United States
Environmental Protection
Agency

Office of
Toxic Substances
Washington DC 20460

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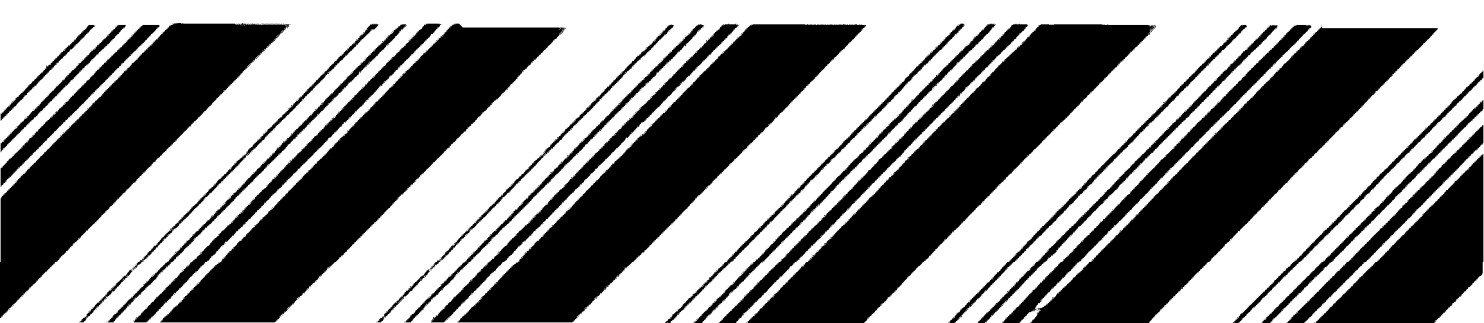
Toxic Substances

EPA

Implementating the Toxic Substances Control Act: Where We Stand



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OFFICE OF TOXIC SUBSTANCES

Implementing the Toxic Substances Control Act:

Where We Stand

Mandate

- TSCA gives EPA authority to identify and control harmful chemicals: those already in commerce and new chemical substances prior to their commercial manufacture
- Responsibilities under TSCA include:
  - -- Requiring industry to provide information about the production, distribution, use, exposure, and health and environmental effects of chemicals
  - -- Requiring industry to test potentially harmful chemicals for health and environmental effects
  - -- Controlling chemicals that pose an unreasonable risk to health or the environment

Scope

- As many as 70,000 chemical substances are currently in commerce
- Perhaps 1,000 new chemical substances will be introduced into commerce annually
- Characteristics of U.S. chemical industry:
  - -- Annual sales exceeded $112 billion in 1977

- -- Chemical and allied products account for approximately 6 percent of the Gross National Product

- -- An estimated 115,000 establishments involved in manufacturing and/or processing chemical products are affected by TSCA

- -- The U.S. Chemical and Petroleum Refinery industries employ about 1.6 million persons -- the 170 largest companies account for over 80 percent of total industry employment

- -- The United States maintains a traditional trade surplus in chemicals, amounting to around $6 billion in 1975, 1976, and 1977

Budget for TSCA

- FY 78 budget for toxic substances abatement and control is $22.9 million; $41.6 million requested for FY 1979; as contrasted with $7 million in FY 1977

- FY 78 budget for toxic substances enforcement is $2.3 million; $4.6 million requested for FY 1979; as contrasted with $0.2 million in FY 1977

- FY 78 budget for toxic substances research and development is $3.6 million; $10.5 million requested for FY 1979; as contrasted with $1.4 million in FY 1977

Implementation Strategy

- Key elements EPA considers fundamental to TSCA strategy in the early stages of implementation:

  - -- Defining priorities for selection of chemical substances for early action

  - -- Using actions under TSCA to further effective control of toxic substances under other laws

  - -- Encouraging actions by industry, beyond the actions directly required by regulation, to minimize risks from chemicals

-- Administering the several provisions of TSCA in a coherent, integrated way

-- Considering the total risks of toxic substances, including global risks

Basic objectives of initial TSCA implementation activities include:

-- Developing the organization and staff necessary to carry out EPA's responsibilities under the Act

-- Defining methods for assigning priorities to chemical substances requiring investigation or regulation

-- Gathering information on the production, use, exposure, and other basic characteristics of important chemicals

-- Developing testing standards for health and environmental effects of concern, and issue rules requiring testing of selected substances or classes of substances

-- Establishing a program for premanufacture notification and review of new chemical substances

-- Regulating the production, use, distribution, and/or disposal of selected substances or classes of substances

Organization and Staff

- EPA is developing several major new systems critical to implementation of TSCA:

  -- Mechanisms for effective review of new chemical substances under section 5

  -- Data systems for efficient retrieval

  -- Toxic Substances Priorities Committee, including senior representatives from other components of EPA

- TSCA Abatement and Control staff in the Office of Toxic Substances currently numbers about 180 persons

  -- 221 positions authorized for FY 78 (includes 31 in Regions), plus 6 for management

  -- 428 requested for FY 79 (includes 46 for Regions), plus 50 for management

  -- 99 actual for FY 77

- Enforcement has approximately 15 positions at Headquarters and another 18 in the Regions

  -- 48 positions authorized for FY 78

  -- 85 requested for FY 79

  -- 3 actual in FY 77

- Research and Development is nearly full staffed as FY 78 positions were reprogrammed from other ORD programs

  -- 45 positions authorized for FY 78

  -- 60 requested for FY 79

  -- 10 actual for FY 77

Determining Priorities

- A major immediate objective is to develop a systematic method for selecting chemical substances for investigation or for regulatory action under TSCA

- In all decisions, risk will be determined by considering both the toxicity of a substance and its estimated exposure

- Chemical substances that may produce chronic health effects will take higher priority than those that produce acute effects

- -- EPA will emphasize those whose effects are either irreversible or slowly reversible and debilitating: e.g., oncogenic, mutagenic, teratogenic, and neurotoxic effects

- -- With respect to cardiovascular, respiratory, immunological, dermatological, and reproductive effects, EPA will determine priorities based on the severity and irreversibility of the effects

- EPA will rely on validated test methods that are generally accepted by scientists

- EPA will give high priority to the environmental effects of substances that are widely dispersed into the environment and either indirectly threaten human health, affect commercially important species, or significantly disrupt ecosystems

Information Gathering Under Sections 8 and 12

- Initial inventory reporting regulations were promulgated in December 1977 under TSCA section 8(a); deadline for reporting was May 1, 1978

- Objective of the inventory is to compile a list of chemical substances as required by TSCA section 8(b) and to establish a profile of the chemical industry (what substances are manufactured where and in what quantities)

  - -- The inventory is expected to be published early in 1979

  - -- Premanufacture notification program under section 5 will begin 30 days after publication of the initial inventory; covers all new chemical substances manufactured or imported (in bulk) into the United States

  - -- Processors may add to the inventory during special 210-day reporting period following publication of the initial version early next year

- EPA is analyzing several options for reporting requirements in the near future, in order to obtain necessary information at various stages of hazard assessment and regulatory development

- EPA is planning to propose general rules for reporting production, use, byproducts, exposure and other information under section 8(a); after the general rules are promulgated, EPA would apply them in subsequent rules to individual substances

- Under section 8(c), EPA is planning to propose a general rule requiring recordkeeping for allegations of significant adverse reactions to health and the environment

- EPA published final rules on July 18, 1978, under section 8(d) to require industry to submit results of relevant health and safety testing already performed on chemicals included in ITC's first report (October 1977)

- Final policy guidance on section 8(e), reporting of substantial risk information, was published on March 16, 1978

- Preliminary guidance on section 12(b), notification of export of PCBs and CFCs, was published on June 7, 1978; a final policy statement on section 12(b), which will supercede the preliminary guidance, will be published soon

- EPA is developing an integrated data system for information on chemical substances; there will be full public access to all nonconfidential information, and confidential business information will be strictly protected

Testing

- Testing standards under TSCA section 4 will be directed at specific characteristics and effects, including oncogenicity, teratogenicity, mutagenicity, and other chronic effects, as well as environmental fate, persistence, and ecological effects

-- These standards will be as consistent as possible with those already developed by EPA under the Federal Insecticide, Fungicide, and Rodenticide Act

-- To assure quality test data, the standards will include rules for Good Laboratory Practices that will be modeled after those used by FDA

-- The first standards -- oncogenicity and other chronic effects -- will be proposed this fall; others will follow throughout 1979

- Through separate rules, the section 4 testing standards will be applied to specific chemicals and groups of chemicals

  -- These rules will be issued periodically once the testing standards are in place; the first such rule will be proposed late this year or early next year

  -- Chemicals and groups of chemicals subject to testing rules will be based on recommendations from the section 4(e) Interagency Testing Committee, EPA's own chemical selection process, and other sources

- Interagency Testing Committee's (ITC) initial report to EPA (October 1977) recommended that priority consideration be given to requiring testing of four individual chemicals (chloromethane, hexachloro-1,3-butadiene, nitrobenzene, and toluene) and six groups (alkyl epoxides, alkyl phthalates, chlorinated benzenes, mono- and di-, chlorinated paraffins, cresols, and xylenes); by October 1978, EPA must initiate action to require the recommended testing or explain why it is not acting

  -- EPA will propose testing rules directed toward the effects to be evaluated; the rules will apply to various substances, as appropriate

- Second Interagency Testing Committee's report issued April 10 -- recommends priority testing consideration for another four individual chemicals and four groups of chemicals: acrylamide, aryl phosphates, chlorinated naphthalenes, dichloromethane, halogenated alkyl epoxides, polychlorinated terphenyls, pyridine, and 1,1,1-trichloroethane; by April 1979, EPA must initiate action or explain its reasons for not doing so

Establishment of Premanufacture Notification

- EPA will publish testing guidelines under section 5 identifying the information it considers necessary to evaluate the risks associated with various classes of chemical substances

- Development of a system for reviewing premanufacture notification is under way in anticipation of the beginning of notification early in 1979 (30 days after publication of inventory)

- Rules for "significant new uses" will follow development of premanufacture notification requirements

Regulation of Chemical Substances

- PCB marking and disposal rules were promulgated February 17, 1978

- PCB regulations implementing the statutory ban on manufacture and use in any way other than totally enclosed manner were proposed June 7, 1978

- Regulations on aerosol uses of chlorofluorocarbons were promulgated March 17, 1978, in a joint action with the Food and Drug Administration and the Consumer Product Safety Commission

- EPA is investigating ways to further reduce chlorofluorocarbon emissions by controlling non-aerosol uses (e.g., air conditioners, refrigerators, solvents), although eventual regulation will be under the Clean Air Act not TSCA

- Ongoing reviews of high-volume, high-toxicity chemicals will produce other candidates for regulation over the next several months

- EPA will run pilot program to provide funds for public participation in rulemaking in connection with PCB ban regulations

State Cooperative Agreements

- $1.5 million is available in FY 78 and FY 79; it will be provided to States under cooperative agreements with EPA

- Funds will be used in a few States for priority programs for chemical risks for which EPA is unable or not likely to take action

- Criteria for these funds are being developed and will be proposed shortly; award of funds is expected in the first half of FY 79

Industry Assistance Office

- Established in January 1977, as required by section 26, to provide technical and other non-financial assistance to industry on TSCA requirements, compliance measures, and Agency policy

- Actions to date:

  -- Letters

     + Over 500 Congressional inquiries answered, plus approximately 500 routine letters (majority from industry) received monthly

     + During the 4-month inventory reporting period, the letter average increased to 3,000 per month with requests for reporting forms and instructions

     + Grand total: 19,500 letters over a 19-month period

-- Telephone calls

+ A toll-free number installed in January 1978 has been used to handle 6,050 calls

+ Approximately 3,750 other telephone requests for assistance have been received

+ Grand total: 9,800 phone calls over a 19-month period

-- Seminars/meetings

+ Planned and helped conduct 32 TSCA inventory training seminars in 28 cities between February 27 and March 17, 1978; more than 3,000 industry representatives reached

+ More than 775 meetings with trade associations and industry representatives held (about 10 per week over a 19-month period)

Relations With Other Agencies

- Interagency Regulatory Liaison Group (IRLG)

  -- Was formed by EPA, FDA, OSHA, and CPSC in August 1977 to facilitate their combined effectiveness in conducting chemical control activities

  -- Eight working groups have been formed on (1) regulatory development, (2) testing standards and guidelines, (3) information exchange, (4) risk assessment, (5) methodologies for epidemiological studies, (6) coordination of enforcement and compliance strategies, (7) research needs, and (8) interagency communication and public education

  -- The results of these specific initiatives, which are currently ongoing, will be used to develop coordinated and integrated approaches in these areas

-- In addition, the four agencies have begun to coordinate their activities in the 10 Federal Regions

Sections 10(b)(1) and 25(b) Interagency Toxic Substances Data Committee (ITSDC)

-- Charge is to establish an EPA system for collection, dissemination to other Federal agencies, and use of data under TSCA

-- Basis will be EPA/CEQ survey of Federal agencies' toxic substances data needs and systems last year

-- About 18 Federal agencies invited to participate

-- Serves as mechanism for coordinating Federal toxic substances regulatory reporting and recordkeeping requirements

TSCA Interagency Testing Committee

-- EPA is a member and provides support as required under section 4(e)

-- Purpose is to recommend chemical substances for priority consideration for testing under TSCA

-- Initial recommendations made in October 1977 and April 1978

-- Recommendations will be revised at least every 6 months; list not to exceed 50 entries at any given time

Conclusions

By end of FY 1979, all aspects of TSCA program will be in operation -- although not each at full capacity

-- Priorities are being set to direct implementation

- Initially more emphasis will be placed on obtaining and analyzing information than on writing specific control regulations

  -- Information is needed for nonregulatory control and for regulation under other authorities as well as under TSCA

- FY 1979 will concentrate on

  -- Premanufacture notification system

  -- Making priority-setting and information systems operational

  -- Developing testing standards and regulations

  -- Conducting hazard assessments

  -- Promulgating reporting and recordkeeping requirements