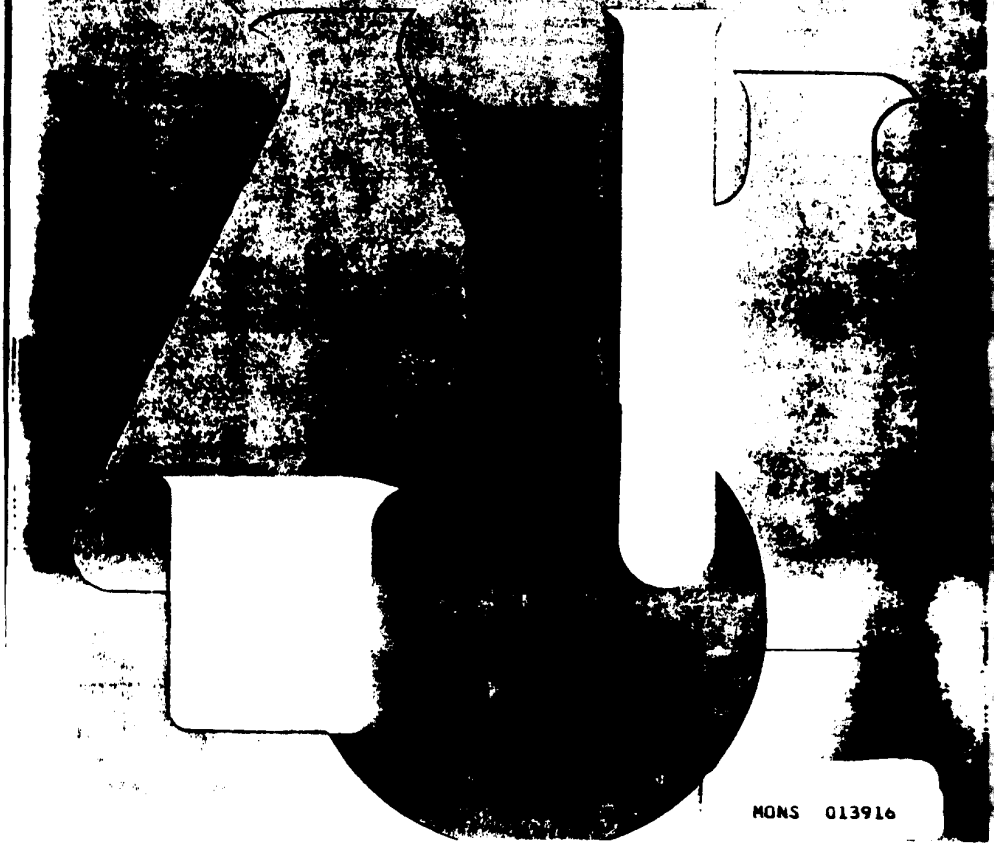
EPA

Administration of the Toxic Substances Control Act

Second Annual Report 1978



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Second Annual Report (1978)

Administration of the Toxic Substances Control Act

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Highlights

This is the Environmental Protection Agency's (EPA) second Annual Report on the administration of the Toxic Substances Control Act (TSCA). This report provides the information required by sections 30, 9(d), and 28(c) of the Act, as well as additional information on the Agency's implementation of the Act.

During the last thirteen months, significant progress has been made in laying the groundwork for implementing many of the major provisions of the Toxic Substances Control Act. In January 1979, EPA published proposed rules under which manufacturers would have to notify the Agency before manufacturing new chemical substances. This premanufacture notification program will begin 30 days after publication of the Agency's initial inventory of chemicals in commerce. EPA expects to publish the initial inventory on or about June 1, 1979.

In April 1979, the Agency expects to issue its first proposed standards for health effects testing. These standards will prescribe methodology for oncogenicity and other chronic health effects testing; simultaneously the Agency will issue proposed Good Laboratory Practice (GLP) standards for health effects testing. The selection of chemicals to be tested in accordance with these standards is proceeding. EPA expects to publish later this year the first proposed rule to require the testing of specific chemicals or groups of chemicals.

Two regulations governing activities involving specific chemicals were issued in 1978. Final regulations dealing with the marking and disposal of polychlorinated biphenyls (PCBs) were issued in February, and final regulations banning nonessential aerosol uses of chlorofluorocarbons were issued in March. Additional regulations dealing with PCBs will be issued in March 1979; they will lay out the rules for implementing the statutory ban on the manufacture, processing, and distribution of PCBs and on non-totally enclosed uses. The Agency also has initiated, in cooperation with the Department of Health, Education, and Welfare, State agencies, and school districts, a national program to identify and deal with deteriorating sprayed asbestos material in public schools; the possibility of supplementing this initial effort with a regulatory program is being examined.

Summary

This section is intended to help readers of this Annual Report locate the information specifically required by certain provisions of the Act that call for annual reporting to the Congress and/or the President.

Section 30 of the Act contains the basic requirement for an Annual Report and specifically calls for the following information:

1. *Testing required under section 4*: Thus far, no testing requirements have been established. See the section on Testing for a description of work in progress on the development of testing standards and rules.

2. *Premanufacture notices received*: Premanufacture notification regarding new chemical substances will not be required until 30 days after the TSCA Inventory is officially published. See the section on Premanufacture Notification for information on the Agency's progress in developing this program.

3. *Rules issued under section 6*: Final rules governing marking and disposal of polychlorinated biphenyls (PCBs) and chlorofluorocarbons (CFCs) were issued last year. Proposed rules to implement the statutory ban on manufacture, processing, distribution, and non-totally enclosed use of PCBs were published in June 1978. See the section on Control Actions for additional information on these rulemaking activities.

4. *Judicial actions under TSCA and administrative actions under section 16*: Two suits raising significant issues have been brought; see the section on Litigation for additional information. Several enforcement actions resulting in civil penalties have been taken; see the section on Enforcement for additional information.

5. *Problems encountered in TSCA implementation*: See the section on Problems for a brief discussion of administrative and policy problems.

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6. *Recommended legislation*: No additional legislation is being recommended at this time.

Section 9(d) requires that the Annual Report include information on coordination of activities under TSCA with related activities with other Federal laws. Such information appears in the section on Coordination and, as appropriate, in other parts of this document.

Section 23(c) requires an annual report on grants made to States. See the section on EPA State Cooperative Agreements for information on the status of this program.

Appendix A contains a list of the principal rules and regulations and other important public notices published thus far.

The initial TSCA Inventory, required under section 8(b) of the Act, will be published on or about June 1, 1979. The initial Inventory is based on approximately 140,000 reporting forms submitted by nearly 7,400 firms. It will include some 45,000 unique chemical substances, most of which will be substances that have a specific chemical structure, such as formaldehyde and benzene. Most of the remaining substances on the Inventory will be undefined, variable composition chemicals, such as castor oil and coal tar.

When the Inventory is published, it will contain the identity of nearly all chemicals reported to the Agency. Confidentiality claims were made for the identify of fewer than 2,000 substances. These will be listed separately with their identities masked to prevent unauthorized disclosure of confidential information.

In addition to obtaining information on chemical substance identity, the Agency collected data on the 1977 production volume of each substance at each manufacturing site (except that small companies did not have to submit these data). EPA will use this information in setting priorities for TSCA activities and for other purposes; for example, where environmental incidents occur, the production-site information will be helpful in identifying possible sources of such contamination.

A substantial portion of the site-specific production data is covered by confidentiality claims. EPA is examining various ways of aggregating and summarizing such data so that it can provide the public with a general picture of commercial chemical manufacturing in the United States.

A second reporting period of 210 days will begin with the official publication of the initial Inventory. It will allow 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 will have an opportunity to ensure that substances which actually were in commerce in 1977 appear on the Inventory, even though they may not have been reported by any manufacturer. Any substance not included in the Inventory will be "new" under TSCA and, therefore, will have to go through premanufacture notification before it can legally be manufactured or processed or imported as a bulk chemical.

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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 before commencing manufacture. A "new chemical substance" is any chemical substance not included on the Inventory of existing substances to be published by EPA under section 8(b). Thirty days after official publication of the initial Inventory, the requirements of section 5 become effective.

During 1978, EPA developed rules and notice forms for the premanufacture program. The Agency proposed the rules and forms in the *Federal Register* on January 10, 1979, allowed a 75-day public comment period, and held public meetings at several places around the country. After reviewing the public record, the Agency will promulgate the rules and forms during the latter part of this year.

The proposed rules include provisions covering: who would have to submit notices and who would not; the types of chemicals subject to notification and those excluded; how, where, and when to submit notices (with special provisions for imports); the information to be included in notices. The rules also would contain EPA's procedures for receiving, processing, and reviewing notices, for handling deficient and invalid notices; and for initiating action to obtain additional data on new chemicals before their introduction or to regulate the production, use, or disposal of new chemicals. Also included would be general provisions for handling and protecting confidential information; special provisions concerning information on chemical identity and use and data from health and safety studies; and procedures for requiring additional reporting under sections 5 and 8 of the Act.

The proposed general notice form would identify the specific information requirements applicable to new chemical substances, including both mandatory and optional information. Manufacturers would be required to submit information concerning testing they have performed and exposures to humans and the environment. At their discretion, they could submit other information that may be useful in EPA's assessment, including information on steps that would be taken to control exposures and on the economic significance of their new chemicals. EPA also published for public comment three other forms designed for use in connection with new imported chemicals.

EPA has given considerable attention to testing of new chemical substances and, in particular, to the need for testing guidelines. The Agency did not propose guidelines with the rules and forms, but it has published in the *Federal Register* a detailed discussion of the major testing issues, as well as alternative ways of providing guidance. This publication also described a number of testing methods EPA considers appropriate for evaluating a wide range of health and ecological effects and environmental fate characteristics. The Agency has asked for public comment on the issues, alternatives, and testing methods. After considering the public comments, EPA plans to issue a formal proposal regarding testing guidelines.

In developing the proposed rules and notice forms, EPA provided extensive opportunity for public participation. The Agency held six public meetings to discuss major issues with representatives of environmental and other public interest groups, organized labor, the chemical industry, and others. Further, EPA staff members had many meetings with representatives of individual groups to discuss specific issues, and the Agency distributed prepublication drafts of the proposed rulemaking for review and comment.

In addition to developing this proposed rulemaking, EPA initiated efforts during 1978 to establish a process for receiving, reviewing, and making regulatory decisions concerning new substances. This included the development of appropriate internal organizational structures, the recruitment of necessary staff, and interaction with other EPA offices and Federal agencies to define their respective involvements in reviewing premanufacture notices.

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Testing

Under section 4 of the Act, the Agency is authorized 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.

Proposed standards for testing of chemicals to determine whether they could produce oncogenic effects (i.e., tumors) and other chronic effects are due to be published in April 1979. Proposed Good Laboratory Practice (GLP) standards for health effects testing will be published at the same time. The testing standards for oncogenic and other chronic effects are largely the same as those contained in EPA's guidelines for pesticide testing. The GLP standards are virtually identical to those issued by the Food and Drug Administration. Other health effects test standards under development include those for acute toxicity, subchronic toxicity, teratology, mutagenicity, and reproductive effects.

Also underway is the development of test standards for ecological effects and chemical fate in the environment. Ecological effects testing will be designed to assess the potential impact of chemicals on aquatic and terrestrial ecosystems. Chemical fate testing will be designed to provide insights into the mobility and persistence of chemicals in air, land, and water; such information is needed to assess exposures and identify populations at risk.

About two dozen chemicals and groups of chemicals currently are candidates for inclusion in rules requiring actual testing. Among them are those recommended by the Interagency Testing Committee established under section 4(e) of the Act. The first testing rule is scheduled to be proposed later this year and will provide a context for dealing with a number of significant policy and technical issues. It will require testing of a limited number of chemicals and groups of chemicals but will be followed by others covering larger numbers of high priority (for testing) chemicals.

Risk Assessment

Assessment of the nature and magnitude of risks that chemicals may present to human health and the environment is a necessary element of most TSCA implementation activities. Risk assessment is necessary in connection with the Agency's premanufacture review of new chemicals and significant new uses, investigation and regulation of chemicals already in commercial use, selection of chemicals for which testing requirements should be established, and, among other things, evaluation of "substantial risk" information submitted under section 8(e). Although risk assessment, in general, always includes an evaluation of information on potential adverse effects (derived from animal testing, epidemiological studies, or other sources) and on environmental and human exposure, TSCA risk assessments cannot all be performed in precisely the same way. They will have to be more or less detailed, depending on time constraints, data availability, and the purpose of each risk assessment. Thus, an initial evaluation of a chemical for which "substantial risk" information is reported under section 8(e) is done very quickly and provides only a preliminary judgment, while a risk assessment to support significant regulatory action generally will take several months and result in production of an exhaustive analysis. Over the past several months, a substantial effort has been devoted to developing a well-defined process for performing each of the various types of risk assessments needed for TSCA implementation. These efforts are now nearing completion.

To permit the Agency to focus resources on the highest priority chemicals as much as possible, all major risk assessment processes will be multi-staged. An example of this approach is the comprehensive process to be used in identifying and evaluating risks associated with the manufacture, processing, distribution, use, and disposal of chemicals already in commercial use. Approximately 45,000 chemical substances are already in commercial use in this country. Performing a detailed evaluation of each one is not practical. In the Agency's comprehensive assessment process, large numbers of chemicals will undergo preliminary assessments designed to indicate which ones are or are not likely to present significant risks and 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 will be made to identify and assess the full range of adverse effects and exposure sources of possible significance to human health and environment.

Chemicals already in commercial use are chosen for risk assessment on the basis of information received from various sources, including chemical companies, other EPA programs and other Federal agencies, and individual citizens and groups. In addition, using the TSCA Inventory of chemical substances as a starting point, the Agency will be selecting chemicals for risk assessment based on information already available or additional information obtained from chemical companies in compliance with reporting and recordkeeping rules to be issued under section 8.

A substantial number of chemicals already have undergone or are undergoing risk assessment. Preliminary assessments of 49 chemicals have been completed. Nineteen chemicals are in the second stage of the comprehensive assessment process, which involves a more detailed review of adverse effects

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and exposure sources. Three are in the third stage, which involves in-depth review of the validity and significance of existing data. These three are asbestos, chlorofluorocarbons, and nitrilotriacetic acid (NTA).

In addition, EPA is cooperating with several other organizations to develop agreed-upon scientific approaches to risk assessment for various effects. For example, EPA participated in the Interagency Regulatory Liaison Group's development of a major document describing a common approach to the scientific assessment of hazard and risk of cancer from chemicals. This approach will be used by EPA in carrying out assessments under TSCA.

Similarly, EPA has sponsored a major scientific review of the more than 25 tests used to predict generic effects of chemicals (mutagenicity). This program, called GENE-TOX, is expected to yield important results later this year to assist EPA and the scientific community in assessments of mutagenicity.

EPA is establishing an Office of Health and Environmental Effects Assessment in the Office of Research and Development to serve as a focal point for Agency-wide efforts to develop agreed-upon risk assessment methods for several key health effects.

Polychlorinated biphenyls (PCBs)

Section 6(e) of the Act requires EPA to establish rules governing the marking and disposal of PCBs and prohibits, with certain exceptions, the manufacture, processing, distribution, and non-totally enclosed use of PCBs. EPA issued marking and disposal rules in February 1978 and is about to issue rules carrying out the statutory prohibitions.

PCBs had been widely used in the United States (and elsewhere) for some 40 years prior to the enactment of TSCA. They had been used primarily as dielectric fluid in transformers, capacitors, and other electrical equipment, but also in hydraulic and heat transfer systems and for various other purposes. Before their human health and environmental hazards were recognized, PCBs had already been widely dispersed in the environment, with the result that measurable amounts can be found in soils, water, fish, milk, and human tissue.

The Agency's PCB marking rules require that PCB containers, transformers, large high-voltage capacitors, and various other PCB-containing items be marked to ensure that persons handling, transporting, and disposing of them are aware that they are subject to the TSCA rules governing processing, distribution, use and disposal. Under certain circumstances, vehicles transporting PCBs also have to be marked.

In general, the PCB disposal rules will require that PCBs and PCB items, when removed from service, be disposed of in high-temperature incinerators, chemical waste landfills, or, in certain cases, high-efficiency boilers having PCB-destruction efficiency of 99.9 percent. 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's Regional Administrators. PCB disposal facilities must meet certain technical specifications included in EPA's rules. Several chemical waste landfills have been found to meet the criteria; several others are being evaluated. Applications for approval of several high-temperature incinerators are under consideration.

The Agency's PCB ban rules will, with a few specified exceptions, prohibit manufacture, processing, distribution, and non-totally enclosed use of PCBs. Unless a specific exemption is sought and granted, all manufacturing of PCBs will be prohibited after the effective date of the EPA rules, and all processing and distribution will be prohibited after July 1, 1979. Persons wishing to continue such activities must petition the Agency for a specific exemption.

EPA estimates that about 750 million pounds of PCBs are still in use. Uses of this material in a totally enclosed manner (e.g., in transformers and capacitors) can continue indefinitely (with servicing to be performed under EPA authorizations valid for a maximum of five years). The Agency's disposal rules apply to about 60 percent of the PCBs now in use. The remaining 40 percent consists almost entirely of PCBs in millions of small capacitors (e.g., those used in household fluorescent lights). Such capacitors are so numerous that regulatory or other control of their disposal would be totally impractical.

Chlorofluorocarbons (CFCs)

In March 1978, jointly with the Food and Drug Administration (FDA) and the Consumer Product Safety Commis-

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tion (CPSC), EPA issued final rules prohibiting manufacturing and processing of chlorofluorocarbons (CFCs) for non-essential aerosol uses. This action was taken on the basis of evidence that CFCs are depleting the stratospheric ozone layer that protects the earth against damaging ultraviolet radiation from the sun.

The FDA's rules apply to the use of CFCs in food, drug, and cosmetic products. EPA's rules apply to all other uses, including most uses of CFCs in pesticides. The Consumer Product Safety Commission worked with EPA and FDA in developing their rules, but because CPSC's and EPA's jurisdiction overlaps, CPSC did not issue separate rules.

EPA is encouraging other nations to take similar action to control aerosol uses of CFCs and is investigating the need to control other uses of CFCs, including their use in refrigeration and cooling systems, in manufacture of foamed material, and as solvents. CPSC, FDA, and other Federal agencies are cooperating with EPA in this investigation. Two public meetings on this problem have been held. EPA expects to make a decision this year on the need for additional regulatory action.

Asbestos

For about 25 years prior to 1973, sprayed asbestos-containing material was used inside buildings for fireproofing, thermal and acoustical insulation, and decorative purposes. In 1973, under the Clean Air Act, EPA prohibited spraying of such material (usually done before buildings were enclosed) because workers and persons in the vicinity were being exposed to asbestos during spraying operations. Application of sprayed asbestos-containing material for decorative purposes was prohibited in 1978.

There is now wide recognition that sprayed asbestos-containing material in many buildings is deteriorating, with the result that the occupants are being exposed to asbestos fibers. Evidence from both occupational and nonoccupational studies indicates that exposure to asbestos fibers can result in the occurrence of asbestosis and other serious lung diseases, as well as some types of cancer.

An undetermined number of public schools are among the buildings where asbestos exposure may be occurring. As an initial step toward dealing with this problem, EPA has initiated a nationwide program designed to help States and school districts identify schools where deteriorating asbestos-containing material should be removed or sealed. EPA has developed and is distributing a detailed technical guidance package and is providing training and technical assistance to State and public school officials. In addition, the Agency is asking school districts to provide information on the extent of the problem and their plans for corrective action.

EPA is also considering the possibility of taking regulatory action to deal with this problem, but will not take such action at least until it has evaluated the first six months' experience with the cooperative Federal-State-school district program. The Agency also is assessing health risks associated with many other uses of asbestos and, in the near future, will decide whether to initiate rulemaking to reduce human exposure related to any of those uses.

EPA has initiated eight enforcement actions dealing with alleged violations of the PCB marking and disposal rules. One was a criminal case involving illicit dumping of PCBs; the other seven were civil actions.

On January 27, 1979, the Agency successfully completed the first criminal prosecution under TSCA when Robert J. Burns and his two sons pleaded guilty to charges stemming from illicit dumping of PCB-contaminated oil along 210 miles of North Carolina roadways. EPA cooperated with the State in investigating the incident. The State still has criminal charges pending, and sentencing has been deferred until the State's case is concluded.

Civil penalties totalling $28,600 have been assessed against two companies for improper disposal of PCBs. Charges involving alleged improper marking, storage, or disposal are pending against five other companies. Other possible violations are being investigated.

Other enforcement activities have included inspections to check on compliance with the rules banning non-essential aerosol uses of chlorofluorocarbons; joint efforts with the U.S. Customs Service to develop procedures for ensuring that imported chemicals comply with TSCA requirements; several investigations related to the section 8(e) requirement for submittal of substantial risk information; and development of procedures for coordinating enforcement activities with other agencies in the Interagency Regulatory Liaison Group (IRLG).

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Reporting and Recordkeeping

Section 8 of the Act empowers EPA to obtain various kinds of information from chemical manufacturers and processors and, in many instances, distributors, as well. Publication of EPA's rules requiring reporting for the TSCA chemical Inventory was the Agency's first use of its section 8 authority. Other activities under section 8 are described here.

Section 8(a) authorizes the Agency to establish rules under which chemical manufacturers and processors can be required to maintain and report information on the identity, structure, uses, and production of chemicals, worker exposures, human health and environmental effects, and other factors. For the most part, EPA expects to use 8(a) rules to obtain information needed to identify and assess potential problems and support control actions under TSCA or other Federal laws. The Agency currently is preparing a proposed rule to require submittal of basic data needed to screen a large number of chemicals for indications of potential problems. In accordance with a statutory requirement specifically applicable to section 8(a), rules under 8(a) will provide for small business exemptions.

Section 8(b) calls for compilation of the TSCA Inventory based on data obtained under an 8(a) rule. EPA's work on the Inventory is described elsewhere in this report.

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 currently is developing a proposed rule to require that such information be maintained and, where specified conditions exist, that it be submitted to the Agency. EPA is attempting to harmonize this proposed rule with similar rules established by the Consumer Product Safety Commission and the Occupational Safety and Health Administration.

Under Section 8(d), the Agency can require submittal of health and safety studies. EPA issued its first 8(d) rule in July 1978; it required reporting of unpublished studies of chemicals that had been recommended for testing by the TSCA Interagency Testing Committee established under section 4(e). EPA's purpose in issuing the rule was to obtain health and safety data for use in determining whether to require the testing the Committee had recommended. In January 1979, after a substantial number of studies had been submitted, thus providing the information the Agency was seeking on studies already performed, the rule was revoked. In the near future, the Agency plans to propose a new 8(d) rule for future use in requiring submittal of health and safety studies.

Under section 8(e), chemical manufacturers, processors, and distributors are required to report information that reasonably supports a conclusion that a chemical substance or mixture presents a substantial risk of injury to health or the environment. As of January 1, 1979, the Agency had received more than 250 substantial risk notifications. A few contained information that has prompted the Agency to put the chemicals in question into the TSCA risk assessment process (which is described elsewhere in this report). Many others contained information of possible interest to other Federal agencies (particularly the Occupational Safety and Health Administration and the National Institute of Occupational Safety and Health), which has been transmitted to them. Still others contained data which had already come to the Agency's attention or which were not significant in terms of their implications for human health or the environment. All 8(e) notices are reviewed within a short time after they are received. A report is prepared on each one and is placed in a public file.

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Data Systems

Section 10(b) of the Act calls for the development of efficient and effective systems for collection, storage, retrieval, and dissemination of information submitted to EPA under the Act, as well as other toxicological and scientific data that could be useful in TSCA implementation. Section 10(b) also calls for the creation of an interagency committee to aid EPA in establishing such systems.

EPA is establishing the Chemicals in Commerce Information System (CICIS) for data submitted to the Agency under TSCA. CICIS is expected to be fully operational about the middle of this year. An automated system for public access to non-confidential CICIS data is being developed and should be in place next year.

In accordance with section 10(b), EPA and the Council on Environmental Quality (CEQ) jointly established the Interagency Toxic Substances Data Committee in February 1978. Members 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, International Trade Commission, and National Science Foundation.

Based on recommendations made in CEQ's report to the Congress under section 25(b) of the Act, the Interagency Committee is constructing a comprehensive Chemical Substances Information Network (CSIN). CSIN will enable users of toxic substances data to have access to a number of data banks, including CICIS. Core components of CSIN will include a file describing each system in the network, designed to direct users to the particular data bank that will meet their needs; chemical identification data for about 500,000 substances and a pointer to other files containing information on particular substances; a storage and retrieval system containing data from chemical testing; a reference system for toxicological and other biomedical journals; information on laboratory animal strains for use in designing testing programs; and information on chemical standards, regulations, and guidelines.

CSIN will represent a significant advance in Federal interagency cooperation in making toxic substances data readily available to meet the needs of governmental and non-governmental organizations. To the extent that it enables Federal agencies to locate and use data that have already been compiled, it can be expected to reduce reporting requirements imposed on chemical companies and other commercial and industrial firms. CSIN is expected to be in partial operation next year. The Interagency Committee has designated EPA as the CSIN administrator.

Data Security and Disclosure

To provide maximum security for confidential business information submitted under TSCA, the Agency has developed detailed procedures to safeguard confidential information through controls on physical security, custody, access, and computer storage and processing. A manual describing these procedures was published in July 1978. During its development, EPA studied security procedures used by other Federal agencies and by chemical companies. A public meeting to discuss a draft of the security manual was held in April 1978.

In September 1978, EPA amended its confidential business information regulations, particularly as they apply to information claimed to be confidential at the time it is submitted under TSCA. The amendments reaffirm EPA's policy of protecting business information that is entitled to confidential treatment, unless disclosure is specifically required by TSCA. The amendments also provide that EPA will always give notice to affected businesses before information claimed to be confidential is publicly disclosed or disclosed to other Federal agencies, Congress, or contractors or under Federal court orders.

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Research

EPA's Office of Research and Development is playing a significant role in TSCA implementation by providing short-term technical assistance in dealing with specific problems and by undertaking longer-term research to develop new knowledge and techniques needed to evaluate and control chemical hazards.

In the health effects testing area, EPA's researchers are developing a variety of screening methods. This effort is focused on behavioral toxicity and neurotoxicity. They also are developing methods that can be used to determine whether a chemical could cause congenital abnormalities that would not necessarily be apparent at birth.

To aid in assessing environmental effects of chemicals, EPA researchers are engaged in validating various ecological effects testing methods and in developing methods that can be used to simulate and predict the fate and transport of chemicals in the environment.

EPA researchers are providing a substantial amount of technical support to the development of the TSCA premanufacture notification program and the Agency's program for identifying and dealing with deteriorating sprayed-on asbestos material in public buildings. In support of the latter effort, EPA researchers are evaluating materials that could be used to coat and seal sprayed-on asbestos and are developing analytical methods for use in assessing exposure levels.

Coordination

Interagency Regulatory Liaison Group (IRLG)

The Interagency Regulatory Liaison Group (IRLG) is a unique partnership of Federal agencies involved in regulating hazardous substances. IRLG originally consisted of four Federal agencies: EPA, Consumer Product Safety Commission, Food and Drug Administration, and Occupational Safety and Health Administration. The Food Safety and Quality Service of the U.S. Department of Agriculture recently became a member.

One of the IRLG's major accomplishments was the recent issuance of a document reflecting the best judgment of scientists in the member agencies on the scientific concepts and methods useful in identifying and evaluating substances that may pose a cancer risk to humans. Publication of the document represented a significant step in the Federal Government's efforts to assure consistent evaluation of cancer-causing substances in the environment, foods, consumer products, and workplaces.

The IRLG also is engaged in an effort to develop testing guidelines acceptable to all member agencies. Draft guidelines for a variety of health effects and environmental tests have already been developed and are being reviewed. Guidelines for documenting epidemiological studies also are being prepared. IRLG's work in this area is designed to reduce testing burdens imposed on the chemical industry by eliminating any unnecessary differences in methodological details that would otherwise require duplicative testing.

IRLG has taken other significant steps to coordinate member agencies' work on development of rules and regulations affecting chemical substances, compliance and enforcement activities, research, data collection and dissemination, and public information and education. Cooperative activities have been undertaken at both Headquarters and Regional Office levels.

International Cooperation

In addition to the United States, several European nations and Japan are regulating commercial chemicals. Recognizing the need to promote effective control of chemical hazards on an international basis while minimizing the creation of artificial trade barriers, EPA is actively participating in international efforts to harmonize various aspects of the several nations' regulatory programs. This includes participation in the activities of the Organization for Economic Cooperation and Development (OECD) aimed at harmonizing testing procedures, terminology, and Good Laboratory Practice standards.

EPA is also participating in the World Health Organization's (WHO) International Program on Chemical Safety and other WHO programs, including the International Agency for Research on Cancer, the Environmental Health Criteria 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 Program (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.

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Public Participation

A significant effort is being made to encourage broad public participation in EPA's activities under TSCA. This effort includes a program to compensate individuals or organizations interested in participating in specific rulemaking proceedings, as well as a program generally aimed at laying the groundwork for informed public involvement in toxic substances control activities.

Compensation

Section 6(b)(4) of the Act authorizes the Agency to provide compensation for reasonable expenses of participating in proceedings for the promulgation of regulations affecting the manufacture, processing, distribution, use, and disposal of chemicals. Compensation can be offered to participants whose involvement would substantially contribute to resolution of relevant issues and whose economic interest is small in comparison to the costs of effective participation or who does not have adquate resources to participate.

Based on procedural rules issued November 30, 1977, compensation was made available for participation in the public hearings on the Agency's proposed rules prohibiting manufacture, processing, distribution, and use of polychlorinated biphenyls (PCBs). One award was made—to the Center for Occupational Hazards in New York City, for assembling and presenting information on the use of PCBs in microscopy.

Grants

To support a pilot program aimed at developing and testing means of involving citizens in toxic substances control activities, the Agency has made a grant of $106,000 to 25 nonprofit groups in the New York-New Jersey area. Their goal is to identify ways in which citizens can participate in the Agency's efforts to find economically and technologically feasible solutions to toxic substances problems. EPA is underwriting the various groups' administrative expenses related to the project; most of the work will be done by some 500 persons participating as volunteers. The volunteers come from business and industry, labor and civic organizations, environmental groups, local government, public health professions, and colleges and universities.

Five additional grants have been made to various national and local groups, including the National Wildlife Federation and the Urban Environment Conference, to support programs aimed at raising the level of public understanding of toxic substances problems through the development of publications and television presentations and through workshops on specific issues.

Advisory Committee

The Administrator's Toxic Substances Advisory Committee consists of sixteen members who represent a broad variety of backgrounds, interests, and expertise. The Committee met six times during 1978 to consider pending program decisions and directions and to advise the Administrator on policy, procedural and technical matters. Substantive advice was given concerning the proposed TSCA implementation approach, premanufacture review, workforce development, international issues, risk assessment procedures, and public participation.

EPA-State Cooperative Agreements

In August 1978, the Office of Toxic Substances announced that it would enter into, and provide financial support for, EPA-State cooperate agreements to enable selected States to develop and implement projects to deal with problems created by toxic substances. A total of $3 million is available to support such cooperative agreements. States that enter into such agreements must provide at least 25 percent of the cost of approved projects.

EPA expects to enter into cooperative agreements with six to ten States. Nine States submitted applications in response to the August 1978 notice. Those applications are being reviewed. Any of the nine that do not receive an award based on these applications, plus any that apply later, will be eligible for awards during a second selection process scheduled for mid-1979.

The nine applications currently being reviewed include proposals for a variety of projects, including development of toxic substances data systems, environmental monitoring activities, epidemiological studies, development of toxic substances emergency response programs, and expansion and improvement of analytical capabilities.

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Work Force

TSCA implementation will require both EPA and the chemical industry to increase their employment of persons trained in various scientific and technical professions. In some of these professions, notably toxicology, pathology, and epidemiology, the supply of trained persons is already barely adequate to meet government and industry needs and will be further strained by increasing requirements for assessment of health hazards not only under TSCA but also under other Federal laws, including those dealing with pesticides and occupational hazards.

Thus far, EPA has been able to identify and hire qualified scientists, even in the shortage categories. Accomplishing this has required extensive recruiting efforts. In a few categories, notably veterinary pathology, industry salaries are sufficiently higher than Federal salaries to force the Agency to obtain expertise through contracts.

EPA is taking various steps to try to improve the situation. The Agency is working with the Office of Personnel Management to set up a hiring register for toxicologists; availability of such a register would make it easier to identify and hire persons qualified in toxicology. Efforts are being made to improve Agency's contacts with educational institutions to provide a better basis for recruitment. The Agency is working with various other Federal agencies to enlist their cooperation in allowing people trained in programs they support to fulfill government employment obligations by working for EPA. Also, the Agency is working with one university to develop a short course that would provide specialized training in toxicology to scientists with appropriate backgrounds; this program will be open to both governmental and nongovernmental scientists.

In addition, EPA is cooperating with the National Academy of Sciences (NAS) in a study aimed at determining whether increases in Federally supported training will be needed. Should such increases be necessary, EPA believes they should be achieved by expanding existing programs, rather than starting new ones, provided that EPA employment is considered an appropriate way to fulfill trainees' obligations to the government.

Industry Assistance

In accordance with section 26 of the Act, an Industry Assistance Office has been established in the Office of Toxic Substances to provide information to the chemical industry about TSCA requirements. The Industry Assistance Office is making a significant contribution to the chemical industry's understanding of TSCA activities.

Assistance and information are provided by various means, including a toll-free nationwide telephone service (which has handled an average of 1,300 calls per month) and distribution of TSCA rules and other documents (averaging about 4,000 copies per month). Three slide presentations have been prepared and are loaned to chemical companies. One provides an overview of TSCA, one explained the Agency's requirements for reporting of information for the TSCA chemical inventory, and one covers the Agency's proposed requirements for premanufacture notification. During the period for TSCA inventory reporting, the Industry Assistance Office held 32 seminars in 28 cities; more than 3,000 chemical industry personnel attended the seminars. In addition, Industry Assistance staff members have participated in more than 900 meetings with representatives of trade associations and individual chemical companies.

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Regional Offices

EPA's ten Regional Offices are involved in various activities that contribute to TSCA implementation. Actual enforcement of TSCA regulations is among the Regional Offices' major roles. This activity involves, among other things, inspections of regulated establishments subject to TSCA regulations, investigations of complaints, and development of cases for prosecution. Over the past year, Regional Offices also have been involved in evaluating high-temperature incinerators and chemical waste landfills to determine whether they meet the Agency's PCB disposal criteria; this effort has been coordinated by EPA's Office of Solid Waste. Regional Offices are now involved in the Agency's nationwide effort to provide technical guidance and support for State and local efforts to reduce asbestos exposures in schools.

Litigation

Thus far, relatively little litigation has been brought under the act. Only two cases have raised major issues.

In *Polaroid Corp.* v. *Costle*, No. 781133S (U.S.D.C.D. Mass.), Polaroid Corporation filed a suit in Federal district court challenging the adequacy of the protection that would be provided for certain chemical identity information the corporation was required to furnish EPA for the Chemical Substances Inventory under section 8(b) of the Act and EPA's Inventory Reporting Regulations (40 CFR Part 710, 42 FR 64572, December 23, 1977) and that it claimed as confidential business information. On June 23, 1978, the court denied Polaroid's request that it be excused from reporting the identity information but issued a preliminary injunction ordering EPA not to disclose outside the Agency any information Polaroid claimed to be confidential. The court was concerned principally with the question of release of confidential information to persons outside EPA (including Congress) without prior notice to the company that supplied the information. On September 8, 1978, EPA issued amendments to its confidential business information regulations (40 CFR Part 2, 43 FR 39997). Among other things, these regulations provide substantial protection for TSCA confidential business information and provide for notice to affected businesses before confidential information is disclosed outside of EPA. Following the issuance of these regulations, Polaroid voluntarily withdrew its suit, and the June 23 court order was vacated.

The other major litigation is a petition by Dow Chemical Company in the U. S. Court of Appeals for the Third Circuit challenging EPA regulations issued under section 8(d) of TSCA (*Dow Chemical Co.* v. *EPA*, No. 78-2203). The regulations (40 CFR Part 730, 43 FR 30984, July 18, 1978) require reporting of health and safety studies that have been conducted on the four substances and six categories of substances recommended by the Interagency Testing Committee on October 12, 1977, for priority consideration for testing under section 4(a) of the Act. Dow alleged that the 8(d) regulations exceed EPA's authority in that they required, first, listing and submittal of studies concerning a chemical substance by persons who manufactured or processed the chemical substance for product research and, second, development and submittal of studies concerning a chemical substance by persons who do not manufacture, process or distribute the chemical substance. Dow also claimed that EPA violated the Administrative Procedure Act by promulgating final 8(d) rules containing certain provisions not contained in the proposal. The Agency recently revoked the rules in question and announced its intent to issue a new set of proposed 8(d) rules. The Agency found the procedural questions raised by Dow "substantial;" however, the Agency specifically stated its disagreement with Dow's position on the proper interpretation of the statute. This case is pending.

Minor cases and their dispositions are given below:

Polaroid Corp. v. *Costle*, No. 78-1235 (1st Cir.)

Protective action, dismissed with other case, cited above.

Risdon Q-Mist Corp. v. *EPA*, No. 78-1427 (D.C. Cir.)

Joint motion to dismiss was filed January 12, 1979. Issue: Proper scope of pesticide exemption in regulations that ban most chlorofluorocarbon aerosol uses (43 FR 11318, March 17, 1978). Exemption was modified December 21, 1978 (43 FR 59500).

Duke Power Co. v. *Costle*, No.

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Problems

78-1239 (4th Cir.)
Dismissed September 12, 1978, by consent. Issue: Proper interpretation of certain provisions of the PCB disposal regulations (43 FR 7150, February 17, 1978). Clarified by *Federal Register* notice (43 FR 33918, August 2, 1978).

With TSCA, as with any major new legislation, it has been necessary to cope with many administrative and managerial difficulties, including those associated with building and housing a new and expanding organization, identifying and hiring qualified professionals, and developing efficient operating procedures and effective working relationships. EPA has not by any means resolved all such difficulties but is making reasonable progress in dealing with them.

To implement TSCA, it is also necessary to resolve many complete policy issues in areas where existing precedents, if any, often are conflicting or controversial and where there often is conflict between the general public interest in protection against unreasonable health and environmental risks and the chemical industry's interest in meeting its customers' needs and making a reasonable profit. EPA must take these competing considerations into account in virtually all TSCA decision-making, whether the question is how to define "small quantities for research and development," or how to set standards under which small chemical companies would be exempt from certain reporting and recordkeeping requirements, or how to ensure that importers and domestic manufacturers are given as equivalent treatment as possible in rules and regulations, or whether to adopt 500 or 50 parts per million as the lowest level that will be subject to the PCB regulations.

One problem that is fundamental is the tension between EPA's needs for scientific and other data for use in identifying and assessing human health and environmental risks and the chemical industry's concern about the costs of providing such data. This is a problem EPA is facing in developing requirements for testing, reporting and recordkeeping, and premanufacture notification. It is particularly troublesome in premanufacture notification, because extensive testing of new chemical substances could inhibit innovation in the chemical industry. EPA expects to issue testing guidelines that will help chemical manufacturers minimize this effect by focusing testing resources on those new chemicals most likely to present significant human health or environmental risks.

Another significant problem is the conflict between the public interest in access to data submitted under TSCA and the chemical industry's interest in protecting trade secrets. For the purpose of compiling the TSCA chemical inventory, the Agency resolved this problem by providing that chemical identities would appear in the published list except where a claim is made that disclosure of the fact that a specific chemical is being manufactured would reveal a trade secret. In the premanufacture program, the problem is more complicated because other provisions of TSCA have a bearing and because chemical manufacturers are especially interested in protecting their competitive position during the period leading up to actual introduction of a new chemical substance. EPA's proposed solution to the problem is described in the Agency's proposed rules for premanufacture notification. As rules are written under other provisions of the Act, the Agency will have to continue to deal with the data confidentiality problem.

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Appendix A

Principal Rules and Regulations and Public Notices

1. March 9, 1977. General Provisions and Inventory Reporting Requirements. 42 FR 13130. Proposed rules governing reporting for the TSCA chemical inventory.

2. April 12, 1977. General Provisions and Inventory Reporting Requirements; Supplemental Notice 42 FR 19298. Guide to the use of the candidate list of chemical substances.

3. April 21, 1977. Procedures for Rulemaking under Section 6 of the Toxic Substances Control Act. 42 FR 20648. Proposed rules.

4. May 13, 1977. Fully Halogenated Chlorofluoroalkanes — Proposed Prohibitions and Notice of CPSC Action. 42 FR 24536. Proposed rules applicable to nonessential aerosol uses of chlorofluorocarbons.

5. May 24, 1977. Polychlorinated Biphenyls (PCBs). 42 FR 26564. Proposed rules for marking and disposal of PCBs.

6. August 2, 1977. General Provisions and Inventory Requirements. 42 FR 26564. Reproposal of rules governing reporting for the TSCA chemical inventory.

7. September 9, 1977. Notification of Substantial Risk under Section 8(e). 42 FR 45362. Proposed Guidance for reporting of "substantial risk" information.

8. October 3, 1977. Supplemental Notice to Proposed Inventory Reporting Requirements; Draft Reporting Forms. 42 FR 53804.

9. October 11, 1977. Regulation of Toxic and Hazardous Substances — Interagency Agreement. 42 FR 54856. Announcement of the formation of the Interagency Regulatory Liaison Group (IRLG).

10. October 12, 1977. TSCA Interagency Testing Committee — Initial Report to the Environmental Protection Agency. 42 FR 55026. First report under section 4(e). Also see 42 FR 58777 for corrections.

11. November 30, 1977. Compensation for Public Participation in Rulemaking under Section 6 of the Toxic Substances Control Act. 42 FR 60911. Temporary rules.

12. December 2, 1977. Procedures for Rulemaking under Section 6 of the Toxic Substances Control Act. 42 FR 61259. Final rules.

13. December 23, 1977. Inventory Reporting Requirements. 42 FR 64572. Final Rules.

14. January 12, 1978. Interim Procedures for Handling Confidential Business Information. 43 FR 1836.

15. January 18, 1978. Public Information — General Provisions; Confidential Business Information under Toxic Substances Control Act and Solid Waste Disposal Act. 43 FR 2637. Proposed rules under the Freedom of Information Act.

16. January 31, 1978. Proposed Rule for Health and Safety Study Reporting. 43 FR 4073. Proposed rule under TSCA section 8(d).

17. February 17, 1978. Polychlorinated Biphenyls (PCBs) — Disposal and Marking. 43 FR 7150. Final rules.

18. February 17, 1978. Interagency Regulatory Liaison Group — Notice of IRLG Work Plans and Public Meetings. 43 FR 53804.

19. March 6, 1978. Inventory Reporting Regulations; Supplemental Clarification; Notice of Meetings. 43 FR 9254.

20. March 16, 1978. Statement of Interpretation and Enforcement Policy; Notification of Substantial Risk. 43 FR 11110. Final guidance under section 8(e).

21. March 17, 1978. Chlorofluorocarbons as Propellants in Self-Pressurized Containers — Prohibition on Use. 43 FR 11301. Final rules.

22. April 3, 1978. Security of Confidential Business Information. 43 FR 13915. Request for public comment on security procedures manual.

23. April 17, 1978. Inventory Reporting Regulations — Supplemental of Clarification. 43 FR 16147.

24. April 19, 1978. Second Report of the Interagency Testing Committee. 43 FR 16684.

25. June 7, 1978. Polychlorinated Biphenyls (PCBs) — Manufacturing, Processing, Distribution in Commerce, and Use Bans. 43 FR 24802. Proposed rules.

26. June 7, 1978. Guidance for reporting exports of PCBs and Chlorofluorocarbons. 43 FR 24818.

27. July 18, 1978. Health and Safety Study Reporting Regulations. 43 FR 30984. Final rules under TSCA section 8(d).

28. July 25, 1978. Security of Confidential Business Information. 43 FR 32186. Notice of availability of security procedures manual.

29. August 2, 1978. Polychlorinated Biphenyls (PCBs) Addendum to Preamble and Correction to Final Rule. 43 FR 33918.

30. August 4, 1978. Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties or the Revocation or Suspension of Permits. Interim and Proposed Rule of Practice. TSCA section 16(a). 43 FR 34730.

31. August 16, 1978. Health and Safety Reporting Regulations. Corrections to final rule. 43 FR 36249.

32. August 25, 1978. Approved PCB Disposal Facilities. 43 FR 38087.

33. August 28, 1978. Notice of availability of funds for cooperative agreements with States. 43 FR 38466.

34. September 8, 1978. Public Information. General Provisions; Confidential Business Information. 43 FR 39997. Final rules under the Freedom of Information Act.

35. September 15, 1978. Health and Safety Study Reporting Regulations. Extension of Reporting Deadline. 43 FR 41205.

36. September 21, 1978. Proposed exemption to chlorofluorocarbons rule. 43 FR 42770.

37. October 24, 1978. Policy for Revised Inventory Reporting; Draft Report Form. 43 FR 49687.

38. October 26, 1978. Response to Interagency Testing Committee Recommendations (October 12, 1977). 43 FR 50133.

39. October 26, 1978. Proposed TSCA Implementation Approach; Request for Public Comment. 43 FR 50139.

40. October 26, 1978. Polychlorinated Biphenyls — Notice of Approved PCB Disposal Facilities. 43 FR 50041.

41. October 30, 1978. Third Reporting of the Interagency Testing Committee. 43 FR 50629.

42. November 1, 1978. Interim Procedural Rules under Section 6 for PCBs Ban Exemption. 43 FR 50905.

43. November 17, 1978. Security of Confidential Business Information; Supplemental Clarification. 43 FR 53817.

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46. November 27, 1978. Chlorofluoroalkanes — Clarification of Final Rule (March 17, 1978) 43 FR 55241.

48. December 4, 1978. Reporting of Health and Safety Studies — Denial of Citizens Petition filed by the Manufacturing Chemists Association. 43 FR 56724.

48. December 21, 1978. Fully Halogenated Chlorofluoroalkanes — Essential use application exemptions for metered valve and total release valve devices. 43 FR 59500.

47. December 20, 1978. Approved PCB Disposal Facilities. 43 FR 59432.

48. January 10, 1979. Premanufacturing Notification Requirements and Review Procedures. 44 FR 2241. Proposed rules.

49. January 19, 1979. Revocation of Rule — Health and Safety Study Reporting. 44 FR 6099. Revocation of rule under section 8(d).

51. February 7, 1979. Notice of transfer of TSCA inventory information to contractor. 44 FR 7811.

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