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Toxic Substances

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EPA

The Toxic Substances Control Act:

An Overview of Its Authorities and Major Activities

Foreword

This handbook has been prepared by the U.S. Environmental Protection Agency's Industry Assistance Office established under the Toxic Substances Control Act of 1976 (TSCA) (Public Law 94-469).

It describes the four major activities around which EPA's TSCA authorities center:

- To gather information on chemicals;
- To require testing of chemicals identified as possible risks;
- To screen new chemicals proven to present a risk;
- To control chemicals proven to present a risk.

Within each of these four areas of authority EPA has made a great deal of progress towards TSCA's implementation. This handbook capsulizes this progress: explaining what the Chemical Substance Inventory is; what the difference between "existing" and "new" chemicals are under TSCA; what premanufacture notification means; the first chemicals recommended for priority testing; what existing health and safety data EPA can request from industry; what chemicals are already being regulated under TSCA . . . and much more.

EPA

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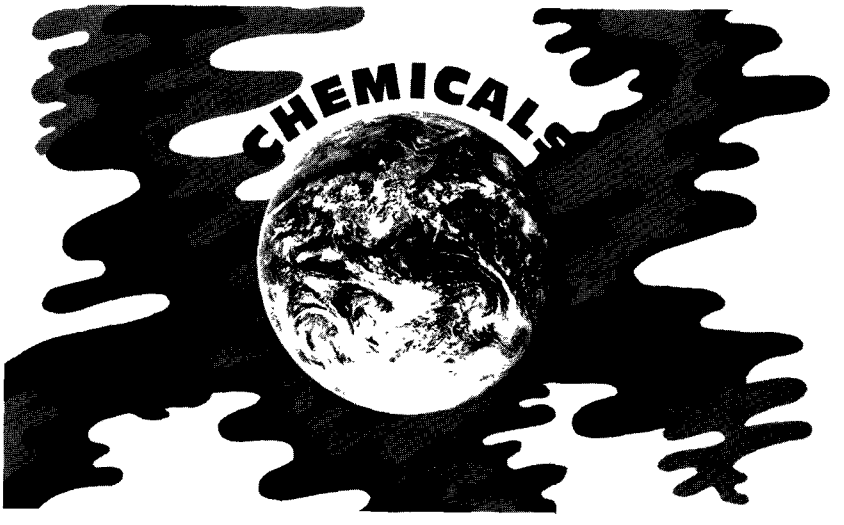
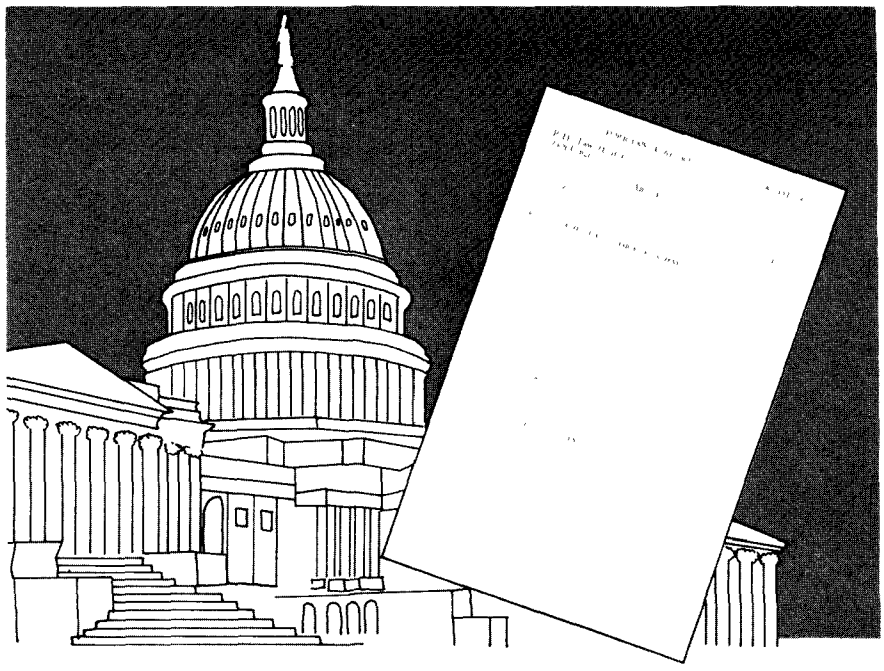
An Overview of Its Authorities and Major Activities





We live in a world in which we are surrounded by chemicals. The air we breathe, and almost everything we touch, eat, or drink contains them. Chemical products protect and enhance our lives and the environment. They are essential to modern life. Yet, we know too little about what effects many chemicals may have on human health and the environment.

Out of this concern, the Toxic Substances Control Act—known as TSCA—was enacted in 1976. Now for the first time the entire chemical industry serving the United States is subject to broad-based Federal regulation. TSCA gives the Environmental Protection Agency—E.P.A.—a broad mandate to protect public health and the environment from unreasonable chemical risks—to gather information on chemicals, to identify harmful substances, and to control those substances whose risks outweigh their benefits to society and the economy.

Although TSCA is a complex law, its basic purpose is simple: to prevent unreasonable chemical risks. It gives EPA the authority to act before harmful chemical substances threaten human health or the environment.

In May 1977, President Carter stressed the need for TSCA's preventive approach in his environmental message to Congress. He said, "The presence of toxic chemicals in our environment is one of the grimmest discoveries of the industrial era. Rather than coping with these hazards after they have escaped into our environment, our primary objective must be to prevent them from entering the environment at all."

Today more than 44,000 chemicals are made or imported for commercial purposes in the United States. Furthermore, several hundred new chemical substances may be introduced into commerce annually. Therefore, the universe of chemical substances potentially subject to TSCA is enormous . . . and growing all the time.

Eight product categories are exempt from the law's authority: tobacco, nuclear material, firearms and ammunition, substances used solely as pesticides, food, food additives, drugs, and cosmetics. These fall under the jurisdiction of other Federal laws.

TSCA is not the first Federal law to address the serious health and environmental problems associated with toxic chemicals in our society. Unlike TSCA, however, the other laws largely enable the government to take action only after widespread exposure and possibly serious harm have occurred. TSCA also fills a number of significant gaps that exist in the other laws.

Under TSCA, EPA's authorities center around four major activities. First, to collect basic information on chemical substances from manufacturers and processors—including importers. Second, to identify potentially harmful substances—and require that industry test them for adverse health and environmental effects. Third, to review all new chemicals for potential health and environmental risks before they are manufactured domestically for commercial purposes or imported into the United States. And fourth, to control unreasonable risks stemming from the manufacture, processing, distribution, use and disposal of a chemical substance.

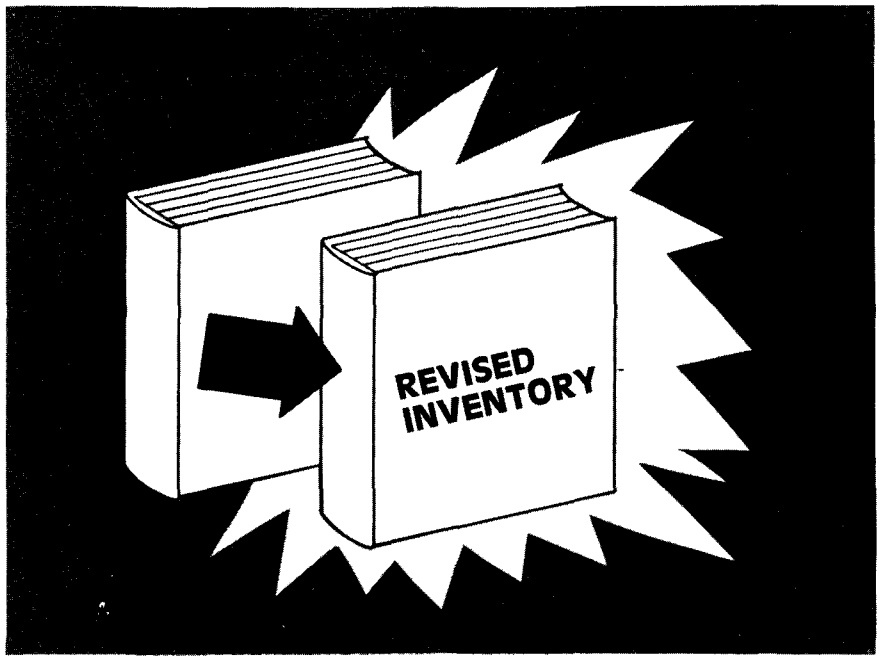
EPA's first major action under TSCA has been to assemble the nation's most comprehensive Inventory of existing chemical substances in U.S. commerce.

The Agency also has collected, for the first time, information on where these chemicals are manufactured and in what quantities. With this information, EPA can begin to select chemical substances for attention and action under TSCA. The information can also be useful to programs under other toxics-related laws, and enables EPA and others to respond far better to chemical emergencies.

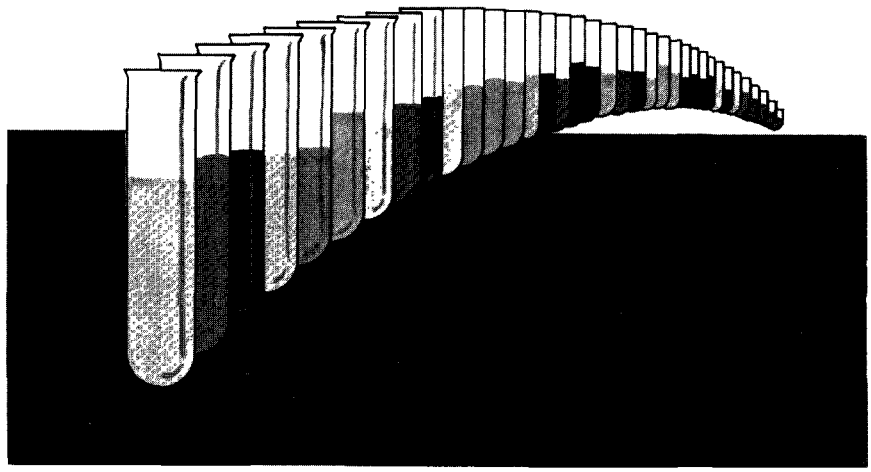
Another important reason EPA has compiled this Inventory is to delineate, for TSCA implementation purposes, between "existing" chemicals and "new" ones.

In December 1977, TSCA Inventory reporting regulations appeared in the *Federal Register*. The regulations set up a 2-phase reporting period. The first phase, now over, called for chemical manufacturers and importers to report chemicals they manufactured, or imported in bulk, for a commercial purpose since January 1, 1975. For over one year EPA compiled these submitted reports . . . which in turn, led to the June 1, 1979 publication of the Initial Chemical Substance Inventory. Listed on this Inventory is approximately 44,000 chemical substances which are manufactured or imported for a commercial purpose in the U.S.

The Initial Inventory's publication triggered the second reporting phase of 210 days—from June 1 through December 31, 1979. During this time, processors—those who buy, use, or distribute chemicals from manufacturers or importers—are to review for completion the list of chemicals reported to EPA by their suppliers and add any chemicals not there, which have been processed for a commercial purpose since January 1, 1975. Also, before, December 31, 1979, importers of chemical substances, which are part of a mixture or an article, should check the Initial Inventory and report to EPA any eligible chemicals which were not included. The reported additions will be incorporated into the Initial Inventory. A Revised Chemical Substance Inventory will be published in 1980.



The Inventory is not a list of hazardous or toxic chemicals. Rather, it is a list of all chemicals that were manufactured, imported or processed for a commercial purpose since January 1, 1975.

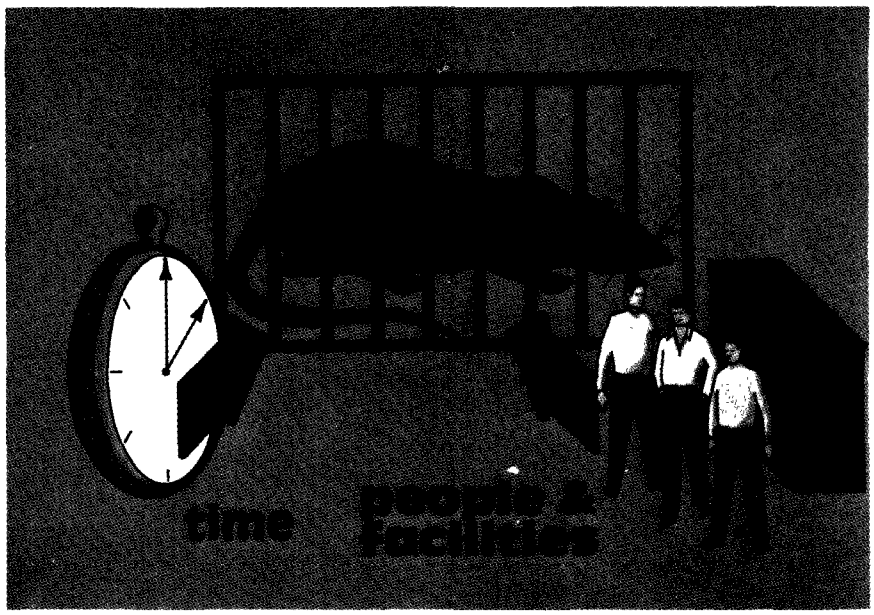


Some information submitted for the Inventory is entitled under TSCA, to confidential treatment. Persons reporting for the Inventory, whether during the initial or now during the revised Inventory reporting phase, are entitled to make confidential claims for the handling of information submitted to EPA. If the chemical identity is claimed confidential, a generic term is to be submitted by the reporter. If EPA approves the claim, the generic name is listed in an appendix to the Inventory. The specific chemical identity would not be publicly disclosed.

EPA has developed strict security procedures to safeguard confidential business information, obtained under TSCA, from unauthorized disclosure. These procedures are in the "TSCA Confidential Business Information Security Manual"—published in September 1978 and available from EPA.

A second major activity, under TSCA, is to require testing of potentially hazardous chemicals by their manufacturers and processors. These data will be used by EPA to determine if the manufacturing, processing, distribution in commerce, use or disposal of these chemicals do, or do not, present an unreasonable risk to human health or the environment.

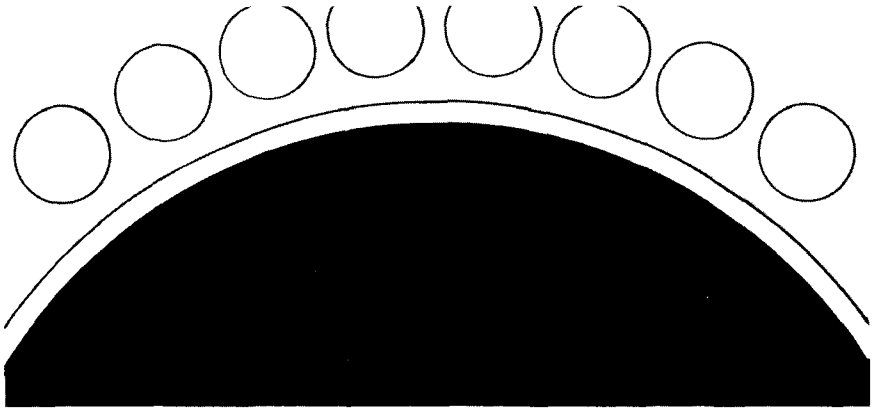
The required testing of a chemical could be to determine certain characteristics that are indicative of the risk it may present—such as its persistence, environmental fate, and ecological effects. Testing could also be required to determine specific health effects of the chemical—such as, its carcinogenicity, mutagenicity, teratogenicity, or behavioral toxicity.



EPA proposed on May 9, 1979 the first testing standards for oncogenicity, and other chronic effects, as well as for good laboratory practices concerning health effects testing. The remaining health effects standards—acute and subchronic toxicity, mutagenic effects, teratogenic reproductive effects, and metabolism studies—were proposed on July 26, 1979. The first environmental testing standards will be proposed in late 1979.

A chemical will be selected for testing because available data on its effects show that it may present an unreasonable risk, or because the chemical is known to have substantial human exposure or environmental release. In either case, EPA must show both that existing data on the chemical's effects are insufficient for determining the risk, and that testing is necessary to develop the needed data.

In requiring testing, EPA must identify the chemical to be tested, specify the standards for development of the test data, and indicate the time period within which the test results are to be submitted to EPA. In determining these testing rules, EPA must consider the relative cost factors of the various protocols that could be used to develop the needed data, and also the foreseeable availability of test facilities and personnel for performing the tests.



Identifying chemicals for testing is one of EPA's major tasks under TSCA. To complement this effort, TSCA established the Interagency Testing Committee to recommend chemicals to EPA for priority testing. The ITC, formed in February 1977, includes representatives of eight Federal Agencies.

Chemicals Recommended for Priority Testing by ITC

Acetonitrile
Acrylamide
Alkyl epoxides
Alkyl phthalates
Aniline and bromo, chloro, and/or nitroanilines
Antimony (metal)
Antimony sulfide
Antimony trioxide
Aryl phosphates
Chlorinated benzenes, mono- and di-
Chlorinated benzenes, tri-, tetra- and penta-
Chlorinated naphthalenes
Chlorinated paraffins
Chloromethane
Cresols
Dichloromethane
1,2-Dichloropropane
Cyclohexanone
Glycidol and its derivates
Halogenated alkyl epoxides
Hexachloro-1,3-butadiene
Hexachlorocyclopentadiene
Isophorone
Mesityl oxide
4,4'-Methylenedianiline
Methyl ethyl ketone
Methyl isobutyl ketone
Nitrobenzene
Polychlorinated terphenyls
Pyridine
Toluene
1,1,1-trichloroethane
Xylenes

The ITC can designate a priority list of up to 50 chemicals for special consideration by EPA. Within 12 months of an ITC recommendation, EPA must either initiate rulemaking proceedings to require testing, or publish reasons for not doing so. In selecting chemicals for the priority list, the ITC is to consider the extent of human exposure and environmental release of the chemicals, as well as all available information on their health and environmental effects. TSCA directs the Committee to give special attention to chemicals known or suspected of causing cancer, gene mutations, or birth defects.

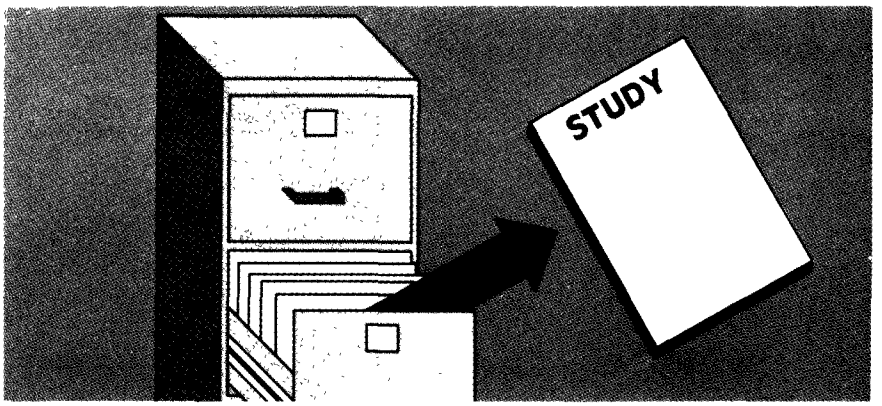
The ITC published its initial priority list in the Federal Register in October 1977. Four individual chemicals and six chemical categories were recommended. Since then the Committee has amended the initial priority list with three additional reports—recommending that 16 more individual chemicals and 7 categories be considered for priority testing.

EPA plans to propose the first health effects testing rule in December 1979 for some of the chemicals and groups of chemicals recommended by the ITC. Chemicals selected through EPA's own process and other sources, of course, also will be subject to testing rules.

Under TSCA, EPA also has broad authority to require that chemical manufacturers report certain kinds of information, and maintain records, on the hazards of particular substances.

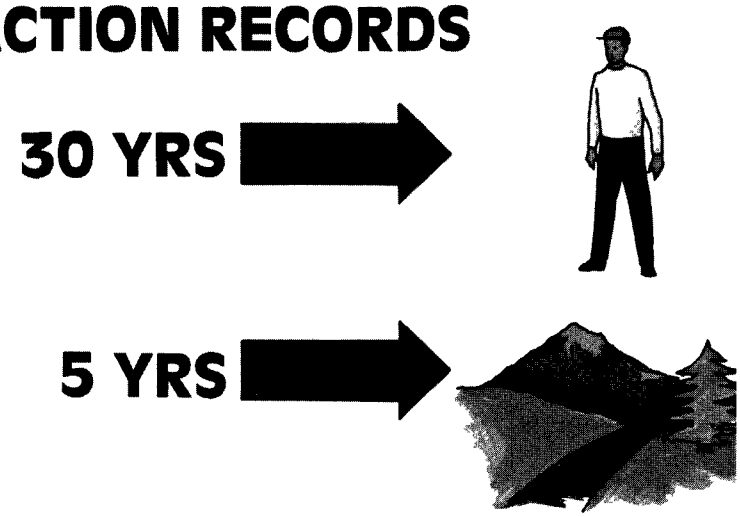
In March 1978 a general policy statement was issued concerning TSCA's substantial risk notification procedures—requiring anyone who has information, which reasonably concludes that a chemical substance presents a substantial risk of injury to health or the environment—to immediately notify EPA.

In July 1978, EPA published its first rule to obtain copies or lists of health and safety studies from any person who manufactures, processes, or distributes certain chemical substances identified in the Interagency Testing Committee's first report. The studies submitted were those initiated, conducted, or simply known about by a person.



In late 1979, the Agency will propose procedures for submitting health and safety studies. This rule, to be finalized by mid-1980, will serve as a model for health and safety study submission requirements for chemicals selected by the Agency for evaluation for testing rules or other regulation.

SIGNIFICANT ADVERSE REACTION RECORDS



In mid-1980 EPA will publish rules requiring manufacturers, processors, and distributors to keep records of "significant adverse reactions" to health and the environment alleged to have been caused by a chemical substance. Under the law, records of alleged employee health effects must be kept for 30 years. All other records of alleged adverse reactions—including consumer and environment effects—must be kept for 5 years. The proposed version of these rules is to be out late in 1979.

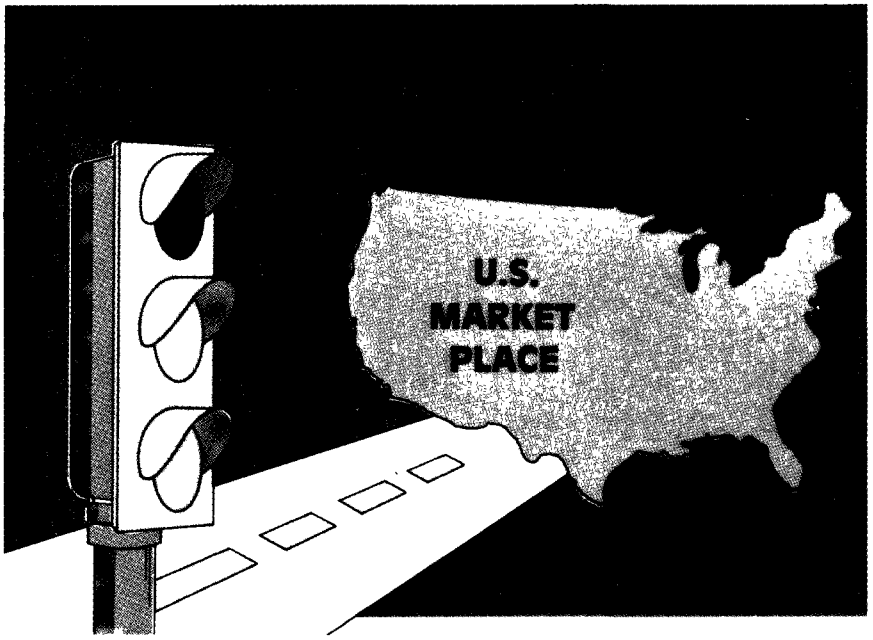
Also, to be proposed in late 1979, are rules under which chemical manufacturers and processors can be required to maintain and report information on the identity, structure, uses, worker exposure and other factors of a chemical needed to identify and assess potential problems and support control actions under TSCA or other federal laws.

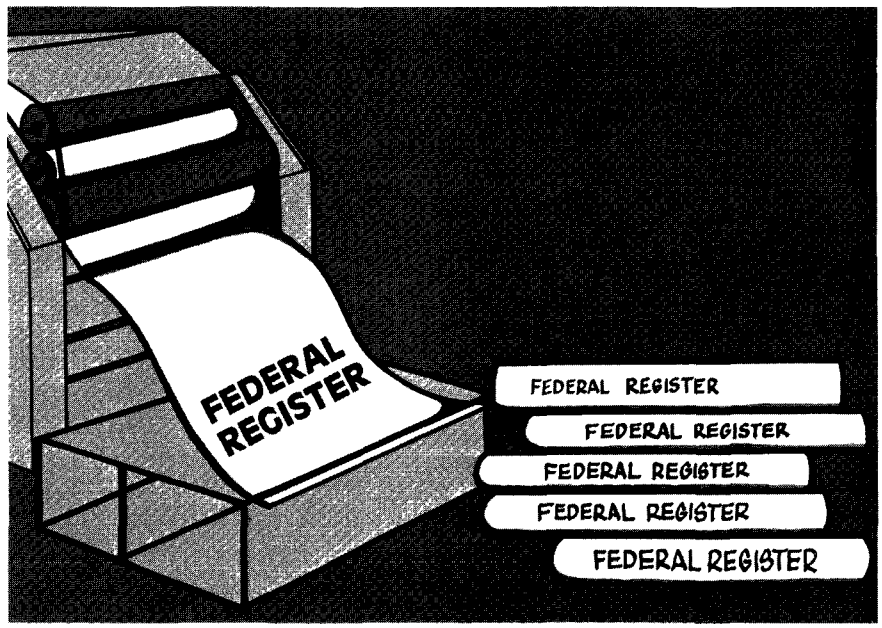
EPA's third major activity, under TSCA, concerns the important premanufacture notification program—which began in July 1979. This "screening" process requires some fundamental changes in the way the chemical industry has operated in the past.

The premanufacture notification review process concerns "new" chemical substances only. New chemical substances are those not listed on the Inventory. Implementation of premanufacture notification is staggered—due to the two-phase reporting method used for the Inventory collection.

Manufacturers of new chemical substances, and importers of new chemical substances in bulk form—that is, substances not listed on the Initial Inventory—became subject to premanufacture notification requirements on July 1, 1979. Proposed premanufacture notification regulations were published in the January 10, 1979 Federal Register. The number and nature of comments received on these proposed rules delayed EPA from publishing final regulations by July 1, 1979. Therefore, interim premanufacture notification procedures appeared in the May 15, 1979 Federal Register. Manufacturers and importers of new chemical substances are to follow these, beginning July 1, until the final rules are released and become effective.

Importers of new chemical substances in mixtures become subject to premanufacture notification requirements 30 days after the 1980 Revised Inventory's publication. Importers of new chemical substances in articles are not now covered under TSCA's premanufacture notification procedure. And, after the Revised Inventory is published in 1980, it will be unlawful for persons to knowingly process or use for a commercial purpose a "new" substance which has not first passed through premanufacture notification. Note that processors, themselves, are not subject to premanufacture notification—but they cannot knowingly use for a commercial purpose a substance that a manufacturer or importer has not first put through TSCA's premanufacture notification review procedure.





Certain information is required to be submitted with all premanufacture notices for the 90-day review by EPA: the common or trade name; the chemical identity and molecular structure; estimated production amounts; proposed use categories; methods of disposal; workplace exposure levels; and a description of byproducts, impurities and other related products. Also, all test data on health and environmental effects related to the manufacture of the substance within the submitter's possession and control, as well as, a description of known or reasonably ascertainable data is required.

EPA cannot require all manufacturers of all new chemicals to generate new test data for a premanufacture notice. EPA, however under TSCA, can require testing for selected chemicals for reasons mentioned earlier—such as insufficient risk evaluation data. If EPA imposes such a requirement, the test data must be submitted with the premanufacture notice. If EPA does not impose such a testing requirement, specific testing is then not required.

Immediately upon receipt of a premanufacture application, EPA must publish notice of its receipt in the Federal Register. For "good cause," such as the need for more data, EPA can order the notification period extended up to an additional 90 days. The review period would then become 180 days.

If the Agency issues an order regulating a substance because not enough information on health and environmental effects has been submitted—even after the extended review period—and the manufacturer objects to the order, EPA can go to a Federal District Court and seek an injunction. The injunction would limit the commercial use of a chemical substance, named in a premanufacture notice, until sufficient data is received to evaluate the risk to health and the environment.

EPA's fourth major activity, under TSCA, is to control chemical substances found to pose an unreasonable risk to human health or the environment. EPA may prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of a chemical. Action under TSCA can range from a complete ban to a simple labeling requirement.

When EPA proposes restrictive regulations on a substance, it must also publish the basis for action in the Federal Register: the effects and exposure amounts to human health and the environment; the use benefits and availability of substitutes; and the economic consequences of such a ruling on the national economy, small business, and technical innovation.

Although there are many other candidates for attention, the only class of chemicals actually named in TSCA for regulation and eventual banning is polychlorinated biphenyls. PCBs are potentially harmful because once released into the environment they do not break apart into new chemical arrangement. In addition, PCBs tend to accumulate

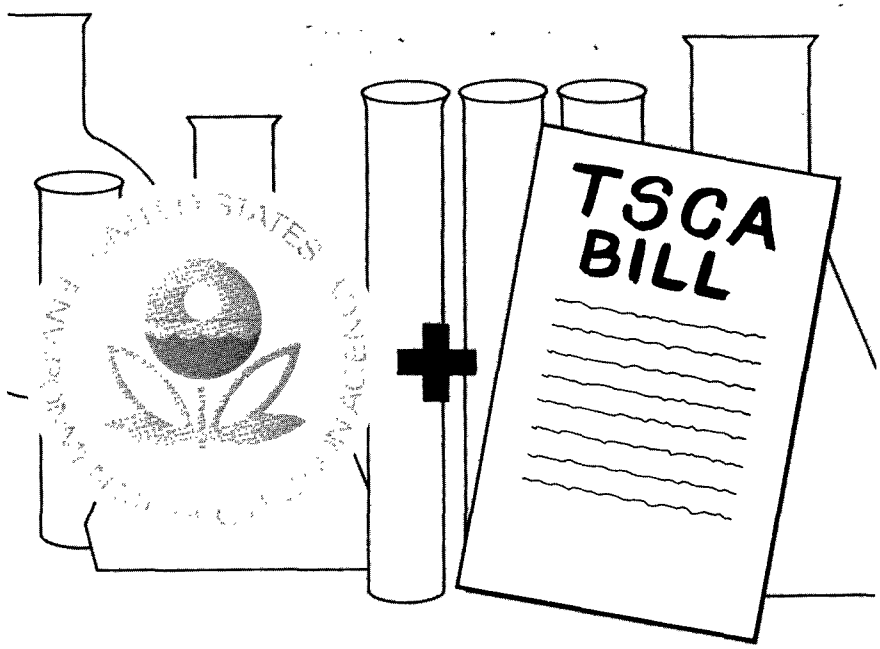
in the tissues of living organisms. This means as PCBs move up in the food chain towards man their concentration increases. Tests show that PCBs cause, among other things, reproductive failures, gastric disorders, skin lesions, and tumors in laboratory animals.

On May 31, 1979 EPA published the Final PCB Ban Rule. Effective as of July 2, 1979, this regulation bans, with certain exceptions, the manufacture, processing, distribution and use of PCBs in other than a totally enclosed manner.

Examples of totally enclosed PCB uses, allowed to continue after July 2, are television sets, air conditioners, and microwave ovens. These items contain PCB components, such as PCB capacitors, but their normal continued use will not result in any exposure to human beings or their environment.

EPA and TSCA also played a major role, along with the Food & Drug Administration and the Consumer Product Safety Commission, in issuing a rule which prohibits chlorofluorocarbons to be used in aerosol products. 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. It is this radiation which has been correlated with skin cancer in humans, and adverse effects to plants and animals. EPA is currently investigating whether to proceed with additional regulation of nonaerosol uses of CFCs, including their use in refrigeration and cooling systems, in the manufacture of foamed material, and as solvents. If a decision is made to further control CFCs, the regulations will be issued under the Clean Air Act, rather than TSCA.



In summary, in its first 3 years the Agency has taken a number of major steps to implement TSCA . . . but much important work remains ahead. Polychlorinated biphenyls and chlorofluorocarbons are now being regulated under TSCA rules. In the future, other chemicals that pose unreasonable risks to health and environment also will be. Priority testing is being planned for those chemicals about which we know too little. Much important information on chemicals manufactured and imported for commercial purposes has been centrally compiled. The Initial Chemical Substance Inventory was published in June 1979, and its revised edition will be out in 1980. And a procedure began in 1979, to evaluate new chemicals before they enter into commercial use. Manufacturers and importers of new chemicals became subject to interim premanufacture notification procedures on July 1, 1979.

TSCA provides the opportunity to better understand the chemicals around us. It also protects the public from unreasonable health and environmental risks. But these goals cannot be achieved in a "vacuum." Consideration also must be given to the continued vitality of our nation's chemical industry.

Thus, in order for TSCA to work, and work effectively, it will take the cooperative efforts of industry, government and the public. We all want essentially the same thing—and it happens to be the mandate of the Toxic Substances Control Act—for the chemicals we continue to use and produce, and for those which are newly introduced, to be as safe as possible.

To obtain copies of any of the publications referenced in this handbook or for further information on TSCA contact the Industry Assistance Office within EPA by . . .

Calling toll free: 800-424-9065
(in Washington, D.C.—554-1404)

or

write to: Industry Assistance Office
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