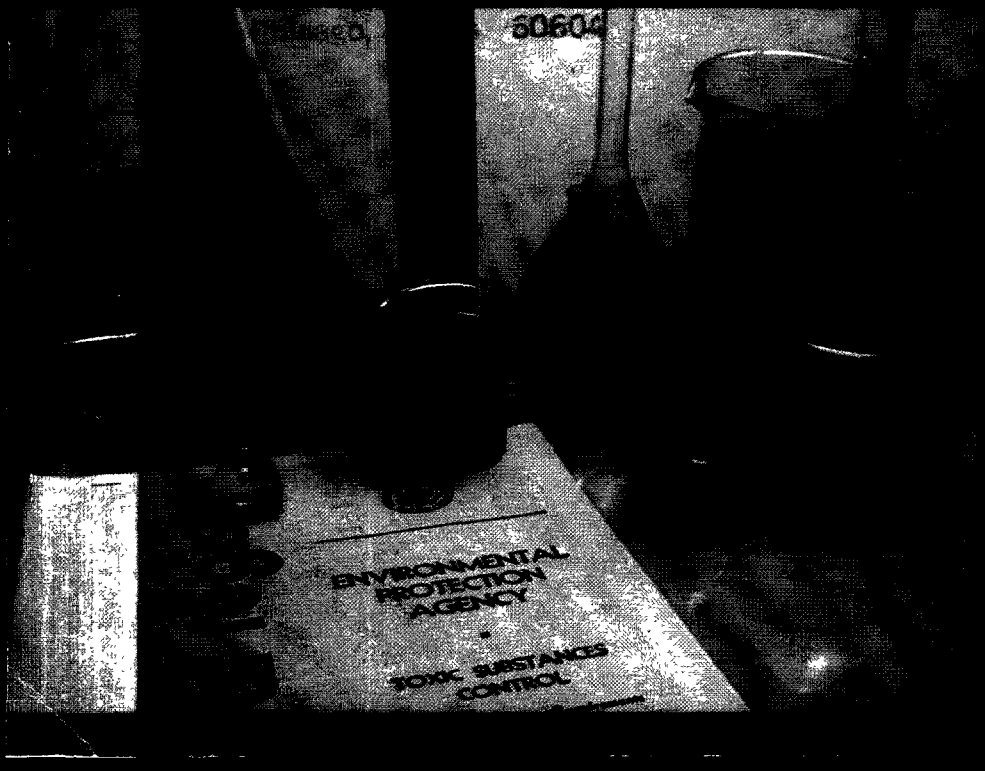
United States
Environmental Protection
Agency

Office of
Toxic Substances
Washington DC 20460

July 1980

The Toxic Substances Control Act

Protecting People and the Environment from Dangerous Chemicals



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ntroduction

Chemistry has indeed given us "better things for better living," as proclaimed a few years ago in a popular advertising slogan.

Chemicals—those found in nature and those created in laboratories—are at the heart of our highly industrialized, technology-based society. They help to protect our health, and to fend off pests. Chemicals help clothe, shelter, and feed us. They are found in innumerable products for our homes, businesses, and industry.

Chemicals are everywhere—in the air we breathe, in the water we drink, in the food we eat, in the plastics, drugs, paints, pesticides, fertilizers, fibers, dyes, detergents, perfumes, explosives, insulation, pipes, phonograph records, and other products we use.

In brief, chemicals are a vital part of our lives; they protect, enhance, and prolong it. And chemicals are a vital part of our national economy: sales of chemicals and allied products in the United States now exceed $146 billion a year, and chemical companies employ some 1.1 million people.

But some chemicals are dangerous—toxic. They can cause illness, and can kill people and other living organisms. Some can harm right away, when inhaled, swallowed, or brought into contact with the skin. Others take their toll over time, affecting the nervous system, causing cancer, birth defects, or genetic mutation—perhaps years after exposure to the substance occurred. Some chemicals are nondegradable, persisting indefinitely in nature; these can accumulate in living things, and work their way into the food chain.

Of course, not all chemicals fit into one of these toxic categories. Many are perfectly safe to humans and the environment if used properly. But what about the rest? Which are of concern and why? Where are they found, and how are people and the environment exposed to them? Many of these questions cannot yet be answered—and therein lies the enormous task facing our society today in coming to grips with the role that chemicals play . . . for better or worse . . . in each of our lives.

Nearly 20,000 chemical compounds may pose some kind of potential toxic risk to human health or the environment. Evidence exists showing that hundreds of these may cause cancer in humans. Because cancer is America's second leading cause of death, topped only by heart disease, much public attention has been focused in recent years on the relationship between chemicals and cancer. While other factors such as cigarette smoking, diet, and consumption of alcoholic beverages also are involved, there is little question that exposure to chemicals—on the job, in our water supplies, in the air we breathe, in the cosmetics we use, and in the food we eat—plays an important role in contributing to our country's alarming cancer rate.

In recent years, there has been a

seemingly unending series of tragic developments involving toxic substances. Consider the following examples:

Asbestos

Asbestos once was considered a health risk only for workers who handled it. Now it is known to be a potential hazard to the health of millions of people, on and off the job, who are routinely exposed to asbestos fibers in the air they breathe. Among those whose health may be endangered are children, teachers, and others in schools where asbestos was sprayed or troweled on ceilings, rafters, beams, and other structural building parts for fire-proofing, insulation, sound-deadening, or decoration.

Asbestos fibers are chemically inert and heat resistant, and they cannot be destroyed. These characteristics have made asbestos very useful for fire-proofing and insulating homes and all kinds of public and private buildings. Other asbestos products include reinforced asbestos cement sheets and pipes, pipe insulation, roofing felt and shingles, floor tiles, patching and taping compounds, brake linings, clutch facings, insulating paper, and protective clothing. Some 800,000 tons of asbestos are mined or processed in the United States each year to make about 3,000 different products, two-thirds of which are used in the construction industry.

Unless it is completely sealed into a product, as in asbestos floor tile, asbestos can easily break into a dust of tiny fibers. These fibers, much smaller and more buoyant than ordinary dust particles, float almost indefinately in the air and can easily be inhaled or swallowed. Once the fibers enter the body, they cause a number of serious diseases:

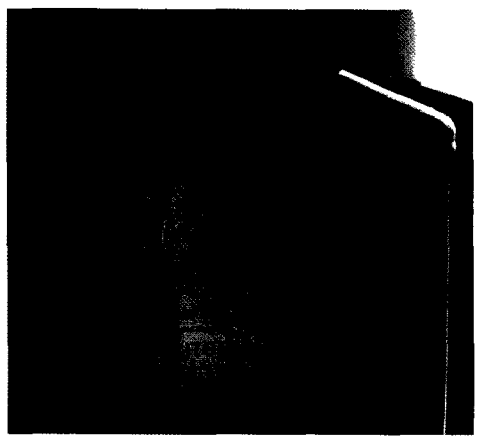
- **Asbestosis,** a chronic disease of the lungs that makes breathing more and more difficult and can cause death.

- **Cancer.** Breathing asbestos fibers can cause lung cancer. Also, since some of the asbestos fibers are rejected by the lungs, and move up to the throat and are swallowed, breathing asbestos also can cause cancer of the esophagus, stomach, intestines, and rectum.
- **Mesothelioma,** a cancer of the membranes that line the chest and abdomen. Mesothelioma almost never occurs in people who have not been exposed to asbestos. It always is fatal.

Once asbestos gets into the body, it remains there indefinitely. It can move from the lungs to almost all other parts of the body, including the brain and the sex organs. Cancer can occur anywhere from 15 to 40 years after the first exposure. No safe limit or "threshold" of exposure is known. Any exposure to asbestos carries some risk to health, and people exposed to low levels of asbestos for a very brief period have later contracted mesothelioma.

Finally, anyone exposed to asbestos who also smokes cigarettes has five times the chance of contracting lung cancer than a cigarette smoker who has not been exposed to asbestos.

The Occupational Safety and Health Administration has established limits for worker exposure to asbestos on the job. The Food and Drug Administration is responsible for making sure that foods, drugs, and cosmetics are not contaminated with asbestos. And the Consumer Product Safety Commission (CPSC) regulates asbestos in consumer products. EPA prohibited the spraying of asbestos materials for fire-proofing and insulation in 1973, banned the use of asbestos that can crumble in pipe and boiler coverings in 1975, and prohibited virtually all uses of sprayed asbestos materials in 1978. In addition, EPA is investigating the cumulative effects on public health of exposure to asbestos—from the time it is mined and milled, through processing and product manufacturing, use and disposal. And EPA also is considering banning all non-essential uses of asbestos and asbestos products. To safeguard the health of school children, teachers, and others who work in schools, EPA has launched a nationwide technical assistance program to help States and school districts identify schools where deteriorating asbestos-containing material should be removed or sealed.



Kepone

In 1950, two employees of the Allied Chemical Company filed a patent for Kepone, a gray insecticide powder. By 1965, Allied Chemical was manufacturing and selling small amounts of Kepone. Then demand increased, and in 1973, a small company, Life Sciences Products, contracted to produce Kepone for Allied Chemical. Life Sciences began production at a converted gasoline station in Hopewell, Virginia in early 1974.

In July 1975, an employee at the Kepone plant in Hopewell went to his private physician, complaining of tremors, weight loss, and nervousness. He could barely hold a cup of coffee, and his eyes moved uncontrollably. Other employees at the Kepone plant had similar symptoms; they had been told by company and other doctors that they had a bad case of "nerves". But this employee's doctor suspected otherwise. He sent a sample of the Kepone plant employee's blood to the U.S. Government Center for Disease Control. The results triggered an investigation that uncovered a monumental horror story.

The Kepone plant employee's blood contained 7.5 parts per million of Kepone—dangerously high. Other employees at the plant were also very sick; about 30 had been in and out of the hospital. More than 200 men, women, and children in the area had detectable levels of Kepone in their blood. Over 50 had "Kepone sickness"—severe tremors, uncontrollable twitching of the eyes, liver damage, and reproductive effects including the future possibility of becoming sterile. There was also the danger of cancer, because Kepone had been shown to cause cancer in test animals.

The Kepone tragedy went far beyond the plant employees and their families. Kepone was found in the James River, which flows past the Hopewell plant. The contamination was severe enough to compel the closing of the entire James River to commercial fishing, depriving 3,800 people of their livelihood. Kepone also contaminated fish in the Chesapeake Bay, and was found in wildlife and birds, especially those that feed on fish.

The Kepone plant was shut down by the State. But it had taken an enormous toll, whether measured in human tragedy and suffering, environmental damage, or financial loss. However, it need not have

happened, for the human and environmental impacts of Kepone were known and ignored by the chemical's producers. They did little, if anything, to protect the plant employees from Kepone and to keep the toxic chemicals out of the air, land, and water.

After the dimensions of the Kepone story became known, the U.S. Environmental Protection Agency estimated that the Hopewell plant could have been made safe with an initial investment of about $200,000. Instead, the damage to people and the environment already totals many millions of dollars and may reach the billions.

Tris

After the U.S. Department of Commerce established mandatory flameproofing standards for children's pajamas and nightgowns in 1972, a fire retardant chemical, called Tris, was developed by industry. It soon was used in about half of the children's sleepwear sold in the nation. In 1973-74, the first year flame-proofing was mandatory, children's burns and deaths from clothing fires declined. But then, EPA-funded researchers at Columbia University discovered that Tris could cause mutations or changes in cells. And the National Cancer Institute found that Tris was a highly potent cancer-causing agent in test animals. Researchers also found that the chemical could be absorbed through the skin. In April 1977, the Consumer Product Safety Commission halted the production and sale of Tris-treated clothing. In an effort to protect children from fire, millions had been exposed to the risk of cancer.

Polychlorinated Biphenyls (PCBs)

PCBs range in consistency from oily liquids to waxy solids and were developed primarily for use as a coolant in electrical equipment—transformers, capacitors, electromagnets, and heat transfer and hydraulic systems. They have also been used as plasticizers in paints, adhesives, and caulking compounds; fillers for casting waxes, and dye carriers in carbonless copy paper. Only after an estimated 450 million pounds of PCBs had entered the environment was it discovered that they cause skin lesions, swollen limbs, eye and liver problems, and may cause cancer and birth defects. PCBs also tend to become more and more concentrated as they move up the food chain, and they are extremely slow to break down in the environment. Like PCBs' distant cousin, DDT, they now are everywhere in the environment contaminating fish in rivers and lakes, cattle, chickens, and food products. More than half the people in the United States have some PCBs in their bodies. The dangerous, persistent chemical is now banned from being made in this country, and has been permitted to remain only in existing, in-service electrical transformers and certain other limited industrial uses.

These incidents are but a few of many. Too often in the past, chemical products were put on the market with little or no awareness of their impact on human health and the environment. In recent years, catastrophies associated with DDT, DBCP, vinyl chloride, thalidomide, asbestos, lead, mercury, Kepone, Tris, PCBs and other toxic substances have captured considerable national attention and concern.

To help prevent similar problems in the future, Congress in 1976 enacted the Toxic Substances Control Act (TSCA), which directs the U.S. Environmental Protection Agency (EPA) "to regulate chemical substances and mixtures which present an unreasonable risk of injury to health and the environment."

EPA already had the authority, under laws enacted earlier, to regulate discharges of toxic substances in waterways and drinking water, emissions of toxic substances in the air, the disposal of toxic and hazardous solid wastes, and the adverse effects of pesticide products.[1] But under these laws, EPA's authority was limited to controlling toxics after damage occurred, placing the Agency in a position only to react to toxic problems rather than to prevent them from occurring. Also, the other laws did not allow for the screening of toxic substances before they entered the market place themselves, or as components of products.

TSCA is one of the most important public health and environmental laws ever enacted by Congress. It closes the gaps in earlier laws, and requires that the health and environmental effects of all new chemicals be reviewed before they are manufactured and put on the market. Also, for the first time with TSCA's authorities, the Federal government can gather information on chemical substances needed to determine their potential for damaging human health and the environment, and to control them, where necessary, to protect the public.

While TSCA cannot prevent human error, it should make future chemical catastrophes much less likely.[2] TSCA's enactment marks a recognition that we live in a chemical age, and that age may be a mixed blessing.

This booklet outlines, in nontechnical language, the programs enacted by Congress in TSCA to protect health and the environment from toxic substances.

[1]The five major Federal laws, enacted prior to TSCA, under which EPA works to control hazardous chemicals, are (1) the Clean Water Act (CWA), (2) the Safe Drinking Water Act (SDWA), (3) the Clean Air Act (CAA), (4) the Resources Conservation Recovery Act (RCRA), and (5) the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)

[2]Eight categories of products are exempt from TSCA, because they are regulated under other Federal laws They are tobacco, nuclear materials, firearms and ammunition, food, food additives, drugs, cosmetics, and pesticides (which EPA regulates under FIFRA)

The Law

The U.S. Environmental Protection Agency (EPA) administers the Toxic Substances Control Act (TSCA). The purpose of TSCA is to identify and control chemicals that pose an unreasonable risk to human health or the environment. Essentially, this is done in four major ways.

First, needed information on chemicals is developed and gathered by EPA . . . Congress recognized during its discussion on TSCA that very little was known about chemicals in the environment. In fact, when the law was passed it was not even known how many chemicals there were, in what quantities they were produced and where, what their byproducts were, who was exposed to them and under what conditions. This information was available only for a handful of existing chemicals. Therefore, Congress gave EPA the authority to compile an inventory of existing chemical substances, and to develop additional information on these basic questions.

The first inventory was published in 1979, based on information reported to EPA by chemical manufacturers, importers, and processors. The inventory—which will be revised and kept current—shows that nearly 50,000 commercial chemical substances are manufactured or imported into the United States. (There are well over 4 million known chemical compounds, but most are research and development chemicals that are not used commercially.)[3]

It is important to note that the chemical inventory is not a list of toxic or hazardous chemicals. Rather, it lists existing chemicals by their specific chemical name (e.g., acetonitrile, bromobenzene, chloromethane, etc.), giving for the first time an overall picture of the chemicals used for commercial purposes in the United States. In addition to being unprecedented, this list is of major importance because chemicals not on the inventory must first be reviewed by EPA for hazardous health and environmental effects before they are allowed into U.S. commerce.

[3]The authority to gather information and control chemicals, under TSCA, extends only to those used for commercial purposes in the United States; research and development chemicals are not covered until their introduction into the U S marketplace

Second, industry is required to provide information (e.g., testing, existing health and safety data) on how chemicals affect human health and the environment . . .

Congress determined in TSCA that adequate information should be developed on how chemicals affect health and the environment, and that those who manufacture and process commercial chemicals should be the ones responsible for developing this information. EPA can issue rules requiring industry to test particular chemicals, and issues testing standards specifying the procedures to be used in conducting tests for certain health and the environmental effects.

To help the Agency determine which potentially toxic chemicals should be tested first, Congress through TSCA created the Interagency Testing Committee (ITC).[4] The ITC identifies and recommends to EPA chemicals it believes warrant priority consideration for health and environmental effects testing.

EPA also has a comprehensive chemical assessment process during which the full range of adverse effects and exposure sources to human health and the environment are identified. This multi-staged process helps select chemicals likely to present significant and unreasonable risks, as well as those for which more additional information, such as through testing, is needed.

Determining which chemical substances need to be tested is a complex job. And the testing itself can be expensive, depending on what the testing is. For example, it takes a team of scientists 2 to 3 years, some 300 laboratory animals, and $300,000 to determine if a single suspect chemical may cause cancer, birth defects—such as cleft palate or mental retardation—or increased abnormalities—such as those suffered by the children of women who took the drug thalidomide.

When the danger signals are present, the testing must be done to prevent more Kepone, PCB, and thalidomide-like tragedies.

TSCA authorizes EPA to require the submission of existing health and safety information by industry and others. This also is a very important way for EPA to determine what information already has been gathered on chemicals, and what gaps exist that may be filled through follow-up efforts. Specifically, anyone who has information that reasonably concludes that a chemical presents a substantial risk of injury to health or the environment must immediately notify EPA. Also, the chemical industry (manufacturers, processors, and distributors) is to keep records of "sig-

[4]The ITC is composed of representatives of the Council on Environmental Quality, the Department of Commerce, the National Science Foundation, the National Institute of Environmental Health Sciences, and the National Institute for Occupational Safety and Health, and of non-voting observers from the Department of Defense and Interior, the Food and Drug Administration and the Consumer Product Safety Commission

nificant adverse reactions" to health and the environment alleged to have been caused by a chemical. 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 environmental effects—must be kept 5 years. EPA has the authority to request copies or lists of these records at any time, as well as to ask for all existing health and safety data on specific chemicals as needed.

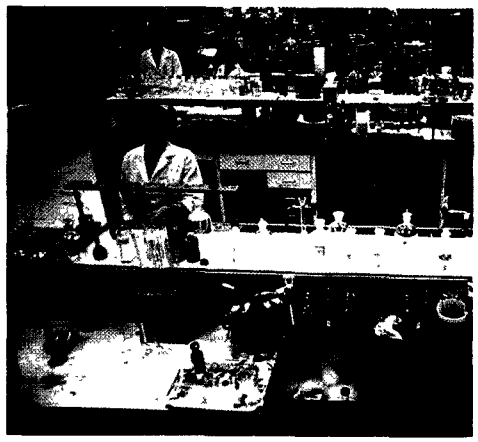
A chemical may be selected for testing because available data on its effects show that it may present an unreasonable risk, or because the chemical is known to have substantial human exposure or environmental release. In either case, EPA must show that existing data on the chemical's effects are insufficient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

Third, chemicals are controlled that pose unreasonable risks to health and the environment . . .

If the risks of a chemical outweigh its benefits to health and the environment, EPA can take a variety of regulatory actions. Regulation may range from labeling requirements and warnings; to limiting the handling, use, or distribution of a chemical, to an outright ban on the manufacture and processing of the chemical. If EPA proposes to regulate a chemical substance, it must publish a notice in the Federal Register substantiating this decision, explaining: exposure levels and effects of the chemical on health or the environment; the chemical's benefits and availability of substitutes; and the economic consequences of regulating the chemical, including the impact on the national economy, small business, and technological innovation.

Under this provision, EPA has banned the manufacture, processing, distribution, and use of polychlorinated biphenyls (PCBs), the only chemical mentioned by name in TSCA. An oily synthetic liquid, PCBs cause skin lesions, swollen limbs, eye and liver problems. It may also cause cancer and birth defects. Because of the known dangers of PCBs, EPA banned their general use as of July 1979. PCBs may no longer be made in the U.S., and may now only be used in sealed systems—such as electrical transformers and capacitors found in television sets, air conditioners, and microwave ovens. With normal use in those products, there is no human or environmental exposure to PCBs.

EPA also has used this provision of TSCA to prohibit the use of chlorofluorocarbons (CFCs) as propellants in aerosol (spray can) products. That action, taken in cooperation with the Food and Drug Administration and the Consumer Product Safety Commission, was based on the growing evidence that CFCs deplete the ozone layer in the



stratosphere which protects the earth from damaging ultraviolet radiation from the sun. Depletion of the ozone may result in increased skin cancer in humans and damage plants and animals.

Fourth, new chemicals are subject to a premanufacture review program before being allowed into the U.S. marketplace . . .

TSCA requires the chemical industry to notify EPA before making or importing a new chemical[5] into the U.S. for a commercial purpose. This requirement is the key preventive measure for protecting people and the environment from dangerous new chemical products. As of July 1979, the maker or importer of a new chemical must submit the following information to EPA at least 90 days before putting the new chemical on the market.

- All available studies on the health and environmental effects of the chemical.
- Its common or trade name.
- Its chemical identity and molecular structure.
- Proposed uses, and estimated amounts to be produced or imported for each use.
- Methods of disposal.
- Workplace exposure.
- Byproducts.

With this information, and considering other pertinent factors, EPA can take one of the following actions.

1. EPA can decide to take no action on a chemical substance. If EPA does not act within 90 days (180 days if the review period is extended because more information is requested), the manufacturer may begin production (or the importer may begin importation) of the new chemical.

2. EPA may regulate a substance until additional health and environmental data is made available to permit an evaluation of the chemical's effects. The regulation may

[5]A "new" chemical substance is one not included on the TSCA inventory, compiled by EPA, which lists existing substances already in U S commerce

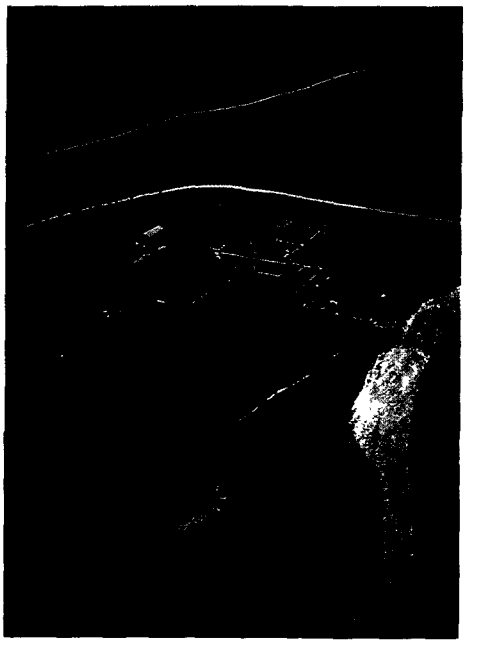
include bans or limits on the production or use of the substance. If the manufacturer objects, EPA can seek an injunction in the Federal District Courts.

3. EPA can prohibit or regulate the manufacture, processing, distribution, use, or disposal of the new chemical, if it finds that the new chemical poses an unreasonable risk to health or the environment. Regulations may range from labeling requirements to more stringent controls such as limiting human or environmental exposure to the chemical to a ban. If EPA intends to prohibit the manufacture, processing, or distribution of the substance, the Agency may issue a proposed order. If the manufacturer objects, EPA may go to court for an injunction. In other cases, EPA may propose a rule in the Federal Register.

4. If immediate regulation is not necessary, but EPA believes that future increases in exposure may cause concerns, the Agency may propose rules requiring the manufacturer and others to report "significant new uses" or other changes in exposures and releases.

5. EPA may also refer the chemical to other EPA programs or other Federal regulatory agencies if it is believed that the chemical shuld be reviewed or regulated under another statutory authority.

Anyone who manufactures or uses a new chemical that has not gone through the premanufacturing review process, and anyone who violates any other requirement of this law, is subject to penalties or fines up to $25,000 for each day of violation, one year in prison, or both. EPA is authorized to inspect chemical manufacturing, processing and storage facilities and to subpoena witnesses and documents to enforce TSCA.



Some Final Words

As directed by Congress in the law, EPA seeks to regulate toxic chemicals "in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purposes of this Act to assure that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment."

To carry out this Congressional mandate, EPA seeks to balance a chemical's risks to society against its benefits to society. EPA considers the seriousness of the risk, the availability of alternatives to the chemical and the risks associated with them, and the economic and social benefits that would stem from the production and use of the chemical.

To help the Agency reach the right decisions as TSCA is being implemented and to help ensure that a chemical does not pose an unreasonable risk of injury to health or the environment, EPA invites the assistance, support, and cooperation of the chemical industry, the scientific community, and all interested citizens and organizations.

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