



Accomplishments And Goals In Reducing Toxic Chemical Risk

FY 1989 Report To Congress On The Toxic Substances Control Act (TSCA)

**(Including Activities Under Section 313, Emergency
Planning And Community-Right-To-Know Act Of 1986)**



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FOREWORD

The Toxic Substances Control Act of 1976 (TSCA), Public Law 94-469, authorized the Environmental Protection Agency (EPA) to identify and regulate chemical substances and mixtures that pose an unreasonable risk of injury or imminent hazard to health or the environment. This report, which covers fiscal year 1989, is the eleventh report to Congress on EPA's administration of TSCA as required in sections 30, 9(d), and 28(c) of the act.

In addition to discussing accomplishments during fiscal 1989, this year's report also discusses EPA's initiatives and strategic outlook for reducing the risk from toxic substances and preventing toxic pollution under TSCA and associated laws.

- Section I (chapters 1, 2, and 3) places the discussion in the context of the national problem of controlling toxic risk. The chapters provide background on the scope of the toxic risk problem, the nature of toxic risk and the role of TSCA and associated laws in chemical risk management and pollution prevention.
- Section II (chapters 4 through 12) addresses EPA program activities dealing with different aspects of the toxic risk problem, integrating into the discussion what has been accomplished, what goals have been set, and what strategies are being considered to achieve these goals in the 1990s.
- Section III contains appendices which provide additional detail on program accomplishments.

This report does not include activities under TSCA Title III (the Indoor Radon Abatement Act, Public Law 100-551). Those activities are reported on separately by EPA's Office of Air and

Radiation Programs in its Report to Congress on Radon Assessment and Mitigation Under Section 118(k), the Superfund Amendments and Reauthorization Act of 1986 (SARA).

HIGHLIGHTS OF FISCAL 1989

In carrying out its mandates under the laws it implements to control toxic chemical use, EPA's Office of Toxic Substances has set the following major goals:

- to ensure that new chemicals, including products of biotechnology, do not enter commerce without appropriate controls;
- to identify existing chemicals that pose unreasonable risks;
- to reduce risks from future marketing and use of existing chemicals;
- to remove especially toxic chemicals, such as asbestos and polychlorinated biphenyls (PCBs), from continued use;
- to ensure strong compliance with and research and development in support of these goals.

Some highlights of agency actions taken in fiscal 1989 to advance these goals follow. (These actions--and many others--are discussed in greater detail in the body of this report.)

Ensuring Control of New Chemicals

The New Chemicals Program is one of the agency's principal pollution prevention programs. Its function is to prevent potential chemical pollutants that have been determined to be hazardous to human health or the environment from entering commerce or the environment.

- In fiscal 1989, the agency received over 1,000 premanufacture notices (PMNs), increasing the total since TSCA's enactment to 12,600. EPA also received voluntarily submitted test data for 53 chemicals and data on eight chemicals as a result of consent orders.
- EPA implemented its exposure-based policy for testing new chemicals in fiscal 1989. This policy requires basic toxicity testing of new chemicals that exceed set production volume, exposure, or release criteria, regardless of the chemical's structural characteristics.
- The agency took steps to make regulation of new chemicals and new chemical uses more efficient: (1) it adopted new procedures that significantly expedite the negotiation and promulgation of consent orders; (2) it published a "generic" rule that makes regulation of new uses of chemicals much more efficient.

Identifying Existing Chemicals That Pose Unreasonable Risk

The Existing Chemicals Program uses a multifaceted strategy to identify which of the thousands of existing chemicals pose unreasonable risks. The components of that strategy are the following:

- screening new data on chemicals to identify new hazards;
- collecting data from industry on manufacturing and use of chemicals of concern;
- requiring industry to conduct studies to fill data gaps on chemicals of concern;

- collecting data on annual emissions and discharges of toxic chemicals and making those data available to the public and to other environmental programs at the federal, state, and local levels;
- conducting risk assessments on suspect chemicals to determine whether controls should be imposed on their future use.

Highlights of fiscal 1989 EPA efforts to identify existing chemicals that pose unreasonable risk include the following:

- The first public release of Toxics Release Inventory (TRI) data, for the 1987 reporting year, occurred in fiscal 1989. (Although the TRI is required not under TSCA, but under section 313 of the Emergency Planning and Community Right-to-Know Act of 1986 [EPCRA], which is title III of SARA, the program is being implemented by the Office of Toxic Substances and the data the program provides are used extensively to implement TSCA.) TRI data are self-reported industry estimates of releases to air, water, and land and of transfers for disposal of over 300 chemicals and chemical categories. For the 1987 reporting year, over 19,000 facilities across the United States submitted TRI reports. Particular efforts were made to help states, other federal agencies, interest groups, and the public obtain access to, interpret, and use TRI data for toxic chemical risk screening and management. The agency published the information submitted, in summarized form, in The Toxics Release Inventory: A National Perspective, which was made available to the public.
- A number of major risk assessment and risk management support activities were initiated or were in progress in

fiscal 1989, including ones concerning CFC substitutes, inhalation exposure to formaldehyde, inert ingredients in pesticides, polychlorinated dibenzo-p-dioxins (PCDDs), polychlorinated dibenzofurans (PCDFs), dioxin in paper, and substitutes for acrylamide grouts.

- Test data received by EPA in fiscal 1989 increased by 25 percent over previous years. In addition, the chemical testing program initiated several major activities important to future progress in the program, including (1) streamlining the program to enable other EPA programs, including Superfund, to nominate chemicals for testing; (2) negotiating programs with chemical trade associations that allow EPA to obtain information useful to both the Existing and New Chemicals Programs; and (3) promulgating a testing exemption rule for chemicals used in research and development and for low-volume chemicals.

Reducing Risks from Marketing and Use of Existing Chemicals

The Existing Chemicals Program focuses on chemicals for which there is maximum potential for reducing risks through government intervention and that cannot be controlled effectively by other federal regulatory programs. Some examples of fiscal 1989 work in this area follow:

- Safe use and disposal of PCBs still in service remain the principal focus of the PCB program. In fiscal 1989, the agency also directed attention to high-volume/low-concentration problems related to PCBs, such as those associated with non-metallic debris ("fluff") from shredding automobiles and household appliances and with groundwater contamination caused by improper disposal of PCB condensate from natural gas pipelines.

- By the end of fiscal 1989, as a result of EPA's efforts to ensure compliance with the requirements of the Asbestos Hazard Emergency Response Act (AHERA), 94 percent of the nation's schools had completed asbestos inspections and developed asbestos management plans. To date, EPA has approved over 1,300 accreditation training courses and 15 state accreditation programs to establish an infrastructure of trained asbestos inspectors, planners, and supervisory personnel. In concert with the National Education Association and the National Parent Teachers Association, EPA published The ABCs of Asbestos in Schools to inform parents and teachers about asbestos and the responsibilities of school officials under AHERA.
- In support of asbestos abatement programs in schools, EPA awarded \$45 million in loans and grants under the Asbestos School Hazard Abatement Act (ASHAA) in fiscal 1989 to help needy schools control asbestos risks. Since 1985, over \$200 million in ASHAA funds have been issued for 2,200 abatement projects, which have the potential to reduce students' and employees' exposure to asbestos by more than 17 million exposure-hours a week.
- A cross-program effort was under way in fiscal 1989 to explore the use of TSCA section 6(a) to encourage the recycling of lead-containing products. The agency is also considering use of TSCA authorities to reinforce existing proscriptions on the use of lead solder in potable water plumbing. In addition, EPA is helping the U.S. Department of Housing and Urban Development (HUD) in its effort to mitigate risk from lead-based paint by (1) developing information for a demonstration of techniques for abating lead-based paint problems in single- and multi-family housing, for conducting a

national survey of the lead-based paint hazard in housing, and for a comprehensive plan to address the hazard; and (2) training program administration personnel and abatement contractors and designers.

Removing Unreasonably Toxic Chemicals from Continued Use

Because some chemicals pose such an unreasonable risk that controls on their use are not sufficient to protect the environment and public health, those chemicals must be removed from continued use.

- In July 1989, EPA published the Asbestos Ban and Phase-out Rule, which bans the manufacture, importation, and processing of about 94 percent of asbestos products by 1997. This regulation will reduce long-term environmental contamination by asbestos and exposures that pose serious health problems.
- In fiscal 1989, EPA prepared final action (issued in January 1990 and effective in May 1990) to prohibit the use of hexavalent chromium, a potent human carcinogen, in comfort cooling towers, which are an integral part of heating, ventilation, and air conditioning systems.

Ensuring Strong Compliance

The toxic substances enforcement program consists primarily of a nationwide program of compliance inspections using federal, state, and contractor support. Highlights of fiscal 1989 compliance and enforcement activities include the following:

- Cooperative programs to monitor compliance with PCB and asbestos regulations continued. States conducted about 1,300 asbestos compliance inspections and about 800 PCB

compliance inspections. In cooperation with 16 states, EPA conducted over 2,400 PCB compliance monitoring inspections and 1,500 asbestos inspections.

- EPA issued 415 administrative complaints under TSCA in fiscal 1989. The agency completed another 319 civil actions and collected over \$4 million in penalties.
- Fiscal 1989 marked the first full year of enforcement of TRI reporting requirements. EPA conducted more than 750 on-site inspections, issued more than 110 administrative complaints, and proposed total penalties exceeding \$4 million. In two major enforcement campaigns, EPA filed coast-to-coast complaints that encouraged greater compliance by industry.

Research and Development

EPA's Office of Research and Development supports the toxic substances program with work aimed at developing, evaluating, and validating health and environmental test methodologies and procedures to improve the predictability of risk estimates, develop exposure monitoring systems, devise environmental fate and effects methods, and provide guidelines for risk assessments. In fiscal 1989, research and development activities associated with the toxic substances program included the following:

- developing a model for assessing indoor air exposure to such chemicals as formaldehyde and chlorinated solvents.
- developing short-term, cost-effective predictive methods for detecting and assessing toxic effects of chemicals.
- developing structure-activity relationships (SARs), through which chemicals can be categorized and grouped,

on the basis of similar molecular structures, for more rapid determination of probable toxicity and risk.

- establishing a scientific information resource to provide more insight into how plants, animals, and ecosystems are affected by toxic substances.

The Environmental Protection Agency's Office of Toxic Substances implements programs under four environmental statutes, all focused on control of toxic chemical use.

- The Toxic Substances Control Act (TSCA) gives EPA the authority and responsibility to protect human health and the environment from unreasonable risks arising from the manufacture, distribution in commerce, use, or disposal of existing and new chemicals.
- The Asbestos School Hazard Abatement Act (ASHAA) directs EPA to help states and local education agencies determine the extent of risks from exposure to asbestos-containing materials in schools.
- The Asbestos Hazard Emergency Response Act (AHERA), title II of TSCA, establishes inspection and abatement requirements for all public and private elementary and secondary schools and requires that EPA examine the issue of asbestos in public and commercial buildings.
- Section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA) of 1986 requires EPA to establish an inventory of toxic chemical emissions from certain facilities.

SECTION I.

UNDERSTANDING TOXIC CHEMICAL RISK

1. SCOPE OF THE TOXIC CHEMICAL RISK PROBLEM

This chapter discusses the scope of the national toxic chemical risk problem in terms of the number of chemicals in commerce, production volumes, uses, examples of the presence of toxic chemicals in the environment, and the need for chemical testing and risk assessment.

Chemical Inventories

TSCA chemical inventory. This inventory, compiled by EPA in accordance with TSCA, lists more than 68,000 chemicals manufactured or processed in the United States since 1975. About 6,200, less than 10 percent, have undergone some review by the toxic substances program. A few hundred of these are regulated by federal and state environmental programs. Of the chemicals which have not been reviewed by EPA, almost two-thirds (about 64 percent) are currently produced in levels below 10,000 pounds per year and thus are not considered priority chemicals. One-third of the 36 percent of chemicals not yet reviewed but produced in excess of 10,000 pounds per year are polymers, which are generally viewed as being of less concern. This leaves approximately 14,000 substances on which EPA attention is focused either because of their nature or their production in high volumes. Little or nothing is known about exposure potential or hazard of most of these chemicals.

Adding to the magnitude of managing chemical information are thousands of new chemicals developed annually for commercial use. Some of these may be toxic and may present unreasonable risks to health or the environment if not controlled. Most new chemicals have little toxicity data when they are ready to go into use, and economic forces within the marketplace are insufficient to lead to elimination of unreasonable risk. Controls on the entry of

new chemicals are therefore necessary to protect public health and the environment.

Toxics Release Inventory. In response to new requirements imposed by section 313 of EPCRA, manufacturers and processors reported that more than 22 billion pounds of 328 toxic chemicals and chemical categories were released or transferred for disposal in 1987. (Certain high-volume, low-toxicity chemicals have subsequently been removed from TRI reporting requirements. If these chemicals were removed from the 1987 TRI, the numbers reported for that year would be reduced to 6.97 billion pounds.) Successively smaller reporting thresholds take effect under EPCRA in 1988 and 1989, and more firms will be brought into compliance with reporting requirements. Sufficient exposure to chemicals covered by section 313 may present a risk of acute or chronic adverse health and environmental effects. All levels of government, as well as the general public, can access and use the TRI database in developing action to reduce exposure to toxic chemicals.

Examples of Toxic Chemicals in the Environment

Asbestos and PCBs have been the subject of special concern, in law and regulation, for the past 20 to 30 years. They have been targets of large regulatory efforts in EPA and provide important examples of the scope and complexity of the problem of assessing and eliminating unreasonable toxic chemical risk.

Asbestos. The "magic mineral" is a naturally occurring family of fibers, which are heat-resistant, odorless, and very durable. Because of these attributes, asbestos has found widespread use in both construction and industry. It is also carcinogenic to humans and in occupational settings can cause a chronic lung disorder, known as asbestosis, and other disease. The potential for harm to people from asbestos depends largely

upon exposure factors--where it is located, the type, frequency, and severity of disturbances to which it is subjected, and whether the material is damaged and to what extent.

Surveys conducted by EPA indicate that asbestos-containing material (ACM) is found in about 31,000 schools and 733,000 other public and commercial buildings nationwide.¹ About half these buildings may have at least some damaged ACM, often thermal system insulation or pipe and boiler wrap in maintenance areas. It is generally accepted that building occupants have a lower potential exposure than maintenance and service workers. When asbestos-containing material is disturbed, however, the possibility of exposure may increase.

PCBs. The amount of PCBs in service has shown some decrease. In 1988, EPA estimated that 282 million pounds of PCBs were in service, down from an estimated 750 million pounds in 1976. (About 1.5 billion pounds of PCBs were produced in the United States from 1929 until 1976.) Because of their stable chemical nature and other characteristics, PCBs have found widespread use as coolants and dielectric fluids in transformers and capacitors, as heat transfer fluids, and as coatings to reduce flammability. PCBs were also widely used in paints, printing inks, dust control agents, and pesticides.

Due to their widespread commercial use and chemical stability, PCBs have become highly dispersed in the environment. Measurable amounts can be found in soils, water, and fish throughout the world. PCBs are also bioaccumulative, and EPA's National Human Adipose Tissue Survey has revealed detectable

¹ Sources: Evaluation of the Asbestos-in-schools Identification and Notification Rule, 1984, USEPA (No. 560/5-84-005), p. xii; and Asbestos in Buildings: A National Survey, 1984, USEPA (No. 560/5-84-006), p. ix.

concentrations in almost all Americans. Exposure to PCBs and some of their combustion by-products can produce carcinogenic and other toxic effects.

Congress specifically banned the manufacture of PCBs in the original enactment of TSCA. It is now clear, however, that phasing out the use of PCBs in new products and managing the large stock of concentrated PCBs found in electrical transformers and capacitors may address only part of a much broader problem. Throughout the United States, soil and structures are contaminated with PCBs from past use, and a variety of products still contain low concentrations of the chemicals. Addressing these problems requires broader involvement of federal and state agencies.

Need for Information

Testing and risk assessment. Asbestos and PCBs are prominent examples of substances in the chemical inventories whose potential risks to people or the environment are sufficiently well known to justify regulatory action. Information about many other chemicals, however, is insufficient to determine whether regulatory action is necessary. A program of testing and risk assessment is essential to provide the needed information. Asbestos substitutes, substitutes for chlorofluorocarbons (CFCs), acrylates, formaldehyde, "inert" ingredients in pesticides, dioxin in wood pulp, brominated flame retardants, vinyl acetate, and others were the subject of EPA testing and risk assessment activities in 1989.

Biotechnology. Among new developments are products of biotechnology, including genetically engineered microorganisms. While expected to provide significant benefits to society in the form of drugs, pesticides, agricultural products, and pollutant degradants, there are concerns about the potential effects of these new commercial products on health and ecological systems.

Microorganisms have the ability to spread in the environment, creating the possibility that they will produce health or environmental effects distant from the site of release; products developed in one locality may pose unforeseen risks in another. The rate of development in biotechnology and the novel health and environmental issues posed by its commercial products create a major challenge in acquiring toxicological data and fashioning new tools for risk assessment and risk management.

NEXT ... Chapter 2 discusses what "toxic chemical risk" means and what factors determine the severity of such risk to health and the environment.

2. NATURE OF TOXIC CHEMICAL RISK

TSCA Objective: Eliminate Unreasonable Risk

The primary objective of TSCA is the elimination of unreasonable risk to health or the environment by chemical substances and mixtures. Reaching this objective does not necessarily require banning a chemical that poses an unreasonable risk, nor does it mean maximum risk reduction. Rather, the requirement is to reduce risk to a reasonable level. This goal can be achieved either through regulatory or voluntary means (such as stimulating industry to develop safer substitutes and reduce unnecessary exposures). Under TSCA, making a finding of unreasonable risk requires a balancing of risks to health and the environment against economic and social costs. The first step in the balancing process is to develop an adequate understanding of the nature of risk posed by a chemical.

Risk cannot usually be directly monitored or measured. Rather, risk is assessed from the measurement, modeling, or analysis of the components of risk--toxicity, potency, dose, and exposure. Assessing chemical-specific risk is therefore a complex scientific and technical endeavor.

Components of Risk

Toxicity. This refers to the ability of a chemical to damage an organism. The risk associated with a toxic chemical is primarily dependent on the chemical's potency, route of exposure, dose, and frequency and duration of exposure.²

Potency. This refers to a dose-response relationship (the concentrations at which a toxic chemical can cause adverse health

² Chemical Exposures: Effects on Health, EPA, 6/87

or environmental effects). Potency is chemical-specific and independent of whether living organisms actually contact the chemical.

Exposure. This deals with the intensity and duration of contact by organism with a chemical through eating, drinking, breathing, or skin contact. Without exposure there is no risk.

Dose. This is the amount of a chemical that enters the body. A person's susceptibility relative to dose is determined by whether exposure is to a combination of chemicals as well as by the exposed person's age, health, nutrition, and history of previous exposures.

In short, toxic risk is a function of how much of a chemical an individual is exposed to, how often, for how long a time, and by what means. Table 2-1 summarizes these and other factors affecting toxicity.

Acute and Chronic Toxicity

The damaging effects of chemical toxicity may result from an acute (brief) exposure, or from chronic (repeated or long-term) exposures.

Acute toxicity. Acute effects often involve high doses over a period measured in minutes or hours. Some chemicals are acutely dangerous in very small doses. For many acutely toxic chemicals, however, effects are often reversible after exposure stops.

Chronic toxicity. Effects from chronic exposure to toxic chemicals occur after a long period, 20 or 30 years in the case of cancers. Information on chronic effects is usually based on animal studies, which are time consuming, complex, expensive, and

require extrapolation from high test doses to the lower doses to which people are exposed. As a consequence of these complications, chronic effects are unknown for many chemicals.

Risk Assessment

A risk assessment is a scientific evaluation that integrates information on:

- a chemical's adverse effects,
- research estimates of human and environmental dose-response relationships,
- judgments on the type and number of human and non-human organisms affected under different conditions of exposure, and
- the uncertainties involved in these estimates and judgments.

A risk assessment produces a characterization of risk which provides both qualitative and quantitative estimates of the nature and probability of damage to humans and other organisms. Such results are vital inputs to EPA and other organizations that make decisions to regulate or manage toxic risk.

Next ... Chapter 3 discusses the regulatory authorities which Congress provided EPA under TSCA and associated laws to manage toxic chemical risk and prevent toxic pollution.

Table 2-1. Factors Affecting Toxicity

Properties of the individual chemical

- Small differences in chemical structure can produce large differences in organism's ability to absorb, metabolize, or excrete a chemical.

Dose, frequency, and duration of exposure

- Acute and chronic exposure effects of a chemical may differ.
- Effects are related to ability of organism to detoxify chemicals.
- Small doses may be tolerated because of organism's ability to metabolize or excrete a chemical.
- Large doses or chronic exposure may produce toxic effects through bioaccumulation.

Route of exposure

- Whether a chemical is inhaled, ingested, or absorbed through the skin is an important determinant of toxicity because each produces a different pattern of metabolism, distribution, or excretion.
- Chemicals differ in which route of exposure produces the most toxic effects.
- Some chemicals are blocked by protective barriers (skin, cilia, etc.), while others are not.

Other environmental exposures

- Toxicity is affected by exposure to a combination of chemicals.
- Exposure need not occur at same time to cause interactive effects.
- Interactive effects can be additive, synergistic, or neutral.

Individual susceptibility

- Age, sex, nutritional and immunological status, genetic characteristics, and state of health affect individual response to toxic chemicals.

Source: Toxic Chemical Release Inventory Risk Screening
Guide (Version 1.0), Vol.1, EPA560/2-89-002,
EPA/OTS, 7/89,
p. 24

Table 2-2. Human Health Effects of Toxic Chemicals

- **Carcinogenicity:** Ability to cause cancerous tumor formation in tissue.
- **Heritable gene and chromosome mutations:** Genetic changes occurring in germ cells, including deficiencies, duplications, insertions, inversions, and translocations of chromosomes, as well as gains or losses of whole chromosomes.
- **Neurotoxicity:** Any adverse effect on the structure or function of the central and/or peripheral nervous system related to exposure to a chemical substance.
- **Reproductive and developmental toxic effects:** Reproductive toxic effects are adverse effects on the male or female reproductive systems, while developmental effects are adverse effects on the developing organism, including death, structural abnormalities, altered growth, and functional deficits (e.g., learning disorders). Developmental toxicity also includes teratogenic effects, which are structural abnormalities which may adversely affect a developing organism.
- **Other chronic effects:** Any adverse effects other than cancer from long-term repeated chemical exposure.
- **Adverse and acute effects:** Adverse effects are any deleterious effects suffered by an organism, while acute effects occur rapidly as a result of short-term exposure to a high concentration of a chemical.

Source: Toxic Chemical Release Inventory Risk Screening Guide (Version 1.0), Vol.1, EPA560/2-89-002, EPA/OTS, 7/89, p. 22

Table 2-3. Environmental Effects of Toxic Chemicals

- **Environmental toxicity:** EPA's indicators of toxicity are particularly concerned with aquatic and avian acute lethal effects, and adverse chronic effects through the food chain.
- **Toxicity and persistence:** EPA is especially concerned about chronic toxicity caused by chemical persistence.
- **Toxicity and bioaccumulation:** Chemicals with high bioconcentration factors have a potential for build-up in the food chain with consequent potential adverse effects on aquatic, terrestrial, and avian organisms.
- **Any significant adverse effect on the environment:** This includes "any ecologically significant change in species interrelationships, such as changes in species behavior, growth, or survival that, in turn, adversely affect the behavior, growth or survival of other species" (section 8(e) of TSCA).

Source: Toxic Chemical Release Inventory Risk Screening Guide (Version 1.0), Vol.1, EPA560/2-89-002, EPA/OTS, 7/89, p. 23.

3. ROLE OF TSCA AND ASSOCIATED LAWS IN TOXIC CHEMICAL RISK MANAGEMENT

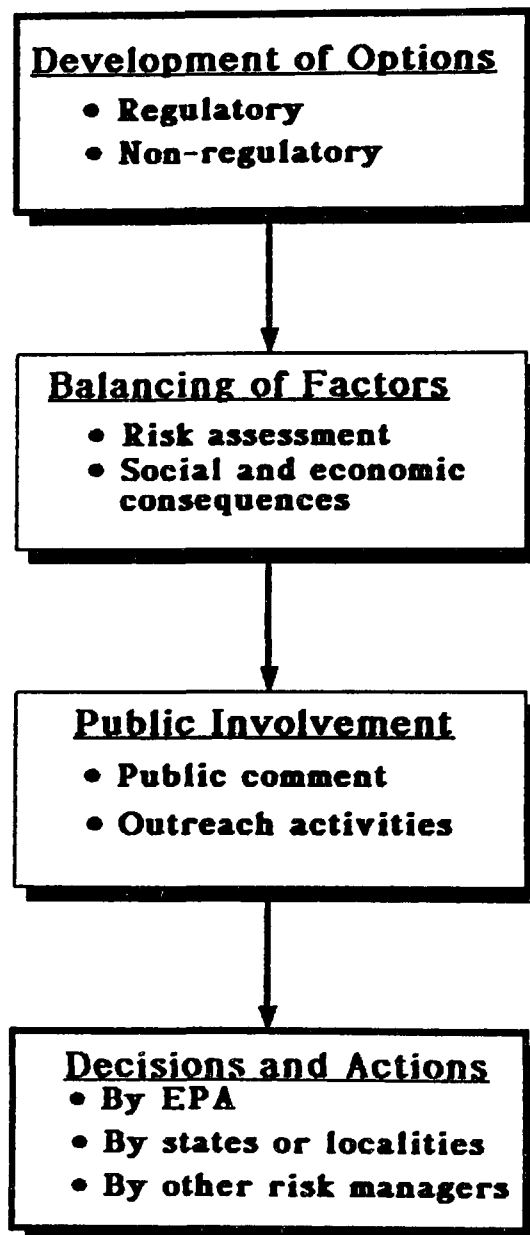
Risk Management

The process of risk management comprises all of the steps taken by EPA in the course of decisionmaking. It involves risk assessment (see chapter 2); development of regulatory and non-regulatory control options; balancing risk against social and economic factors; and public involvement. Figure 3-1 depicts the risk management process.

EPA has diverse responsibilities and authorities under TSCA title I, TSCA title II (AHERA), ASHAA, and EPCRA. Under TSCA title I, EPA is charged with carrying out the full risk management process. EPA has the regulatory authority to control chemicals in all environmental media, including chemicals that are subject to regulation under certain other environmental statutes; EPA can:

- intervene throughout the chemical lifecycle to reduce unreasonable risks during manufacturing, processing, distribution in commerce, use, and disposal;
- require testing of existing chemicals that may present an unreasonable risk to people or the environment;
- require testing of existing chemicals that are produced in substantial quantities and that enter or may enter the environment in substantial quantities or which may have significant or substantial human exposure;
- prevent pollution by regulating new chemicals and new uses of existing chemicals;
- effect cooperation among overlapping legal authorities;
- enforce remedies, including chemical product labeling and outright bans; and
- seek penalties and settlements to achieve compliance.

Figure 3-1. The Process of Risk Management



The provisions of AHERA, ASHAA, and EPCRA allow EPA to support the risk management process of other government bodies and agencies by promulgating regulatory standards, disseminating information, and providing technical and financial assistance.

Regulation of Asbestos and PCBs

AHERA, passed by Congress in 1986, is one of a group of laws (including the Clean Air Act, Occupational Safety and Health Act, and others) that regulates exposure to asbestos in occupational and non-occupational settings. AHERA requires public school districts and private schools, called local education agencies, to inspect their buildings for asbestos hazards, prepare asbestos management plans, and carry out response actions in accordance with EPA regulations. Local education agencies must also notify parent and teacher organizations about the availability of management plans. Implementation of plans began on July 9, 1989.

AHERA also requires state accreditation of asbestos inspectors, planners, and abatement workers, and the certification of testing laboratories in accordance with EPA standards.

AHERA directed EPA to study and report on asbestos exposure risks in public and commercial buildings. This was completed in February 1988 and outlined the agency's short-term plan for addressing asbestos in these facilities. In addition, the law established the Asbestos Trust Fund to receive enforcement penalties and loan and grant repayments from awards made under ASHAA.

ASHAA, signed into law in 1988, provides loans and grants to needy schools to abate serious asbestos hazards in their buildings. Through 1989, about \$202 million has been provided to 1,571 schools for nearly 2,200 individual abatement projects.

Asbestos risks are also managed under section 6 of TSCA, which has recently been used to ban or phase out future use of asbestos products. Asbestos risk management efforts may also involve cross-media cooperation among EPA programs, such as asbestos air emissions under the Clean Air Act and asbestos disposal under the Resource Conservation and Recovery Act (RCRA).

As in the case of asbestos in schools under AHERA, Congress explicitly required regulation of PCBs under TSCA section 6(e). PCB health and environmental threats are diverse and ubiquitous. Consequently, while EPA is the primary manager of PCB risks, the involvement of the states is essential to effective risk management.

Accomplishments during fiscal 1989 and goals in managing the risks of asbestos, PCBs, and other substances under TSCA are discussed in chapter 7.

Toxics Release Inventory

EPCRA section 313 created the TRI, the first and only multi-media environmental release database, to inform the public and all levels of government of routine releases of more than 300 toxic chemicals and chemical categories.

Affected businesses included under Standard Industrial Classification codes 20 through 39 must submit reports annually to the host state and to EPA on releases from facilities to air, water, and land. Reporting is required of manufacturers and processors of at least 75,000 pounds of any of the listed chemicals during 1987, 50,000 pounds during 1988, and 25,000 pounds during 1989, and of users in any other way of 10,000 pounds or more during those and subsequent years. (Manufacturers and processors are also required under other sections of EPCRA to make reports to certain local authorities.) All sources of waste

are to be considered, including those listed in Table 3-1.

Accomplishments and goals under EPCRA section 313 are discussed in chapters 6 and 7.

Summary

Taken together, TSCA title I, AHERA, ASHAA, and EPCRA provide a broad base of authority to develop a more integrated multi-media, multi-chemical approach to toxic risk management and pollution prevention. Integration can be accomplished through:

- more effective use of information as a risk reduction tool; and
- more cooperation and burden-sharing among the "toxics community," the domestic and international groups concerned with control of toxic substances.

Next ... Section II (chapters 4 to 12) discusses fiscal 1989 accomplishments in testing, information management, assessing and managing toxic risk, and preventing toxic pollution under TSCA title I, AHERA, ASHAA, and EPCRA. Also discussed are goals and strategies for instituting improvements in risk management and pollution prevention over the next several years. Details of fiscal 1989 accomplishments are supplemented in Section III.

Table 3-1. Some Sources of Industrial Toxic Chemical Releases

Fugitive or non-point sources

- Equipment leaks from pumps, valves, flanges
- Building ventilation systems
- Evaporative losses from surface impoundments

Stack and other point air sources

- Vents from reactors and other process vessels
- Storage tank vents
- Stacks or vents from pollution control equipment

Water sources

- Process outfalls
- Washings from containers, etc.
- Pollution control devices
- Stormwater runoff

Solids, slurries, and non-aqueous sources

- Filter cakes
- Spent catalysts
- Pollution control wastes and treatment sludges
- Vessel or tank residues
- Spills and sweepings
- Spent solvents
- Byproducts

Source: Estimating Releases and Waste Treatment Efficiencies for
the Toxic Release Inventory Report Form, EPA560/
4-88-002, EPA/OTS, 1987

SECTION II.

PROGRAM ACCOMPLISHMENTS AND STRATEGIES

4. TESTING EXISTING CHEMICALS

Background

Section 4 of TSCA gives EPA authority to require manufacturers and processors to test an existing chemical, if EPA finds that:

- the chemical may present an unreasonable risk to health or the environment, or that the chemical is or will be produced in substantial quantities, and (a) it may enter the environment in substantial quantities, or (b) there may be significant or substantial human exposure or substantial environmental release; and
- insufficient data exist about health or environmental effects of the chemical to predict the impacts of its manufacture, processing, distribution in commerce, use, or disposal; and
- testing is needed to develop data on which to make such predictions.

If EPA makes these findings for a chemical or category of chemicals, it can issue a test rule to require tests of health and environmental effects, chemical fate, or any other test relevant to risk assessment (i.e., exposure). To expedite the testing, EPA and test sponsors may agree to an enforceable consent order.

EPA's Chemical Testing Program was established under section 4 of TSCA. Test priorities for existing chemicals are recommended to EPA by the Interagency Testing Committee (ITC). The ITC was established by section 4(e) and consists of representatives from 18 federal agencies, including EPA. The ITC categorizes chemicals for testing as either designated or non-designated. EPA is required under section 4(e) to respond to ITC-designated chemicals by initiating rulemaking within twelve months or publish its reasons for not doing so. Non-designated

chemicals are dealt with expeditiously, but resource constraints may affect the review process for these chemicals. ITC recommendations do not exclude EPA from establishing independent chemical testing priorities.

The ITC and EPA also coordinate priorities for testing with other federal agencies and international organizations. EPA routinely reviews the studies of other agencies and the scientific literature for relevance to the agency's risk assessment and risk management activities.

Accomplishments During Fiscal 1989

Chemical testing actions. The Chemical Testing Program noted significant accomplishments in fiscal 1989:

- Data on 35 chemicals were received under section 4(a) test rules (chemicals listed in Appendix B)
- Five test rules were proposed
- Eight final test rules were issued
- Five testing consent orders were issued
- Three procedural rules were developed

Appendix C gives details on these rules and consent orders and on other actions. In addition, 22 testing rules are under development.

Promulgated test rules and consent orders have generated a 25 percent increase in the amount of data received compared to previous years. Further increases in data are expected as laboratories complete ongoing testing and initiate new tests.

EPA estimates that it will cost \$5.8 million to \$10.9 million for industry to conduct the tests that were required by

rules promulgated in fiscal 1989. Industry will also bear the cost for testing required by consent orders.

Initiatives Affecting Future Program Success

Program streamlining. The Chemical Testing Program made its rulemaking process more efficient to better utilize testing resources. As a result, it is now accepting the nomination of chemicals arising from EPA's implementation of other laws, such as RCRA and SARA, provided they meet the TSCA section 4 requirements described above.

Exemption rule. The Chemical Testing Program amended its procedural rule in order to treat manufacturers who produce chemicals in low volume or who produce chemicals for research and development as processors are treated.

Testing agreements with industry. Negotiations have been conducted with chemical trade associations to obtain test data on existing chemicals. This information will be used as a database to provide analog data for use in TSCA section 5 new chemical assessments. In May 1989 a consent agreement for acrylates was negotiated with the Special Acrylates and Methacrylates (SAM) Panel of the Chemical Manufacturers Association. This agreement enables EPA to collect data on a large category of chemicals. The acrylates agreement is discussed more fully in chapter 5.

Strategy for the 1990s

Goals. The challenge for EPA and other members of the toxics community is to accelerate the pace of screening and testing of chemicals. In the 14 years since the enactment of TSCA, relatively few chemicals have been screened. (See chapter 1.) While some of the unscreened chemicals may be polymers or others of low risk, the large number of remaining unscreened

chemicals requires us to seek more effective and productive ways to go beyond managing the risks we know about, to determining what risks exist and managing these risks.

Means to achieve goals. EPA envisions two strategic steps to speed up the screening and testing program significantly: First, the agency needs to develop a priority list for screening and testing purposes. High-exposure chemicals must be of top concern because, if they are toxic, high risk will result unless controls are imposed. Persistent bioaccumulative chemicals should also get early attention for similar reasons.

Second, the assistance of other agencies and countries in sharing the burden of screening and toxicity testing will be essential. To accomplish this, a consortium of domestic and international organizations will allocate the screening and testing burden and coordinate the effort. Over time, we can expect agreement that chemicals entailing high exposure, environmental release, or other potentially hazardous characteristics must have a minimum set of test data to remain in commerce.

See chapter 7 for a fuller discussion of the strategy now being implemented in the Office of Toxic Substances for accelerating the pace of existing chemical testing, risk assessment, and risk management.

NEXT ... Chapter 5 discusses how EPA has used its pollution prevention authority under section 5 of TSCA to address the risks posed by new chemicals and new uses of existing chemicals.

5. CONTROLLING ENTRY OF NEW CHEMICALS

Background

Under TSCA section 5, EPA has the responsibility to review new chemical substances. New chemicals are defined as those not on the TSCA chemical inventory, which is EPA's comprehensive list of chemicals in commerce. Most new chemicals have few toxicity test data available when they are about to enter commerce. When EPA has insufficient data to predict a new chemical's health and environmental effects, the agency can prohibit or limit the manufacture, processing, distribution, use, or disposal of the chemical for 90 days pending development of test data if it finds the chemical may present an unreasonable risk to health or the environment, or that the chemical is or will be produced in substantial quantities, and (a) it may enter the environment in substantial quantities, or (b) there may be significant or substantial human exposure or substantial environmental release. Under section 5(f), EPA may also ban or limit manufacture if a determination is made that activities involving a new chemical will present an unreasonable risk.

Under TSCA section 5(a), manufacturers and importers are required to provide EPA with a premanufacture notice (PMN) at least 90 days in advance of producing or importing a new chemical for non-exempt commercial purposes. EPA's New Chemicals Program reviews and evaluates the potential risk posed by a new chemical and decides whether controls are appropriate. Some genetically engineered microorganisms are considered to be new chemical substances subject to section 5 review.

TSCA does not require prior testing by the manufacturer and, consequently, most PMNs are not accompanied by toxicological testing data. In the absence of test data, EPA's evaluation

relies on SARs, a method of projecting toxicity by using structure-activity relationships.

In 90 percent of cases, EPA has not acted to limit commercial production at the end of the 90-day period. In the remaining 10 percent, the PMN process has resulted in restrictive action by EPA or the company has acted voluntarily in light of EPA's concerns for health or environmental effects. The PMN review and evaluation process necessarily requires that EPA's responsibility to reduce risk be exercised in the context of encouraging innovation, particularly to ensure that overly strict conditions are not imposed on the marketing of safer substitutes for existing chemicals. Under the New Chemicals Program, consent orders that restrict chemical manufacture pending development of test data may be negotiated with a company submitting a PMN.

Section 5 regulations also require a manufacturer to submit a Notice of Commencement of Manufacture within 30 days of non-exempt commercial manufacture after the PMN review period has expired. At this point the chemical is added to the TSCA chemical inventory.

EPA is also authorized under section 5(a) to regulate new uses of a chemical pending an EPA review. Significant new use rules (SNURs) require manufacturers or processors to submit a notice to EPA prior to manufacturing or processing a chemical for a significant new use. SNUR authority is an important means of targeting uses that may involve significant exposures to toxic chemicals.

Accomplishments During Fiscal 1989

New chemical actions. More than 1,000 valid PMNs were received by EPA during fiscal 1989, increasing the total since the enactment of TSCA to almost 12,600. (Compared to the 2,400

valid PMNs received in fiscal 1988, a substantially lower number of PMNs was received in fiscal 1989. This may be attributed to a speedup in submissions prior to the October 1988 effective date of a \$2,500 user fee for PMN reporting.) Including exemption applications, the number of chemical substance submissions to EPA since the program began is more than 15,000. Voluntary testing in response to EPA concerns occurred in 53 cases during 1989 and the same number of PMNs were subject to new section 5(e) consent orders. During the last year, EPA also received test data on eight chemicals as a result of section 5(e) consent orders. Details of new chemical actions through fiscal 1989 are given in Appendix D.

Expedited new chemical consent orders. During fiscal 1989, EPA continued to improve on its procedures to expedite development of section 5(e) consent orders, which are negotiated with a company when the agency determines that a new chemical may present an unreasonable risk of injury to human health or the environment or that a new chemical will be produced in substantial quantities and may result in substantial human or environmental exposure. EPA adopted new procedures for the development of relatively routine section 5(e) orders, which reduces negotiation of standard section 5(e) order language and speeds order preparation and review both inside and outside the agency. The expedited procedure differs from the previous procedure in two ways: Instead of EPA sending a draft order to the company for comment, EPA, at the outset, sends a "5(e) action letter" and generic order intended to provide the company an understanding of the terms of the proposed order, and EPA signs the order before the company signs it.

Expedited new chemical follow-up rules. In the case of a section 5(e) consent order that applies to the manufacturer of a particular new chemical substance, a SNUR is promulgated under section 5(a)(2) to extend the terms of the section 5(e) consent

order to all future manufacturers and processors of that substance. A company intending to manufacture or process a substance for a "significant new use" as defined by a SNUR must submit a notice to EPA, which, upon making the appropriate findings, can issue another consent order and amend the SNUR for that particular substance, if necessary.

EPA published its expedited follow-up rule, or "generic SNUR," on July 27, 1989 [54 FR 31298]. This procedural rule provides an expedited rule-making procedure and a codification of standardized regulatory language. The generic SNUR will simplify the preparation of individual SNURs for chemicals subject to section 5(e) orders and for other selected new chemicals that have completed premanufacture review. This rule will significantly enhance EPA's ability to issue comprehensive regulation of new chemical substances quickly and inexpensively.

Study of testing requirements under section 5(e) consent orders. EPA conducted an internal study to measure how much information is being received through testing requirements that are triggered under consent orders with certain manufacturers. By May 1989, 330 chemicals had been regulated by section 5(e) consent orders. Of these, 66 include testing requirements that are triggered at specified production volumes. In general, the findings indicate that the companies have complied with the testing requirements of production-triggered orders. Nearly 83 percent of the data required under these orders is expected to be received by EPA in the near future.

Evaluation of exposure-release-based policies. In early 1988, the Office of Toxic Substances introduced a policy to require basic toxicity testing for new chemicals based on high-production volume and anticipated levels of human exposure and environmental release. Since its implementation, the exposure-based policy has proved to be a vital and significant

complement to the traditional risk-based review of new chemicals. A total of 180 PMNs have entered the exposure-based review process. Of these, 142 cases have resulted in testing decisions from the agency. To date, PMN submitters have agreed to test or have signed TSCA section 5(e) consent orders for 85 of these substances.

In fiscal 1989, 69 exposure-based reviews were conducted. Fifty-three cases resulted in testing decisions by the agency. Of the 47 TSCA section 5(e) consent orders issued for fiscal 1989 PMNs, 26 were exposure based in nature.

Policy on free-radical initiators. A clarification of reporting requirements under section 5 for polymers manufactured using free-radical initiators was published in the June 28, 1989, Federal Register [54 FR 27174]. It is now required that free-radical initiators be listed in the polymer description when the manufacturing process uses initiators at the level greater than two percent by weight. This policy applies only to polymers not listed on the TSCA chemical inventory as of the effective date of the FR notice. The policy clarification arose as a result of a specific enforcement action.

Initiatives Affecting Future Program Success

Streamlining the New Chemicals Program. Growth of the New Chemicals Program under section 5 has demanded changes to optimize resources and productivity. The initiatives being considered cover four major areas:

- reducing administrative burdens and costs of running the program,
- improving hazard and monitoring data collection for new chemicals,
- reducing the overall number of notices submitted for EPA

review by expanding the exemption categories, and

- reducing the burden of preparing consent orders under section 5(e).

Many of the initiatives can be implemented without revisions to the PMN rule itself, while others may require rulemaking. Currently, several options to amend the rule are under consideration.

EPA-industry dialogue on the New Chemicals Program. EPA has increased its efforts to open a dialogue on regulatory strategies for new chemical substances by holding periodic meetings and workshops with chemical industry and trade associations in the United States.

Acrylate testing agreement. In December 1987, EPA representatives and the SAM Panel of the Chemical Manufacturers Association began a series of meetings in an attempt to provide additional information on the potential health effects of acrylate compounds. Available data indicate that some acrylates are carcinogenic in animals. However, questions have been raised by both EPA and the SAM Panel regarding the adequacy and appropriateness of a number of the carcinogenicity bioassays. More than 450 acrylates are in the TSCA chemical inventory and a large number of PMNs have been filed for new acrylate substances. Both EPA and the SAM Panel have expressed a desire to know more about the potential human carcinogenic effects of these substances. Under an agreement reached in May 1989, the SAM Panel committed to perform additional toxicity testing to improve understanding of the nature of these effects and to assist in the refinement of an appropriate strategy for managing potential risks associated with acrylates.

Risk management options for CFCs and halons. Chapter 4 discussed the Chemical Testing Program's initiative in reviewing human and environmental hazard information for those chemicals identified as major potential substitutes for CFCs and halons. Because of the tentative nature of product development, the New Chemicals Program is concerned with setting a level of regulation (if any) during the years when data on CFC/halon substitutes are being obtained and reviewed for potential health and environmental effects. The New Chemicals Program must develop risk management options in the absence of complete data on the substitutes. Accordingly, the Office of Toxic Substances and the Office of Air and Radiation Programs, in consultation with environmental and trade representative organizations, are developing options for the review and regulation of all CFC and halon substitutes. Review of substitutes reported as PMN chemicals will be made in light of EPA's overall approach to CFC and halon substitutes.

Biotechnology reporting rule. Due to the potential for novel health and environmental issues posed by microbial products, there is a consequent need for toxicological data, risk assessment techniques, and improvements in associated scientific skills. To date, EPA has received a small number of PMNs for field release organisms; however, the high rate of innovation of this technology portends a major increase in field release PMNs in the next few years.

Policy for a coordinated federal framework for regulation of biotechnology was published in the Federal Register on June 26, 1986 [51 FR 23313]. Under this policy, microorganisms altered through deliberate human intervention to contain genetic material from dissimilar source organisms (intergenerics) are "new chemicals" subject to PMN requirements under TSCA section 5, if they are manufactured for TSCA purposes. TSCA purposes include general commercial and environmental applications, such as metal

leaching, pollutant degradation, and enhanced nitrogen fixation in plants. EPA plans to develop rules to ensure that EPA will receive for review:

- notices for "new" microorganisms for commercial purposes, including research and development applications for environmental releases; and
- notices for manufacturing, processing, importing, distribution, use or disposal of microorganisms which represent significant new uses or significantly different exposures.

In addition, EPA will initiate rulemaking to exempt from review microorganisms used in certain contained systems.

To aid development of these proposed rules, EPA solicited public comment on key issues in a February 15, 1989, Federal Register notice [54 FR 7027]. (A companion notice [54 FR 7026] solicited comments on issues related to regulation of microorganisms under the Federal Insecticide, Fungicide, and Rodenticide Act.) Plans are to propose these rules during fiscal 1991 and promulgate a final rule in fiscal 1992.

Strategies for the 1990s

Goals. New chemicals should not pose any unreasonable risk when introduced into commerce. EPA's goal is to encourage the chemical industry to develop safe chemicals and to develop and exercise the ability to identify potentially risky chemicals before they are manufactured. Success in preventing unreasonable risk from new chemicals is limited by the difficulty of predicting risk in the absence of some or all data. An expanded ability to predict risk is therefore a major subsidiary goal to preventing unreasonable risk.

Another goal of the New Chemicals Program is to promote

voluntary action as a substitute for regulatory action. Because unreasonable risk determinations often require costly testing, a manufacturer may agree to take the more economically expedient step of reducing exposure as if a chemical presented an unreasonable risk rather than perform the analysis and testing.

Means to achieve goals. The preferred approach to preventing unreasonable risk of injury from toxic chemicals is to prevent toxic pollution in the first place. This can be achieved if the chemical industry incorporates a more vigorous environmental ethic into their R&D programs. Such an effort would involve more premanufacture testing, better techniques for risk prediction and risk assessment, and a commitment to the development and marketing of safer chemicals. The biotechnology industry, in particular, has an opportunity to adopt this ethic at an early stage in its development. An incentive for the chemical industry is that EPA may place fewer last-minute controls on products coming through the PMN review process if a commitment to risk reduction is demonstrated in a PMN.

EPA will attempt to find additional incentives to encourage the introduction of safer chemicals. The environmental benefit is that new and safer products will begin to replace older, more hazardous products now in the marketplace.

EPA will also seek to improve prediction of risk in the absence of data through an expanded SAR capability. This effort, involving extending SAR endpoints for other than cancer and aquatic effects, will also require an expanded testing and toxicological analysis program.

NEXT ... Chapter 6 discusses EPA's growing emphasis on making the chemical data it collects more accessible to others involved in analysis of environmental data and risk management.

6. ROLE OF INFORMATION IN MANAGING TOXIC CHEMICAL RISK

Background

Section 8 of TSCA and section 313 of EPCRA provide EPA with tools to use in gathering information to identify, evaluate, and manage risk from toxic chemicals. Section 8 of TSCA authorizes EPA to require reporting and recordkeeping on chemical substances and mixtures. Section 313 of EPCRA requires that companies report annual emissions of hazardous chemicals and that EPA compile this data in a Toxics Release Inventory and make it publicly available. (Additional information about toxic and hazardous materials is available locally under other sections of EPCRA, and taken together, provide a total picture of community risk. EPCRA requires state governors to set up local emergency planning committees to receive and make publicly available information from facilities in their states. EPCRA requires these facilities to report inventories of hazardous chemicals and to provide notification of accidental releases of chemicals that are defined as extremely hazardous.)

Requirement to maintain records. Section 8(a) of TSCA authorizes EPA to require chemical manufacturers, importers, and processors to maintain records and report certain information to the agency. Under 8(a), the Preliminary Assessment Information Rule (PAIR), originally published on June 22, 1982 [47 FR 26992], manufacturers of listed chemicals are required to report general production, use, and exposure information. These data are especially important to the agency's review of designated chemicals recommended by the Interagency Testing Committee for priority testing.

EPA also promulgated the Comprehensive Assessment Information Rule (CAIR) on December 22, 1988 [53 FR 51698], under section 8(a), to coordinate information collection among federal

agencies. Chemicals subject to CAIR are nominated by EPA or other federal agencies. Data collected in 1986 pursuant to the Inventory Update rule, another 8(a) rule, also support chemical screening activities.

Requirement to publish the TSCA Chemical Inventory. Section 8(b) requires EPA to compile, maintain, and publish an inventory of chemicals in commerce, called the TSCA Chemical Inventory. Chemicals on the inventory are considered to be existing chemicals. Chemicals that are not listed on the inventory are considered to be new chemicals; these fall under section 5 requirements for submission of premanufacture notification and review by EPA. Chemicals that pass the PMN review and go into production are added to the inventory upon the agency's receipt of a Notice of Commencement of Manufacture.

Requirement to maintain records on adverse reactions. Under section 8(c), manufacturers and certain processors must maintain records of alleged "significant adverse reactions" to chemicals. This information must be submitted to EPA on request.

Requirement to submit unpublished studies. Section 8(d) requires manufacturers, processors, and distributors of chemicals to submit lists of unpublished health and safety studies on chemicals, which are specified in amendments to a model rule.

Requirement of "substantial risk" notification. Section 8(e) requires EPA to be immediately notified when new information reasonably supports the conclusion that a chemical substance presents a "substantial risk" to health or the environment. Historically, EPA also receives a large number of voluntary submissions related to chemical toxicity and exposure.

EPCRA section 313 reporting requirements. Under section 313 of EPCRA, each facility covered by the reporting requirement must

submit a report by July 1 of toxic chemical releases during the previous calendar year. The first reports, covering calendar year 1987, were due July 1, 1988. EPA developed a reporting form with instructions and technical guidance on how to calculate toxic releases from a facility. A company must submit reports to EPA and to the states in which the host facilities are located. EPA is required to make the data in the reports available to the public through a TRI computer database. The database is intended to help answer citizens' questions about chemical releases in their community. The users of data are also likely to include researchers from government or universities conducting health and environmental analyses. EPA expects to use the data in a variety of ways, including as a screening tool to develop priorities for eliminating unreasonable toxic risk, reducing unnecessary exposures, and preventing toxic pollution.

Accomplishments During Fiscal 1989

In fiscal 1989, the Office of Toxic Substances focused on using information more effectively. Chemical data from a variety of sources were successfully integrated into a comprehensive database, and there was a significant increase in the number of people who accessed and used the data to improve toxic chemical risk management. The Office of Toxic Substances will continue to improve information management in the 1990s.

Information received under TSCA section 8. In fiscal 1989, EPA received and reviewed a substantial amount of information on existing chemicals. Under section 8(a), 115 PAIR submissions and 640 CAIR submissions were received. More than 1,000 chemicals were added to the TSCA Chemical Inventory. In response to section 8(d) requirements, EPA received 1,565 submissions of health and safety studies or toxicity data. In addition, EPA received almost 290 initial and supplemental "substantial risk" notifications under section 8(e). Another 164 voluntary

notifications were also received for review. EPA made the health and safety studies collected under section 8(d) publicly available through the National Technical Information Service and through an on-line public database.

Uses of TSCA section 8 information. The information generated under section 8 authorities is essential to the EPA risk assessment and risk management efforts. Section 8(d) unpublished industry studies, for example, provide the agency with safety, health, and environmental data which might otherwise never come to light. Section 8(e) "substantial risk" notification data provide an important input to EPA's risk assessment activities, and are routinely shared with other federal agencies. For example, EPA received animal carcinogenicity data on refractory ceramic fibers from industry under section 8(e). The agency is using the data to assess substitutes for asbestos. EPA is also assessing epidemiological data submitted by industry on o-toluidine and aniline, which indicates increased cancer risk among workers are currently being assessed. EPA has forwarded this data to other federal agencies, including the National Institute of Occupational Safety and Health (NIOSH) and the Occupational Safety and Health Agency (OSHA). EPA is using animal retinopathy data submitted by industry under 8(e) to assess potential risks posed by certain aromatic ether diamines, and EPA has shared toxicologic and exposure data with NIOSH, OSHA, and other agencies.

Chemical Hazard Information Profiles. During fiscal 1989, EPA prepared Chemical Hazard Information Profiles (CHIPs) on five chemicals. To prepare CHIP documents, EPA reviews a wide range of literature and data sources, and solicits information from companies, government agencies, and other institutions involved in chemical risk assessment.

Since the end of fiscal 1989, CHIPS have been superseded by

a new document--referred to as a "screening dossier"--whose content and format have been designed to speed up the screening of existing chemicals.

Substitute Hazard Profiles. These are preliminary risk identification documents prepared to ensure that TSCA regulatory actions will not encourage an equally or more hazardous chemical or use to be substituted for the chemical or use being considered for regulation. Last year, Substitute Hazard Profiles were prepared for lead and cadmium covering uses in 11 product categories. Appendix E provides details about these submissions and actions in fiscal 1989.

TSCATS. Another major activity contributing to increased integration of and access to chemical information was the TSCA Test Submissions (TSCATS) database, which is a "pointer" file on difficult-to-acquire, unpublished chemical test information. TSCATS indexes chemical test submissions and health and safety data required under TSCA sections 4, 8(d), and 8(e) and includes voluntary FYI submissions. The database contains more than 11,000 documents describing 47,800 test studies on 3,550 unique chemicals. Access to TSCATS and the studies it captures is provided in several formats, including magnetic tape, direct on-line, microfiche copies, and Compact Disk Read-only Memory (CD-ROM). Among the users of the database are federal and state agencies, researchers, risk assessors and managers, chemical industry, trade and professional associations, and health and environmental professionals.

In addition to TSCATS, approximately 50 other toxic chemical-related databases are maintained by the Office of Pesticides and Toxic Substances.

Compilation and publication of Toxics Release Inventory. In another significant event in fiscal 1989, EPA successfully met

the EPCRA section 313 requirement to compile the TRI and make it available on-line through the National Library of Medicine's TOXNET system. Anyone with access to a personal computer, modem, and communications software can use the TRI, for a small fee, to obtain toxic emissions data by geographic area, facility, chemical released, or any other search criteria. Use of the database has already been heavy, constituting 43 percent of total TOXNET usage with 69,000 searches and 2,500 connect hours in just 3 1/2 months.

To create the database for the National Library of Medicine, EPA first developed an internal database on the agency's mainframe computer and entered into it more than 74,000 reports submitted by about 19,000 facilities for 1987. Following extensive data quality checks, the data were uploaded into the library's system. It became available to the public on June 19, 1989. To enable citizens to capture TRI data in a suitable format, EPA developed software that converts the TRI data into dBase format and allows the generation of a wide variety of reports. This software is being distributed on PC diskette free of charge.

In addition to the public database, EPA also made the TRI information available through a variety of electronic and non-electronic means. EPA published a national report, "The Toxics Release Inventory: A National Perspective,"³ which describes the database and presents extensive summary information in texts, charts, and graphics. Magnetic tapes of the entire database and PC diskettes of data for individual states were distributed to requesting states and made available for purchase through the Government Printing Office and the National Technical Information Service. Microfiche versions of the database, or

³ EPA 560/4-89-005, Pesticides and Toxic Substances (TS-779), June 1989

portions thereof, were distributed at the beginning of 1990 to more than 1,400 federal depository libraries and public libraries in almost 2,400 counties across the country. EPA made significant progress towards the development of a CD-ROM version of the database, to be made available in fiscal 1990. Citizens can also contact the TRI Reporting Center for copies of individual forms submitted by facilities.

Promoting use of TRI data. During fiscal 1989, a great deal of effort was put into facilitating and promoting use of TRI data. Numerous courses were conducted to train state personnel and EPA staff on using both the internal EPA data system and the publicly available NLM system. Within the agency, a data use subgroup was formed to promote the use of TRI data by EPA regional and program offices, and a computer bulletin board was established to describe and track analyses performed by those offices. A number of EPA regional offices produced summary reports for their regions or compiled TRI data for individual states or metropolitan areas. Regional TRI staff also worked actively with EPA regional media personnel to urge use of TRI data for cross-checking permit data and other applications.

EPA also developed and published the "Toxic Chemical Release Inventory Risk Screening Guide, Version 1.0" (EPA 560/2-89-002, July 1989) to assist state and local decisionmakers in using TRI data to develop priorities for investigating facilities, chemicals, and exposed populations. Two training sessions in use of the guide, risk communication, and use of the NLM database were held for state and local officials in McLean, Virginia, and Denver, Colorado.

Financial assistance to TRI users. Because one of the potential impediments to use of TRI data is the cost of buying the necessary equipment and paying the National Library of Medicine's hourly charge, EPA initiated a pilot effort to provide

limited financial assistance to states, localities, and certain public interest groups. EPA received 21 requests for fee waivers to use the TRI database and approved 17 of these. The average fee waiver granted under the pilot project was \$1,400. At least one project was approved in each EPA region except for Region 7, where no applications were received. Recipients were local or county governments or local emergency planning committees. One state university and a couple of environmental groups were also approved.

In all but one case, the fee waiver recipients did not use their waiver or used only a small portion of it. The most frequently cited reasons for this were:

1. People are interested in the TRI data, but they do not have the time to work with it or are not sure how to put the data to use.
2. The TRI system was found to be difficult to access or use.

The Office of Toxic Substances interviewed the contacts for the 17 pilot projects to determine their experiences with trying to use TRI. The information obtained has been useful in helping to target resources and in identifying outreach techniques that some participants tried. Ultimately, a decision was made not to offer fee waivers but instead to operate a TRI user assistance service, called TRI-US, during a trial period to determine what kinds of information or assistance is needed by TRI users. The service has been heavily used. In the near future, the Office of Toxic Substances will evaluate this project to determine whether it should be continued or how it should be revised.

Other financial assistance was provided to four states, which received about \$45,000 each through a cooperative agreement

with the National Governors Association for TRI data management, use, and quality assurance projects. Also, New York State received a grant of \$64,000 under TSCA section 10 to integrate TRI data into a geographic information system.

TRI outreach program. As in previous years, EPA conducted extensive industry outreach campaigns to increase awareness of and compliance with section 313 requirements. EPA regional offices were key to this effort, conducting 97 industry workshops and seminars with more than 8,000 attendees and providing a wide range of other technical assistance.

A new development in the industry outreach program was the production of a comprehensive reporting package, which included all the major documents needed to report chemical releases or emissions. The reporting package was mailed to all facilities that filed 1987 reports to assist them in completing their reports for 1988. EPA also developed and distributed a brochure to assist industries in complying with the new supplier notification requirements. Other events of the 1989 outreach program were a national EPCRA Trade Association meeting and a "Train the Trainers" course designed to teach state personnel, industry representatives, consultants, EPA regional staff, and others how to train people in complying with section 313 requirements and completing the reporting form. Also, EPA expanded the hours of operation of the EPCRA telephone assistance hotline and increased the number of specialists available to answer technical questions.

TRI petition process. Section 313 allows EPA to modify the list of chemicals covered by the law and establishes a petition process to allow anyone to request removal or addition of chemicals to the list. EPA received 49 petitions as of May 1990, 11 of which were received in fiscal 1989. Also in 1989, EPA granted petitions to delist three chemicals, proposed to grant

delisting to four additional chemicals, and denied petitions to delist three chemicals. EPA also published a proposal to add 10 chemicals to the TRI list for reasons of carcinogenicity and human chronic toxicity.

Initiatives Affecting Future Program Success

PC Conference. In October 1989, the Office of Toxic Substances and the Office of Information Resources Management co-sponsored the First Conference on Public Access to Environmental Data. The purpose was to initiate a dialogue with groups inside and outside the agency on public access and to stimulate interest in using personal computers for the analysis of environmental data and risk management. The audience included representatives from environmental/public interest groups, industry, academia, librarians, journalists, congressional staff, and other federal, state, and local agencies, as well as EPA staff. EPA expects to hold a second conference in the future to maintain momentum in increasing integration of and access to chemical data.

TSCATS enhancement. To make TSCATS more useful in managing chemical risks, EPA is examining the feasibility of entering and indexing submissions more quickly and of adding to the database abstracts summarizing test results.

Access to TSCA Chemical Inventory. In fiscal 1989, EPA began reorganizing the inventory for greater access. The inventory contains production data, which are updated every four years, on chemical substances of greatest concern. Development has begun on a format to make non-confidential production data available to general users.

Use and utility of TRI data. The following efforts are under way to improve the outreach and compliance efforts and

refine the section 313 reporting rule:

- EPA supported development of a publication to help environmental journalists interpret and report on toxic chemicals and the TRI data. The guide, Chemicals, the Press, and the Public: A Journalists' Guide to Reporting on Chemicals in the Community, was published in the fall of 1989.
- Information from a major compliance survey and detailed telephone and site audits will be used to better target enforcement and outreach efforts.
- A screening process and criteria are being developed to evaluate chemicals for possible addition to or deletion from the section 313 list. Industrial classifications outside the manufacturing sector are being examined to determine if any should be added to the regulation's coverage.
- EPA is examining the feasibility of requiring reporting of "peak release" data, including the largest volume of release over an eight- or 24-hour period, as well as total days of release for the facility.
- Development of an assistance program to provide grants and cooperative agreements to states under TSCA section 28 for projects that will improve the quality of the TRI data. In fiscal year 1989, EPA awarded \$1 million in grants to 11 states for TRI data quality assurance projects. The grants were provided to build at the state level the capacity to evaluate the quality of facility submissions in order to assure the quality of the database created from them. Improving the quality of the database will increase the utility of the TRI data for state programs in identifying, communicating, preventing, and controlling toxic chemical risks. The following states received funds: Ohio, Minnesota, Kansas, Colorado, California, North Carolina, Connecticut, Kentucky, Louisiana, Maryland, and Missouri. The grants ranged from a low of \$24,285 (Kansas) to a high of \$131,550 (North Carolina).

On March 8, 1991, EPA published a Federal Register notice announcing the availability of \$800,000 in TRI grant funds to establish programs of TRI data management, analysis, use, and quality assurance to assist states in preventing or eliminating toxic chemical risks. The expanded purpose of the grant program is reflected in its title--the TRI Data Capabilities Program, as opposed to the earlier TRI Data

Quality Assurance Program. The deadline for applications for fiscal year 1991 funding is June 6, 1991.

The fiscal year 1992 budget requests \$1 million for TRI state grants.

Strategies for the 1990s

Goals. EPA intends to expand significantly the use of information as a risk reduction tool. The TRI database has already had a great influence in intensifying the chemical industry's concerns about the local and national health and environmental risks which may be posed by their products. TRI has also increased cooperative efforts among EPA, the states, and the public as more interest in toxic risk management has developed at the local level. Data and their interpretation are the principal requirements for sharing the opportunities of risk management among the larger toxics community.

Means to achieve goals. EPA will seek to integrate data on toxic substances across program lines and to support multi-media, multi-chemical, multi-facility risk assessments, regulation, and enforcement. EPA will also encourage the development of state programs to collect and report information helpful to the agency in identifying chemicals for product bans or restricted use actions.

NEXT ... Chapter 7 discusses EPA's accomplishments in risk assessment and risk management in fiscal 1989 and its goals and strategies for implementing major improvements in the Existing and New Chemicals Programs in the 1990s.

7. ASSESSING AND MANAGING TOXIC CHEMICAL RISK

Background

Risk assessments are essential to the risk management process. They allow the evaluation of how alternative regulatory and non-regulatory actions would reduce risk. They also support the decision to initiate or not initiate the risk management process for chemicals that have passed through an initial screening.

The major risk management activities in the Office of Toxic Substances during fiscal 1989 centered on PCBs and asbestos. PCBs and asbestos in schools share the distinction of having been singled out by Congress for control: PCBs under TSCA section 6(e) and asbestos under AHERA. A further common element is that state and local governments have joined EPA regional offices as partners in control efforts.

The Office of Toxic Substances also supported actions during the year to reduce risks from lead and to prohibit the use of hexavalent chromium in comfort cooling towers.

Accomplishments in Risk Assessment in Fiscal 1989

Ongoing and completed risk assessments. In fiscal 1989, assessments of the risk to health were ongoing or completed for the following:

- Use of lead solder in potable water plumbing in support of the Office of Drinking Water
- Asbestos substitutes (in support of the Asbestos Ban and Phase-out Rule issued under TSCA section 6)
- Updating the risk assessment for inhalation exposure to formaldehyde

- Disposal of lead batteries in municipal solid waste in support of the Office of Solid Waste*

Chlorofluorocarbons/halons risk management support. In fiscal 1989, a cross-program effort in EPA supported risk assessments of CFCs and halon substitutes. This joint program--the CFC Substitutes Human Health and Environmental Effects Program--ensures all relevant factors are considered in decisions concerning the acceptability of CFC and halon substitutes. The Office of Air and Radiation has the primary responsibility in EPA for activities related to the 1987 Montreal Protocol on Substitutes that Deplete the Ozone Layer. The Office of Toxic Substances carries the responsibility for reviewing the human and environmental hazard and exposure information for chemicals identified as major potential substitutes for CFCs and halons.

Pre-risk management risk assessment projects. Ongoing pre-risk management risk assessment projects include:

- Assessment of the hazards of a large group of potentially hazardous compounds used as "inert" ingredients in pesticide formulations. This project is being performed in cooperation with the pesticides program.
- Development of a risk assessment strategy and a work plan in anticipation of the receipt of the results of testing of twelve chemicals for the presence of PCDDs and PCDFs and their brominated analogs. This testing was required by EPA in a 1987 test rule [52 FR 21412]. Positive results will trigger initiation of a risk assessment with a one-year completion date.

* This health risk assessment was not completed, and there is no intention of issuing a final study. Issues related to management of lead are now being handled via the agency's overall lead strategy, which includes an ongoing negotiated rulemaking.

PCDDs/PCDFs risk assessment. A major multi-media assessment of risks to humans and the environment from exposure to PCDDs and PCDFs that are inadvertently formed during pulp paper bleaching operations was undertaken in fiscal 1989. The toxic substances program solicited and has received the active participation of the Offices of Water, Air and Radiation, and Solid Waste, as well as the Food and Drug Administration (FDA), Consumer Product Safety Commission (CPSC), and NIOSH. EPA completed the risk assessment and announced its decision on the need for additional regulation on April 30, 1990, in accordance with the terms of a consent decree developed between EPA, the Environmental Defense Fund, and the National Wildlife Federation.

Accomplishments in Asbestos Risk Management in Fiscal 1989

EPA has taken a series of actions since 1971 to reduce or eliminate exposures to asbestos. Asbestos was first regulated by EPA under the Clean Air Act as a hazardous air pollutant, and more recently under TSCA and AHERA. Also, EPA is one of several agencies, including OSHA and CPSC, which together provide regulatory programs spanning a broad spectrum of occupational and non-occupational exposures to asbestos.

Asbestos Ban and Phase-out Rule. On July 12, 1989, EPA published a final rule [54 FR 29460] under section 6 of TSCA to ban the manufacturing, importing, and processing of most asbestos products in three stages, beginning with certain products on August 27, 1990, and with others on August 25, 1993, and August 26, 1996. Table 7-1 lists the products affected and the stages into which they fall. Corresponding bans on the distribution of asbestos products will occur in 1992, 1994, and 1997. The stage at which each asbestos product is banned is based on the projected availability of a safe substitute for that product.

The rule provides that exemptions from the ban may be granted only if specific criteria for submitting exemptions are met. To obtain an exemption, an applicant must show that the use described in the application would not pose an unreasonable risk to human health and must demonstrate evidence of good faith efforts to develop substitutes for the use described in the application. EPA imposed this ban because, despite public and private sector actions to reduce harmful asbestos emissions in the workplace, significant levels of asbestos fibers continue to be released during the production, use, and disposal of asbestos products. The agency concluded that the possibility of ongoing fiber releases from these products pose an unreasonable health risk since safer asbestos-free substitutes are or soon will be available.

Unlike other asbestos regulations, which are limited to remedial actions, this rule prevents future risks to human health by eliminating or greatly reducing the products that have the potential for releasing asbestos fibers.

Asbestos in schools. In fiscal 1989, EPA continued its efforts to ensure compliance with AHERA, which established a comprehensive program for addressing asbestos problems in the nation's public and private schools. In October 1989, the agency announced that 94 percent of the school districts and private schools had inspected their school buildings for asbestos and developed asbestos management plans as required by AHERA. EPA is taking action, including civil penalties, to bring the remaining schools into compliance (See chapter 8).

In addition to its enforcement efforts, the agency has also helped schools select and carry out the most appropriate asbestos control options by ensuring an adequate supply of trained, accredited asbestos professionals and by offering guidance on asbestos to school officials and parents. By the end of fiscal

1989, EPA had approved more than 1,300 accreditation training courses and 15 state accreditation programs in its efforts to establish an adequate infrastructure of qualified personnel.

In June 1989, EPA, in conjunction with the National Education Association and the National Parent Teacher Association, published the booklet The ABC's of Asbestos in Schools. The publication helps parents and teachers learn about asbestos in schools and outlines the responsibilities of school officials to protect school children and employees from possible asbestos exposure. EPA has also published a wide range of documents to assist individuals in successfully carrying out the more technical aspects of the AHERA regulation.

Under the ASHAA, EPA awarded \$45 million in loans and grants in fiscal 1989 to help the most financially needy public and private non-profit primary and secondary schools abate asbestos hazards. Since the first ASHAA awards were issued in 1985, EPA has provided \$201.8 million for nearly 2,200 school asbestos abatement projects. Based on the abatement projects supported, these awards should reduce the weekly exposure of schoolchildren and employees to asbestos by 17.3 million hours. Details of the loan and grant program awards since 1985 are given in Appendix F.

In fiscal 89, the Office of Toxic Substances continued to work with the National Institute of Standards and Technology (NIST) to develop a laboratory accreditation program for laboratories which analyze bulk asbestos materials by polarized light microscopy (PLM). In fiscal '88, in an effort to provide a source of accredited laboratories for local education agencies, the Office of Toxic Substances issued "interim accreditations" to PLM laboratories which had successfully participated in EPA's round-robin testing program. This effort was continued into fiscal '89 until the NIST program became operational. In September 1989, NIST had accredited 500 PLM laboratories. The

**Table 7-1. Status of Asbestos Products Under
the Ban and Phase-out Rule***

The stage at which each product is banned is based on the projected availability of a safe substitute for that product.

First Stage Ban: 8/27/90

Felt Products

- Pipeline wrap
- Roofing felt
- Flooring felt

Asbestos cement (A/C) Products

- A/C sheet, corrugated
- A/C sheet, flat

Products out of use

- Vinyl asbestos floor tile
- Asbestos clothing

Second Stage Ban: 8/25/93

Friction Products**

- Drum brake linings (OEM)
- Disc brake pads, LMV (OEM)
- Disc brake pads, HV (OEM)
- Clutch facings
- Automatic transmission components
- Industrial and commercial friction products

Gaskets

- Beater-add gaskets (except some industrial uses)
- Sheet gaskets (except some industrial uses)

OEM - original equipment market
 AM - after market
 LMV - light and medium vehicles
 HV - heavy vehicles

Third Stage Ban: 8/26/97

Coatings

- Roof coatings
- Non-roof coatings

Paper Products

- Commercial paper
- Rollboard
- Millboard
- Corrugated paper
- Specialty paper

Friction Products

- Brake blocks (OEM)
- Brake blocks (AM)
- Drum brake linings (AM)
- Disc brake pads, LMV (AM)
- Disc brake pads, HV (AM)

A/C Products

- A/C pipe
- A/C shingle

Not banned

- Missile liners
- Asbestos diaphragms
- Battery separators
- Arc chutes
- Acetylene cylinder filler
- Textile products (except clothing)
- Asbestos reinforced plastic
- Sealant tape
- High-grade electrical paper
- Asbestos packings
- Some industrial use of sheet gaskets
- Some industrial uses of beater-add gaskets

- * Federal Register No. 132, July 12, 1989, p. 29460 [54 FR 29460]
- ** For OEM motor vehicle brakes, ban is effective next model year after second stage ban.

Office of Toxic Substances and NIST also continued to coordinate the construction of a laboratory accreditation program for laboratories analyzing air samples for asbestos by transmission electron microscopy.

Asbestos in public and commercial buildings. This is another area in which EPA accelerated its efforts in fiscal 1989. In addition to approval of the AHERA training courses and state accreditation programs noted above, EPA provided financial and technical assistance to states and public and private organizations to help them enhance their asbestos control, management, and accreditation programs. The agency views these efforts as vital to ensure an adequate infrastructure of well-trained asbestos professional available for work in the country's more than 3.6 million public and commercial buildings.

Initiatives Affecting Future Asbestos Program Success

In its 1988 Report to Congress, EPA Study of Asbestos-Containing Materials in Public Buildings, EPA stressed that the lack of basic information about asbestos exposure and the efficacy of various management and abatement strategies "limits the agency's present ability to assess options, draw conclusions, and make recommendations concerning the regulation of asbestos in public and commercial buildings." With this in mind, EPA began the following information gathering initiatives in fiscal 1989. These initiatives are helping the agency better evaluate the impact of regulating asbestos in public and commercial buildings:

AHERA rule evaluation. EPA began a major evaluation of the AHERA rule to assess its implementation in schools and to help determine the need for additional regulation in non-school buildings.

EPA asbestos research. EPA continued and completed several research projects on the effectiveness of various asbestos management and abatement techniques. This includes a study by the Office of Research and Development on the effectiveness of air filtration equipment and methods of carpet cleaning. The Office of Research and Development also made progress in developing an analytical method for measuring asbestos in floor tile. These R&D activities will improve the scientific and technical basis for shifting the management of asbestos to a more risk-based approach.

EPA has also undertaken activities to improve risk estimation to aid asbestos risk management decisionmaking. For example, a technical paper has been submitted to a scientific journal on the use of electron microscopy measurements.

Health Effects Institute project. EPA sponsored a major public-private research project under the direction of the Health Effects Institute, an environmental research organization based in Cambridge, Massachusetts. This research was initiated by a \$2 million congressional appropriation and \$2 million in matching private funds and it represents EPA's principal research effort to learn more about asbestos exposures in buildings. About \$12 million is targeted for this effort. The uses of the research results is discussed below under Asbestos Program Strategies for the 1990s.

Policy dialogue. EPA began a policy dialogue with all the groups affected by the problems posed by asbestos in buildings to help the agency determine the most appropriate programmatic and, if necessary, regulatory response to those problems.

Asbestos Program Strategies for the 1990s

Goals. Of the risks associated with friable asbestos in schools, the risks to maintenance, service, and abatement workers are the greatest. Ensuring that workers receive the precautions already required by EPA and OSHA is a paramount goal related to eliminating unreasonable risk. A continued programmatic emphasis on basic training and accreditation and vigorous compliance efforts remain as critical strategic elements into the future. These same elements are the primary means of also reducing unnecessary exposure to asbestos.

A further goal is to strengthen the EPA-state partnership by increasing the number of states with accreditation programs consistent with AHERA, the number of states which will assume responsibility for implementing the asbestos-in-schools program, and the number of states with accreditation programs for asbestos workers dealing with public and commercial buildings.

Means of achieving goals. Research data from the Health Effects Institute project is expected to provide information on the relative contribution of episodic exposures and total exposures to asbestos in buildings. Also, new information will be developed regarding both the efficacy of removal as an abatement technology and the long-term effectiveness of managing asbestos in place through operation and maintenance protocols. The EPA policy dialogue and the ongoing evaluation of AHERA, in conjunction with the Health Effects Institute's research results, is expected to afford some analytical basis for considering which elements, if any, are necessary to address the broader problem of asbestos in public and commercial buildings.

Providing opportunities and incentives for voluntary participation is key to enhancing the state and public sector

roles. Where states have independent authority and are interested in assuming responsibility for particular portions of the program, EPA will recognize, defer to, and support to the extent possible their initiatives. This will produce a mutually advantageous working arrangement in which EPA will be able to leverage its resources on the basis of the state's activities.

Private sector incentives will remain predominately driven by considerations of tort liability and the cost of asbestos abatement. However, they will also be positively influenced by agency technical assistance and by well-conceived and forcefully executed enforcement policies. Coordinated EPA enforcement activities, coupled with increased training and technical assistance, will be aimed at directing private-sector initiative and involvement in public health directions.

Initiatives Affecting Future PCB Program Success

Historically, the PCB program has concentrated its efforts on phasing out new product use of PCBs and on managing the estimated 750 million pounds of PCBs which remained in use as of 1976, when TSCA was enacted. Priority has been given to the safe management of high-volume/high-concentration PCB electrical equipment for the remainder of its useful life and to its safe disposal. This is reflected in the recently promulgated Notification and Manifest Rule (see below), which is a major regulation concerning PCB storage, transportation, and disposal. By the mid-1990s EPA expects that a significant amount of PCB-containing equipment will have been retired from service and the PCBs safely disposed of. While regulating this process, EPA is also turning its attention to another tier of widespread PCB problems, which can be characterized as high volume/low concentration PCB problems. The principal accomplishments in fiscal 1989 concern initiatives aimed at raising the priorities of this group of PCB problems.

Notification and Manifest Rule. EPA promulgated the Notification and Manifest Rule on December 21, 1989 [54 FR 32716]. This rule affects several thousand generators and storers of PCBs by imposing a tracking system for PCB waste. The principal problems this rule addresses are the improper storage of PCB wastes by commercial storers and the abandonment of such wastes when companies go out of business. The rule requires (1) generators, storers, disposers, and transporters of PCB waste to notify EPA of their activities, (2) manifesting of PCB waste from generation to disposal, and (3) commercial storers of PCB wastes to apply for approval of their commercial storage facilities, provide a closure plan, provide financial assurance, and be subject to a background check of the business and of key personnel for criminal violations of environmental laws.

Exemptions. Another rule, proposed in August 1988 [53 FR 32326], which addresses 12 individual and class petitions for exemption from prohibition against the manufacture, processing, and distribution of PCBs in commerce was promulgated on May 22, 1990.

Non-metallic debris. This is one of the high-volume/low-concentration problems EPA is continuing to investigate. PCBs are sometimes found in non-metallic debris ("fluff") that results when autos and major household appliances are shredded to recover metals. Fluff has been found to contain PCBs at regulated concentrations (above 50 parts per million) and is disposed of in municipal landfills. It also contains other hazardous materials, such as lead and cadmium.

Superfund site cleanup. EPA has found that 17 percent of Superfund cleanup sites contain PCBs. This fact has prompted the agency to develop cross-program work groups to address the problems of site remediation under both the requirements of TSCA

and the Comprehensive Environmental Response Compensation and Liability Act of 1980 (CERCLA).

PCB contamination in natural gas pipelines. Since 1981 EPA has monitored 13 interstate natural gas pipeline companies due to the PCB contamination in their systems. EPA believes most of the contamination was caused by PCB lubricants used in natural gas pipelines being released into the pipeline itself. The PCBs are mobile within the systems, usually combining with natural gas condensate composed of water and constituents of natural gas. The mobility of the PCBs in the system makes their regulation and control problematic.

In recent years, EPA has sought enforcement actions against pipeline companies for improper disposal of PCB condensate in pits, ponds, and lagoons which may contaminate groundwater. Currently, EPA is operating under a Memorandum of Understanding (MOU) with the Federal Energy Regulatory Commission (FERC) which requires EPA to approve all proposals to abandon in place or remove segments of the pipeline system submitted to FERC. In addition to pipeline removal and abandonment projects, EPA has been regulating PCB contamination at air compressor stations in interstate natural pipeline systems.

Although PCB contamination in natural gas pipelines is primarily managed through TSCA, in some circumstances it is also managed through other federal and state laws. In fiscal 1989, EPA continued to meet with interstate pipeline companies to consider various abandonment and removal proposals. In fiscal 1990, EPA has begun development of technical guidance to the pipeline industry to expedite the approval of abandonment-in-place projects.

PCB Strategy for the 1990s

While managing "traditional" PCB concerns, EPA will also give higher priority to the more difficult management problems associated with high-volume/low-concentration problems, such as those described above.

Goals. Because PCB contamination is ubiquitous and the potential management resource requirements can be large, program emphasis must be placed on risk-based priorities. Consequently, EPA intends to: (1) develop and apply a strong risk-based approach to managing PCB contamination, (2) ensure prompt and adequate disposal of PCBs no longer in service, and (3) focus enforcement actions on cases and violators representing the greatest potential threat to health and the environment.

Means to achieve goals. EPA intends to implement a more diversified management approach involving federal, state, and local governments. A broader role will be developed for states and localities in disposal and management of cleanup operations. Also, full compliance of federal facilities with applicable requirements will be vigorously pursued.

Diversification also requires EPA to look for opportunities to link PCB management under TSCA with waste management and decontamination programs elsewhere in the agency and in the states. Examination of the adequacy of existing PCB regulations under TSCA to support an integrated waste management program is a high priority. Also, current joint research of EPA's Office of Pesticides and Toxic Substances and Office of Research and Development will be expanded to provide new risk assessment and risk management tools needed to address management of low-concentration PCB problems.

Lead -- Risk Management Support Activities in Fiscal 1989

Lead in municipal waste. In support of the Office of Solid Waste, the Office of Toxic Substances conducted an analysis of lead- and cadmium-containing products which enter municipal waste, and preliminarily identified those for which viable and less hazardous substitutes might exist. The report, "Uses and Substitutes Analysis for Lead and Cadmium Products in Municipal Solid Waste," was delivered to OSW in September 1989.

An additional task undertaken for OSW was to determine the feasibility and desirability of employing TSCA section 6(a) to divert lead acid storage batteries and other lead-containing products from the municipal waste stream to secondary smelters for recycling. The report, "Factors Bearing on Use of TSCA to Reduce Introduction of Lead into Municipal Waste and the Environment," was completed in November 1989. The report will provide the basis for a regulatory investigation under TSCA section 6(a).

Lead pollution prevention program. This is a cross-program effort within EPA, under the leadership of the Office of Toxic Substances, to undertake several initiatives to reduce human exposure to lead. Within the Office of Toxic Substances, the effort will explore the feasibility of using TSCA section 6(a) to: (1) reduce the overall consumption of lead, (2) encourage recycling of lead-containing products and the use of substitutes for lead, and (3) restrict or ban uses of lead associated with high exposure. An evaluation of economic incentives to achieve these ends is part of the program.

Lead in paint. The Lead Paint Poisoning Prevention Act of 1971 placed the responsibility for lead-based paint hazard

mitigation and research entirely with HUD. The 1989 EPA and HUD Appropriations Conference Report directed the two agencies to develop a Memorandum of Understanding stipulating, among other things, the support that EPA would provide to HUD in satisfying several requirements mandated in the Housing and Community Development Act of 1987. In the Memorandum of Understanding, dated April 1989, EPA also agreed to join with HUD in recruiting and chairing an interagency task force established for lead-based paint program development.

The requirements are that HUD report to Congress on the findings and recommendations of a demonstration of abatement techniques in HUD-owned single- and multi-family housing, conduct a national survey of the extent of the lead-based paint hazard in housing in the United States, and submit a "comprehensive and workable plan" by September 1990 for addressing the lead-based paint problem. EPA is providing technical assistance in two major areas: (1) development of information needed to complete the demonstration, survey, and plan, and (2) training of HUD and public housing personnel in program administration and training of contractor and designer personnel in safe and effective work practices.

Other Risk Management Activities in Fiscal 1989

On June 10, 1985, EPA published a Notice of Intent to list chromium or hexavalent chromium as a hazardous air pollutant under Section 112 of the Clean Air Act. The notice presented estimates of emissions from 11 sources, including comfort cooling towers, which are an integral part of heating, ventilation, and air conditioning or refrigeration systems. Hexavalent chromium has been determined to be a potent human carcinogen.

On March 2, 1988, EPA issued a proposed prohibition on use of hexavalent chromium in comfort cooling towers under authority

of TSCA section 6. During fiscal 1989, EPA prepared the final action prohibiting the use of hexavalent chromium in comfort cooling towers. The prohibition was issued on January 3, 1990 [55 FR 222], with an effective date of May 18, 1990.

Risk Management Strategy for Existing Chemicals

The Office of Toxic Substances is redirecting its efforts in the Existing Chemicals Program to use TSCA more effectively. The following changes are taking place.

Chemical screening. To support making decisions on risk reduction, chemical screening will be linked more directly to risk management. The Office of Toxic Substances will begin screening clusters, or like groups, of chemicals together. Screening activities will also build on growing international efforts where EPA is already in a principal role, such as in the Organization for Economic Cooperation and Development (OECD). In the meantime, EPA has begun selecting chemical clusters for screening and expects to provide screening results in the fall of 1990.

Chemical testing. Wherever possible, the Office of Toxic Substances will use model, or generic rules, to maximize productivity. The Office of Toxic Substances will also initiate a program to identify chemical testing priorities. This program will define the universe of data needs for TSCA chemicals, provide for government and public participation to determine national testing priorities, and focus the testing effort on the highest priority data needs.

Risk management. Opportunities for risk management will be considered at all stages of the risk assessment process to allow earlier actions to be taken when appropriate. In addition, the process will use a graduated response to risk reduction,

employing a step-wise review and a delegation of all but regulatory decisionmaking to lower levels in the Office of Toxic Substances to expedite action. The menu of regulatory actions will also include concepts such as "product stewardship," where a manufacturer assesses the safety, health, and environmental information on its products throughout their lifecycle and takes appropriate steps to protect employee and public health and the environment. In addition, the process will include associated technical assistance activities similar to those used in EPA's asbestos-in-schools program: citizen and consumer guides, technical control guidance and worker instructional pamphlets, training materials, and dialogues on key issues.

NEXT ... Chapter 8 discusses compliance and enforcement program activities and civil enforcement actions undertaken in fiscal 1989.

8. COMPLIANCE AND ENFORCEMENT

Background

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 inspectors uncover violations of TSCA requirements, EPA levies civil penalties, as authorized by TSCA section 16.

Program Development Activities During Fiscal 1989

During fiscal 1989, EPA developed and issued compliance monitoring strategies for AHERA and the Asbestos Abatement Projects Worker Protection Final Rule. EPA also developed an interim final enforcement response policy for AHERA.

EPA continued cooperative enforcement programs to monitor compliance with the PCB regulations in California, Connecticut, Iowa, Kansas, Maryland, Michigan, Missouri, New Hampshire, New Mexico, North Dakota, Ohio, Puerto Rico, Texas, and Washington. Kentucky and Minnesota also entered into PCB cooperative enforcement agreements with EPA. The states conducted approximately 1,300 PCB compliance inspections during fiscal 1989.

EPA also formalized cooperative enforcement agreements to monitor compliance with asbestos regulations in Arizona, Colorado, Idaho, Iowa, Maryland, New Hampshire, Oklahoma, Texas, Vermont, West Virginia, and Wisconsin. In addition, New Mexico received EPA approval to expand its cooperative agreement to

address asbestos as well as PCBs. The states conducted about 800 asbestos compliance inspections in fiscal 1989.

Compliance Actions

EPA conducted a broad range of inspections for TSCA compliance during fiscal 1989. In cooperation with 16 state agencies under the terms of enforcement grants-in-aid, EPA conducted 2,456 PCB compliance monitoring inspections. Also, the agency conducted 1,548 asbestos inspections under cooperative agreements with the American Association of Retired Persons and Arizona, Colorado, Idaho, Iowa, Maryland, New Hampshire, New Mexico, Oklahoma, Texas, Vermont, West Virginia, and Wisconsin.

EPA also monitored compliance with TSCA sections 4, 5, 8, and 13 requirements. Nine laboratories were inspected to determine if they were in compliance with Good Laboratory Practice requirements. During these inspections, the agency completed 27 audits of health and environmental tests to determine if testing had been done according to test protocols and if reports accurately reflected study findings. EPA also conducted 507 inspections to determine compliance with section 5 and 8 requirements.

International Cooperation

EPA signed Memoranda of Understanding with the Netherlands and with the Federal Republic of Germany regarding Good Laboratory Practice programs. Each Memorandum of Understanding calls for the reciprocal recognition of each country's Good Laboratory Practice compliance program, acceptance of test data generated in each country for evaluation of safety, and implementation of procedures for continuing mutual cooperation between the countries.

Civil Enforcement Actions

EPA issued 415 administrative complaints in fiscal 1989 under TSCA section 16. Another 319 civil action cases were completed during the year with total penalties exceeding \$4 million. Over 1,300 cases are pending resolution. Table 8-1 provides the number of cases and penalties by region for fiscal 1989 and since the beginning of the enforcement program.

Among the most significant actions were seven cases filed and settled in fiscal 1989 involving chemical substances imported in violation of sections 5 and 13 premanufacture notification and import certification requirements. More than \$1.2 million in total penalties were collected in these cases.

EPA completed its first full year of enforcement of the EPCRA section 313 toxics release reporting requirement. The agency accomplished 755 on-site facility inspections and issued more than 110 administrative complaints, with proposed penalties exceeding \$4 million. These accomplishments were the result of two major enforcement initiatives, which consisted of coast-to-coast filings of administrative complaints and attracted significant media attention. Packaging the complaints maximized EPA's enforcement leverage and led to an increase in the greater number of companies reporting their emissions.

EPA also issued administrative complaints against four federal facilities during the year. The Air Force, Coast Guard, and two Department of Energy contractors operating federal facilities were issued complaints for PCB violations. Civil penalties were collected from the DOE contractors. Summaries of

Table 8-1. Administrative Civil Actions Taken Under Section 16 of TSCA,
Complaints Issued, Cases Completed, and Amounts Assessed
(by Region)*

<u>Region</u>	<u>No. Cases Issued FY '79-'89</u>	<u>No. Cases Issued FY '89</u>	<u>No. Cases Completed FY '79-'89</u>	<u>No. Cases Completed FY '89</u>	<u>No. Cases Pending FY '89**</u>	<u>Civil Penalties Collected in FY '89</u>	<u>Civil Penalties Collected in FY '79-89</u>
1	208	21	138	16	70	\$ 241,050	\$ 1,481,439
2	593	29	479	34	114	356,070	3,910,387
3	395	57	269	45	126	543,180	2,115,293
4	362	13	219	15	143	113,970	785,467
5	1,007	86	808	87	199	489,225	6,616,801
6	390	24	319	20	71	78,850	1,947,619
7	503	42	248	19	255	121,112	1,018,292
8	430	43	325	23	105	97,380	1,031,045
9	258	19	223	21	35	115,080	1,428,000
10	355	60	149	31	206	407,064	1,230,570
HQ	70	21	45	8	25	1,506,979	7,321,994
<hr/>							
Total	4,571	415	3,222	319	1,349	\$4,069,990	\$28,886,907

* All actions taken involve alleged violations of TSCA sections 4, 5, 6, 18, and 13.

** Includes cases carried over from fiscal years 1979 to 1988.

these and other civil enforcement actions during fiscal 1989 appear in Appendix G.

NEXT ... Chapter 9 discusses litigation and citizen's petitions under TSCA.

9. Litigation

Lawsuits are filed against EPA under TSCA either to compel EPA to undertake certain actions or to invalidate actions the agency has already taken.

In the past, the greatest amount of defensive litigation under TSCA involved PCBs. There was extensive litigation on PCB rulemaking resulting from the 1980 decision invalidating EPA's original PCB rules. All PCB litigation after 1980, however, has resulted in EPA agreeing to conduct additional rulemaking. Fiscal 1989 saw the end, for all practical purposes, of PCB litigation resulting from the 1980 decision. Formal ending of all cases occurred in fiscal 1990. Currently, there is only one significant active PCB lawsuit, a challenge to EPA's approval of a PCB disposal facility in Henderson, Kentucky. Occasionally, defendants in PCB administrative enforcement cases appeal judgments to the U.S. Court of Appeals.

The largest number of cases in the past few years are those challenging EPA actions under section 4(a) of TSCA to require testing of chemicals. Nine cases have been filed. Two were filed in the early stages of the agency testing program by the Natural Resources Defense Council, a public interest group. The earliest case, in 1980, compelled EPA to increase the speed of its testing program. The next case, in 1984, invalidated aspects of EPA's negotiated testing agreements. Seven cases have been filed over the past few years by the industry groups challenging test rules. Three of these cases--on fluoroalkenes, ethylhexanoic acid, and mesityl oxide--have resulted in opinions by the U.S. Courts of Appeals. A case on cumene was decided in April 1990. The other cases are settled or are in the process of being settled.

The first two cases upheld EPA's authority to require testing under TSCA section 4(a)(1)(A). The court in the mesityl oxide case remanded the rule to EPA, and EPA is negotiating a testing consent order to require testing of mesityl oxide. The cumene decision required EPA to articulate standards for requiring testing under TSCA section 4(a)(1)(B), and EPA is working on establishing such criteria.

EPA has been sued under the section 21 citizens' petition provision to compel the agency to regulate dioxins, to require testing of certain chemical substances present in the environment of the southwest of Chicago, to regulate asbestos in buildings, and to amend its PCB regulations. The dioxin case has been settled. The Chicago testing case is still pending, after having originally been filed in 1985. A challenge to the constitutionality of section 21 was dismissed by the court during fiscal 1989. Procedural motions in the PCB case were decided in 1990. One asbestos case, filed by the Service Employees International Union (SEIU), was effectively mooted by passage of AHERA, which dealt with the issues raised in the suit. SEIU also sued the agency in U.S. District Court for denying its citizens' petition to commence a rulemaking affecting asbestos in public and commercial buildings. As of the end of fiscal year 1989, activities in this suit were being held in abeyance pending a policy dialogue that SEIU anticipated would lead to the beginning of rulemaking.

In 1989, EPA completed its successful defense of its asbestos in schools regulation mandated under AHERA, when the Supreme Court denied a review requested by the National Gypsum Company of a U.S. Court of Appeals ruling in the agency's favor.

New major cases filed in fiscal 1989 involved challenges to EPA's asbestos activities. The most important was the challenge

to the agency's regulation banning use of asbestos in most products. Eight petitions for review were filed in the U.S. Court of Appeals. The case is pending.

Finally, in the last few days of fiscal 1989, the state of Colorado requested a U.S. District Court to declare that schools for physically and emotionally disabled children run by its Department of Institutions are exempt from AHERA provisions requiring management of asbestos in schools. The basis for the Colorado suit is a law enacted by its legislature specifically exempting those schools from AHERA. Various procedural issues are being decided in this case.

A petition for review was filed several years ago with respect to the first significant new use rule under TSCA section 5(a)(2). That case has been settled.

A summary of cases during fiscal 1989, including citizens' petitions and other challenges, is provided in Appendix H.

NEXT ... Chapter 10 discusses how EPA works with other federal agencies and the international community to assess and manage chemical risks.

10. RELATIONSHIP OF TSCA TO OTHER FEDERAL AND INTERNATIONAL ACTIVITIES

Interagency Activities During Fiscal 1989

Section 9(d) of TSCA requires that EPA report annually on its efforts to coordinate its TSCA activities with related activities of other federal agencies.

EPA continues to negotiate Memoranda of Understanding with other federal agencies regarding confidential business information submitted to the agency under TSCA. EPA's statutory obligation is to safeguard confidential business information. So, the agency's approach to sharing data, while as flexible as possible, is constrained by its legal responsibilities. In specific instances, EPA has worked with companies to have them provide confidential business information directly to another federal agency when that agency is unable to meet EPA's requirements for protecting data.

Currently, NIOSH is considering the need to enter into an Memorandum of Understanding on data-sharing with EPA, and the U.S. Customs Office has expressed some interest in accessing TSCA Confidential Business Information.

EPA also receives recommendations on existing chemical testing priorities from the Interagency Testing Committee, established under section 4(e) of TSCA and composed of representatives from EPA, OSHA, NIOSH, NIEHS, NCI, NSF, DOC, and CEQ⁴. EPA has also solicited the participation of FDA⁵, CPSC,

⁴ CEQ - Council on Environmental Quality, NIEHS - National Institute of Environmental Health Sciences, NCI - National Cancer Institute, NSF - National Science Foundation, DOC - Department of Commerce

and NIOSH in a multi-media risk assessment of PCDDs and PCDFs.

During fiscal 1989, the Office of Toxic Substances continued to work with the ONE Committee (OSHA, NIOSH, EPA). Composed of the three federal agencies most concerned with occupational safety and health and worker exposure, this group meets monthly. Its primary aim is communication, coordination, and cooperation both on actions related to specific chemicals and on broad issues associated with programs administered by these agencies. Work on such chemicals as acrylamide, asbestos, lead, cadmium, and solvents took place during 1989 and continues to the present time.

The development and promulgation of the Asbestos Ban and Phase-out Rule benefited greatly from the cooperation and advice of OSHA and CPSC. EPA is also coordinating with OSHA with respect to worker protection aspects of the EPA's asbestos-in-buildings program.

EPA has also signed a Memorandum of Understanding to support HUD's efforts in mitigating risks from lead-based paint.

International Activities During Fiscal 1989

EPA's major TSCA-related international activities during fiscal 1989 were with the OECD and are listed here.

1. Expert Meeting on OECD Clearinghouse (Copenhagen, January 1989).

Decisions were reached concerning the role of clearinghouses within the OECD and agreement made on the general objectives, scope, and expected results of

⁵ FDA - Food and Drug Administration

clearinghouse efforts. Clearinghouses represent an important vehicle for developing cooperative, multinational efforts on existing chemicals as part of the OECD's effort to share the burden. The United States is an active participant in a majority of the 20-plus clearinghouses.

2. 12th Joint Meeting of the OECD's Chemicals Group and Management Committee (Paris, March 1989).

The 12th Joint Meeting endorsed a recommendation on monitoring compliance with Good Laboratory Practice requirements. This draft decision was supported by the United States. The 12th Joint Meeting also reviewed and endorsed clearinghouse efforts to come up with a way to obtain testing and assessments of the highest volume chemicals in the OECD countries.

3. Screening Information Data Set Effort on High-Production-Volume Chemicals (SIDS/HPV).

During fiscal 1989, the OECD successfully got under way efforts to assemble an inventory of the 1,000 chemicals produced in the largest quantities in OECD countries. After sorting the chemicals according to data availability, a subset of 150 priority chemicals will be developed. Screening tests will then be used to assess the risks of the chemicals internationally and to set priorities by the OECD.

The United States has actively sought international cooperation in testing and assessing existing chemicals and was an active participant in this successful effort, which was led by Sweden and the Federal Republic of Germany. At the 13th Joint Meeting in November 1989,

member countries agreed that a basic level of test data is needed on these high-production-volume chemicals, and they committed to an international effort.

These data are referred to as the Screening Information Data Set (SIDS). While the scope of the test set is relatively limited, the OECD agreement to test 147 chemicals is a major achievement and an important first step in international cooperation.

For most countries, including the United States, the responsibility and cost of testing will be borne by industry as part of a voluntary and cooperative effort. At least 18 OECD countries will participate in the testing program. Chemicals will be tested for the following parameters:

- Basic chemistry
- Environmental fate
- Acute/chronic ecotoxicity
- Acute toxicity
- 45-day sub-chronic toxicity test with reproductive and developmental screens
- Mutagenicity

The development of the U.S. position on this agreement was facilitated by the Conservation Foundation and involved participation of interest groups and industry. The chemicals are currently being divided among member countries. The United States will be responsible for testing about 25 percent of the substances--other countries will test the rest. It is anticipated that up to 450 chemicals will be handled via

this cooperative testing and assessment program over the next five years.

4. United States/Federal Republic of Germany
Cooperative Effort.

The governments and industry of the United States and the Federal Republic of Germany agreed in June 1989 to conduct a series of tests on 2,4-dinitrotoluene, a chemical of common interest to both countries. Testing will be done voluntarily by industry in both nations.

5. 13th Joint Meeting of the OECD's Chemicals Group and
Management Committee (Paris, November 1989).

The 13th Joint Meeting agreed to undertake an effort to test and assess high-production-volume chemicals using an approach involving sponsor countries and voluntary testing by industry. (See item 3 above for more information.)

6. OECD Workshop on New Chemicals Notification
Procedures (Paris, November 1989).

This workshop brought together representatives from almost all OECD countries to discuss their approaches in dealing with new chemical notification schemes. The workshop was quite successful and several important recommendations were developed.

Of importance to the United States was the recommendation that it collaborate with the European Community (EC) in a study in which the United States would:

- assess the hazards of a series of new chemicals in the EC by analyzing SARs; and
- compare the results of the SAR analysis with the results of the Minimum Premarket Data (MPD) tests that the EC requires be done on new chemicals.

The study's objective is to determine the degree to which U.S. SAR analyses would have changed had the MPD been available during initial assessment. (Section 5 of TSCA does not require submission of a base set of test data as part of the premanufacture notification.) While carrying out the study, the United States will evaluate the value of MPD in improving our calls. Efforts have been initiated to work with the Commission of the European Community in designing and implementing the study.

The study is similar to the so-called Retrospective Study, which was proposed in 1984 but never carried out due to inadequate funds.

7. Hazard Assessment Advisory Body (HAAB).

The HAAB advises the Joint Meeting on hazard/risk assessment issues. Within the HAAB, the United States is collaborating with the Netherlands in three projects. These efforts focus on different aspects of environmental risk assessment: extrapolation from lab studies to field effects; use of SARs in screening and regulating chemicals; and approaches to assessment of contaminated sediments.

NEXT ... Chapter 11 discusses TSCA-related research and development activities in EPA during fiscal 1989.

11. RESEARCH AND DEVELOPMENT

Background

Research on chemical substances is performed to support the needs of TSCA. Efforts are geared toward evaluating the risks associated with manufacturing and using new and existing chemicals, and in developing engineering controls to mitigate that risk.

The research program is centered on improving the predictability of human-risk estimates and developing better ways of performing environmental risk assessments--including development of exposure monitoring systems, environmental fate and effects methods, and assessment guidelines.

Additional research develops and evaluates release and control methods for new and existing chemicals, SARs as predictors of chemical fate and biological effects, and procedures for ensuring the human and environmental safety of the products of biotechnology.

Major Research Issues

Indoor air exposure. A frequent exposure medium encountered in TSCA risk assessments is indoor air. This has been the case for formaldehyde, chlorinated solvents, and paradichlorobenzene projects, among others. As part of the process of assessing risk, it is necessary to perform an exposure assessment. A common way to do this is to model the indoor air concentration levels of the chemical of interest. EPA's Office of Research and Development developed an indoor air exposure model to be used for indoor air exposure assessments. The Office of Research and Development also developed a procedure to test the performance of

the model against measured concentrations of chemicals in indoor air.

Test methods development. TSCA enables EPA to require companies to test selected existing chemicals for toxic effects. EPA is responsible for providing guidance for testing and evaluating the toxic properties of such substances. The ultimate goal is to develop short-term, cost-effective, predictive methods for detecting and assessing the toxic effects of chemicals.

The Office of Research and Development conducts a program for conducting such tests, including methods and protocols for acute, chronic, and sublethal effects testing and appropriate guidelines for their use. These are sometimes performed to evaluate questionable data or to provide data where otherwise not available. Research provides carefully screened bioassays and other methods for measuring and analyzing chemicals and dose, for improving monitoring, for determining human and environmental effects such as carcinogenic, reproductive and immunotoxic problems and to reduce the uncertainties associated with risk assessments. Research products support the TSCA regulatory policy and decisionmaking process.

Structure-activity relationships. The SAR is key to quickening the pace of regulatory reviews. It allows EPA to evaluate a chemical based on the similarity of its molecular structure to chemicals with known toxic activity. Using the SAR approach, chemicals can be grouped together to allow rapid determination of probable toxicity and environmental risks.

The SAR approach is proving vital for reviewing and screening new chemical substances under section 5 of TSCA, and for evaluating other chemical pollutants as well. The research includes ongoing accumulation of data on plant uptake, on fate of organic chemicals, on fish toxicity and reactivity of chemicals

in air. Methods and models which can predict toxicity, bioaccumulation, and kinetics of biotransformation are being refined based on new information, to provide more accurate predictions or expand the class of chemicals that may be included. Computerized expert systems for estimating reactivity parameters and persistence of toxic chemicals in aquatic and terrestrial habitats are being developed and used.

Special human data needs. To improve the agency's ability to estimate human risk, these activities examine population groups exposed to environmental contaminants which are suspect toxicants to determine if biological indicators of dose or effects are being related to environmental levels of exposure. Data are also being developed on adverse effects as measured by traditional epidemiological studies.

Ecology: transport/fate/field validation. To evaluate the likely problems a toxic chemical may cause in the environment, it is necessary to understand probable chemical exposure concentrations and durations, movement through ecosystems, degradation rates and products, effects, and residue sites and levels. More specifically, the Office of Research and Development is establishing a scientific information resource on how plants, animals, and entire ecosystems are affected by toxic substances. In the research program, techniques are developed, validated, and used to assess hazards and exposures and to estimate the fate of toxic chemicals. This provides the basis for designing mathematical models capable of predicting chemical transport, transformation, and fate.

Among the many related issues included are intermedia transfer, chemical specific characterization (e.g., chemical photolysis and hydrolysis rate constants), processes of the receiving environment, comparative toxicological responses, system level effects (community alterations), effects of

toxicants on plant and animal development, recovery, persistence, and bioaccumulation. There is an emphasis on using and developing state-of-the-art science techniques to fill recognized data gaps, to determine potential adverse impacts of an increasing list of toxicants, and to help formulate preventive or remedial actions that are scientifically credible and legally defensible.

Health: markers, dosimetry, and extrapolation. Research on health effects is focused on developing methodologies to extrapolate data from high to low doses and between mammalian species in order to enhance human health risk assessment predictability. Additional studies involve defining the relationship between biological markers of exposure and non-cancer health endpoints, such as neurotoxicity and immunotoxicity, as well as genotoxic endpoints. Dosimetry studies are examining dermal and inhalation routes of exposure. Extrapolation research is focusing on genetically mediated health effects.

Exposure monitoring. The major TSCA-related monitoring research efforts are directed toward improving the monitoring systems designed to estimate total human exposure. Research is also continuing on approaches for multi-media/multi-pathway monitoring systems that generate data which will provide an estimate of total human exposure. EPA is also conducting studies to incorporate environmental dose into personal exposure monitors to provide a better understanding of the contribution of different exposure routes to pollutant intake.

The National Human Adipose Tissue Survey (NHATS) continued to collect and analyze tissue specimens to provide exposure data. NHATS analyzed the specimens for dioxins and furans, diphenylethers and semivolatile organic compounds. The National

Academy of Sciences will submit a report on its review of the NHATS program in 1991.

Biotechnology. Certain microorganisms fall within the regulatory framework of EPA under TSCA. EPA is developing procedures to assess the potential risks and benefits of the use of these microorganisms. As a cooperative adjunct, a research program has been initiated to develop evaluative methodology and gather scientific information that would identify and adequately describe effects on the environment that may result from the introduction of genetically altered microorganisms into the environment.

Six areas of research were identified as essential for risk assessment:

- development of methods for the detection and enumeration of novel organisms in complex environmental samples;
- determination of survival and growth in the environment;
- assessment of the stability and transfer frequency of introduced genetic material in the intracellular and extracellular environment;
- development of data and predictive models for transport from the point of application or release to other locations;
- detection of adverse environmental response (ecological effects, toxicity, host range change, etc.) due to the introduced organisms; and
- determination of changes in host range.

Each of these areas is currently being investigated by selected research laboratories. The strategy for program development has, as a critical component, established an in-house scientific staff to build the necessary information database and to develop appropriate methods and protocols for risk assessment. Concurrently, staff scientists share responsibility for

developing a complimentary extramural program and interactive information exchange with scientists in the fields of genetics, biochemistry, ecology, and microbiology.

The program deals with both recombinant and non-recombinant bacteria, fungi, and viruses. In all areas, a primary objective is to produce appropriate scientific information for developing protocols.

In the health research area, studies are being conducted to determine the genetic stability and function of a baculovirus expression vector in vertebrate cells. Methods are also being developed to evaluate the potential health consequences of deliberate or inadvertent release of genetically altered organisms.

Engineering research is focused on the evaluation of experimental data on kill-tank efficiency and development of risk management models reflecting loss-prevention techniques for large-scale premanufacture notification processing facilities.

Engineering release and controls. In the new chemicals area, models, based on workplace exposure and release of existing chemicals, are being developed. These models will assist in predicting workplace exposure for classes of new chemicals that the agency does not have adequate information. Treatability of dyes in wastewater is ongoing. Model development is under way for predicting glove permeation. In the asbestos-research area, efforts are focused on verifying the adequacy of guidance for schools, and in developing control strategies for maintaining effective work area isolation under negative air pressure in tall buildings. Establishing priorities of the major-release chemicals is under way to support the EPCRA section 313 reporting requirements.

Ecology: ecotoxicity and risk assessment. In 1986, the Office of Research and Development initiated a comprehensive research program in response to the recognized need of the toxic substances program to improve the capability for assessing and predicting chemical risk to ecosystems. Several goals were established for this research:

- identify critical ecological components for assessment;
- develop techniques for extrapolating laboratory and limited field data to other systems;
- provide systematic procedures to permit consistent ecological evaluations among analysts; and
- provide insights into a better understanding of the consequences of environmental insult from chemicals.

The Office of Research and Development's approach is primarily one of developing system-independent mathematical models and protocols for exposure and hazard assessment and embedding them in a computer-based "Decision Support System." This system will provide convenient access to these scientific tools essential for completing ecological risk assessment.

To achieve its goal, the Office of Environmental Processes and Effects Research, of the Office of Research and Development, has established an Ecological Risk Assessment Research Program which relies heavily on results from EPA's base chemical exposure and hazard assessment research and development efforts. The major emphasis in the current program is to integrate results from these two areas to provide the scientific basis for assessing ecological risks. The present state of the art of research in chemical exposure and hazard evaluation has not adequately covered all subject areas needed to provide tools for ecological risk assessment. Existing research results, ongoing research in the areas of chemical exposure and hazard evaluation,

and complementary new research conducted in this program will provide a foundation for developing a scientifically sound ecological risk assessment capability for the agency.

Support. For certain assessments and other toxicological problems, Office of Research and Development staff members are often called upon to interpret data or render other technical and scientific judgments. These are achieved through coordinated expert reviews, workshops, and topical conferences that draw upon the internal and extramural scientific community. Special workshops, symposia, and in-house training programs assist in preparing regulatory staff at the state, regional, and national levels to apply the information and assessment tools developed through the Office of Research and Development.

A summary of EPA's TSCA-related research and development activities is provided in Appendix I.

NEXT ... Chapter 12 discusses other TSCA-related activities and accomplishments during fiscal 1989.

12. OTHER TSCA-RELATED ACTIVITIES

Chemical Export Notification Program

Section 12(b) of TSCA requires any person who exports or intends to export a chemical substance or mixture to notify EPA if certain regulatory actions have been taken with respect to that substance or mixture under sections 4, 5, 6, or 7 of TSCA.

Written notice must be submitted for the first export or intended export to a particular country each year. It must be postmarked within seven days of forming the intent to export or no later than the date of export. It must include the name of the regulated chemical, the name and address of the exporter, and the section of TSCA under which EPA has taken action.

EPA is then required to send a letter to the importing country, usually at its Washington embassy, within five working days after the receipt of the company's export notice. Letters to foreign embassies include the name of the regulated chemical exported, a summary of the regulatory action taken, and the name of an EPA official to contact for further information. Copies of pertinent Federal Register notices are included.

During the past five years, the number of section 12(b) notices received by EPA has increased significantly, primarily because of the number of section 4 final test rules and testing consent orders promulgated. Table 12-1 shows the growth of the program since 1985.

From January 1989 through October 1989, EPA responded to more than 275 inquiries from approximately 20 countries for additional information on exports. Inquiries were for (1) shipment-specific information, (2) clarification on the U.S. export notification process, (3) information concerning section 4

test results, and (4) health/ environmental studies, etc.

Table 12-1. Chemical Export Notifications, Fiscal 1985-89

<u>Fiscal</u>	<u>Notices Received</u>	<u>No. Chemicals Subject to Notification</u>	<u>Letters Sent to Foreign Countries</u>
1985	820	10	533
1986	2,000+	20	869
1987	2,400	40	1,035
1988	4,200	120	2,155
1989*	5,300	125	3,100

* Through 10/15/89

EPA published a proposed rule on July 12, 1989, to change notification requirements for section 12(b). The proposed rule will require exporters to submit a one-time notice for section 4 actions. That is, after the one-time notice for a chemical subject to section 4 action, no further annual notification is required. No changes in reporting requirements are proposed for sections 5, 6, and 7 of TSCA. EPA believes that this change will provide a more useful notice to foreign governments and reduce the reporting burden on both EPA and industry.

TSCA Assistance Information Service

Passage of TSCA in October 1976 established EPA's Industry Assistance Office (IAO)--renamed the Environmental Assistance Division in 1989--to assist the chemical industry and others in understanding and complying with requirements of the act. In 1977, the TSCA Assistance Information Service was established to provide such technical assistance. Since that time, the service has grown and now supports implementation of AHERA, EPCRA, and other EPA programs addressing toxic substances. The service also acts as an information center for labor, environmental groups,

other government agencies, and private citizens. Assistance is provided by personnel responding to inquiries received by telephone or by mail.

The volume of information flow has grown as the number of regulations under TSCA has increased. During 1989 the service responded to 34,600 telephone calls and more than 2,600 letters. The service distributed over 82,700 documents in response to these calls and letters.

TSCA State Program Support

Table 12-2 summarizes funding of EPA's cooperative agreements with various states under TSCA.

TSCA-Related Reports

A large number of reports covering many different activities related to TSCA and associated laws are produced every year by EPA. A number of the more significant reports are listed in Appendix J, including the National Technical Information Service number for reports available from that organization.

Table 12-2. Funding for TSCA State Cooperative Agreements,
Fiscal 1985-91

<u>Fiscal</u>	<u>Type of Support</u>	<u>Amount</u>	<u>No. Recipient States</u>
1985	Enforcement support*	\$ 1,500,000	11
	Program development**	705,000	13
1986	Enforcement support	\$ 2,201,100	17
	Program development	1,523,500	21
1987	Enforcement support	\$ 2,200,000	19
	Program development	385,000	5
1988	Enforcement support	\$ 2,200,000	21
	Program development	1,042,645	17
1989	Enforcement support	\$ 2,200,000	23
	Program development	0	0
1990	Enforcement support	\$ 3,110,300	30 (est.)
	Program development	1,500,000	21 (est.)
1991	Enforcement support	\$ 5,100,000 (proposed)	37 (projected)
	Program development	2,000,000 (proposed)	unavailable

* Enforcement support typically includes support for TSCA section 6 actions, including compliance inspections and case development. Cooperative agreements are awarded under section 28 of TSCA. In some cases, EPA may have had more than one cooperative agreement with a single state in a given year (e.g., separate agreements for PCBs and asbestos).

** Program development typically has covered support for states to develop asbestos contractor and inspection training and certification programs. This does not include Asbestos Inspection and Management Plan Assistance Program monies in fiscal 1987 and fiscal 1988 of \$20 million for local education agencies. Projected program development funding for fiscal 1991 includes first-time funding of \$1 million for the TRI and \$0.5 million for PCBs.

SECTION III.

APPENDICES

APPENDIX A

Major Fiscal 1989 TSCA Actions

<u>Section of Law</u>	<u>Description</u>	<u>Date</u>
4(e)	23rd Interagency Testing Committee (ITC) report to the Administrator (53 FR 46262).	11/16/88
	24th ITC report to the Administrator (54 FR 31248).	07/27/89
4(a)	<u>Test Rules:</u>	
	Hexafluoroproylene Oxide (2nd ITC List). Notice of proposed rulemaking termination. Manufacturing and processing information demonstrated that workplace exposure is being controlled and is not expected to present unreasonable risk to health (53 FR 40244).	10/14/88
	Commercial Hexane (non-ITC). Notice of proposed rulemaking repropose the pharmacokinetics test requirements and the associated test guideline (53 FR 45289).	11/09/88
	Pentabromoethylbenzene (15th ITC list). Withdrawal of proposed rule for chemical fate and environmental effects. Data received by EPA since proposal of test rule indicate no ongoing or intended manufacture or processing of the substance (53 FR 47228).	11/22/88
	Oleylamine (13th ITC list). Notice of final rulemaking requires that certain TSCA health effects test guidelines be used as the test standards for the required studies, and that test data be submitted within specified times (53 FR 48542).	12/01/88

Section of Law	Description	Date
<u>Test Rules:</u>		
	Tributyl Phosphate (18th ITC list). Notice of final rulemaking requires manufacturers and processors to perform tests for health effects, environmental effects, and chemical fate (54 FR 33400).	08/14/89
	1,1,1-Trichloroethane (2nd ITC list). Consent order to perform mutagenicity and neurotoxicity tests (54 FR 34991). This rule constitutes an additional EPA response to the ITC. In 1984, EPA issued a final Phase I test rule requiring developmental toxicity testing.	08/23/89
	Methyl Ethyl Ketoxime (19th ITC list). Notice of final rulemaking requires manufacturers and processors of methyl ethyl ketoxime to perform tests for health effects (54 FR 37799).	09/13/89
<u>Test Standards/Guidelines/Procedural Rules:</u>		
	Technical amendments to certain chemical fate and health effects test guidelines; final rule (53 FR 49148).	12/06/88
	Mouse visible specific locus test require- ment; proposed amendment in test rules (53 FR 51847).	12/23/88
	Testing consent agreements and test rules; proposed rule (54 FR 21237).	05/17/89
	Technical Amendments to test rules and consent orders; final rule (54 FR 27352).	06/29/89
	TSCA test guidelines--technical amend- ments; final rule (54 FR 29715).	07/14/89

Section of Law	Description	Date
<u>Test Standards/Guidelines/Procedural Rules:</u>		
	TSCA good laboratory practice standards; final rule (54 FR 34034).	08/17/89
	Procedures governing testing consent agreements and test rules; interim final rule (54 FR 36311).	09/01/89
5(a)(2)	Significant new use rules; general provisions for new chemical follow-up-- final rule (54 FR 31298).	07/27/89
	Pentabromoethylbenzene. Withdrawal of proposed test rule; proposed signifi- cant new use of chemical substances (53 FR 47228).	11/22/88
	Mixture of 1,3-Benzenediamine, 2(or 4)- Methyl-4,6(or 2,6)-Bis(Methylthio)-. Proposed determination of significant new uses--proposed rule (53 FR 52443).	12/28/88
	Benzenamine, 4-Chloro-2-Methyl-Benzen- amine, 4-Chloro-2-Methyl-Hydrochloride; Benzenamine, 2-Chloro-6-Methyl. Signi- ficant new use of chemical substances --3 chemicals--final rule (54 FR 12445).	03/27/89
	Pentabromoethylbenzene. Significant new use of chemical substance--final rule (54 FR 18283).	04/28/89
	1,3-Benzenediamine, 4-(1,1-Dimethyl- ethyl)-ar-methyl. Proposed determina- tion of significant new uses--proposed rule (54 FR 23228).	05/31/89
	Polymers Manufactured Using Free-Radical Initiators; Clarification of Reporting Requirements (54 FR 27174).	06/28/89

Section of Law	Description	Date
<u>Test Standards/Guidelines/Procedural Rules:</u>		
	Mixture of 1,3-Benzenediamine, 2-Methyl-4,6-Bis(Methylthio)-and 1,3-Benzenediamine, 4-Methyl-2,6-Bis(Methylthio)-. Significant new uses--final rule (54 FR 38381).	09/18/89
	2,4-Pentanedione. Significant new use of a chemical substance--proposed rule (54 FR 39548).	09/27/89
<u>Consent Orders:</u>		
5(e)	Consent order. Acrylic copolymer, sodium salt (P88-854)	10/20/88
	Consent order. Cyclo-substituted alkyl prognoic acid derivative (P88-1445)	10/20/88
	Consent order. Dimethyl octenes mixture and 2-methyl-6-methyleneoctane (P88-1375)	10/23/88
	Consent order. Di(substituted)alkyl hydrogen acid phosphite (P88-1628)	10/26/88
	Consent order. Polyester resin (P88-1540)	11/07/88
	Consent order. (P85-567)	11/08/88
	Consent order. Unsaturated silyl ester; Aliphatic silylated amino ester (P88-388,715)	12/07/88
	Consent order. Acrylated polymer (P88-1109)	12/21/88

Section of Law	Description	Date
<u>Consent Orders:</u>		
	Consent order. 4-Methyl-2-phenyl-1H-imidazole-5-methanol; Substituted triazine isocyanurate; 2-Methyl-1H-imidazole, adduct with 1,3,5-triazine-2,4,6(1H,3H,5H)-trione, hydrate (P86-65,66,67)	12/23/88
	Consent order. Carboxylated novolak acrylate (P88-1616)	01/05/89
	Consent order. Polypiperidinol acrylate-methacrylate (P88-1304)	01/12/89
	Consent order. p-Menthadienes and m-menthadienes mixture plus 3-c arene, para-cymene, and camphene (P88-1718)	01/25/89
	Consent order. Amine salt (P85-941)	01/31/89
	Consent order. Terpene resin; Poly-terpene resin (P88-1617,1623)	02/06/89
	Consent order. Substituted cresol (P87-68)	02/16/89
	Consent order. Functional acrylate (P88-2133)	02/22/89
	Consent order. Asymmetrical aromatic diacyl peroxide (P88-862)	02/27/89
	Consent order. Phenol, 4,4'-(9H-fluoren-9-ylidene)bis- (P88-831)	03/07/89
	Consent order. Epoxy resin (P88-837)	03/07/89
	Consent order. Poly(teiazinyl piperazine) (P88-436)	03/17/89

Section of Law	Description	Date
<u>Consent Orders:</u>		
	Consent order. 1,2-Epoxybutane, 2-propenoic acid, dibut, ylene glycol mono-2-propenoic acid esters, dibut, 1,2-butanediol, 2-hydroxybutyl acetate; 1,2-Epoxybutane, 2-propenoic acid (P87-930,931)	03/29/89
	Consent order. 2,5-Dimercapto-1,3,4-thiadiazole reaction product (P88-1460)	03/30/89
	Consent order. Acrylate modified with urethane (P88-875)	04/04/89
	Consent order. Complex alkyl aryl imide (P88-1514)	04/05/89
	Consent order. Dodecanoic acid (P87-1436)	04/06/89
	Consent order. Trimethylopropane fatty acid diacrylate (P88-2463)	04/11/89
	Consent order. Acid functional polyester with low molecular weight acid (P88-1857)	05/03/89
	Consent order. Strain RMB7101; Strain RMB7201; Strain RMB7401; Rhizobium meliloti (P88-1116,1118,1120, P89-280 (modification))	05/19/89
	Consent order. Alkyleneamine alkylphenol mannish (P89-388)	05/25/89
	Consent order. Fluorene-containing diaromatic diglycidyl ether epoxy resin (P88-997)	06/02/89
	Consent order. Fluorene-containing diaromatic amine; Fluorene-containing diaromatic amine (P88-998,999)	06/02/89

Section
of Law

Description

Date

Consent Orders:

Consent order. Bradyrhizobium japonicum; Bradyrhizobium japonicum; Bradyrhizobium japonicum strains; Bradyrhizobium japonicum (P88-1275,1277, P89-340/341 (modification))	06/02/89
Consent order. Polyether polyamine (P88-2334)	06/06/89
Consent order. 2,2,6,6-Tetrakis(bromomethyl)-4-oxa-1,7-diol (P87-1273)	07/10/89
Consent order. Quaternary ammonium compound (P89-116)	07/17/89
Consent order. Substituted diethylsuccinate (P87-1417)	08/01/89
Consent order. Alkyl amine (P89-268) (revoked)	08/21/89
Consent order. Substituted phenol sulfonic acid (P88-2341)	08/31/89
Consent order. Modified fatty acid, amine salt (P88-1889)	09/12/89
Consent order. Modified phenol formaldehyde resin (P89-279)	09/20/89
Consent order. Azo compound (P88-2470)	09/21/89
Consent order. Carbopolycyclicolazo-alkylaminoalkylcarbomomo-cyclic ester, halogen acid salt (P88-1682)	09/22/89

Section of Law	Description	Date
<u>Consent Orders:</u>		
6	Procedures for Rulemaking Under Section 6 of the Toxic Substances Control Act--Final Rule (54 FR 21622)	05/19/89
	Asbestos. Manufacture, importation, processing and distribution in commerce prohibition--final rule (54 FR 29460)	07/12/89

APPENDIX B

Chemical Data Received Under TSCA Section 4(d) in Fiscal 1989

EPA received data on the following 35 chemicals under TSCA section 4(d) requirements during fiscal 1989:

biphenyl
anthraquinone
hydroquinone
1, 2-dichlorobenzenes
1, 2-dichloropropane
ethyl methacrylate
vinylidene fluoride
cresols
tetrabromobisphenol-A
methyl tert butyl ether
1, 2, 4, 5-tetrachlorobenzene
aniline
2, 6-dichloro-4-nitroaniline
2-chloroaniline
propylene dichloride
dichloropropanol
dihydrosafrole
dibromomethane
ortho-cresol
para-cresol
commercial hexane
diethylene glycol butyl ether
methyl chloride
parachlorobenzotrichloride
p-nitrophenol
c9 aromatic hydrocarbon fraction
cumene
4-nitroaniline
2-nitroaniline
oleylamine
3, 4-dichloroaniline
mercaptobenzothiazole
octamethylcyclotetrasiloxane
alkyl phthalates
2, 3, 5, 6-tetrachloro-2, 5-cyclohexadiene 1, 4-dione

APPENDIX C

**Summary of TSCA Section 4 Chemical Testing Actions
in Fiscal 1989**

Testing in Response to the Interagency Testing Committee (ITC)

<u>Date</u>	<u>Chemical</u>	<u>Action</u>	<u>ITC List</u>
10/14/88	Hexafluoropropylene oxide	Termination of proposed rule; ends rulemaking that would require mutagenicity, oncogenicity, and reproductive effects testing.	2
11/22/88	Pentabromoethylbenzene	Withdrawal of proposed rule; proposal to require chemical fate and environmental effects testing.	1
12/1/88	Oleylamine	Notice of final rulemaking; specifies test standards and reporting requirements for health effects testing.	1
1/9/89	Alkyl phthalates	Consent order; requires chemical fate and environmental effects testing of: dimethyl phthalate; di-n-butyl phthalate; dihexyl phthalate; di-2-ethylhexyl phthalate; di-(heptyl, nonyl, undecyl) phthalate; diisodecyl phthalate; diundecyl phthalate, and ditridecyl phthalate.	
1/10/89	Octamethylcyclotetrasiloxane (OMCTS)	Consent order; requires chemical fate and environmental effects testing.	1

Date	Chemical	Action	ITC List
2/24/89	Diisodecyl phenyl phosphite (PDDP)	Consent order; requires neurotoxicity testing.	
4/3/89	Triethylene glycol monomethyl, monoethyl and monobutyl ethers	Consent order; requires toxicological testing.	1
4/3/89	Triethylene glycol monomethyl ether	Notice of final rulemaking; requires developmental neurotoxicity testing.	1
5/17/89	1, 6-Hexamethylene diisocyanate	Notice of proposed rulemaking; proposes testing for oncogenicity, mutagenicity, reproductive toxicity, developmental toxicity, neurotoxicity, pharmacokinetics and hydrolysis.	22
8/14/89	Tributyl phosphate	Notice of final rulemaking; requires health effects, environmental effects and chemical fate testing.	18
8/23/89	1, 1, 1-Trichloroethane	Consent order; requires mutagenicity and neurotoxicity testing.	2
9/13/89	Methyl ethyl ketoxime	Notice of final rulemaking; requires health effects testing.	19

APPENDIX D

Summary of New Chemical Actions in Fiscal 1989

Description	Actions Fiscal '89	Actions Mid '79 to 9/30/89
Total Valid New Chemical Substance Submissions Received (PMNs, Test Market, Polymer, and Low Volume)	1,493	15,333
<u>Valid PMNs Received</u> (includes Biotechnology)	1,032	12,597 ^a
PMNs Requiring No Further Action	1,477	10,501
Voluntary Testing in Response to EPA Concerns	53	245
Voluntary Control Actions by Submitters	0	45
PMNs Withdrawn in Face of Section 5(e)/5(f)	69	330
PMNs Subject to Section 5(e) Consent Orders ^b	53	435 ^a
Section 5(e) Consent Orders Signed	4	233
PMNs Subject to Unilateral Section 5(e) Orders ^b	0	16
PMNs Subject to Section 5(f) Rules	0	4
Number of Chemicals for which Commencement Manufacture Notices Were Received	890 ^c	5,126
Submissions of Bona Fide Intent to Manufacture	467	3,884
New Substances Subject to Proposed Significant New Use Rules (SNURs)	2 ^d	60
New Substances Subject to Final SNURs	1 ^d	16
Test Data Received as a Result of Section 5(e) Consent Orders	8	39
<u>Valid Test Market Exemption Applications Received</u>	28	503
Granted	22	437
Withdrawn	3	43
Denied	0	7
<u>Valid Polymer Exemption PMNs Received</u>	174 ^e	1,135

Description	Actions Fiscal '89	Actions Mid '79 to 9/30/89
No Further Action Required	313	1,052
Withdrawn	3	137
Converted to Conventional PMNs	0	16
<u>Valid Low Volume Exemption Notices Received</u>	259 ^e	1,090
No Further Action Required	278	1,079
Withdrawn	5	28
Ineligible	0	1

a: Includes 106 synfuel PMNs.

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

c: This number includes PMNs received in previous fiscal years for which commencement of manufacture notices were received in fiscal 1989.

d: This number includes substances which were the subject of PMNs received in previous fiscal years but for which proposed or final rules were not published until fiscal 1989.

e: This number includes some fiscal 1988 exemptions that went to disposition in fiscal 1989.

APPENDIX E

**Summary of TSCA Section 8 Information Submissions
and Actions in Fiscal 1989**

Type of Submission	No.
<u>Section 8(a) submissions</u>	
Preliminary Assessment Information Rule (PAIR) submissions	114
Comprehensive Assessment Information Rule (CAIR) submissions	640
Follow-ups on prior CAIR submissions	4
Other submissions	3
<u>Section 8(b) additions to TSCA chemical inventory</u>	1,044
<u>Section 8(c) reports of alleged significant adverse reactions</u>	1
<u>Section 8(d) submissions</u>	
Health and safety studies or toxicity test data submissions	1,565
Follow-ups to prior submissions	100
<u>Section 8(e) "substantial risk" notifications</u>	
Initial notifications	74
Supplemental/Follow-ups to initial notifications	215
Voluntary "For-Your-Information" (FYI) notifications	164
Follow-up FYI notifications	2
<u>Chemical Hazard Information Profiles (CHIPS) completed</u>	5
2,4-pentanedione	
piperidinyl-based UV light stabilizers	
benzotriazol-based UV light stabilizers	
N-cyclohexylthiophthalimide	
aromatic ether diamine (generic name)	
<u>Lead/Cadmium Substitute Hazard Profiles (no. product categories)</u>	11
batteries (nickel/cadmium, silver/cadmium)	
soldered products	
electroplating	
glass and ceramics	
pigments (plastic, rubber)	
plastics	
brass and bronze (plumbing pipes, valves, gears, bushings)	

Summary of the ASHAA Loan and Grant Program, Fiscal 1985-89

TOTAL

APPLICANTS

	<u>1985</u>	<u>1986</u>	<u>1987-1*</u>	<u>1987-2</u>	<u>1988*</u>	<u>1989</u>
LEAs	1,107	371	292	340	328	1,110
Schools	5,095	1,211	1,030	1,015	986	2,383
Projects	8,548	2,389	1,967	1,769	1,722	4,125
Costs	\$535.8M	\$211.6M	\$162.5M	\$177.9M	\$170.3M	\$367.7M

TOTAL QUALIFIED APPLICANTS**

LEAs	587	241	136	208	185	682
Schools	1,832	644	408	489	441	1,361
Projects	2,847	1,247	774	820	721	2,093
Costs	\$186.6M	\$93.6M	\$41.4M	\$94.7M	\$79.0M	\$123.2M

TOTAL AWARDEES

LEAs	198	173	133	35	103	231	<u>TOTALS</u> 873
Schools	340	295	366	56	187	327	1,571
Projects	417	421	663	66	226	401	2,194
Award	\$45.0M	\$47.0M	\$34.2M	\$8.0 M	\$22.6M	\$ 45.0M	\$201.8M
Public Award	\$39.8M(88%)	\$41.4M(88%)	\$29.1M(85%)	\$ 7.32M(91%)	\$19.8M(88%)	\$40.6M(90%)	\$178.0M(88%)
Private Award	\$5.2M(12%)	\$ 5.6M(12%)	\$ 5.1M(15%)	\$ 0.6M(9%)	\$ 2.8M(12%)	\$ 4.4M(10%)	\$ 23.8M(12%)
Loan Award	\$33.2M(74%)	\$34.3M(73%)	\$24.6M(72%)	\$4.3M(54%)	\$15.4M(68%)	\$25.4M(56%)	\$137.2M(68%)
Grant Award	\$11.8M(26%)	\$12.7M(27%)	\$ 9.6M(28%)	\$3.7M(46%)	\$ 7.2M(32%)	\$19.6M(44%)	\$ 64.6M(32%)
Exposure-hours							
Reduced	4.7M	3.5M	2.5M	0.544M	2.02M	4.02M	17.3M

* Only unfunded 1986 applications were considered for 1987-1. Only unfunded 1987-2 applications were considered for 1988 awards.

** Reflects those determined qualified after EPA technical review: ACM friable, damaged, and exposed or in air plenum and local education agency (LEA) within lower 70% of U.S. school districts, based on public school per capita income or private school budget per pupil.

APPENDIX G

Civil Enforcement Actions Expanded Case Summaries

U.S. v. Boliden Metech: An EPA Administrative Law Judge (ALJ) issued a decision including assessment of a \$32,000 penalty in this Region I case involving PCB violations at the Boliden Metech site in Providence, RI. Boliden was found to have violated TSCA when it improperly stored and disposed of PCB-contaminated shredded metal and debris. Boliden shreds used computers and electronic equipment. This case was vigorously contested and is currently the subject of a companion case filed in the United States District Court of Rhode Island.

The ALJ's opinion had several significant aspects: (1) it is not always necessary to take a "representative sample" to prove a violation of the PCB regulations; (2) procedures for taking samples set forth in the TSCA inspection manual are "guidelines". Failure by EPA to follow sample collection procedures of TSCA "are not fatal" and does not destroy the validity of the samples; (3) EPA is not required to prove that spilled PCBs were released into the surrounding soil to prove improper disposal; (4) the PCB regulations require analysis "by any scientifically valid method"; (5) EPA's PCB tests are reliable; and (6) sampling outside a company's property (in this case sampling in the Providence River) does not violate unreasonable search and seizure prohibitions of the Fourth

Amendment to the Constitution. This decision supports EPA's efforts to regulate the storage and disposal of PCB-contaminated shredded material and debris. A companion action seeking an injunction and remedial order was filed in the District Court of Rhode Island in May 1989.

In the Matter of the City of Detroit: A decision was issued in this case finding that the city of Detroit has violated the PCB regulations at four sites in Detroit where PCBs were spilled at levels in excess of 500,000 parts per million (ppm). A penalty of \$264,000 was imposed for the violations.

In the Matter of Dow Chemical Company: EPA filed a TSCA civil administrative complaint against Dow Chemical Company (Dow), on June 16, 1987. The complaint charged Dow with 227 counts of illegal manufacture of a new polycarbonate plastic, without having first submitted a premanufacture notice (PMN) in accordance with TSCA section 5. On September 20, 1989, the Chief Judicial Officer approved a settlement of the action which requires Dow to pay a \$405,200 civil penalty. The settlement figure takes into account numerous actions and expenditures undertaken by Dow to address the cause of the violations, including comprehensive internal audits and improved training programs.

In the Matter of Ensco, Inc: EPA's right to inspect PCB facilities were strengthened in June 1989, when an EPA ALJ rejected the company's attempt to limit agency inspections. In May 1989, Energy Systems Co., Inc. (Ensco) filed for an authorization to conduct discovery. In support of this legal action, Ensco said EPA inspections of its PCB and hazardous waste incineration facility at El Dorado, AR, were so much more frequent than at any other facility that they were unconstitutional under the due process and equal protection clauses of the Constitution. Under a 1986 contract with EPA, Ensco is permitted to dispose of PCBs at El Dorado. In 1987, EPA insisted the authorization be amended so that the facility could be inspected by the state of Arkansas up to three times a day. The cost of the inspections is borne by Ensco.

In rejecting Ensco's claim, the ALJ said the discovery request was "actually an attack on the contract entered into with the state of Arkansas" and that "this is not the appropriate forum to test the validity of this or any other contract." The ALJ also ruled that the disposal permit conditions were binding, and he rejected the company's attempt to claim that EPA's inspection requirements, which are greater than at other facilities, were unfair.

In the Matter of Hodag Chemical Corporation: In early 1988, EPA

initiated an enforcement action against Hodag Chemical Corporation of Skokie, IL. EPA's complaint alleged violation of the PCB use rules for operating a heat transfer system that contained more than 50 parts per million PCBs for use in (among other things) the manufacture or processing of food, drugs and cosmetics. EPA's complaint also alleged violations of the PCB marking and recordkeeping regulations. Hodag's defense was that in 1971 or 1972, Monsanto removed PCB oil from this heat transfer system long before the promulgation of the PCB rules in 1978.

On November 14, 1988, the ALJ ruled that section 15(1) and (3) of TSCA established a standard of strict liability, and that a violation may be found for violations thereof even when the violation is unknowing. The ALJ went on to rule that as a matter of law the terms PCB and PCBs include mono-chlorinated biphenyls, and that when a corporation has knowledge of information in its files which would trigger a legal duty to act it cannot escape liability because the particular responsible corporate official was unaware of that information. A fine of \$14,500 was imposed.

In the Matter of Eastman Kodak Co.: In a recent pretrial order, an EPA ALJ denied a motion by Eastman Kodak Co., to compel discovery by EPA in a TSCA premanufacturing notice case. The ALJ also denied a motion seeking "amplified summaries" of EPA's prehearing exchange. In denying Kodak's motion to compel

discovery, the ALJ said that although discovery can lead to admissible evidence and judicial economy, "discovery, as a litigation art, can be put to inappropriate uses." He also held that "there is no basic constitutional right to pretrial discovery in administrative cases." The ruling also affirms that discovery, other than what is ordered by a judge for pretrial exchange is to be subject to stringent review by a court.

In the Matter of McCloskey: This administrative enforcement action was brought pursuant to TSCA, 15 U.S.C. Section 2601 et seq. In August of 1987, McCloskey voluntarily self-disclosed its TSCA violations after completing a full audit at its three facilities. During the conduct of the audit, the respondent discovered that they had, on multiple occasions, manufactured 26 chemical substances in violation of TSCA section 5, which requires a person intending to manufacture a new chemical substance for commercial purposes to submit to EPA a premanufacture notice at least 90 days prior to the first such manufacture. The failure to comply with these requirements is a violation of TSCA Section 15(1)(B). After promptly self-disclosing these violations to EPA, the respondent then filed the appropriate TSCA section 5 notices (PMNs, polymer exemption applications, etc.) for all 26 substances. This includes filing PMNs on six substances which had been out of production for more than five years. All chemicals completed the TSCA review without

imposition of a Section 5(e) or 5(f) order.

On March 7, 1989, EPA and McCloskey agreed to a settlement which required McCloskey to pay a \$615,650 penalty, submit an article on TSCA compliance to three trade journals, and conduct an Emergency Planning and Community Right-to-Know Act (EPCRA) Section 313 seminar for its customers. McCloskey has performed all of its required duties under this agreement, and has broadened its EPCRA section 313 seminar to include all of EPCRA rather than solely the Toxic Release Inventory reporting requirement.

In the Matter of Minolta Corporation: EPA reached settlement with the Minolta Corporation resolving violations under sections 5 and 13 of TSCA. Under the administrative consent agreement, Minolta will pay a \$600,000 civil penalty, develop a TSCA compliance and training program, hold a seminar in Japan on TSCA compliance, and place advertisements in ten national publications highlighting TSCA requirements.

In the Matter of Riverside Furniture Corporation: In this case involving failure to report under section 313 of EPCRA by a Fort Smith, AR, furniture manufacturer, EPA obtained the first administrative determination of liability under EPCRA and the

first administrative decision awarding penalties under this significant toxic chemical reporting statute. On March 27, 1989, an ALJ granted EPA's motion for a partial accelerated decision finding the respondent liable under the act and holding that lack of knowledge is not a defense to liability under section 313. On July 26, 1989, EPA prosecuted the first EPCRA administrative hearing on the assessment of penalties, and on September 28, 1989, the ALJ issued an initial decision, ordering civil penalties in the amount of \$75,000 against Riverside. In the opinion the ALJ stated that "the success of EPCRA can be attained only through voluntary, strict and comprehensive compliance with the act and regulations ... and a lack of such compliance will weaken, if not defeat, the purposes expressed [in the act]."

In the Matter of Rollins Environmental Services, Inc.: An EPA ALJ has rejected a claim that a general statute of limitations restricts EPA from taking an enforcement action under the TSCA. Rollins Environmental Services, Inc., claimed EPA was precluded from bringing action in a PCB case because the violations took place more than five years before the complaint was issued. Rollins acknowledged that TSCA does not contain a statute of limitations clause, but argued that the general federal five-year statute of limitations governing enforcement does apply.

On July 13, the ALJ cited an April 2 ruling in the Tremco

case (see accompanying case in this section) that the general federal statute of limitations provision did not apply to EPA administrative penalty actions under TSCA. The ALJ also rejected Rollins' claims that since the federal statute of limitations provision applies to other EPA measures, it should also apply to TSCA. The judge ruled that the other laws differed from TSCA because TSCA alone provides for civil penalty assessment with enforcement left to the federal District Court. The other laws include enforcement provisions ruling that the clock begins only when the inspection is made. Rollins also claimed that it did not violate TSCA when it incinerated kerosene containing less than 50 parts per million of PCBs in a non-TSCA permitted incinerator. The judge ruled that the disposal of the PCBs, although below 50 parts per million violated TSCA because PCBs cannot be diluted with liquid to avoid proper disposal in a PCB incinerator.

In the Matter of Schnee-Morehead, Inc.: On January 25, 1989, EPA filed a civil administrative complaint against Schnee-Morehead, Inc., for numerous violations of the TSCA section 5 premanufacture notification requirements. The violations involved four polymers and occurred over many years. The settlement agreement in this case, filed on January 26, 1989, requires Schnee-Morehead to pay a \$597,000 civil penalty, over the course of two years.

In the Matter of SED Inc., et al. (TSCA): In a decision issued December 8, 1988, by the Chief ALJ, the controlling officer of a defunct corporation was held individually liable for a \$35,000 penalty for improper disposal of PCB waste materials by the corporation he controlled. The ALJ held, following a three-day hearing, that a corporate agency whose act, default, or omission causes a corporation to violate TSCA is himself individually liable for the violation - the first such holding in an administrative action under this statute. The case involved liability for PCBs left behind by a corporation which accepted PCBs for disposal and then went out of business. It was held that abandonment constitutes improper disposal for TSCA purposes and that the financial inability of respondents to pay for proper disposal did not absolve them from liability.

In the Matter of 3M Company: EPA issued a civil administrative complaint against the Minnesota Mining and Manufacturing (3M) Company of St. Paul, MN, proposing a \$1.3 million penalty for numerous violations of TSCA sections 5 and 13. The violations, which 3M voluntarily disclosed to EPA, involved the failure to notify EPA prior to importing two new chemicals not on the TSCA Section 8(b) inventory list and falsely certifying to the U.S. Customs Service that the illegally imported chemicals were in compliance with TSCA.

By interlocutory order dated August 7, 1989, the ALJ granted judgment for EPA with respect to 3M's liability for all counts alleged in the complaint. The precedential decision also struck 3M's statute of limitations defense. In striking the defense, the ALJ found that TSCA's new chemicals provisions are among the most important and significant provisions of TSCA. A hearing will be scheduled to determine the appropriate penalty amount to be assessed against 3M.

In the Matter of Toledo Edison: EPA initiated an administrative enforcement action against Toledo Edison for violation of the PCB storage and disposal requirements. A PCB transformer at the Toledo Edison Davis-Besse Nuclear Power Plant had ruptured, spilling PCB-contaminated oil into a settling basin that contained radionuclide contaminated water. Toledo Edison completed an initial cleanup under supervision of EPA representatives. The cleanup generated 26 55-gallon drums of material which were contaminated with both PCBs and radionuclides. Toledo Edison could not dispose of this waste within one year as required by the PCB regulations because there are no facilities licensed to dispose of this type of waste. Toledo Edison petitioned the EPA administrator for an exemption from the one-year storage limit; the administrator denied Toledo Edison's request.

Negotiations with Toledo Edison resulted in the simultaneous filing of a civil administrative complaint and a consent order resolving the complaint. The consent order required that Toledo Edison: (1) complete the cleanup to PCB rule specifications; (2) continue good faith efforts to obtain an acceptable disposal method; (3) store the PCB/radionuclide waste in a more stringent manner than that required by the PCB regulations; (4) submit extensive reports; (5) remove all PCB transformers from the facility; and (6) pay an \$18,000 civil penalty.

In the Matter of Tremco: This PMN administrative enforcement action was brought pursuant to the TSCA, 15 U.S.C. Section 2601 et seq. The enforcement case involved both voluntarily self-disclosed violations and violations discovered by EPA during the conduct of a TSCA investigation. In 1983, Tremco had notified EPA that they had illegally manufactured three chemical substances. This notification was made in Tremco's cover letter which transmitted a PMN for each of these substances. Each of the chemicals completed the TSCA review without imposition of a section 5(e) or 5(f) order. In 1987, during a routine review of PMNs, an EPA inspector from the National Enforcement Investigations Center (NEIC) uncovered the 1983 letter and, based on this letter, conducted an October 1987 inspection of Tremco's Barbourville, KY, plant site. The inspector was able to verify the existence of TSCA violations dating back to 1979 and was able

to document TSCA Section 5 violations during the PMN review period which were not self-disclosed in the aforementioned cover letter.

In 1988, EPA filed an administrative complaint against Tremco. Tremco responded to the complaint by raising the general federal statute of limitations (28 U.S.C. section 2462) as an affirmative defense. EPA moved the court to strike the statute of limitations defense as inapplicable to TSCA administrative enforcement actions. On April 7, 1989, the ALJ ruled that the general federal statute of limitations does not apply. The judge ruled that statutes of limitation ordinarily do not run against the United States unless Congress explicitly directs otherwise, and there is no legislative intent to apply 28 U.S.C. Section 2462 to TSCA penalty proceedings. This important decision allows EPA to address violative conduct (e.g., improper PCB disposal, improper asbestos abatement, and illegal chemical manufacture) which may have initially occurred more than five years prior to issuance of the complaint, but which continue to pose a risk to human health and the environment. On July 17, 1989, EPA and Tremco entered into a consent agreement which required Tremco to pay a \$145,000 civil penalty.

In the Matter of University of Idaho: This enforcement action is only the second in the nation to be brought under the TSCA Worker

Protection Rule [40 CFR section 763, subpart G promulgated pursuant to TSCA section 6(a)] which addresses the protection of public employees involved in the abatement of asbestos-containing materials. The state university employees were exposed during a building renovation and the university was charged with violations of the asbestos work practice standards. The university was charged with failure to protect the workers from asbestos exposure and failure to minimize the hazards involved during removal of asbestos. A settlement agreement was reached and under the terms of the signed consent agreement and final order the university agreed, without admitting liability, to undertake an extensive program to provide asbestos information to the community and to the state of Idaho through the implementation of an asbestos hotline.

U.S. v. USPCI, Inc.: A site inspection and document review indicated that this facility in Utah failed to adhere to all of the requirements of the approval issued by the agency under TSCA for the operation of a commercial PCB dechlorination unit. The 57-count complaint alleged the improper processing of PCBs for 55 separate batches, along with annual document violations for two years. The agency found no evidence that PCBs had been insufficiently processed or released to the environment, but the violations were viewed as serious because such facilities are permitted by the agency and must therefore be held to a strict

standard of care. The case was settled for a total expenditure by respondents of \$450,000, including a \$175,000 cash penalty, the purchase of a \$118,000 emergency response vehicle for Tooele County, UT, and the planning and operation of household hazardous waste collection days in the state.

APPENDIX H

Citizens' Petitions and Other Litigation

Litigation Challenges to Agency Denials of Citizens' Petitions:

Environmental Defense Fund (EDF) and National Wildlife Federation

(NWF) v. Thomas (No. 85-0973, D.D.C.): Plaintiffs brought this action after EPA had denied, in part, their TSCA section 21 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.

In early 1986 plaintiffs filed a motion requesting the court to order EPA to initiate rulemaking because the agency's explanation published in the Federal Register was improper as a matter of law. EPA opposed plaintiffs' request arguing that its denial was in accordance with statutory requirements. In March 1987, the court denied plaintiffs' motion, stating that under TSCA the form of the denial does not affect the type of judicial action permitted under TSCA section 21. The court reasoned that, when EPA denies a section 21 petition, plaintiffs are only entitled to a de novo proceeding before the court, regardless of the reasons stated by the agency.

In July 1988, EDF and NWF reached a settlement with EPA under which the agency agreed, within specified time frames over a number of years, to undertake certain actions relating to dioxins. Some actions would be under TSCA authority, but many would be taken under authority of other agency-administered statutes. Specifically, EPA agreed to consider the appropriate agency actions to take with respect to (1) commercial chemicals that testing shows are contaminated with dioxins, (2) activities at pulp and paper mills that could cause dioxin contamination, (3) wastes from the wood preservative industry, and (4) air emissions from municipal waste combustors. In addition, EPA agreed to issue studies on hospital waste incinerators.

In September 1988, EDF and NWF filed an appeal from the district court's opinion that they were only entitled to a de novo proceeding when EPA denied their petition.

Environmental Defense Fund (EDF) and National Wildlife Federation (NWF) v. EPA (No. 88-5325, D.C. Cir.): In November 1988, EDF and EPA agreed to a settlement regarding attorneys' fees in the district court litigation. EPA and NWF were unable to agree on attorneys' fees and filed briefs on the issue. The court's decision is pending.

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 denying their petition filed pursuant to section 21 of TSCA in April 1985. The petition had requested EPA to identify business entities in the southeast area of Chicago which were releasing 11 named chemical substances into the environment and to initiate rulemaking under TSCA section 4(a) to require testing on the chemical substances -- including testing for cumulative and antagonistic effects.

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

The discovery process, wherein each side may request documents and depositions from the other side, has been completed.

Two steel companies, which had intervened as defendants, filed a motion to dismiss the complaint in July 1988. They argued that TSCA section 21 violates the separation of powers

doctrine of the U.S. Constitution because it authorizes a federal district court to order EPA to initiate rulemaking after a de novo trial. Plaintiffs argued that section 21 was no different from any other statute allowing a court to review agency decisionmaking. The court denied this motion, holding that section 21 does not violate the separation of powers doctrine because it only authorizes a federal court to order an executive agency to initiate a rulemaking. The outcome of the rule is still within the agency's discretion.

Service Employees International Union (SEIU) v. Reilly (No. 89-0851, D.D.C.): In November 1988, SEIU filed a citizens' petition under TSCA section 21 requesting EPA to issue rules affecting asbestos in public and commercial buildings other than schools. On March 28, 1989, EPA denied the petition stating that it needed additional information on risk reduction before it could consider whether to issue the rules requested by SEIU. EPA did not, however, permanently rule out a regulatory response at some later time. In addition, EPA announced a public meeting to gather data and hear arguments to assist the agency in assessing what future activity is necessary to deal with asbestos in public and commercial buildings.

On March 31, 1989, SEIU filed suit in federal district court to compel initiation of a rulemaking. However, the first public meeting, held in June 1989, convinced EPA to hold further

meetings. As a result, SEIU asked that its suit be held in abeyance while the meetings were being conducted, expressing its belief that the meetings might result in EPA's voluntarily initiating rulemaking. At the end of fiscal year 1989, the meeting process was continuing and the SEIU lawsuit remained in abeyance.

Dr. David G. Walker v. EPA (No. H-87-3552; S.D. Tex., Houston):

In March 1987, Dr. Walker filed a citizens' petition under TSCA section 21 asking EPA to exclude from its current regulations polychlorinated biphenyls (PCBs), containing three chlorine atoms or less. EPA denied the petition on the grounds that in previous proceedings involving PCBs the agency had already considered, and rejected, the arguments raised by Dr. Walker. The court is currently considering various procedural motions raised by EPA and plaintiff.

OTHER CHALLENGES:

Michael D. Vanderveer and City of Evansville, Indiana v. EPA and Unison Transformer Services, Inc. (No. EV86-183C, D.C. Ind.) and **Citizens for Healthy Progress, Inc. v. EPA** (No. 86-0155, D.C.

Kentucky): These two suits, now consolidated, were filed against EPA regarding the agency's approval in January 1987 of a PCB disposal facility in Henderson, Kentucky. At this facility, operated by Unison Transformer Services, Inc. (Unison), PCBs are

chemically separated from transformer fluid and are then shipped to other facilities where permanent disposal takes place.

Plaintiffs requested a permanent injunction against operation of the facility, stating that EPA needed to consider criteria applicable under the Resource Conservation and Recovery Act in addition to criteria under TSCA when approving the Unison facility and that the operation of the facility would present an unreasonable risk of harm to plaintiffs. Plaintiffs also argued that EPA lacked authority to permit the Unison process under TSCA regulations and that they were unable to evaluate the risks caused by the facility because EPA and Unison have not disclosed the identity of the chemical used to separate PCBs.

EPA argues that its approval was in accordance with its TSCA regulations and that TSCA is the appropriate authority to approve the Unison facility. The parties are awaiting the court's decision.

Shell Chemical Co. v. EPA 826 F.2d 295 (5th Cir. 1987): On January 7, 1986, four manufacturers of mesityl oxide (MO) and the Chemical Manufacturers Association filed in the Court of Appeals a petition for judicial review of EPA's section 4 rule requiring health effects testing of MO. The proceeding was held in abeyance pending EPA's consideration of the manufacturers'

petition under section 21 of TSCA to withdraw the test rule. EPA denied the petition on August 21, 1986 (51 F.R. 30216).

The manufacturers reinstituted the lawsuit and also filed an action in District Court, on September 26, 1986, challenging the denial of their section 21 petition. The District Court stayed the case pending the outcome of the reinstituted lawsuit in the Court of Appeals.

In August 1987, the Court of Appeals remanded the case "for EPA to make supplemental findings in the administrative record concerning the changes in MO use that have occurred since the testing rule was promulgated and, if determinable, that will occur in the foreseeable future." (826 F.2d 298) The court stayed implementation of the rule pending EPA's updated factfinding.

Since the rule is being reconsidered, the District Court litigation was dismissed without prejudice to refile another citizens' petition should a subsequent rule be issued. EPA and manufacturers are currently negotiating a consent order to conduct the testing.

Chemical Manufacturers Association v. EPA (No. 88-1352, D.C. Cir.): On February 26, 1988, EPA issued a testing rule for diethylene glycol ether and its acetate (DGBE/DGBA). The rule

requires three tests to be conducted initially ("first-tier"), and would require a "second-tier" developmental neurotoxicity study if the results of the first tier tests are positive. CMA challenged the requirement for the second tier study. Since the first-tier tests was not due until September 1989, parties requested and received a stay of the litigation.

Chemical Manufacturers Association v. EPA (No. 88-4710, 5th Cir.): On September 26, 1988, CMA and five manufacturers and processors filed a petition for review of a section 4 rule requiring testing of the chemical cumene, the thirty-first highest production chemical in the United States. EPA issued this rule under the authority of section 4(a)(1)(B), which authorizes the agency to require testing if it finds that a chemical is produced in substantial quantities and that it is or may be released into the environment in substantial quantities or that there is or may be substantial exposure to the chemical.

Along with its petition for review, CMA filed a motion for stay of the rule arguing that, pending the decision on the merits, the manufacturers would be irreparably harmed by being forced into non-recoverable start-up costs for testing. CMA argued that these costs would be unfair because CMA was likely to succeed on the merits of the case. The motion was denied. Oral argument was held on June 7, 1989.

CMA did not contest EPA's finding that cumene is produced in substantial quantities. CMA argued, however, that EPA could not require testing unless EPA showed levels of cumene in the environment that would cause harm if cumene were found to be hazardous. Further, CMA argued that, to require testing under section 4, EPA must show that the chemical persists and that people are exposed to the chemical.

EPA argued that the plain language of section 4(a)(1)(b) gives EPA authority to test chemicals in the absence of information indicating that the substance is hazardous. Further, EPA argued that it has authority to require testing of chemicals produced in substantial quantities when either there is or may be substantial release to the environment of such chemical or there is or may be substantial or significant human exposure to the chemical.

In the case of cumene, EPA found substantial production along with substantial release and potential substantial human exposure to cumene. EPA argued that it had substantial evidence to support its findings based upon a production volume of 4.5 billion pounds per year, annual releases to the environment of 3 million pounds each year, and exposure to 790 workers (as provided by a CMA survey) along with potential exposure to 13.5 million people who live in the vicinity of cumene manufacturing

and processing facilities. At the end of fiscal year 1989, the parties were awaiting a decision in this case.

Safe Buildings Alliance (SBA) v. EPA 846 F.2d 79 (D.C. Cir. 1988): The D.C. Court of Appeals upheld EPA's asbestos-in-schools rules issued under the AHERA. The rules had been challenged by SBA -- an association of companies that formerly manufactured asbestos products. The court extended substantial deference to EPA, holding that the agency's rules were reasonable in light of the somewhat contradictory demands of AHERA, the uncertainties regarding the health effects of low-level asbestos exposure, and the tight timetable AHERA imposed on EPA to issue regulations.

In August 1988, National Gypsum Company, one of the petitioners before the Court of Appeals, filed a petition for certiorari before the Supreme Court. The briefs on this petition by both National Gypsum and EPA essentially repeated the arguments made before the Court of Appeals.

The Supreme Court denied certiorari in November 1989.

Chemical Manufacturers Association (CMA) v. EPA (No. 89-1153, D.C. Cir.): CMA filed a petition for review of the CAIR which EPA issued pursuant to TSCA section 8(a). CAIR establishes a general framework for detailed reporting on chemicals by their

manufacturers (including importers) and processors. As initially promulgated, CAIR requires the submission of information for 19 chemicals. EPA intends to conduct future rulemakings to require reporting on other chemicals as the need arises.

On July 19, 1989, EPA issued a request for additional comments on certain revisions to the CAIR rule in response to comment and concerns raised by CMA and other industrial groups. EPA is seeking a stay of the briefing schedule in this case pending the outcome of any rulemaking process to revise the CAIR rule.

Corrosion Proof Fittings, et al. v. EPA and consolidated cases (No. 89-4596, 5th Cir.): Petitioners brought this action to seek review of EPA's final rule under TSCA section 6(a) banning future manufacture, importation, processing, and distribution in commerce of asbestos in almost all products. Eight petitions for review have been filed in various circuits of the U.S. Court of Appeals challenging the same rule. Several of these petitions have already been transferred to the 5th Circuit where they have been consolidated with Corrosion Proof Fittings. The remaining petitions have motions to transfer pending before the appropriate circuit. Issues and a briefing schedule will be developed over the next few months.

Colorado Department of Institutions v. EPA (No. 89-1631, D. Colo.): The Colorado Legislature enacted a law in its 1989

session declaring the schools in the state Department of Institutions exempt from the requirements of the Asbestos Hazard Emergency Response Act (AHERA)¹. EPA officials indicated to state officials that the agency believed the law did not create a valid exemption. On September 20, 1989, the department requested the federal district court to restrain EPA from inspecting or otherwise interfering with the operation of its schools. Arguments are expected to be presented to the court early in fiscal year 1990.

APPENDIX I

Summary of Research and Development Activities Fiscal 1989 Accomplishments

A. TEST METHODS DEVELOPMENT

ENVIRONMENTAL PROCESSES

- Report on neoplasms induced by methylazopyrmethanal acetate in the Guppy Poecilia reticulata (9/89).
- Report on carcinogenicity of the widely used herbicide alachlor in freshwater and marine fish (9/89).
- Report on preliminary assessment of using Mekada for predicting the carcinogenic potential of chemicals (3/89).

HEALTH

- A critical appraisal of the Functional Observational Battery (FOB) and Motor Activity (MA) as a screen for acute neurotoxicity (9/89).

B. HEALTH: MARKERS, DOSIMETRY, EXTRAPOLATION

- Interim report on a database of initiatives, promoters and noncarcinogens; in vivo biochemical studies of halogenated hydrocarbons (11/88).
- Annual report for fiscal 1988 on markers and dosimetry research activities for exposure monitoring (12/88).

C. SPECIAL HUMAN DATA NEEDS

- Development of methodology for the use of biochemical markers in epidemiology studies (9/89).

D. ECOLOGY: TRANSPORT, FATE AND FIELD VALIDATION

ENVIRONMENTAL PROCESSES

- Report on role of co-metabolism in the biodegradation of xenobiotic chemicals (4/89).
- Report on problems associated with published environmental fate constants (3/89).
- Report on EXAMS subroutines for predicting microbial transformation rates of aquatic pollutants by attached populations (7/89).
- Report on comparative sensitivity of larval stages of pelagic spawning estuarine fishes to toxic substances (7/89).
- Report on an evaluation of cluster analysis techniques for determining community level effects (9/89).
- Report on physical scale effects of laboratory microcosms in assessment of benthic macro-invertebrate community structure (9/89).

E. ENGINEERING

- Report on the fate of C. I. Disperse Blue 79 in aerobic and anaerobic treatment systems (6/89).

F. EXPOSURE MONITORING

- Interim report on human exposure model development (Benzene) (1/89).

G. STRUCTURE-ACTIVITY RELATIONSHIPS

HEALTH

- Summary report for HERL-OTS collaborative SAR research on relevant classes of chemicals (9/89).

ENVIRONMENTAL PROCESSES

- Report on current use of SAR for predicting biotransformation of chemicals (8/89).
- Report on mechanisms - specific QSAR models for fathead minnow acute and chronic toxicity (5/89).
- Unified QSAR strategy for predictive ecotoxicology and initial environmental risk assessments (7/89).

H. BIOTECHNOLOGY

ENVIRONMENTAL PROCESSES

- Review of progress in Biotechnology/MPCA assessment program (5/89).

HEALTH

- Design and evaluation of animal models to study potential health effects related to exposure to pollutant-degrading microorganisms (2/89).

ENGINEERING

- Assessment of potential for worker exposure to GEMS in large-scale processing facilities (10/88).
- Assessment of treatment technologies for wastewaters from large-scale PMN processing facilities (9/89).

I. ECOLOGY: ECOTOXICITY AND RISK ASSESSMENT

ENVIRONMENTAL PROCESSES

- Report on maintenance and updating of PHYTOTOX database for support of ecological risk assessments (12/88).
- Report on relative uncertainty of loading vs. other components of toxic substances models (8/89).
- Report on comparison of laboratory microcosms and natural pond responses to Dursban (1/89).
- Internal report on products of the Ecorisk Research Program (5/89).

J. SUPPORT

MONITORING

- Report on instrument spectra database development (12/88).
- Report on fiscal 1988 asbestos quality research activities (9/89).

ENVIRONMENTAL PROCESSES

- Support consists of providing technical and scientific judgments and assessments through scientific expertise or peer assessments; review of test rule documents; validation of toxicity tests; support for exposure and risk assessments; updating TSCA testing guidelines; involvement in new chemical (TSCA section 5, PMN), existing chemical and EPCRA program activities and through conducting special reviews, workshops and demonstrations that provide information and tools for generating and enhancing regulatory and managerial decisions.

APPENDIX J

Major TSCA-Related Reports Published in Fiscal 1989

		<u>EPA NO. (NTIS NO.)</u>
TSCA Report to Congress FY87 and FY88	U.S. Environmental Protection Agency, Office of Pesticides and Toxic Substances, Environmental Assessment Division, Washington, D.C.	EPA560/1-89-001
Toxic and Hazardous Substances	U.S. Environmental Protection Agency, Office of Pesticides and Toxic Substances, Environmental Assessment Division, Washington, D.C.	EPA560/1-89-002
Preliminary Evaluations of Initial TSCA Section 8(e) Substantial Risk Notices Jan. 1987 - Dec. 1988	U.S. Environmental Protection Agency, Office of Pesticides and Toxic Substances, Environmental Assessment Division, Washington, D.C.	EPA560/2-89-001 (PB89 182 687/AS)
Toxic Chemical Release Inventory Risk Screening Guide. Volume I The Process. Volume II Appendices	U.S. Environmental Protection Agency, Office of Pesticides and Toxic Substances, Existing Chemical Assess- ment Division, Washington, D.C.	EPA560/2-89-002) (PB90 122 128/AS)
Chemical Releases and Chemical Risk	U.S. Environmental Protection Agency, Office of Pesticides and Toxic Substances, Existing Chemical Assess- ment Division, Washington, D.C.	EPA560/2-89-003

EPA NO. (NTIS NO.)

Title III List of List
(Disk Version) Revised
Dec. 1988

U.S. Environmental Protection Agency,
Office of Pesticides and Toxic
Substances, Economics and Technology
Division, Washington, D.C.

EPA560/4-88-003
(PB89 158 653)

Toxic Chemical Release
Inventory Reporting
Form R and Instructions
(Revised 1988 version)
Jan. 1989

U.S. Environmental Protection Agency,
Office of Pesticides and Toxic
Substances, Economics and Technology
Division, Washington, D.C.

EPA560/4-88-005
(PB89 164 248)

Compliance Package

U.S. Environmental Protection Agency,
Office of Pesticides and Toxic
Substances, Economics and Technology
Division, Washington, D.C.

EPA560/4-89-001

Toxic Chemical Release
Inventory Questions and
Answers

U.S. Environmental Protection Agency,
Office of Pesticides and Toxic
Substances, Economics and Technology
Division, Washington, D.C.

EPA560/4-89-002
(PB89 164 255/AS)

Supplier Notification
Requirements: Under
Section 313 of the
Emergency Planning and
Community Right-to-Know
Act. Requirements
Effective January 1,
1989

U.S. Environmental Protection Agency,
Office of Pesticides and Toxic
Substances, Economics and Technology
Division, Washington, D.C.

EPA560/4-89-003
(PB89 192 892)

EPA NO. (NTIS NO.)

Common Synonyms for
Chemicals Listed Under
Section 313 of the
Emergency Planning and
Community Right-to-Know
Act. Dec. 1988

U.S. Environmental Protection Agency,
Office of Pesticides and Toxic
Substances, Economics and Technology
Division, Washington, D.C.

EPA560/4-89-004
(PB89 168 843)

Toxics-Release Inventory:
A National Perspective

U.S. Environmental Protection Agency,
Office of Pesticides and Toxic
Substances, Economics and Technology
Division, Washington, D.C. GPO 055-000-
0290-8 \$14.

EPA560/4-89-005
(PB89 208 144)

Toxic Chemical Release
Inventory: A National
Perspective, Executive
Summary

U.S. Environmental Protection Agency,
Office of Pesticides and Toxic
Substances, Economics and Technology
Division, Washington, D.C. GPO 055-000-
0289-4 \$1.50

EPA560/4-89-006
(PB89 208 151)

Guidelines for Conducting
the AHERA TEM Clearance
Test to Determine
Completion of an
Asbestos Abatement
Project

U.S. Environmental Protection Agency,
Office of Pesticides and Toxic
Substances, Exposure Evaluation
Division, Washington, D.C.

EPA560/5-89-001

Dioxins and Dibenzofurans
in Adipose Tissue
or U.S. Vietnam Veterans
and Control

U.S. Environmental Protection Agency,
Office of Pesticides and Toxic
Substances, Exposure Evaluation
Division, Washington, D.C.

EPA560/5-89-002

Identification of SARA Compounds in Adipose Tissue. Final Report	U.S. Environmental Protection Agency, Office of Pesticides and Toxic Substances, Exposure Evaluation Division, Washington, D.C.	EPA560/5-89-003 (PB90 132 564/AS)
Comparison of Airborne Asbestos Levels Determined by Transmission Electron Microscopy (TME) Using Direct and Indirect Transfer Techniques	U.S. Environmental Protection Agency, Office of Pesticides and Toxic Substances, Exposure Evaluation Division, Washington, D.C.	EPA560/5-89-004
	U.S. Environmental Protection Agency, Office of Pesticides and Toxic Substances, Exposure Evaluation Division, Washington, D.C.	EPA560/5-89-005
Determination of Reaction of the Gas-Phase in the Troposphere. Theory and Practice. Part I. Hierarchal Test Scheme	U.S. Environmental Protection Agency, Office of Pesticides and Toxic Substances, Exposure Evaluation Division, Washington, D.C.	EPA560/5-89-006 (PB90 143 165/AS)
Determination of Rates of Reaction in the Gas-Phase in the Troposphere-Theory and practices. Part II. Rate of Direct Photoreaction: Screening-Level Test	U.S. Environmental Protection Agency, Office of Pesticides and Toxic Substances, Exposure Evaluation Division, Washington, D.C.	EPA560/5-89-007

EPA NO. (NTIS NO.)

File Update of Six Interrelated Files of the Environmental Fate dataBase (EFDB): Biodeg	U.S. Environmental Protection Agency, Office of Pesticides and Toxic Substances, Exposure Evaluation Division, Washington, D.C.	EPA560/5-89-008A
File Update of Six Interrelated Files of the Environmental Fate Data-Base (EFDB): Biolog	U.S. Environmental Protection Agency, Office of Pesticides and Toxic Substances, Exposure Evaluation Division, Washington, D.C.	EPA560/5-89-008B
File Update of Six Interrelated Files of the Environmental Fate data-Base (EFDB): CASLST	U.S. Environmental Protection Agency, Office of Pesticides and Toxic Substances, Exposure Evaluation Division, Washington, D.C.	EPA560/5-89-008C
File Update of Six Interrelated Files of the Environmental Fate DataBase (EFDB): Chemfate	U.S. Environmental Protection Agency, Office of Pesticides and Toxic Substances, Exposure Evaluation Division, Washington, D.C.	EPA560/5-89-008D
File Update of Six Interrelated Files of the Environmental Fate Data Base (EFDB): Datalog	U.S. Environmental Protection Agency, Office of Pesticides and Toxic Substances, Exposure Evaluation Division, Washington, D.C.	EPA560/5-89-008E
File Update of Six Interrelated Files of the Environmental Fate Data Base (EFDB): Xref	U.S. Environmental Protection Agency, Office of Pesticides and Toxic Substances, Exposure Evaluation Division, Washington, D.C.	EPA560/5-89-008F

EPA NO. (NTIS NO.)

Fish Toxicity Screening
Data. Part I. Lethal
Effects of 964 Chemicals
upon Steelhead Trout
and Bridgelip Sucker

U.S. Environmental Protection Agency,
Office of Pesticides and Toxic
Substances, Health and Environmental
Review Division, Washington, D.C.

EPA560/6-89-001
(PB89 156 715/AS)

Fish Toxicity Screening
Data. Part II. Lethal
Effects of 2,014 Chemicals
Upon Sockeye Salmon,
Steelhead Trout and
Threespine Stickleback

U.S. Environmental Protection Agency,
Office of Pesticides and Toxic
Substances, Health and Environmental
Review Division, Washington, D.C.

EPA560/6-89-001
(PB89 156 715/AS)

Summary of the EPA Work-
shop on Carcinogenesis
Bioassay Via the Dermal
Route

U.S. Environmental Protection Agency,
Office of Pesticides and Toxic
Substances, Health and Environmental
Review Division, Washington, D.C.

EPA560/6-89-002
(PB90 146 309/AS)

Summary of the Second EPA
Workshop on Carcinogenesis
Bioassay Via the Dermal
Route

U.S. Environmental Protection Agency,
Office of Pesticides and Toxic
Substances, Health and Environmental
Review Division, Washington, D.C.

EPA560/6-89-003
(PB90 146 358/AS)

Toxic Substances Control
Act (TSCA) Test
Submissions Database
(TSCATS) Comprehensive
Quarterly Update Tape

U.S. Environmental Protection Agency,
Office of Pesticides and Toxic
Substances, Information Management
Division, Washington, D.C.

EPA560/7-89-012A-D
(PB88 912 900)

EPA NO. (NTIS NO.)

Toxic Substances Control Act (TSCA) Test Submissions Database (TSCATS) Quarterly Update (microfiche)	U.S. Environmental Protection Agency, Office of Pesticides and Toxic Substances, Information Management Division, Washington, D.C.	EPA560/7-89-011A-D
Reporting Facility, Name and Address	U.S. Environmental Protection Agency, Office of Pesticides and Toxic Substances, Information Management Division, Washington, D.C.	EPA560/7-89-001
1987 Toxic Release Inventory (mag. tape)	U.S. Environmental Protection Agency, Office of Pesticides and Toxic Substances, Information Management Division, Washington, D.C.	EPA560/7-89-002
Office of Toxic Substances Scientific and Technical Reports: 1983-1988 (update)	U.S. Environmental Protection Agency, Office of Pesticides and Toxic Substances, Information Management Division, Washington, D.C.	EPA560/7-89-003
Toxic Substances Control Act. (TSCA) Chemical Substances Inventory Reissued Preferred Name File, May 1989 Reissued Synonym File	U.S. Environmental Protection Agency, Office of Pesticides and Toxic Substances, Information Management Division, Washington, D.C.	EPA560/7-89-004A-B