activities, while 45 chemicals were subject to the development of either a section 5(e) or 5(f) order (see Table 1).

(3) Rules Issued Under Section 6. During FY 1985 one immediately effective proposed rule was published under section 6 regarding asbestos. This rule, to protect state and local public employees not protected by current OSHA regulations, establishes a permissible exposure level and requires use of certain work practices during abatement activities (see Chapter 4, Existing Chemicals).

Five actions related to PCBs were issued in FY 1985. On November 8, 1984, a final rule was published modifying the definition of "totally enclosed manner" to more accurately reflect the Agency's framework for assessing PCB exposure. On July 17, 1985, a final rule was published addressing fire-related risks associated with PCBs in electrical transformers. On April 4, 1985, a proposed rule incorporating by reference certain test methods to be used to meet particular PCB testing requirements was published. On August 29, 1985, a proposed rule was published responding to 22 PCB exemption petitions. Also on August 29, 1985, a notice of denial was published in response to a PCB petition for exemption (see Chapter 4, Existing Chemicals).

(4) Judicial Actions under TSCA and Administrative Actions under Section 16. Judicial actions involved PCBs, asbestos, dioxins, significant new use rules, [EPA's testing program under section 4 of TSCA], section 21 citizens petitions, and confidentiality of business information under section 14 of TSCA. Parts of the PCB litigation are likely to be settled; two cases await decision. The asbestos case is pending. Two suits were filed to compel EPA to regulate, one with respect to dioxins and the other to require testing of certain chemical substances present in the southeast area of Chicago; both are pending. A petition for review was filed related to the first significant new use rule under section 5(a)(2); briefing has been stayed pending further rulemaking. A suit was filed challenging EPA's handling and disclosure of confidential business information; the case was settled with a consent order that requires reporting of certain changes to EPA's security procedures for handling such information (see Chapter 7, Litigation).

A total of 733 civil enforcement complaints were issued in FY 1985. In addition, there were 2 criminal and 6 civil referrals to the Department of Justice, and 1,136 Notices of Noncompliance were issued (see Chapter 6, Compliance and Enforcement).

(5) Major Problems in Administering the Act. No major problems were encountered in FY 1985 in administering TSCA.

(6) Recommended Legislation. No legislative changes are sought at this time.

Section 28(c). This section requires a report on grants to States during the year. There were no grants administered under TSCA in FY 1985. Grants associated with asbestos were administered under the authority of the Asbestos School Hazard Abatement Act (ASHAA) (see Chapter 4, Existing Chemicals).

Section 9(d). This section requires that EPA's efforts to coordinate its TSCA activities with related activities of other Federal agencies be reported annually.

During FY 1985, EPA continued, in several formal and informal agreements with other Federal government programs, to address specific chemical activities with respect to the development and implementation of regulations under TSCA. One of these continued efforts is participation in the Federal Asbestos Task Force, of which OSHA, the CPSC and EPA are charter members. Other members include the Food and Drug Administration, the National Institute of Occupational Safety and Health, National Institute of Environmental Health Sciences, and the National Cancer Institute.

In FY 1985, under an interagency agreement, EPA and NIOSH continued work on developing occupational exposure assessments on 1,3-butadiene, methylenebis(2-chlorobenzenamine) (MBOCA), acrylamide, and 4,4'-methylenedianiline, and control technology assessments on 1,3-butadiene and MBOCA. The purpose of this agreement is to use the occupational expertise of NIOSH in EPA's assessment program.

In FY 1985, the Agency was instrumental in forming an inter-agency group to examine high-priority solvents of concern not only to EPA, but also to other regulatory agencies. The workgroup examines solvents from a scientific policy standpoint in order to develop a coherent position in regulatory strategy development for the Federal government.

EPA is currently reviewing draft memoranda of agreement with OSHA and CPSC to ensure that chemical problems are handled expeditiously under the most appropriate authority. One chemical, 4,4'-methylenedianiline, was referred to OSHA for regulatory consideration. Another chemical, 1,3-butadiene, to be referred to OSHA, is undergoing final review.

The Agency continued to participate during FY 1985 on the Working Group on Biotechnology, established by the Cabinet Council on National Resources and the Environment. The group discusses major Federal interagency issues on biotechnology and develops a coordinated position on them. A joint statement was prepared by the Office of Science and Technology Policy, Food and Drug Administration, and the Department of Agriculture, and was published in December 1984. A final policy statement will be published in FY 1986.

The Agency continued its participation in an interagency agreement with the U.S. Army for a compilation of methods for estimating physicochemical properties of inorganic chemicals and metallo-organics. This project will enhance current capabilities used routinely for estimating properties of PMN chemicals.

In an interagency agreement with the National Bureau of Standards (Department of Commerce), a study was conducted to assess the state of fire toxicology, evaluate fire hazard models in use, and develop written guidelines for applying these methods to commercial use. Another study provides OTS with data on exposure to formaldehyde in an occupational setting, the plywood and textile industry.

Chemical Advisories are coordinated with other Federal agencies as appropriate.

Appendix C

Section 4 Test Studies* Received

Acrylamide
4-Chlorobenzotrifluoride
2-Chlorotoluene
Methyl Isobutyl Ketone/Methyl Ethyl Ketone
Isophorone
4-(1,1,3,3-Tetramethylbutyl)phenol
Tris(2-ethylhexyl) Trimellitate
Bis(2-ethylhexyl) Terephthalate
Alkyl Phthalates
Chlorinated Paraffins
Dichloromethane
1,3-Dioxolane
Oleylamine
Formamide
2-Phenoxyethanol
Aryl Phosphates
Propylene Oxide
Bisphenol A
Sodium N-Methyl-N-oleoyltaurine

*102 studies on 38 chemicals

Appendix D

Summary of NTP Studies

National Toxicology Program (NTP) Studies* Reviewed

Dichloromethane
o-Phenylphenol
4-Vinylcyclohexene
N-Butyl chloride
Chlorendic Acid
Tetrachloroethylene
Ephedrine Sulfate
8-Hydroxyquinoline
CI Basic Red 9 Monohydrochloride
Dimethyl Morpholinophosphoramidate
Decabromodiphenyl Oxide
CI Disperse Blue
HC Red No. 3
Sodium Hypochlorite Phosphate
Chlorinated Paraffins (C_{23}, 40% Cl)
Chlorinated Paraffins (C_{12}, 58% Cl)

*16 studies on 16 chemicals

Appendix E

Chemical Hazard Information Profiles (CHIPs)

Methyl bromide (update)	02/20/85
Phenylethanol	05/17/85
Phthalimide	07/03/85
Dimethoxyethyl Phthalate	07/22/84
Triethyl Phosphate	07/29/85
Dimethyl Hydrogen Phosphite	08/14/85
Nonylphenol	09/17/85
Vinylcyclohexene	09/19/85
Chloromethylpropene	09/19/85
Tri(alkyl/alkoxy)phosphates (4 Chemicals)	09/23/85
Dichloro-2-butene	09/26/85
Triphenyl Phosphite	09/27/85
DDE Resin	09/30/85

Substitute Hazard Profiles

Asbestos:	
Aramid fibers	11/02/84
Polytetrafluoroethylene	11/02/84
Polyethylene	11/02/84
Polypropylene	11/02/84
Polyester	11/02/84
Ductile Iron Pipe	11/02/84
Metalworking Fluids:	
Adipic Acid	02/08/85
Caprylic Acid	02/08/85
Azelaic Acid	02/08/85
Sebacic Acid	02/08/85
Dodecanedioic Acid	02/08/85
Stearic Acid	02/08/85
Mixtures of C_{11}, C_{12} Carboxylic Acids	02/08/85
Formaldehyde - Wood Uses:	
Methylene Diphenylene Diisocyanate (MDI)	06/11/85
Poly (MDI)	06/11/85
Phenol	06/11/85
Phenol Formaldehyde Resin	06/11/85
Ammonia	06/11/85
Methylene Chloride:	
1,1,2-Trichloro-1,2,2-trifluoroethane	09/26/85
Trichloroethylene	09/26/85
Tetrachloroethylene	09/26/85
Carbon tetrachloride	09/26/85
1,1,1-Trichloroethane	09/26/85

Appendix F

FY 1985 section 21 Citizens' Petitions

Date Filed	Who Filed	What Action Requested	EPA's Disposition	Date of Disposition
07/17/84	Citizens for a Better Environment and Irondalers Against the Chemical Threat	That EPA issue a rule to: 1. Clean up the Southeast section of Chicago, Illinois; 2. Conduct an investigation prior to rulemaking to study the health effects from many toxic substances in air, land, and water in the SE Chicago area; and 3. Use TSCA authorities to assess and remedy the public health situation as a whole, and not with piecemeal regulations.	Denied	10/31/84 49 FR 43764
09/11/8	Natural Resources Defense Council, Inc.	That EPA ban the use of asbestos in original equipment and replacement brakes for on-road cars and trucks.	Granted	12/19/84 49 FR 4931
10/22/84	Environmental Defense Fund and National Wildlife Federation	That EPA commence regulatory action on dioxins and dibenzofurans (denied) and initiate multimedia investigations and research (granted)	Partial Grant	1/30/85 50 FR 4426
4/23/85	Citizens for a Better Environment and Irondalers Against the Chemical Threat	That EPA issue a rule under section 4 requiring the scientific testing of certain toxic chemical substances and mixtures identified as pollutants in Southeast Chicago.	Denied	7/26/85 50 FR 30517