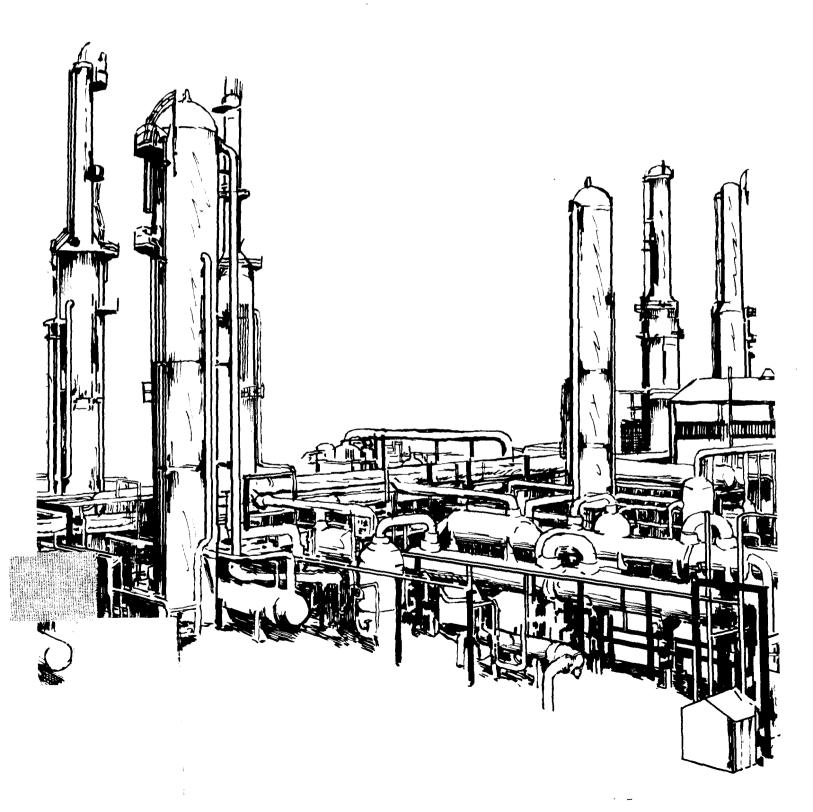
EPA

Administration of the Toxic Substances Control Act (1980)



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Introduction

This Report to Congress summarizes progress made during 1980 by the Environmental Protection Agency (EPA) in implementing the Toxic Substances Control Act (TSCA). It fulfills the congressional reporting requirements of the Act, including those contained in sections 30, 9(d), and 28(c) of TSCA, and reports on broader TSCA program activities from the beginning of fiscal year 1980 through the end of calendar year 1980 (October 1979–December 1980).

In enacting TSCA, Congress established a number of new requirements and authorities for identifying and controlling toxic chemical hazards to human health and the environment. Accordingly, ims now exist under TSCA to gaster information about the toxicity of particular chemicals and the extent to which people and the environment are exposed to them, to assess whether they cause unreasonable risks to humans and the environment, and to institute appropriate control actions after carefully weighing their risks against their benefits to the Nation's economic and social wellbeing.

To insure wise and informed decision-making by the government, TSCA gives EPA authority to gather certain kinds of basic information on chemical risks from those who manufacture and process such substances. The law also enables EPA to require companies to test the toxic effects of specified existing chemicals, and stipulates that the Agency review the safety of all new chemicals before they are manufactured. To prevent unreasonable risks, EPA under TSCA may select from a broad range of control actions, from requiring hazard-warning labels to outright bans

on the manufacture or use of especially hazardous substances. TSCA authorizes EPA to regulate a chemical's unreasonable risks at any stage in the substance's life-cycle: in manufacturing, processing, distribution in commerce, use and/or disposal.

In prescribing these authorities, Congress intended that prudence be exercised in implementing TSCA. Accordingly, EPA's actions under TSCA recognize the implicit reality that the chemical industry plays a vital role in the economy of the United States: its annual sales approach \$146 billion and generate an annual trade surplus of about \$10 billion; the production of chemicals and allied products accounts for roughly 6 percent of the Gross National Product; and the industry employs about 1.1 million people. More than 55,000 chemical substances are presently manufactured or processed for commercial use in the United States, and several hundred more are introduced each year.

Under TSCA, EPA must also remain sensitive to the Act's potential impact on small, nondiversified companies. Research done by the Agency shows that chemical production is distributed very unevenly among the 115,000 establishments involved in the manufacture or processing of chemicals. Of these establishments, 32 percent produce only one chemical product, and 63 percent produce five or fewer. Most chemical firms are small—53 percent employ fewer than 100 people—although relatively few large companies contribute most of the total quantity manufactured.

One of the main assumptions underlying TSCA is that too often, the hazards of particular chemicals have been recognized only after extensive harm has occurred to human health and the environment. Asbestos, polychlorinated biphenyls (PCBs), and the flameretardant chemical TRIS are well-known examples. There also is justifiable concern about the many other chemicals-many of them substances in common or rapidly growing use throughout society-whose ill-effects have never been adequately determined through laboratory testing. In other instances, adverse effects are suspected but have not been proven to the extent necessary for regulatory decisionmaking. Rather than imposing the financial burdens of answering the most pressing of these questions directly on the U.S. taxpayer, TSCA makes it industry's responsibility to develop missing data where there is a bona fide indication of potential risk.

The Report describes EPA's TSCA programs for gathering information, performing risk assessments, and controlling hazardous chemicals, and discusses progress made in each of these areas during and beyond the last year. The Agency's basic approach in implementing TSCA has been to use the law's various tools to strategically stimulate better and more timely industry assessments of chemical risks-as often as possible without the need for formal regulation. In addition to holding down the burdens of government regulation on private industry, this approach should lead to more rapid and cost-effective achievement of the Agency's main

statutory goals than would a chemicalby-chemical regulatory approach. In a number of instances, for example, when the TSCA program has identified a suspect chemical, industry has voluntarily undertaken such riskreduction measures as improving in-plant emission controls and instituting data-gathering programs such as toxicity testing.

Implementing organization: Implementing TSCA is the responsibility of the EPA Office of Pesticides and Toxic Substances. A major reorganization of this office took place in August 1980; TSCA program responsibilities once shared by three Deputy Assistant Administrators are now consolidated under a single Deputy Assistant Administrator. Two of the three Deputy Assistant Administrator positions were abolished, and a new position was created, that of Associate Assistant Administrator for Toxics Integration; as before, overall responsibility for the TSCA program continues to be that of the Assistant Administrator for Pesticides and Toxic Substances, a position which reports directly to the Administrator. Changes brought about by this reorganization are resulting in more efficient coordination and more streamlined decision-making through new institutional mechanisms for setting policy, more discriminating allocations of resources, and programwide tracking of important projects. (See Table 1, Implementation of TSCA by Section of the Law, During Calendar Year 1980.)

Table 1. Implementation of TSCA, by Section of the Law, During Calendar Year 1980

Section of law	Description	Action	Date
4(a)	Acrylamide: response to ITC testing	Proposed	7/18/80
	recommendations	decision	(45 FR 48510
4(a)	Testing for health effects: chloromethane,	Proposed	7/18/80
	chlorinated benzenes	rule	(48524)
4(c)	Exemption policy and procedures for testing rules	Proposed	7/18/80
		rule	(45 FR 48512
4(b)	Testing standards: laboratory practices,	Proposed	11/21/80
	environmental fate, ecological effects	rule	(45 FR 77332)
5(e)	Prohibit manufacture of 6 phthalate esters, pending	Proposed	4/23/80
	development of health and environmental data	order	
5(a)	Significant New Use Rule (SNUR): processor	Proposed	8/15/80
	reporting for TSCA-exempt chemicals	rule	(45 FR 54642
5(e)	Prohibit manufacture of new confidential chemical	Proposed order	9/5/80
5	Clarification of important annualing (DAAN)		0/22/00
5	Clarification of importer reporting (PMN)	Proposed	9/23/80
E(-)	Chamical appairie CAILID	order	(45 F
5(a)	Chemical-specific SNUR	Proposed	11) (0
E(-)	De teat to describe to the second of	rule	(45 FR 78970
5(a)	Revised interim policy for premature notification	Interim	11/07/80
5 ()	B 6	policy	(45 FR 74378
5(a)	Draft regulatory analysis; proposed economic	Proposed	11/13/80
	impact analysis	rule	(45 FR 74945)
6(a)	Prohibit PCBs in agricultural chemical plants	Proposed	5/09/80
		rule	(45 FR 30989)
6(a)	Prohibit transfer and disposal of TCDD dioxin	Final rule	5/19/80
	wastes without advance notification		(45 FR 32676
6(a)	Asbestos in schools (identification and public	Proposed	9/17/80
	notification)	rule	(45 FR 61966
6(a)	CFC production limitations	Advance	10/07/80
•		notice of	(45 FR 66726)
		proposed	
		rulemaking	
8(a)	Notification of PBB/TRIS manufacturing and import	Final rule	10/24/80
0,0,			(45 FR 70728
8(a)	Information for preliminary assessments (level A)	Proosed	4/28/80
O(u)	midification for prominery assessments (1676) 747	rule	(45 FR 28172
8(c)	Maintain records on and sometimes report	Proposed	8/05/80
O(C)	allegations of adverse health and environmental	rule	(45 FR 51855
	effects	Tule	(45 1 11 5 1050
12(b)	Export notifications to foreign governments	Final rule	12/16/80
			(45 FR 82844)
13	TSCA compliance for chemical imports	Proposed	12/1/80
100A comp		policy	(45 FR 79726)
		statement	
20	Citizens' suits	Proposed	6
20	CHIZOIIS SUIES	rule	(45 P) 448
		iuio	(70)

Section 4: Testing of Chemical Substances and Mixtures

Section 4 of TSCA gives EPA authority to require manufacturers or processors of existing chemicals (i.e., those already in commerce) to test the toxic effects of certain designated substances. EPA exercises this authority by rule only when it can make certain statutory findings about the substance involved and when industry fails to develop the needed data on its own. These required findings are that a chemical may present an unreasonable risk; that there are insufficient data already available with which to perform a reasoned risk assessment; and that testing is necessary to provide such data. A testing rule also may be based on an Agency finding of substantial production kposure to humans or the onment, in addition to findings of insufficient data and need for testing.

Testing standards: Testing required by rule is performed according to prescribed standards promulgated by EPA in close consultation with other government agencies, non-government scientific experts, industry, foreign governments, and the general public. These standards define precise and enforceable scientific procedures for performing the required testing, thereby assuring uniformly reliable and consistent results from a variety of domestic and foreign sources of data. EPA is issuing generic testing standards for various physical/chemical properties, health effects, and environmental effects, rather than issuing separate standards for each chemical-specific testing rule it writes. These generic standards invite uniformity in the acquisition of data and facilitate consistency with existing domestic and international testing procedures. The standards are incorporated by reference nemical-specific testing rules and e modified as necessary to fit a chemical's special requirements.

Health effects testing standards: Health effects standards for acute, subchronic, and chronic toxicity, oncogenicity (tumors), mutagenicity (gene mutations and chromosome aberrations), teratogenicity (birth defects), reproductive effects, metabolic studies, and Good Laboratory Practices (GLPs) were proposed in 1979. In 1980, substantial effort was devoted to reviewing these proposed standards in response to numerous public comments. Also, significant effort was made to harmonize TSCA health testing standards with those of other U.S. Government agencies in the Interagency Regulatory Liaison Group (IRLG), and with international testing standards developed by the 24-nation-member Organization for Economic Cooperation and Development (OECD). These tasks have largely been accomplished, and final TSCA health testing standards will be published in 1981.

Chemical behavior testing standards: In 1980, EPA proposed five standards for evaluating the behavior of chemicals released into the environment. These standards address the measurement of several chemical and physical properties, that pertain to the determination of how a chemical migrates through the environment. The proposal also includes Good Laboratory Practice (GLPs) standards for performing environmental testing. The proposed GLPs cover the management, operation, and maintenance of facilities and equipment in a testing program.

These proposed standards are the first in a series of environmental testing standards scheduled for proposal in 1981. Substantial effort was devoted in 1980 to harmonizing the TSCA environmental testing standards with those of the other IRLG agencies and with the OECD testing standards.

Interagency Testing Committee: An Interagency Testing Committee (ITC) was established under TSCA to recommend chemicals to EPA for priority testing under section 4 of the Act; the ITC cannot recommend more than 50 priority chemicals or chemical groups at any given time. Within 12 months of EPA's receipt of individual ITC recommendations, the Agency must either initiate rulemaking for requiring testing or publish its reasons for not doing so.

Proposed testing rules: On July 18, 1980, EPA proposed the first TSCA testing rule under authority of section 4(a) of the Act. The proposed rule would require testing of chloromethane and selected chlorinated benzenes, all of which had been recommended for priority testing by the ITC. On the same date, EPA also announced its intention not to require additional health effects testing of acrylamide, which also had been recommended for priority testing by the ITC. (See below.)

The proposed chloromethane rule would require testing for oncogenicity (tumorcausing properties) and teratogenicity (induction of structural birth defects). This proposal was based on the finding that chloromethane may cause these adverse effects, and that there currently are insufficient data in these areas.

The proposed chlorobenzene rule would require testing 11 structurally related chemicals for oncogenicity, structural teratogenicity, and reproductive, chronic, and subchronic effects, based on the potential that these substances may present an unreasonable risk. Initial testing would be performed on 6 of the 11 substances, with decisions on the remaining ones pending review of testing performed on the first group.

EPA's proposed decision not to require additional health effects testing on acrylamide is based on the finding that sufficient evidence exists that it is a potent neurotoxin at very low levels; the Agency also found that industry-sponsored carcinogenicity testing was already under way. As a result, industry testing resources can now be devoted to chemicals about which less is known, and EPA will be able to determine whether regulatory controls are needed to reduce acrylamide's known and potential risks without further testing.

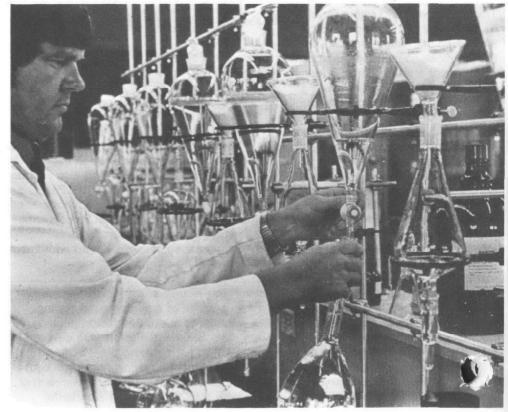
Testing costs: Under TSCA, EPA is required to establish an equitable procedure for distributing among the various manufacturers and processors of a chemical the costs of testing that substance under a section 4 rule. This requirement is partially implemented in the proposed rule on chloromethane and the chlorinated benzenes by providing policies and procedures for exemptions from the rule to avoid duplicative testing. In 1980, EPA also has been developing a proposed reimbursement rule that would provide the structure for determining how exempt companies would share in the testing costs incurred by the company performing the tests. This rule would call for voluntary costsharing wherever possible; EPA would be involved only to settle disputes that individual companies bring before the Agency because of their inability to resolve the issues themselves.

Because the first TSCA testing rules have been proposed for public comment and have not yet taken effect, no costs for testing chemicals were actually borne by industry in 1980.

Testing rule schedule: The ITC has submitted a total of seven priority lists to EPA; they include 23 individual chemicals and 20 chemical groups or categories the committee wants EPA to

chemicals and 20 chemical groups or categories the committee wants EPA to consider for testing rules. However, because of a lack of testing standards, delays caused by an extensive information-gathering and assessment process for evaluating an ITC recommendation, difficulties in hiring a full staff for the Office of Toxic Substances, and other problems, EPA has not been able to initiate rulemakings in response to the ITC recommendations within the one-year period Congress

provided for making a decision. In 1979, the Natural Resources Defence Counsel (NRDC), challenged EPA's reasons for not initiating these rulemakings. On February 4, 1980, the court announced its decision in NRDC's favor and instructed EPA to establish a schedule for responding to the backlog of ITC recommendations. The court has not yet issued a final order, however. (See the "Litigation" section in this Report.) In response to this lawsuit and to EPA's own concerns about the section 4 program, the Agency has reevaluated and substantially modified its processes for evaluating ITC recommendations and for developing section 4 rules. This should contribute to more efficient and timely testing rule development in future.



Section 5: Notification and Review of New Shemicals

health and environmental considerations are more easily addressed before than after a chemical is produced and introduced into commerce. Thus, under TSCA EPA has a series of special authorities for assessing and acting to prevent new-chemical risks and those arising from significant new uses of existing chemicals previously subjected to the new-chemicals review program. In using these authorities, however, the Agency must remain vigilant to not unduly impeding the technologicalinnovation of new chemicals. Also, the Act provides for exempting certain new chemicals from notification; for example, new substances manufactured inall quantities for use only in search and development are exempt from section 5 notification requirements. TSCA also allows the Agency to grant an exemption for new chemicals used for test-marketing purposes, if doing so will pose no unreasonable risks of injury to health or the environment. EPA has received a total of 50 test-marketing applications: it has granted 34 such applications and denied 2; 3 were found not be bona fide test-marketing applications: and 11 remain under review.

The authors of TSCA recognized that

Premanufacture notification: The heart of the new-chemical review program is the premanufacture notification (PMN) requirements created by TSCA. Section 5 requires manufacturers or importers to give EPA 90-day advance notification of their intent to introduce a new chemical

substance into commerce, "new" being defined as any commercial chemical not listed on the TSCA inventory of existing substances. They must also submit available risk-related data including results of relevant health and safety studies, projected production or import volumes, exposure estimates, and intended methods of disposal. Even though the Agency is required to ascertain whether a new chemical poses unreasonable risks, it cannot require manufacturers to perform prescribed testing of new chemicals.

Based on its review of submitted information, EPA may act under section 5(e) or 5(f) to reduce or eliminate unreasonable risks that exist or may exist. The Agency also may issue a significant new-use rule requiring manufacturers or processors to notify EPA in the future if they intend to produce or process a chemical for uses beyond those given in their original notice, which are significant in health and environmental terms.

By late 1980, the rate of PMNs received by EPA was about 50 per month. A number of notices contained insufficient information to assess whether the notice chemicals posed unreasonable risks. In several of these cases, the Agency prepared orders prohibiting or limiting the production of the new chemical until and unless the manufacturer submitted additional data. In some cases, the information was submitted and no control action was needed. In others. manufacturers withdrew the substances from the process, thus dropping temporarily or permanently their plans to produce the substances. (See Table 2.)

PMN rule: On August 15, 1980, the Agency proposed a rule extending PMN reporting requirements to certain chemical processors. The Agency clarified its overall interim PMN policy in a November 7, 1980, Federal Register notice. This notice discusses PMN notice contents, use of notice forms, confidentiality of submitted information and the development of test-marketing exemptions.

Table 2. Section 5 PMN Actions or Other Dispositions, January-November 1980

EPA action or	No.		
other disposition	chemicals	PMN status	Date
Mfr. agreed to test	1	Completed	1/80
Mfr. agreed to test	1	Completed	4/80
5(e) order proposed	6	Withdrawn	5/80
5(e) order developed .	1	Withdrawn	5/80
Mfr. agreed to test	1	Labeled	6/80
Mfr. agreed to test	2	Review suspended	9/80
PMN reviewed by EPA	1	Withdrawn	9/80
5(e) order proposed	1	Withdrawn	10/80
Negotiations	2	Review suspended	10/80
Mfr. assessing concerns	1	Review suspended	11/80
Mfr. assessing concerns	1	Review suspended	11/80
PMN reviewed by EPA	2	Withdrawn	11/80
Mfr. agreed to test	1 .	Review suspended	11/80
Negotiations	_1_	Review suspended	11/80
TOTAL	22		

Importer clarification: In response to public comments, EPA published a clarification of the definition of "importers" previously proposed in the Federal Register on January 10, 1979. This clarification states that the principal importer, as defined in the clarification, would be responsible for submitting the PMN. The clarification responds to issues raised in previous public comments and will be incorporated into the final PMN rules to be issued in 1981.

PMN costs: On November 13, 1980, in a further step toward completing the final PMN rules to implement section 5, EPA published its "Proposed Economic Impact Analysis" and "Draft Regulatory Analysis" of the proposed PMN rules.

New-chemical testing guidance: Premanufacture assessment of newchemical risks is a critical element of the overall TSCA strategy for preventing unreasonable risks to health or the environment. EPA's ability to perform this function depends on the quality of data submitted in PMNs: the better the data, the more confident the risk assessment. Therefore, a high-priority activity in 1980 was to develop nonenforceable guidance for manufacturers to follow in testing new chemicals. This guidance is identical to international premarket testing recommendations developed by the OECD and agreed upon in 1979 by the United States (see International activities), and was published by EPA early in 1981. It identifies a base set of data that are generally needed to conduct premanufacture assessments; in addition, it calls for flexible application of this base set to accommodate the diverse types of chemicals and exposure situations represented in actual PMNs.

PMN review: EPA screens each incoming notice to segregate chemicals that do not appear to present an unreasonable risk from those that need a more thorough and detailed risk assessment. For those subject to a detailed assessment. EPA considers all data and information supplied by the manufacturer, as well as inferential information drawn from data on structurally similar chemicals already in commerce. Based on this review. EPA determines whether any action needs to be taken to reduce risk. If EPA takes no action, the manufacturer may proceed to manufacture the chemical. If EPA perceives a potential unreasonable risk, any of the actions that appear in Table 3 may be taken.

Extension of review period: In some cases, TSCA authorizes an extension of the 90-day review period for up to an additional 90 days, to permit completion of the detailed assessment. In 1980, the review period was extended for 21 of the 383 notices submitted. (See Table 3.)

Table 3. Overview of PMN Activities, April 1979-December 1980

Total number submitted	383
Still under review	100
Review period extended	21
Referral to other programs	18
In line for SNUR	45

Section 5(e): Section 5(e) of TSCA authorizes EPA to propose an order to regulate the manufacture, processing, distribution, use, or disposal of a new chemical pending development of information with which the Agency can make a reasoned evaluation of the chemical's health and environmental effects. This authority is used when there is reason to believe that a chemical will have significant or substantial exposure or may present an unreasonable risk of injury to health or the environment, but where the manufacturer has not voluntarily submitted sufficient data for a reasoned risk assessment. For example, preliminary testing data or a structural analogy to a known toxic chemical reveal that the chemical could prese an unreasonable risk. If the intended use would lead to significant human or environmental exposure, but the manufacturer did not voluntarily submit appropriate information to support a risk assessment, then EPA could issue a section 5(e) order prohibiting or limiting manufacture of the chemical or certain of its uses, pending submission and evaluation of the requested information. Under section 5(e), EPA may also act if there is a lack of sufficient data, and the chemical will be manufactured in substantial quantities so as to result in substantial human or environmental exposure.

During 1980, EPA proposed orders concerning eight new chemical substances. In the first instance, EPA had received PMNs for a group of six chemicals intended to be used in the manufacturing of plastics. While the notices were being evaluated, the National Cancer Institute released preliminary testing results showing that another chemical of the same type caused cancer in rodents. In addition, structurally similar chemicals were known to be toxic to aquatic life. When EPA issued a proposed 5(e) order on the basis of these concerns, the manufacturer withdrew its notices. Later during 1980, EPA proposed a 5(e) order use evidence indicated that the substance was likely to be a skin sensitizer. Again, the manufacturer withdrew its notice. In one other case, EPA had completed drafting of a 5(e) order, but the manufacturer withdrew its notice before the order could be

On six other occasions in 1980, manufacturers voluntarily withdrew notifications of new chemicals that EPA had identified or was considering for section 5(e) orders. In each case, EPA noted the possibility of significant toxicity or exposure, and the available information was insufficient for a reasoned assessment of whether regulation was warranted. (See Table 2 for a summary of the actions taken by EPA in the PMN program). In such cases, normally the Agency attempts to elicit voluntary cooperation from industry, resulting in negotiated withdrawal or suspension of a notice pending adequate testing or the development of a safer substitute. These manufacturers may resubmit their es at any time when additional rmation becomes available, or in the interim they may develop safer

substitutes for the withdrawn chemicals.

formally proposed.

New chemical follow-ups: Because production volume, manufacturing sites, uses, and disposal practices may all change significantly over time in ways that cannot be foreseen at the time a risk assessment is performed on a PMN, EPA laid groundwork in 1980 for a program to monitor commercial development of selected new chemicals after they have passed through the PMN assessment. Only carefully selected PMN chemicals will be subject to the program.

EPA is developing the policy and procedural framework through which manufacturers and processors would notify the Agency about significant new uses for selected chemicals that have been through a premanufacture risk assessment. TSCA provides authority for such rules based on consideration of changes in production volumes, uses, or other factors affecting exposure.

In November 1980, EPA proposed the first chemical-specific significant new use rule (SNUR). This proposed rule would require a manufacturer or processor to notify the Agency 90 days in advance of significantly increased production (as defined in the rule) for the use described in the original PMN, or manufacture or processing for any use not in the PMN. Although concerned that the substance may be toxic, EPA did not take regulatory action on this PMN chemical because anticipated production volume was low, exposure controls at the manufacturing site were strict, and extremely limited exposure was anticipated from the stated use. Promulgation of this chemical-specific SNUR, scheduled for early 1981, will permit a second review before a chemical substance is manufactured or processed for other uses or in significantly higher volumes.

By December 1980, approximately 50 other chemicals for which PMNs had been submitted had been identified as candidates for SNURs. In each case, EPA had significant concerns about chemical toxicity or potentially high future exposure.

EPA's use of the follow-up reporting and SNUR authorities in TSCA exemplifies the Agency's flexible regulatory strategy for TSCA discussed in the Introduction. EPA expects that identification of a chemical for follow-up reporting will signal concern for potential future risks and that manufacturers and processors will often respond by seeking methods of production or new uses that will minimize risk. In addition, the Agency expects manufacturers and processors to often voluntarily perform appropriate toxicity tests before manufacturing a chemical for uses that would result in greater human or environmental exposure.

The significant new use notice requirements do not become effective unless certain specific changes in production volume, end use, or other factors occur in the manufacturing or processing of chemicals subject to SNURs. Therefore, the reporting burden will fall only on manufacturers and processors of specific chemicals, and then only if they manufacture or process the chemicals for uses that may involve significant increases in exposure over what was proposed in the PMN or current uses of chemical substances on the TSCA Revised Chemical Substances Inventory.

Section 6: Regulation of Hazardous Chemical Substances and Mixtures

Polychlorinated Biphenyls (PCBs)

Chemical control: Under section 6 of TSCA, EPA has the authority to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of a chemical already in commerce that is found to pose an unreasonable risk to human health or the environment. A number of possible control options are available, ranging from total prohibition to labeling. In 1980, EPA undertook activities intended to lead to control actions against polychlorinated biphenyls (PCBs), chlorofluorocarbons (CFCs), asbestos, and 2,3,7,8-tetrachlorodibenzo-paradioxin (TCDD).

Final control action, PCBs: In TSCA, Congress singled out PCBs alone for both immediate regulation and phased withdrawal from the market; the only exceptions to this are where EPA grants authorizations or exemptions or creates exclusions for specific activities. PCBs are of concern because tests on laboratory animals show that they cause, among other effects,

reproductive failures, gastric disorders, skin lesions, and tumors. Moreover, PCBs persist when released into the environment and tend to accumulate in tissues of living organisms. This means that as PCBs move up in the food chain toward humans, their concentration and thus their potential for harm increases.

Action against PCBs was initiated in February 1978, when EPA issued final PCB marking and disposal rules. Fifteen months later, the Agency promulgated a final rule banning the manufacture, processing, distribution, and non-totally enclosed uses of PCBs.

In July 1979, the Environmental Defense Fund (EDF) filed a suit against EPA challenging aspects of the Agency's final PCB ban rule. On October 30, 1980, the court ruled in favor of EDF on two of the three major issues in the case, and remanded certain portions of the rule to EPA for further proceedings. (See the "Litigation" and "Major Problems" sections of the Report.)

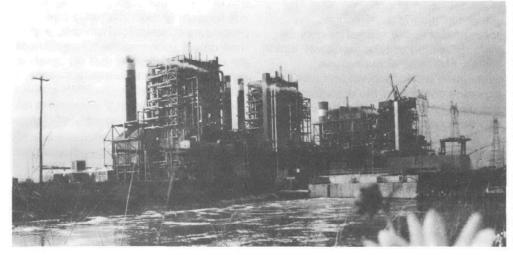
On May 9, 1980, because of the serious potential consequences to public health

from food accidentally contaminated with PCBs, EPA, the U.S. Department of Agriculture, and the U.S. Food and Drug Administration simultaneously proposed rules banning the use of PCBcontaining equipment from food and feed-processing plants and storage facilities; federally inspected meat, poultry, and egg product establishments; and agricultural chemical facilities where pesticides and fertilizer are manufactured or stored. EPA's proposal would amend the final PCB regulation under section 6 by prohibiting the use of such items as PCB-containing capacitors and transformers in all facilities manufacturing, processing, or storing fertilizers or agricultural pesticides. The rule was proposed before the court's remand of the PCB rule (see below), and may be affected by future actions taken to comply with the court mandate.

TCDD

Final control action, TCDD: TCDD (2,3,7,8-tetrachlorodibenzo-para-dioxin) is a highly toxic chemical found as an unintended contaminant in other substances, particularly phenoxy herbicides such as 2,4,5-TCP. TCDD, known commonly as "dioxin," is a known carcinogen in laboratory animals, and produces a wide range of other adverse health effects (chloracne and organ dysfunction, for example). Some studies show a relationship between exposure to dioxin and the occurrence of these effects in some human populations.

In March 1980, EPA proposed a rule under section 6(a)(6) of TSCA prohibiting Vertac, Inc., from disposing certain TCDD-contaminated wastes produced at its Jacksonville, Arkansas, facility; the proposed rule also required



other firms to notify EPA of intended disposal of TCDD-contaminated wastes. This rule was made immediately effective on the date of proposal under provisions of section 6(d). Following completion of the required publiccomment period, the Agency promulgated a final rule in May 1980 describing in detail the actions that Vertac must take regarding its TCDDcontaining waste. The rule also requires anyone who intends to dispose of wastes resulting from the production of the suspended phenoxy herbicide 2.4.5-TCP (2.4.5-trichlorophenol), or from its pesticide derivatives, to notify EPA at least 60 days before disposal so the Agency can determine the adward of the proposed disposal method; 2,4,5-TCP is contaminated with TCDD.

Chlorofluorocarbons (CFCs)

Rulemaking proceeding initiated, CFCs: Considerable scientific evidence has been put forward that chlorofluorocarbons (CFCs) deplete the atmosphere's stratospheric ozone layer, which protects the earth from damaging ultraviolet radiation. In March 1978, EPA, the Food and Drug Administration, and the Consumer Product Safety Commission promulgated a ban on all nonessential uses of CFCs as aerosol propellants. But because the use of CFCs in various nonaerosol applications (such as industrial solvents, plastic foam manufacturing, and refrigeration and air conditioning) has continued to grow, the Agency has been investigating the need for and possible structure of add and controls on CFCs in the Units States.

Therefore, on October 7, 1980, EPA published an Advance Notice of

Proposed Rulemaking (ANPR) that discussed possible futher options for controlling nonaerosol uses of CFCs in the United States under the Clear Air Act and TSCA. The ANPR discussed several possible regulatory strategies and requested comment from interested parties. One of these strategies called for limiting future CFC manufacturing and use by restricting the total amount of CFCs that can be produced and then allowing market forces to distribute CFC production among competing applicants.

Asbestos

Proposed control action, asbestos in schools: Scientific evidence points to asbestos fibers as a cause of lung damage and certain types of cancer in humans. For many years asbestos was widely used to insulate buildings, in industrial and commercial products, and in other building materials. The practice of spraying asbestos in buildings was virtually halted in 1973; by that time, however, many schools and other buildings had already been constructed with asbestos-containing materials (sprayed or otherwise).

The EPA program to reduce asbestos hazards in buildings, particularly schools, began in March 1979 with a nationwide voluntary technical assistance program to help States and local school districts identify friable (crumbling) asbestos materials in school buildings and to take corrective actions where necessary. Because thousands of schools did not participate in this program, EPA proposed a rule in September 1980 that would require all public and private primary and secondary schools to identify this type of asbestos and notify school employees and other appropriate people of the

results of such inspections. The U.S. Department of Education simultaneously proposed a rule giving details on how to obtain Federal funding of detection and abatement programs carried out through that Department under special legislation; this proposed rule also would require States to report to the Department on results of funded programs. An EPA rule under TSCA to require other suitable control measures to reduce exposure to particularly serious asbestos situations in schools is expected to be proposed late in 1981.

Potential asbestos substitutes and use rulemaking proceeding: Actions by EPA and other groups investigating the hazards associated with exposure to asbestos has stimulated private-sector research to identify and develop reasonable substitute materials and products for asbestos. For example, in July 1980, EPA, the Consumer Product Safety Commission, and the Interagency Regulatory Liaison Group sponsored a "National Workshop on Substitutes for Asbestos" in order to gather economic, technical, and health-related information about potential asbestos substitutes. This information is being used to develop and evaluate regulatory and nonregulatory alternatives for reducing human health risks associated with exposure to asbestos. Approximately 600 representatives from industry, labor, government, and other groups participated in the workshop.

Although there is no known material that can replace each or every asbestos use, participants in this workshop group agreed that substitutes are available for many specific uses (the workshop proceedings are available to the public). EPA plans to use this information in developing a rule to reduce unreasonable risks from exposure to asbestos materials in commercial and industrial uses.

Section 8: Reporting and Record-Keeping

Chemical information reporting: As noted previously, approximately 55,000 chemicals are presently manufactured and distributed in U.S. commerce. A major challenge for the TSCA program is to develop a mechanism for identifying those chemicals likely to damage human health or the environment so that appropriate action can be taken by industry or EPA.

Because there is no data base that includes both available toxicity and exposure data on large numbers of these chemicals, the Agency has an exceedingly difficult task before it. The reporting authorities in section 8, however, provide mechanisms for systematically obtaining such needed data. In 1980, the Agency devoted substantial effort to developing appropriate rules to implement these authorities.

Section 8(a): This section of TSCA permits EPA to promulgate rules under which chemical manufacturers and/or processors are required to maintain records and report to the Agency the identities and quantities of chemicals they produce, as well as the use, the by-products of the manufacture of those chemicals, data on health and environmental effects, the extent of exposure to workers, and the manner of disposal.

EPA's approach to implementing this requirement is designed to be as efficient and unburdensome as possible. One approach, for example, involves three levels of reporting. At the first level, a modest amount of information would be obtained on approximately 2.300 chemicals selected primarily for their large production volumes and hence potentially large exposures. Other chemicals would be added later. After those data were assessed, additional data on a portion of those chemicals would be required in a second, more detailed level of reporting. Similarly, a third level of reporting would provide additional data needed on still fewer chemicals-those identifed as most likely to create an unreasonable risk to health or the environment. In general, the third level would be chemicalspecific: that is, a separate rule tailored to the specific information needs for a given chemical. With this information available on the highest-priority chemicals, EPA would work with industry to achieve appropriate risk reductions and to undertake regulatory action when necessary.

Proposed rule, section 8(a): The first-level reporting rule under section 8(a) was proposed in February 1980. It identifies 2,300 chemicals and calls for available information on amounts produced, uses, and certain exposure data. Small manufacturers are exempt from the rule as proposed. Work began on the second-level and third-level reporting rules in 1980; the second-level rule is scheduled for proposal in 1981.

Proposed asbestos rule, section 8(a): To better evaluate various exposures and potential economic impacts, the Agency is scheduled to propose a rule under section 8(a) in early 1981 to require miners, importers, and processors of asbestos to report on their production, number of employees, asbestos releases, waste disposal, and pollution control equipment, and to summarize their existing monitoring data from the Occupational Safety and Health Administration and the Mine Safety and Health Administration. In an effort to reduce the overall costs of this rule, the Agency intends to require comprehensive reporting from only a representative sample of the many manufacturers and importers of asbestos-containing products.

Proposed rule, section 8(a), generic small-business exemption standards: Generic standards are being developed to exempt small businesses from reporting and recordkeeping requirements under section 8(a). A notice relating to this activity and announcing public meetings was published in the Federal Register on October 6, 1980. Under these rules, businesses defined as "small" would be exempt from section 8(a) requirements unless the chemical that is manufactured or processed is subject to certain proposed or final TSCA actions, including section 6 control regulations and section 4 testing rules. The first rule is scheduled for publication in 1981.

Proposed rule, section 8(c): In July 1980, EPA proposed a rule interpreting section 8(c) of TSCA and establishing procedures for maintaining records of allegations to EPA. This section of the Act requires manufacturers, processors, and distributors of chemical substances and mixtures to keep records of significant adverse reactions to health or the environment allegedly caused by their chemicals. These records may be required to be submitted to EPA under certain circumstances. The rule is expected to fill a large gap in occupational health data and reveal patterns of adverse health effects. These patterns then can be analyzed to identify to curhemicals so that manufacturers or Eigen take the necessary steps to an take the necessary steps to reduce the effects of the identified chemicals.

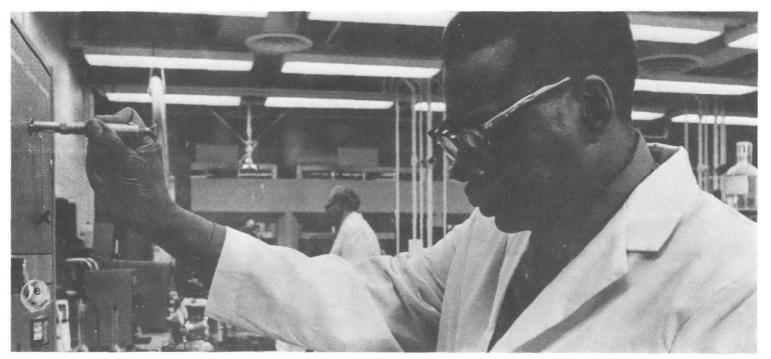
Proposed rule, section 8(d): A proposed rule to implement section 8(d) of TSCA was published on December 31, 1979. This section authorizes EPA to

promulgate rules requiring manufacturers, processors, and distributors of chemicals to submit health and safety studies that they have conducted or that are reasonably ascertainable by them. Chemicals recommended by the Interagency Testing Committee for testing and other chemicals selected by EPA would be subject to the rule. Because it reaches unpublished studies, this provision will greatly increase the body of available data on health and environmental effects. The rule is scheduled for promulgation in 1981.

Section 8(e): Section 8(e) requires chemical manufacturers, distributors, and processors to inform EPA immediately if they obtain information indicating that a chemical presents a substantial risk of injury to health or the environment. This reporting requirement was self-implementing and has been in effect since January 1977 (the effective data of TSCA). On March 16, 1978,

EPA published a section 8(e) policy statement providing guidance for submitting the required information (43 FR 11110).

Substantial-risk reporting has heightened industry awareness of potential chemical risks, often resulting in manufacturers, processors, and distributors taking action on their own to minimize exposure to hazardous substances. To date, EPA has received, evaluated, and prepared status reports on 370 section 8(e) notices, 54 during FY 1980, In addition to considering whether formal action may be necessary under TSCA to prevent unreasonable risks, the Agency has referred a number of notices to other government programs for appropriate followup attention. Two volumes of substantial-risk-notice status reports have been published as part of the TSCA Chemical Assessment Series. (See Bibliography at end of this Report.)



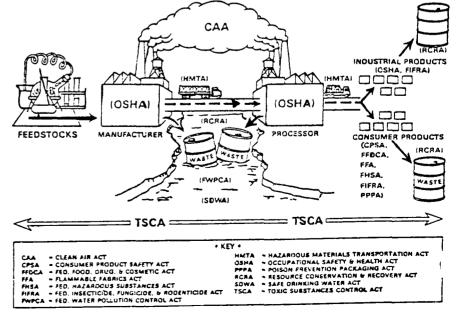
TSCA Section 9(d): Relationship of TSCA to Other Federal Laws

Coordination with other chemical-control programs: Implicit to TSCA is the need to coordinate with other Federal programs involved in toxic chemical regulation, as called for under section 9(d) of the Act. Substantial progress toward building cooperative arrangements was made in 1980, including signed operational procedures with the Consumer Product Safety Commission (CPSC) and joint deliberations with Occupational Safety and Health Administration (OSHA), CPSC, and Food and Drug Administration (FDA) staff on major toxic-chemical issues.

Toxic Substances Priority Committee (TSPC): The TSPC is an EPA-wide committee comprised of Deputy Assistant Administrators involved in managing various statutory programs having to do with toxic substances in air, water, etc.; it is chaired by the Associate Assistant Administrator for Toxics Integration, a position located within the Office of Pesticides and Toxic Substances. The Committee serves as a mechanism for coordinating consistent and nonduplicative approaches to chemical regulation within EPA, to ensure that during the early stages of problem identification, risk assessment, and preregulatory analysis of chemicals. the Agency decides which program office should take the lead and what analytical, technical, coordinative, and regulatory steps are appropriate. Among the chemicals the TSPC is currently examining are chlorinated solvents, chlorinated dioxins, arsenic, and benzidine.

Interagency Regulatory Liaison Group (IRLG): The IRLG, which includes EPA, CPSC, FDA, OSHA, and the Food Safety and Quality Service of the Department of Agriculture, seeks to integrate and coordinate information and activities on a government-wide basis, in order to avoid duplication of effort and promote cost-effective chemical control programs. A number of routine, stafflevel mechanisms were maintained in 1980 to insure full participation of EPA's TSCA activities in the ongoing IRLG program.

LEGISLATIVE AUTHORITIES AFFECTING THE LIFE CYCLE OF A CHEMICAL



Source: EPA Journal, July/August 1979.

Section 16: Enforcement

Under section 16(a) of TSCA, EPA may levy civil penalties for violation of several sections of the Act. All of EPA's FY 1980 enforcement actions under section 16 involved alleged violations of the section 6 PCB rules. EPA conducted 616 PCB compliance monitoring inspections and filed a total of 64 civil complaints during the fiscal year; 34 cases were completed, and \$172,130 in civil penalties was assessed. Figures for each Region are shown in Table 4.

The largest single penalty, \$40,000, was assessed against the Pierce Packing Company of Billings, Montana. In 1979, PCBs leaking from a damaged

resformer into the plant's wastewater tment system contaminated animal feed ingredients. The tainted feed was then fed to poultry and livestock, contaminating in turn meat, poultry, eggs, soups, and bakery items.

Approximately 800,000 chickens, 3,800,000 eggs, 4,000 hogs, 74,000 bakery goods, and 800,000 pounds of assorted animal feeds and feed ingredients had to be destroyed to protect the public from possible exposure to the contaminated goods.

Criminal cases must be filed on EPA's behalf in Federal court by the Department of Justice. A major criminal action was initiated under section 16(b) of TSCA against Wes-Con, Inc., a waste disposal company in Boise, Idaho, for alleged improper disposal of PCBs. On July 30, 1980, the Department of Justice announced a grand jury indictment against Wes-Con on the grounds that the company allegedly emptied PCB wastes into its own landfill and then concealed that activity by generating false and misleading disposal records. The trial is scheduled to take place in 1981.

EPA has also taken action to enforce compliance with other TSCA requirements, although so far there has not been a need in these instances to invoke section 16. The Agency conducted 16 inspections to monitor compliance with the interagency ban on nonessential aerosol uses of CFCs, and 6 inspections to determine compliance with import requirements under section 13. Also in FY 1980, the Agency inspected 83 of 98 firms that failed to meet the deadline for reporting identities

of existing chemicals as required under section 8 of TSCA, to insure that the substances reported late to the Agency were not in fact new chemicals subject to the PMN requirements of section 5.

In a major enforcement policy development during FY 1980, EPA issued a generic penalty policy that sets forth Agency policy for applying the statutory criteria for assessing civil penalties under TSCA. Regulation-specific penalty policies for PCBs, PMN, and section 8(b) enforcement were also issued.

Table 4. Administrative Civil Actions Taken Under Section 16 of TSCA Through FY 1980: Complaints Issued, Cases Completed, and Amount Assessed (by Region)

Region	Number of complaints issued	Number of cases completed	Total civil penalty amount assessed	
I	5	3	\$ 9,600	
11	9	0	_	
IH	5	4	11,900	
IV	2	1	3,750	
V	10	6	44,000	
VI	21	12	37,880	
VII	6	_	_	
VIII	2	5	49,500	
IX	3	3	15,500	
X		_	_	
Headquarters	1			
TOTAL	64	34	\$172,130	

The EPA Office of Enforcement (OE) has also been an active participant in the overall TSCA regulations development process. Along with this process, OE has been shaping specific enforcement strategies for implementation once requirements are promulgated. These strategies identify and rank possible violations of the regulation, identify the tools available for compliance monitoring and how they will be used, provide a formula for determining application of inspectional resources, and establish policy for determining civil penalties under the regulation. Strategies for operating programs were implemented through the compliance monitoring inspections described above.

Preliminary strategies were developed during FY 1980 along with enforcement staff participation in TSCA rulemaking. They include strategies for the enforcement of the section 6 dioxin, asbestos, and CFC production rules; section 5 significant new use rule; section 8(a), (c), and (d) reporting requirements; section 12 and 13 import/export requirements; and section 4 ecological and health effects testing, reimbursement, and testing standards rules.

The Office of Enforcement also actively participates in several significant cooperative efforts. During FY 1980, OE initiated interagency programs with the General Services Administration and the Department of Energy to gain compliance with the PCB rule by Federal facilities. Under OE leadership, the Interagency Regulatory Liaison Group (IRLG) implemented a referral inspection program to improve interagency referral of possible violations and better coordinate the Federal response to emergency incidents that threaten public health or the environment. Enforcement staff began working with the Organization for Economic Cooperation and Development (OECD) to foster the international implementation of compliance monitoring programs, assuring international adherence to good laboratory practices standards, and participates on the Toxics Enforcement Committee, an EPA interagency committee that fosters coordination in toxics regulation development and enforcement strategy and policy development.

Other TSCA enforcement activities included entering into contracts for inspection support, sample analysis, policy and strategy research, and training manuals and materials. A pilot cooperative program with the States for TSCA enforcement activities was also initiated in FY 1980. In addition, a number of outreach activities were undertaken to involve interested organizations in the enforcement program, including the development of a system for handling citizen complaints.



Section 28(c): State Programs

Section 28(c) of TSCA authorizes EPA to award grants to States for programs to prevent or eliminate problems created by toxic substances that EPA is unable or unlikely to act upon under TSCA. On August 28, 1978, EPA announced in the *Federal Register* the availability of \$3 million for this Federal assistance program and provided guidance to prospective applicants. This announcement also described a two-cycle award process; approximately half the funds would be distributed each time.

Nine states (Arkansas, California, Illinois, Iowa, Maryland, Michigan, New Yey, New York, and Wisconsin) lied for funds in the first cycle. In April 1979, cooperative agreements (grants requiring substantial Federal involvement) were awarded to the five States italicized in the previous sentence. (See Table 5.)

Nine new State applications were received in the second cycle (Colorado, Connecticut, Delaware, Louisiana, Michigan, Minnesota, North Carolina, Oklahoma, Puerto Rico; Illinois applied again in 1980). Including seven applications held over from the first cycle, a total of 16 State applications were considered by EPA. In February 1980, cooperative agreements were awarded to three States (New Jersey, North Carolina, and Puerto Rico*).

On February 11, 1980, EPA announced in the *Federal Register* the availability of an additional \$1.25 million for a third and final cycle in this State cooperative agreements program. Eleven States (Illinois—which submitted two proposals—Louisiana, Maryland, Michigan, Minnesota, New Jersey, New York, Ohio, Puerto Rico, Tennessee) have applied for these funds. Once decisions are made on these applications early in 1981, EPA will have obligated almost all of the \$4.5 million appropriated by the Congress for this TSCA program.

Table 5. State Cooperative Agreements Program, 1980-1981

	Project grants awarded	Amount (in \$)
Cycle 1		
Maryland	Toxic substances registry	230,935
Department of		
Health and Mental		
Hygiene		
Michigan	Critical materials program	504,50 0
Department of		
Natural Resources		
New Jersey	Toxic substances investigation and integration unit; expand a	453,947
Department of	current project monitoring volatile organic compounds in air	
Environmental		
Protection		
New York	Program to identify, characterize and plan for managing toxic	348,000
Department of	substances	
Conservation		222.247
Wisconsin	Study health problems related to formaldehyde vapors from	202,947
Department of	mobile home construction materials	
Health and		
Social Sciences		
Cycle 2		
New Jersey	Study the movement, distribution and uptake of in-place	794,053
Department of	mercury; monitor emission of selected toxic substances;	
Environmental	assess the ecological effects of water contaminants; establish	
Protection	and operate a Toxic Substances Information Resource Center;	
	conduct a field application study of in-vitro mutagenesis tests	
North Carolina	Program to identify, assess and plan to control toxic	385,000
	substances by profiling substances, identifying sources and	
	level and duration of exposure, and developing a plan to	
	control substances posing unreasonable risk	
Puerto Rico	Develop and manage the Commonwealth's toxic substances	258,394
Environmental	management strategy; expand an existing public participation/	
Quality	awareness program	

^{*} As defined in TSCA "State" means any territory or possession of the United States.

Section 30: Litigation

Environmental Defense Fund, Inc. v. Environmental Protection Agency (No. 79-1500, D.C. Cir.): The Environmental Defense Fund petitioned for review of EPA's regulations under TSCA sections 6(e)(2) and (3) governing manufacture, processing, distribution, and use of polychlorinated biphenyls (PCBs). The petition challenged three elements of the regulation: EPA's determination that certain commercial uses of PCBs are "totally enclosed" and therefore exempt from regulation under TSCA: the limitation of applicability of the regulation to materials containing PCBs in concentrations greater than 50 parts per million; and EPA's decision to permit 11 non-totally enclosed uses of PCBs. On October 30, 1980, the Court found that there was no substantial evidence in the record to support the first two elements and remanded them to EPA for further proceedings. The third element was upheld.

Olin Corporation v. EPA (No. 79-1437, 4th Cir.): General Electric Company v. EPA (No. 79-1816, D.C. Cir.); and Aluminum Co. of America v. EPA (No. 79-1811, D.C. Cir.): In 1979, Olin, General Electric, and Alcoa challenged EPA's authority under section 6(e) of TSCA to regulate PCBs that are created incidentally or unintentionally as by-products of the manufacturing process and are then totally destroyed. These proceedings have been stayed until EPA reaches a decision on exemption petitions submitted by the three companies.

Dow Chemical Company v. Douglas Costle (Civ. Action No. 79-581, D. Del.): In 1979, Dow challenged EPA's decision to include monochlorobiphenyls in its PCB regulations, by bringing suit in the Federal District Court of Delaware. The Court dismissed the suit for lack of jurisdiction and Dow appealed. *Dow Chemical Co. v. Costle* (80-1498, 3rd Cir.). Dow has obtained a stay of its appeal pending the outcome of an EPA administrative civil penalty action against it for unlawful production of the monochlorobiphenyls.

Warren County v. State of North Carolina, et al. (No. 79-560-CIV-5, E.D.N.C.): The Warren County government and private citizens sued the State of North Carolina and EPA officials, challenging EPA's approval of a PCB landfill located in Warren County in July 1979. The plaintiffs have argued that EPA was required to prepare an environmental impact statement and failed to do so, that the Agency improperly waived certain EPA PCB disposal requirements, and that such a landfill was barred by local ordinance. This case has not been decided.

T. Mitchell Langdon et al. v. James B. Hunt et al. (No. 86-487-CIV-5, E.D.N.C.: In July 1980, plaintiffs sued private defendants and State and EPA officials for damages resulting from private dumping of PCBs on North Carolina roads and to prevent such dumping in the future. Initial pleadings are still being filed.

Natural Resources Defense Council (NRDC) v. Costle (No. 79 CIV. 2411, S.D.N.Y.): NRDC brought suit in 1979 to challenge EPA's implementation of TSCA section 4(e). This section requires EPA either to initiate a test rule or publish its reasons for not doing so, within one year after a chemical is recommended for priority testing by the Interagency Testing Committee (ITC). EPA responded to the first two ITC reports by stating it would not initiate rulemaking within the year because its evaluation of the ITC recommendations

was incomplete and basic scientific and policy issues remained unresolved. NRDC argued that this response did not meet the statutory requirements. Industry groups intervened on EPA's behalf. In February 1980, the court ruled in favor of NRDC and ordered EPA to submit a compliance schedule for responding to the backlog of ITC recommendations. The present schedule proposed by EPA to the court would, if adopted, require the Agency to propose test rules or announce decisions not to require testing of chemicals in the first five ITC reports by the end of 1983.

Vertac Chemical Corporation v. EPA (No. 80-1596, 8th Cir.): In July 1980, Vertac filed a petition for review of EPA's rule prohibiting it from disposing of certain wastes containing 2,3,7,8-tetrachlorodibenzo-para-dioxin (TCDD) and requiring disposal of other TCDD-containing waste in landfills suited for PCB disposal. Vertac withdrew the petition in September 1980.

Aluminum Company of America and Northwest Alloys, Inc. v. Donald Dubois, Douglas Costle, and Environmental Protection Agency (No. C801178V, W. D. Washington): Plaintiffs sued the EPA Administrator, the Regional Administrator for Region X, and the Agency as a whole for declaratory judgment that section 11(a) of TSCA does not authorize EPA to designate EPA contractors as EPA representatives for purposes of performing statutory inspections and for an injunction to prevent such inspections. EPA has filed a motion to dismiss the complaint for lack of jurisdiction and because section 11 clearly authorizes EPA to designate contractors as representatives for purposes of inspections. The court has not acted on EPA's motion.

(c. p. c.) [1]

Other TSCA Activities

TSCA section 12(b): On December 16, 1980, EPA issued final procedural rules for domestic chemical exporters to submit notifications of export to EPA of their intent to export or their actual export of chemical substances or mixtures subject to certain regulatory actions under TSCA. Exporters must submit one notice per year for each chemical and country of import.

requires the U.S. Customs Service to refuse entry into the U.S. customs territory of chemical substances, mixtures, and articles containing chemical substances or mixtures that do make mply with rules issued under T. On December 1, 1980, the Customs Service proposed rules to implement this section. Concurrently, EPA proposed a policy statement concerning its responsibilities under section 13. The policy statement is scheduled to be made final in 1981.

TSCA section 20: On June 25, 1980, EPA proposed procedural rules concerning citizens' civil actions under section 20 of TSCA, which authorizes citizens to initiate suits to restrain violations of TSCA or to compel implementation by EPA of TSCA's nondiscretionary authorities. The proposed rules set forth procedures for the statutorily required notice to the Administrator and alleged violator prior to filing suit. The final rule will be promulgated early in 1981.

TSCA section 26(a), Industry Assistance Office: The Industry Assistance Office (IAO), which is required by statute, is the contact point for communication between the TSCA regulated community and the Office of Toxic Substances. To assist the chemical industry's understanding of Agency policy and the Act's requirements for implementation, IAO provides an information-response service that in 1980 handled an average of 3,600 tollfree telephone inquiries and 4,000 document requests per month. A total of 9.483 copies of the TSCA Revised Chemical Substances Inventory were distributed to producers who must screen their developmental chemicals to see if they are new and thus subject to premanufacture notification.

In 1980, to alert businesses that process food, feed, and fertilizer to the need to remove PCBs from their equipment, an instructional booklet in layman's language was written by IAO and mailed (in coordination with FDA) to some 200,000 establishments. In addition, new instructional slide-tape presentations were made covering section 4 testing requirements, section 5 premanufacture notification, section 6 PCB control, and section 8(e) substantial risk notification. These programs are available free from IAO's slide-tape lending library.

IAO insures that impacted manufacturers and processors receive notice of TSCA actions within 10 days of their publication in the Federal Register. In response to the demand from broader TSCA constituencies, IAO reproduced 106 documents for a total stock of 1.03 million copies available for distribution in 1980. There are now some 25,000 persons or organizations on the IAO mailing list; to avoid unnecessary mailing and printing charges, however, most dissemination is to targeted subgroups or specially developed sublists for individual rulemakings.

All persons interested in TSCA can learn about its activities through the bimonthly TSCA Chemicals-in-Progress Bulletin and by using IAO's toll-free telephone number to pursue particular information. Throughout the year, IAO conducts preproposal liaison efforts for rule development in order to promote technical feasibility, minimize adverse impacts, and insure a meaningful yield to the Agency from compliance. In addition, a pilot field consultancy program directed by IAO to assist small businesses with their premanufacture notices is now in operation in Chicago and parts of New Jersey. The average rate of usage is about 22 assistance sessions per month.

Innovation study: In November 1980, EPA released a report on a study designed to help the Agency better analyze TSCA's effects on innovation in the chemical industry. The study gives a number of proposals for changing the Agency's implementation of the law to lessen any undue negative effects that may surface.

The report, Supporting Innovation: A Policy Study, was prepared by the Center for Policy Alternatives, Massachusetts Institute of Technology. Its authors conclude that although the impact of TSCA is not predictable, it is iust as likely to stimulate innovation such as in the development of new, safer chemicals—as it is to discourage innovation in other aspects of the industry. The study recommends a group of six management initiatives that could be used to offset any negative effects on innovation. As a complement to this report, EPA has begun a 3-year study to obtain an in-depth analysis of innovation in the chemical industry. It will provide detailed empirical data that are needed before conclusive statements about TSCA's effects can be made.

Administrator's Toxic Substances Advisory Committee: (ATSAC): The Administrator's Toxic Substances Advisory Committee reflects a range of expertise from industry, environmental, and labor organizations, State and local government health programs, and medicine and law. In 1980 the committee met five times and dealt with many toxic substances issues including the following: the nationwide school asbestos removal and awareness program; confidentiality of information reported for the TSCA chemical inventory; the premanufacture notification program for new chemicals; and the proposed TSCA testing standards and rules.

Science Advisory Board: The EPA Science Advisory Board (SAB) provides principal scientific counsel to the Administrator. Foremost among the several SAB subcommittees that take an interest in Agency activities under TSCA is the Toxic Substances Subcommittee. In FY 1980, for example, the SAB Subcommittee on Toxic Substances reviewed the overall TSCA program, the proposed testing rules, the TSCA chemical risk-assessment process, and the technical support document for the school asbestos rule. In the coming year, it is anticipated that the SAB will review the premanufacture program and the section 8 substantial risk followup process, in addition to section 4 testing standards and rules. Finally, it is expected that the SAB will review, on its own initiative, a number of the longer-term issues that will confront the Agency in the area of toxic substances control.

EPA Research Committee: The EPA Research Committee system has been established over the last two years to serve as a cornerstone for program planning in the Office of Research and Development (ORD) and to effect a formal liaison mechanism between ORD and the program offices within EPA. There are 13 Research Committees, each of which is co-chaired by a senior manager from ORD and a senior manager from the corresponding program office. EPA regional offices, Office of Enforcement, and Office of Planning and Management are represented on each committee as well. The Chemical Testing and Assessment Research Committee plans research activities relevant to TSCA.

International activities: EPA recognizes the economic and social advantages of international cooperation in chemical testing and control: elimination of potential nontariff trade barriers that might result from differing national programs and improved efficiency in allocating limited testing and assessment resources. In 1980, significant TSCA program resources were devoted to harmonizing chemical testing programs among the 24 member nations of the Organization for Economic Cooperation and Development (OECD), TSCA program staff participated in all aspects of this OECD work, including chairing expert groups on long-term toxicology and good laboratory practices and a subgroup on direct human exposure assessment.

A major milestone was reached in May 1980 when the OECD Chemicals Group endorsed the work of the expert groups and achieved consensus on approximately 44 guidelines for chemical testing for physical/chemical properties, degradation/accumulation characteristics, and toxicity; principles of good laboratory practices; a set of data that should be generated for an initial risk assessment before a chemical is marketed; the need to develop an updating mechanism to modify accepted test guidelines as the state-of-the-art advances; and the principle of mutual acceptance of data, whereby data generated by OECD methods in one country will be accepted for purposes of assessment in another.

TSCA program staff also was involved in developing compatible approaches to exchanging confidential business information and in constructing an international glossary of key terms for use by nations in developing control legislation for toxic chemicals. Following the May 1980 meeting, EPA instituted a program to harmonize its testing standards, developed under both TSCA and the pesticides program, with those developed in the OECD. As a result, differences between like tests for different regulatory programs have been minimized, thereby reducing industry's burden and allowing testing resources to be used more efficiently.

or Problems

Implementation of section 4: EPA's Third Annual Report on TSCA (1979) discussed problems encountered in the implementation of section 4 of the Act. It also mentioned then pending litigation brought by the Natural Resources Defense Council with respect to the Agency's failure to respond to the testing recommendations of the Interagency Testing Committee (ITC) within the statutory period of one year, and that the Court had found against EPA and directed the Agency to submit a plan for complying with section 4(e). Since that date, the Agency has submitted to the Court a schedule for compliance. Affidavits accompanying the schedule submitted to the Court set out in detail difficulties encountered by

the Agency in its implementation of section 4, as well as EPA efforts to make more efficient (1) the way in which supporting materials are developed for test rules, and (2) internal procedures for handling test rules and ITC recommendations. The Agency would be required to report to the Court on a biannual schedule its compliance efforts and any difficulties encountered in meeting the schedule.

PCB remand: As a result of litigation brought by the Environmental Defense Fund, two major portions of the Agency's PCB Ban Regulations were invalidated by the U.S. Court of Appeals for the District of Columbia Circuit. Both the definition of "PCBs" as PCBs in concentrations of 50 parts per million (ppm) or greater and the designation of intact, non-leaking PCB-containing transformers, capacitors and electromagnets as "totally enclosed" uses of PCBs (and therefore exempt from regulation) were found to be unsupported by substantial evidence in the rulemaking record. The impact of the Court's October 30, 1980, decision, when it becomes effective, is to make applicable the broad prohibitions of section 6(e) of TSCA; portions of the regulation invalidated had the effect of softening the impact of the 6(e) prohibitions.

Since the October 1980 decision, the Agency has been in the process of deciding how to proceed with new rulemaking efforts with respect to each of these two issues. This process has included filing multi-party motions in the D.C. Circuit to withhold the effectiveness of the Court's decision pending further rulemaking or factgathering efforts. Underlying these motions to the Court are undertakings by industry groups to supply factual information necessary for further rulemaking and a program of inspection and maintenance of PCB equipment that would have to be instituted by persons seeking the benefit of a delay in the effectiveness of the Court's decision. The most serious problem presented by the Court's decision is that the Agency has little factual information about the manufacture, processing and distribution and use of PCBs in concentrations below 50 ppm but has reason to believe that a ban on these activities would disrupt major industries in the United States.

Recommendations for Additional Legislation

No recommendations for additional legislation were determined necessary in 1980 to carry out the purposes of TSCA.

Appendix

TSCA Publications, 19ა0— Selected Bibliography

TSCA Chemical Assessment Series

Chemical Hazard Information Profiles (CHIPs), August 1976-August 1978. EPA 560/11-80-011. Initial Evaluations of Substantial Risk Notices, Section 8(e), January 1, 1977-June 30, 1979. EPA 560/11-80-008

Initial Evaluations of Substantial Risk Notices; Section 8(e), July 1, 1979–January 30, 1980. EPA 560/11-80-020

Preliminary Risk Assessment: Phase I, Benzidine, Its Congeners, and Their Derivative Dyes and Pigments. EPA 560/11-80-019

Assessment of Testing Needs: Chlorinated Benzenes. EPA 560/11-80-014

Assessment of Testing Needs: Acrylamide. EPA 560/11-80-016

Assessment of Testing Needs: Chloromethane. EPA 560/11-80-015

Support Document: Approaches to Exposure Assessment. EPA 560/11-80-017

Toxics Integration Policy Series

State Administrative Models for Toxic Substances Management. EPA 560/13-80-018

Toxics Information Series

Asbestos, April 1980 PCBs, June 1980

TSCA General Publications

Chemicals-in-Progress Bulletin (bimonthly)
Citizens' Guide to Toxic Substances Information
(October 1980)

Toxic Substances: A Brief Overview of the Issues Involved April 1980

Dealing with Toxic Chemicals: A Citizen's Role (slide show and handbook, May 1980)

TSCA: Protecting People and the Environment from Dangerous Chemicals (July 1980)
Laws for Life (slide show, produced under a grant to the Urban Environmental Conference, December 1980)

Exposure (a monthly newletter produced under a grant to the Environmental Action Foundation)

The Toxic Substances Dilemma: A Plan for Citizen Action (produced under a grant to the National Wildlife Federation)

Administration of the Toxic Substances Control Act (1979) (July 1980)

Perspectives on the Top 50 Production Volume Chemicals, July 1980. EPA 560/13-80-027 TSCA Status Report for Existing Chemicals.

EPA 560/13-80-033 (printout)

Directory of Federal Coordinating Groups for Toxic

Substances, 2nd ed. EPA 560/13-80-008 Overview of Federal Toxics Programs. EPA 560/13-80-015

Environmental Protection Agency—Office of Toxic Substances

Selected Contractor Reports, FY 1980*
Acute Toxicity Testing Criteria for New Chemical Substances. EPA 560/13-79-009 (NTIS Order #: PB 80-111-073)

Analytical Protocols for Making a Preliminary Assessment of Halogenated Organic Compounds in Man and Environmental Media. EPA 560/13-79-010 (NTIS Order #: PB 80-162-168) Arsenic: A Preliminary Materials Balance. EPA 560/6-79-005 (NTIS Order ® : PB 80-162-217)

Asbestos-Containing Materials in School Buildings: Bulk Sample Analysis Quality Assurance Program. EPA 560/12-79-001 (NTIS Order #: PB 80-217-243)

Atmospheric Reaction Products of Organic Compounds. EPA 560/12-79-001 (NTIS Order #: PB 80-301-384)

Cadmium and Lead Levels in Human Blood and Kidney, A Literature Search. EPA 560/13-80-002 (NTIS Order #: PB 80-220-221)

Chemicals Identified in Human Biological Media, A Data Base. First Annual Report, October 1979. Volume 1, Part 1. EPA 560/13-79-011 (NTIS Order #: PB 80-183-288)

Chemicals Identified in Human Biological Media, A Data Base. First Annual Report, October 1979. Volume 1, Part 2. EPA 560/13-79-011a (NTIS Order #: PB 80-183-296)

Determination of Pentachlorophenol and Hexachlorobenzene Residues. EPA 560/13-3-30 (NTIS Order #: PB 80-222-672)

Economic Impact Analysis of Proposed Identification and Notification Rule on Friable Asbestos-Containing Materials in Schools EPA 560/12-80-004

Economic Impact Analysis of Proposed Section 5 Notice Requirements. Parts I, II, II. EPA 560/12-80-005, 005-A, 005-B

Economic Implications of Regulating Chlorofluorocarbon Emissions from Nonaerosol Applications. EPA 560/12-80-001. Flexible Urethane Foam and Chlorofluorocarbon Emissions. EPA 560/12-80-001-A. An Executive Briefing. EPA 560/12-80-001-B. Effects on Chemical Production. EPA 560/12-001-c

Economic Impact Analysis of Proposed Test Rule for Chloromethane and Chlorobenzenes. EPA 560/11-80-021 (NTIS Order #: PB 80-215-411)

Effect of Phosphorus Control Options on Lake Water Quality. EPA 560/11-79-011 (NTIS Order #: PB 80-123-698)

Environmental Sources of Trichloroethylene Exposure: Sources Contribution Factors. EPA 560/11-80-009 (NTIS Order #: PB 80-213-432)

Failure to Produce Arsenic Neurotoxicity in the Rat. EPA 560/11-80-022 (NTIS Order #: PB 80-209-505)

Formulation of a Preliminary Assessment of Halogenated Organic Compounds in Man Environmental Media. EPA 560/13-79-006 Order #: PB 80-112-170)

^{*} These technical reports were prepared under contract for the Office of Toxic Substances and were published during 1980. The list reflects the types of research being funded by the office and contains titled that are available through the National Technical Information Service (NTIS). Those titles with an asterisk have recently been sent to NTIS and can be requested by title and EPA report number.

Investigation of Selected Potential Environmental Contaminants: Epichlorohydrin. EPA 560/11-80-006

Investigation of Selected Potential Environmental Contaminants: Haloalcohols. EPA 560/11-80-004 (NTIS Order #: PB 80-197-957)

Investigation of Selected Potential Environmental Contaminants: Styrene and Ethylbenzene. EPA 560/11-80-018.

Materials Balance for Anilines. Level I— Preliminary. EPA 560/13-80-013 (NTIS Order #: PB 80-185-394)

Materials Balance for Benzene. Level I— Preliminary. EPA 560/13-80-014 (NTIS Order #: PB 80-185-663)

Materials Balance for Chlorobenzenes. Level I— Preliminary. EPA 560/13-80-001 (NTIS Order #: PB 80-173-651)

Materials Balance for Chlorophenols. Level I— Preliminary. EPA 560/13-80-004 (NTIS Order #: PB 80-185-960)

terials Balance for 1,2-Dichloroethane. Level I liminary. EPA 560/13-80-002 (NTIS Order #: PB 80-177-132)

Materials Balance for Methyl Chloroform. Level II. EPA 560/13-80-003 (NTIS Order #: PB 80-175-730)

Methodology for Estimating Direct Exposure to New Chemical Substances. EPA 560/13-79-008 (NTIS Order #: PB 80-102-262)

Organic Solvent Use Study. Final Report. EPA 560/12-79-002 (NTIS Order #: PB 80-301-342)

Proceedings of the EPA Workshop on the Environmental Scoring of Chemicals. EPA 560/11-80-010 (NTIS Order #: PB 80-194-640)

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Sampling and Analysis of Selected Toxic Substances. Task I: Polybrominated Biphenyls in Air and Soil at Two User Sites. EPA 560/13-80-005 (NTIS Order #: PB 80-176-373)

Structure-Reactivity Coorelations for Environmental Reactions. EPA 560/11-79-012 (NTIS Order #: PB 80-110-323)

Supporting Innovation: A Policy Study. EPA 560/12-80-002

Test Methods for Definition of Effects of Toxic Substances on Behavior and Neuromotor Function. EPA 560/11-79-010 (NTIS Order #: PB 80-109-101)

Toxic Substances Control Act Chemical Substances Inventory: Cumulative Supplement, July 1980. Computer Tape EPA 560/13-80-025 (NTIS Order #: PB 80-220-007)

Volatile Corrosion Inhibitors and Boiler Water Additives—Potential for Nitrosamine Formation. EPA 560/11-80-023 (NTIS Order #: PB 80-221-195)

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45 FR 9248

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April 18, 190. Inventory Reporting; Statement of Policy, Late Submissions Under Section 8(b) of TSCA. 45 FR 26452

April 21, 1980. Premanufacture Notices, Status Report of March 1980. 45 FR 26815

April 28, 1980. Pesticides and Toxic Substances General Recordkeeping and Reporting Requirement: Preliminary Assessment of Information; Notice of Public Meetings for 8(a) Level Proposed Rule. 45 FR 28176

May 1, 1980. Polychlorinated Biphenyls (PCBs), Expiration of the Open Border Policy for PCB Disposal; Notice, 45 FR 29115

May 9, 1980. Polychlorinated Biphenyls (PCBs) Manufacturing, Processing, Distribution in Commerce, and Use Prohibitions; Proposed Restrictions on Use at Agricultural Pesticides and Fertilizer Facilities. 45 FR 30989

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July 18, 1980. Part V. Acrylamide; Response to the Interagency Testing Committee; Exemption from Test Rules, Proposed Statement of Policy and Procedures; Chloromethane and Chlorinated Benzenes Proposed Test Rule, Proposed Health Effects Standards Amended. Notice and Requests for Comments. 45 FR 48510

July 23, 1980. Carbamic Acid, Bis(Methoxymethyl) Isopropyl Ester; Denial of Test Marketing Exemption. 45 FR 49160

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July 29, 1980. Availability of TSCA Revised Inventory. Notice of Availability. Transfer of TSCA Premanufacture Notification Information to Contractor; Data Transfer. Certain Chemicals, Premanufacture Notice. 45 FR 50544, 50420, 50418

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