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Environmental Protection
Agency

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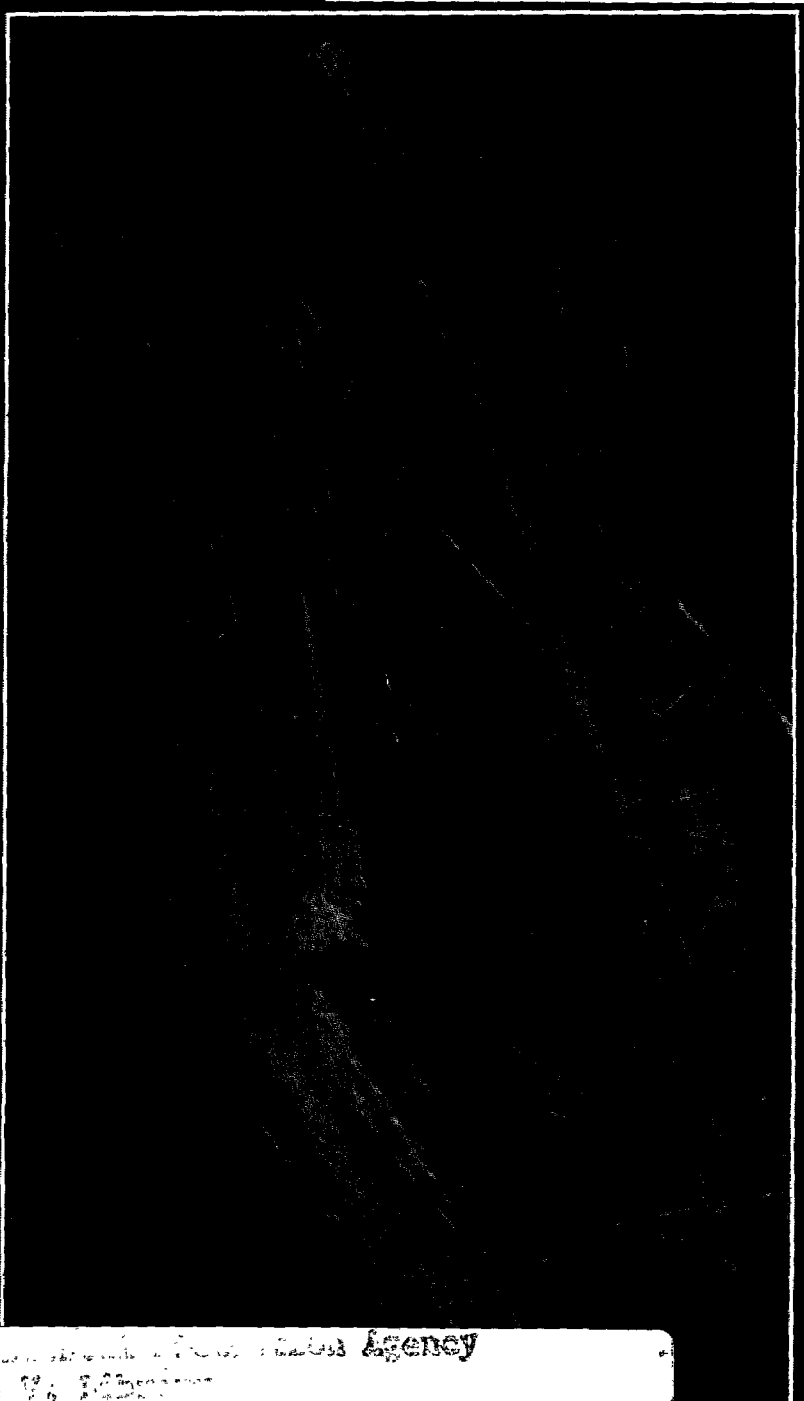
EPA

The Toxic Substances Control Act



Chemicals are all around us—in our air, our water, and our food, and in the things we touch. Many of these chemicals have become essential to our lives, and their production contributes significantly to our national economy However, for many of them we have little knowledge of the ill effects they might cause after many years of exposure. The Toxic Substances Control Act, which was signed into law in October 1976, is designed to improve our understanding of chemicals around us and to provide controls on those that may threaten health or the environment.

Background: Recognizing Chemical Risks

There has been a dramatic surge in the development of synthetic organic chemicals since World War II. Presently there are an estimated two million recognized chemical compounds. Chemical sales now exceed $100 billion per year, with over 30,000 chemical substances in commerce. To these, a thousand new ones may be introduced each year

Chemicals play an important role in protecting, prolonging, and enhancing our lives Synthetic fibers are used to replace human tissue and to create our easy-to wear wardrobe. Plastics have been molded for use in almost every phase of our activities—in transportation, communications, and industrial and consumer goods. Our leisure time has been enhanced, for example, by durable, low-maintenance pleasure boats and other recreational equipment made from plastics. Also, the chemical industry makes a significant contribution to the national economy, with sales representing more than six percent of our Gross National Product. Millions of workers are employed by the chemical industry or chemically-dependent industries.

However, while we have enjoyed the extensive economic and social benefits of chemicals, we have not always realized the risks that may be associated with them.

In the last few years, many chemicals commonly used and widely dispersed have been found to present significant health and environmental dangers Vinyl chloride, which is commonly used in plastics, has caused the deaths of workers who were exposed to it Asbestos has long been known to cause cancer when inhaled. Mercury has caused debilitating effects in Japan

Perhaps the most vivid example of the danger of uncontrolled chemical contaminants is the family of chemicals called polychlorinated biphenyls, or PCB's. It was not until after tens of millions of pounds of PCB's were produced and released into the environment, however, that scientists realized how toxic and persistent they were. Despite limited restrictions imposed in the early 1970's by industry to reduce the production and to restrict use of PCB's to electrical equipment where escape to the environment would be minimal, high levels of PCB's continue to persist in the Great Lakes and other major waters across the

Nation. Over the past few years, we have found PCB's in our bodies and even in the milk of our nursing mothers. Recently, some close relatives of PCB's, polybrominated biphenyls, or PBB's, have posed a similarly grave threat to human health and the environment. Accidental use of PBB's in animal feed led to the contamination of thousands of Michigan cattle, which had to be slaughtered. The health effects of PBB's on the Michigan farming families who were exposed to PBB's and consumed PBB-contaminated products are still uncertain.

In 1971, the President's Council on Environmental Quality developed a legislative proposal for coping with the increasing problems of toxic substances. Over the next five years, Congress held many days of hearings, debated and amended the provisions in committee, failed to resolve the differences between the House and Senate bills in the 92nd and 93rd Congresses, and finally enacted the present legislation in the fall of 1976 The law grants the U S Environmental Protection Agency (EPA) significant new authority that should greatly improve our ability to anticipate and address chemical risks before it is too late to undo the damage.

The following sections briefly describe the major provisions of the new law The discussion is intended to familiarize the public with the provisions of the law but not to constitute an authoritative legal statement of it

Scope of the Law

The Toxic Substances Control Act authorizes EPA to obtain from industry data on the production, use, health effects, and other matters concerning chemical substances and mixtures. If warranted, EPA may regulate the manufacture, processing, distribution in commerce, use, and disposal of a chemical substance or mixture. Pesticides, tobacco, nuclear material, firearms and ammunition, food, food additives, drugs, and cosmetics are exempted from the Act. These products are currently regulated under other laws.

Testing of Chemicals

The EPA Administrator may require manufacturers or processors of potentially harmful chemicals to conduct tests on the chemicals Testing may be directed to evaluate the characteristics of a chemical, such as persistence or acute toxicity, or to clarify its health and environmental effects, including carcinogenic, mutagenic, behavioral, and synergistic effects. Before requiring testing, the Administrator must set forth the need for such testing. Specifically, the Administrator must find that (1) the chemical may present an unreasonable risk to health or the environment, or there may be substantial human or environmental exposure to the chemical; (2) there are insufficient data and experience for determining or predicting the health and environmental effects of the chemical; and (3) testing of the chemical is necessary to develop such data. The manufacturers or processors of a chemical must bear costs of

testing that chemical

Testing requirements under this section must be promulgated by regulation, after opportunity for comments and an oral presentation at a hearing A manufacturer or processor of a proposed new chemical may petition the Administrator to develop testing standards for the chemical

An interagency committee of government experts on chemical substances will advise the Administrator concerning chemicals that should be tested, but his actions are not limited to those recommended by the committee The eight committee members will represent the Departments of Labor, Commerce, Health, Education, and Welfare (including the National Cancer Institute, the National Institute for Occupational Safety and Health, the National Institute of Environmental Health Sciences), the National Science Foundation; the Council on Environmental Quality, and EPA. The committee may designate, at any one time, up to 50 chemicals from its list of recommended substances for testing. Within one year, the Administrator must either initiate testing requirements for those designated chemicals or publish in the Federal Register his reasons for not initiating such requirements.

Premanufacture Notification

Manufacturers of new chemical substances must give the Administrator 90 days notice before the manufacture of the chemicals Any chemical which is not listed on an inventory of existing chemicals to be published by the Administrator will be considered "new" for purposes of the premanufacture notice requirement.

The Administrator may designate a use of an existing chemical as a significant new use, based on consideration of the anticipated extent and type of exposure to human beings or the environment. Any person who intends to manufacture or process a chemical for such a significant new use must also report 90 days before manufacturing the chemical for that use

In both of the above cases, the Administrator may extend the 90-day premanufacture review period for an additional 90 days for good cause.

Notices submitted by the manufacturers for new chemicals or significant new uses of existing chemicals are to include the name of the chemical, its chemical identity and molecular structure, proposed categories of use, an estimate of the amount to be manufactured, the byproducts resulting from the manufacture, processing, and disposal of the chemical, and any test data related to the health and environmental effects which the manufacturer has. In addition, if a rule requiring testing of the chemical or members of its chemical class has been promulgated, the manufacturer must submit test data developed

from that testing along with the other information.

The Administrator may publish a list of new chemicals or classes of new chemicals that present or may present an unreasonable risk of injury to health or the environment if they are introduced into commerce. When a manufacturer of a new chemical which is on that list submits his premanufacture notice, he must submit data which he believes show that the chemical will not present such a risk

The Administrator may determine that there is inadequate information to evaluate the health or environmental effects of a new chemical whether or not it is on the list described above In that event, he may issue an order 45 days before the expiration of the premanufacture review period to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of a chemical pending acquisition of additional data. If the manufacturer files objections to the order, the Administrator may seek a court injunction to prevent manufacturing of the chemical until data are developed which indicate that the substance does not present an unreasonable risk.

The Administrator may find that there is a reasonable basis to conclude that a new chemical presents or will present an unreasonable risk of injury to health or the environment In that event, he may follow similar procedures involving an order, and, if appropriate, court action to prohibit the manufacture of the chemical If a total ban does not appear necessary, the Administrator may propose a rule that becomes immediately effective limiting the manufacture or use of a proposed chemical or regulating its distribution in commerce, use, or disposal

For certain new chemicals, the Administrator must publish his reasons in the Federal Register if he does not initiate regulatory action during the premanufacture review period These include chemicals subject to testing requirements, those listed by the Administrator as possibly presenting an unreasonable risk, and chemicals whose use was designated as a significant new use.

Exempt from the premanufacture notification requirement are chemicals. (1) included in categories of chemical substances listed on the inventory of existing chemicals, (2) produced in small quantities solely for experimental or research and development purposes; (3) used for test marketing purposes, and (4) determined by the Administrator not to present an unreasonable risk A person must apply for an exemption described by (3) and (4) on a chemical-by-chemical basis

In addition, a person may apply for an exemption from premanufacture notification requirements if a chemical exists only temporarily and there is or will be no human or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environmental exposure This exemption is directed to chemicals which exist as the result of a chemical reaction in the manufacture or processing of a mixture or another chemical substance

Regulation of Hazardous Chemical Substances and Mixtures

The Administrator may prohibit or limit the manufacturing, processing, distribution in commerce, use, or disposal of a chemical substance or mixture if he finds that these activities or any combination of them presents or will present an unreasonable risk of injury to health or the environment. Labeling may be required for a chemical or any article containing the chemical A manufacturer may be required to make and keep records of the processes used in manufacturing a chemical and to conduct tests to assure compliance with any regulatory requirements. Further, the Administrator may require a manufacturer to give notice of any unreasonable risk of injury presented by his chemical to those who purchase or may be exposed to that substance. A manufacturer also may be required to replace or repurchase a substance which presents an unreasonable risk.

In proposing regulatory actions, the Administrator must provide an opportunity for comments by all interested parties, including an oral presentation at a hearing, and in certain circumstances, cross-examination. For those unable to afford the costs of participating in rulemaking proceedings, the Administrator may provide compensation.

A rule limiting, but not banning, a chemical may become immediately effective when initially proposed in the Federal Register if the Administrator determines that the chemical is likely to present an unreasonable risk of serious or widespread injury to health or the environment before normal rulemaking procedures could be completed However, in the case of a rule prohibiting the manufacture of the chemical, the Administrator must first obtain a court injunction before a rule can be made immediately effective.

If a chemical contains a hazardous contaminant as the result of a certain manufacturing process, the Administrator may order the manufacturer to change his process to avoid such contamination If a chemical contains a contaminant which may present an unreasonable risk of injury to health or the environment, the manufacturer may be required to give public notice and to repurchase or recall the product.

In addition, the law requires that the Administrator take action to regulate polychlorinated biphenyls, by issuing labeling and disposal regulations by July 1977, restricting the chemical's use to closed systems by January 1978, prohibiting all production by January 1979, and distribution in commerce by July 1979

For those chemicals that present an imminent and unreasonable risk of serious or widespread injury to health or the environment, the Administrator may ask a court to require whatever action may be necessary to protect against such risk

Record-Keeping and Reporting

The law authorizes the Administrator to issue rules requiring manufacturers and processors of selected chemicals to report to EPA the name of each chemical, its identity, its proposed uses, estimates of production levels, description of byproducts, adverse health and environmental data, and number of workers exposed to the chemicals Manufacturers of chemical mixtures and research chemicals are exempt from these requirements unless the Administrator determines such reporting is necessary to enforce the Act. Similarly, in the absence of a determination that reporting is necessary because of an unreasonable risk, small manufacturers are exempt from reporting except for chemicals that are subject to proposed or promulgated testing requirements or limitations under the regulatory provisions of the Act

The Administrator is required to publish a list of all existing commercial chemicals This list, which will be published initially by fall 1978 and updated thereafter, will contain all chemicals manufactured or processed for commercial purposes in the United States or imported into the United States within the last three years.

The law requires any person who manufactures, processes, or distributes in commerce any chemical substance or mixture to keep records of significant adverse reactions to health or the environment that allegedly were caused by the chemical Records concerning health effects on employees must be kept for 30 years, other records for five years

The Administrator may request any health and safety studies on specific chemicals known or available to any person who manufactures, processes, or distributes such chemicals in commerce. In addition, if such a person has information which indicates that a chemical presents a substantial risk of injury to health or the environment, he must notify the Administrator.

Relationship to Other Federal Laws

The Administrator may determine that an unreasonable risk presented by a chemical may be prevented or sufficiently reduced by action under a Federal law not administered by EPA. If he does, the Administrator will request the agency administering the other law to determine whether the risk exists and if the agency's action would sufficiently reduce the risk If the agency finds no risk or takes action directed to the risk, EPA may not take any regulatory action directed to the same risk.

The law directs the Administrator to use other laws

administered by EPA to protect against unreasonable risks, such as the Federal Water Pollution Control Act or the Clean Air Act, unless the Administrator determines that it is in the public interest to protect against such risks under the Toxic Substances Control Act

Disclosure of Data

Confidential data, such as trade secrets and privileged financial data, will be protected from disclosure by the Administrator. All health and safety information on chemicals in commerce submitted under the Act is subject to disclosure. A person submitting other types of data to EPA may designate any part of it as confidential. If the claims of confidentiality are subject to question or if the release of such data is essential for the protection of health or the environment, the Administrator shall notify the person who submitted the data in advance of any contemplated release

Civil and Criminal Penalties

Any person who fails or refuses to comply with any requirement made under the law may be fined up to $25,000 for each day of violation of the law Persons who knowingly or willfully violate the law, in addition to any civil penalties, may be fined up to $25,000 for each day of violation, imprisoned up to a year, or both

Effect on State Laws

With certain exceptions, as set forth below, the Act will not affect the authority of any State or political subdivision to establish regulations concerning chemicals If EPA issues a testing requirement for a chemical, a State may not establish a similar one. If EPA restricts the manufacture or otherwise regulates a chemical under the Act, a State may only issue requirements which are identical, mandated by other Federal laws, or prohibit the use of the chemical. In response to a request by a State, the Administrator may grant an exemption under certain conditions Specifically, the Administrator may grant exemptions if the State requirement (1) would not cause a person or activity to be in violation of a requirement under the Act, and (2) would provide a greater degree of protection and not unduly burden interstate commerce.

Actions by Citizens

Any person may bring a civil suit to restrain a violation of the Act by any party or to compel the Administrator to perform any nondiscretionary duty required by the Act In addition, any person may petition the Administrator to issue, amend, or repeal a rule under the testing, reporting, or restriction sections of the Act The Administrator has 90 days to respond to a petition. If he takes no action or denies a petition, the party has the opportunity for judicial review in a U.S. district court. In both civil suits and citizens' petitions, the court may award reasonable legal costs and attorney fees if appropriate

Exports and Imports

In the case of a chemical produced for export that presents an unreasonable risk to health or the environment of the United

States, the Administrator may regulate the chemical. He may also require testing of any exported chemical if such testing is necessary to determine whether there is such a risk to the United States. If a person is exporting, or intends to export, a chemical for which data are required to be submitted under the testing or manufacturing notification sections, he must notify the Administrator. The Administrator is responsible for notifying the governments of the importing countries of the availability of such data. Similarly, if a person is exporting a chemical subject to a regulatory order or action, he must notify the Administrator who in turn will notify the appropriate governments.

With respect to imports, no chemical substance, mixture, or article containing a chemical substance or mixture will be allowed into the customs territory of the United States if it fails to comply with any rule or is otherwise in violation of the Act.

Research, Monitoring, and Data Systems

There are several provisions in the Act that call for expanded research and related activities by EPA and other Federal agencies. The Administrator, in consultation with the Secretary of Health, Education, and Welfare (HEW), may enter into contracts and make grants for research, development, and monitoring. In addition to establishing a data system within EPA for data submitted under the Act, the Administrator is responsible for designing and establishing a system for toxicological and other scientific data accessible to all Federal agencies. The Council on Environmental Quality is responsible for studying standard classification and storage systems for chemical substances.

Other research required by the Act to be conducted by the Administrator in consultation with the Secretary of HEW concerns techniques for screening chemical effects and for monitoring chemicals. In addition, the Secretary of HEW has special responsibility related to inexpensive and efficient methods for determining the health and environmental effects of chemicals.

State Programs

The Act authorizes $1.5 million each year for grants to assist States to prevent or eliminate risks associated with toxic substances when the Administrator is unable to take action. The amount of the grant shall be no greater than 75 percent of the costs of the program. In awarding grants, the Administrator shall take into account the seriousness of the health effects that are associated with the chemical substances and the extent of human and environmental exposure to them in the State.

Enforcement of the Act

For purposes of administering the Act, the Administrator or his representative may inspect any establishment in which chemicals are manufactured, processed, stored, or held before

or after their distribution in commerce. No inspection shall include financial, sales, pricing, personnel, or research data unless specificed in an inspection notice.

The Administrator may subpoena witnesses, documents, and other information as necessary to carry out the Act.

Civil actions concerning violations on lack of compliance with the Act may be brought in a U S. district court for judicial review Any chemical substance or mixture that was manufactured, processed, or distributed in commerce in violation of the Act may be subject to seizure

Judicial Review

Not later than sixty days after a rule is promulgated, any person may file a petition for judicial review of such rule with the U S. Court of Appeals for the District of Columbia Circuit or with the U.S Court of Appeals for the circuit of his residence or business.

Employee Protection

If an employee believes that his employer has discriminated against him because of the employee's participation in carrying out the Act, he may file a complaint with the Secretary of Labor. The Secretary shall investigate the alleged discrimination and, if warranted, may order the employer to remedy the effects of any such discriminatory action. Employees and employers may obtain judicial review in the U.S Courts of Appeals.

The Administrator will evaluate the potential effects on employment of regulatory actions under the Act. In response to a petition by an employee, the Administrator may investigate and hold public hearings concerning job losses or other adverse effects allegedly resulting from a requirement under the Act The Administrator will make public his findings and recommendations.

Administration of the Act

There are several provisions that deal with general administration of the Act Among them is a provision authorizing the Administrator to require fees to defray the cost of reviewing testing data and premanufacture notifications Such fees shall not exceed $2,500 or, in the case of small business concerns, $100

As required by the Act, EPA has established an office to provide technical and other nonfinancial assistance to manufacturers and processors respecting the requirements of the Act

Finally, the Administrator will waive compliance with any provision of the Act if requested by the President for national defense purposes

Further Information

Single copies of the Toxic Substances Control Act and of this brochure are available without charge from the Printing Management Office (PM-215), Environmental Protection Agency, Washington, D.C 20460

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