



Administration of the Toxic Substances Control Act (1979)



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Introduction

This is the Annual Report on the Environmental Protection Agency's (EPA) administration of the Toxic Substances Control Act (TSCA) for the year 1979. This report addresses the information required in sections 30, 28(c), and 9(d) to be reported annually to the President and the Congress, as well as additional information concerning the Agency's implementation of the Act.

Highlights of 1979 Progress

In the last 12 months, actions were taken on all major TSCA provisions, including those dealing with reporting and recordkeeping, premanufacture notification, testing, and chemical control.

Reporting and recordkeeping. On June 1, 1979, the Agency published the initial Chemical Substances Inventory. It lists over 44,000 commercial chemical substances used in the United States that were reported by their manufacturers or importers. On October 31, the Inventory's first supplement added 3,000 more chemicals to this listing.

Other information reported to EPA by the chemical industry during the 1978 Inventory reporting period included production volume estimates and plant locations. A computer system to enable the Agency to make effective use of this important information is partially complete. In cooperation with other Federal agencies, EPA has also begun to develop a network to link existing chemical data systems of the Federal Government. This will facilitate public access to this information. Strict security procedures adopted by EPA in 1978 were further improved in 1979 to prevent unauthorized disclosure of confidential business information. Approximately one-third of the reports submitted for the Inventory had one or more confidentiality claims; production volume was the item most frequently claimed confidential.

Over 40 substantial risk notices for chemical substances were received in 1979. More than 300 substantial risk notifications have now been received and acted upon by the Agency since 1977.

The Agency received substantial information in response to the July 1978 rule requiring submission of unpublished health and safety studies on the first chemicals recommended by the Interagency Testing Committee for priority testing. After a lawsuit was filed, challenging the validity of the rule, the Agency voluntarily revoked the rule in January 1979. On December 31, 1979, EPA proposed a new section 8(d) rule to exercise essentially the same authority as the revoked rule, although substantial new issues have been raised.

Premanufacture notification. On July 1, 1979, the premanufacture notification program began for manufacturers and bulk importers of new chemical substances (those not listed on the Inventory). Interim compliance procedures for this program, required by statute to begin one month after the Inventory's publication, were published on May 15, 1979. A portion of the January 10, 1979, proposed premanufacture notification regulations was repropose on October 16, 1979. EPA plans to finalize these regulations in the fall of 1980, once public comments have been received and evaluated on the required economic impact assessment for this program.

Thirty-seven premanufacture notices were received in 1979, covering a total of 40 new chemicals.

Testing. On May 9, 1979, the Agency proposed test standards for oncogenic (tumor-forming), non-oncogenic chronic, and combined oncogenic and non-oncogenic chronic health effects. In addition, on July 26, 1979, test standards were proposed for mutagenic effects, teratogenic and reproductive effects, general metabolism testing, and a variety of acute and subchronic toxicity studies. Good laboratory practices for each of these standards also were proposed.

Progress is underway on developing test standards for a number of environmental toxicity and chemical fate characteristics, along with good laboratory practices for each. These standards will be proposed in 1980.

These generic test standards when promulgated will be incorporated by reference into test rules for specific chemicals. The first rule for specific chemicals or categories of substances will be proposed in the first months of 1980.

By the close of 1979, 38 chemicals and categories of chemicals had been recommended for testing by the section 4(e) Interagency Testing Committee.

Chemical Control. On May 31, 1979, the final ban rule for polychlorinated biphenyls (PCBs) was issued. This rule banned the manufacture, processing, distribution, and non-totally enclosed use of PCBs after July 1, 1979. The May 1979 rule also reduced the minimum PCB concentration in materials covered by both the ban and the 1978 marking and disposal rules from 500 parts per million (ppm) to 50 ppm.

Due to mounting evidence that exposure to asbestos fibers can cause lung damage and several types of cancer, EPA initiated a nationwide technical assistance program in March 1979 to help States and school districts identify school buildings where deteriorating asbestos material should be removed or sealed.

In addition, EPA published an Advanced Notice of Proposed Rule-making (ANPRM) on October 17, 1979, which discussed evidence that exposure to asbestos in mining, milling, and processing presents serious health risks. The notice revealed the Agency's preliminary strategy for developing rules to control unreasonable asbestos risks, and asked for comments on several issues and information needs.

EPA continued to investigate the feasibility of controlling non-aerosol applications of chlorofluorocarbons (CFCs); a decision will be made in early 1980. In March 1978 the Agency, acting jointly with the Food and Drug Administration and the Consumer Product Safety Commission, banned all non-essential uses of CFCs in aerosol propellants.

The Agency began to work with the Occupational Safety and Health Administration to develop proposed rules, that would require warning labels on chemical substances and mixtures that pose acute or chronic (cancer) hazards to workers manufacturing or handling them.

Summary/Guide to Required Information

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 a reference to a more detailed explanation, within this report, is given here.

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

Testing required under section 4—No testing rules for specific chemicals have yet been proposed. However, test standards and good laboratory practices for health effects testing were proposed during 1979. These generic standards, when promulgated, will be incorporated by reference into test rules for specific chemicals. Thirty-eight chemicals and categories of chemicals have been recommended for testing under TSCA by the Interagency Testing Committee. See the section on "Testing" for additional details.

Premanufacture notices received—The premanufacture notification program for manufacturers and importers of new chemicals began on July 1, 1979. Premanufacture notices for 37 new chemicals have been received and reviewed; one chemical is to be referred for follow-up action. See the section on "Premanufacture Notification" for additional information.

Rules issued under section 6—Final rules banning the manufacture, processing, distribution, and non-totally enclosed use of polychlorinated biphenyls (PCBs) were published on May 31, 1979, and became effective on July 1, 1979.

An ANPRM concerning asbestos-containing materials in schools was issued on September 20, 1979. This action announced the Agency's intent to require, by rule, that schools be surveyed for deteriorating asbestos materials, and, where necessary, require the removal or reduction of

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asbestos risks found. Another ANPRM was published on October 17, 1979, to discuss the Agency's strategy for developing rules to control unreasonable health risks in mining, milling, processing, and use of asbestos and asbestos-containing materials.

A proposed rule is being written to require workplace hazard warning labels for chemical substances and mixtures that pose acute or cancer hazards.

Investigation continues on the feasibility of controlling non-aerosol applications of chlorofluorocarbons (CFCs); a decision is expected during the first half of 1980. See the section on "Control Action" for additional information.

Judicial actions under TSCA and administrative actions under section 16—Six suits were brought: three involved PCBs; one involved asbestos-containing materials in school buildings; one raised issues under section 4; and another concerned a rule promulgated under section 8(d). See the section on "Litigation" for additional information.

Several enforcement actions resulting in civil penalties have been taken; most were violations of PCB control and marking/disposal rules. See the section on "Enforcement" for additional information.

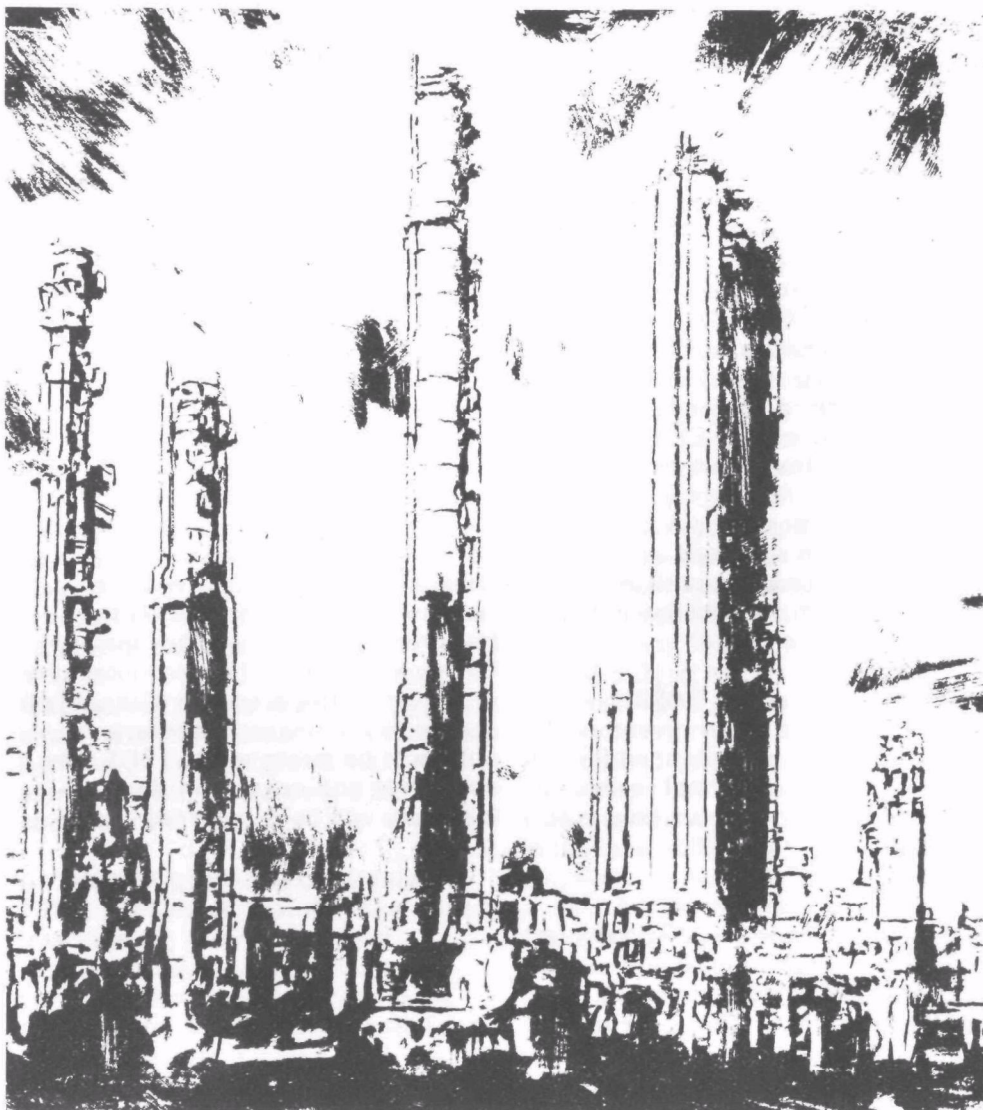
Problems encountered in TSCA implementation—See the section on "Problems" for a brief discussion of administrative and policy problems.

Recommended legislation—No legislative changes are sought at this time.

Section 28(c). This section requires a report on grants to States during the year. In April 1979 grants were awarded to Maryland, Michigan, New Jersey, New York and Wisconsin to prevent or eliminate unreasonable risks associated with chemicals for which EPA is unable, or unlikely, to take action under TSCA. See the section on "State Cooperative

Agreements" for additional information.

Section 9(d). This section requires that EPA's efforts to coordinate its TSCA activities with related activities of other Federal agencies be reported annually. This information appears in the section on "Coordination", and, as appropriate, in other sections of this report.



TSCA Chemical Substances Inventory

The initial TSCA Chemical Substances Inventory, required under section 8(b) of the Act, was published in four volumes on June 1, 1979; a first supplement followed on October 31, 1979.

Volume I lists 43,278 unique chemical substances and their Chemical Abstract Service (CAS) Registry numbers, as well as 363 generic name substances whose specific identities were claimed confidential by the submitting chemical manufacturers and importers. The remaining three volumes are access guides to the actual inventory: Volumes II and III comprise the Substance Name Index, in which preferred names and various synonyms are listed alphabetically. Volume IV contains the Molecular Formula and UVCB (unknown or variable composition, complex reaction products or biological materials) Indices. In addition to the four-volume Inventory, EPA published a two-volume Trademark and Product Name List. This listing is not part of the initial Inventory, and was a one-time publication compiled solely to help chemical processors determine whether a chemical substance was listed on the Inventory.

The supplement added 3,000 substances to the initial Inventory. A second supplement is planned for February 1980, and a final revised Chemical Substances Inventory is to be published in July 1980.

In compiling the Inventory, the Agency also received 1977 production volumes (in broad ranges) and manufacturing sites of each chemical (small companies did not have to submit these data). To facilitate access to this information, it has been

fully computerized. An example is the Regional Chemical Information Directory which lists the Inventory chemical production information within each of the ten separate areas of EPA's Regional Offices.

A portion of the site-specific data was claimed confidential. However, 68 percent of the total information submitted for the Inventory was not claimed as confidential. Production volume was the item most frequently claimed confidential. EPA is examining ways of summarizing these data to provide the public with a general but meaningful picture of commercial chemical manufacturing in the United States.

With publication of the initial Inventory, a second reporting period of 210 days began (June 1 - December 31, 1979). It allowed processors and users of chemical substances (as well as importers of chemical substances as part of mixtures or articles) to report substances not included on the initial Inventory. Thus, processors and users had an opportunity to insure that substances that actually were in commerce in 1977 appear on the Inventory, even though they may not have been reported by a manufacturer or importer. The processors' input will appear in the revised Inventory edition to be published in 1980. Any substance not included in the Inventory will be considered "new"

under TSCA, and thus subject to EPA's premanufacture notification program before it can legally be manufactured, processed, or imported.

Due to the two-phase reporting period, the published Inventory temporarily will not include all the reported substances. Consequently, a Master Inventory File, in a computer-based information system, is maintained by the Agency for immediate access to submitted data.

Reporting and Recordkeeping

Section 8 of TSCA empowers EPA to obtain various kinds of information from chemical manufacturers and processors and, in many instances, distributors. This can include information on mixture composition, byproducts, impurities, uses, exposures, and toxicity. EPA's first use of the section 8 authority was the December 1977 publication of the reporting rules for the TSCA Chemical Substances Inventory; since then, several activities have been initiated under this portion of TSCA.



Under section 8(a), EPA is developing a set of reporting rules to support its comprehensive chemical risk assessment program. The first proposed rule, called the "Preliminary Assessment Information Rule," will be proposed early in 1980; an Advanced Notice of Proposed Rulemaking (ANPRM) for this rule was published on June 27, 1979. Two other proposed rules will follow later in the year. The first rule will apply to about 2,300 chemicals and will collect general exposure information for initial priority-setting and risk evaluation. The second and third rules will progressively apply to fewer chemicals and will collect the detailed data needed to decide whether to regulate or require testing of the chemical. The rules requiring more detailed data will provide useful information for other Federal agencies, as well as EPA.

Section 8(a)(3) requires the Administrator to exclude, by rule, small manufacturers and processors from most recordkeeping and reporting requirements under section 8(a). To date, EPA has developed several small business exclusion criteria for separate section 8(a) rules. To provide consistency and to alleviate the cumulative burden of these rules, EPA is developing generic small business exclusion standards to apply to all section 8(a) rules. These standards will be published for comment in 1980.

An ANPRM published on October 17, 1979, announced that the Agency is investigating the regulation of commercial and industrial uses of asbestos fibers under section 6. In addition, the ANPRM described that a section 8(a) rule is being developed to obtain asbestos information not

otherwise available for this regulatory process. The section 8(a) rule is expected to be proposed in the spring of 1980.

Also under section 8(a), the PBB (polybrominated biphenyls)/Tris (Tris-2,3 dibromopropyl phosphate) Notice Rule was proposed on October 12, 1979. This rule would require manufacturers and importers of PBBs or Tris to notify the Agency if they either are or intend to manufacture or import these substances. The notice would contain information on use, production volumes, byproducts, and worker exposure.

Another section 8(a) rule to be proposed in early 1980 will require reports on the composition of chemical trade name products. The rule will obtain information needed to assign specific names to chemical substances reported for the Chemical Substances Inventory and under premanufacture notice requirements that result from reactions involving trade name chemical products. To reduce the regulatory burden, the Agency requested, by letter, that manufacturers of trade name reactant products voluntarily submit the information. Those that comply will not be subject to this section 8(a) rulemaking.

A proposed amendment to the December 1977 Inventory reporting rules, published on October 22, 1979, established a January 1, 1983, deadline for maintaining records supporting the initial Chemical Substances Inventory reporting.

Section 8(c) authorizes the Agency to require manufacturers, processors, and distributors to maintain and submit information on allegations of adverse health and environmental effects of chemicals. EPA is developing a rule to require that this information be maintained and, under pre-specified conditions, submitted to the Agency. EPA is attempting to coordinate this proposal with similar rules established by the Consumer Product Safety Commission and the Occupational Safety and Health Administration. The Agency expects to propose the rule for public comment in early 1980.

Under section 8(d), the Agency can require the submittal of health and safety studies. EPA's first section 8(d) rule, issued in July 1978, required the reporting of unpublished studies about chemicals recommended for priority testing consideration by the TSCA Interagency Testing Committee. EPA issued the rule to obtain health and safety data to help determine whether to require the testing the Committee had recommended. In January 1979, after receiving the information sought by the Agency, EPA voluntarily revoked the rule. On December 31, 1979, the Agency proposed a new section 8(d) rule which considered issues raised in the initial rulemaking, as well as substantial new issues.

Under section 8(e), chemical manufacturers, processors, and distributors are required to report information suggesting that a chemical substance or mixture presents a substantial risk of injury to health or the environment. To date, the Agency has received more than 320 substantial risk notifications; 48 of these were submitted in 1979. A few prompted the Agency to include chemicals in the TSCA risk assessment process. Several contained information of possible interest to other Federal agencies, particularly the Occupational Safety and Health Administration and the National Institute for Occupational Safety and Health; this information has been transmitted. Still others contained data already known to the Agency or that did not predict significant implications for human health or the environment. All section 8(e) notices are carefully reviewed and a report prepared on each is placed in the public file.

Other related reporting and recordkeeping authorities include sections 12, 13 and 20. Section 12(b) requires persons exporting or intending to export a chemical substance or mixture subject to certain TSCA actions (sections 4, 5, 6, or 7) to notify EPA. The Agency in turn must notify the importing country of the EPA regulatory action. On October 2, 1979, the Agency proposed a section 12(b) rule to govern submission of these notices to EPA. The proposed procedures were effective immediately as interim guidance for notices of PCB and CFC exports.

Section 13 requires the Secretary of the Treasury to refuse entry of any chemical substance into the United States if it violates a TSCA rule. EPA is consulting with the United States Customs Service on the development of this rule. The Agency held public meetings to discuss the importation of TSCA-regulated substances in late 1979. The proposed rule will be published in early 1980.

Section 20 authorizes any person to take civil action against violators of TSCA section 4, 5, or 6 rules. It also authorizes civil actions against EPA to compel performance on any non-discretionary act or duty under TSCA. EPA will develop a rule for plaintiff procedures in order that the Agency, or any alleged violator, may have 60 days notice of civil action intentions. This rule should be published for comment early in 1980.

Data Systems

In accordance with section 10(b) of the Act, EPA is developing computer-based data systems to collect, store, retrieve, analyze and disseminate information submitted to EPA under TSCA, and other relevant toxicological and scientific data.

EPA has developed the Chemicals in Commerce Information System (CICIS) to store and retrieve TSCA data. This system contains TSCA confidential business information and reflects state-of-the-art computer security techniques. The system's modules represent functional TSCA activities. The first module, the TSCA Inventory, became operational in late 1979, and several information services have been derived from it, including subsystems for Freedom of Information Act requests and the Inventory profiles for EPA Regional Offices mentioned earlier. Other current CICIS modules support the TSCA premanufacture review process and manage health and safety study submissions.

The Interagency Toxic Substances Data Committee (ITSDC), formed in February 1978 by EPA and the Council on Environmental Quality, is continuing its work to construct a comprehensive Chemical Substances Information Network (CSIN). Members of ITSDC include the Department of Health, Education, and Welfare and several of its component agencies, the Departments of Labor, Commerce, Agriculture, Interior, Defense, Transportation, State, and Energy, the Consumer Product Safety Commission, and the National Science Foundation.

CSIN will enable toxic substances information users to have access to a number of data banks, including CICIS. Initial components of CSIN will include: a Chemical Information Resources Directory (CIRD) to direct users to particular data banks that will meet their needs; a Chemical Substances Nomenclature System (CSNS) to identify about 1,000,000 substances and direct users to other files containing information on particular substances; a Toxicology Data Management System (TDMS) to store and retrieve data from chemical testing; a Laboratory Animal Data Bank (LADB) for information on laboratory animal strains to be used in designing testing programs; and a Chemical Regulations and Guidelines System (CRGS) for information on chemical standards, regulations, and guidelines.

EPA administers CSIN, which will be in partial operation early in 1980. CSIN will significantly advance making chemical data readily available to both governmental and non-governmental organizations.



Data Security and Disclosure

To protect confidential business information submitted under TSCA from unauthorized disclosure, EPA published the TSCA Confidential Business Information (CBI) Security Manual in July 1978. The manual includes procedures for physical security, custody, access, and computer processing.

The 1978 manual is being revised to reflect experience gained through the handling of CBI submitted in response to rules or regulations promulgated under TSCA. The revised security manual will continue to protect TSCA CBI from unauthorized disclosure, but will provide greater operating efficiency by streamlining procedures for handling and gaining access to it. The revised manual is scheduled for publication in mid-1980. To supplement the Agency's CBI handling procedures, a training and awareness program is in full operation at EPA Headquarters and throughout the Regional Offices. Attendance is mandatory for all EPA employees who are allowed access to TSCA CBI.

With the expanding development and growing use of computer systems to store, control, and retrieve data submitted under TSCA, particular attention is being given to the protection of TSCA CBI. Current computer operations are continually audited to insure that applicable state-of-the-art security capabilities are explored and utilized as new systems are placed into operation.

In addition, mechanisms to segregate confidential from non-confidential data are in place, as well as methods to provide EPA Headquarters and Regional Offices access to non-confidential information submitted under TSCA. This accessibility facilitates timely responses to Freedom of Information Act requests. Various information dissemination vehicles are being explored to make non-confidential information more readily available to the general public.

Initial negotiations with other Federal agencies led to draft security plans being developed for the transfer and protection of TSCA CBI. After these plans are approved by EPA, Interagency Agreements for the controlled exchange of confidential information will be made in 1980.

Premanufacture Notification

Under section 5 of the Act, any person who intends to manufacture or import a new chemical substance for commercial purposes in the United States must submit a notice to EPA at least 90 days prior to its manufacture or importation. A "new chemical substance" is one not included on the Inventory of existing substances. The requirements of section 5 became effective July 1, 1979, under interim guidance published in May 1979.

On January 10, 1979, EPA proposed rules and notice forms for the premanufacture notification (PMN) program. Subsequently, due to the number and nature of comments received, the Agency decided to repropose portions of the January 10 notice. The Agency published the reproposal on October 16, 1979, allowed a 45-day comment period, and held public meetings with representatives of the chemical industry, public interest groups, organized labor, and others. The Agency expects to promulgate the rules and forms in mid to late 1980. EPA's objective in reproposing the January 1979 rules and forms was to: (1) obtain information to permit a preliminary assessment of the risks associated with the manufacture, processing, distribution in commerce, use and disposal of new chemical substances; and (2) obtain this information at minimum cost to submitters. In revising the notice forms, EPA considered the minimum information and level of detail necessary for such a preliminary assessment, the likely availability of such information, and the associated costs.

Since January 1979, EPA has further refined its process for reviewing PMNs, including a more precise definition of the minimum information needed for each phase. The revised form is designed to provide EPA with enough information to: (1) select some substances for more detailed evaluation and for which additional exposure or toxicological data are needed; (2) identify some that will be subject to requirements for follow-up reporting concerning their commercial development; (3) eliminate others from further consideration; and (4) select a limited number for immediate regulatory attention.

Since the July 1, 1979, effective date of the premanufacture program, EPA has received 37 PMNs covering 40 new chemicals. Of those PMNs EPA has reviewed, the Agency thus far plans to refer one chemical for future follow-up action; more are expected in 1980.

Testing

Section 4 of the Act authorizes rules requiring manufacturers and/or processors of chemical substances or mixtures to test how these substances affect human health and the environment. The Act requires that these testing rules include standards specifying the procedures to be used in conducting required tests.



The Agency is developing a full range of generic health and environmental effects test standards to be incorporated, by reference, into test rules for specific chemicals. During 1979, the Agency proposed test standards covering all major areas of health effects, except neurotoxicity, behavioral testing and behavioral teratogenicity testing. In May, proposed test standards were published for oncogenic (tumor-forming) effects, for non-oncogenic chronic health effects, and for combined oncogenic and non-oncogenic chronic effects. Good laboratory practices for health effects testing were also proposed. In July, test standards were proposed for mutagenic effects, teratogenic and reproductive effects, general metabolism testing, and a variety of acute and subchronic toxicity studies. Substantial efforts have been made to insure consistency, wherever possible, between the TSCA test standards and other Federal and international testing guidelines. A public meeting was held in October 1979 to receive comments on the proposed health effects standards.

Development of test standards for environmental effects is proceeding rapidly. Standards for a number of environmental toxicity and chemical fate characteristics are expected to be published in 1980, along with good laboratory practice standards for environmental effects testing.

Efforts to evaluate chemicals for inclusion in section 4 testing rules and to develop operating procedures for implementing TSCA's testing authority are a high priority. To date, 38 chemicals and categories of chemicals have been recommended by the TSCA Interagency Testing Committee (ITC) for testing under section 4. EPA responded within 12 months to each of the first two sets of ITC recommendations, presenting the Agency's reasons for not having initiated rulemaking under section 4(a). However, a district court recently held that EPA's response was inadequate and ordered the Agency to submit a compliance plan. The Agency plans to propose the first section 4 rule, requiring health effects testing for several chemicals or categories recommended by the ITC in the Spring of 1980.

Section 4 also requires EPA to establish procedures for exempting manufacturers or processors whose testing would duplicate that already being performed, as well as a procedure to set equitable reimbursement by parties exempt to the testing rules. Proposed exemption procedures are being developed and will be published with the first testing rule. Reimbursement procedures were the subject of an Advanced Notice of Proposed Rulemaking published in September 1979.

Risk Assessment

A necessary component of most TSCA implementation activities is an assessment of the nature and magnitude of risks that chemicals may present to human health or the environment. Among other things, risk assessment is an integral part of the Agency's premanufacture review of new chemicals, investigation and regulation of existing chemicals in commerce, selection of chemicals for testing requirements, and evaluation of substantial risk information submitted under section 8(e).

Over 320 substantial risk notices have been received by the Agency since January 1, 1977; approximately 48 of these were received during 1979. Chemicals identified from this and other sources are subject to a multi-staged chemical assessment process.

In the Agency's comprehensive assessment process, large numbers of chemicals undergo preliminary assessments designed to select those likely to present significant risks and to identify those for which additional information is needed. In each stage, some chemicals will be chosen for more intensive investigation; ultimately, where it is apparent that control action is needed, detailed risk evaluations will be prepared. In this process, efforts are made to identify and assess the full range of adverse effects and exposure sources of possible significance to human health and the environment. All components of EPA's monitoring and environmental survey program are in place and operating to support TSCA risk assessment actions.

A number of chemicals have already undergone or are undergoing risk assessment. Preliminary assessments of more than 40 chemicals were completed in 1979. About one-third of these were selected for more detailed assessment, possibly leading to regulatory action in the future. Many more were found to be of potential concern but sufficient data on use, exposure, and environmental release to support decision-making are lacking at this time. These chemicals will be included in data gathering efforts under section 8(a) of the Act (described in the "Reporting and Recordkeeping" section of this report).

In-depth assessment activities begun last year on asbestos and chlorofluorocarbons are continuing. The in-depth assessment of nitroacetic acid (NTA), also commenced in 1978, has been suspended pending re-evaluation of the health effects data by the National Toxicology Program.

In addition to assessments of "existing" chemicals on the TSCA Inventory, assessment of "new" chemicals subject to the section 5 premanufacture notification program, also began during 1979. (See the "Premanufacture Notification" section of this report for further details.)

Control Actions

Polychlorinated Biphenyls (PCBs)

Section 6(e) of the Act requires EPA to establish rules governing the marking and disposal of PCBs, and to prohibit, with certain exceptions, their manufacture, processing, distribution and non-totally enclosed use. The marking and disposal rules were issued in February 1978. In May 1979 a final rule banned the manufacture, processing, distribution and non-totally enclosed use of PCBs. This rule also reduced from 500 parts per million (ppm) to 50 ppm the minimum PCB concentration in materials covered by both regulations.

The Agency's marking rules require that most PCB-containing items and storage areas be marked. In general, the disposal rules require high-temperature incineration of all liquids with greater than 500 ppm PCBs, and the burial in chemical waste landfills or destruction in high-efficiency boilers for all other PCBs. For certain large-volume materials sometimes contaminated with PCBs, such as dredge spoil and municipal sewage sludge, alternative disposal methods may be approved by EPA Regional Administrators. All PCB disposal facilities must meet certain technical criteria; currently, eight chemical waste landfills have been approved. Applications for approval of high-temperature incinerators are under consideration; decisions are expected in 1980.

The Agency's ban rules became effective on July 1, 1979, with certain exemptions. The Act allows EPA to grant exemptions upon specific request. To date, EPA has received about 40 petitions for exemptions to continue the manufacture of chemicals in which PCBs are produced as byproducts in most cases at concentrations greater than 50 ppm, with the final products having less than 50 ppm PCBs. EPA has also received approximately 300 petitions for exemptions from the processing and distribution in commerce bans.

The ban rules published in May 1979 included EPA's proposed disposition of the manufacturing petitions. Hearings were held in July; final disposition is expected in April 1980.

EPA estimates that approximately 750 million pounds of PCBs are still used in transformers and capacitors. Because of an incident involving the PCB contamination of poultry feed and the subsequent contamination of large amounts of poultry, eggs and egg products, EPA, in cooperation with the Food and Drug Administration and the Department of Agriculture, has instituted a program to inform the food, feed, fertilizer and agricultural pesticide industries about the special hazards of PCBs in these kinds of establishments. The program also will inform these industries of methods for identifying, removing and properly disposing of PCB-containing equipment. The three agencies also are gathering additional information on the potential for future contamination incidents. This information may provide the basis for future regulations.

Asbestos

Studies of humans and animals provide evidence that exposure to asbestos fibers, even at low concentrations and for short time periods, can result in lung damage and several types of cancer. Because asbestos is present in many products, humans may be exposed in the workplace, near asbestos processing facilities, and through routine daily activities. For many years, sprayed asbestos-containing materials were used inside buildings for fireproofing, thermal and acoustical insulation, and decorative purposes. These uses are now prohibited under the Clean Air Act because of resulting human exposure from the spraying operations.

Sprayed asbestos-containing material in many buildings is deteriorating, with the result that the occupants are being exposed to asbestos fibers. An undetermined, but probably large, number of schools are among structures where asbestos exposure may be occurring. EPA has initiated a nationwide technical assistance program designed to help States and school districts identify schools where deteriorating asbestos-containing material should be removed or sealed. EPA has published a detailed technical guidance package, and is providing training and technical assistance to State and local school officials.

The technical assistance program has provided extensive information on the proper analysis of bulk insulation materials for asbestos. A week-long training course in polarized microscopy was conducted at each of EPA's 10 Regional Offices during 1979. A standard analytical protocol for the asbestos analysis of bulk materials is currently being prepared and field tested before being distributed to participating laboratories. A quality assurance program to complement the issuance of the standard protocol is underway to monitor the sample analysis provided by laboratories. Additional activities include the preparation of a photomicrographic particle atlas to assist laboratories in the proper identification of fibrous materials in bulk samples.

EPA is concerned that participation in this program may not sufficiently reduce the health risk to people exposed in schools, and is determining whether rulemaking may be necessary. To inform the public of the Agency's concern, EPA published an ANPRM. This Notice discussed EPA's concern for protecting the public, identified several issues that needed resolution, and requested public comment. EPA anticipates that any developed rule would require schools to be surveyed to determine if they contain deteriorating asbestos materials. If serious problems are identified, action to reduce the risk, such as removal of the asbestos, would be required. Further, all schools containing asbestos would have to periodically re-evaluate the condition of asbestos-containing materials.



In addition to its uses in buildings, asbestos still is used widely in several thousand industrial and commercial products. About 30 million tons has been used in the United States this century; and the total is increasing by about 750,000 tons each year. Because asbestos resists decomposition, it can remain in the biosphere for extremely long periods, resulting in prolonged exposure to humans. Therefore, EPA is concerned that continuing the mining, milling, processing, and use of asbestos and asbestos-containing articles may present unreasonable health risks. EPA has begun an investigation of potential human exposures during the asbestos life cycle (i.e., exposures occurring in mining, milling, processing, fabrication of articles, installation of products, use, demolition, and disposal). This investigation also will examine the availability of substitute materials and products, the benefits associated with asbestos uses, and the socio-economic impacts of various alternatives for reducing human

exposures. From this investigation EPA will propose rules to eliminate unacceptable health risks including the possibility of a complete, phased-in ban of all non-essential uses of asbestos. An ANPRM concerning this investigation was published on October 17, 1979, with an additional notice extending the public comment period and discussing a further option published on December 17, 1979. These Notices discussed evidence that exposure to asbestos presents serious health risks, EPA's strategy for developing rules to control unreasonable risks from asbestos, and presented for comment several issues and information needs.

Chlorofluorocarbons (CFCs)

In March 1978, acting jointly with the Food and Drug Administration and the Consumer Product Safety Commission, EPA issued final rules prohibiting the manufacture and processing of chlorofluorocarbons (CFCs) as propellants in non-essential aerosol applications.

During 1979, EPA continued to encourage other nations to take actions to control CFC emissions. EPA also continued investigating the desirability and feasibility of controlling non-aerosol CFC applications. Two other nations took steps to control CFCs during 1979. Norway banned non-medical aerosol CFC uses, and the Netherlands required the labeling of aerosol cans containing CFCs. In addition, the European Economic Community (EEC) proposed a 30% reduction of CFC aerosol uses from 1976 levels; member nations are to achieve the reduced levels by December 1981.

In December 1979 the National Academy of Sciences (NAS) issued a report, "Stratospheric Ozone Depletion of Halocarbons: Chemistry and Transport", showing that ozone depletion is occurring twice as rapidly as previously suspected. A 1976 NAS report projected a steady-state depletion rate of 7.5%; the 1979 report estimates a rate of 16.5% if emissions continue at 1977 levels. NAS will shortly release a second report, entitled "Prevention of Ozone Depletion by Chlorofluorocarbons", discussing the health and environmental effects of ozone depletion. The report also will examine alternatives to CFCs in non-aerosol applications.

EPA is presently considering both domestic CFC control methods and strategies for further international action. A decision on future EPA actions will be based on the findings of the two NAS reports, economic analyses, and internal assessments of health and environmental impacts. The Agency's decision is expected by the summer of 1980.

Hazard Warning Rule

Over the past several months, EPA has been working with the Occupational Safety and Health Administration (OSHA) to develop proposed labeling rules for industrial chemical substances and mixtures distributed in U.S. commerce. The proposed rules are being designed to insure that industrial firms and their employees have easy access to information about the hazards of chemical products they handle, thus enabling them to alleviate associated risks.

EPA's proposed rule is being written to require hazard warning information for chemical substances and mixtures that pose acute (toxicity, irritation, and flammability) or cancer hazards. For acute hazards, EPA is considering a labeling procedure based on an industry consensus standard adopted by the American National Standards Institute. For cancer hazards, EPA plans to require warnings for chemicals known or believed to pose human cancer risks based on acceptable epidemiological studies or animal testing.

EPA's proposal will complement OSHA's, which is being written primarily to require disclosure of the identity of chemical substances and mixtures. EPA's rule will be proposed under section 6(a)(3) of TSCA, which authorizes the Agency to require that substances and mixtures "be marked with or accompanied by clear and adequate warnings and instructions." The Agency would establish such requirements only after considering both the costs and benefits.

Enforcement

During 1979, EPA conducted 679 inspections to monitor compliance with the PCB rules and found potential violations at 248 facilities. These figures suggest that slightly over one-third of those subject to the rule may be in violation. Many of the violations were minor and were corrected in the inspector's presence; others resulted in enforcement actions being taken against firms; and the remainder are still under investigation.

A total of 56 enforcement actions were initiated by EPA during 1979 for alleged violations of the PCB rules. Combined penalties of \$72,000 were assessed in the 12 civil administrative cases now complete; 16 other cases are still in administrative litigation. Notices of noncompliance were issued in 22 cases. In four cases civil court actions were filed by the Department of Justice to remedy serious situations that posed risks to health or the environment; two of these have been completed.

Criminal prosecutions resulting from the illegal disposal of PCBs along North Carolina roadways continued in 1979. One defendant pleaded guilty in January 1979; another was expected to go on trial soon.

In addition to enforcing the PCB rules, EPA also conducted inspections to monitor compliance with section 8(b) Inventory requirements and rules banning non-essential uses of chlorofluorocarbons. EPA also completed several section 8(e) substantial risk investigations.

Other enforcement activities included: initiating a cooperative program with the General Services Administration to bring Federal facilities into compliance with the PCB rule; and developing strategies and program guidance for enforcing existing and proposed rules. EPA's toxics enforcement efforts also led to the development of the Consolidated Rules of Practice Governing Administrative Assessment of Civil Penalties and Revocation or Suspension of Permits, which provides standard procedures for administrative enforcement proceedings under five EPA-administered statutes. In addition, the Agency led the development of procedures for coordinating enforcement activities with other agencies in the Interagency Regulatory Liaison Group.



Research

EPA's Office of Research and Development provides both short-term technical assistance on specific chemicals and longer-term research for new techniques to evaluate and control chemical hazards.

Agency researchers are working on several screening methods for health effects testing, with a focus on behavioral toxicity and neurotoxicity. Methods also are being developed to determine if a chemical could cause congenital abnormalities that would not necessarily be apparent at birth.

In the environmental effects testing area, EPA researchers are involved in validating ecological effects testing methods, and developing models to simulate, for prediction purposes, the fate and transport of chemicals in the environment.

The Agency's premanufacture notification program also is receiving technical research support. Further, EPA researchers are evaluating materials that could be used to coat and seal sprayed-on asbestos in buildings, and are developing analytical methods to assess the exposure levels from asbestos-containing materials.

In 1979, the Agency's Research and Development and Toxic Substances Program Offices established a joint Research Committee on Chemical Testing and Assessment. Other Agency offices including Enforcement, Planning and Management, and the Regional Offices, also participate in activities of the Committee. The participants meet at least quarterly to discuss research needs and priorities for a toxics research program. Subcommittees on Health Effects, Environmental Fate and Effects, and Monitoring have provided R&D recommendations for 1980. The Committee also will be drafting a strategy for toxics research that spans the next several years.



Coordination

Interagency Regulatory Liaison Group (IRLG)

The Interagency Regulatory Liaison Group (IRLG) is a unique partnership of Federal agencies involved in regulating hazardous substances. Its goals are to improve public health through sharing information, avoiding duplication of effort, and developing consistent regulatory policies. The IRLG consists of five Federal agencies: EPA, the Consumer Product Safety Commission, the Food and Drug Administration, the Occupational Safety and Health Administration, and the Food Safety and Quality Service. Other agencies participate in relevant specific projects.

One of the IRLG's major accomplishments was the recent joint issuance of a document dealing with the scientific concepts and methods for identifying and evaluating substances alleged to pose a cancer risk. This document served as the basis for the Federal Regulatory Council's "Statement of the Regulation of Chemical Carcinogens," contributed to CPSC's decision to withdraw its similar proposed carcinogen policy, and is providing a basis for other government carcinogen policies. The Statement also is expected to help expedite individual regulatory decisions.

The IRLG also is engaged in developing testing guidelines acceptable to all member agencies,

and has completed five draft health effects testing guidelines that were reviewed by the member agencies' staffs and released for public comment. The guidelines cover testing for eye irritation, acute dermal toxicity, acute inhalation toxicity, acute oral toxicity, and teratogenicity. Guidelines for an additional 12 health effects and 9 environmental tests have at least been partly drafted. IRLG's work in this area should reduce the chemical industry's testing burdens by eliminating unnecessary differences in methodological details that otherwise would require testing duplication.

IRLG has taken other significant steps to coordinate member agencies' work to develop rules and regulations affecting chemical substances. New regulatory coordinating groups were formed on benzidine dyes and chlorinated dioxins. A rulemaking coordination model was the October 17, 1979, Advanced Notice of Proposed Rulemaking on asbestos commercial products, published by EPA, at the same time the Consumer Product Safety Commission released a similar notice. Each of those notices called for the sharing of data and avoidance of duplication. In addition, formal agreements were made with other regulatory agencies for conducting joint risk assessments, sharing confidential business information, and coordinating public education on asbestos and PCB risks.

Numerous other IRLG coordination projects in the areas of compliance and enforcement activities, research, data collection and dissemination, and public information and education are underway. Cooperative activities are taking place at both Headquarters and Regional Office levels.

Integration of Toxics Information

In addition to coordinating control action with other Federal agencies, for chemicals of current interest, EPA completed a data base and framework for future chemical coordination opportunities.

In June 1979, EPA published the "Directory of Federal Coordination Groups for Toxic Substances". This Directory references Federal toxic chemical coordinating groups (e.g., committees and task forces), and enables better communication between agencies and the groups themselves. In early 1980, an updated edition of the Directory will be published. Also planned for release in spring 1980 is a second publication to be entitled "Federal Toxic Substances Programs—An Overview". This will be an organizational reference to Federal programs regulating, or supporting the efforts of toxic substances control, as well as provide summaries of statutory authorities.

The "EPA Chemical Activities Status Report" was another coordination reference published in April 1979. It catalogs, by chemical, the completed and on-going assessment work and control activities within EPA programs. This document will be expanded and revised in 1980.

A further example of non-regulatory chemical integration was the EPA-wide work group on chlorinated dioxins. This group coordinated Agency policies on dioxin assessments and evaluations, sampling and analytical protocols, and provided waste disposal guidance to the EPA Regional Offices.

International Cooperation

In addition to the United States, several European nations and Japan are regulating commercial chemicals. Recognizing the need to promote effective international control of chemical hazards, while avoiding unnecessary trade barriers, EPA is actively participating in international efforts to harmonize various aspects of several nations' regulatory programs. EPA continues its lead role in the Organization of Economic Cooperation and Development (OECD) Chemicals Program for harmonizing international regulatory approaches in the control of chemicals. The Agency has the U.S. lead in coordinating OECD Chemicals Group activities, and participates in all six chemicals testing expert groups, as well as the groups addressing good laboratory practices, confidentiality, and a glossary of key terms.

In the interest of harmonization, EPA discussed with the European Community (EC) TSCA and the EC's approach to regulating toxic substances. The Agency is actively sharing with foreign countries and international bodies (e.g., through the OECD and bilateral contacts with Japan, Switzerland, Canada, Mexico and the EC) information and system approaches.

Since Congressional acceptance of the Multilateral Trade Agreement of the Standards Code in the summer of 1979, EPA has worked with the Office of the U.S. Trade Representative to coordinate policy on standards negotiations that might affect regulation of chemicals in commerce.

EPA also is participating in the World Health Organization (WHO) International Program on Chemical Safety and other WHO programs, including the International Agency for Research on Cancer, Environmental Health Criteria Program, the Human Monitoring Program, and the *Codex Alimentarius* Commission (which implements the joint Food and Agriculture Organization/WHO Food Standards Program).

EPA has been designated by the United Nations Environmental Programme (UNEP) as the U.S. National Correspondent to the International Registry of Potentially Toxic Chemicals. The International Registry, which is part of UNEP's global environmental assessment program will provide an internationally accessible data base on chemical substances.



State Cooperative Agreements

Section 28 of TSCA authorizes EPA to award grants to States to establish and operate programs to prevent or eliminate problems created by toxic substances. State applications for such grants must: (1) set forth the need for a grant; (2) identify the agency(ies) that will establish and/or operate the program; (3) describe the actions proposed to be taken under the program; (4) assure that the program will be integrated with other public health and environmental programs; (5) provide for reports and evaluations as EPA may require; and (6) contain other information requested by EPA.

On August 28, 1978, EPA announced in the *Federal Register* the availability of \$3 million for this Federal assistance program, and provided guidance to prospective applicants. The announcement also described a two-cycle award process, each awarding approximately half the funds. The first cycle was to end 135 days after publication, while the second would be completed later in 1980.

Nine States (Arkansas, California, Illinois, Iowa, Maryland, Michigan, New Jersey, New York, and Wisconsin) applied for first cycle funds. In April 1979, cooperative agreements (grants requiring substantial Federal involvement) were awarded to Maryland, Michigan, New Jersey, New York, and Wisconsin.

Maryland: \$230,935 to the Department of Health and Mental Hygiene to develop a toxic substances registry.

Michigan: \$504,500 to the Department of Natural Resources to develop a Critical Materials Program.

New Jersey: \$453,947 to the Department of Environmental Conservation to (a) develop a Toxic Substances Investigation and Integration Unit, and (b) expand a current project to monitor volatile organic compounds in air.

New York: \$348,000 to the Department of Environmental Conservation to develop a program to identify, characterize, and plan for the management of toxic substances problems.

Wisconsin: \$202,847 to the Department of Health and Social Services to study health problems related to formaldehyde vapors emanating from mobile home construction materials.

Nine new State applications were received for the second cycle (Colorado, Connecticut, Delaware, Illinois, Louisiana, Michigan, Minnesota, North Carolina, Oklahoma, and Puerto Rico); including seven applications held over from cycle one. Sixteen State applications are being considered for funding in the second cycle. Awards of second cycle agreements will occur in January 1980.

Also in January of 1980, EPA will announce in the *Federal Register* the availability of the balance of funds identified for this program.

Public Participation

Considerable effort is being made to encourage broad public participation in EPA's TSCA activities. This effort includes designing a pilot program to compensate individuals or organizations interested in participating in specific rulemaking proceedings. It also involves informing the public on how to effectively participate in toxic substances activities.

Financial Compensation (Intervenor Funding)

Section 6(c)(4) of the Act authorizes the Agency to provide compensation for reasonable expenses of participating in TSCA regulatory proceedings. Compensation may be offered to participants if their involvement would substantially contribute to the resolution of relevant issues; if their economic interest is small in comparison to the costs of effective participation; or if they could not otherwise afford to participate.

During 1980, EPA will fund a pilot program to provide limited financial compensation for three TSCA rules: (1) Commercial and Industrial Uses of Asbestos Fibers; (2) Asbestos Materials in School Buildings; and (3) Chemical Hazard Warning Labels. The total intervenor funding for these three rulemakings will be approximately \$30,000.

Grants

As part of the effort to inform the public about toxic substances issues and activities, small grants were awarded to more than fifteen national, State and local non-profit organizations. Under these grants, informational materials, a training course, and technical issue papers are being prepared; conferences and workshops are being held; and local task forces are being set up in regions across the country.

In addition to increasing the general public's level of understanding about toxic substances problems, a major effort is underway to involve labor, public interest, environmental, public health, urban, minority, civic and educational groups in toxic substances issues.

Advisory Committee

The Administrator's Toxic Substances Advisory Committee, whose members represent a broad variety of backgrounds, interests, and expertise, met three times during 1979 to consider pending program decisions and directions, and to advise the Administrator on policy, procedural and technical matters. Substantive advice concerned the proposed TSCA implementation approach, premanufacture review, asbestos control, testing procedures, international issues, risk assessment procedures, and public participation.

Industry Assistance



In accordance with section 26(d) of the Act, an Industry Assistance Office was established in January 1977. This Office provides information about TSCA requirements to members of the chemical industry and their trade organizations.

Assistance and information provided in 1979 included handling an average of 2,200 telephone calls, and distributing an average of 6,000 document copies each month. Four slide presentations explaining particular TSCA actions were developed for industry use, and have been loaned to 382 companies for seminars and meetings. One provided an overview of TSCA; each of the others explained TSCA rules on proposed premanufacture notification requirements, asbestos, and the revised inventory reporting rules. Several "Q&A" booklets were published for the proposed premanufacture notification requirements, polychlorinated biphenyls, asbestos, and reporting procedures for both the initial and revised editions of the Chemical Substance Inventory.

The Office handled arrangements for 23 meetings to obtain formal comments from the public on proposed regulatory actions, and met on several hundred occasions with individual company representatives to clarify regulatory issues or to provide assistance in carrying out TSCA requirements.

The Office received requests for and mailed over 7,200 copies of the initial Chemical Substances Inventory and its first Supplement.

Regional Offices

The ten EPA Regional Offices are actively participating in TSCA implementation activities. They are providing technical aid and guidance to help State and local officials reduce asbestos exposures in schools, and are helping utilities and States to comply with the PCB rules.

The Regional Offices serve as a communication front line on TSCA and toxics-related issues to industry, State and local governments, special interest groups, and private citizens. Several Regions are conducting extensive public education programs on toxic substances. One such effort is underway in New Jersey, where a wide variety of chemical-related problems exist. Corrective measures for chemical spills and information on the health and environmental effects of toxic chemicals are two more services provided. An example was the technical assistance EPA Regional Offices gave to Midwest and Western State organizations and private

citizens following the PCB contamination of poultry, eggs, and egg products in these areas during the summer of 1979.

EPA's ten Regional Offices are located in: (1) Boston, Massachusetts; (2) New York City, New York; (3) Philadelphia, Pennsylvania; (4) Atlanta, Georgia; (5) Chicago, Illinois; (6) Dallas, Texas; (7) Kansas City, Missouri; (8) Denver, Colorado; (9) San Francisco, California; and (10) Seattle, Washington. Each serves the surrounding States; the Seattle Office assists Alaska, the San Francisco Office aids Hawaii and Guam, and the Virgin Islands and Puerto Rico are served by the New York City Office.



Work Force



TSCA's implementation has increased EPA's and the chemical industry's need for employees trained in scientific and technical professions. The supply of trained professionals in some of these areas, notably toxicology, pathology, and epidemiology, is barely adequate to meet current needs. The increasing requirements for hazard assessments under TSCA and other Federal laws will further strain this situation.

Through extensive recruiting efforts, EPA has identified and hired qualified scientists in some of these shortage categories. However, in some areas, such as veterinary pathology, industry salaries are considerably higher than those offered by government. As a result, the Agency has had to obtain certain expertise through contracts with private organizations.

Various steps are being taken by EPA to improve this situation. The Agency is working with the Office of Personnel Management to set up a hiring register for toxicologists. Efforts are being made to improve EPA's recruiting contacts with educational institutions. The Agency is working with other Federal agencies to enlist their cooperation in allowing people trained in programs they support to fulfill government employment obligations by working at EPA. Also, the Agency worked with one university to develop a short, specialized training course in toxicology that is now available to scientists with appropriate backgrounds.

In addition, EPA is cooperating with the National Academy of Sciences (NAS) in a study to determine the adequacy of federally supported training. If increases are necessary, EPA believes existing programs should be expanded rather than new ones started.

EPA is participating in the National Institute of Environmental Health Sciences' (NIEHS) evaluation of their Environmental Toxicology Training Program. A study is underway to survey the types of toxicological training offered, graduate employment histories, present and future employer needs, and program expansion capacities. The results of this study will document specific employer needs for toxicologists. They also will support NIEHS' efforts to expand environmental toxicology training, which, in turn, will facilitate the implementation of laws, such as TSCA, that require the assessment of the effects of toxic substances on human health and the environment.

Litigation

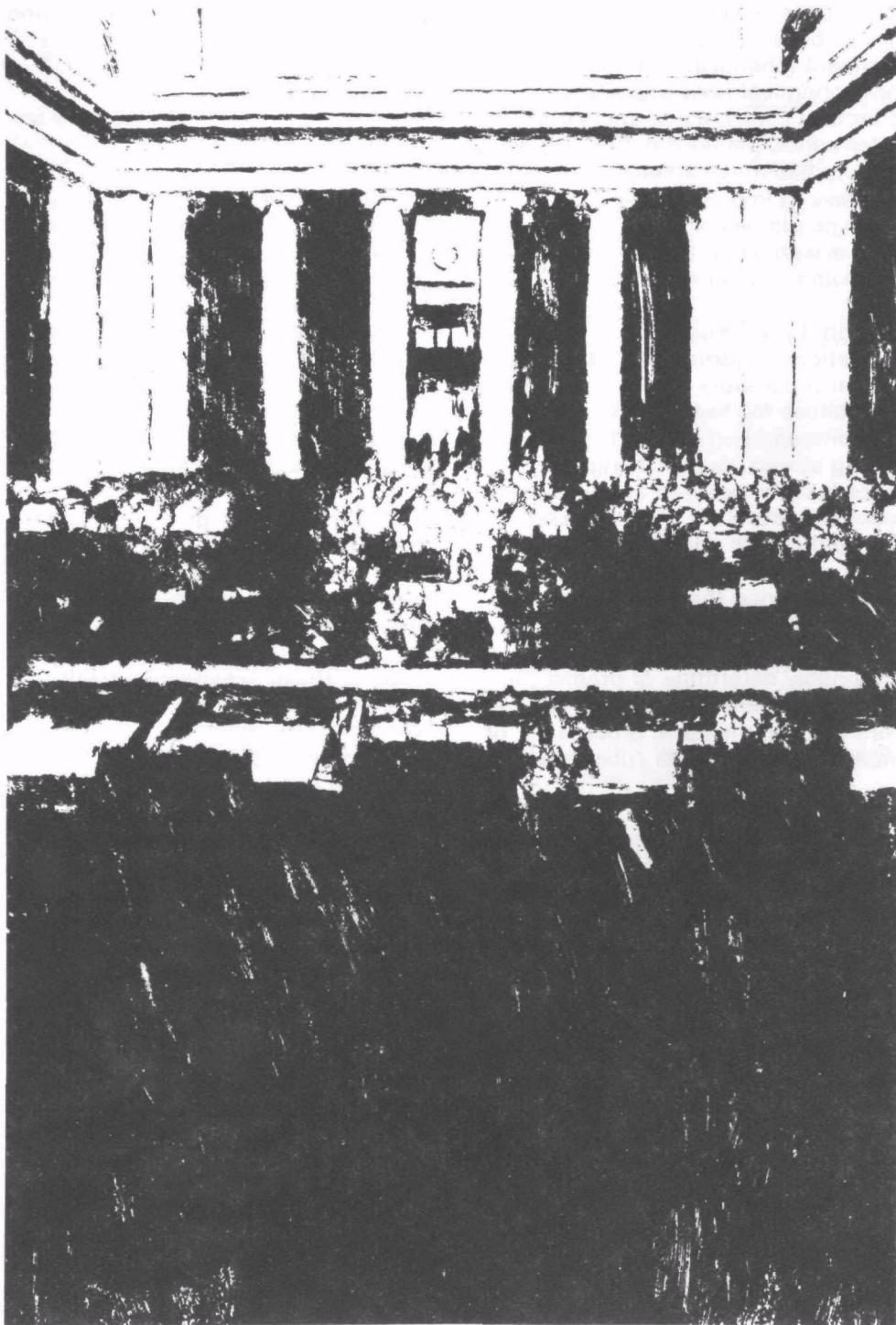
In 1979, several lawsuits were brought under the Act. Three cases involved PCBs. In *Environmental Defense Fund v. Environmental Protection Agency* (No. 79-1580, D.C. Cir.), the Environmental Defense Fund (EDF) petitioned the Federal Court of Appeals for the District of Columbia Circuit for review of the Agency's PCB regulation issued on May 31, 1979 (44 FR 31514) under section 6(e) of TSCA. EDF challenged the Agency's decision to define the minimum concentration of PCBs for most purposes at 50 parts per million, and also alleged that some or all of the PCB use authorizations allowed under the regulation are not supported by substantial evidence in the record. Two other cases involving this regulation, brought by Alcoa (No. 79-1811) and General Electric Company (No. 79-1816), have been consolidated with the EDF appeal. A number of other parties, including the Edison Electric Institute, the National Electrical Manufacturers Association, the Electronic Industries Association, Joy Manufacturing Company, and thirty-one utilities, also have intervened in the EDF appeal. None of these cases has been decided. A petition for review of the PCB regulation has also been filed in the Federal Court of Appeals for the Fourth Circuit in Richmond, Virginia (*Olin Corporation v. Environmental Protection Agency* No. 79-1437, 4th Cir.). Olin has filed an appeal in the event that EPA should later deny its pending exemption petition to manufacture a chemical with a PCB contaminant in the process. This case had not been decided by the year's end.

The third PCB case, *Dow Chemical Company v. Douglas Costle* (D. Del.), was filed in the Federal District Court in Wilmington, Delaware in December 1979. Dow contends that monochloro biphenyls are improperly included with the Agency's regulatory definition of PCBs. The court granted EPA's motion and dismissed Dow's suit on the grounds that the court lacked jurisdiction to hear the case against the Agency. The court noted that Dow could have filed an appeal in a U.S. Court of Appeals within 60 days after promulgation of the regulations.

EDF v. Costle, C.A.D.C. No. 79-1360, involves the issue of asbestos-containing materials which have been applied in school buildings. The Environmental Defense Fund (EDF) on December 21, 1978, petitioned EPA under section 21 of TSCA to regulate such materials. On March 21, 1979, the Agency denied the petition because it believed that the fastest way to reduce the risk posed by asbestos in schools would be to establish a non-regulatory program to provide technical guidance and assistance to State and local officials to identify and abate problems from asbestos-sprayed materials in schools, 44 FR 20290 (April 4, 1979). Such a program was announced in the *Federal Register* on March 23, 1979, 44 FR 17790. *EDF v. Costle* was filed in the District Court for the District of Columbia in response to the denial of the petition to compel the Agency to initiate a rulemaking proceeding. The Agency shortly thereafter reconsidered the issues presented and decided to grant the petition. This decision was announced in the *Federal Register* on July 13, 1979, 44 FR 40900. In addition, on September 20, 1979, EPA published an advance

notice of proposed rulemaking discussing its plans for the rulemaking proceeding, 44 FR 54676. As a result of these actions, EDF voluntarily dismissed its action in the District Court on October 20, 1979. The fifth case raised issues under TSCA section 4. Section 4(e)(1)(A) establishes an Interagency Testing Committee (ITC) to recommend to the EPA Administrator which chemical substances and mixtures should receive priority consideration for testing rules. Within 12 months of the time that the ITC designates chemicals, EPA must initiate a rulemaking proceeding or publish a *Federal Register* notice explaining the Administrator's reasons for not initiating rulemaking (section 4(e)(1)(B)). EPA responded to the first two ITC reports by stating that rulemaking was not being initiated within the year because EPA had not yet completed its evaluation of the ITC's recommendations or resolved several basic scientific and policy issues. The Natural Resources Defense Council (NRDC) sued EPA, *NRDC v. Costle*, No. 79-Civ. 2411 S.D.N.Y., arguing that the response was deficient and that EPA had to make the final determination within twelve months to initiate or not initiate rulemaking, giving section 4(a) reasons for its decision. Industry trade groups intervened on the government's behalf. The Judge granted NRDC's motion for summary judgement and ordered the Agency, to submit a plan for complying with section 4(e).

Finally, Dow Chemical Company filed a petition for review of a rule that the Agency promulgated under section 8(d), *The Dow Chemical Company v. EPA*, No. 78-2203 (3rd Cir.). Section 8(d) authorizes EPA to obtain health and safety studies on chemicals. In August 1979 the court held for EPA on the two technical issues of statutory interpretation that were in dispute: (1) chemicals manufactured or processed by commercial companies like Dow for research and development are manufactured or processed "for commercial purposes" and are, therefore, subject to Agency authority under 8(d); and (2) EPA may obtain copies of health and safety studies from any person in possession of such study.



Problems

Four major sections of TSCA require or authorize EPA to issue regulations: section 4 (chemical testing), section 5 (new-chemical reviews), section 6 (chemical control), and section 8 (information gathering). While the Agency has made substantial progress in implementing each of these provisions, various problems have arisen along the way, especially in issuing section 4 testing rules.

Section 4 authorizes EPA to issue regulations requiring manufacturers and/or processors to test chemical substances for health and environmental effects and to issue testing standards specifying the procedures to be used in conducting required tests. One of the problems the Agency has encountered in developing rules under section 4 has been in making the finding required under section 4(a)(1)(A)(ii) that existing data are insufficient to reasonably determine or predict the effects on health and the environment from the manufacture, processing, or disposal of a chemical substance.

To determine that existing information is insufficient the Agency has gone through a number of steps:

- (1) search the published literature for relevant information;
- (2) determine whether a rule is necessary under section 8(d) to collect unpublished health and safety studies, and if so, issue such a rule;
- (3) validate the methodologies and conclusions of relevant studies;
- (4) interpret the significance of information on adverse health and environmental effects; and
- (5) determine whether the available information is sufficient to find that activities associated with the chemical substance may present an unreasonable risk, but insufficient to reasonably determine or predict the effects of those activities on health or the environment.

This process of collecting and evaluating relevant information on the health and environmental effects of chemicals being considered for a section 4 testing rule has been extremely resource-intensive and time-consuming. Therefore, the Agency is re-evaluating its approach based on the length of time it is taking to develop the first testing rule. If these problems cannot be resolved satisfactorily within the Agency, it may propose legislative amendments designed to remedy them.

Appendix A

TSCA 1979: Principal Rules, Regulations and Public Notices Published in the Federal Register

1. January 2, 1979. TSCA: Policy for Implementation and Enforcement. 44 FR 108.
2. January 10, 1979. Proposed Regulations for TSCA Premanufacturing Notification Requirements and Review Procedures. 44 FR 2240.
3. January 19, 1979. EPA Sprayed Asbestos in Schools: EDF Petition; Request for Comments. 44 FR 4009.
4. January 30, 1979. Notice of Administrator's Toxic Substances Advisory Committee Meeting. 44 FR 5939.
5. January 31, 1979. EPA Health and Safety Study Reporting Regulations; Revocation of Rule Published July 18, 1978. 44 FR 6099.
6. February 5, 1979. Premanufacture Notification Requirements & Review Procedures: Notice of Meetings and Availability. 44 FR 6957.
7. February 7, 1979. EPA Transfer of TSCA Inventory Information to Contractor. 44 FR 7811.
8. February 27, 1979. Premanufacture Notification Requirements; Notice of Meeting. 44 FR 11099.
9. March 12, 1979. Disposal of PCB-Contaminated Soil and Debris: Citizens' Petition. 44 FR 13575.
10. March 16, 1979. TSCA Section 5 Testing Guidelines. 44 FR 16240.
11. March 20, 1979. Interagency Toxic Substances Data Committee: Current Membership. 44 FR 16959.
12. March 23, 1979. Asbestos-Containing Materials in School Buildings; Announces Program and Provides Guidance Package. 44 FR 17790.
13. March 23, 1979. Toxic Substances Control; Confidential Business Information. 44 FR 17673.
14. March 28, 1979. TSCA: Guidance for Premanufacture Notification Testing Correction. 44 FR 18549.
15. March 29, 1979. Extends Comment Period for Third ITC Report. 44 FR 18733.
16. April 4, 1979. Sprayed Asbestos in Schools; Denials of Citizens' Petition. 44 FR 20290.
17. April 6, 1979. Notice of Administrator's Toxic Substances Advisory Committee Meeting. 44 FR 20784.
18. April 19, 1979. FDA and TSCA: Quality Assurance for Bioresearch Studies; Memorandum of Agreement with the Environmental Protection Agency. 44 FR 24233.
20. April 27, 1979. Interagency Regulatory Liaison Group; Public Meeting. 44 FR 24903.
21. May 9, 1979. Proposed Health Effects Test Standards for Toxic Substances Control Act Test Rules. 44 FR 27333.
22. May 9, 1979. Good Laboratory Practice Standards for Health Effects. 44 FR 27362.
23. May 9, 1979. Asbestos in Buildings; Denial of Petition. 44 FR 27257.
24. May 11, 1979. Fully Halogenated Chloroalkanes, Toxic Substances Control Act. 44 FR 27702.
25. May 14, 1979. Response to Interagency Testing Committee Recommendations. 44 FR 28095.
26. May 15, 1979. Toxic Substances Control: Initial and Revised Inventories; Premanufacturing Notification Requirements and Review Procedures. 44 FR 28557.
27. May 15, 1979. Toxic Substances; Premanufacturing Notices; Monthly Status Report. 44 FR 28410.
28. May 25, 1979. Interim Policy on Premanufacture Notification Requirements and Review Procedures; Review by Executive Office of the President. 44 FR 30424.
29. May 29, 1979. Improving Environmental Regulations; Final Report Implementing Executive Order 12044. 44 FR 30988.
30. May 31, 1979. Polychlorinated Biphenyls (PCBs) Manufacturing, Processing, Distribution in Commerce and Use Prohibitions. 44 FR 31514.
31. May 31, 1979. Procedures for Rulemaking Under Section 6 of the Toxic Substances Control Act; Interim Procedural Rules for Exemptions from the PCB Processing and Distribution in Commerce Prohibitions. 44 FR 31558.
32. May 31, 1979. Polychlorinated Biphenyls (PCBs); Proposed Rulemaking for PCB Manufacturing Exemptions. 44 FR 31564.
33. May 31, 1979. Polychlorinated Biphenyls (PCBs); Amendment to Criteria for Chemical Waste Landfills. 44 FR 31567.

34. May 31, 1979. Fully Halogenated Chlorofluoroalkanes; Exemption for Inkless Fingerprinting Systems. 44 FR 31238.

35. June 1, 1979. Fourth Report of the Interagency Testing Committee; Receipt of the Report and Request for Comments. 44 FR 31866.

36. June 14, 1979. Premanufacture Notices: Status Report for May 1979. 44 FR 34193.

June 14, 1979. TSCA Fully Halogenated Chlorofluorocarbons; Proposed Rule. 44 FR 34167.

38. June 27, 1979. Chemical Substances: Reporting and Recordkeeping; Advanced Notice of Proposed Rulemaking. 44 FR 37517.

39. June 28, 1979. Toxic Substances: Postponement of Public Meeting Date. 44 FR 37682.

40. July 3, 1979. Extension of Premanufacturing Notification Period. 44 FR 39026.

41. July 9, 1979. Disposal of PCB-Contaminated Soil and Debris; Denial of Citizens' Petition. 44 FR 40132.

42. July 13, 1979. TSCA Grant of Petition to Initiate Rulemaking Proceeding to Regulate Sprayed Asbestos in Schools. 44 FR 40900.

43. July 20, 1979. Proposed Rulemaking for Polychlorinated Biphenyls (PCBs); Manufacturing Exemptions. 44 FR 42727.

44. July 26, 1979. Proposed Health Effects Test Standards for TSCA Test Rules and Proposed Good Laboratory Practice Standards for Health Effects. 44 FR 44054.

45. July 30, 1979. Receipt of Premanufacture Notice. 44 FR 44930.

46. August 16, 1979. Council on Environmental Quality: Report to the President by the Toxic Substances Strategy Committee. 44 FR 48134.

47. August 21, 1979. IRLG: Testing Standards and Guidelines Work Group; Availability of Draft Guidelines and Public Meeting. 44 FR 49015.

48. September 18, 1979. Receipt of Premanufacture Notice. 44 FR 54118.

49. September 18, 1979. Data Reimbursement Under Sections 4 and 5 of TSCA. 44 FR 54284.

50. September 19, 1979. Fully Halogenated Chlorofluoroalkanes; Final Rule. 44 FR 54298.

51. September 19, 1979. Fully Halogenated Chlorofluoroalkanes; Inkless Fingerprinting Systems. 44 FR 54297.

52. September 19, 1979. Polychlorinated Biphenyls Disposal Requirements; Amendment to Final Rule, Sedgwick County, Kansas. 44 FR 54296.

53. September 20, 1979. Asbestos-Containing Materials in School Buildings; Advance Notice of Proposed Rulemaking. 44 FR 54676.

54. October 2, 1979. Proposed Rule and Interim Guidance for Notification of Export for PCB and Fully Halogenated Chlorofluoroalkanes. 44 FR 56856.

55. October 10, 1979. National Emissions Standards for Identifying, Assessing and Regulating Airborne Substances Posing a Risk of Cancer; National Emissions Standards for Hazardous Air Pollutants; Advance Notice of Proposed Generic Standards 44 FR 58642.

56. October 12, 1979. Submission of Notice of Manufacture or Importation of PBBs and Tris; Proposed Rule. 44 FR 59106.

57. October 16, 1979. Reproposal of TSCA premanufacturing Notice Forms and Provisions of Rules. 44 FR 59764.

58. October 17, 1979. Commercial and Industrial Use of Asbestos Fibers and Consumer Products Containing Asbestos. 44 FR 60056.

59. October 17, 1979. Statement of Regulation of Chemical Carcinogens; Policy and Request for Public Comments. 44 FR 60038.

60. October 18, 1979. Granting of Citizens' Petition To Initiate Regulatory Proceedings To Control Asbestos Cement Pipe. 44 FR 60155.

61. October 22, 1979. Exports of Toxic Substances; Notification of Export Under Section 12(b), TSCA, Proposed Amendment to Inventory Reporting Requirements. 44 FR 60763.

62. November 9, 1979. Availability of a Supplement to the TSCA Chemical Substances Inventory. 44 FR 65180.

63. November 21, 1979. Polychlorinated Biphenyls; Approved PCB Disposal Facilities. 44 FR 66989.

64. November 21, 1979. Polychlorinated Biphenyls (PCBs); Proposed Amendment to the Disposal Requirements for Large PCB Capacitors in Chemical Waste Landfills. 44 FR 66851.

65. November 23, 1979. Reporting Requirements: Submission of Notice of Manufacture or Importation of PBBs and Tris; Corrections. 44 FR 67183.

66. November 23, 1979. Data Reimbursement Under Sections 4 and 5 of the Toxic Substances Control Act; Extension of Comment Period. 44 FR 67183.

67. November 23, 1979. Interagency Regulatory Liaison Group: Epidemiology Work Group; Availability of Draft Guidelines. 44 FR 67232.

68. November 26, 1979. Premanufacture Notice Status Report for October 1979. 44 FR 67523.

69. November 20, 1979. Premanufacture Exemption Application. 44 FR 66671.

70. November 29, 1979. Polychlorinated Biphenyls (PCBs), Manufacturing, Processing, Distribution in Commerce, and Use Prohibitions; Clarification and Proposed Amendment on Hydraulic Machines. 44 FR 68489.

71. December 7, 1979. Priority List of Chemical Substances Recommended for Testing; Fifth Report of the Interagency Testing Committee to the Administrator, EPA, Receipt of the Report, Request for Comments; and Corrections to the Fourth Report of the Interagency Testing Committee. 44 FR 70663.

72. December 17, 1979. Commercial and Industrial Use of Asbestos Fibers; Extension of ANPRM Comment Period and Announcement of Additional Control Option. 44 FR 73127.

73. December 31, 1979. Proposed Rule for Health and Safety Data Reporting; Submission of Lists and Copies of Health and Safety Studies. 44 FR 77470.