United States
Environmental Protection Agency
Washington DC 20460

January 1985

EPA

Toxic Substances Control Act (TSCA)

Report to Congress for Fiscal Year 1984

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Abbreviations

ANPR	Advance Notice of Proposed Rulemaking
CHIP	Chemical Hazard Information Profile
CPSC	Consumer Product Safety Commission
DOL	Department of Labor
EAR	Extramural Activity Report
EPA	U.S. Environmental Protection Agency
EPACASR	EPA Chemical Activities Status Report
FDA	Food and Drug Administration
GLP	Good Laboratory Practice
IFIS	Industry File Information System
IPP	Intermedia Priority Pollutant (document)
IPCS	International Program on Chemical Safety
IRMC	Inter-Regulatory Risk Management Council
IRPTC	International Register of Potentially Toxic Chemicals
ITC	Interagency Testing Committee
MOU	Memorandum of Understanding
NIOSH	National Institute for Occupational Safety and Health
NTA	Negotiated Testing Agreement
NTIS	National Technical Information Service
NTP	National Toxicology Program
OECD	Organization for Economic Cooperation and Development
ORD	Office of Research and Development
OSHA	Occupational Safety and Health Administration
OTS	Office of Toxic Substances
PCB	Polychlorinated biphenyl
PMN	Premanufacture notification
ppm	Parts-per-million
SEIU	Service Employees International Union
SNUR	Significant New Use Rule
TSCA	Toxic Substances Control Act
UNEP	United Nations Environment Program
WHO	World Health Organization

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Introduction

The Toxic Substances Control Act (TSCA) was enacted by Congress to protect human health and the environment from unreasonable risks. Virtually all of the provisions of the Act have been implemented. Programs are now operating under the Act to review and regulate new chemicals, where necessary; to gather information about the toxicity of specific chemicals and the extent to which people and the environment are exposed to them; to bring about industry testing where existing data are inadequate; to assess whether particular chemicals cause unreasonable risks to humans or the environment; and to institute appropriate control actions after carefully weighing the risks against the benefits to the nation's economic and social well-being provided by specific chemicals.

To help ensure informed decisionmaking by the government, TSCA gives the Environmental Protection Agency (EPA) authority to gather basic information on certain chemicals from manufacturers, processors and distributors. The law enables EPA to require companies to test chemicals to obtain data needed to evaluate their risks and stipulates that companies are to submit to EPA certain specified information on all new chemicals before they are manufactured. To prevent unreasonable risks, EPA, under TSCA, may select from a broad range of control actions, from requiring hazard-warning labels to outright bans on the manufacture or use of substances that present unreasonable risks at any stage in a chemical's life-cycle: in manufacturing, processing, distribution in commerce, use or disposal.

This seventh annual report to Congress summarizes the progress EPA has made in implementing the Act during FY 1984. It fulfills the Congressional reporting requirements of TSCA sections 9(d), 28(c), and 30 and highlights significant programs and Agency progress in achieving a high level of health and environmental quality in FY 1984 (see Appendices A and B).

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Highlights of the Year

Program Implementation

FY 1984 saw EPA refine and focus its activities to more effectively carry out the Act. EPA reviewed and, where necessary, regulated new chemicals more proficiently; followed selected new chemicals as they matured in the marketplace; used a wide range of regulatory and non-regulatory tools to gather and disseminate information on the risks of specific chemicals; initiated rulemaking to control unreasonable risks from certain chemicals; identified several chemicals as likely section 9 referral candidates to other agencies; finalized other rules; integrated the new and existing chemicals programs more effectively; stepped up enforcement of the Act; and intensified its program to assure the quality of tests that are performed for TSCA purposes.

New Chemicals Review

EPA's new chemicals program matured during FY 1984. The Agency received about 1,200 Premanufacture Notices (PMNs), which is comparable to the number received in FY 1983. The final PMN rule, which became effective early in FY 1984, established uniform requirements for PMN reporting and recordkeeping. EPA issued more orders under section 5(e), controlling exposure pending the development of necessary data, than in any other year.

FY 1984 saw the first use of section 5(f) by the Agency to prevent the formation of potentially cancer-causing nitrosamines from certain new metalworking fluids. Since similar existing metalworking fluids present similar concerns, EPA is addressing them by advising metalworking fluid formulators and users of their potential hazards and of ways to avoid these hazards in parallel with investigating the need for a regulation to prohibit certain formulations that produce nitrosamines. This is an excellent example of the close interplay between EPA's new and existing chemical activities.

FY 1984 also marked the issuance of the first final Significant New Use Rule (SNUR), which extended the requirements of a section 5(e) order to other manufacturers and processors of the specified chemical, who could have otherwise made or processed the chemical without the restrictions placed on the original PMN submitter.

FY 1984 also saw EPA lay the foundation for addressing what may be its most challenging emerging new chemicals issue; biotechnology. United States industry is an international leader in biotechnology development, and EPA is dedicated to protecting health and the environment without unduly impeding innovation. Two major activities occurred in FY 1984; first, EPA participated in a Cabinet Council activity to coordinate all Federal biotechnology activity. Second, EPA drafted a preliminary policy statement on biotechnology. This document was published for comment in December, 1984.

Existing Chemicals

The evaluation and control (where needed) of existing chemicals were high priorities in FY 1984. EPA adopted a flexible approach, making full use of TSCA's regulatory and non-regulatory tools to gather and disseminate important risk information and to control or take steps to control unreasonable risks.

EPA used a wide variety of information-gathering tools in FY 1984. The Agency signed its first Final Test Rule under section 4 on 1,1,1-trichloroethane. EPA responded to certain of the new designations of the Interagency Testing Committee (ITC) with decisions not to test because agreement had already been reached with industry to undertake voluntary testing programs. These agreements are known as Negotiated Testing Agreements (NTAs). In a number of instances, similar dispositions were made for the backlog of fourteen ITC chemicals. In all, NTAs played a major role in FY 1984; 162 tests were received and 14 new NTAs were entered into. However, a decision of the District Court for the Southern District of New York, entered on August 23, 1984, indicated that EPA may no longer respond to ITC designations through NTAs. As a result, EPA will need to reevaluate its section 4 testing program in FY 1985. In addition, EPA also covered 75 chemicals in proposed and final section 8 rules in FY 1984.

In addition, EPA performs monitoring studies to gather information on human exposures. The National Human Adipose Tissue Survey (Adipose Survey) is a good example. Valuable information such as the decline of polychlorinated biphenyls (PCBs) in human tissues and the high levels of hexachlorobenzene (HCB) helps EPA to evaluate the effectiveness of its regulations and to target future activities. As a complement to the Adipose Survey, EPA is considering establishment of a pilot program for a National Blood Network Survey (Blood Survey) to determine the prevalence and levels of toxic substances in human blood.

EPA completed review of 27 chemicals in FY 1984 to see if regulatory action was needed. Another 52 chemicals are undergoing review. EPA accorded high-priority review under section 4(f) to two chemicals in FY 1984. The first was 1,3-butadiene, an important reactant in producing synthetic rubber products, which caused a high incidence of cancer in laboratory animals. The other chemical was formaldehyde, which also caused cancer in laboratory animals. The Agency gave high-priority review to formaldehyde exposures in mobile and conventional homes, as well as to apparel workers. EPA also issued Advance Notices of Proposed Rulemaking (ANPRs) on the section 4(f) uses of both formaldehyde and 1,3-butadiene. In addition, an ANPR was issued for certain glycol ethers that have been widely used as solvents and are associated with certain birth and reproductive effects. EPA was especially concerned about their consumer and trade uses.

EPA was active in issuing regulations on PCBs in FY 1984. Three final rules were promulgated. The first rule set a numerical cut-off for the inadvertent generation of PCBs. The second rule took action on 109 exemption requests from the ban of PCBs. The third rule established certain uses for small quantities of PCBs in research and development. The Agency also issued both an ANPR and a proposed rule based on the potential risks associated with PCB transformer fires.

FY 1984 marked EPA's first use of Chemical Advisories. These Advisories are not rules; rather, they inform relevant audiences about the hazards that specific chemicals present, and provide practical steps to minimize or eliminate those hazards. The first advisory covered used motor oil handled by service station workers, engine mechanics, and other workers. Used motor oil causes skin cancer in laboratory animals. Two other Advisories were issued on certain cutting fluids which could form nitrosamines, a class of potential human carcinogens. One advisory was directed at formulators, the other at end users. The Agency also issued a Chemical Advisory on leaking underground storage tanks to raise the awareness of storage tank owners regarding possible leaks, and to help them determine whether their own tanks are leaking.

Asbestos was a high priority for EPA in FY 1984. The ongoing technical assistance program for schools and other buildings was expanded. A recent survey suggests that the technical assistance program has been effective; most schools that have found asbestos have either initiated or completed abatement. In FY 1984, the Agency announced plans to establish three pilot centers to provide information and training on identifying and abating

asbestos hazards in schools and other buildings, and to establish a model state contractor certification program to ensure that abatement work is performed correctly and safely. Late FY 1984 saw the enactment of the Asbestos School Hazard Abatement Act, which provides limited funds in loans and grants for asbestos abatement activities in schools. EPA drafted application forms and established a preliminary implementation plan in FY 1984. EPA plans to provide $45 million in financial aid by June 1985.

International Activities

FY 1984 was also an active year internationally. In April, the United States and the Organization for Economic Cooperation and Development (OECD) members agreed that before any banned or severely restricted chemicals are exported, the exporting country will notify the receiving country. This agreement, which is modeled after section 12(b) of TSCA, affords receiving countries the opportunity to rationally determine how to deal with such chemicals. In March of FY 1984, the OECD, with input from EPA, agreed on the issues they will address through 1987. Some of the more significant issues are exchange of confidential information, compliance with Good Laboratory Practices (GLPs), and hazard assessment methods.

Enforcement

In FY 1984, EPA stepped up its compliance activities under TSCA. The number of inspections more than doubled from FY 1983. In FY 1983, EPA inspections focused primarily on PCB compliance. While the PCB issue was still important in FY 1984, EPA emphasized compliance with other TSCA requirements as well. The bulk of the inspections were on PCBs (nearly 1,500), on asbestos-in-schools (nearly 2,000), and on the Chemical Substances Importer Rule (nearly 500). In addition, there were over 200 inspections on new chemicals, more than 150 inspections for compliance with reporting and recordkeeping under TSCA section 8, and nearly 50 laboratories were inspected for compliance with GLPs.

Enforcement was also emphasized. Eighty-two civil complaints were issued for alleged violation of the asbestos-in-schools rule; these are the first complaints issued by EPA under this rule.

Indemnification Report to Congress

Under section 25 (a) of TSCA, EPA is required to conduct a study to determine whether and under what conditions, if any, indemnification should be accorded any person as a result of any action taken by the Administrator under Federal laws administered by EPA. On February 3, 1984, the Administrator sent the Indemnification Report to

Congress. The report concluded that there is no justification for expanding the existing indemnification programs at EPA nor for creating new programs because there are very few actual uncompensated losses. Many potential losses are prevented, reduced, or shifted by administrative action. Other losses are compensable under the Federal Tort Claims Act, the Tucker Act, or the Equal Access to Justice Act.

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New Chemicals

Program Status

Under section 5 of TSCA, EPA is responsible for reviewing new chemicals prior to manufacture or import. For purposes of premanufacture review under TSCA, "new" chemicals are those not listed on the TSCA Chemical Substances Inventory. This inventory of existing chemicals is EPA's comprehensive list of chemical substances in commerce. Under section 5(a), manufacturers must provide 90-day notification to the Agency, through the PMN.

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

EPA continued to make significant strides in FY 1984 to further refine the PMN review process, develop appropriate analytical methods for reviewing new chemicals, perform reviews quickly and, where necessary, regulate new chemicals. With standardized procedures and a submission form required by the PMN rule, which became effective in October 1983, and with EPA's accumulated experience in new chemical review, the PMN program has evolved into a very effective mechanism for identifying problems and managing risks. The PMN rule was a major milestone for the new chemical review program and represented the culmination of several years of effort to create effective, standard procedures for PMN reporting and recordkeeping. In addition to ensuring consistent enforcement of section 5 provisions, procedures under the final rule enable EPA to review the large number of PMN submissions the Agency is receiving. EPA received close to 1,200 PMNs in FY 1984, bringing the total received since the inception of the program to over 4,200. Most of the new chemicals reviewed under this preventive program did not require regulatory action. Wherever necessary, however, the Agency took appropriate action according to several

regulatory options available under section 5 of TSCA. EPA issued PMNs affected by 5(e) orders prohibiting or controlling 41 PMNs pending the development of data, bringing the aggregate total of PMNs affected by 5(e) orders issued since 1979 to 173. In addition, 35 PMNs were withdrawn by their submitters in FY 1984, in anticipation of EPA action under sections 5(e) or 5(f). Table 1 summarizes new chemical actions taken in FY 1984, and also gives aggregate totals since 1979.

Table 1

Summary of New Chemical Actions October 1, 1983-September 30, 1984

Actions	No. of PMN Actions in FY'84	Aggregated Total Since Beginning (mid-1979)
Submission of Bona Fide Intent to Manufacture	530	1,517
Valid PMNs Received	1,192	4,201[a]
PMNs Requiring No Further Action	936	3,452
Voluntary Testing in Response to EPA Concerns	20	78
Voluntary Control Actions by Submitters	4	37
PMNs Voluntarily Withdrawn in Light of EPA Concern	35	59
PMNs Subject to section 5(e) Consent Orders*	40	173[a]
PMN Unilateral 5(e) Orders*	1	14
PMNs Subject to section 5(f) Rules	4	4
Number of Chemicals for which Commencement of Manufacture Notices Were Received	584**	1,830**
New Chemicals Subject to Proposed Significant New Use Rules	18***	23****
New Chemicals Subject to Final Significant New Use Rule	2***	2
Valid Test Market Exemptions		
Received	80	313
Granted	67	276
Granted with modification	10	10
Withdrawn	3	18
Denied	0	9

[a] *Includes 106 synfuels.*

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

***This number includes PMNs received in previous fiscal years for which commencement of manufacture notices were received in FY 1984.*

****This number includes chemicals which were the subjects of PMNs received in previous fiscal years, but for which proposed or final rules were not published until FY 1984.*

*****This number excludes seven chemicals that were subject to SNUR proposals, but for which the PMNs were subsequently withdrawn.*

In FY 1984, the Agency implemented aggressive approaches to obtain additional information on PMN chemicals which were suspected of presenting unreasonable risks and to control exposures to these chemicals. TSCA section 5(e) orders placed controls on more PMN chemicals pending development of needed data in that year than in any other year. One innovative approach to systematically gathering needed data was to establish "delayed trigger" TSCA 5(e) orders which required submission of test data before production could exceed a specified production volume or time period. In this way, the Agency can receive needed data without unduly impeding innovation.

FY 1984 saw the first use of section 5(f) by the Agency. Section 5(f) authorizes EPA to issue an immediately effective rule to control new chemicals that present an unreasonable risk to health or the environment. The first immediately effective section 5(f) rule, issued January 23, 1984, applied to: (1) the substance known generically as the triethanolamine salt of tricarboxylic acid, intended for use as a ferrous metal corrosion inhibitor in metalworking fluid concentrates, and in hydraulic fluids; and (2) an intermediate used in the formulation of the corrosion inhibitor. Under certain circumstances, this chemical would produce N-nitrosodiethanolamine (NDELA), a nitrosamine which causes cancer in laboratory animals. The rule prohibited the practices that lead to the formation of NDELA and required distributors to notify customers of this restriction. Two similar rules were issued in June and September, 1984.

Exemptions

EPA may grant exemptions from full PMN review for substances produced for test marketing if the substances do not present an unreasonable risk to health or the environment. These exemptions are limited to the time necessary to complete test marketing. If the chemical is marketed for further commercial purposes, a PMN would be required. During FY 1984, 80 test market exemptions were received, 77 were granted (10 with modification), none were denied, and 3 were withdrawn in the face of EPA concerns. EPA places upon the submitter the burden of establishing the finding that an unreasonable risk does not exist. If the data submitted in the test market exemption application do not establish this finding, the application is not granted.

Section 5(h)(4) authorizes EPA to exempt chemicals from the PMN process if the Agency finds that such chemicals will not present an unreasonable risk of injury to health or the environment. In response to petitions from the Chemical Manufacturers Association and other

industry trade groups, EPA evaluated certain chemicals and categories of chemicals as candidates for exemptions. In 1982, EPA published proposed rules to partially exempt from the PMN requirements certain polymers, site-limited intermediates (chemicals that react to form other chemicals at their site of manufacture), and chemicals produced in low volume (less than 10,000 kg/yr).

After reviewing public comments, in FY 1984 EPA decided to postpone promulgation of the site-limited/low volume exemption rule, and to develop a final polymer exemption rule. Under this rule, polymers with a number-average molecular weight greater than 1,000, and polyesters manufactured solely from a list of approved reactants would be eligible for an accelerated (21-day) PMN review. Certain categories of polymers are excluded from the exemption. The final polymer exemption rule is currently being reviewed and is expected to be promulgated in early FY 1985. The Agency is also developing the low-volume exemption rule for promulgation in FY 1985.

Biotechnology

Perhaps the greatest emerging challenge for the New Chemicals Program in FY 1984 was addressing the rapidly advancing biotechnology industry. United States industry is an international leader in the development of this technology, which clearly has the potential for revolutionary new applications in the near future. EPA is committed to fostering the development of beneficial uses of biotechnology while protecting human health and the environment from unreasonable risk. Biotechnology promises great benefits for the United States and the international economy in areas including pollution abatement, agriculture, energy, and pharmaceuticals. At the same time, biotechnological products present unique regulatory challenges.

During FY 1984, the Agency developed a policy statement to clarify the applicability of TSCA and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to new microorganisms produced through biotechnology and used for commercial purposes. This statement describes EPA's plan for reviewing microbial products and solicits comments on a wide range of science and policy issues. It was published, along with similar statements by the Department of Agriculture and the Food and Drug Administration (FDA), early in FY 1985. The types of products that are likely to fall under TSCA jurisdiction include microorganisms used to leach minerals from ore, purify chemicals, enhance oil recovery, and degrade cellulose. The section 5 PMN requirement will be

the principal applicable regulatory authority — EPA has concluded that the genetic material in new microorganisms and the new organisms, themselves, developed through advanced techniques of biotechnology will be considered as new chemical substances subject to PMN requirements, if used for TSCA purposes. In addition, the Agency could use section 8 to gather information, section 4 to issue rules requiring testing of microorganisms, section 6 to regulate specific hazardous microorganisms, and/or section 7 to seek immediate judicial action in case of imminent hazards.

In FY 1984, the Office of Toxic Substances (OTS) worked closely with EPA's Office of Research and Development (ORD) to begin developing a research program to support PMN review of genetically engineered organisms. The Agency's goals in biotechnological research are to develop risk assessment methods for life forms being sold, distributed, and used in the open environment or where they may be dispersed by inadvertent release. In FY 1984, OTS and ORD held several workshops to identify the highest priority research needs required to meet these goals.

Since biotechnology products cross many Federal jurisdictions, EPA is committed to a coordinated interagency approach to biotechnology. EPA is participating in a Working Group on Biotechnology, established by the Cabinet Council on Natural Resources and the Environment. The purpose of this group is to coordinate the overall Federal approach to the regulation of biotechnology, while ensuring that innovation in biotechnology and the development of socially useful products are not unduly inhibited.

Because of its international significance, EPA is also participating in an OECD working group on biotechnology safety and regulations. The group is looking at scientific principles governing review of genetically engineered organisms, as well as relevant member country regulations.

Followup Program

An important aspect of both the premanufacture review program and the existing chemicals program is the policy to continue to monitor both new and existing chemicals that may be of concern if their uses change, or production volumes significantly increase from those estimated during their initial review. EPA uses its Significant New Use authority under section 5 (SNURs) to accomplish this purpose. SNURs are also used to extend the terms and conditions of the section 5(e) order to the other manufacturers and processors of that chemical who

otherwise could make or process the chemical without the restrictions placed on the original submitter.

The first final new chemical SNUR was published in FY 1984 on potassium N,N- bis(hydroxyethyl) cocoamine oxide phosphate and on potassium N,N-bis-(hydroxymethyl) tallowamine oxide phosphate. EPA must be notified if a manufacturer or user intends to use either chemical in certain consumer products at a concentration greater than five percent. EPA would then review this notice to see if the new use might present an unreasonable risk. All new chemical regulatory authorities would be available if needed.

EPA also proposed nine SNURs covering 18 new chemicals in FY 1984, to provide guidance to persons who intend to manufacture, import, or process a chemical subject to a SNUR.

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

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Existing Chemicals

Program Status

TSCA gives EPA the authority to evaluate and control risks associated with chemicals at any or all stages of development, from manufacture through disposal. Under the Existing Chemicals Program, the Agency's goal is to reduce or eliminate unreasonable risks of injury to health or the environment from chemicals that are already in commerce. The objectives of the program are to: (1) gather needed information; (2) identify and evaluate potential risks; (3) decide if risk management is required to reduce risks; and then (4) define and implement the necessary actions.

Information-gathering

EPA has a wide array of sources of information on chemical risks: section 4 testing; section 5 Significant New Use Rules; testing from other sources, such as National Toxicology Program (NTP) risk information under section 8(e); EPA-generated monitoring; chemicals subject to citizen petitions under section 21; and chemicals identified as potentially risky under EPA's New Chemicals Program. These sources are the starting point for determining which chemicals present unreasonable risks. In the area of information-gathering, the Agency has received 162 testing studies submitted under section 4 (Appendix C), and 16 test studies on 15 chemicals from the NTP (Appendix D). Since promulgation of the generic 8(a) and 8(d) information-gathering rules in FY 1982, the Agency has received 4,671 studies and reports on existing chemicals. Under section 8(e) EPA received 130 notices of substantial risk, 38 of which were initial submissions and 92 supplemental or followup submissions. In addition, the Agency received 227 "For Your Information" (FYI) submissions. FYI submissions are provided by companies when they do not believe that the 8(e) requirements are necessarily triggered, but they want to notify the Agency of new information.

Chemical Testing

Section 4 of TSCA was established in response to the specific concern that the effects of chemical substances and mixtures on human health and the environment were not adequately documented or understood. EPA's chemical testing program is one of the focal points for developing and accumulating test data under TSCA. Tests may be required where: the data are insufficient to

determine or predict effects, testing is needed to develop such data, and (1) the chemical may present an unreasonable risk to health or the environment or (2) the chemical is produced in substantial quantities and there is significant or substantial human exposure, or substantial quantities reach the environment. The Administrator takes these data into account in determining whether, or how, to regulate or control potentially hazardous substances under TSCA. These data are also used to provide scientific information for other EPA offices, as well as for other regulatory agencies.

Section 4 also established the ITC to review available data on a variety of chemicals and to designate chemicals for priority testing consideration. The ITC forwards its recommendations to EPA in the form of a "Priority List." This Committee, under the Act, must consider revising its list every six months. TSCA gives EPA only one year to perform an independent analysis of available information on the designated chemicals, and either initiate rulemaking to require testing of the chemical, or publish its reasons for not doing so.

EPA issued the first final Test Rule in FY 1984, requiring that 1,1,1-trichloroethane (TCEA) be tested for developmental toxicity. TCEA is a high-production volume chemical, with an estimated 26 million workers and millions of consumers exposed to it from products such as aerosols, adhesives and paints.

The Agency has developed the policy of negotiating testing agreements with industry in order to respond to the ITC's recommendations within the statutory time frame. Negotiated testing agreements were a major portion of EPA's TSCA section 4 program in FY 1984. However, a U.S. District Court issued a decision in a suit brought by the NRDC (NRDC v. US EPA, 83 Civ. 8844, U.S. District Court Southern District of NY) late in the year, which found that Negotiated Testing Agreements on chemicals recommended by the ITC were not sanctioned under TSCA. The Agency will reevaluate its section 4 testing program in FY 1985.

In FY 1984, EPA responded to a total of 43 ITC related actions covering 30 chemicals. Fourteen were backlogged designations, 16 were new ITC designations and 13 were post-initial determinations. These produced: 17 decisions not to test; 14 Negotiated Testing Agreements; 5 ANPRs; 6 proposed rules, and 1 final rule. In addition, the Agency signed a Final Rule setting forth procedures for test rule development and for the granting of exemptions under TSCA section 4(c). This rule will be published in early FY 1985. Table 2 shows FY 1984 actions taken on ITC-designated chemicals.

Table 2

Responses to Interagency Testing Committee (ITC) Designations

Date	Chemical Category	Action Rule	ITC List
11/4/83	Acetonitrile	Final Negotiated Testing Agreement (NTA); health effects testing.	4
11/8/83	Alkyltin compounds (Includes 7 Chemicals)	Decision not to test; EPA does not believe there is sufficient basis to find that these substances may present an unreasonable risk to the environment, or that there is, or may be, substantial environmental release.	7,11
11/14/83	Bis(2-ethylhexyl)-terephthalate	Proposed negotiated testing agreement; preliminary decision not to initiate rulemaking. Final NTA June 4, 1984.	11
11/14/83	1,3-Dioxolane	Proposed negotiated testing agreement; preliminary decision not to initate rulemaking. Final NTA August 10, 1984.	11
11/14/83	Tris(2-ethylhexyl)-trimellitate	Proposed negotiated testing program; preliminary decision not to initiate rulemaking. Final NTA June 4, 1984.	11
11/15/83	4-(1,1,3,3-Tetra-methylbutyl)phenol	Proposed negotiated testing agreement; preliminary decision not to initiate rulemaking. Final NTA July 20, 1984.	11
12/7/83	Chlorobenzenes	Proposed rule-related notice; tentative withdrawal of proposed test requirements, except for proposed requirement for oncogenicity testing of 1,2,4-trichlorobenzene and proposed health effects tests for 1,2,4,5-tetrachlorobenzene, based on EPA's analysis of data and ongoing industry testing. Proposed negotiated testing agreement.	1
12/29/83	Aryl phosphates	Advance notice of proposed rulemaking; testing appears necessary to complete rulemaking assessment of the health and environmental effects.	2
12/29/83	Formamide	Final Negotiated Testing Agreement; health effects testing.	10
12/30/83	Glycidols	Advance notice of proposed rulemaking to solicit public comment on EPA's rationale of selecting chemicals from this category and to define testing EPA is considering proposing.	3
12/30/83	Hexafluoropro-pylene oxide	Proposed rule; mutagenicity, oncogenicity, and reproductive effects testing. Teratogenicity and epidemiology testing not recommended.	2
12/30/83	Halogenated alkyl epoxide (others)	Decision not to test for members of the halogenated alkyl epoxide category, other than hexafluoropropylene oxide.	2
1/3/84	Cyclohexanone	Proposed negotiated testing agreement for health effects; decision not to test for environmental effects.	4
1/3/84	Anilines	Advance notice of proposed rulemaking. EPA is seeking comment on test substances, route of administration, and sub-categorization. Also seeking information on exposure, available health data, and data on environmental effects and chemical fate.	4
1/3/84	Ethylene oxide	Decision not to test, based on available data, ongoing testing for this chemical, and on regulatory actions being undertaken by EPA and Occupational Safety and Health Administration (OSHA).	1
1/4/84	Propylene oxide	Proposed rule for teratogenicity testing.	1
1/4/84	1,2-Butylene oxide	Decision not to test; available data and data from ongoing industry testing of this chemical should be sufficient to determine carcinogenicity; postpone decision until results of mutagenicity testing are analyzed; not pursuing ITC recommendation for epidemiological study.	1

Table 2

Date	Chemical Category	Action Rule	ITC List
1/4/84	Low production alkyl epoxides	Advance notice of proposed rulemaking; defines rationale for selecting chemicals and regulatory approaches being considered.	1
1/4/84	Quinone	Proposed rule; carcinogenicity, chemical fate, and environmental effects testing. Teratogenicity testing not proposed.	5
1/4/84	Hydroquinone	Proposed rule; to evaluate toxicokinetics, and neurotoxic, reproductive, teratogenic, and mutagenic effects. Epidemiological studies and chemical and environmental effects testing also proposed.	5
1/6/84	1,2-Dichloro propane	Proposed rule; health effects including neurotoxicity, mutagenicity, teratogenicity, and reproductive effects. Environmental effects include acute and chronic toxicity tests for aquatic invertebrates and an aquatic plant test.	3
1/13/84	Chlorobenzenes	Proposed rule; chemical fate and environmental effects tests on mono-, di-, and trichlorinated benzenes; chemical fate or environmental effects testing of the tetrachlorobenzenes or pentachlorobenzene not proposed at this time.	1 & 3
1/17/84	Isophorone	Final Negotiated Testing Agreement; health effects testing.	4
5/21/84	Methylolurea	Advance notice of proposed rule-making; solicit data on exposure, environmental releases, health effects, chemical fate and environmental effects of urea-formaldehyde (UF) resins; collect information on the chemical composition of various UF resins; seek public comment on criteria for selecting test substances.	12
5/21/84	Calcium naphthenate	Decision not to test; based on ongoing industry testing.	12
5/21/84	Cobalt naphthenate	Decision not to test; based on ongoing industry testing.	12
5/21/84	Lead naphthenate	Decision not to test, based on ongoing industry testing.	12
5/21/84	2-Phenoxyethanol	Decision not to test; based on ongoing industry testing.	12
6/4/84	Fluoroalkenes	Proposed decision to adopt a negotiated testing program; decision not to test 3,3,3-trifluoro-1-propene and trifluoroethane.	7
6/19/84	Dichloromethane	Proposed rule withdrawn; additional data received and ongoing testing sufficient to predict effects on human health.	2
6/19/84	Nitrobenzene	Proposed rule withdrawn; additional data received and ongoing testing expected to provide sufficient data to determine or reasonably predict effects of nitrobenzene on human health. Additional data on environmental effects led Agency to conclude that the current data do not support findings necessary to require testing.	3
7/31/84	Acrylamide	Decision not to test; decision not to require health effects testing.	2
Signed 9/5/84	1,1,1-Trichloro-ethane	Final Test Rule; health effects testing. The costs of conducting the developmental toxicity test are estimated to range from $62,134 to $186,403 with annualized costs ranging from $16,000 to $48,300. Based on these test costs and an analysis of the market characteristics of TCEA, the economic evaluation indicates that the potential for a significant adverse economic impact as a result of this test rule is low.	2

Reporting and Recordkeeping

Section 8 of TSCA authorizes EPA to require reporting and recordkeeping on chemicals, substances, and mixtures This provides the Agency with a mechanism to review and identify chemicals that might be of concern.

- Section 8(a) authorizes EPA to promulgate rules requiring manufacturers and processors to maintain records and report certain risk information to the Agency.

- Under section 8(c), as implemented, companies must maintain records of alleged "significant adverse reactions." This information must be provided to EPA upon request.

- Section 8(d) requires certain manufacturers, processors, and distributors to submit health and safety studies to EPA.

EPA has issued rules implementing sections 8(a) and 8(d). These rules detail the procedures for submitting information, establish the types of information to be submitted, and list chemicals on which the information is to be submitted. The list of chemicals is revised as necessary when EPA needs the data to assist in fulfilling other statutory requirements, or to assist in evaluating a chemical brought to the Agency's attention under various mechanisms. There are implementing regulations for section 8(c), and EPA has issued a policy statement to implement section 8(e).

The following activities were initiated in FY 1984.

- The Agency issued two final rules under section 8(a) in FY 1984. The first covers chlorinated terphenyls (CTs). The second covers chlorinated napthalenes (CNs). Any current or planned manufacture or import of these chemicals must be reported to EPA. Small businesses are exempt from these rules. The CT rule was published on March 26, 1984 (49 FR 11181) and the CN rule was published on August 24, 1984 (49 FR 33649).

- In addition, as each new ITC list is submitted to EPA, the Agency automatically amends the section 8(a) preliminary assessment information and 8(d) rules to include the chemicals on each list. This ensures that all available information is submitted to the Agency for use in decisionmaking for section 4 test rules.

- The final 8(c) rule became effective on November 21, 1983. It requires that manufacturers and processors keep records of allegations of significant reactions to health or the environment that were caused by a chemical. These records must be maintained by the industry; they are submitted to the Agency upon request. This rule will also

assist industry in identifying substantial risk cases, and may trigger reporting to the Agency under TSCA section 8(e).

Monitoring

EPA's monitoring program under TSCA provides important information on existing chemicals.

A Blood Survey designed to determine the levels and prevalence of toxic substances in human blood would complement the Adipose Survey since the chemical classes being targeted include elemental toxics and volatile organics, whereas the Adipose Survey has focused on semi-volatile organics. This network would be conducted with the cooperation of the three national blood collection agencies — The American Red Cross, the American Association of Blood Banks, and the Council of Community Blood Centers. Pilot testing of the network and chemical analytical protocols will be conducted in FY 1985, and full network operation is scheduled to begin in FY 1986.

In FY 1984, results from the Adipose Survey produced the first "exposure-based" list of chemicals that will undergo OTS review for potential "unreasonable" risk levels. This is in direct contrast to previous chemical lists which have been based solely on toxicological (health effects) data. In the last several years, results of adipose tissue analyses have shown that the level of PCBs in humans is declining. Continued analysis, incorporating more recent data, indicates that this trend is continuing. The Adipose Survey also generated data on hexachlorobenzene (HCB) indicating a high frequency of human exposure to that chemical. In FY 1984 and FY 1985, EPA will perform its first risk assessment that is based upon body burden levels of HCB. These body-burden data, along with toxicological evidence, have triggered a federally coordinated initiative to gather information on sources of exposure to HCB.

Information from these broad studies helps EPA plan future TSCA ambient monitoring programs, identify candidates for testing under section 4 or for regulatory controls under TSCA authorities, and evaluate the effectiveness of TSCA actions in protecting human health and the environment.

Risk Evaluation

EPA's information-gathering sources are evaluated in a five-phase process. These phases are termed: entry review, problem characterization, information-gathering and risk analysis, risk reduction analysis, and risk management. Only those chemicals for which significant risks are identified will complete all of the phases. Chemicals which are found not to pose significant risks are dropped from further evaluation.

The various actions which result from these evaluations include initiation of rulemaking under: section 6 for risk control; under section 5 for reporting of significant new uses; under section 8 for information reporting or recordkeeping; under section 4 for testing; development of section 9 referrals to other agencies; and issuance of chemical advisories to inform those concerned of measures that can be taken to mitigate potential risks.

Table 3 summarizes Existing Chemicals Program activities.

Table 3 Summary of Existing Chemical Actions

Information-gathering	**# in FY 1984**
Testing Studies Received under section 4 (See Appendix C)	162
Section 8(d) Health and Safety Studies	3,918
Section 8(e) Submissions Received	130
Initial Submissions	38
- Supplemental/Followup Submissions	92
- "For Your Information" (FYI) Submissions	227
National Toxicology Program - Studies Reviewed (See Appendix D for listing of the 15 chemicals)	16
Risk Evaluation - Action/Chemical	**# in FY 1984**
Chemical Evaluations	
Drop from further evaluation	9
- Continued assessment	52
- Referred for Regulatory Investigation	3
- Section 4(f) Designations	2
- Section 8a/SNUR Referrals	8
Chemical Hazard Information Profiles (See Appendix E for listing)	21
Section 21 Petitions Received (See Appendix F)	5
Risk Management - Action/Chemical	**# in FY 1984**
Advance Notices of Proposed Rulemaking/ Proposed Rules under section 6(a)	3
Proposed and Final Rules under section 6(e)	9
Chemical Advisories	4

Chemical Hazard Information Profiles

In FY 1984, EPA prepared Chemical Hazard Information Profile (CHIP) documents for 21 chemicals (Appendix E). CHIPS are sometimes prepared as part of the first phase of existing chemical reviews. They are brief summaries of readily available information concerning the health and environmental effects and exposure potential of a chemical. Information-gathering for a CHIP is generally limited to a search of secondary literature sources such as computerized databases, abstracts, government reports, scientific review documents, and reference works. While

literature search for a CHIP is not intended to be exhaustive, in-depth searches on specific topics may be done on a case-by-case basis. Relevant literature is usually reported as a narrative summary. Any experimental conditions and results are briefly described for relevant studies. These profiles collect and identify data gaps. EPA uses CHIPs in risk evaluations, not only under TSCA, but under other authorities as well.

TSCA section 21 Petitions

Section 21 of TSCA, 15 U.S.C. 2620(a) and (b), provides that any person may petition the EPA Administrator to initiate a proceeding for issuing, amending, or repealing a rule under various sections of the Act.

The Administrator may hold a public hearing or may conduct such investigation or proceeding as he deems appropriate in order to determine whether or not the petition should be granted. If the Administrator grants the petition, the Agency must begin promptly to initiate the action requests by the petitioner. If the Administrator denies the petition, the reasons for denial must be published in the *Federal Register.* Finally, the petitioner may start a civil action in a district court of the United States to compel the Administrator to initiate a rulemaking proceeding requested in the petition.

Five section 21 petitions were received in FY 1984 (Appendix F). A total of 24 petitions have been filed since February 1978, when the first section 21 petition was received; 17 petitions have been denied, and 5 have been granted.

Risk Management

Ensuring that unreasonable risks from existing chemicals are adequately managed is a high priority for EPA. The Agency is using both regulatory and non-regulatory means to eliminate or minimize unreasonable risks. FY 1984 actions are presented below.

Glycol Ethers: 2-Ethoxyethanol, 2-Methoxyethanol and Their Acetates —2-EEA and 2-MEA

2-EEA and 2-MEA are high-production chemicals used primarily as solvents in paints, coatings and inks, and as deicers in jet fuel. Animal studies conducted from 1981 through 1984 demonstrated that these particular glycol ethers cause fetotoxic effects in rats, mice, and rabbits. The exposure data available to EPA indicate that significant numbers of workers and consumers may be exposed to these chemicals at significant levels. EPA is especially concerned about consumer and trade uses of these chemicals. Consequently, on January 24, 1984, EPA published an ANPR in the *Federal Register* (49 FR 2921). EPA is investigating the consumer and certain workplace risks of glycol ethers, and is evaluating alternatives under sections 6 and 9 of TSCA.

Methylene Bis(2-chloroaniline) - (MBOCA)

MBOCA is a curing agent used to manufacture certain polyurethane plastics. This chemical, a demonstrated animal carcinogen, is not currently manufactured in the United States. No OSHA standard for it exists. EPA's primary concern is for persons who work for plastics formulators using MBOCA (generally small firms). MBOCA was the subject of an ANPR on May 23, 1983 (48 FR 22954). EPA is exploring both regulatory and nonregulatory options for managing the risks associated with MBOCA.

Formaldehyde

Formaldehyde is an industrial chemical with many uses. Since 1980, accumulating evidence indicates that formaldehyde causes cancer in animals and may pose a cancer risk to humans. In May 1984, EPA announced that certain formaldehyde exposures would receive high priority review because of the possibility of a significant risk of widespread harm to humans from cancer. The Agency also published an ANPR on May 23, 1984 (49 FR 21870) initiating a regulatory investigation of the two largest exposed populations: apparel workers and residents of housing built with formaldehyde-releasing wood products. The ongoing regulatory investigation is evaluating the risks and the risk management options.

1,3-Butadiene

On January 5, 1984, EPA announced it was initiating an accelerated 180-day review of 1,3-butadiene under section 4(f) of TSCA, and requested information to help it, and OSHA, determine whether to initiate appropriate action to prevent, or reduce risk from this chemical. After reviewing this information, EPA announced on May 15, 1984 (49 FR 20524), that it was initiating a regulatory investigation to evaluate the risks as well as the need for risk management. An inhalation bioassay conducted by the NTP in 1983 indicates that 1,3-butadiene is strongly carcinogenic in mice. The bioassay, supported by a previous industry-sponsored test in rats, also identified potential reproductive effects associated with this chemical.

1,3-Butadiene is a high-volume chemical, approximately three billion pounds of which is consumed per year in the United States, mostly in the manufacture of rubber and plastic products. Human exposure data are limited, but they indicate that some workers may be exposed to levels that produced tumors in the experimental animals. Many more workers are exposed to levels that are above 5-10 parts-per-million (ppm). The current OSHA standard of 1,000 ppm, 8-hour time-weighted average (TWA), is based on acute toxic effects. In FY 1985, EPA will work with OSHA to develop a strategy to deal with 1,3-butadiene.

4,4'-Methylenedianiline - (4,4'-MDA)

4,4'-MDA is a high-production chemical used primarily as an intermediate in the manufacture of other chemicals and plastics. In June 1979, 4'4-MDA was designated for testing consideration by the ITC. In June 1982, the NTP completed a study which indicated serious carcinogenic potential. Prompted by this study, the evidence of possible high level workplace exposure, and the absence of a Federal workplace standard, EPA initiated a high-priority review under section 4(f). On September 20, 1983, EPA and OSHA issued a joint ANPR. In FY 1984, EPA assessed the risk management options and anticipates referring 4,4'-MDA to OSHA in FY 1985.

Polychlorinated Biphenyls

PCBs continued to be an area of major attention for EPA and the public in FY 1984. Section 6(e) of TSCA bans the manufacture, processing, distribution in commerce, and use of PCBs, with certain exceptions.

In FY 1984, three final rules were promulgated on PCBs in the July 10, 1984 *Federal Register* (49 FR 28154-28209). The first rule set numerical cutoffs for the inadvertent generation of PCBs. A second rule took action on 109 individual and class petitions for exemptions from the PCB bans. The third rule established PCB use authorizations for small quantities in research and development, and other limited uses. Two other regulatory action PCBs were initiated in FY 1984.

The first rule, referred to as the Inadvertently Generated PCBs Rule, limits the concentration of PCBs inadvertently generated in manufacturing processes, and concentrations in certain processes which recycle PCBs. The Inadvertently Generated PCBs Rule also sets limits on the discharge of wastes to water, ambient air, and to solid waste streams from these processes. This rule also includes an authorization under certain circumstances for the continued use of low levels of PCBs in heat transfer and hydraulic systems.

The second final rule in FY 1984, referred to as the Exemptions Rule, granted 58 individual and class petitions for exemption from the prohibitions against the manufacture, processing, and distribution in commerce of PCBs, after determining that these activities do not pose an unreasonble risk of injury to health or the environment, and that the petitioners had made good faith efforts to find or develop a substitute for the PCBs. Fifty-one petitions were denied in this rule.

The third final rule in FY 1984 authorized the use of PCBs in small quantities for research and development in certain applications in microscopy and as optical fluids.

In addition to the three final rules, EPA initiated two other regulatory actions regarding PCBs in FY 1984. In the

March 23, 1984, *Federal Register,* EPA published an ANPR (49 FR 11070) soliciting comments on the fire-related risks posed by PCB transformers. In this notice, EPA announced its intention to develop a proposed rule that would seek to reduce the risks caused by fires in PCB electrical transformers. On September 28, 1984, the Administrator signed a proposed rule (49 FR 39966).

Finally, on July 23, 1984, EPA published a proposed rule (49 FR 29625) to modify the March 31, 1979 PCB rule by redefining the term "totally enclosed manner" for PCB-related activities, and changing other portions of the rule to clarify the Agency's position on exactly what constitutes significant exposure to PCBs.

Asbestos

EPA is committed to eliminating unreasonable risks posed by asbestos exposures. The Agency has had an abiding concern about asbestos because of the well-documented hazards associated with inhalation of asbestos fibers. Since 1979, EPA has provided technical assistance to schools and other building owners. FY 1984 saw expansion of this technical assistance program. Increasingly throughout the year and peaking during the summer of FY 1984, public interest focused attention on asbestos. During FY 1984, for example, EPA received over 75,000 telephone calls requesting technical assistance and requests for approximately 80,000 asbestos documents.

Due to the crucial need to educate the public about asbestos in buildings, EPA greatly expanded its outreach efforts in FY 1984. The Agency announced the establishment of three pilot information centers in FY 1985 at the regional level to provide information concerning the identification and abatement of asbestos hazards, and to educate and train people in proper asbestos identification and abatement techniques. These centers will sponsor technical symposia and conferences to train people involved in various aspects of asbestos identification and abatement. Target audiences for the centers will include: maintenance personnel, building managers and owners, school officials, parents, architects, abatement contractors and workers. These pilot information centers will also serve as information clearinghouses to distribute guidance documents, manuals, and audio-visual materials.

Another important outreach effort was initiated in FY 1984. EPA plans to help establish a State contractor certification program for abatement contractors in FY 1985. This program will include model State legislation designed to establish effective contractor certification

programs at a State level, and pilot contractor certification programs set up in several States. During FY 1984 the Agency worked with three States to establish these pilot programs. This will lead to more effective abatement of asbestos hazards and reduce risks to both abatement workers and people using buildings with asbestos hazards. If these programs are successful, EPA may expand them to additional States in FY 1985.

Still another important new initiative in FY 1984 was the effort to implement the Asbestos School Hazard Abatement Act of FY 1984, which Congress passed in August. This Act established a loan and grant program to support abatement programs in schools with the most serious asbestos problems and demonstrated financial need. Interim abatement loan and grant application forms have been developed and will be distributed early in the next fiscal year. EPA expects that the first-year funds will be allocated by June, 1985.

In FY 1984, EPA conducted a national survey to determine the extent of asbestos-containing friable materials in buildings. This survey was part of OTS' effort to deal with the broader problem of public exposure to asbestos from friable asbestos building materials. The primary objective of the survey was to generate valid national estimates of the number of buildings that have asbestos-containing materials for use in OTS' asbestos program. Overall, approximately 80 percent of all buildings represented by the survey do not contain friable asbestos materials. Thus, of the 3.5 million buildings represented by the survey, it is estimated that about 2.8 million buildings do not contain friable asbestos.

EPA also conducted a survey on compliance with its Asbestos-in-Schools rule as well as on the extent of abatement in schools that found asbestos. Although compliance with the major provisions of the rule was low, most schools made an effort to inspect, and most schools that found asbestos have either initiated or completed abatement.

Chemical Advisories

FY 1984 marked the first use of Chemical Advisories by EPA. An advisory is written to give individuals or organizations information on the hazards of specific chemicals, and practical steps that can be used to minimize or eliminate these hazards. Advisories are distributed directly to those who can taken action to reduce risk. They are not rules. They are written by EPA after consultation with interested parties such as companies, labor organizations, public interest groups, and other agencies. Chemical Advisories are designed to be

used where an increased awareness of potential risk is likely to lead to meaningful precautions, and are addressed and distributed to individuals or organizations for whom the information is most useful. They are intended to encourage voluntary risk-reduction actions by individuals or organizations, or as a complement to a regulatory action.

During FY 1984, EPA issued four Chemical Advisories: one on used motor oil (published in English and Spanish); one each to formulators and metalworkers on metalworking fluids; and one on leaking underground storage tanks.

Used Motor Oil

Service station workers, engine mechanics and any other workers who handle motor oil were advised to minimize skin contact with used oil, and to remove any used oil from their skin promptly. The advisory was issued after a laboratory study showed that mice developed skin cancer after their skin was exposed to used motor oil twice weekly for most of their life span without being washed off.

Metalworking Fluids

Adding inorganic nitrite corrosion inhibitors to metalworking fluids containing secondary and tertiary amines results in the formation of nitrosamines, particulary n-nitrosodiethanolamine (NDELA). Recent studies indicate that NDELA is an animal carcinogen at relatively low doses. In FY 1984, EPA initiated a regulatory investigation under section 6 of TSCA to explore the need for, and feasibility of, risk management regulations.

In September 1984, as an interim measure while rulemaking was being considered under section 6, the Agency issued two chemical advisories concerning the addition of inorganic nitrites to water-based metalworking fluids containing secondary and tertiary amines. The first advisory, which is directed to formulators, recommends that nitrites not be added during formulation of metalworking fluids that contain amines; it also recommends that fluids containing both nitrites and amines be labelled to warn users of potential nitrosamine contamination. The second advisory, addressed to end users, also advises against adding nitrites to amine-containing fluids, and recommends precautions to reduce exposure to metalworking fluids that may be contaminated with nitrosamines.

Leaking Underground Storage Tanks

Gasoline, other petroleum products, hazardous wastes, and other chemicals are stored in above-ground and underground tanks of various sizes, construction materials, and designs. Evidence suggests that leaking underground storage tanks are a significant cause of

groundwater contamination in several parts of the country and may be leading to serious contamination of water supplies.

In FY 1984, EPA began to examine this problem in depth to gather as much data as possible to better characterize its scope and magnitude.

In addition, EPA is taking two major actions in this area. First, OTS has issued a Chemical Advisory alerting owners and operators of underground motor fuel storage tanks to the potential problems should a leak occur. As the advisory explained, leaks from tanks and pipes not only represent sources of drinking water contamination, but can also damage underground structures (such as sewer lines and telephone cables), present fire or explosion hazards, and damage crops, livestock, and wildlife. Even in small amounts, long-term exposure to motor fuels may cause health problems. A background booklet, prepared to supplement information available in the Chemical Advisory, also provides information on how to test for, report, and repair underground leaks.

Second, OTS designed a statistically-based national field study of motor fuel tanks to help assess the magnitude of the leaking tank problem and to develop sound information upon which to base Federal regulations. A pilot survey conducted in FY 1984 was designed to test the entire field survey procedure. In addition, OTS is assisting other EPA offices to implement those portions of the recently passed Resources Conservation and Recovery Act Amendment which apply to underground storage tanks.

TSCA section 9 and Workplace Referrals

One important effort during FY 1984 was the development of an interim policy for referring workplace exposure problems to the Department of Labor (DOL). Under TSCA, EPA is responsible for protecting public health from unreasonable risks arising from the manufacture or processing of chemicals. Similarly, DOL is responsible, under the Occupational Safety and Health and the Mine Safety and Health Acts, for protecting the health of workers. When toxic chemical exposures occur primarily within the workplace, jurisdictional issues must be resolved to ensure that these exposures are adequately addressed without unnecessary duplication of effort. Section 9(a) of TSCA authorizes EPA to refer chemical problems to other agencies. EPA and DOL initiated efforts during FY 1984 to develop a comprehensive Memorandum of Understanding (MOU) that would govern relationships between the two agencies concerning workplace risks.

5

Quality of Data

EPA has long been concerned about the quality of data that are submitted under TSCA. The Agency is dealing with this issue by establishing guidelines for acceptability of tests and by vigorously auditing laboratories to ensure that good laboratory practices are used.

Test Guidelines

EPA develops generic test methods guidelines that are cited as standards in promulgated test rules, or are used as the basis for deriving acceptable chemical-specific test standards for test rules (47 FR 13012). EPA has anticipated testing needs by developing guidelines for a wide variety of test methods in the health, environmental, and chemical fate areas. These guidelines are available through the National Technical Information Service (NTIS). EPA ensures that test methods are consistent and of acceptable scientific quality by ensuring that each guideline is peer-reviewed by scientists in other EPA program offices, and by expert scientists in the academic community, State and Federal agencies, public interest groups, and industry.

EPA reviews responses from solicited public comments and other information-gathering procedures to ensure that selected guidelines and promulgated standards reflect the most current and valid testing practices. Where the review warrants, EPA updates guidelines and/or standards. During FY 1984, EPA updated six guidelines. Among the updates were revisions of three Acute Toxicity Testing guidelines. These revised guidelines reflect the Agency's policy concerning the need to assess the potential acute effects of chemicals, while reducing to a scientifically acceptable minimum the number of animals used in tests.

The Agency also is continuing its program of coordination and harmonization of test guidelines with the OECD. In FY 1984, EPA distributed for review four new OECD generic test method guidelines in the health and chemical fate areas.

Good Laboratory Practices

In addition to establishing test guidelines, EPA scrutinizes the quality of data upon which it must make crucial decisions in other ways.

On November 29, 1983, the Agency promulgated a Good Laboratory Practice Standards Rule (48 FR 53922) which became effective on December 29, 1983. This rule established GLPs for conducting health effects and environmental effects testing under TSCA. It specifies requirements for areas such as facility operations, maintenance of equipment, and recordkeeping, and is intended to ensure the quality and integrity of data submitted to the Agency under TSCA.

EPA's Compliance Monitoring Staff has the lead responsibility within the Office of Pesticides and Toxic Substances for inspecting laboratories for compliance, and for auditing studies to determine if test reports reflect study results accurately and completely. This program is coordinated with, and supported by the EPA, FDA, and the NTP. Under this compliance monitoring program, the EPA Regional Offices or the FDA conduct GLP inspections of laboratories. Audits of studies are also conducted by EPA, and report reviews are conducted by EPA scientific staff, with support from the NTP. In FY 1984, EPA conducted nearly 50 laboratory inspections.

6

Toxics Integration

During FY 1984, the Toxics Integration Program continued to develop policies and procedures to coordinate and integrate Agency and Federal activities related to toxic substances. These activities included: 1) developing and managing various databases and information resources to improve internal and external interagency coordination; 2) developing Agency-wide chemical strategies; and 3) coordinating OTS activities with those of other EPA offices and Federal agencies. All of these measures were designed to avoid duplication and coordinate a consistent approach to evaluating and controlling toxic chemicals.

Databases

The fourth edition of the *EPA Chemical Activities Status Report* (EPACASR) was published in FY 1984. It provides brief descriptions of the Agency's chemical-specific activities as they affect more than 3,800 chemicals and chemical categories. The computer database, which includes descriptions of a number of activities conducted by agencies other than EPA, as well as EPA's efforts, addresses some 8,400 chemicals and chemical categories. Printed copies of the EPACASR, available through the NTIS, provide an important reference source for anyone following chemical regulatory and pre-regulatory activities.

Computer printouts on chemicals of concern have been provided on request to governmental bodies who need to identify available information resources and contact points. Efforts to provide direct computer access to these organizations are in progress, and a tape version of the EPA portion of the database is currently available commercially through the NTIS.

EPA also developed the *Guide to EPA Activities on Toxic and Hazardous Chemicals*. This document provides EPA managers with overview information on the status of EPA's planned, ongoing, and completed activities on chemicals, especially those chemicals which are addressed by more than one EPA program.

The guide, along with EPACASR, is a tool used to: 1) direct EPA managers to other programs that may provide information on a chemical substance of interest to the

program; and 2) highlight chemical substances of interest to more than one program by pointing out a potential need for coordinating the general or specific activities of the entire Agency, or of selected programs.

To ensure that all EPA programs are coordinated, a crosswalk document was developed during FY 1984 to provide Chemical Abstract Service (CAS) registry numbers for 1,545 of the 1,632 active pesticide ingredients currently registered. Before this document appeared, EPA identified active ingredients solely by internal file numbers. Assigning CAS registry numbers has facilitated communication between data holders in EPA, and between EPA and other agencies.

In addition to chemical-specific databases, EPA also developed other databases concerning industry activities. During FY 1984, the Industry File Information System (IFIS) became operational. An automated guide to EPA's industry regulations as viewed from a chemical's perspective, IFIS enables the user to determine, for a particular industry, which chemicals are used or produced, and whether and how these chemicals are regulated, including the statutory authority. A document was also prepared that identifies key EPA staff who are working in over 77 industry categories. Lead program office contacts have been provided for each industry category. This document, like EPACASR, is becoming a standard EPA reference tool.

The Extramural Activity Report (EAR) was issued during FY 1984 to ensure contract coordination within the Agency. It includes descriptions of toxics-related projects being developed under contracts as well as cooperative agreements or assistance programs funded by EPA. Its purpose is to assist in planning and developing extramural efforts by providing a source of information about extramural projects currently being funded throughout the Agency. Coordinating these efforts has improved their quality and consistency, and duplications have thus been avoided.

Chemical Strategies

A major effort in FY 1984 was the continued development of Agency-wide chemical strategies to deal with issues concerning arsenic and lead, while another new effort addressed hexachlorobenzene (HCB).

During FY 1984, the Agency directed efforts in its arsenic and lead strategies toward regulatory and evaluation activities in both its air and pesticide programs, and in the Superfund Program.

HCB has been detected in almost all human fat samples taken in monitoring studies. Moreover, HCB

shares many toxic properties of other highly chlorinated aromatic hydrocarbons, for example, dioxins and chlorinated dibenzofurans. HCB has been shown to be carcinogenic and teratogenic in animals, and it is suspected of being a human carcinogen. Human beings appear to be exposed to it from a variety of sources.

The HCB effort is preregulatory and will be completed in 1986. EPA and other Federal agencies will use this effort to: 1) identify sources and routes of exposure; 2) define exposure and body-burden levels that may cause adverse health and environmental effects; and 3) compare these levels with measured or estimated levels of exposure so that populations and environmental compartments at risk can be identified. A strategy will then be developed to direct EPA's efforts on the most critical problems concerning HCB.

These efforts will lead to developing multi-media health and exposure assessment documents to be used by all EPA programs and other Federal agencies. These documents are tools for managers to use to save resources and avoid duplication.

Coordination Activities

By participating in various key Agency work groups on specific chemicals of interest to OTS and other programs, chemical data available within OTS are identified to ensure that the most upto-date information is used to develop Agency regulations. Chemical data collected under TSCA are currently being used and analyzed by the Offices of Research and Development (ORD) and Solid Waste and Emergency Response to support their research and regulatory efforts.

During FY 1984, several EPA Regional offices were briefed on the various information resources available within OTS that they may use to develop assessment documents and conduct site-specific analyses. As more TSCA data become available, these data are being made available to other EPA program offices.

Other Activities

Other FY 1984 projects which helped to improve coordination and avoid duplication included an exposure assessment initiative, and the continued development of intermedia documents concerning various chemicals.

The exposure assessment activity brought together those program offices that conduct exposure assessments, and convened a body that revised the Agency's exposure assessment guidelines. As a result of the development of this guideline, EPA intends to develop comprehensive exposure documents that meet its multiple requirements.

Under its program for developing multi-media assessment documents, EPA completed three new Intermedia Priority Pollutant documents (IPPs) in FY 1984 on chlordane, ethylene dibromide, and nickel. In addition, four of the original IPPs covering benzene, chlorinated organic solvents, PCBs and 2,3,7,8-TCDD were updated. The program to develop IPPs began in FY 1983 when these documents were completed on 23 chemicals. IPPs are designed to provide an overview of current regulatory and technical information on a group of toxic chemicals of intermedia concern. Topics covered include: physical/chemical properties; health and environmental effects; production, use, release, and exposure; regulatory status; recommended criteria and standards; spill cleanup/disposal and a description of analytical methodologies. EPA Headquarters and the Agency's Regional offices use IPPs in their daily activities.

7

Compliance and Enforcement

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

Program Actions

During FY 1984, EPA developed and issued a general TSCA Compliance Monitoring/Enforcement Strategy and specific compliance monitoring strategies for: TSCA section 13 Import Requirements; the TSCA section 8(c) rule; and the TSCA section 8(d) rule. EPA developed and issued enforcement response policies for TSCA sections 8, 12, and 13 reporting and recordkeeping regulations, and a revised enforcement policy for the TSCA section 6 Asbestos-in-Schools Rule.

Compliance Actions

During FY 1984, EPA stepped up inspection activities under TSCA; the number of inspections more than doubled from FY 1983. The EPA, along with four State agencies cooperating under the terms of enforcement grants-in-aid, conducted 1,440 PCB compliance monitoring inspections. In addition, the Agency, operating under a cooperative agreement with the American Association of Retired Persons and one State agency, conducted 1,945 asbestos-in-schools inspections. The Agency conducted 7 inspections to monitor compliance with the interagency ban on nonessential aerosol uses of chlorofluorocarbons, and conducted 14 inspections to determine compliance with the dioxin rule under section 6. The Agency also conducted 212 compliance inspections at facilities subject to section 5 requirements.

During FY 1984, the Agency also monitored compliance with section 4 and 5 requirements, TSCA section 8 reporting and recordkeeping requirements, and the section 13 import rule. The Agency inspected 47 laboratories conducting testing under TSCA to determine if the laboratories were in compliance with GLP requirements. During these inspections, EPA performed 162 data audits of health and environmental tests to

determine if testing had been conducted according to test protocols, and if reports accurately reflected study findings. The Agency also conducted over 500 section 5 compliance inspections, and inspections to determine compliance with section 8(a) level A reporting requirements, and with section 8(c) rules requiring manufacturers, processors, and distributors to keep records of significant adverse reactions to chemicals. Inspections to determine compliance with section 8 were conducted at 162 firms. On January 1, 1984, a policy statement interpreting the U.S. Customs Service's Chemical Substances Import Rule became effective (see Section 10, *International Activities).* A total of 494 inspections were conducted to determine compliance with this rule.

Civil Enforcement Actions

In FY 1984, most of the enforcement actions under section 16 involved alleged violations of the PCB rules. As a result of PCB inspections, the Agency filed a total of 283 civil complaints during the fiscal year. The Agency also issued 82 civil complaints for alleged violations of the section 6 asbestos-in-schools requirements. These complaints represent the first asbestos enforcement actions taken by the EPA under TSCA. In addition, EPA issued 11 civil complaints for alleged violations of section 5. Figures for each EPA Regional Office appear in Table 4.

Table 4

Administrative Civil Actions Taken under section 16 of TSCA, Complaints Issued, Cases Completed, and Amounts Assessed (by Regions)*

Region	Total No. Complaints Issued FY'79-84	No. Complaints Issued FY'84	Total No. Cases Completed FY'79-84	No. Cases Completed** in FY'84	Total No. of Cases Pending	Total Civil Penalties Collected (in $) FY'84	Total Civil Penalties Collected (in $) FY'79-84
1	29	12	18	6	11	86,468	175,090
2	142	40	88	17	54	227,000	951,000
3	81	45	46	18	35	116,325	256,425
4	67	40	35	19	32	86,272	150,167
5	286	100	184	59	102	345,315	1,154,979
6	114	32	84	22	30	71,050	363,940
7	83	30	60	22	23	99,480	275,430
8	75	30	53	14	22	124,815	357,815
9	53	25	31	10	22	158,000	279,375
10	37	16	20	9	17	51,750	82,710
HQ.	17	6	10	6	7	362,750	482,750
Total	984	376	629	202	355	1,779,243	4,548,211

**All actions taken involved alleged violations of the PCB Rule, Dioxin Rule, and sections 5, 6, and 8(e).*
***Includes cases carried over from FY-1980-FY 1983.*

8

Litigation

Environmental Defense Fund, Inc., v. Environmental Protection Agency **(No. 79-1580, D.C. Cir.)**

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

Last year's annual report discussed the litigation and progress in settlement negotiations involving the August 18, 1982, electrical equipment rule. Early in FY 1984, EPA entered into two separate agreements whereby parties who had filed petitions for review agreed to dismiss their suits should the Agency conduct two additional PCB rulemaking proceedings within agreed-upon time limits. In one rulemaking, EPA amended its PCB rule to reflect current Agency policies concerning PCB exposure assessment; EPA decided to delete the definition of "significant exposure," which stated that any exposure to PCBs is significant, in favor of a statement that recognizes that significant exposure depends upon the quantity of the PCBs involved, the likelihood of exposure to humans, and the effect of exposure. In the second rulemaking, EPA will deal with risks from fires involving transformers containing PCBs. The Agency expects to complete the fires rule in FY 1985.

A petition for review of the October 12, 1982, PCB rule was filed by the Chemical Manufacturers Association in December 1982. By agreement of the parties, approved

by the Court, this petition was stayed pending further PCB rulemaking. No further action has been taken on this petition to date, nor is any expected since the July 1984 rule has apparently resolved the Association's concerns.

In late September 1984, petitions for review were filed on the July 1984 rule by the American Die Casting Institute and Outboard Marine Corporation in the Seventh Circuit, and by the American Paper Institute and Fort Howard Paper Company in the D.C. Circuit. Settlement discussions are proceeding in these cases.

After the issuance of the July 1984 rule, the proceedings in the following previously reported cases have been terminated: *Olin Corporation v. EPA* (No. 79-1437, 4th Cir.); *General Electric Company v. EPA* (No. 79-1816, D.C. Cir.); *Aluminum Company of America v. EPA* (No. 79-1811, D.C. Cir.); *The Dow Chemical Company v. Ruckelshaus* (No. 82-3536, 3d. Cir.) and *The Dow Chemical Company v. Ruckelshaus* (No. 80-1498, 3rd. Cir.) [The latter case is an appeal from *The Dow Chemical Company v. Costle* (Civ. Action No. 79-581, D. Del), described in previous annual reports.] The settlement agreement in the Dow consolidated cases was described in last year's report. The terms of the agreement were carried out during FY 1984.

NRDC v. EPA (No. 82-2039, D.D.C.)

On July 18, 1983, public interest groups challenged EPA's decision not to take steps to place formaldehyde on a priority track for evaluation under section 4(f) of TSCA. Under section 4(f), if EPA receives information which indicates that there may be a reasonable basis to conclude that a chemical presents a significant risk of serious or widespread harm to human beings from cancer, gene mutations, or birth defects, within 180 days EPA shall initiate appropriate action under sections 5, 6, or 7 of TSCA to prevent or reduce the risk, or publish in the *Federal Register* a finding that the risk is not unreasonable.

Plaintiffs claimed that EPA's decision, in early 1982, not to evaluate formaldehyde under section 4(f) was unlawful for two reasons. First, plaintiffs argued that EPA applied too strict a standard for triggering the 4(f) "significant risk of serious or widespread harm" finding. Second, plaintiffs claimed that the decision was tainted by unlawful Agency conduct because EPA had held private meetings with industry groups in the summer of 1982 and had improperly evaluated animal test data.

In response to this litigation, EPA revoked its 1982 decision on formaldehyde and announced it would issue a new decision in May 1984. The court stayed the

proceeding until the new decision was published. In May 1984, EPA declared that two general categories of formaldehyde exposure triggered the section 4(f) "significant risk of serious or widespread harm" finding: (1) exposure associated with manufacture of apparel from fabrics treated with formaldehyde-based resins and (2) exposure from residence in conventional and manufactured (mobile) homes containing construction materials in which certain formaldehyde resins are used. EPA simultaneously issued an ANPR which the Agency considered a fulfillment of its related duty under section 4(f) to "initiate appropriate action" within 180 days. In the ANPR, the Agency announced an investigation to consider the appropriate ways in which it could most effectively regulate formaldehyde. The plaintiffs disagreed that this action constituted the appropriate action under section 4(f) and filed an additional round of motions on the issue.

After hearing arguments by both parties, the court decided that the May 1984 decision entirely supplanted the 1982 decision and the further controversy on whether the ANPR constituted "appropriate action" raised issues on a different administrative record that had not been presented to the court. Accordingly, the court dismissed the case as moot without prejudice to the plaintiffs' right to bring a complaint concerning EPA's May 1984 action, if and when appropriate.

***NRDC v. U.S. Environmental Protection Agency* (No. 83 Civ. 8844, S.D.N.Y.)**

In this case, plaintiffs challenged four aspects of EPA's statutorily-mandated chemical testing program under TSCA section 4 (see discussion in *Chemical Testing).* Specifically, plaintiffs challenged: (1) using negotiated testing agreements in lieu of initiating rulemaking under TSCA section 4(a); (2) issuing an ANPR rather than a notice of proposed rulemaking; (3) the use of a two-phase rulemaking process in which EPA first decides whether to test a chemical and, in a subsequent phase, decides what methodology should be used; and (4) the failure to issue final rules for a number of proposed test rules which were issued in 1980 and 1981.

On August 23, 1984, the court issued an Order and Opinion stating that the Agency did have discretion both to initiate rulemaking by issuing an ANPR and to use a two-phase rulemaking process as long as its use does not delay rulemaking unreasonably. The Court, however, found that the use of negotiated testing agreements for ITC-designated chemicals was not supported by TSCA or its legislative history. The Court ordered EPA to meet with plaintiffs to construct a schedule to convert the

challenged negotiated agreements into statutory test rules, and also take final action on the three outstanding proposals. On September 24, 1984, the Agency and plaintiffs submitted a jointly proposed schedule for action on the eight chemicals subject to the Court's Opinion and Order. The Court adopted this schedule as part of its Final Judgment and Order of October 30, 1984.

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

SEIU is seeking standards for determining when an asbestos hazard requiring correction exists in schools, requirements for abatement activities where such hazards exist, and standards for performing abatement activities, including standards to protect persons performing abatement. SEIU argues that EPA has a mandatory duty to issue such rules based on promises made by the Agency in response to citizens' petitions. Alternatively, SEIU has argued that EPA has failed to complete rulemaking actions on asbestos hazards in a reasonable time. The SEIU brought this action to require EPA to propose these rules and a rulemaking timetable within 30 days. SEIU has also asked the Court for preliminary relief of the same nature.

Only the preliminary injunction has been argued to date. EPA argued that preliminary relief is an extraordinary remedy and is particularly inappropriate in this case, since EPA has no mandatory duty to issues rules, has not unreasonably delayed responding to SEIU's request to conduct rulemaking, and has an ongoing asbestos program that is working to alleviate the asbestos problem.

The parties are awaiting the Court's decision.

9

State Programs

During FY 1984, under the authority of section 28(c) of TSCA, EPA continued to support previously awarded State grants to assist in programs that prevent or eliminate problems created by toxic substances. Since 1978, 11 toxic substances programs in 8 States have been implemented with EPA assistance.

The availability of $3 million for this Federal assistance program was announced in August 1978. These funds were distributed in a two-cycle award process. Half were distributed in 1979, and the other half in 1980. Availability of an additional $1.25 million was announced in February 1980, and a third and final cycle was initiated. Appendix G shows the status of these awards.

By the end of FY 1984, ten State cooperative agreement projects were completed, of which eight were completed in FY 1984. These involved the Wisconsin study of health problems related to formaldehyde in mobile home construction; the North Carolina toxic management project; the Puerto Rico* toxic substances management strategy and expansion of public participation/awareness programs; the Michigan Critical Materials Program and Interdepartmental Risk Assessment (two cooperative agreements); the Maryland Toxic Substances Registry program to ensure safe and effective containment of toxic substances in storage tanks (two cooperative agreements); and the New York project to integrate the services of State and local governmental agencies to manage toxic contamination problems.

Finally, under two cooperative agreements, New Jersey completed the following projects: the Toxic Substances Investigation and Integration Unit; the Mobile Monitoring Unit; a study of in-place mercury; an Emissions Monitoring Program; a study of the sub-lethal effects of toxic chemicals on aquatic organisms; field applications of *in vitro* mutagenesis tests; and the Technical Information Resources Center.

The cooperative agreement with the Illinois Department of Health to develop an integrated voluntary system to detect morbidity and mortality rates resulting from

** As defined by TSCA, "State" includes any U.S. territory or possession.*

exposure to toxic substances, ongoing since 1981, was extended at no cost from June 1984 through June 1985.

In addition, EPA has had an ongoing pilot TSCA cooperative agreement program to monitor compliance with the PCB regulations in the States of Connecticut, Maryland, Michigan, and Ohio since 1981. These four States conducted 350 compliance inspections during FY 1984.

In May 1984, EPA awarded the State of California a cooperative agreement to conduct compliance monitoring activities concerning the presence of asbestos in schools. Twenty-seven local education agencies were inspected during FY 1984.

10

International Activities

Since the passage of TSCA, EPA has been involved in a variety of international activities centering on approaches to evaluating and controlling toxic substances. EPA considers these programs of critical importance for many reasons. Toxic substances issues often transcend national boundaries. In addition, varying national regulation of chemicals can affect international trade and influence the economic stability of the chemical industry. These international activities include the exchange of information and expertise, which offers significant benefits to all participating nations. EPA promotes the success of these international programs by sharing its technical expertise and its broad experience in chemical review and control.

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

During FY 1984, EPA participated in several projects designed to advance the harmonization aims of the Chemicals Program. EPA played an important role in the success of two major activities. An initiative on existing chemicals, consisting of four sub-projects to identify information needs of member countries, was completed. As a result of these existing chemical activities, member states reached agreement on a common format for conducting chemical reviews and on criteria for determining whether the health and environmental data on chemicals are adequate. In addition, EPA led an effort to develop a referral mechanism in order to improve access to unpublished information on chemicals. This effort has been called the Switchboard, and a small number of countries will participate in an experimental implementation of it in early 1985.

After two years of intensive effort, member states

reached agreement on guiding principles to govern the exchange of information on exports of banned or severely restricted chemicals. These principles, for which TSCA section 12(b) served as a model, were formally adopted by the OECD Council in a Recommendation in April 1984.

In a major ongoing effort, EPA participated in the OECD Test Guidelines Program. Activities are concentrated in the Updating Panel, whose mandate is to ensure that OECD Test Guidelines are kept current with the state-of-the-art. EPA serves as an advisor to the panel. Developing OECD Test Guidelines will improve the quality of data developed worldwide, and reduce the need for duplicative testing.

During FY 1984, considerable time and effort were devoted to developing and promoting agreement on a three-year workplan (1985-1987) for the Chemicals Program. As a result of extensive member state deliberations in the spring and fall, program activities were reorganized along more efficient lines, and the group agreed to focus its efforts on assessing hazards and developing model agreements for the exchange of confidential information and compliance with good laboratory practices. Renewed emphasis was placed on upgrading work in the area of economic aspects of chemicals control.

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

The IPCS was established in response to a recognized need for a collaborative international approach to evaluate the effects of chemicals on health and the environment. Member state experts work within the IPCS to develop assessment documents on chemicals, set exposure guidelines, coordinate testing when appropriate, and promote technical cooperation and training. EPA serves on the Program Advisory Committee to IPCS, which met in the fall of 1984 in Nairobi. During FY 1984, EPA participated in establishing the IPCS priority list to develop assessment documents and assist in preparing assessment documents on methylene chloride and epichlorohydrin. EPA also assumed the lead responsibility for an assessment document on glycol ethers.

Importing Chemicals

In December 1983, EPA published its policy statement (48 FR 55462) under section 13 of TSCA, which explained how EPA would interpret the U.S. Customs Service's chemical substances import rule (48 FR 34734).

Section 13 of TSCA requires the Secretary of the Treasury to refuse entry into U.S. Customs territory of any chemical substance mixture, or certain article if it fails to comply with any rule in effect under TSCA, or if it is offered for entry in violation of section 5 or 6.

Under the Customs rule, an importer of a chemical shipment must certify at the port of entry, for shipments entering commerce in the U.S., that either:

- The shipment is subject to TSCA and complies with all applicable rules and orders under TSCA; or
- The shipment is not subject to TSCA.

Under the Customs Rule, the EPA Administrator must:

- Determine whether detained shipments and their entries comply;
- Notify Customs when EPA is aware of shipments that should be detained;
- Identify steps necessary to bring detained shipments into compliance, or that must be taken when shipments are not brought into compliance; and
- Take action to store or dispose of abandoned noncomplying shipments.

TSCA requires that chemical substances must be included on the TSCA Inventory before they can be imported into this country, unless it is solely for research and development in small quantities. Persons who wish to import chemical substances which do not appear on the Inventory must comply with PMN requirements and review procedures in the PMN Rule (40 CFR 720, 48 FR 21722).

Appendix A

Summary/Guide to Information Required By Congress

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

Section 30. This section contains the basic requirement for an Annual Report and requests the following information:

(1) ***Testing.*** In FY 1984, EPA issued 14 negotiated testing agreements. The Agency published 17 decisions not to test. In addition, the Agency published five ANPRs, six notices of Proposed Rulemaking, and 1 final rule.

(2) ***Premanufacture Notices (PMNs).*** EPA received 1,192 PMNs during FY 1984 which brought the total received since the program's beginning in mid-1979, to 4,201. (None of these chemicals were subject to rulemaking under section 4.) In FY 1984, 24 cases underwent voluntary testing or control activities, while 45 chemicals were subject to the development of either a section 5(e) or 5(f) order (see section 3, *New Chemicals,* and Table 1).

(3) ***Rules Issued under section 6.*** During FY 1984, ANPRs were issued for four chemicals under section 6(a): (1) formaldehyde; (2) 2-ethoxyethanol (2-EEA), 2-methoxyethanol (2-MEA), and their acetates; and (3) 1,3-butadiene. Formaldehyde is used in materials to construct mobile and conventional homes and in the garment industry. 2-EEA and 2-MEA are used primarily as solvents in paints, coatings, inks, and as deicers for jet fuels. 1,3-butadiene is another high-volume chemical that is used to manufacture rubber and plastic products.

Under section 6(e) the following actions were taken: 1 ANPR; 5 proposed rules; and 3 final rules.

In addition, in FY 1984 EPA used the authority of section 5(f)(2) to ban the addition of nitrites and/or nitrosating agents in metalworking fluids in three immediately effective section 6(a) rules.

(4) ***Judicial Actions under TSCA and Administrative Actions under section 16.*** Judicial actions in FY 1984 involved PCBs, formaldehyde, asbestos, and EPA's testing program under section 4 of TSCA. Parts of the PCB litigation were settled, and three additional petitions for review of rulemaking were filed regarding PCBs. Three suits were filed to compel Agency action regarding formaldehyde, asbestos, and EPA actions under its section 4 testing program. The formaldehyde suit was dismissed. The decision on the testing program has resulted in the Agency's being ordered to undertake additional action. The asbestos case is pending.

A total of 376 civil enforcement complaints were issued in FY 1984. In addition, there were three criminal and seven civil referrals to the Department of Justice, and 1,349 Notices of Noncompliance were issued (see Section 7, *Compliance and Enforcement).*

(5) ***Major Problems in Administering the Act.*** On August 23, 1984, the Federal Court and the Southern District of New York rendered the opinion in a suit brought by the NRDC against EPA (83 Civ. 8844 S.D.N.Y.), that Negotiated Test Agreements were not a legal means of complying with section 4 of TSCA.

Under the new ruling, EPA will be required to promulgate test rules or issue decisions not to test for chemical substances which have been designated by the ITC for priority testing consideration. Thus, the Agency will respond to the ITC's designations initiating rulemaking proceedings by issuing decisions not to require testing.

(6) ***Recommended Legislation.*** EPA considered possible amendments to TSCA in FY 1984. This process will continue during FY 1985.

Section 28(c). This section requires a report on grants to States during the year. Six State Cooperative Agreement projects were completed in FY 1984. These were undertaken by Maryland, Puerto-Rico, Michigan, New York, and New Jersey (two cooperative agreements). One additional State grant is due to be completed in 1985.

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

During FY 1984, EPA continued, in several formal and informal agreements with other Federal government programs, to address specific chemical activities. One of these efforts is participation in the Federal Asbestos Task Force, of which OSHA, the CPSC and EPA are charter members. The FDA, National Institute of Occupational Safety and Health (NIOSH), National Institute of Environmental Health Sciences, and the National Cancer Institute joined during FY 1984. A second effort includes the adoption of an interim policy for determining when, and under what circumstances, EPA will refer chemical problems to OSHA for its consideration. Preliminary steps have also been taken to establish a Memorandum of Understanding between OSHA and EPA in order to foster coordination, avoid duplication, and ensure that chemical problems are handled expeditiously under the most appropriate authority. Finally, EPA began preparing two section 9(a) reports for consideration of referral of 4,4'-MDA and 1,3-butadiene to OSHA.

In FY 1984, under joint agreements, EPA and NIOSH worked on developing occupational exposure assessments on 1,3-butadiene, methylene bis(2-chloroaniline)—(MBOCA), acrylamide, and 4,4'-methylenedianiline-(4,4'-MDA), and control technology assessments on 1,3-butadiene and MBOCA, as well as a respirator evaluation strategy for new chemical substances. The purpose of these joint agreements is to use the occupational expertise of NIOSH in EPA's assessment program.

In FY 1984 the Agency was instrumental in forming the IRMC to examine high-priority solvents of concern not only to EPA, but also to other regulatory agencies. The IRMC examines solvents from a scientific policy standpoint in order to develop a coherent position in regulatory strategy development for the Federal government.

Appendix B

Major FY 1984 TSCA Actions

Section of Law	Description	Date
4(a)	For listing of testing decisions see Table 2	
	Good Laboratory Practice Standards	12/29/83
4(b)	Testing Guidelines Published	9/24/84
4(f)	Formaldehyde: Reconsiderations, Solicitation of Comment Notice	11/18/83
	1,3-butadiene: Initiation of Accelerated Review Notice	1/5/84
	Formaldehyde: Determination of Significant Risk (Advance Notice of Proposed Rulemaking)	5/23/84
5(a)	Substituted Polyglycidyl Benzeneamine (Proposed Significant New Use Rule)	12/29/83 (Corrected 1/31/84)
	Substituted Methylpyridine and Substituted 2-phenoxypyridine (Proposed Significant New Use Rule)	1/3/84
	Dicarboxylic Acid Monoester (Proposed Significant New Use Rule)	1/3/84
	Derivative of Tetrachloroethylene (Proposed Significant New Use Rule)	1/3/84
	8-Acetyl-3-Dodecyl-7,7,9,9-Tetramethyl-1,3,8-Triaza-spiro-[4,5]Decane-2,4-dione (Proposed Significant New Use Rule)	1/13/84
	Substituted Methylpyridine and Substituted Phenoxypyridine (Proposed Significant New Use Rule)	2/6/84
	Potassium N,N-Bis(Hydroxyethyl); Cocoamine Oxide Phosphate and Tallowamine Oxide Phosphate (Final Significant New Use Rule)	9/5/84
5(a)	Alkyl Aryl Phosphine (Proposed Determination of Significant New Use)	9/20/84
	Hexamethylphosphoramide (HMPA) and Urethane (Proposed Determination of Significant New Use on Existing Chemicals).	Signed 9/27/84
	Substituted Bromothiophine (Proposed Determination of Significant New Use)	9/28/84
	Certain Chemicals (Proposed Determination of Significant New Use); P-83-906 (Brominated Aryl Alkyl Ether); P-83-908 (Ethylated Amino Phenol); P-83-909 (Amino Phenol); and P-83-910 (Aniline Ether)	9/28/84
5(e)	Consent Order; Disubstituted Heterocycle - Use of appropriate protective equipment by workers to reduce inhalation exposure and reduce possible carcinogenic effect.	11/8/83
	Consent Order; Brominated Aryl Alkyl Ether - Requires use of long-sleeved impervious protective gloves and labeling during manufacturing and processing.	11/22/83

Section of Law	Description	Date
	Consent Order; Ethylated Aminophenol - Requires use of long-sleeved impervious protective gloves and labeling during manufacturing and processing.	11/22/83
	Consent Order; Aminophenol - Requires use of long-sleeved impervious protective gloves and labeling during manufacturing and processing.	11/22/83
	Consent Order; Anilino Ether - Requires use of long-sleeved impervious protective gloves and labeling during manufacturing and processing.	11/22/83
	Consent Order; Substituted Phenylacetamide - Requires use of full face shield and long-sleeved impervious gloves during processing.	12/7/83
	Unilateral Consent Order; Alkyl-substituted aromatic amine. Company withdrew instead of complying with order.	12/8/83
	Consent Order; Alkyl Aryl Phosphine - Requires use of NIOSH-approved air-supplied positive respirators and protective clothing and gloves, restrictions on liquid/solid waste handling, informing employees on toxicity with written warning, and maintaining records.	1/16/84
	Consent Order; Unsaturated Aliphatic Diether - Requires use of impervious gloves, that all operations are conducted in a ventilated laboratory bench hood, packaging to prevent leakage, and maintaining records pending development of information.	1/23/84
	Consent Order; Trisubstituted Aniline - Requires use of protective gloves, packaging to prevent spills, labeling, and record maintenance pending development of information.	2/29/84
	Consent Order; Polyol Carboxylate Ester - Requires impervious protective gloves, chemical safety goggles, clothing over exposed body areas, NIOSH-approved respirators, employee safety meetings and labeling.	4/9/84
	Consent Order; Aliphatic Triol Ester Methacrylate - Requires use of gloves, clothing over exposed body areas, chemical safety goggles, employee safety training program, labeling, approved disposal procedures, and recordkeeping pending development of information.	5/25/84
	Consent Order; Polyester Acrylate Ester - Requires use of gloves, clothing over exposed body areas, chemical safety goggles, employee safety training program, labeling, approved disposal procedures, and recordkeeping pending development of information.	5/25/84
	Consent Order; Aliphatic Acrylate Ester - Requires use of gloves, clothing over exposed body areas, chemical safety goggles, employee safety training program, labeling, approved disposal procedures, and recordkeeping pending development of information.	5/25/84

Section of Law	Description	Date
5(e)	Consent Order; Polyether Acrylate - Requires use of gloves, clothing over exposed areas, chemical safety goggles, employee safety training program, labeling, approved disposal procedures, and recordkeeping pending development of information.	5/25/84
	Consent Order; Aliphatic Ester Methacrylate - Requires use of gloves, clothing over exposed areas, chemical safety goggles, employee safety training program, labeling, approved disposal procedures, and recordkeeping pending development of information. (2 Chemicals)	5/25/84
	Consent Order; Halogenated Alkene - Requires use of respirators if time weighted average airborne concentrations are not kept to 10 ppm, NIOSH-approved respirator, impervious gloves, clothing over exposed body areas, and employee safety meetings pending development of information. (2 Chemicals)	6/13/84
	Consent Order; Halogenated Alkane - Requires use of respirators if time weighted average airborne concentrations are not kept to 1 ppm, NIOSH-approved respirators, impervious gloves, clothing over exposed body areas, employee safety meetings pending development of information.	6/13/84
	Consent Order; Substituted Aromatic Polymer - Requires use of impervious protective gloves, clothing over exposed body areas, face shields, employee safety training meetings, and recordkeeping pending development of information. (7 Chemicals)	7/27/84
	Consent Order; Substituted Pyridine - Requires venting vapor emissions outside work area, local ventilation at drumming station, wearing NIOSH-approved respirators, impervious suits, gloves, face shields, and chemical goggles, and employee safety training meetings pending development of information. (2 Chemicals)	8/6/84
	Consent Order; Poly(OXY-1,4-butanediyl)-X-(1-OXO-2-propenyl) —w-[(1-OXO-2-propenyl)OXY]-: Prohibits manufacture, import, processing, distribution in commerce, use and disposal for any non-exempt commercial purpose except in accordance with the order's detailed restrictions. Requires impervious gloves, chemical or safety goggles, clothing over exposed areas, employee safety training meetings, and labeling.	8/13/84
	Consent Order; 2-Chloro-N-Methyl-N-Substituted Acetamide - Requires NIOSH-approved respirator, impervious safety gloves, employee safety training meetings, labeling, and recordkeeping pending development of information.	8/13/84
	Consent Order; Substituted Phenol - to be manufactured, imported, and processed solely for use on an antioxidant/ stabilizer for polymers. Requires use of impervious gloves, employee safety training meetings, labeling and recordkeeping pending development of information.	8/13/84

Section of Law	Description	Date
	Consent Order; Halogenated Aromatic Ether - Manufacturing/ processing requires protective equipment, employee safety equipment, employee safety training meetings, labeling, and recordkeeping pending development of information.	9/13/84
	Consent Order; Substituted Oxirane - May present carcinogenic and pulmonary edema hazard via dermal exposure and inhalation. Requires personal protective equipment at any site controlled by the company, employee safety training meetings, and recordkeeping.	9/25/84
	Consent Order; Substituted Alkyl Halide May present carcinogenic and pulmonary edema hazard via dermal exposure and inhalation. Requires protective equipment at any site controlled by the company, employee safety training meetings, and recordkeeping.	9/25/84
	Consent Order; Perhalo Alkoxy Ether - May cause pulmonary edema via dermal exposure and inhalation. Requires protective equipment, employee safety training meetings, and recordkeeping. (3 Chemicals)	9/25/84
	Consent Order; Polychlorinated Alkylated Aromatic Hydrocarbon-Requires protective equipment, employee safety training meetings, labeling, and record-keeping pending development of information.	9/26/84
	Consent Order; N,N,N'N'-Tetraglycidyl-1,3-bisaminomethyl Cyclohexane Cannot be manufactured in USA. Processing and use in USA requires personal protective equipment, employee safety training meetings, labeling and record-keeping.	9/26/84
	Consent Order; Urea Condensate with Poly[oxy(methyl-1,2-ethanediyl)] Alpha-(2-aminomethylethyl)-omega-(2-aminomethyl-ether)- Requires environmental controls pending development of information.	9/26/84
5(f) and 6(a)	Prohibition of Nitrites in Metalworking Fluids (2 Chemicals): (Immediately Effective Proposed Rule)	1/23/84
	Triethanolamine Salt of a Substituted Organic Acid-Restrictions on Use in Metalworking Fluids: (Immediately Effective Proposed Rule)	6/14/84
	Mixed mono and diamides of an organic acid (Immediately Effective Proposed Rule)	9/20/84
6(a)	2-Methoxyethanol and 2-Ethoxyethanol and Their Acetates; Initiation of Regulatory Investigation (Advance Notice of Proposed Rulemaking)	1/24/84
	1,3-Butadiene; Initiation of Regulatory Action: (Advance Notice of Proposed Rulemaking)	5/15/84
	Formaldehyde; Determination of Significant Risk (Advance Notice of Proposed Rulemaking)	5/23/84
6(e)	Polychlorinated Biphenyls (PCBs); Manufacturing, Processing and Distribution in Commerce Exemptions (Proposed Rule)	11/1/83

Section of Law	Description	Date
6(e)	Polychlorinated Biphenyls (PCBs); Manufacture, Processing, Distribution in Commerce and Use Prohibitions; Use in Microscopy and Research and Development (Proposed Rule)	11/17/83
	Polychlorinated Biphenyls (PCBs); Exclusions, Exemptions and Use Authorizations (Proposed Rule)	12/8/83
	Polychlorinated Biphenyls (PCBs); Manufacture, Processing, Distribution in Commerce and Use Prohibitions; Use in Electrical Transformers (Advance Notice of Proposed Rulemaking)	3/23/84
	Polychlorinated Biphenyls (PCBs); Manufacturing, Processing, Distribution in Commerce and Use Prohibitions; Response to Individual and Class Petitions for Exemptions (Final Rule)	7/10/84
	Polychlorinated Biphenyls (PCBs); Manufacturing, Processing, Distribution in Commerce, and Use Prohibitions; Exclusions, Exemptions, and Use Authorizations (Final Rule)	7/10/84
	Polychlorinated Biphenyls (PCBs); Manufacturing, Processing, Distribution in Commerce and Use Prohibitions-Use in Microscopy and Research and Development (Final Rule)	7/10/84
	Polychlorinated Biphenyls (PCBs); Modification of Definition of Totally Enclosed Manner for PCB Activities (Proposed Rule)	7/23/84
	Polychlorinated Biphenyls (PCBs) Manufacture, Processing, Distribution in Commerce and Use Prohibitions: Use in Electrical Transformers (Proposed Rule) (signed in FY'84 and counted as FY'84 output)	10/11/84
8(a)	Preliminary Assessment Information: Amendment to Include Four Chemicals from 13th ITC List (Final Rule)	12/14/83
	Preliminary Assessment Information: Manufacturer Reporting Amendment Adding Mesityl oxide (Proposed Rule)	1/12/84
	Chlorinated Terphenyl, Submission of Notice of Manufacture or Importation (Final Rule)	3/26/84
	Technical Amendment to Above Rule	8/10/84
	Preliminary Assessment Information: Amendment to Include 14th ITC List (Final Rule)	5/29/84
	Preliminary Assessment Information: Amendment to Include IIth ITC List (Final Rule)	6/25/84
	Preliminary Assessment Information: Manufacture Reporting Amendment Adding Mesityl Oxide (Final Rule)	6/25/84
	Chlorinated Naphthalenes - Submission of Notice of Manufacture or Importation (Final Rule)	8/24/84
8(c)	Records and Reports of Allegations That Chemical Substances Cause Significant Adverse Reactions to Health or the Environment; Recordkeeping and Reporting Procedures (Final Rule)	8/22/83

Section of Law	Description	Date
8(d)	Health and Safety Data Reporting: Amendment to Add Four Chemicals From 13th ITC List (Final Rule)	12/14/83
	Health and Safety Data Reporting: Submission of Lists and Copies of Health and Safety Studies on Six Chemicals on IIth ITC List, and a Designated Mixture Containing Substances from the 10th ITC List (Final Rule)	1/13/84
	Health and Safety Data Reporting: Submission of Lists and Copies of Health and Safety Studies on Five Chemical Substances (Proposed Rule)	2/16/84
	Health and Safety Data Reporting: Amendment to Add Five Chemicals From 14th IIC List (Final Rule)	5/29/84
	Health and Safety Data Reporting: Submission of Lists and Copies of Health and Safety Studies on Five Chemical Substances (Final Rule)	7/27/84
13	Chemical Importers and Exporters: Requirements and Restrictions Policy for Import of Chemical Substances (Final Rule)	12/13/83
21	Denial of Citizens' Petition-PCB Manufacturing, Processing, Distribution in Commerce, and Use Prohibitions (Final Rule-Related Notice)	1/13/84
	Response to Citizens' Petition-Asbestos; Abatement of Friable Asbestos Containing Materials in Schools; Inspection/Abatement of Friable Asbestos Containing Materials in Public/Commercial Buildings	3/07/84
	Denial of Citizens' Petition to Delete Inorganic Glasses as Mixtures, and Excluding from the TSCA Inventory a Category of Substances Called Structural Polymers (Including Inorganic Glasses) Classifying These as Not Being Chemical Substances *Per Se* For Inventory Purposes.	9/20/84
	Receipt of Petition by the Natural Resources Defense Council, Inc., That EPA Ban Use of Asbestos in Original Equipment and Replacement Brakes for On-Road Cars and Trucks.	Pending 9/30/84
	Receipt of Citizens' Petition to Eliminate or Reduce Disposal and Emission of Toxic Substances Into Environment of Southeast Chicago From Multiple Polluting Sources.	Pending 9/30/84
25	Indemnification Report to Congress On February 3, 1984, the Administrator sent the Indemnification Report to Congress to fulfill section 25(a) of TSCA which requires that EPA determine when, if ever, the government should compensate people for losses caused by EPA action. The report concluded that there is no justification for expanding the existing indemnification programs at EPA nor for creating new programs. The primary reason is that there are very few actual uncompensated losses. Many potential losses are prevented, reduced, or shifted by administrative action. Other losses are compensable under a general statute, for example, the Federal Tort Claims Act, the Tucker Act, or the Equal Access to Justice Act.	2/3/84

Section of Law	Description	Date
	Chemical Advisories	
	Notice of Potential Risk, Used Motor Oil (Published in English and Spanish)	2/84
	Notice to Formulators of Metalworking Fluids, Potential Risk from Nitrosamines	8/84
	Notice to Workers of Potential Risk, Nitrosamines in Metalworking Fluids	8/84
	Leaking Underground Storage Tanks Containing Motor Fuels: A Chemical Advisory	8/84

Appendix C

Section 4 Test Studies* Received

Alkyl phthalates
Chlorinated paraffins
4-chlorobenzotrifluoride
2-chlorotoluene
Methyl isobutyl ketone
1,2-Butylene oxide
Chlorinated benzenes
2-phenoxyethanol
Chloromethane
Calcium napthenate
Cyclohexanone
Acetonitrile
**162 studies on 12 chemicals*

Appendix D

Summary Of NTP Studies

National Toxicology Program (NTP) Studies* Reviewed

1,1,1,2-tetrachloroethane
Benzene
tris (2-ethylhexyl) phosphate
1,3-butadiene
Diallyl phthalate
Hamamelis water (witch hazel)
8-hydroxyquinoline
HC Blue No. 1
Chlorodibromomethane
Eugenol
1,3-dichloropropene
Dimethyl hydrogen phosphite
Crysotile asbestos
HC Blue No. 2
2-Chloroethanol
**16 studies on 15 chemicals*

Appendix E

Chemical Hazard Information Profiles (CHIPs) Prepared

Alkylated phenol sulfides, 8/84
Aminophenol (ortho-), 3/84
Aminophenol (para-), 3/84
Butylated hydroxytoluene, 8/84
Diallyl phthalate, 9/84
Diethylhexyl adipate, 9/84
Dihydrosafrole, 3/84
Epoxy/chlorohydroxypropyltrimethylammonium chloride, 7/84
Ethylenediamine tetra(methylene phosphonic acid), 2/84
Hydroxylamine, 9/84
Methyl bromide, 9/84
Methylcyclopentadienyl manganese tricarbonyl, 10/83
Methylene diphenyldiisocyanate (MDI), 6/84
Methylnitropropyl-4-nitrosoaniline, 12/83
Naphtha (Petroleum) solvents, 9/84
Quinoline, 12/83
Sulfolane, 6/84
Tetrachloro-1-propene (1,1,2,3), 9/84
Toluene diisocyanate (TDI), 7/84
Toluidine (ortho-), 2/84
Vinyl acetate, 5/84

Appendix F

FY 1984 section 21 Citizens' Petitions

Date Filed	Who Filed	What Action Requested	EPA,s Disposition	Date of Disposition
10/12/83	Cannelton Industries, Inc.	That EPA amend its PCB regulations to provide EPA Regional Administrators authority to approve alternate disposal methods for non-liquid PCBs, including contaminated soils.	Denied	1/13/84 49 FR 1697
11/16/83	Service Employees International Union (SEIU) of AFL-CIO	That EPA initiate rulemaking to require the abatement of Friable Abestos Containing Materials (FACM) in public and private elementary and secondary schools. In addition, provide rulemaking concerning inspection and abatement of FACM in public and commercial buildings.	Granted	3/7/84 49 FR 8450 6/14/84 49 FR 24552
6/15/83	Society of the Plastics Industry (SPI)	That EPA amend the Inventory reporting rule by deleting the designation of inorganic gasses as mixtures and excluding from the Inventory a category of substances SPI calls structural polymers, by classifying them as chemical non-substances.	Denied	9/20/84 49 FR 36844
7/17/84	Citizens for a Better Environment and Irondalers Against the Chemical Threat	That EPA issue a rule to: 1. Clean up the Southeast section of Chicago, Illinois; 2. Conduct an investigation prior to rulemaking to study the health effects from many toxic substances in air, land, and water in the SE Chicago area; and 3. Use TSCA authorities to assess and remedy the public health situation as a whole, and not with piecemeal regulations.	Pending as of 9/30/84	
9/11/84	Natural Resources Defense Council, Inc.	That EPA ban the use of asbestos in original equipment and replacement brakes for on-road cars and trucks.	Pending as of 9/30/84	

Appendix G

TSCA section 28 State Cooperative Agreements Program

State/ Department	Project Grant Descriptions and Status	Amount ($)	Grant Period
Illinois Department of Public Health	**Purpose:** Develop an integrated voluntary system detecting morbidity and mortality rates resulting from exposure to toxic substances. **Current Status:** Wrote and disseminated a brochure and newsletter to State and local health officials and medical professionals to explain the Environmental Toxicology Program and obtain information on disease clusters and trends in local communities. Follow-up investigations are being conducted by the Department. A guide and a questionnaire are being prepared to assist in epidemiological investigations. State mortality and birth data are being organized and computerized for easier access. Cancer surveillance data from 16 counties are being compiled. In one county, an investigation of birth outcome and maternal history is underway. Illinois has been granted a no-cost extension from June 1984 to June 1985.	475,626	3/81-6-85
Maryland Department of Health and Mental Hygiene	**Purpose:** Develop a computer-based toxic substances registry. **Current Status:** The registry now contains information on 250 chemicals, an incidents record, industrial survey reports, all OSHA violations, birth defects data and a record of all occupationally related diseases. The final report was received and distributed.	230,953	4/79-4/83
Maryland Department of Health and Mental Hygiene	**Purpose:** Develop a program to assure the safe and effective containment of toxic substances in storage tanks. **Current Status:** Guidance and procedures manuals and an implementation plan have been completed. Seminars have been conducted. Final report received.	100,000	3/81-12-83
Michigan Department of Natural Resources	**Purpose:** Develop an interdepartmental risk assessment process intended for use by the Michigan Departments of Agriculture, Natural Resources, and Public Health. **Current Status:** The final report on the Interagency Risk Assessment Process has been completed and received. The risk assessment process is divided into two parts, the actual risk assessment and risk management, which includes an analysis as well as the course of action to take to reduce or eliminate the risk. Specific elements of this project included: the review of mathematical methods for assessment of carcinogenic risk; methods for assessing non-carcinogens; evaluation of environmental fate processes, data acquisition, estimation and predictive modeling for use in exposure evaluation; and individual projects for development and management of general investigatory information on occupational exposure, food chain contaminants as well as specific studies on PCB silo contamination and toxaphene in Michigan sportfish.	532,258	3/81-12-83
Michigan Department of Natural Resources	**Purpose:** Develop Critical Materials Program to prevent and eliminate unreasonable exposure to toxic substances. This was to be achieved through the development and implementation of a computerized toxic substances data system. **Current Status:** This project has been completed. The final report was received and a summary was distributed.	504,500	4/79-9/82

State/ Department	Project Grant Descriptions and Status	Amount ($)	Grant Period
New Jersey Department of Environmental Protection	**Purpose:** Set up toxic substances investigation and integration unit; expand current project monitoring volatile organic compounds in air. **Current Status:** The Toxic Substances Investigation and Integration Unit has identified and investigated various hazardous waste sites in New Jersey. Cancer and birth defects clusters have been investigated. The mobile monitoring van is completed and is currently operating throughout the State. Final reports on both projects have been received.	453,947	4/79-4-84
New Jersey Department of Environmental Protection	**Purpose:** Study movement, distribution and uptake of in-place mercury; monitor emissions of selected toxic substances; assess the ecological effects of water contaminants; establish and operate a Toxic Substances Information Resources Center; conduct a field application study of *in vitro* mutagenesis tests. **Current Status:** Additional sampling of biota has been done and analyzed for mercury and other heavy metals. Methods and resources required for sampling and analysis of various environmental emissions from selected groups of facilities have been identified and field tested. Research on the effects of environmental stress in aquatic organisms has been completed. Summary reports of toxic substances research and other educational materials have been prepared and are now available. The study on mutagenic assays performed on waste water samples has been completed. Final reports on all these projects, as well as an executive summary, have been received.	794,053	3/80-4/84
New York Department of Environmental Conservation	**Purpose:** Identify, characterize and plan for managing toxic substances. **Current Status:** The grantee proposed to use New York's experience in the Niagara River Project as the basis for a State-wide management plan. This proposal was revised to include the State's experience in projects other than the Niagara River, and to abstract from that Project only those characteristics that can be reasonably expected to be applicable to other sites around the State. A final report was received.	348,000	4/79-6/84
North Carolina Office Natural Resources	**Purpose:** Identify, assess and plan to control toxic substances by: profiling substances; identifying sources, level and duration of exposures; and developing a plan to control substances posing an unreasonable risk. **Current Status:** The project has been completed. Chemical guidance packages have been received and distributed.	385,000	3/80-12/83
Puerto Rico Environmental Quality Board	**Purpose:** Develop and manage the Commonwealth's toxic substances management strategy; expand an existing public participation/awareness program. **Current Status:** This project has been completed. A Public Participation Plan was prepared which focused on a seminar featuring the inclusion of PCBs, asbestos substances and (TSCA) regulations to the *Regulation for the Control of Hazardous and Non-Hazardous Solid Waste* (State regulations), which was presented on October 6, 1983.	258,394	3/80-10/83
Wisconsin Department of Health and Social Sciences	**Purpose:** Study health problems related to formaldehyde vapors from mobile home construction materials. **Current Status:** This study is complete. The final report was received and distributed.	202,947	4/79-9/82

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