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WORKING PAPER NO. 21

THE TOXIC SUBSTANCES CONTROL ACT: OVERVIEW AND EVALUATION

by

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FOREWORD

This study is one of a series commissioned by the Economic Council's Regulation Reference which deals with various aspects of environmental regulation. These studies do not profess to cover the whole field of environmental regulation but they do focus on several important areas of concern.

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RÉSUMÉ

RÉGLEMENTATION DES PRODUITS CHIMIQUES TOXIQUES
Vue d'ensemble et évaluation

Les substances toxiques atteignent l'environnement de plusieurs façons et ceci, à cause de certains raisons d'ordre économique, politique ou technologique. La Toxic Substances Control Act (TSCA, PL 94-469) des États-Unis a pour but de contrôler l'émission des substances chimiques anciennes et nouvelles qui, après étude, se sont révélées dangereuses à la fois pour l'homme et pour l'environnement.

Le principal objectif du présent rapport est d'examiner l'expérience américaine en ce qui a trait à la rédaction et la mise en vigueur de la TSCA, et d'identifier les questions importantes qui se dégagent de cette expérience.

Le rapport débute par un bref historique de la TSCA et une description des questions légales précises qu'elle soulève. Il examine ensuite de quelle façon les risques que présentent les substances toxiques sont déterminés pour les besoins de la réglementation dans ce domaine, et traite des répercussions économiques du contrôle de ces substances. La détermination du risque est étudiée selon les effets produits sur la santé humaine et animale et sur l'environnement, et les effets économiques, d'après les coûts imposés à l'industrie et aux consommateurs.

Le rapport se termine par une discussion sur l'administration et la mise en vigueur des programmes.

SUMMARY

Toxic substances reach the environment in a number of ways and for a number of economic, political, and technological reasons. The Toxic Substances Control Act (TSCA, PL 94-469) is intended to control new and existing chemical substances which are determined to present unreasonable risk to health or the environment.

The primary purpose of this report is to review the U.S. experience in drafting and implementing TSCA and identify key issues that have emerged from this experience.

The review begins with a reference to the legislature history of TSCA and the delineation of specific legal issues arising under TSCA.

The report next explores the subjects of risk determination in toxic substances regulation and economic impacts of controlling toxic substances. Risk determination is addressed in terms of health effects and environmental effects. Economic impacts are discussed in terms of the costs to industry and consumers.

The report concludes with a discussion of program management and implementation.

CHAPTER I

INTRODUCTION

Goals of Toxic Substances Control

The Toxic Substances Control Act (TSCA),(PL. 94-469) is intended to control new and existing chemical substances which are determined to present unreasonable risk to health or the environment. (Costle, March 1979, p. 1)

Issues and responsibilities which are of special concern to the EPA in implementing a toxic substances control program are:

(1) Detection and monitoring - determining a chemical's mode of entry into the environment, its environmental fate, and its potential for human exposure

(2) Testing - determining how predictions of chronic effects to health and the environment can be made accurately, rapidly, and at minimal cost

(3) Health effects - determining the ability of chemicals to cause cancer, birth defects, mutagenic effects, or chronic diseases, and the mechanisms by which these effects occur

(4) Ecological effects - determining which chemicals present hazards to ecosystems, and the long term result of changes which may occur in an ecosystem

Exposures and Effects of Toxic Substances

Toxic substances reach the environment in a number of ways and for a number of economic, political, and technological reasons. They may be introduced from point-source discharges or from non-point sources. A chemical compound may become a serious pollutant if it fulfills most of the following prerequisites: large industrial production, use susceptible to environmental leakage, high toxicity, tendency to bioaccumulate and persist, and high dispersion tendency. (Hutzinger, in Hutzinger, 1978, p. 13)

Potentially toxic substances may affect us in many ways. These effects may be persistent and irreversible. Large populations may be exposed for long periods of time before the exposure and subsequent toxicity become evident. (Sasnett, 1979, p. 3) Often it is difficult to determine a direct causal relationship between exposure to a toxic substance and the development of a specific health effect.

Exposure to some substances, such as chlorine gas, may result in an immediate, acute effect. Effects of other substances are not detectable until after a long latency period

and may include subtle but irreversible physical problems. (Sasnett, 1979, p. 1) Although the immediate danger from exposure to toxicants is morbidity or death to the present generation, a more serious concern is the possibility that gene mutation could affect subsequent generations.

Toxic substances also adversely affect environmental systems, causing chronic and acute effects in organisms, accumulating in plant and animal tissues, and otherwise interfering with normal ecological processes.

Industrial and Public Perspectives

Under TSCA, a company may be required to submit toxicological test data, detailed chemical identification, and production data. Industry officials are concerned with delays in starting production, costs of compliance, and possible chilling effect on innovation. There is also the question of confidentiality and protection of trade secrets.

In the past few years, the public has increasingly perceived the chemical industry as being a contributor to environmental pollution. (Zentner, November 1979, p. 26) Episodes such as the Kepone incident and the realization of the health effects of such incidents as Love Canal, have created anxiety in residents of areas where the chemical industry is highly concentrated. The public is becoming increasingly concerned with not only the discomfort of pollution

but also the potential health threats that toxic pollutants pose. Regarding the determination of "unreasonable risk" or "acceptable risk" the public is likely to ask: Acceptable to whom? and Based on what criteria? (Sasnett, 1979, p. 5)

The differing perspectives of industry and the public place the two groups on different sides of the "acceptable risk" question. On the one hand, the public tends to argue that because the level at which substances cause cancer or other health effects is not known, any exposure to such compounds should be eliminated. On the other hand, industry contends that such a zero exposure standard is both unreasonably stringent and economically too costly, so more realistic standards should be set. (Zentner, November 1979, p. 25.)

Good Science versus Good Regulation

The current state of knowledge about the lasting environmental or health effects of the chemical boom has been described as "something like a block of swiss cheese - a fair amount of substance but still a lot of holes." (Costle, 1979, p. 1) Both industry and public policy makers are plagued with uncertainties caused by the fragmentary knowledge of toxic substances and their potential effects. The regulators cannot rely on science to provide complete risk information, since some uncertainty will always be present. In the face of potential threats to public health and the ecosystem, the

EPA must act to regulate toxicants despite these uncertainties.

The conflict between good science and good regulation stems from the differing approaches which scientists and regulators take in dealing with toxic chemical problems and the uncertainties which surround them. The scientist's approach tends to be a cautious one; when confronted with a great deal of uncertainty, the scientist avoids drawing conclusions and calls for additional study and research (Jellinek, March 17, 1980, p. 2). Regulators, on the other hand, cannot afford to postpone decision-making until certainty is known. There appears to be a difference in perspective and responsibility between the scientist and the regulator (Jellinek, March 17, 1980, p. 3). While the scientist prefers to delay decision-making until a high degree of certainty is established, the regulator often must act to prevent potential harm to the public and the environment. Scientists accept or reject hypotheses based on scientific evidence that is subject to predetermined probabilities of error. To be acceptable, hypotheses must generally fit within confidence limits of 95 percent. That is, scientific evidence is at least 95 percent certain. This level of certainty has not generally prevailed in judicial or administrative situations. "Beyond a reasonable doubt" for criminal cases and "preponderance of the evidence" for civil cases provide the accepted standard.

Until recently, much of the EPA's focus has been on the

waste products of our industrial society. With the passage of the Toxic Substances Control Act, the EPA is required to weigh the potential risks of a substance against the social and economic benefits resulting from the active use of the substance. Before the EPA is permitted to act it must determine that a chemical poses an "unreasonable risk" to the environment or human health. The measurement of risks and benefits posed by chemical substances has proven to be a formidable task. Regulatory decisions must be made with less than perfect scientific knowledge which intensifies the problems between science and regulation. Douglas Costle, EPA Administrator, sums up the problem:

> "When you enter the world of action, you find that people have to act day in and day out without conclusive proof of the rightness of their actions." (March 1979, p. 1)

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CHAPTER 2

THE TOXIC SUBSTANCES CONTROL ACT (TSCA): RELATIONSHIP TO OTHER TOXICS CONTROL LEGISLATION, LEGISLATIVE HISTORY, AND LEGAL ISSUES

I. INTRODUCTION

The enactment of TSCA on October 11, 1976 created a new addition to the already large and growing body of legislation regulating toxic or hazardous substances. TSCA was a controversial piece of legislation as signified by the fact that five years passed from TSCA's first introduction into the legislative process in 1971 until its passage in 1976. This chapter traces the evolution of the current U.S. approach to controlling toxic materials. The differences in each of the various pieces of legislation are compared with regard to the definition of a toxic substance, the type of regulation, their degree of protection sought, the role of economic analysis in establishing standards, and the assignment of the burden of proof for establishing whether a particular substance is or is not hazardous.

II. EVOLUTION OF CURRENT POLICY ON TOXIC SUBSTANCES

Prior to the passage of TSCA, EPA did not have adequate authority to deal with toxic substances. The coverage of existing environmental laws was unsatisfactory to Congress because of three particular problems. First, EPA could not act until after human or environmental exposure to a toxic chemical had occurred. Second, it was recognized that most toxic substances were not exclusively air or water pollutants, but were to be found in varying quantities of air, water, soil, food, and industrial and consumer products. Third, there was no authority for the collection of data to determine the totality of human and environmental exposure to a chemical substance (House Report No. 94-1341, 94th Cong., 2nd Sess., 1975).

TSCA was intended to be the base for all toxic substances legislation in that it would allow EPA to consider the full range of hazards associated with a particular chemical. Regulation under TSCA would apply throughout the entire range of activity associated with a chemical, beginning at the pre-manufacture stage. Coverage under the law would not be limited to a particular media, but could consider the total exposure of an individual from any source. Finally, TSCA would provide a focus for the collection of data to determine the totality of human and environmental exposure to a chemical substance.

In providing a base for toxic substances regulation, TSCA would be used in conjunction with other legislation, including the Clean Air Act (P.L. 91-604); the Federal Water Pollution Control Act (P.L. 92-500) and the Clean Water Act Amendments (P.L. 95-217); the Resource Conservation and Recovery Act (P.L. 94-580); the Safe Drinking Water Act (P.L. 93-523); the Occupational Safety and Health Act (P.L. 91-596); the Federal Insecticide, Fungicide, and Rodenticide Act and the Federal Environmental Pesticide Control Act (P.L. 92-516); and the Federal Food, Drug, and Cosmetic Act of 1938.

These statutes, including TSCA, give EPA broad authority over toxic substances control, including the manufacture, distribution, use, and final disposal of a substance. Implemented individually, each act provides only limited regulatory powers to the EPA. With proper coordination, joint implementation of all these acts (using TSCA as a base) should result in an effective comprehensive regulatory program. To date, however, regulatory actions have been slow and processes essential for full implementation of TSCA have not been developed. Careful coordination will be necessary to avoid overlap and inconsistency in the regulations.

Review of Related Legislation

The Clean Air Act imposes limitations on emissions into the atmosphere from new and existing sources to insure

that ambient concentrations of pollutants are lowered or kept below levels necessary to protect public health and welfare. Section 112 of the Act is directed specifically toward toxic substances. Under this section, the Administrator of EPA is directed to issue a list containing each hazardous pollutant for which the EPA intends to issue emission standards. With the exception of fuel additives, however, there is no direct control of the use of substances that may be emitted into the air or of processes that may produce such emissions (Miller, Toxic Substances Control, Vol. III, 1979).

Like the Clean Air Act, the Federal Water Pollution Control Act (FWPCA) and the 1977 Amendments to the Act contain provisions specifically directed toward toxic substances. Section 307 provides for the listing and setting of standards for hazardous chemicals discharged into waterways. Presently, the EPA has proposed water quality criteria for sixty-five hazardous substances (Arbuckle, 1978, p. 313). Disclosure limitations have been proposed for nine chemicals including DDT, aldrin-dieldrin, PCBs, toxaphene, and cadmium and mercury compounds.

The Food and Drug Administration regulates exposures arising from the ingestion of food or drugs or the application of cosmetic products. Food and food additives are regulated under the original Food, Drug, and Cosmetics Act of 1938 and under the Food Additives Amdendment of 1958. A part of the

1958 amendment known as the Delaney clause has recently generated intense controversy. The Delaney clause, which provides for an absolute and automatic prohibition on the addition of carcinogenic substances, is increasingly controversial, largely because this prohibition is in force regardless of the desirable properties an additive may have. A strong argument has been made that the Delaney clause should be replaced with a rule that allows for some type of cost-benefit analysis (Portney, pp. 123, 139).

The Food, Drug, and Cosmetic Act also contains general safety provisions that allow the FDA to prohibit the sale of food that "contains any poisonous or deleterious substance which may render it injurious to health." FDA's regulation of the substances found in drugs and cosmetics differs from the food additive regulations, as FDA must demonstrate that an ingredient is unsafe before action can be taken. There is no requirement for pre-market testing or registration. When deemed necessary, it is up to the FDA to sue in federal court or initiate a proceeding which will lead to the banning of a specific product (Portney, p. 124).

The Occupational Safety and Health Act of 1970 established the Occupational Safety and Health Administration (OSHA). Section 6 of the Act requires that strict health standards be set which would assure a healthful working environment. OSHA has issued final health standards for asbestos,

vinyl chloride, coke oven emissions and a group of fourteen carcinogens. In late 1975 standards were proposed for ten other substances. In October 1977 OSHA proposed to develop three kinds of generic standards which would classify a substance about which too little is known. Under the proposed system, an appropriate action would be taken as soon as OSHA determines the category in which a substance belongs. OSHA would therefore no longer be working on a case by case basis but rather with groups of related substances at the same time, thus reducing the time spent on individual substances (Arbuckle, p. 314 and Portney, pp. 122-123).

The Federal Insecticide, Fungicide, and Rodenticide Act of 1964 (FIFRA) and the Federal Environmental Pesticide Control Act of 1972 (FEPCA) that amended FIFRA provide for the registration of all pesticides and the uses to which they are put, the certification of individuals who apply certain restricted pesticides, and pre-market testing of all new pesticides. All pesticide registrations expire every five years and must be renewed. The administrator of the EPA may deny the registration of a particular pesticide or may cancel a pesticide use for any reason. Finally, the administrator may immediately suspend the use of a pesticide which constitutes an "imminent hazard" (Portney, p. 126).

The Safe Drinking Water Act of 1974 directs the administrator of the EPA to establish recommended maximum

contaminant levels (MCLs) for toxic substances which may have an adverse effect on the health of persons in order to ensure an adequate margin of safety. The EPA has already established recommended maximum contaminant levels for arsenic and the pesticides endrin, lindane, methoxychlor, toxaphene, (2,4-D), (2,4,5-TP), and Silvex. EPA has also issued standards for total trihalomethanes.

The Resource Conservation and Recovery Act of 1976 (RCRA) deals with "Hazardous Waste Management" under Subtitle C. Under this Act, EPA is to establish standards governing the generation, transportation, treatment, storage, and disposal of hazardous wastes as defined under section 1004(5) (Portney, p. 128).

As will be discussed later, the Toxic Substances Control Act (TSCA) was intended to fill the regulatory gap in the legislation previously discussed. As in the pesticide regulatory acts, TSCA requires testing of new substances and suspension of hazardous substances which constitute an "imminent hazard." TSCA, however, rejects the rigid pre-clearance regulatory scheme in these pesticide acts and follows a system of notice and selective interdiction. Most importantly, TSCA is designed to prevent hazardous substances from entering the environment, while much of the prior legislation deals with chemicals already released into the environment.

There are several inconsistencies among these laws,

protection which is to be afforded, placing the burden of proof on either the government or the proponent of a particular substance may give a significant advantage to the other. In many instances, the manufacturer would be in the best position to determine whether a particular substance will constitute a hazard. Many courts, however, will defer to the assumed expertise of a regulatory agency. Any presumption made on the part of the courts on the hazards of a particular substance as determined by the federal agency would be difficult to overcome by manufacturers.

There is also an important inconsistency between the various pieces of toxic legislation which involves cost and benefit analysis. The Safe Drinking Water Act along with TSCA, OSHA, FIFRA, and FEPCA call for some weighing of the costs and benefits involved in regulating a toxic substance. The Clean Air Act, FWPCA, and RCRA are silent on this particular issue. The Federal Food, Drug, and Cosmetic Act calls for cost-benefit analysis for drugs and cosmetics regulation but not for the regulation of food additives (Portney, pp. 131-132).

To provide for the coordination of TSCA with other related federal statutes, section 9d requires the EPA Administrator to consult and coordinate with other federal agencies and departments to avoid duplication. In addition, EPA, FDA, OSHA, and the Consumer Products Safety Commission (CPSC) have entered into an agreement establishing the Inter-Agency Regulatory

Liaison Group to coordinate those agencies' requirements, standards, and enforcement programs. The CEQ has also established the Toxic Substances Strategy Committee to eliminate duplication and to coordinate research and regulatory activities.

Table 2 .1 provides an overview of TSCA and other federal legislation regulating toxic substances. For each piece of legislation, the table summarizes the definition of toxic or hazard used, the type of regulation that may be imposed, degree of protection to be achieved by regulation, burden of proof requirements, and whether balancing of costs is mandated.

TABLE 2.1 FEDERAL LEGISLATION REGULATING TOXIC SUBSTANCES

Legislation	Definition of toxic or hazard	Type of regulation	Degree of protection	Burden of proof	Balancing of costs
1970 Clean Air Act Amendments	"an air pollutant . . . which . . . may cause, or contribute to, an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness" Section 112(a)(1)	Emission standards	". . . an ample margin of safety to protect the public health . . ." Sec. 112(b)(1)(B)	EPA	No
Federal Water Pollution Control Act	". . . pollutants which will . . . cause death, disease, behavioral abnormalities, cancer, genetic mutations, physiological malfunctions . . . or physical deformations." Sec. 502(13)	Effluent standards, ambient standards	". . . ample margin of safety." Sec. 307(a)(4)	EPA	No
Occupational Safety and Health Act	Not defined	Exposure standards	"adequately assures to the extent feasible that no employee will suffer material impairment of health or functional capacity . . ." Sec. 6(b)(5)	OSHA	Yes. Sec. 6(b)(5)
Toxic Substances Control Act	those substances ". . . presenting an unreasonable risk of injury to health or the environment . . ." Sec. 6(a)	Premarket notification and testing; prohibitions on manufacturing, processing, and distribution; information on chemical components must be supplied to EPA	Not specified	Proponent	Yes. Sec. 2(b)(3)
Food and Drug Administration	Not defined	Labeling; bans on products deemed "unsafe"	". . . necessary for the protection of public health . . ." Sec. 406[346]	Proponent for drugs and food additives; FDA for cosmetic ingredients	No, in case of food additives; yes, for drugs and cosmetics
Federal Insecticide, Fungicide, and Rodenticide Act and the Federal Environmental Pesticide Control Act	One which results in ". . . unreasonable adverse effects on the environment or will involve unreasonable hazard to the survival of a species declared endangered . . ." (imminent hazard). Sec. 2(l)	Registration of all pesticides and uses; permits for applicators; cancellation or suspension of specific pesticides or uses	Not specified	Proponent	Yes. Sec. 6(b)(2)
Safe Drinking Water Act	". . . contaminant(s) which . . . may have an adverse effect on the health of persons." Sec. 1401(1)(B)	Maximum contaminant standards	". . . to the extent feasible . . . (taking costs into consideration) . . ." Sec. 1412(a)(2)	EPA	Yes. Sec. 1412(a)(2)
Resource Conservation and Recovery Act	one which "may cause, or significantly contribute to an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness; or, pose a . . . hazard to human health or the environment . . ." Sec. 1004(5)(A)(B)	Standards for generators, transporters of hazardous waste; permits for treatment, storage or disposal of hazardous waste	"that necessary to protect human health and the environment . . ." Sec. 3002-3004	EPA	No

Reprinted from U.S. Environmental Policy, Portney, 1978, pp. 130-131.

III. LEGISLATIVE HISTORY OF TSCA

The legislative history of TSCA began when President Nixon signed the National Environmental Policy Act (P.L. 19-190) on January 1, 1970. The Act (NEPA) established a national policy for the environment, placed new responsibilities on federal agencies to consider environmental factors, and created a Council on Environmental Quality in the Executive Office of the President. Russell E. Train, EPA Administrator in 1973-1976, was appointed chairman of the newly created Council and served in that capacity until 1973 (Council on Environmental Quality, 1971, p. 20).

The Council on Environmental Quality (CEQ) was charged with making recommendations to the President on national policies for improving environmental quality. The Council's ability to perform this function was strengthened by the Environmental Quality Improvement Act of 1970 which created an Office of Environmental Quality to provide staff support for the CEQ. The Act also authorized funds for the staff support for the CEQ and its staff to $800,000 for fiscal year 1970 and $1,450,000 for 1971 (CEQ, Annual Report, 1971, p. 21).

The public became more aware of the problems presented by hazardous chemicals with the realization that many potential cancer-causing substances were present in the environment.

The World Health Organization had estimated that between 60 percent and 90 percent of all cancers were caused by environmental factors. A series of events further emphasized the need for some kind of control of toxic substances (Portney, pp. 106-109).

The first such event was the discovery in the late 1960's of the widespread contamination of food, water, and soil by certain highly toxic compounds of organic mercury. In the early 1970's, polychlorinated biphenyls (PCBs) were found to be carcinogenic. These chemicals had been widely used in industry, and had been released in relatively large quantities into the environment. It was this particular discovery which most heavily publicized the need for controls of hazardous chemicals (Portney, pp. 106-109).

In 1970, CEQ began studying the problem of increasing exposure to potentially toxic substances. During the summer and early fall of 1970, CEQ's staff collected and analyzed information on hazardous chemicals not being controlled under the air and water pollution statutes; the number of new chemicals being marketed annually was also evaluated. The Council was assisted by the President's Office of Science and Technology, the National Library of Medicine, and the EPA. Although the data collection, analysis and much of the writing of the report was substantially completed by December 1970, CEQ's report was not published until 1971,

being delayed by the process of formulating the legislative program to introduce a Toxic Substances Control Act (CEQ, Toxic Substances, 1971, p. iii).

In its report, the CEQ first discussed toxic substances, their quantities, and the diversity of products in which they are present. CEQ noted that approximately two million chemical compounds were known and about 250,000 new chemical compounds were being introduced yearly. It was further estimated that as many as 1,000 known chemical compounds were suspected of being carcinogenic and that 10 to 20 percent of the new compounds presented environmental threats. The Council also examined ways in which these substances entered the environment, their transport within the system, and their effect on man and other organisms. CEQ's report also detailed technological and legal approaches to control the introduction of toxic substances into the environment (CEQ, Toxic Substances, pp. 1-6).

It was CEQ's opinion that existing laws were inadequate to control the actual and potential dangers of toxic substances. CEQ cited several factors which undermined the government's attempt to control these chemicals including: (1) Water and air pollution standards were mainly concerned with pollutants which occur in large quantitites. (2) Technology to completely eliminate discharges of many toxic pollutants was often unavailable. (3) There was a

serious lack of advance information about the environmental or health effects of the rapidly increasing number of chemicals being produced each year. (4) Problems in proving adverse chronic health effects of substances on which manufacturers and consumers have become dependent made regulation difficult. (5) Finally, since no one agency or statutory program was completely responsible for all toxic substances in the total environment, information about all forms of discharges or their effects was not centrally collected or utilized (CEQ, Toxic Substances, pp. iv-vi).

CEQ reached the conclusion that the toxic substances problem required a systematic, comprehensive approach that considered the flow of these chemical substances from development to production. CEQ recommended that this could best be achieved through a Toxic Substances Control Act. This Act would require the testing of new chemical compounds or chemicals designed for new uses; gather information about chemical production and uses; and control the production, distribution, or use of any chemical having proved harmful to health or the environment (CEQ, Toxic Substances, pp. 21-22).

In early October of 1970, CEQ met with representatives of several federal agencies to discuss the outlines of a proposed toxic substances bill. Similar meetings were held throughout October and November 1970, and CEQ began

drafting a toxic substances control bill. By early December, the draft was completed and informal negotiations were initiated with the Department of Commerce, the agency thought most likely to oppose any new regulation of industry within the Nixon Administration (Dolgin, 1974, p. 154).

The CEQ transmitted the draft of the bill to the Office of Management and Budget (OMB) and to the White House in early January of 1971. Negotiations followed with new drafts being prepared by CEQ on January 22, 25, 28, February 2, and February 7. Although there were many controversial points, the key issue was whether the Environmental Protection Agency (EPA) would have the power to impose regulations on a new chemical before it was commercially produced. Both CEQ and the EPA strongly favored this provision while the Commerce Department and the White House opposed it (Dolgin, p. 155).

In the early part of February of 1971, agreement was reached on all parts of the bill. The Toxic Substances Control Act was introduced as H.R. 5276 in the House by Rep. Staggers and as S. 1478 in the Senate by Sen. Hart (Dolgin, p. 156).

From the onset, the proposed Toxic Substances Control Act was the target of an intense lobbying effort. Du Pont, Dow Chemical, the Manufacturing Chemists Association, and the

American Chemical Association led the chemical industry effort to defeat the bill. The effort was to be successful for five years, despite counter-efforts by consumer groups, environmental groups, labor organizations, the EPA and the CEQ. It would take two toxic substances incidents in 1975 to finally effect TSCA's passage.

The Senate Commerce Committee rewrote the entire bill, adding stronger and more sweeping provisions regulating both new and existing chemicals. This new version of the bill, introduced by Sen. Spong was the subject of hearings held by the Environment Subcommittee of the Senate Commerce Committee. In February of 1972, the sub-committee staff produced a working draft of a new bill which added a requirement that new chemicals be submitted to EPA before being marketed. This particular provision would be the subject of intense debate in later hearings, floor debates, and conference negotiations. The full committee met on May 5th and issued a revised version of S. 1478 which closely resembled the February staff draft (Sen. Rep. No. 92-783, 92nd Cong., 2nd Sess., 1972).

Throughout this time, the House had taken no action. When first introduced in the House on March 1, 1971, the bill had been referred to the House Committee on Interstate and Foreign Commerce. Toxic chemical legislation was not a high priority item for the House Committee; the legislation

was also hindered by a jurisdictional dispute between the subcomittees chaired by Rep. Moss and that of Rep. Rogers. Ultimately the bill was given to Rep. Moss. On August 7th, the subcommittee reported the legislation to the full committee (Dolgin, p. 156).

While the bill was in the House subcommittee, the Senate version, S. 1478, had passed the Senate by a vote of 77-0. An industry sponsored amendment to weaken the pre-market notification was defeated 42-28. The House Commerce Committee reported out its version of TSCA on September 28th and the House approved the bill on October 13, 1972 by a vote of 240-61. The next day the Senate voted to agree to the House version with two amendments by a vote of 29-22. However, time did not permit a conference between the two Houses, so the effort was lost (Dolgin, p. 157).

In 1973, the bill was introduced in the 93rd Congress by Senators Hart, Magnuson, and Tunney; the Nixon Administration also re-introduced its version of the bill. When it became clear that both the House and Senate versions would contain some type of pre-market control, the Nixon Administration reversed its position and endorsed a limited pre-market screening provision. The Senate bill was reported out of committee on June 26th and passed by the Senate on July 18, 1973. The House bill was reported out on June 29th and passed the House on July 23, 1973 (Dolgin, p. 157).

A conference committee was formed to settle the differences between the Senate version and the House version. The central issue concerned the extent of pre-market testing and safety certification which would have to precede commercial use of a chemical, and the amount of authority EPA would have in relation to pre-market testing. The conference committee never reached an agreement, and the legislation failed again (Druley, pp. 12-13).

Legislation was once again introduced in the 94th Congress. In the Senate, S. 776 was introduced by Sen. Tunney. On the House side, different bills were introduced by Reps. Eckhardt, Brodhead, and McCollister. The Eckhardt and Brodhead versions were superseded by a new bill, H.R. 10318, and approved by the Interstate and Foreign Commerce Committee's subcommittee on Consumer Protection and Finance. In the full House Committee, a compromise was worked out between the majority and minority party positions and a new version, H.R. 14032, was reported out of the Commerce Committee in June 1976 (Druley, p. 12).

Hearings were held in the Senate before the Commerce Committee's subcommittee on the Environment. During the mark-up sessions before the full committee, Sen. Hartke offered a new version that tracked closely the language of the House version. The Full Committee accepted this new

version and reported it out favorably to the Senate as S. 3149 (Druley, p. 12).

The Senate then passed its version of TSCA on March 26, 1976 by a vote of 60-13. On August 23, 1976, the House passed its version in the form of a replacement amendment to S. 3149 by a vote of 319-45, and requested a conference with the Senate. The conference committee met first on September 1, 1976 and showed an interest in settling any differences quickly (Druley, p. 13).

The last remaining point of difference between the Senate and House hinged on the particular mechanism to be used for regulating distribution of new chemicals pending the test results. The Senate position allowed rulemaking by the EPA, leaving it to a chemical manufacturer to seek injunctive relief from a U.S. district court. The House position required EPA to seek a court order in order to control or ban production of chemical substances pending the testing results. The conference committee on September 14th reached a compromise by allowing rulemaking by the EPA, but requiring EPA to seek a court order pending the testing results (Druley, p. 12).

The conference report was approved by both Houses on September 28th, the Senate voting 73-6 in favor of the bill, and the House voting 360-35. The bill was then sent to the White House. Although the EPA Administrator and CEQ both

supported its enactment, OMB still opposed the bill on the grounds that the Act's pre-market notification requirements were unnecessarily broad. Despite opposition by the OMB, President Ford signed the bill into law on October 11, 1976 as Public Law 94-469 (Druley, pp. 21, 27).

During the 94th Congress, the Senate Commerce Subcommittee on the Environment held hearings on S. 776 on March 3, 5, 10, and on April 15, 1975. In the previous four years of debate on toxics regulation Congress had heard testimony on poisoning from mercury, on the incidence of cancer from diethyl stilbestrol, the effects of exposures to PCBs and other harmful effects of certain chemical compounds (Dolgin, p. 158).

During the 1975 hearings, testimony was presented concerning a new case study on cancer deaths of chemical plant workers resulting from exposure to bis (chloromethyl) ether. Administration witnesses in favor of the toxic substances legislation were Russell W. Peterson, chairperson of the CEQ, and Russell Train, Administrator of the EPA and former chairperson of CEQ (Hearings on S. 776, U.S. Sen., 94th Cong., 1st Sess., pt. 1, pp. 58).

For various reasons, a number of chemical industry representatives testified against the bill. Aldrich Chemical Company and Fike Chemicals both expressed alarm at the great cost that would be imposed on chemical companies in order to

comply with the various provisions of the bill, especially the testing requirements (Hearings on S. 776, pt. 1, pp. 335-337).

The Manufacturing Chemists Association and the American Chemical Association were two groups that supported the concept of toxic substances control but expressed objection to legislation (such as TSCA) which would impose broad, sweeping controls. On the other hand, labor organizations such as the United Steelworkers and environmental groups such as the Sierra Club saw a great need for such legislation (Hearings on S. 778, pt. 1, pp. 140-226).

Further hearings were held on October 24, 1975 when a question arose concerning estimates of the cost of the testing program that would be required under the law. The EPA had originally estimated this cost to the chemical industry as $45 million a year, but later raised the estimate to between $79 million to 142.5 million. However, this sum was still very low in comparison to a cost study by Dow Chemical that put the testing cost of industry at $2 billion annually (Hearings on S. 776, pt. 2, p. 94).

Another estimate commissioned by the Manufacturing Chemists Association predicted costs between $358 million to $1.3 billion. The subcommittee requested the General Accounting Office (GAO) to undertake a review of all three estimates. Harry S. Havens, Director, Office of Program

Analysis (GAO); Dr. Denis J. Dugan, Associate Director; and Dr. Kenneth M. Brown, Senior Economist, testified as to the results of their comparison of the three cost studies (Hearings on S. 771, pt. 2, p. 82).

The GAO study confined its analysis to the information contained in the three studies because of the short amount of time in which to complete the work. There was no attempt to verify the accuracy of basic technical data which was accepted at face value. The report emphasized that one of the main goals of the proposed act would be to provide information on new chemicals which would allow steps to be taken to guard against possible toxic substances. The crucial question was whether these costs were justified by the potential benefits. It was noted that the three reports reviewed addressed only a part of the whole cost to industry, possible benefits to society were discussed only in passing, and the total cost to society as a whole was not even mentioned (Senate Hearings on S. 776, pt. 2, p. 83).

In making their comparisons, the GAO report found reasonably close agreement between the EPA and the Manufacturing Chemists estimates of the cost per test for new chemical substances. The main source of difference between the two studies lay in the assumption they made about the number of new chemical substances which would require testing. This difference stemmed from a significant difference in inter-

pretations of the requirements of the proposed act. The GAO report, however, concluded that the EPA interpretation was closer than the industry studies as to what the legislation would entail. The two industry studies seemed to interpret the legislation as calling for testing of many chemicals when in fact only screening and reporting would be necessary (Senate Hearings on S. 771, pt. 2, p. 84).

The GAO report noted that the EPA study assumed that costs per tests of new chemicals would be about the same as costs per test of existing chemicals. The GAO report, however, believed that the average cost of testing existing chemicals would exceed that of new chemicals. With new chemicals, the industry could choose to drop the item if the testing became too expensive or the outlook for success looked too bleak. It was the conclusion of the GAO report that the Dow Chemical study, which gave the highest cost figure, was the least reliable. It was based upon an interpretation of the act which seemed to greatly overstate the amount of testing that would be required (Senate Hearings on S. 776, pt. 2, pp. 84-85).

Based on the data available in the three studies, the GAO report concluded that the costs to industry would likely fall within a range that included the EPA high estimate and went somewhat higher to take account of the likelihood that EPA had underestimated the costs of testing

existing chemicals. That yielded estimates of cost in the range of $100 to $200 million per year (Senate Hearings on S. 776, pt. 2, pp. 84-85).

The House Interstate and Foreign Commerce Subcommittee on Consumer Protection and Finance held hearings on June 16 and July 9-11, 1975. Environmental groups and labor organizations again supported the passage of the toxic substances legislation. The chemical companies once again voiced their disapproval and Du Pont stated that the nation could not afford to expend its resources on unnecessary and costly testing. Finally, Dow Chemical indicated that they opposed the passage of any type of toxic substances bill, and that such legislation was not needed and would lead to inflation and loss of jobs (House Hearings on H.R. 7229, etc., 94th Cong., 1st Sess., pp. 211-322).

Most of the testimony in both Houses was directed to the implementation of any type of toxic substances control act and especially the pre-market control and testing requirements. With the exception of a few chemical companies, most of the witnesses acknowledged a basic need to regulate toxic substances before they were in a position to cause harm. The impact of CEQ's report on Toxic Substances was significant; two toxic substances were highly publicized and most likely provided the final impetus for the passage of TSCA. In January 1975, a link was confirmed between worker exposure

to vinyl chloride and a rare form of cancer, angiosarcoma of the liver. In mid-1975, workers in a small Virginia manufacturing plant had sustained severe neurological and reproductive damage from exposure to the chemical Kepone. Federal and state health agencies were widely criticized for failure to prevent these two tragic events. These chemical disasters had finally brought home the Council of Environmental Quality's message on the dangers of toxic substances.

IV. LEGAL ISSUES ARISING UNDER TSCA

A. Protection of Confidentiality

Since a principal function of TSCA is the collection of information on chemical substances, concern for the protection of genuine trade secrets is of great importance.

If a manufacturer feels that the information it is submitting to the EPA is important and should be considered confidential, the material should be designated as such. In a recent federal district court action, Polaroid Corporation sought a preliminary injunction barring EPA from disclosing under TSCA information on 20 chemicals which the company claimed were trade secrets. The court in Polaroid Corp. v. Costle, 11 ERC 2134 (D.C. Mass. 1978) first held that it could not grant the injunction under TSCA because the Act clearly granted exclusive jurisdiction for review of EPA regulations under the Act to the Civil Courts of Appeal. The district court did, however, grant the injunction because it found that releasing the information on the 20 chemicals which Polaroid claimed were trade secrets would amount to deprivation of property without due process of law in violation of the Fifth Amendment to the U.S. Constitution.

On September 8, 1978, EPA issued amendments to its

confidential business information regulations providing substantial protection for TSCA confidential information and providing for notice to affected businesses before confidential information is disclosed outside EPA. Polaroid then withdrew its suit and the court order was vacated (Arbuckle, pp. 275-276, 1979).

Another controversial area dealing with confidentiality concerns section 14(b). This section specifies that data from health and safety studies must be disclosed, and cannot qualify as trade secrets or confidential. Section 14(b) was included to permit the public to participate and to be informed of the potential hazards of dangerous materials. The chemical industry complains that health and safety testing data, when disclosed, can allow a competitor to estimate the directions of a firm's research and further possibilities of use of a chemical substance. Also disclosure of this data may point to the plan of product development depending upon the new substance involved (Miller, pp. 44, 58).

The chemical industry is also beginning to question the treatment of chemical identities under Section 5 premanufacturing notification notices. The chemical substance involved is by its nature of great value to the first developer of the substance as that firm has a competitive edge over other firms. Under section 5 most of the data received would be considered health and safety data which under section 14(b)

is basically public information, except where the information would reveal processes or formulation of mixtures (Miller, p. 45).

The chemical industry points out that contrasting with section 14(b) is a specific provision in section 5(d) which seemingly requires nondisclosure of such data. The proviso in section 5(d) states that the EPA must identify the chemical by generic class unless it determines that more specific identification is required in the public interest. It is argued that the provision requiring generic identification of a chemical in a public notice is controlling over the general requirement in section 14 regarding health and safety data. Thus, during the premanufacture notification period (90-180 days), EPA would not be able to disclose the chemical identity contained in a health and safety study in a premanufacture notification. The issues involving confidentiality will most certainly result in litigation but not until TSCA becomes more fully implemented (Miller, p. 58).

B. Interpretation of Regulatory Responsibilities

Major legal questions which arise when dealing with complex legislation involve the amount of discretion afforded to the agency under an act and how the agency interprets its powers under a particular statute. The chemical industry is already questioning whether the provisions of TSCA are to be

narrowly construed or broadly interpreted as EPA would indicate.

C. Distribution of Agency Responsibilities

Under section 9 if the Administrator has a reasonable basis to conclude that a chemical substance or mixture presents an unreasonable risk of injury and if the Administrator makes discretionary determination that the risk may be prevented or reduced by action taken under a Federal law not administered by the EPA, then the Administrator must give the other agency an opportunity to act. Section 9(a) prohibits the Administrator from acting under section 6 or 7 with respect to the risk about which the Administrator notified the other agency, if the other agency takes one of two alternative courses of action. If the other agency issues an order declaring that the activity specified in the Administrator's report does not present the unreasonable risk described in the report, or if the other agency does initiate action to protect against the suspected risk, the Administrator is precluded from taking action under sections 6 and 7 (Conference Committee, Toxic Substances Control Act, 94th Cong., 2nd Sess., 1976, p. 82).

A problem that arises stems from the fact that once the other agency determines that no action is warranted, whether EPA is in accord with the decision or not, EPA cannot thereafter bring an enforcement action of its own under

sections 6 or 7. The chemical industry contends that although section 9 does not specifically prohibit EPA from requiring testing of the suspected hazardous chemicals under section 4, testing requirements would come under the same type of regulatory action as in sections 6 and 7. This clearly is an issue that may have to be resolved in the courts.

D. Determination of TSCA's Limitations

Another issue revolves around the amount of discretion the Administrator has in determining whether a suspected risk may be prevented or reduced by action taken under TSCA, a federal law not administered by the EPA, or another law that is administered by the EPA. One part of this question concerns how broadly the EPA may interpret TSCA in implementing the act. The chemical industry is also worried that discretion in other sections of the Act such as in the pre-manufacturing notification requirements in section 5 may be abused. In short, the chemical industry has regarded TSCA as an information gathering and notification statute and not a licensing statute. They regard with great distrust any appearance that the EPA may move TSCA away from being a model for balancing health and environmental issues with economic considerations to becoming another complex and overbroad regulatory scheme which would stifle productivity, innovation, and capital formation (Miller, p. 9).

E. Exports

A final example where the chemical industry regards EPA as interpreting TSCA too broadly concerns exports under section 12. Subsection (a) exempts from the provisions of TSCA any chemical substance or mixture manufactured, processed, sold, or held for sale solely for export from the United States. This exemption does not apply to any substance, mixture, or article that the Administrator finds would cause or contribute to an unreasonable risk to the health of persons or environment of the United States. Subsection (b) also allows the Administrator to require testing for the purpose of determining whether or not such substance or mixture presents an unreasonable risk of injury to health or to the environment of the United States (Congressional Conference Report, 94th Cong., 2nd Sess., 1976, p. 88).

The EPA is proposing that section 5 as well as section 4 applies to substances manufactured in this country for export. The EPA believes that the section 5 pre-manufacturing notification requirement is necessary to cover the loophole of people manufacturing chemicals within the United States and shipping them abroad and nonetheless having worker exposure as well as other health and environmental exposure occurring within the United States. The chemical industry contends that the EPA is interpreting the requirements of section 12 regarding exports too broadly (Miller, p. 19).

V. CONCLUSIONS AND RECOMMENDATIONS

TSCA was designed to fill the regulatory gaps left by the other statutes by providing a means of discovering adverse effects on health and the environment before new chemical substances are manufactured, and controlling their adverse effects during all phases of the chemical's manufacture, process, sale, use, and disposal.

Coordination between the various statutes regulating toxic substances will be crucial to the success of the total regulatory program. Coordination is not only needed to avoid inconsistent, overlapping, and duplicative requirements, it is also crucial that coordination on matters such as scientific precepts, priority determinations, deadlines, and regulatory approaches be achieved. Although there is much regulatory inconsistency among the various toxic substances legislation, this can be overcome with the proper coordination between the various agencies or departments charged with implementing the different statutes and by using TSCA as a base for gathering and disseminating information about toxic substances.

The various legal issues involve the natural growing pains that a complex piece of legislation experiences as full implementation is achieved. As with any piece of lengthy, complex, and technical legislation, there will be ambiguities

within the statutory language that will account for honest differences of opinion between the regulators and those being regulated. Although the different legal issues that arise do indicate a lack of careful analysis in the drafting of the statutory language, political pressures will continue to impact proposed legislation resulting in political compromises.

Serious problems have developed from the lack of a definition of "unreasonable risk" and the amount and type of information which is needed to determine an "unreasonable risk." Although it was the intent of the Congress not to limit the EPA with regard to this determination, the lack of guidance seriously inhibits the formulation of acceptable testing and notification requirements. The EPA, if not Congress, must promulgate guidelines in this area to forestall further difficulties.

The legal issues regarding the confidentiality of information, TSCA's relationship to other federal laws, inspections, exports, and assessment of civil penalties hinge on the limits to the delegation of powers to the regulatory agency by the Congress. As EPA attempts to interpet TSCA broadly and the chemical industry reads the statute narrowly, legal questions and litigation are inevitable. Another related question is whether the present court system is equipped to handle the highly technical and complex litigation

arising under TSCA. The debate concerning the benefits of a "science court" over the present legal system is a valid one. However, as most of the legal issues arising under TSCA have their beginnings on the question of what the limits are of EPA in its interpretation of the regulatory requirements of TSCA, the present court system is best equipped to settle the problems. The court always has the power to appoint expert "masters" in highly technical matters to assist the court in its determination.

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Chapter 2

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CHAPTER 3

RISK DETERMINATION IN TOXIC SUBSTANCES REGULATION

I. INTRODUCTION

Toxic substances regulation is a complex process, requiring the integration of various kinds of information, obtained with varying degrees of certainty. The total risk, or hazard, associated with a particular chemical involves both its inherent toxicity and the dosage that will be experienced. Thus, two kinds of assessments must be made: the chemical's potential effects on human health and environmental systems, and the extent and routes of exposure and environmental release. These assessments must be evaluated in a social and economic context to determine an acceptable level of risk; finally, control measures must be imposed to ensure that the acceptable levels are not exceeded.

Each step in the process presents serious problems. Testing procedures for both health and environmental injury attributable to toxic substances are not well developed or standardized, making validation and replication of results difficult. Additionally, attempts to quantify a chemical's toxicity are weakened by the statistical limitations of the currently used tests, and a lack of understanding of many disease mechanisms. In determining the reasonableness of

the risk presented by a substance and designing appropriate control measures, risk-benefit analyses must be performed which compare units of human health risk, environmental contamination, social equity, and economic costs. Even under conditions of perfect information flow these judgments would be difficult; with the added problems of risk assessment uncertainties, technological control difficulties, and inadequate access to information concerning the social and economic impacts of regulation, decision-making for controlling. the manufacture, marketing, or use of a substance is complicated further.

The presence of uncertainty does not diminish the need to make decisions for controlling toxic chemicals. It does, however, require that the inadequacies and margins of error in the scientific and economic knowledge be recognized, so that limited regulatory resources are effectively used, the most critical research needs are identified, and regulatory choices reflect the best judgment of decision-makers.

II. RISK DETERMINATION

A. Health Effects

The deleterious health effects related to chemical exposure can be classified as genetic or non-genetic. Genetic effects are irreversible and often progressive; these include cancer, birth defects, and genetic damage. Non-genetic effects are usually reversible and nonprogressive; these include chronic and acute poisoning, behavioral abnormalities, irritation of sensitive tissues, appearance of lesions, and others.

Four basic types of tests are employed to obtain estimates of a chemical's potential for adversely affecting human health. Each has inherent limitations which must be considered in assessing total risk.

1. Assessments based on chemical structure and properties. "Structure-activity" relationships are associations between carcinogenicity or other effects and the structural characteristics of a compound. Attempts have been made to predict the toxicity of chemicals on the basis of their molecular structure and physical properties. For example, hydrogen atoms in organic molecules and "bay regions" in polycyclic aromatic molecules are considered risk factors (Weinstein, 1979, p. 356). However, since many closely related chemicals (e.g., methanol and ethanol) may have

vastly different effects, molecular structure has only limited utility in estimating toxicity, although it may be useful as a screening mechanism for determining the need for advanced testing.

2. Epidemiological studies. Epidemiological studies, in which large numbers of individuals that have been exposed to varying doses of a chemical over time are surveyed, provide the most definitive evidence of a chemical's health risk to humans (Weinstein, 1979, p. 345). Observational and descriptive epidemiologic studies can suggest possible relationships between exposures and effects; analytical studies are efforts to measure specific effects. Two types of analytic studies are common:

(a) Prospective cohort studies, in which the incidence of disease in specific populations exposed to different levels of a chemical is recorded and compared. The major difficulty with this method is logistical in nature: particularly for genetic effects (carcinogenicity, teratogenicity, and mutagenicity) the time period required between initiation of the study (exposure to the chemical) and the recording of statistically adequate numbers of disease cases is often long, and the costs of the experiments are therefore high;

(b) Case control studies, in which past exposure to a chemical is measured in individuals with and without the health effect in question. The principle limitation of this approach is the questionable validity of information provided about exposures which may have occurred over a long period in the past (National Academy of Sciences, 1979, p. 50).

Other problems in epidemiologic research are common to both types of studies. The long latency period for many effects obscures causal relationships. Risk estimates obtained may be biased by the impact of exposure to other disease causing agents such as cigarette smoke. Moreover, it is often impossible to accurately account for the background level of the effect that would be manifest without exposure to the chemical (Schneiderman, 1976, p. 79). Because of the statistical error involved and these difficulties in maintaining a controlled experiment, good estimates of risk-exposure relationships are generally limited to cases where 1) the incidence of the effect being investigated is increased by at least 100 percent over the background effects, or 2) the study is conducted in a more controlled setting, usually an occupational environment (Ames, 1979, p. 588). Epidemiological studies have been most useful to date in suggesting associations between specific chemicals and effects, and

identifying a need for additional testing to quantify the risk.

3. In vitro tests. Over eighty short-term in vitro tests are in different stages of development and use. These tests are aimed at identifying 1) genetic damage and mutations in microorganisms, 2) genetic damage and mutations in cultured mammalian cells, and 3) transformations in the growth of mammalian cells (Weinstein, 1979, p. 353). The principal advantage of in vitro tests is their relatively low cost (a few hundred to a few thousand dollars per chemical tested) and short time frame (one to three weeks for many studies).

Many of the recently developed tests have successfully combined a sensitive microorganisms test system with the mammalian metabolic conversion system necessary to allow identification of chemicals which may present a genotoxic hazard to humans (Ramel, 1978, p. 246). Of these tests, the most significant and widely used is the in vitro method on Salmonella, developed by Bruce Ames and now commonly called the Ames test. The test is performed by combining on a petri plate the chemical to be tested, histidine-requiring bacterial mutants, and homogenized liver from rodents or human autopsy. After incubation, the number of bacterial colonies is recorded, each colony consisting of descendents of a bacterium having a functional histidine gene which has mutated from a histidine defective gene. Varying doses of the chemical

are tested, to generate quantitative dose-response relationships. Mutagenetic chemicals can be detected at extremely low doses (Ames, 1979, p. 590).

The importance of the Ames test and others for human carcinogenicity risk assessment rests on assumptions as to the relationship between mutagenicity and carcinogenicity. Experimental evidence indicates that most and possibly all known carcinogens are also mutagens. Ames reports that about ninety percent of carcinogenic substances cause mutations in the Salmonella test (1979, p. 590). Conversely, very few noncarcinogens tested were mutagenic, and these few may in fact be very weak carcinogens that were not so identified due to statistical limitations of the animal carcinogenicity tests.

Lack of perfect correlation between mutagenicity and human carcinogenicity prevents highly accurate dose-response conclusions from being derived from Ames test results. Because the different in vitro, short-term tests provide slightly different information, conducting a battery of such tests is the favored approach (Ramel, 1978, p. 246). The time and cost advantages associated with these tests make them particularly useful as a screening tool for identifying potentially hazardous chemicals worthy of further investigation.

One additional advantage of the short-term tests is their usefulness in analyzing mixtures of chemicals. Many of the toxic substances to which humans and environmental systems are exposed are present in complex mixtures; cigarette smoke and industrial emissions are good examples. Determining the total toxicities of these mixtures may be more relevant to risk control than assessing the separate toxicities of the components (Ramel, 1978, p. 248).

4. Animal bioassays. The experimental mainstay for assessing both genetic and non-genetic health effects is animal testing. Because their two-year lifespans and small size make them convenient experimental subjects, the most frequently used species, especially in carcinogenicity studies, are rats and mice, although dogs, monkeys and other mammals are sometimes used (Weinstein, 1979, p. 348). Carcinogenicity tests normally involve exposing the selected animal populations to varying dosages of a chemical over a period of about two years, at which time the animals are autopsied to detect tumors. Other toxicity studies, such as tests for tissue irritation, sterility, or enzyme inhibition involve different procedures, and may include monitoring the response over time.

Formal guidelines have been developed by the National Cancer Institute (NCI) for animal testing procedures. These call for testing of both sexes of two different species of

rodents, with two unequal doses of the chemical and one "no-dose" control; in addition, the exposure route (inhalation, ingestion, etc.) is to approximate as closely as possible the primary route of human exposure (Weinstein, 1979, p. 348). Since fifty animals of each species, sex, and dosage group are typically tested, the total number of animals required is 600. Bioassays such as these will cost from $100,000 to $500,000 and take two to four years to complete (Ames, 1979, p. 589).

Although the high costs and long time period necessary for obtaining risk data limit the feasibility of animal studies for comprehensive testing of large numbers of chemicals, these tests do offer significant advantages: the experimental conditions can be carefully controlled and exact dosages can be accurately administered and monitored.

The value of animal tests for establishing a chemical's risk to humans is related to the confidence with which the animal responses can be translated to humans. All known human carcinogens with the sole exception of arsenic have been shown to be carcinogenic in some animal system (Schneiderman, 1976, p. 72). This would indicate that animal systems are unlikely to produce many false negative results. However, a large number of materials which carry no evidence of causing adverse effects in man have demonstrated toxicity in animal tests. Nitrosamines, for example, are potent

carcinogens in nearly every species tested, but as yet have no proven effects in humans (Schneiderman, 1976, p. 73). The fact that a chemical is carcinogenic on a test strain does not guarantee its toxicity in humans, and the possible occurrence of these false positive results must be acknowledged in evaluating animal test data.

Differences in size, life span, and metabolic rate between humans and animal test species affect both the design and interpretation of bioassays. One key problem lies in determining the human dosage of a chemical that is equivalent to the dose administered to test animals. In practice, differences in life span and metabolic rates between humans and animals are often assumed to have cancelling impacts, leaving body size as the major factor to consider. Two approaches to making the dose extrapolation have been suggested: (1) considering the effective dose to be inversely proportional to body weight, and (2) considering the effective dose to be inversely proportional to body surface area (or weight to the two-thirds power). These two methods yield substantially different estimates of effective dose. Basing extrapolations on body weight, and assuming that humans weigh 2500 times as much as mice, a dose of 1 mg/day in mice is equivalent to a dose of 2500 mg/day in humans. Using body surface area as the basis for extrapolating, the effective dose in humans is only (2500) 2/3, or 184 mg/day (Weinstein,

1979, p. 350). The body surface area method is clearly more conservative, and has become the accepted approach.

B. Environmental Effects

Both the biological and nonbiological components of environmental systems may be injured by exposure to toxic chemicals. Biological effects at the species level include disruptions in physiological processes, increased susceptibility to disease, and genetic and behavioral changes. Ecological communities may suffer decreased stability and contamination of food chains as toxics accumulate in organisms. Nonbiological effects include aesthetic effects, such as the production of odors and discolorations, corrosion and other damage to structures, damage to soils and to water quality, and atmospheric modifications such as stratospheric ozone depletion.

Toxic substances in the environment may be viewed in two ways. One is to examine a substance's fate, or what happens to a substance after it enters the environment (i.e., what effects the environment has on the substance). The other is to observe what happens to the environment after entry of a substance (i.e., what

effects the substance has on the environment). In short, the effects of toxic substances in the environment are determined by the fate of the chemical in the environment and the specific ecological effects manifested in response to the chemical's presence.

Toxic substances reach the environment through a number of avenues and for a number of economic, political, and technological reasons. When introduced to the environment, either intentionally, as from point source discharges and pesticide and fertilizer applications, or unintentionally, as from nonpoint sources, runoffs, and accidental spills, toxic substances enter an interrelated system characterized by the flow of energy through it and the circulation of nutrients within it. A substance may interact with environmental agents to promote rapid dispersion and degradation, or it may resist environmental breakdown, concentrating instead within natural systems. This description of transport and persistence in the environment is the essence of chemical fate.

Ecological effects are specific reactions to exposure to toxic substances, manifested in the subcellular, suborganismal, individual species, community, or higher levels of organization. The study of these effects is more concerned with what happens to the living system after the advent of

chemicals rather than what happens to the chemical in the environment.

1. Chemical Fate. A chemical's fate in the environment largely determines the effect that the chemical will have on the environment. The determinants of chemical fate, however, are more difficult to delineate.

Chemical properties and physical processes, though they may indicate pathways for environmental transport of chemicals, primarily affect the degradability of substances, determining their persistence and availability over time. This knowledge of chemical structure and biological and environmental data reveal structure/activity relationships which may be used to predict environmental fate (Environmental Protection Agency Draft, 1980, pp. 5-7). Table 3.1 summarizes certain physical and chemical properties which influence the environmental fate of a chemical.

These same chemical and physical processes, as well as general information regarding a substance's production, use, and disposal and characteristics of the receiving environment, affect chemical transport, determining the availability of substances to the various media and the accumulation of substances within environmental systems.

TABLE 3.1: Properties of Aquatic Environmental Systems Affecting Fate and Concentration of a Chemical

Property
Surface area
Depth
pH
Flow/turbulence
Carbon in sediment
Temperature
Salinity
Suspended sediment concentration
Tropic status
Absorption spectra (ultraviolet, visible)

Properties of a Chemical Affecting the Concentration of a Chemical in Aquatic Environments	
Property	
Molecular structure	
Water solubility	
Vapor pressure	
Absorption spectra (ultraviolet, visible)	
Particle size (if substance is particulate)	
Rate Constants	
Photodegradation (ultraviolet, visible)	
Biological degradation	
Chemical degradation	
Evaporation	
Sediment binding	
Uptake by organisms	
Depuration by organisms	
Partition Coefficients	
octanol: water	
air: water	
sediment: water	

(Source: Johnson and Parrish, 1978, pp. 73-74)

Information on production such as quantity of a substance manufactured or imported, number and location of production plants, and sales figures reveal much concerning the scope and location of possible exposures and methods of consumptive uses. This use of information, in turn, may identify populations or subpopulations prone to significant exposures and avenues where substances can be expected to enter the environment. The disposal of toxic substances also influences the media through which it enters the environment. For example, incineration promotes air transport, wastewater treatment promotes water transport, and landfill disposal could promote subsurface transport to groundwater through leaching (EPA Draft, 1980, p. 16-17). Also, environmental factors such as wind speed and direction, tidal motion, river currents, and surface water runoff, which serve as carriers for chemicals, are other important determinants of a chemical's movement in a particular area.

2. Chemical Persistence

Persistence is the ability of a substance to remain in a stable condition, resisting environmental agents which may degrade or transform it. It is not per se an environmental effect of a particular substance, but it influences, with mobility, a substances effect, over an area over time.

The relative persistence contributes to and identifies the ability of a substance to bioaccumulate, or to be transformed or degraded.

Some of the tests for persistence include the examination of chemical properties and structure to see whether it may be destroyed by some other chemical, photochemical, or oxidation process, or whether it may be degraded aerobically by microorganisms; the examination of ecosystems to see whether pollutants may be biologically removed without disrupting the environment; and the examination of physical processes such as vapor pressures, activity coefficients of substances in water, and polarity and molecule size governing absorption and diffusion, to see whether substances may disappear by scattering or enter into the food web (Waggot and Wheatland, in Hutzinger, 1978, p. 150). Since most organic environmental reactions are non-reversible, it is essential that degradable chemicals be closely monitored for possible harmful degradation products, that these byproducts be identified, their concentrations measured, and their formation rates gauged (Stern, 1978, p. 90).

3. Determining Ecological Effects. Biomonitoring, or monitoring for ecological effects, combines the features of biological monitoring with those of chemical monitoring systems (Koeman, et al., in Hutzinger, 1978, pp. 339-347). In this way, biological responses of test species correlate with chemical and/or physical stimuli, and these response parameters identify possible toxic ecological hazards, given an understanding of the chemicals involved.

A typical biomonitoring system applied to aquatic ecosystems, monitors toxicity by investigating such responses to a pollutant as the loss of rheotaxis in fish (the ability of a fish to maintain its position as it swims upstream), the respiratory patterns and the locomotor activity of a fish, and the ability of a fish to maintain an upright position in a tube revolving around a flow of water. This last parameter is supposed to be a measure of fitness sensitive to toxic stimulus (Koeman, et al., pp. 341-342). Increasing the number of parameters would further broaden the scope of biomonitoring to detect virtually any adverse change in the test organism, such as lowered body weight, mutation frequency, and reproductivity.

Histological examinations of tissues from organisms which have been exposed to suspected toxics can reveal sub-lethal effects, such as enzyme damage and tumor formation. The offspring of exposed organisms have frequently been examined for evidence of teratogenic effects.

Fish often secrete mucus after exposure to toxic substances. A coughing response can subsequently be observed, as the organisms attempt to rid their gills of the mucus. The "cough test" monitors changes in the breathing rates of fish to measure stress resulting from exposure to toxic substances (Armstrong, 1979).

Currently, the EPA is proposing that the single species, or surrogate, approach be adopted to evaluate the effects of chemicals on ecological communities. This method is favored by industry as well as EPA, and is also being used in Canada, Japan, and Sweden (Environmental Protection Agency, 1979a, p. 13).

With this method, organisms (plants, animals, and microorganisms) are chosen as representative of larger taxonomic or functional groups on the basis of their roles in food chains and other ecosystem functions. Ecosystem level effects are then predicted from the results of these single-species tests, similarly to human health effects assessments based on single-species animal tests. Although

the surrogate approach is a practical and cost-effective way to screen large numbers of chemicals, several limitations should be noted:

(1) Care must be taken in extrapolating data from the tested species to the natural system. Sensitivity to the chemical may vary widely between closely related species and between different ecotypes in the same species. Also, a decision must be reached concerning the number of test species which should be studied in order to predict system responses to chemical exposure.

(2) Accepted test procedures for representatives of certain taxonomic groups are lacking.

(3) The surrogate method is unable to adequately consider the hazard to ecosystem stability caused by chemical contamination of food webs. Chemicals which create no observable toxic effects may be accumulated to a degree that can cause damage in primary or secondary consumers. In addition, the impact of degradation products of certain substances may be more detrimental than that of the substance itself; this is not evaluated by single-species testing. EPA notes that "the state of the art is such that published methods for screening level determinations of the impact of bioaccumulation

and the identification of toxic degradation products do not exist," although the potential for bioaccumulation and degradation can be estimated by physical and chemical means (Environmental Protection Agency, 1979 a).

(4) Single-species testing also fails to measure interspecific interactions such as host-parasite relations, symbioses, population balances, and others.

With microcosm testing, assemblages of interacting organisms are placed in a simulated ecosystem. Within the microcosm, the fate of a pollutant in a system is observed, revealing its availability and structural alterations in the environment. This examination of chemical fate helps determine the effect of a substance on the behavior of animals subjected to sublethal doses, indicating the broader impact of a chemical on the environment (Bourquin, 1978, pp. 95-99).

Two approaches can be taken with respect to microcosm testing: (1) Creating groups of organisms which function as simple food chains, or (2) Taking actual collections of organisms from natural systems, such as a soil core or pond water samples. By observing species interactions and monitoring processes such as energy flow, biogeochemical

cycles, and system stability, the broader ecological consequences of exposure are more realistically assessed than with single-species or other testing. However, better methods of replicating functional microcosms and measuring the parameters most indicative of environmental stress are needed (Environmental Protection Agency, 1979a, p. 17).

III. TESTING PROCEDURES FOR RISK ASSESSMENT: TIERED TESTING

In risk assessment, decisions concerning whether to test a particular substance and especially the type and extent of testing that is appropriate are often as difficult as conducting the tests. The high cost imposed by many risk-determining tests, and the large number of these chemicals which enter the market annually makes complete testing of all chemicals essentially impossible. At some point, the benefits of more sensitive risk determination are off-set by the testing costs and the possibility of inhibiting the development of a useful product. For assessing the risk presented by new chemicals the choice of testing procedure will be influenced by:

- previously gathered information on toxicity and exposure;
- benefits associated with the chemical's use and production;

- the costs of performing necessary tests;
- a subjective factor related to the value placed by society and regulators on relative certainty about the safety of a chemical.

Four broad types of testing schemes have been proposed. The first, known as a comprehensive base set, requires that a set of tests be conducted which produces sufficient data for at least preliminary risk assessment for all chemicals. Because of the diversity of chemicals requiring testing and the high costs of conducting the tests necessary to determine toxicity this approach is not generally considered a viable one (44 FR 16247). A second approach defines categories of chemicals, and provides a base set of tests for each category based on chemical structure, intended use, and other factors; some of the testing problems associated with the diversity of substances requiring testing are thus avoided. A flexible base set program allows testing to be tailored to a particular substance, based on its characteristics and expected exposure patterns. The major weakness of this approach is that the probability increases that insufficient or inappropriate information will be developed (44 FR 16248).

In light of the disadvantages of these testing guidelines, step-wise, or tiered testing, is becoming recognized as

the most cost-effective and time-efficient method of obtaining comprehensive risk assessment information concerning a chemical's anticipated health and environmental effects, environmental fate, and human exposure levels (Ramel, 1978, p. 246).

The EPA defines a tiered testing scheme as one in which "tests or groups of tests are arranged in a hierarchical structure. Testing begins in the lowest tier and proceeds as appropriate to higher tiers. Decisions on whether to go on to higher tier tests or to exit from the testing scheme are made according to decision rules or criteria." Tiered testing offers several distinct advantages:

- decisions can be made at a number of points in the testing process, and those tests that are most relevant to a specific chemical can be identified and applied; furthermore, results from lower level tests can be validated in higher level experiments;
- uniformity in the testing procedures and data interpretation is enhanced;
- the need for more expensive confirmative tests is eliminated where screening tests yield negative results (Hushon, et al., 1979, p. 1203).

Although tiered testing is designed to minimize the testing and analysis required to determine the hazard connected

with a chemical, it must include a comprehensive set of tests to measure all aspects of exposure and effects. In general, screening tests comprise the first tier of testing; positive results from these tests indicate a need to perform additional testing to (1) prove or disprove the toxic potential, or (2) improve the reliability of its assessment. Screening tests are followed by other predictive and confirmative tests in higher levels.

In the tiered testing programs developed thus far, the major criteria for selecting a test and placing it at a particular level have been:

- the time required for the test;
- the level of training necessary for performing the test;
- the estimated cost per compound tested;
- the predictive or confirmatory nature of the test;
- the accuracy and sensitivity of the test;
- the necessity of the test for evaluating an effect;
- the difficulty of conducting the test and interpreting its results (Hushon, et al., 1979, p. 1204).

Typically, first testing levels contain basic physical and chemical property determinations, as well as short term toxicity tests. First level tests should be sensitive indicators of adverse effects, yet pass compounds which present no

hazard. Ideally, these tests are relatively inexpensive, produce no false negative results and very few false positive results, and offer some prediction as to the nature of the effect produced by substances that require additional testing (Hushon, et al., 1979, p. 1204).

Higher order tests usually obtain more accurate data which serve to confirm or disprove a chemical's potential for toxicity. These tests are more complex, time-consuming, and costly. At this level of testing, results are expressed more quantitatively, and test conditions more realistically simulate natural conditions. Microcosm, chronic effects studies, and epidemiologic studies may be appropriately included at this level.

It is important to note that tiered testing schemes can be constructed which emphasize equally the detection of all effects for all substances, or which focus on detecting specific effects, such as carcinogenicity or acute toxicity. Because validated short-term tests may not exist for all effects (e.g., chronic toxicity or animal oncogenicity) the more complex and expensive tests required for these effects may be placed at higher tiers, thus omitting the usual initial screening process for these effects. Alternatively, these tests may be included in the first tier, with the result that the objective of minimizing time and testing costs is defeated. Tiered testing systems based heavily on economic

considerations are constrained by two factors: (1) since sequencing of tests is largely determined by their costs, thoroughness and accuracy of the risk information can be questionable, and (2) effects which can be diagnosed by inexpensive tests are consequently given priority over effects which require expensive testing to detect (44 FR 16248-9).

To be uniformly applied, tiered testing systems must contain criteria at each tier for determining whether a chemical should undergo testing at the next higher level, additional testing at the same level, or no further testing. The decision criteria, often known as "triggers", can be general and qualitative or specific and quantitative; they may be flexibly applied or rigidly followed. The nature of decision criteria has a significant impact on both the expense of testing and the value of the system in adequately determining risk (44 FR 16248). Decision criteria can be based on a number of factors, such as:

- a chemical's potential for exposure or environmental release, based on estimates of production volumes, specific uses, or other data;
- a chemical's potential for bioaccumulation or environmental persistence, as determined by its physical and chemical properties (octanol-water partition coefficient, water solubility, etc.);

- the acute animal toxicity of a chemical, or other bioassay data or parameters.

Of the numerous tiered testing schemes developed by the scientific community, most have been concerned with one particular aspect of hazard evaluation, such as environmental fate or mutagenicity. The EPA is in the process of developing a comprehensive tiered testing system as part of its TSCA regulations, and has considered sample programs submitted by the National Academy of Sciences, the Conservation Foundation, the European Economic Community, the American Society for Testing and Material, several chemical manufacturers, and other interested parties.

One example of a complex tiered testing system designed for new chemical risk assessment is that developed by the MITRE Corporation of McLean Virginia for the Federal Republic of Germany's Environmental Agency. The system is structured around four levels of increasingly complex tests:

Level 0: information and basic tests required of all substances at the time of notification of manufacture; included are mutagenicity/carcinogenicity in vitro screens, and tests for acute and subacute toxicity.

Level 1: tests which require a short time frame and which are simple and inexpensive, selected on the basis of exposure estimations. For

bioassays, dosages, routes of administration, and specific test organisms are selected according to results of the Level 0 tests.

Level II: tests of greater complexity and costs, which attempt to simulate the anticipated exposure conditions; tests are included for biomagnification; cell culture assays are conducted to assess mutagenicity potential.

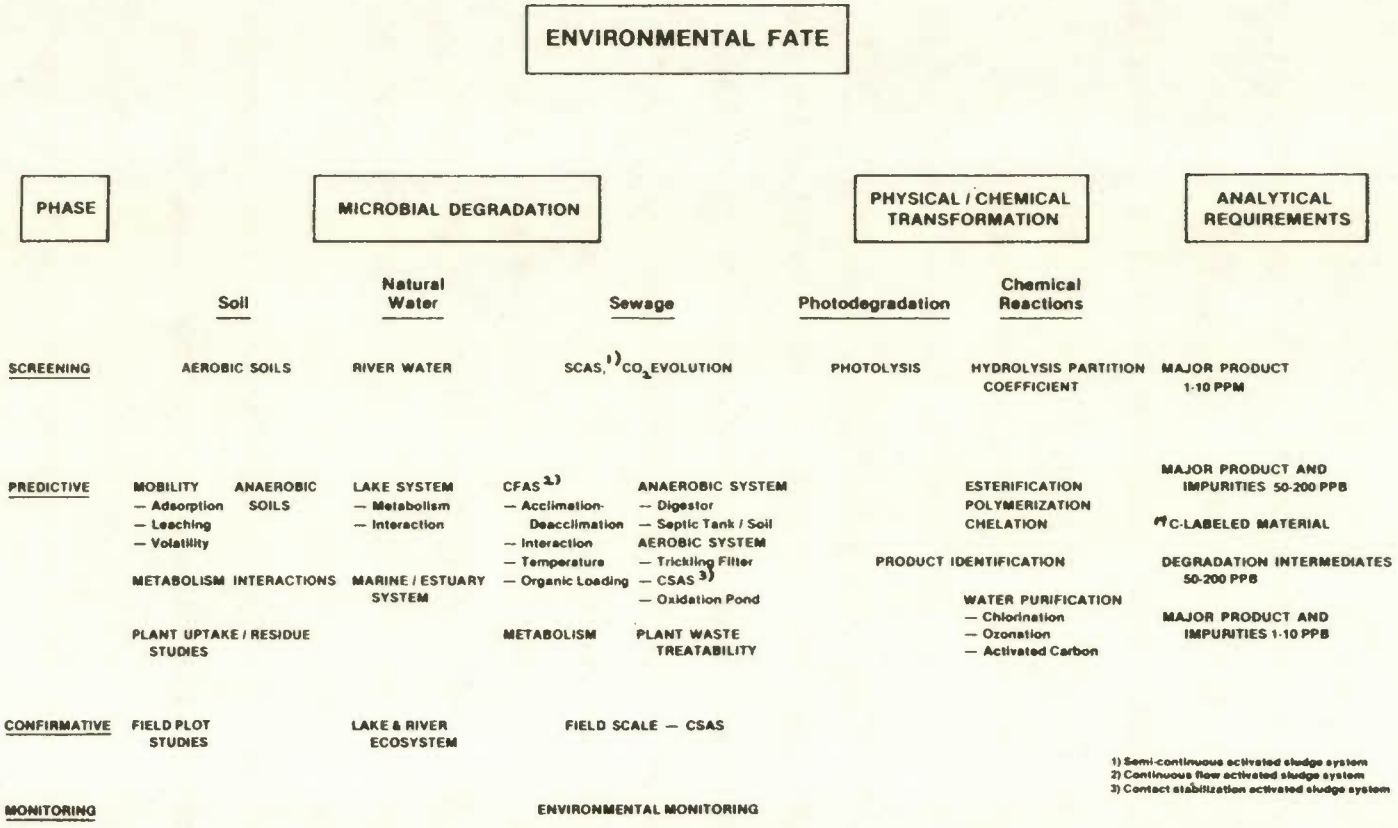
Level III: highly complex, expensive and time-consuming tests, which may be difficult to interpret with respect to human health effects. Examples of these are chronic toxicity tests, microcosm studies, and limited area field studies. Additional tests for bioaccumulation are included, as are tests for chromosome aberrations. Teratogenicity tests involving studies of live born progeny and decreased fertility rates may be conducted (Hushon, et al., 1979, 1205-6).

R. A. Kimerle, an aquatic biologist for Monsanto, has developed a testing scheme specifically for environmental effects and fate. He proposes testing in four tiers, building in stepwise fashion from screening studies of acute toxicity to more

stringent predictive and confirmative studies of a substance before introduction to the market place, followed by monitoring studies after market entry (1978, pp. 132-146). In Fig. 3.2, Kimerle identifies studies designed to gain a better understanding of the environmental effects of microbial degradation and physical/chemical transformation at each of the four stages. In a discussion session after Kimerle's presentation at an American Society for Testing and Materials (ASTM) symposium on Estimating the Hazard of Chemical Substances to Aquatic Life, the strategy for tiered testing was revealed as a procession "through succeeding tiers, (yielding) an increased understanding of environmental concentrations and toxic concentrations producing biological effects... From this greater understanding of the relationship between environmental concentration and concentrations producing biological effects, a more accurate risk assessment results which permits more confident decisions" (1978, p. 149).

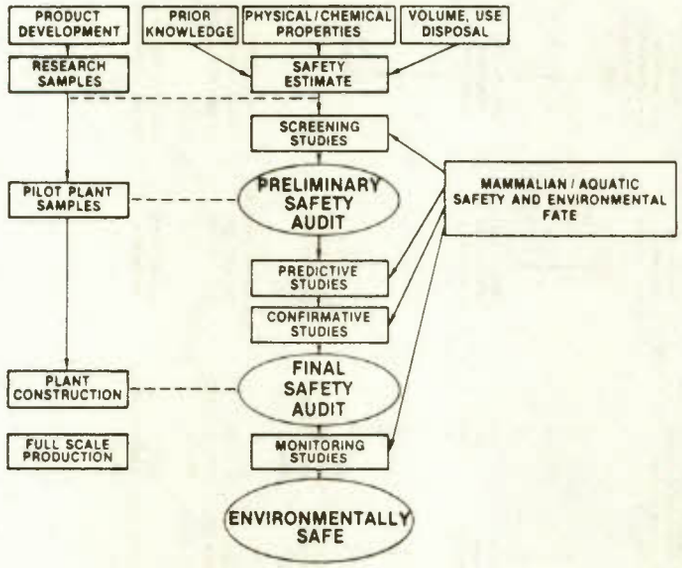
In the overall evaluation of hazard, Kimerle merges environmental fate studies with results from mammalian and aquatic toxicity tests, so that the determination of risk can be made at any point from screening studies to monitoring studies (See Fig. 3.3). The Aquatic Hazard Evaluation Criteria for this tiered system is shown in Fig. 3.4. Screening, the first tier, consists only of short-term acute tests. Predictive studies include short-and long-term chronic toxicity studies,

Fig. 3.2



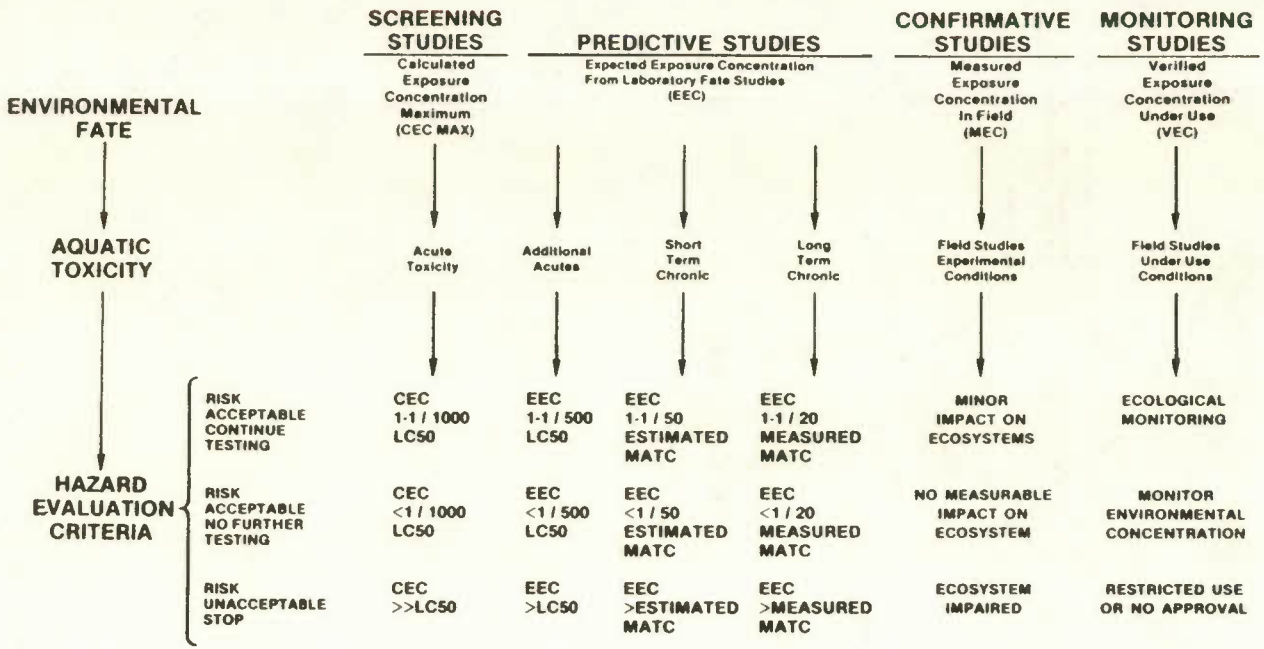
(Source: Kimerle, 1978, p. 137)

FIG. 3.3



(Source: Kimerle, 1978, p. 134)

Fig. 3.4



(Source: Kimerle, 1978, p. 139)

where test results are given the most weight. Confirmative tests are field studies designed to answer questions of environmental safety. Finally, monitoring studies yield ultimate confirmation of concentrations under use conditions. This may entail ecological monitoring if more testing is needed, environmental concentration monitoring if no further testing is needed, and restricted use or no approval if risk is unacceptable or production should be stopped.

IV. MONITORING

The following sections deal with current and future monitoring activities which may be performed by governmental agencies and industry to detect toxic substances in the ambient environment, in the workplace and in individuals.

The burden of the actual collection and analysis of monitoring data is borne by the industrial sector, generally for the purpose of gathering information about exposure to toxic substances. Some networks have been developed by the EPA for ambient monitoring, especially of air and water, but sampling of the environment near the producer of a toxic chemical is usually done by the industry itself.

A recent trend in governmental monitoring has been the development of sampling procedures that an industry should follow in order to ensure the comparability and quality of data

produced. To date, no official procedures have been published, nor has there been an organized effort by the EPA to monitor toxics under the auspices of TSCA. Instead, most governmental monitoring activities stem from other EPA divisions established by previous environmental acts. Information can then be recalled from these divisions when needed for the purposes of regulation.

Section 10(d) of TSCA states: "...monitoring techniques and instruments which may be used in the detection of toxic chemical substances and mixtures which are reliable, economical, and capable of being implemented under a variety of conditions..." should be used. TSCA also authorizes activities that will develop a scientific basis for monitoring techniques and will promote programs and workshops to train people to implement monitoring programs. The Act consistently emphasizes the effects on human beings of exposure to toxic substances and the magnitude of exposure. Useful ways to evaluate these effects are through monitoring the ambient environment and the workplace, and through surveillance of the individual.

When monitoring the ambient environment and workplace or surveilling an individual's response, many factors must be considered. No machine can perform all three types of monitoring activities and often a machine performing one type

of monitoring for one toxic cannot provide decisive information concerning that toxic. Each type of monitoring requires a different technique (eg. network design), different instruments and quality assurance of data obtained. These components -- technique, instruments and quality assurance -- are presented for each type of monitoring (ambient, workplace and surveillance) depending on the media into which the toxic is introduced. Media evaluated are: the atmosphere, liquids and solids. Table 3.5 gives a limited summary of the types of monitoring, the instruments and techniques available and the media monitored.

TABLE 3.5

M E D I A

Type of Monitoring	Atmosphere	Liquid	Solids
AMBIENT instrumentation	(1) sample collection lines or device (2) air mover or transmission lines (3) central processor or separate analyzer (4) flow or volume monitor	(1) sample collection device for H_2O (2) water flow or volume meter (3) analyzer -- gas chromatography, mass spec	(1) soil scooper and container (2) soil core sampler
techniques	(1) direct reading continuous sampling systems (2) direct reading batch type systems (3) manual systems - spot monitoring	same as ambient atmosphere techniques	manual spot check system
WORKPLACE instrumentation	(1) same as ambient (2) except on a (3) smaller scale (4) badges - passive monitor	(1) sample collector	none
techniques	same as above	(1) spot sampling system	spot check monitoring
SURVEILLANCE OF INDIVIDUALS instrumentation	(1) breath test machine	(1) urine sampler (jar) (2) blood sampler (syringe)	(1) surgical tools (2) tissue analyzer
techniques	system spot checking	systemic spot checking	(1) spot check of tissue banks (2) autopsies

A. Air

Generally there are four parts to an instrument which collects ambient and workplace air quality samples: the sample collection lines or device, the transmission lines or air mover, the flow or volume monitor, and a central processor or separate analyzer. These can be parts of a direct reading continuous sampling system which provides an instantaneous estimation of toxic substances, a direct reading batch-type system which provides observations after a discrete time period, or a manual system which requires highly trained personnel and must be employed often to provide useful results.

Each instrument should be placed to provide maximum coverage of the atmosphere at minimum cost. Achieving maximal coverage is dependent on the system's mode of operation as well as other factors such as the number of pollutants to be monitored, the number of sources of the toxic and the meterological flow of the area.

Workplace monitoring of the air quality is much like ambient air quality monitoring, except it is performed on a smaller scale. The monitor should be placed in an area that most closely simulates the breathing zone of the worker. Most workplace monitors are based on ambient monitoring designs and are usually called active monitoring instruments.

Certain other workplace monitors are considered passive monitoring instruments. Of these, badges which have a film sensitized to the toxic being investigated are useful because they are inexpensive and less cumbersome than active instruments. These are of limited utility, however, in that they can only monitor one toxicant at a time.

Both ambient and workplace monitoring instrumentation techniques often lack the ability to distinguish between chemical compounds or elements. The data produced may be affected by environmental interferences such as humidity and dust. Reactive chemicals can also affect the operation of all the monitors. Thus, assurance of the quality of data is crucial, as these random problems may bias the data produced. Quality assurance is dependent on the adequate upkeep of the machinery, collaborative and repeated testing of ambient and workplace air and continuous calibration of the instruments and the entire monitoring network.

The quality of data obtained through the surveillance of individuals exposed to a toxic through air is also questionable. One way to monitor an individual exposed to an airborne toxic is to perform a breath test, by which traces of toxics in the expirated air are measured. A quality assurance problem results when a toxic has passed

through the air passages. The toxic may have changed characteristics, therefore negating the assurance that the toxic measured and observed by the respiratory machine is in fact the initial chemical to which the worker was exposed.

B. Liquids

Water is the liquid of concern in the ambient environment. In order to analyze the effect of a new toxic chemical's introduction into the hydrologic cycle, both surface and groundwater may require continuous observation to establish baseline concentration levels and evaluate current compliance to standards.

Ambient levels of toxics are monitored in water much as they are in air. Often, though, due to the nature of the media, monitoring ambient constituents in the water is easier than monitoring air. Water monitoring instruments usually have a sample collector, flow or volume meter and central processor or separate analyzer. A mover of the media (such as the vacuum or fan parts needed for monitoring air) is generally not needed for surface water sampling, but groundwater monitoring may require some type of pump to obtain a bona fide sample.

Continuous, batch-type and manual systems are classifications that also apply to water monitoring. Some

combination of the three is often developed to monitor toxics and the indicators of a toxic's presence in the water. The detection of indicators (eg. BOD, TOC, pH, and fecal coliform) is often as important as the measurement of the toxic chemical, as these indicators may help identify the toxic constituent. More important to the evaluator, though, are extrapolations that can be made from these indicator measurements concerning the effect of the toxic concentration on living organisms in water.

As with air monitoring, the rationale for the placement of monitors is maximal coverage at minimum cost. The variability of the constituents in the water and depth, flow and width of the water body makes this goal a four dimensional task. Continuous monitoring of four dimensions is very expensive. Even if conducted repeatedly varying the depth, measurement site, and the toxic constituent monitored, batch-type tests treat the water as an isolated medium by eliminating the dimension of flow. Manual sampling and monitoring is highly susceptible to error with respect to all four parameters.

The quality of data gained from the sample may be limited by other factors. Because there are so many parameters to manipulate when monitoring a toxic, non-comparability of data taken in two different networks disallows verification

of data by repeated sampling. Environmental interferences, machinery failure, different capabilities of instruments used in analysis, and contamination of the sample during preparation for analysis are other quality control problems encountered in water monitoring.

A performance audit of the instrumentation and techniques used in ambient water monitoring has been suggested and the organization of the mass of data already obtained is being undertaken by the EPA. This should lessen some of the data quality assurance problems encountered when evaluating water monitoring data for a toxic chemicals effect in the ambient environment.

The monitoring of liquid media that a worker would be exposed to through ingestion is limited to drinking water on the premises.* Monitoring of drinking water within the workplace is not as difficult as ambient monitoring or monitoring for accidents. For example, toxics may enter the drinking water if water lines are crossed, if a drinking water pipe is infiltrated by contaminated water, or, if upon contact with the air the drinking water picks up the toxic. Sampling and analysis of the water should be performed regularly to ensure limited exposure to a toxic.

Surveillance of liquids in the individual centers around blood and urine analysis. A wide range of techniques,

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* The exception to this would be the occurence of an accident resulting in the intake of a liquid involved in the production process.

based on many different principles can be used for analysis of samples. This type of monitoring system, however, is difficult to manage to obtain meaningful analysis of exposures. Who should be monitored, at what intervals and for how long are questions that must be considered in surveillance studies.

Some monitoring systems identify high risk groups depending upon the toxic involved; others survey as many people as possible to detect patterns in the blood and urine analyses and relate these patterns to different levels of exposure. Both methods are based on sound principles (to aggregate or disaggregate the sample population) but the data produced is often dependent on the parameters used to define the population or chemical exposure. For example, parameters used to define a high risk group or a level of minimum acceptable detection of a chemical in all blood and urine samples can pre-determine the ways the production and analysis of data will proceed.

C. Solids

Ambient monitoring of solids in the environment is centered around the analysis of soils. Soils collect and trap toxic constituents transported either artificially or by nature (via wind, water, or air transport). Soil sampling systems, then, do not suffer from many of the problems that air

and liquid monitoring do such as continuous movement of the medium sampled. Soils can be sampled with a scooper or a core sampler, and parameters can be analyzed with respect to the time period over which they were deposited, the probable way in which they were deposited (eg., water, wind scattering) and of their source if the constituent can be traced. If the source of a toxic is natural an assessment of the geological and morphological characteristics of the area would most likely uncover the toxic's source. If deposition is artificial, the patterns and activities of man in the area will usually provide information as to the origin and method of deposition.

One problem in ambient monitoring involves the interelationship between biota and soils. Some toxics can be taken up by plants and then transferred to animals. The concentration in a soil sample, then, is not necessarily the initial concentration deposited. In addition, toxics may react with other chemicals in the soil and become non-toxic or a non-toxic may react with another non-toxic chemical or be respired by a plant and become a toxic chemical. In these cases, concentration and origin of the chemical are hard to assess, and past and intermediate effects become undiscernable from current effects of the toxic.

Workplace monitoring of solids is not extensive. Solids such as foods exposed in the workplace and then ingested by the

worker have gained some monitoring attention recently due to the discovery that workers in a pesticide factory were digesting the toxic chemical kepone.*

Tissue analysis of individuals exposed to a toxic chemical is a common method of surveillance. Tissue masses in the human body collect and accumulate toxics from the blood stream; skin tissue may collect toxics from the air or by direct contact. Surgical instruments are used to collect these affected tissues and chemicals are used to preserve the tissue sample. Sampling techniques and networks usually single out high risk groups such as those which have had a known exposure. Random sampling and tissue analysis for toxics may be done on corpses investigated in autopsies and on tissues stored in tissue banks.

Tissue analysis of an individual is beneficial if the tissues are properly preserved, if tissues from many individuals are obtained, and if a specific chemical is sought.

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* These workers ate their lunch in a factory where dust contaminating kepone was collected by the food and subsequently eaten.

V. INTERPRETING RISK ASSESSMENT DATA

A. Non-genetic Health Effects

The concept of a "no observed effect level", or NOEL, underlies the standard approach to quantifying non-genetic health risks from animal test data. The NOEL method assumes that a threshold dose level exists for non-genetic responses to chemical exposure, i.e., a dosage level exists below which no adverse effect will occur. This is generally accepted for most pharmocological and toxicological reactions (Gehring, 1977, p. 427).

The EPA defines the no-effect level as "the level (quantity) of a substance administered to a group of experimental animals at which those effects observed or measured at high levels are absent and at which no significant differences between the group of animals exposed to the quantity and an unexposed group of control animals maintained under identical conditions is produced" (Cornfield, 1977, p. 694). Determining an acceptable daily intake rate (ADI) of the substance is then accomplished by measuring the NOEL and dividing that quantity by some "safety factor." The ADI of a chemical is defined as the dose that is anticipated to be without lifetime risk to humans when taken daily; it is not, however, a guarantee of absolute safety. The National Academy of Sciences notes that "the presumed absence of toxic effects at any particular level in an experimental system may not be adequate to protect

especially sensitive population subgroups, such as the fetus, infants, the infirm, or the aged." (1979, p. 3.)

Experimental determination of the NOEL in laboratory animals involves uncertainties which must be considered in deriving acceptable intake concentrations of toxic chemicals. Simply defining the adverse effects being considered can be difficult, and the definition chosen can bias the measurement of the no-effect level; only slight changes in definition can create wide variations in the level. If, for example, a twenty percent reduction in enzyme activity is defined as an adverse effect, problems arise in justifying a dosage which causes a nineteen percent reduction as a no-effect level. Behavioral effects such as changes in feeding and mating habits can be especially difficult to define and quantify meaningfully.

Statistical biases associated with animal testing should also be recognized. The number of animals used in a toxicity study may affect the NOEL that is measured, as the statistical probability of observing an induced effect increases with larger experiments. Consequently, small studies are likely to produce higher no-effect levels than large studies (National Academy of Sciences, 1979, p. 11).

A range of safety factors from 10 to 5000 has been presented for use with toxicity data. For chronic (long

term, repeated) exposure, a 100-fold safety factor is usually applied. Developed by Lehman and Fitzhugh in 1954, the concept assumes that animals have a ten-fold greater resistance to toxic effects than humans, and that a ten-fold differential in sensitivities also exists within the human population (National Academy of Sciences, 1979, p. 9).

The 100-fold safety factor applied to the highest NOEL measured in animal studies is a standard international toxicological procedure for establishing the acceptable daily intake for humans, endorsed by the World Health Organization. Still, limitations in its application are well recognized. There is little or no empirical justification for choosing any safety factor, and thus selecting a factor of 100 is not necessarily sufficient to ensure against adverse health effects. Some of the points which are considered important in choosing a reasonable safety factor are:

- variations in susceptibility among exposed individuals;
- the most sensitive target organs or systems that will be affected by the chemical;
- the nature of the dose-response relationship, if known;
- the chemical's potential interactions with other chemicals or drugs;
- the nature and severity of injury at which the effect of the exposure becomes irreversible;

- potential cumulative effects of exposure to the chemical (such as for heavy metals exposures).

B. Risk-estimation for Genetic Health Effects

A risk-estimation method is generally employed in interpreting biassay data for genetic effects, especially carcinogenicity. This approach involves the downward extrapolation of experimentally generated dose-response curves from observed effects to lower dose levels where response data does not exist (Cornfield, 1977, p. 694). A typical dose-response curve is shown in Figure 3.6. On the graph, response represents the proportion of a population that exhibits a specific effect, rather than the degree of an individual's response to a chemical. As would be expected, the curve shows that for most toxicological responses, the percentage response increases with increases in dosage.

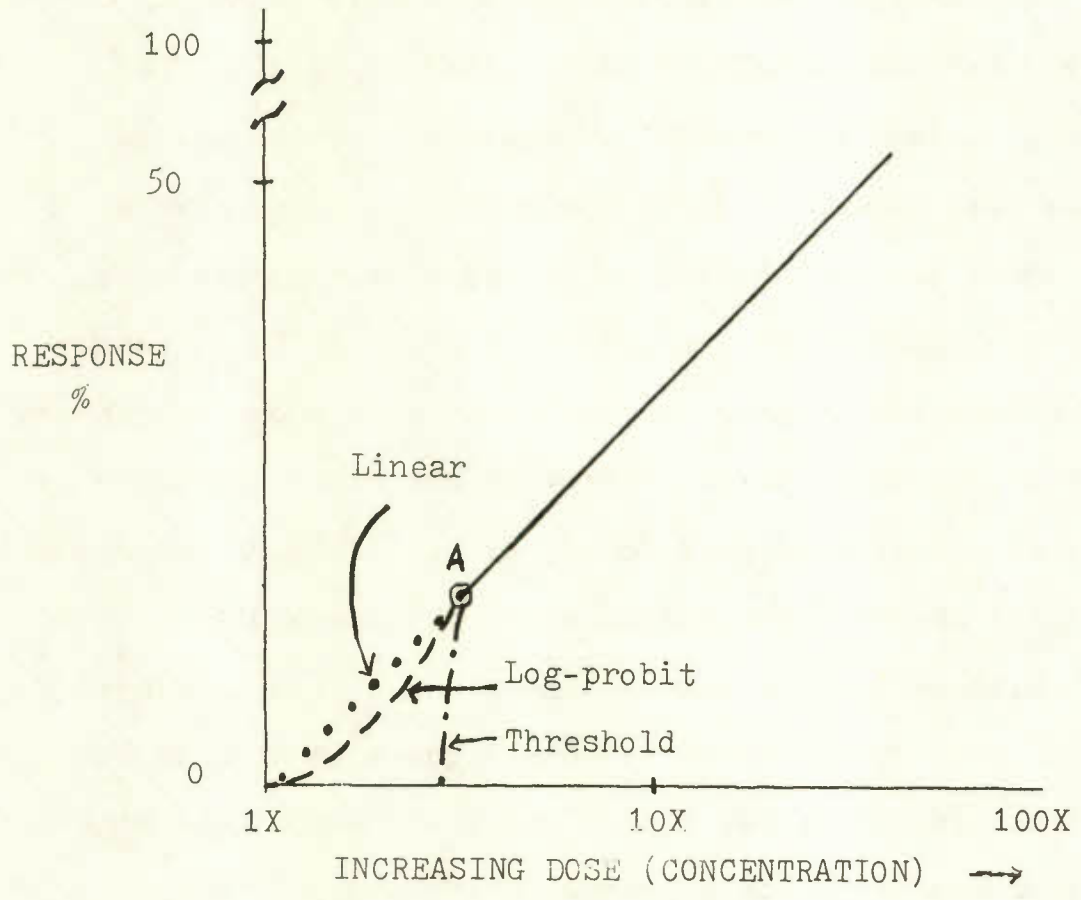
The key to determining safe levels of exposure to chemicals lies with interpreting the shape of the dose-response curve for doses below those which yield response data. Statistical limitations rule out the feasibility of determining low dose response rates experimentally. Using the usual sample of fifty animals, the chance of detecting one incidence of cancer in 10,000 would be less than 0.5 percent (Weinstein, 1979, p. 348). Detection of a one percent

incidence of cancer in test animals would require using 10,000 animals; to demonstrate with a 95 percent level of confidence that a given low dose of a chemical causes fewer than one cancer in a million individuals would require using at least six million animals (Doniger, 1978, p. 513). These popularly called "mega-mouse" experiments are considered impracticably expensive and subject to laboratory errors which impair the reliability of the results. Nonetheless, the National Center for Toxicological Research is currently investigating the response to low doses of a known carcinogen in over 24,000 mice, in an attempt to detect the presence or absence of a threshold dose level, or provide some empirical support for one of the existing extrapolation models.

Risk-estimation assumes the absence of a threshold dose level for carcinogenic effects: there is no dose at which induction of cancer cannot occur. A number of mathematical models have been presented which express the probability of a response occurring as a function of dose; these are applied to experimentally generated data to extrapolate the curve below the point shown as A in Figure 3.6. Most of the commonly used models assume the absence of a threshold dose.

The most widely used extrapolation equations are based on linear and single-hit models (Weinstein, 1979, p. 352). The linear model predicts that risk is directly proportional

Figure 3.6



(Source: Gehring, 1977, p.427)

to the exposure dose. It can be expressed as

$$I(d) = kd, \text{ when } d \leq 1/k,$$

$$= 1, \text{ when } d > 1/k,$$

where d represents the dose, I(d) is the incidence of cancer, and k represents the carcinogenic potency, defined as the natural logarithm of two, divided by the dose which gives a fifty percent incidence of cancer.

The single-hit model assumes that cancer can be induced by the reaction of a single chemical molecule with a single somatic cell; once this reaction has occurred, an irreversible process of disorganized, cancerous growth is initiated. This model is supported by data for radiation induced cancer, which apparently follows a linear dose-response pattern down to an induced incidence rate of approximately 0.1 percent.

Both the linear and single-hit models preclude a threshold response. At low doses, the models yield roughly equivalent curves which indicate that response is proportional to dose, as shown by the dotted line in Figure 3.6. Linear and single-hit models generally give the highest (most conservative) estimates of percentage responses at given low doses; this is the common justification for their use in predicting low dose risk (Cornfield, 1977, p. 695). Multiple-hit models of cancer induction require that either multiple hits

on a single target, or single hits on multiple targets are responsible for the cancer induction; these yield slightly lower levels of response to given doses (National Academy of Sciences, 1979, p. 28).

Tolerance distribution based models are founded on the idea that individuals in a population at risk have varying tolerances for a toxic substance below which a dose will produce no response; above the tolerance level, a dose will produce a response. The log-probit, or log-normal model has been generated by further assuming that these tolerances vary among individuals according to some known probability, and that the distribution of tolerances is normal against the logarithm of dose (National Academy of Sciences, 1979, p. 25). The proportion of individuals which demonstrates the effect increases with dose, often according to an approximate sigmoid relationship with the logarithm of dose (illustrated by the dashed line in Figure 3.6).

The prominent flaw in this model is that the normal distribution may not be valid in the tails of the curve, and so the probability of a response occurring at a given low dose may be overestimated (Cornfield, 1977, p. 695). To account for human tolerance distributions more variable than those of laboratory animals, it has been suggested that the actual slope used to calculate responses at low dose be no

greater than the average time slope; this modification, called the Mantel-Bryan model, is the conceptual equivalent of the standard ten-fold safety factor used in toxicology to account for human variation, and may improve the validity of the log-probit model (Cornfield, 1977, p. 695).

Logistic models are based on the assumption of a logistic distribution of the logarithms of the individual tolerances in the population and a theoretical description of certain chemical reactions. The value of this function in describing the behavior over time of different chemical reactions has been noted by some researchers (National Academy of Sciences, 1979, p. 26). However, neither the log-probit or logistic models have much theoretical basis for cancer induction, and their use is based largely on mathematical convenience.

The choice of an extrapolation model has significant implications for risk assessment at low doses. While doses which yield responses in the observable range (i.e., a lifetime incidence rate of ten to ninety percent) show little variation in response rates among the different models, the responses predicted by the models at low dosages can be widely divergent, differing by a factor of up to 1,000,000 on the size of a dose that creates a risk of one cancer in one million individuals (Doniger, 1978, p. 513).

The most important consequence of applying any model for extrapolation is its implications for regulatory efforts. Even if the magnitude of the risk could be more solidly established, the marginal risk imposed by increasing increments of dose is determined by the model chosen. If marginal risk is very large, then even small increases in the allowable exposure will severely impact human health, and limits on exposure should be rigidly enforced. On the other hand, if the incremental risk is relatively small, extensive efforts to prevent small violations of exposure limits may not be worthwhile (Doniger, 1978, p. 514). Clearly, the extrapolation models cannot provide precise estimates of low dose risk, although they can permit ranking of chemical carcinogens in rough order of potency, and establish credible outer limits for the hazard presented at different doses.

High doses are necessarily administered to test species in order to obtain statistically valid response levels. This complicates a central problem of interpreting carcinogenicity tests: determining whether low doses retain an ability to cause cancer, or whether they are detoxified in the same manner as noncarcinogenic chemicals. If DNA repair or other detoxification mechanisms do exist for carcingens, can the assumption that threshold response levels do not exist be relaxed? The more conservative and more

widely accepted view is that thresholds do not exist, but a number of scientists argue that complex metabolic routes can minimize the impact of exposure to carcinogenic substances, and that no-effect levels can be observed in many cases (Maugh, 1978, p. 37).

One theory suggests that very high test doses may increase the incidence of cancer because their very quantity overwhelms the biochemical pathways that detoxify smaller, more realistic doses. Gehring notes that even if a carcinogen attacks the critical site in a cell (the probability of which is very low for small doses), cellular repair mechanisms can often restore DNA to its original state (1977, p. 427). Tumors will therefore only result when doses are such that DNA repair is inhibited. Gehring further states that for many chemicals, excretion, activation, and detoxification are active transport or enzymatic reactions are best understood by Michaelis-Menton (concentration, or dose, dependent) kinetics. By calculating the changes in cancer-causing metabolites associated with changes in the dose of the carcinogen, he explains why excessive doses of a chemical may cause discernable increases in cancer levels, while smaller doses have no apparent impact on response rates.

Cornfield proposes a kinetic model which demonstrates that deactivating reactions (such as DNA repair and detoxification) may become saturated at high doses (1977, p. 696). The

model predicts a dose-response curve with the hockey stick shape characteristic of threshold responses (the dot-dash line in Figure 3.6). Cornfield writes that "the existence a no-effect or threshold level for... carcinogens... is not precluded. Whether such levels do or do not exist depends on the presence of at least one irreversible protective reaction, but there seems no present reason for believing that all carcinogenic processes are characterized by the absence of such reactions..." He advocates the determination of a "saturation dose" in risk assessment procedures for carcinogens, similar to the no-effect level determination for non-genetic health risks (1977, p. 698).

A final piece of evidence which supports the threshold hypothesis for carcinogenic responses is the relation between the dose of a carcinogen and the latent period between exposure and initiation of tumor growth (Maugh, 1978, p. 40). It is generally accepted that the latent period increases as dose is reduced. At least two researchers have found that the product of the dose and a power of time is a constant; this may imply the existence of a practical threshold, since at very low doses the latent period is several multiples of the animal's life span.

The importance of the threshold controversy is its implication for controlling risk. If a threshold level can be established for carcinogenic responses to specific chemicals,

then they may be considered virtually risk-free at very low doses. These acceptable dosages might, as Cornfield suggests, be determined in a manner parallel to the ADI determinations for noncarcinogenic toxics. Some exposure to these chemicals would then be tolerated if the benefits associated with their use were believed to outweigh the risks. However, the evidence for a zero-tolerance for exposure to carcinogens lends support to a zero-exposure regulatory goal, such as that mandated for food additives by the Delaney clause.

Because this type of control is nearly impossible to ensure, the concept of virtual safety introduced by Mantel and Bryan has been adopted by the Food and Drug Administration (Cornfield, 1977, p. 694). A dose, D_O, of the carcinogen is said to be virtually safe if $f(D_O) \leq P_O$, where P is some near-zero quantity (10^{-8}, according to Mantel and Bryan), and f is computed from the extrapolation equation chosen. The virtually safe dose (VSD) is then computed as $f^{-1}(P_O)$. Hence, the VSD depends on the extrapolation applied, and is limited in its validity by the difficulties associated with each model (Cornfield, 1977, p. 695).

C. Interpreting Data from Ecological Effects Testing

Safe concentrations for organisms are calculated similarly to the NOEL method of determining acceptable human intake levels. An application factor (resembling the safety

factor in ADI calculations) is combined with the LC_{50} concentration determined experimentally, to derive the maximum acceptable concentration (MAC). This can be shown as:

$$(LC_{50}\text{-96 hours}) \times \underset{\text{factor}}{(\text{application})} = \text{MAC}$$

As with the safety factors discussed previously, little empirical evidence exists to justify the choice of one application factor over any other (Armstrong, 1979). For aquatic systems, the application factors included in the EPA's water quality criteria are widely used. These are:

0.10 for non-persistent compounds;

0.05 for persistent compounds; and

0.01 for persistent compounds with long-term exposure.

D. Interactions Between Toxic Chemicals

Although research to determine the risk associated with toxic substances is nearly exclusively single-chemical in focus, humans and natural environments are only rarely exposed to "pure" doses of a chemical. More often, exposure is to mixtures of substances, which may cause very different responses as a result of interactions between chemicals. The combined effect of such mixtures may be additive, synergistic, or antagonistic, depending on reactions for which little information is available.

Additive effects for certain chemicals have been proven by epidemiological research; e.g., the additive effect of cigarette smoke and alcohol on oral cancer incidence rates is well documented (National Academy of Sciences, 1979, p. 47). Two types of additive effects have been theorized: (1) independent joint action in which the substances act independently and with different modes of action, and (2) similar joint action in which the substances have the same mode of action but act independently so that one component of the mixture can be substituted at a constant proportion for the other (National Academy of Sciences, 1979, p. 45).

Several models have been offered to explain synergistic (greater than additive) and antagonistic (less than additive) effects of mixtures of toxic substances. The exceptionally high levels of lung cancer mortality among the population jointly exposed to cigarette smoke and asbestos is the best known synergistic health effect. Most of the models presented have incorporated information about the routes of administration of a chemical, its sites of action, the physiological systems that it affects, and the range of tolerances in the biological system under examination. Specifically for carcinogenic responses, the concepts of initiation-promotion and cocarcinogenesis may explain interactive effects. Some research indicates that a prolonged

period of exposure to some promoting agent may be necessary before cancer can be induced (National Academy of Sciences, 1979, p. 45). While direct cancer-causing agents can be discovered through in vitro testing and animal bio-assays, promoting agents may show no signs of carcinogenicity in laboratory experiments, though they react synergistically with initiating agents to increase cancer incidence rates. Cocarcinogenesis involves the administration of mixtures of chemicals, or the influence of modifying factors on cancer induction processes.

The lack of understanding of toxic chemical interactions has required that most estimates of total toxicity for simultaneous exposure to different chemicals have been based on simple additive models. A harmonic mean formula, as shown below, is an accepted method of calculating total toxicity for mixtures of non-carcinogenic compounds:

$$\frac{1}{\text{predicted } LC_{50}} = \frac{P_A}{LC_{50} \text{ of compound A}} = \frac{P_B}{LC_{50} \text{ of compound B}},$$

where P_A and P_B are the fractions of component A and B respectively, and the LC_{50} for components A and B are the dosages found to cause fifty percent mortality in test animals (National Academy of Sciences, 1979, p. 5).

The EPA applies a similar method to toxicity determinations in aquatic systems; for multiple toxics in water, the

following relationship must hold:

$$\frac{S_1}{MAC_1} + \frac{S_2}{MAC_2} + \cdots + \frac{S_n}{MAC_n} \leq 1$$

where S represents the concentration of the chemical, and the MAC is the LC_{50} concentration determined from experimental data (Armstrong, 1979). It must be noted, however, that in extending the general harmonic mean formula to multi-component mixtures, more uncertainty is introduced as more interactions may be occurring.

VI. RISK ASSESSMENT UNDER THE TOXIC SUBSTANCES CONTROL ACT

Chemical risk assessment and regulation under the Toxic Substances Control Act of 1976 (P.L. 94-469) is accomplished through four major activities:

(1) the formulation of a chemical inventory, primarily for purposes of distinguishing "old" from "new" chemicals;

(2) the requirement of pre-manufacturing and processing notifications by manufacturers;

(3) the requirement of testing for certain chemical substances identified as having risk potential;

(4) placing controls on the manufacture, distribution, or use of chemicals proven to present a reasonable risk to human health or environmental systems.

A. The Pre-Manufacturing Notification Program

The pre-manufacturing notification has been considered the heart of the TSCA regulatory scheme, and marks a significant change in the U.S. approach to controlling hazardous chemicals (Environmental Protection Agency, 1979b, p. 10). For the first time, measures to protect public health and the environment can be considered and adopted before the entry of a toxic chemical into the market.

At least ninety days before production of newly developed chemicals, or production of existing chemicals for "significant new uses", manufacturers must submit to the EPA Premanufacturing Notification materials. Part 1 of the notice form requires information concerning the chemical's identity, expected production volumes, anticipated uses, and transportation patterns. Parts 11 and 111 provide information used by the EPA in assessing the risk associated with the new chemical.

1. Part 11. Information supplied in Part 11 of the notice form is the primary basis for risk assessment. Section A requires that the submitter indicate the properties and effects of the substance, the types of tests used to determine them, and any conclusions, evaluations, or assessments made concerning the test results. Additionally, the submitter is required to explain any risk evaluations he

has made, and should determine whether the data reported are sufficient to allow quantification of the risk presented by the chemical (44 FR 2250).

Sections B and C of Part 11 require statements regarding human exposure and environmental release at manufacturing and processing sites. This includes:

- information on worker exposure, involving the expected routes of exposure, the number of persons that will be exposed, and the magnitude, duration, and frequency of exposure;
- information on environmental release (including estimates of the maximum and average amounts and concentrations of the chemical that will be discharged);
- statements regarding the types of pollution control equipment used to limit the discharge of the chemical.

Section D requires information on general population exposures resulting from use of products containing the chemical. Such products and their uses must be identified; the consumer market population and the frequency and duration of human exposures must be estimated.

2. Part III. Part III of the notice form is optional. It requests specific information concerning the economic and other non-risk impacts of the new chemical relevant to determinations of the reasonableness of the risk presented by the substance. Other data which may be supplied include descriptions of the overall testing and evaluation scheme used to assess the toxicity of a chemical, structure-activity relationship information, industrial process and use restrictions, and industrial hygiene programs that will be used to control human exposure (44 FR 2250).

3. EPA Use of the Pre-Manufacturing Notification Form. As noted in the applicable regulations (44 FR 2244):

> "EPA will use the notices as a point of departure for performing its risk assessments and unreasonable risk judgements, and not as the exclusive source of information for such decisions. However, the Agency will be limited in its ability to obtain information not included in the premanufacturing notices within the statutory review period. To the extent time will permit, EPA will use its statutory authorities and other means (literature searches, contractor support, consultations with scientific and engineering experts) to supplement and verify submittals by manufacturers. In some cases where data in the notices are incomplete or otherwise inadequate, the Agency may make worst case assumptions about possible exposures and risks associated with particular chemical substances."

B. Required Testing of Existing Chemicals

Risk-determining testing may also be required for existing chemicals when:

- the introduction or presence of a chemical presents an "unreasonable risk" to human health or the environment (U.S. Congress, TSCA, 1976, Sec. 4);
- there is insufficient evidence available to assess the risk potential of a chemical; and
- testing is necessary to provide such evidence.

In requiring testing for a particular chemical or category of chemicals, the EPA must specify both standards for developing the test data and the time period allowed for submitting the results.

Recommendations as to which chemicals and categories of chemicals should be given testing priority are made by the TSCA Interagency Testing Committee (ITC). In developing its list of priority chemicals, the committee is directed to consider (in order of relative importance):

- exposure data, including the production volume, environmental release, occupational exposure, and non-occupational human exposure to the chemical;
- the similarity of the chemical to others known to present risk of injury to human health or the environment;

- the existing risk assessment data on the substance, and the extent to which additional testing is likely to produce data useful for more accurately determining risk;
- the availability of facilities and personnel for conducting the necessary testing (U.S. Congress, TSCA, 1976, Sec. 4(e)).

The Committee has encountered certain problems in developing their priority lists for chemical testing on the basis of these criteria. The lack of a central data system of consolidated chemical information is a major impediment to accurately determining the most critical testing needs. Of the data systems that do exist, many are not formatted uniformly so as to enable ready comparisons of information. Information on projected uses and exposures has been particularly difficult to obtain (Environmental Protection Agency, 1977, p. i).

C. Regulatory Controls for Toxic Substances

Section 6 of TSCA provides the EPA with the authority to impose controls to protect against injury to human health or the environment caused by exposure to a chemical. If evidence exists that the manufacture, processing, distribution, use, or disposal of a chemical substance presents an "unreasonable

risk of injury to health or the environment", EPA may apply any of several requirements to the extent necessary to protect against such risk (U.S. Congress, TSCA, 1976, Sec. 6(a)). The manufacturing, processing, or distribution of the chemical manufactured, processed, or distributed for a particular use can be restricted. EPA may also require that the substance or products containing the substance carry specified warnings and instructions. The manner or method of disposal of the chemical may be determined by the Agency, as well as any manner or method of commercial use of the chemical.

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Chapter 3

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CHAPTER 4

ECONOMIC IMPACTS OF TOXICS CONTROL

I. INTRODUCTION

The regulation of toxic chemicals under TSCA imposes substantial economic burdens -- most directly on industry, but also on government, and subsequently the consumer. Framers of the statute were aware of the potential economic impact, and accordingly including economic considerations in the determination of "reasonableness" of actions promulgated under TSCA (section 2(c)). The continuing commitment to control of chemical hazards is expensive; there is little doubt that costs will continue to rise.

In this chapter the economics of TSCA are explored. A more general review of pollution economics and of alternative theories of pollution control, which provides a beneficial background to a discussion of the economic impacts of TSCA, is given in Appendix I.

Chemical manufacturers are to bear the primary costs of toxics regulation. The most direct costs result from the responsibility for data development (section 2(b)(1)), i.e., costs of testing and screening. Significant costs will result from the impact of regulatory actions, such as bans, restrictions, and delays. Administrative costs will also be substantial, and a variety of less significant costs will be incurred for fees, litigation, and other activities.

Because the Environmental Protection Agency (EPA) has yet to make a final decision about the manner of enforcement, any estimates of the economic impact of the law are bound to be uncertain. As of late 1978, no total assessment of the economic impact of the law on chemical manufacturers had been made. The Chemical Manufacturers Association (CMA, formerly MCA) is presently engaged in a pilot study of TSCA's impact due to be completed by July 1980; a full-scale study, if performed, will not be finished until 1982. EPA is to begin a massive, multi-year (3-5) economic impact study in mid-1980. CMA and EPA have been unable to coordinate a cooperative study. Understandably, chemical industry representatives have been extremely apprehensive about the effect that TSCA might have on the industry. This concern is anticipated in the statute which specifically states that toxics regulation should be enforced

> ...in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose...(to prevent) unreasonable risk of injury to health or the environment (TSCA 2(a)(3)).

Additionally, section 6(c) calls for consideration of "economic consequences" of regulatory actions and of benefits derived from a potentially regulated substance.

One method of quantifying economic impacts is the use of dollar-based cost-benefit studies. However, this approach does have limitations. The present lack of specific guidelines and regulations for the implementation of TSCA prevents firm estimation of effects.

Most importantly, direct and indirect costs are difficult to determine, and benefits are still harder to identify and quantify. Equity questions and conflicts between social and individual values create additional problems in calculating the economic impacts of TSCA implementation. As Epstein notes:

> Cost-benefit analyses...do not adequately reflect the delayed costs of deregulation, or the failure to regulate, in terms of disease, death, and environmental degradation. (Epstein, 1980, p. 49)

Because of the inherent limitations of these cost-benefit analyses, cost-effectiveness, a more qualitative approach, may be a more appropriate "yardstick." With limited funds available for toxics control, regulation should aim to produce maximum output in terms of reductions in adverse health and environmental effects at minimal cost. Importantly, cost-effectiveness does not require quantification of health or environmental effects --costs or benefits. A GAO study asks with regard to testing

> ...at what level of strictness of testing requirements do marginal testing costs start to exceed the marginal benefits of the information generated (U.S., Senate, 1975 (2), p. 93).

II. COSTS OF TESTING

Seventy-five percent of all chemicals in production in the U.S. have annual production volumes of less than 100,000 pounds. Making conservative assumptions about sale prices, gross margins on sales product lines and start-up costs, it appears that for many new chemicals, it will not be economically feasible to perform much testing for health or environmental effects. For some chemicals, manufacturers may therefore decide to forego production rather than incur the costs of testing. The low production volumes anticipated for many chemicals may mean that the profits from their sales would be insufficient to cover the cost of the necessary testing; thus, some low market potential chemicals will likely not be produced. Consequently, it is possible that pre-manufacture testing sufficient to produce the information needed for a reasoned risk assessment could inhibit innovation in the chemical industry. A major objective of any testing scheme is to minimize this effect by focusing testing efforts on substances which, because of anticipated exposure or preliminary indication of toxicity, are more likely to present

a risk to health or the environment. Perhaps the most difficult situation arises when a new chemical substance is expected to be produced in small quantities but for a use that will expose large segments of the population.

Considering the pre-manufacture review program as a whole it is difficult to predict accurately the actual degree to which chemical innovation may be inhibited by the testing guidelines. It will depend on the accumulative individual decisions of many manufacturers developing a variety of chemicals for diverse uses. However, the public will benefit from the greater certainty that those chemicals that are produced do not present an unreasonable risk to health or to environment.

Costs estimated for testing the properties and effects with which EPA could be concerned range from a few hundreds or thousands of dollars for many of the chemical fate and ecological effects tests to tens of thousands and even hundreds of thousands of dollars for some of the health effects tests. Biodegradation tests, for example, cost in the neighborhood of $5,000 to $12,000 to perform, while subchronic health tests may cost $100,000 or more and chronic toxicity and oncogenecity studies may cost $300,000 to $700,000. By focusing on certain effects, EPA could reduce the cost of testing for particular substances. However, the Agency would do so at

the expense of obtaining information about many effects. Because some of the more expensive tests relate to human health effects, it might be difficult to implement this "effects of concern" alternative in such a way as to both reduce cost and protect important public health values (44 Federal Register 16249; Mar. 16, 1979).

III. EFFECTS ON INDUSTRY

TSCA, like many foreign toxics laws, is structured so that the burden of regulation (i.e., reporting, testing) falls primarily upon industry. In 1978, Robert Roland, president of the (then) Manufacturing Chemists Association (MCA), said concerning TSCA: "already innovation has been stifled, production curtailed, inflation fueled, our ability to compete in foreign markets hampered, and our domestic markets opened to cheaper foreign imports."

Industry estimates of their total costs related to TSCA have run as high as two billion dollars per year -- more than ten times EPA's estimate of $80 to $140 million per year. Under TSCA, industry will bear four types of major costs:

1. testing/screening costs
2. administration/reporting costs
3. costs resulting from delays
4. other indirect costs

(U.S. Senate, 1975(2), p. 94)

In 1975 three different estimates of the costs to industry resulting from TSCA (as proposed S. 776) were made. EPA estimated the total yearly cost at $80 to $140 million; MCA's estimate was $360 million to $1.3 billion; Dow Chemical predicted a cost of $2 billion. A summary of the results of these three studies appears in Table 4.1. The General Accounting Office (GAO) performed a review and comparison of the three studies and estimated the total costs of TSCA at $100 to $200 million per year. As a representative of GAO noted, "differences appear to stem from significant differences in interpretation of the proposed act" (U.S., Senate, 1975(2)). As mentioned previously, current studies are scheduled for completion in 1982, or later.

A. Cost Estimate Methodologies

The Dow estimate was obtained by estimating Dow's costs and multiplying by a factor to estimate total industry costs (Dow sales are approximately 4 percent of all chemical industry sales). The GAO report notes that this method of extrapolation effectively results in the use of a 4 percent non-random sample.

The MCA used the largest amount of data to form their estimate: 45 companies, representing 24 percent of total chemical industry sales, were surveyed. However, the source data

Table 4.1 - Comparison of TSCA Cost Estimates
(U.S., Senate, 1975(2), p. 94)

	EPA (low)[4]	EPA (high)[4]	MCA No. 4 (lowest)	MCA No. 1 (highest)	DOW
1. Screening & testing:					
a) Screening:					
No. of chemicals	1,000	1,000	(1)	(1)	(1)
Cost per chemical	3,300	5,500	(1)	(1)	(1)
Total (millions)	$3.5	$5.5	(1)	(1)	(1)
b) Testing new chemicals:					
No. of chemicals	150	150	1,230	7,900	916
Cost per chemical	20,000	40,000	51,900	33,700	382,000
Total (millions)	$3	$6	$63.8	$266.5	$350
c) Testing old chemicals:					
No. of chemicals	200	200	65	100	482
Cost per chemical	22,500	42,500	465,000	411,000	1,000,000
Total (millions)	$4.5	$8.5	$30.2	$41.1	$482
Total (millions)	$11	$20	[2]$79.0	[2]$292.6	[3]$712
2. Administration and reporting (millions)	$19.5	$41.5	$64	$82.0	$133
3. Delays (millions	$10.0	$19.5	$24	$86.0	$145
4. Bans or restrictions (millions)	$37.5	$60.0	$165	$195.0	$965
5. All other (millions)	$.5	$.5	$26	$669.4	----
Total cost (millions)	$78.5	$141.5	$358	$1,325.0	$2,000

1) included in testing
2) net of $15,000,000 for current testing
3) net of $120,000,000 for current testing
4) to the nearest $0.5 million

were unavailable for GAO review. Although the EPA Administrator is indeed delegated broad rule-making authority under TSCA, the MCA study probably overestimates the extensiveness of regulation.

MCA's minimum impact case, Scenario 4, assumes "...selective pre-market screening of new substances and applications with displacement of innovation" (MCA, 1975, p. 166). The maximum impact assumption, Scenario 1, entails

> maintenance of innovation under comprehensive pre-market screening of all major new substances and applications with selective screening of minor ones, as well as broad application of other TSCA provisions (MCA, 1975, p. 165).

Additionally, MCA predicts $78-114 million in start-up costs.

EPA's assumptions are based on legislative history, intensive staff work, experience with other environmental laws, and consultation and advice from various parties (p. 4). GAO criticized the EPA report for poor documentation.

One may assume that EPA probably has a more accurate conception of the extent of regulation that will be required under the act, since EPA will be the enforcing agency. Industry, however, feels best suited to make impact assessments. Industry may indeed have a better feel for the costs of required testing. However, because private industry is motivated by profit, especially in the short-term, it may be to their advantage to overstate the costs of regulation

in order to discourage more extensive regulation (See Epstein). For example, it now appears that the costs of banning chloroflourocarbons (CFCs) are only half of those once predicted by industry. As a result industry may lose credibility. On the other hand, government agencies, such as EPA, may tend to understate impacts in order to expand responsibilities.

B. Screening and Testing Costs

The EPA study breaks out the screening costs which appear in Table 4.2. As of September, 1979, EPA's estimate of the costs of submitting pre-manufacture notices (PMNs) was $1,200-8,900 per chemical (EPA, 1979). Costs of submitting claims for confidentiality were estimated at $900-1400 per chemical. An appropriate average total cost might be $6000 per new chemical. An Owens Chemical representative recently estimated costs of confidentiality claims at $4000 or more, a figure which includes some litigation costs (ES&T, 1980, p. 130). The MCA study does not separate screening costs from testing costs. However, both studies do assume close consultation between EPA and industry thoughout the process.

The EPA study assumes "a selective approach" to testing requirements dependent on factors such as "...contemplated uses and likely exposure patterns, anticipated market

Table 4.2 Estimated Costs of Premarket Screening
(U.S., EPA, 1975, p. 10)

Administrative Costs of Notification of New Commercial Chemicals

A.	No. of new chemicals	600
B.	Ave. admin. cost per chem. notif.	$3-4,000
C.	Total (AxB)	$1.8-2.4 million

Administrative Costs of Notification of New Uses

A.	No. of sign. new uses reported	400
B.	Ave. no. of rpt. estab. for each new use during 1st year of use	4
C.	Ave. admin. cost per new use notif.	$1-2,000
D.	Total (AxBxCxD)	$1.6-3.2 million

Total Screening Costs	$3.4-5.6 million

volume, physical and chemical properties of the chemical, and existing health and environmental effects data" (U.S., EPA, 1975, p. 8). The breakdown of EPA's estimated costs of testing appears in Table 4.3. (Note that the EPA estimates in Table 4.1 include "current testing," i.e., testing anticipated without TSCA). EPA has arbitrarily assumed that ten percent of the chemicals would require major, chronic effects, testing, in addition to more limited testing.

A breakdown of MCA's testing costs estimates also appears in Table 4.3. Note that screening costs are included in testing costs. MCA observes that costs may be shared between manufacturers of the same substance.

Table 4.3 demonstrates that discrepancies in the testing cost estimates in Table 4.1 are a result of the varying estimates of (1) costs of testing, and (2) the number of chemicals to be tested. As observed by GAO, the cost estimates of EPA and MCA per new chemical test closely coincide. Most of the difference between the total testing costs arises from differing estimates of the number of chemicals requiring testing. EPA's total cost estimate is based on "extensive low-cost reporting and selective testing." As the responsible agency, EPA probably has the most realistic estimate of the manner and extent of regulation.

Table 4.3: Estimated Costs of Testing
(U.S., EPA, 1975, p. 8 and
MCA, 1975, pp. 171-3, 181-3)
(M=million)

	EPA lowest	EPA highest	MCA highest	MCA lowest	
1. Existing Chemicals					
A. ltd. tests[1]					
number	180	180	20	10	
cost/chem	10,000	20,000	63,000	63,000	
subtotal (M)	$1.8	$3.6	$1.3	$0.6	
B. med. tests[2]					
number	---	---	50	30	
cost/chem			306,000	306,000	
subtotal (M)			$15.4	$9.2	
C. high tests[3]					
number	20	20	30	25	
cost/chem	200,000	400,000	815,000	815,000	
subtotal (M)	$4.0	$8.0	$24.5	$20.4	
less testing without TSCA	$1.4	$2.9	$5.0	$5.0	
old chem total (M)	$4.4	$8.7	$36.1	$25.2	
2. New Chemicals and Uses				lowest new use	lowest new chem.
A. ltd tests					
number	135	135	7,500[4]	1,350	1,150
cost/chem	10,000	20,000	17,000	1,700	17,000
subtotal (M)	$1.4	$2.7	$126.4	$2.4	$19.4
B. med tests					
number	---	---	365[6]	45	140
cost/chem			309,000	30,900	309,000
subtotal (M)			$112.5	$1.4	$43.2
C. high tests					
number	15	15	35[6]	5	10
cost/chem	200,000	400,000	816,000	81,600	816,000
subtotal (M)	$3.0	$6.0	$28.6	$0.4	$8.2
less testing without TSCA (M)	$1.5	$2.9	$10.0	$2.0	$8.0
new chem/use tot (M)	$2.9	$5.8	$256.5	$2.2	$62.8
Total testing costs	$7.3	$14.5	$292.6	$90.2	

Table 4.3, cont'd

1) limited tests: subacute animal and short-term environmental

2) medium tests: chronic animal and short-term environmental, or subacute animal and long-term environmental

3) high tests: chronic animal and long-term environmental

4) 1,350 new use, 6,150 new chemical

5) 45 new use, 320 new chemical

6) 5 new use, 30 new chemical

There are significant differences in the estimated costs of testing existing ("old") chemicals. MCA's estimate per chemical is approximately $400,000; EPA estimates a cost of $40,000 per chemical. The GAO review observes that industry, motivated by the already committed investment, would perform more extensive testing of old chemicals in hopes of proving their safety. Thus, MCA's cost per chemical estimate is probably more accurate. GAO combines EPA's number of old chemicals to be tested and MCA's cost of testing per chemical to yield a total old chemical testing cost estimate of $60-65 million (U.S., Senate, 1975(2), p. 98). In a recent case (July, 1979) involving EPA and the National Resources Defense Council (NRDC), an EPA representative estimated chronic testing costs at $800,000-$930,000 -- a range which brackets MCA's 1975 estimate of $815,000.

C. Administrative Costs

Table 4.4 summarizes EPA's administrative costs estimates. These figures are based on the anticipated impact of "a relatively simple two-page Government form" (U.S. EPA, 1975, p. 17). Dow estimates the costs of submitting such a form to be $40 rather than the $100-200 estimated by the EPA (1975, p. 17). EPA does note that control costs may be higher for some firms which find "reorientation (of) internal data collection procedures" necessary.

Table 4.4: Estimated Costs of Administration
(U.S., EPA, 1975, p. 16)

REPORTING REQUIREMENTS (Section 8)

Estimated Costs of Reporting
(M = million)

Annual Reports			
A.	Average No. of Chemicals To Be Reported	1,500-2,000	
B.	Average No. of Reporting Establishments per Chemical	25	
C.	Total No. of Reports (A x B)	37,500-50,000	
D.	Average Cost per Report	$100-200	
E.	Total Annual Cost of Annual Reports (C x D)		$3.8-10M
Record Keeping			
A.	No. of Firms Requiring Major Systems	20-30	
B.	Average Cost of Installing and Operating a Major System for Five Years	$350-450K	
C.	No. of Firms Requiring Medium Systsms	1,000	
D.	Average Cost of Installing and Operating a Medium System for Five Years	$35-55K	
E.	No. of Firms Requiring Minor Systems	10,000	
F.	Average Cost of Installing and Operating a Minor System for Five Years	$10-20K	
G.	Portion of Costs which Would be Incurred without Act	1/2	
H.	Five-Year Incremental Costs of Record Keeping [(A x B) + (C x D)+ (E x F)] x (1-G)	$71-134M	
I.	Annual Costs of Record Keeping (H x 1/5)		$14.2-26.8M
Health and Safety Studies			
A.	No. of Chemicals to be Searched for Inclusion in Bibliography	400-600	
B.	Average No. of Firms Searching each Chemical	25	
C.	Average Cost per Search	$100-250	
D.	No. of Studies to be Submitted	200-300	
E.	Average Cost in Preparing Each Study for Submission	$2,000	
F.	Total Annual Costs [(A x B x C) + (D x E)]		$1.4-4.4M
	Total		$19.4-41.2M

MCA's administrative costs estimates appear in Table 4.5, based on the following identified activities:

> (Maintaining organization) includes internal administration of TSCA compliance, awareness program, interpretation or [sic] regulatory developments, outside counsel and close coordination with EPA...: expenses, 20%; outside consultation, 40%; extra non-testing manpower, 40% (maximum impact scenario). (MCA, 1975, p. 170)

D. Delay Costs

Delay costs, primarily in the form of foregone income, will be substantial for long delays resulting from the need for in-depth testing. The costs will be less significant for the normal 90-day delay from PMN to approval and production during which time normal pre-production activities can continue. However, the PMN delay may be substantial if EPA is allowed to rule PMN's as insufficient and effectively "stop the 90-day clock." The EPA and MCA estimates of delay costs appear in Tables 4.6 & 4.7, respectively. EPA assumes that delays for limited testing may last nine months; major testing delays may approach three years. "Since 90 percent of the affected chemicals will be subjected to limited test requirements, the average delay time is estimated to be one year" (U.D., EPA, 1975, p. 11). The largest differences between the EPA and MCA predictions stem from the estimates of the number of substances to be affected.

Table 4.5: Estimated Costs of Administration
(MCA, 1975, pp. 170, 180)

Administration Low	Scope of Coverage	$ 1975 Unit Cost	$ 1975 Total Cost	Comments
* Maintain organization				
- Major	100 Companies	$100K	$ 10.0 Million	* This includes internal administration of TSCA compliance, awareness program, interpretation or regulatory developments, and close consultation with EPA before undertaking extensive testing and all other phases.
- Medium	1,400	10	14.0	
- Minor	10,000	2	20.0	
			44.0	
* Maintain records				
- Major	100	$ 40K	$ 4.0 Million	* This includes rule imposed record keeping, annual reporting and maintaining of adverse effects data.
- Medium	1,400	10	14.0	
- Minor	1,000	2	2.0	
			20.0	
Total			$ 64.0	
			$300 Million	

Administration High	Scope of Coverage	$ 1975 Unit Cost	$ 1975 Total Cost
* Maintain organization			
- Major	100 Companies	$ 100K	$ 10.0 Million
- Medium	1,400	10	14.0
- Minor	10,000	2	20.0
			44.0
* Maintain records			
- Major	100	$ 40K	$ 4.0 Million
- Medium	1,400	10	14.0
- Minor	10,000	2	20.0
			38.0
Total			$ 82.0 Million
			$600.0 Million

Table 4.6: Estimated Costs of Delay
(U.S., EPA, 1975, p. 10)
(M = million)

Delays due to Testing Requirements

A.	No. of New Chemicals Delayed	150	
B.	Average Delay Time	1 Year	
C.	Average R&D Investment in Each Chemical at Time of Delay	$500K	
D.	Cost of Capital	10-15%	
E.	Total Costs (A x B x C x D)		$7.5-11.3M

Delays due to Industrial Uncertainties as to Governmental Actions

A.	No. of New Chemicals Delayed	200	
B.	Average Delay Time	1/4-1/2 Year	
C.	Average R&D Investment in Each Chemical at Time of Delay	$500K	
D.	Cost of Capital	10-15%	
E.	No. of Significant New Uses	400	
F.	Portion of New Uses Delayed by Industry	1/4	
G.	Average Delay Time	1/4-1/2 Year	
H.	Average R&D Investment in Each New Use at Time of Delay	$50K	
I.	Total Costs [(A x B x C) + (E x F x G x H)] x D		$2.6 - 7.9M
	Total		$10.1 -19.2M

Table 4.7: Estimated Costs of Delay
(MCA, 1975, pp. 174, 184)

VII. Delay high	Number of Substances	$ 1975 R&D Expenditures	Duration of Delay	$ 1975 Interest Cost of Delay @ 10%	Comments
* New substances					
- Time cost of sunk R&D expenditures before testing					
** Low $	4,725	$ 708.9 Million	1/2 years	$ 35.4 Million	* Each new substance is assumed to have $150K average sunk expenditures.
** Medium $	250	37.5	3	11.3	
** High $	25	3.8	4	1.5	
				48.2	
- Time cost of testing expenditure					* Each new application is assumed to have $125K average sunk expenditures.
** Low $	4,725	$ 73.2 Million	1/2 years	$ 3.7 Million	
** Medium $	250	76.3	3	15.2	
** High $	25	20.3	4	5.1	* It is assumed that the time cost of delay of substances which fail toxicity testing are borne by those which pass.
	5,000			24.0	
* New applications					
- Time costs of sunk R&D expenditures before testing					* Apportioning factors for 3 year test costs are 3:2:1 and for 4 years test costs 4:3:2:1
** Low $	1,255	$ 156.9 Million	1/2 years	$ 7.8 Million	
** Medium $	42	5.3	3	1.6	
** High $	3	0.4	4	0.2	
	1,300			9.6	
- Time cost of testing expenditure					
** Low $	1,255	$ 19.5 Million	1/2 years	$ 1.0 Million	
** Medium $	42	12.8	3	2.6	
** High $	3	2.4	4	0.6	
	1,300			4.2	
Total				$ 86.0 Million	

Table 4.7 (continued)

VII. Delay low	Number of Substances	$ 1975 Expenditures	Duration of Delay	$ 1975 Interest Cost of Delay @ 10%	Comments
* New substances					
- Time cost of sunk R&D expenditures before testing					
** Low $	1,150	$ 172.5 Million	1/2 years	$ 8.6 Million	* Each new substance is assumed to have $150K average sunk expenditures.
** Medium $	140	21.0	3	6.3	
** High $	10	1.5	4	0.6	
	1,300			15.5	
- Time cost of testing expenditure					* Each new application is assumed to have $125K average sunk expenditures.
** Low $	1,150	17.8 Million	1/2 years	$ 0.8 Million	
** Medium $	140	42.7	3	8.5	
** High $	10	8.1	4	2.0	* It is assumed that the time cost of delay of substances which fail toxicity testing are borne by those which pass.
	1,300			11.3	
* New Application					
- Time costs of sunk expenditures before testing		This represents 10% of the Scenario 1 costs on Exhibit IV-2, page 2, or $1.4 million.			
** Low $					
** Medium $					
** High $					
- Time cost of testing expenditure					
** Low $					
** Medium $					
** High $					
Total				$ 28.2 Million	

E. Ban or Restriction Costs

Bans and restrictions could result in significant costs to industry. However, considering the wording and intent of TSCA, bans and restrictions will be promulgated only on a sound economic basis, i.e., the benefits of any ban or restriction should offset the costs. However, industry will incur some costs (such as the absence of return to invested capital, loss of revenues, etc.) which may well not be offset by their benefits from regulatory actions.

Table 4.8 contains the EPA estimates of costs resulting from bans and other regulatory restrictions. EPA feels that regulation will be only selectively restrictive. Accordingly, anticipated actions include restriction on certain uses, labelling and quality control requirements, and prohibition of uncontrollable and extremely hazardous new or minor use chemicals (U.S., EPA, 1975, p. 13).

The MCA study does not break down its estimates of ban or restriction costs ("extraordinary" costs): $195 and $165 million per year are anticipated for the low and high cases, respectively.

F. Other Costs

MCA's worst case scenario includes costs of $600 million for "maintenance of innovation." This consists of additional

Table 4.8: Estimated Costs of Bans/Restrictions
(U.S., EPA, 1975, pp. 12-3)
(M = million)

Estimated Costs of Regulatory Actions

Limitations with Significant Impact (Section 6)

A.	No. of New Chemicals Banned	2	
B.	R&D Investment for Each Chemical at Time of Ban	$3M	
C.	Percentage of R&D Investment Recoverable	20%	
D.	Cost of Banning New Chemicals [A x B x (1-C)]		$ 4.8M
E.	No. of Minor Use, Existing Chemicals Banned	1	
F.	No. of Manufacturers Involved with Each Minor-Use Chemical	4	
G.	Investment of Each Manufacturer	$5M	
H.	Percentage of Investment Amortized at Time of Ban	50%	
I.	Percentage of Remaining Investment Recoverable through Recovery of Land, Facilities, & Equipment	25%	
J.	Percentage of Remaining Investment Recoverable through Tax and Other Financial Arrangements	25%	
K.	Costs to Manufacturers of Banning Existing Chemicals E x F x G x [(1-H) - (1-H)(1-I-J)]	$5M	
L.	Costs to Suppliers (.5 x K)	$2.5M	
M.	Costs to Processors (.5 x K)	$2.5M	
N.	Total Costs of Banning Minor Use, Existing Chemicals (K + L + M)		$10 M
O.	No. of Actions Limiting Uses of More Significant Existing Chemicals	1	
P.	No. of Manufacturers Involved in Each Action	8	
Q.	Investment of Each Manufacturer in Each Chemical	$20M	
R.	Percentage of Overall Investment Affected by Each Action	20%	
S.	Percentage of Investment Amortized at Time of Action	50%	
T.	Percentage of Remaining Investment Recoverable through Recovery of Land, Facilities, and Equipment	25%	
U.	Percentage of Remaining Investment Recoverable through Tax and Other Financial Arrangements	25%	
V.	Costs to Manufacturers of Limiting Uses (x P x Q x R x [(1-S) - (1-S)(1-T-U)]	$8M	
W.	Costs to Suppliers (.5 x V)	$4M	
X.	Costs to Processors (.5 x V)	$4M	
Y.	Total Costs of Limiting Uses (V + W + X)		$16 M
Z.	Costs of Limitations on 4 Chemicals (D + M + Y)		$30.8M
AA.	Range of Costs for 3 to 4 Chemicals	$23.1- 30.8M	

Table 4.8 (Continued)

Limitations with Lesser Impact (Section 6)

A.	No. of New Chemicals Banned	2	
B.	R&D Investment for Each Chemical at Time of Ban	$500K	
C.	Percentage of R&D Investment Recoverable	20%	
D.	Cost of Banning New Chemicals [A x B x (1-C)]	$800K	
E.	No. of Actions Limiting Uses of Minor Chemicals	2	
F.	No. of Manufacturers Involved in Each Action	4	
G.	Investment of Each Manufacturer	$2M	
H.	Percentage of Overall Investment Affected by Each Action	20%	
I.	Percentage of Investment Amortized at Time of Action	50%	
J.	Percentage of Remaining Investment Recoverable through Recovery of Land, Facilities, and Equipment	25%	
K.	Percentage of Remaining Investment Recoverable through Tax and Other Financial Arrangements	25%	
L.	Costs to Manufacturers of Limiting Uses E x F x G x H x [(1 - I)(1 - J - K)]	$800K	
M.	Costs to Suppliers (.5 x L)	$400K	
N.	Costs to Processors (.5 x L)	$400K	
O.	Total Costs of Limiting Uses (L + M + N)		$1.6M
P.	No. of Labelling Actions	5	
Q.	No. of Manufacturers Affected by Each Action	10	
R.	Cost for Each Manufacturer	$20K	
S.	Costs of Labelling Actions (M x N x O)		$1M
T.	No. of Quality Control Actions	1	
U.	No. of Manufacturers Affected by Each Action	10	
V.	Costs for Each Manufacturer	$100K	
W.	Costs of Quality Control Actions (T x U x V)		$1M
X.	Costs of 10 Regulatory Actions (D + O + S + W)		$4.4M
Y.	Range of Costs for 10 to 20 Actions		$4.4-8.8M

Imminent Hazard (Section 7)

A.	No. of Existing Chemicals Banned	1 every 3 years	
B.	No. of Manufacturers Affected by Each Action	6	
C.	Investment of Each Manufacturer	$10-20M	
D.	Percentage of Investment Amortized at Time of Ban	50%	
E.	Percentage of Remaining Investment Recoverable through Recovery of Land, Facilities, and Equipment	25%	

Table 4.8 (Continued)

F.	Percentage of Remaining Investment Recoverable through Tax and other Financial Arrangements	25%	
G.	Costs to Manufacturers of Each Ban B x C x [(1 - D) - (1 - D)(1 - E - F)]	$15-30M	
H.	Costs to Suppliers (.5 x G)	$7.5-15M	
I.	Costs to Processors (.5 x G)	$7.5-15M	
J.	Costs of Each Action (G + H + I)	$30-60M	
K.	Costs per Year (1/3 x J)		$10-20M
Total			$37.5-59.6M

funds required to maintain traditional levels of innovation under conditions of increased research and development (R&D) costs; apparently, the estimate also includes funds used "to cover TSCA compliance costs" (MCA, 1975, p. 164). This may be double counting of administrative costs.

According to the GAO review, it seems that firms would reduce, rather than increase, research and development expenses due to a decreased rate of return on such spending. And in fact, the MCA report admits that "...the probable long-term economic impact will be more like the displacement of innovation scenario, rather than the maintenance scenario" (MCA, 1975, p. 217). This displacement may be as great as 33 percent. There is some evidence to show that a decline in innovation occurred in the drug industry as a result of similar 1962 drug laws (Grabowski, 1976, p. 3). If these laws affect innovation, they may bias innovation toward development of safer products. Some funds might be shifted to testing R&D in hopes of decreasing testing costs. GAO feels that these R&D costs are not properly costs of TSCA, since successful testing R&D yields net benefits to industry.

EPA estimates that fees for processing data will average $2,000 per submission. It is assumed that fees will be waived for 100 of 350 "hardship cases." The resulting total estimate is $500,000. Envisioning more extensive regulation, MCA estimates the cost of submission to be $2,500, as shown in Table 4.9.

Table 4.9: Estimated Costs of Fees
(MCA, 1975, pp. 175, 185)

* Fees high	No. of Substances	$1975 Unit Cost	No. Manufacturers Affected	$1975 Total Cost
- Existing substances	100	$ 2.5K	4	$ 0.3 Million
- New substances	5,000	2.5	1	12.5
- New applications	1,300	2.5	1	3.3
				16.1
* Fees low				
- Existing substances	65	$ 2.5K	4	$ 0.2 Million
- New substances	1,200	2.5	1	3.0
- New applications	130	2.5	1	0.3
				3.5

* Fees (not to exceed $2500) are required from those submitting test data under TSCA.

MCA's estimated costs of "close control of manufacturing and marketing" are shown in Table 4.10. "Close control is defined as adulteration analysis, labelling and other controls short of production or use limitations by EPA" (MCA, 1975, p. 175). The EPA study probably includes these costs under bans/restriction costs.

The MCA also estimated costs of litigation, that is "judicial review of EPA actions and civil action brought by third parties," stating that:

> Litigation is assumed to occur in 10% of the cases involving existing substances, and 1% of those involving new substances or applications, reflecting relative sunk investment in each (MCA, 1975, p. 175).

These estimates appear in Table 4.11.

Table 4.10: Estimated Costs of Close Control (MCA, 1975, pp. 175, 185)

VIII. Close Control of Manufacturing and Marketing	Number of Substances	$1975 Cost Per Substance	Number of Manufacturers Affected	$1975 Total Cost	Comments
high					
*Existing major chemicals	30	$ 150K	8	$36 Million	*Close control is defined as adulteration analysis, labeling and other controls short of production or use limitations by EPA.
*Existing minor chemicals	60	50	4	12	
*New substances and applications	50	50	1	2.5	
Total				$50.5 Million	
VIII. Close Control of Manufacturing and Marketing	Number of Substances	$1975 Cost Per Substance	Number of Manufacturers Affected	$1975 Total Cost	
low					
*Existing major chemicals	15	$ 150K	8	$18 Million	
*Existing minor chemicals	30	50	4	6	
*New substances and applications	30	50	1	1.5	
Total				$25.5 Million	

Table 4.11: Estimated Costs of Litigation
(MCA, 1975, pp. 175, 185)

*Litigation	No. of Substances	$1975 Cost per Substances	No. Manufacturers Affected	$1975 Total Cost
high				
- Existing substances	30	$ 50K	4	$1.5Million
- New substances and applications	50	25	1	1.3
				2.8
*Litigation low				
- Existing Substances	15	$ 50K	4	$0.8Million
- New substances and applications	30	25	1	0.8
				1.6

*Litigation is assumed to occur in 10% of the cases involving existing substances, and 1% of those involving new substances or applications, reflecting relative sunk investment in each.

Table 4.12 shows MCA estimates of start-up costs. Proportionally, these organization costs include: "out-of-pocket expenses" (20 percent), outside counsel (40 percent), and personnel additions (40 percent. The large costs of major company record-keeping systems involves establishment of computerized systems.

Both EPA and MCA anticipate other "unquantified potential economic impacts of TSCA." These include diversion of R&D of foreign countries, test marketing abroad before domestic introduction, wasting of patent time during testing and compliance, accidental loss of confidentiality, and reduced chemical development incentives.

G. Benefits

Toxics control may result in benefits to industry. Controls or process changes may increase efficiency or recover valuable "wastes." Substitute production factors (e.g., CO_2 for CFC) may be less expensive. Reduction of occupational exposures should improve worker health and reduce costs of sick leave and disability payments. Most importantly, the pre-market control approach may well avoid the disruption and costs caused by regulation of an existing hazard "...after large commercial investments and the associated labor force are in place" (U.S., EPA, 1975, p. 7).

Table 4.12: Estimated Start-Up Costs
(MCA, 1975, pp. 169, 179)

A. Industry-Side Startup Activities--Second Half of 1976

	Scope of Coverage	$1975 Unit Cost	$1975 Total Cost	Scope of Coverage	$1975 Unit Cost	$1975 Total Cost
Develop organization for TSCA compliance	low	low	low	high	high	high
Major	100 Companies	$ 30K	$ 3.0 Million	100 Companies	$ 30K	$ 3.0 Million
Medium	1,400	20	28.0	1,400	20	28.0
Minor	10,000	1	10.0	10,000	2	20.0
			41.0			51.0
Set-up record-keeping systems						
Major	100	$100	$10.0 Million	100	$ 100K	$10.0 Million
Medium	1,400	10	14.0	1,400	10	14.0
Minor	1,000	1	1.0	10,000	1	10.0
			25.0			34.0
Submit in-progress health and safety studies, and historical						
New substances reports	250 Substances	$ 2K	$ 0.5 Million	1,300 Substances	$ 2K	$ 2.6 Million
Existing substances reports	175	2.5	0.4	750	2.5	1.9
40 yr. bibliography	15,000 Substances and 5 companies each	0.75	11.3	50,000 Substances and 5 companies each	0.5	25.0
			12.2			29.5

The MCA report admits that "adulteration, inspection and reporting provisions could, in turn, have both a preventive and and corrective effect" (p. 223). It is conceivable that TSCA will affect consumer perceptions so as to make chemicals more marketable.

IV. MACROECONOMIC EFFECTS

The MCA analysis is the only one of the three studies considered which estimates macroeconomic effects. MCA concluded that TSCA would result in:

20 - 80,000 fewer jobs
a decrease in GNP of $260 - 1570 million (1972)
an increase in inflation of up to 0.5% (wholesale price index)
a decrease in the trade balance as high as 25% (1972)

Low figures largely represent displacement of innovation; high figures include impacts of maintenance of innovation. Both assume conditions of comprehensive premarket screening.

These costs do not account for ripple effects in related industries or for less quantifiable effects such as company failures and increased industry concentration or other market effects.

MCA cites a 1973 NSF study which perhaps indicates some increased concentration in the pesticide industry resulting from federal pesticides regulation. However, GAO reports that "...the MCA study uses questionable methodology to arrive at the large negative (economic) impacts" (U.S.,

EPA, 1975, p. 1). The trade balance is not expected to be significantly affected because of "the strong international position of U.S. industry" and passage of similar regulations abroad.

Any macroeconomic benefits will be diffused and difficult to determine.

V. EFFECTS ON CONSUMER

Consumers will also incur costs as a result of toxics control under TSCA, although no thorough estimates of their extent have been prepared. These costs may include the delay or loss of benefits from a restricted or banned chemical. Consumers may experience direct costs in the form of higher prices, resulting from regulatory costs passed on by chemical producers, though it is possible that industry will internalize some of its increased costs so as not to decrease demand. The concept of consumer surplus provides one method of analyzing consumer costs of toxics regulation (see EPA, 1977, Petlzman, pp. 21-29).

The consumer benefits of toxics regulation should be substantial, but are particularly difficult to quantify. It is obvious that TSCA will help to protect the public from exposure to harmful substances, especially in an imminent hazard situation.

VI. CONCLUSIONS

Toxics regulation, under TSCA, is designed to consider economic impacts. However, costs estimates are critically dependent on regulations and guidelines of implementation, which are at this time uncertain. Industry, as intended, will bear a major portion of the costs of this legislation: $100-200 million per year. Major costs to industry will be in the form of testing costs, costs resulting from regulatory actions (delays, bans, restrictions), and administrative costs. TSCA may have significant macroeconomic effects as well. Consumers may forego benefits from regulated chemicals and will probably pay higher prices. Benefits to all sectors will be diffuse and difficult to identify.

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Chapter 4

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CHAPTER 5

PROGRAM MANAGEMENT: EPA RELATIONS AND COORDINATION

I. INTRODUCTION

The Office of Toxic Substances (OTS) in the Environmental Protection Agency (EPA) is charged with the implementation of the Toxic Substances Control Act (TSCA). In addition to the internal processes of administering the legislation, OTS must consider many external inputs, coordinating efforts with interested and affected parties outside EPA in accordance with TSCA. The implementation and administration of the Act involves the following relationships and activities:

Intra-agency: Coordination and integration of TSCA into existing EPA programs.

Interagency: The relations of EPA with other regulatory agencies, interagency groups, and data coordination among the agencies.

Intergovernmental: Coordination of State and Federal programs.

Extra-agency:

- Environmental Groups: input from these public interest groups; litigation.

- Industry: interactions between the regulator (EPA) and the regulated -- negotiations, litigation, regulatory actions.

Scientific Community: inputs from the scientific community into the regulatory process.

II. INTRA-AGENCY COORDINATION

To administer the major environmental laws, EPA is divided along media lines, with offices for solid waste, for water, and for air, with each office regulating the chemical pollutants that entered the environment through their respective media. Laws dealing with a particular media provide legal authority for programs within each office.

Toxic substances control, however, cuts across media lines. Consequently, an important problem in implementing the Act is the integration of TSCA with existing EPA programs. As Section 9(b) states:

> "The Administrator shall coordinate actions taken under this Act with actions taken under other Federal laws administered (by EPA)".

The Office of Program Integration and Information (OPII) is one of four Deputy Assistant Administrator (DAA) level offices within OTS. Under the direction of Dr. Marilyn Bracken, this office is responsible for integrating the toxic substances regulatory program into existing EPA programs. OPII has been working to reduce the burden of TSCA, where possible, by matching TSCA requirements with existing programs and by combining TSCA and other EPA functions so as to minimize the duplication of effort. OPII expects, for example, that the chemical monitoring requirements in TSCA can "piggy-back" onto existing monitoring that is done by EPA (Chemical Week, 24 May 1978, p. 32).

Plans are being made to eliminate this office, however, by raising its function to an Associate Assistant Administrator (AAA) level. The AAA would then report directly to the Assistant Administrator for Toxic Substances. This will allow the AAA to have some oversight function over DAA level offices, and thus better coordinate and integrate TSCA programs without having to compete with other DAA level offices.

To assist in this integration of the programs under TSCA the Toxic Substances Priority Committee (TSPC) was created. This internal group within EPA is named by and responsible to the Assistant Administrator for Toxic Substances. It's function is to establish and execute the relationships of TSCA's authorities with other EPA laws, and to integrate EPA's approaches and activities related to toxic substances (EPA, June 1979, p. 75).

One goal of TSCA was to fill regulatory gaps in previous environmental laws; as a result, the scope of the Act is extensive. Because of the cross-cutting approach of TSCA and its broad scope, there are jurisdictional overlaps with the other laws administered by EPA, as well as with laws administered through other federal agencies. Section 9(b) places first responsibility for control on existing legislation, stating that, in coordinating actions taken under TSCA with those taken under laws also administered by

EPA, authority under the other laws should be used unless

> "the Administrator determines, in the Administrator's discretion, that it is in the public interest"

to take action under TSCA.

The regulation of chloroflourocarbons (CFC) by the EPA provides an example of overlapping jurisdictions of TSCA and another law administered by EPA. EPA had the authority to ban CFCs in aerosol uses under both the Clean Air Act (CAA) and under Section 6 of TSCA. To act through CAA would have necessitated having all states with manufacturers of CFCs file changes in their state implementation plans. Because the ban was much easier to administer under TSCA, the authority of the toxics law was used instead (EPA Journal, May 1978, p. 22).

III. INTERAGENCY RELATIONS

Relationships between EPA and other federal departments and agencies have an important impact on toxic chemical regulation. Although EPA is granted an impressive amount of authority under TSCA, it is not the only agency with responsibilities for toxic substances control; a number of federal agencies have been granted authorities for toxics regulation by other legislation.

Twenty-four Federal laws are addressed to chemicals with the potential for human exposure (Selig, 1980). EPA

administers some of the most important laws dealing with these chemicals; in addition to TSCA, the Agency administers the Safe Drinking Water Act (SDWA), Clean Water Act (CWA), Clean Air Act (CAA), Resource Conservation and Recovery Act (RCRA), and the Pesticide Act (FIFRA). Authority to implement the other laws providing the chemical substance regulation is dispersed throughout the Federal Government:

(1) The Food and Drug Administration (FDA), through the Food, Drug, and Cosmetic Act (FDCA), has authority over food, food additives, drugs, and cosmetic items. These substances are excluded from regulation under TSCA.

(2) The Atomic Energy Commission (AEC) regulates nuclear material, also excluded from TSCA, under the provisions of the Atomic Energy Act (AEA).

(3) The Occupational Safety and Health Administration (OSHA) is responsible for maintaining health and safety in the workplace, and can regulate exposure to chemicals in the workplace under the Occupational Safety and Health Act.

(4) The Department of Transportation (DOT) regulates the transport of chemical substances through the Hazardous Materials Transportation Act (HMTA) (Selig, 1980)

(5) The Consumer Product Safety Commission is responsible

for protecting the public from dangerous products in the marketplace, and can regulate chemicals posing a threat to the consumer.

Additionally, some responsibilities under TSCA are granted to other agencies, and cooperation between EPA and these agencies is required by the legislation:

(1) The Council on Environmental Quality (CEQ) is required by Section 25(b) of TSCA to coordinate a feasibility study for establishing a standard chemical classification system and a data storage network.

(2) Section 26(a) authorizes other Federal agencies and departments, upon request of EPA, to make services, personnel, and facilities available to EPA to assist in carrying out the Act, and also to furnish EPA with information, data, estimates, and statistics that EPA needs to administer TSCA.

(3) Section 10(d) calls for cooperation of EPA with HEW in developing monitoring programs at the local, State, and Federal level.

(4) EPA is expected to consult with NIOSH before prescribing epidemiologic studies of employees under Section 4 testing.

(5) EPA is required to consult the Attorney General and the FTC before requiring one manufacturer to reimburse

another for testing done to meet section 4 testing requirements.

Coordination of programs dealing with toxic chemicals in different federal agencies is effected through five major interagency groups discussed below. These groups have been established in accordance with TSCA requirements to provide input and assistance to EPA in administering the Act, and to coordinate EPA activities with the programs, functions, and actions of other agencies.

The Interagency Testing Committee was created by section 4(e) of TSCA. The Committee consists of eight members designated by the Act --one representative each from EPA, the Occupational Safety and Health Administration (OSHA), the Council on Environmental Quality (CEQ), the National Institute for Occupational Safety and Health (NIOSH), the National Institute of Environmental Health Sciences (NIEHS), the National Cancer Institute (NCI), National Science Foundation (NSF), and the Department of Labor. The Food and Drug Administration (FDA), Department of Defense, Department of Interior, and Consumer Product Safety Commission (CPSC) are liaison members.

ITC makes

> "recommendations of chemical substances to the Administrator (in EPA) to be given priority

> consideration for proposing test rules under section 4(a). The committee may at any one time designate up to fifty of its recommendations for special priority consideration by EPA. Within twelve months of that designation EPA must initiate rulemaking to require testing or publish in the Federal Register its reasons for not doing so (Federal Register, 1 June 1979, p. 131868).

The committee presented EPA with the first priority list in October 1977. Four revisions to the priority list have been made by ITC, meeting the requirement of section 4(e) that the list be revised at least every six months (Federal Register, 14 May 1979, p. 28095).

The Interagency Toxic Substances Data Committee (ITSDC) is co-chaired by the EPA and the CEQ. The ITSDC was established jointly by these two agencies to meet requirements under sections 10(b)1 and 25(b) of TSCA, which specify the need for interagency coordination with respect to chemical information collection, dissemination, and classification. The ITSDC has twenty-one members from eighteen federal agencies. The committee interfaces directly with the Office of Program Integration and Information in the Office of Toxic Substances. Its activities include:

- Studying ways to facilitate collection, analysis, and exchange of data among Federal agencies and other groups;

- Working to minimize the burden of reporting on the private sector by coordinating the chemical data and information projects of the Federal agencies;
- Making recommendations about dissemination of data outside of EPA; and
- Carrying out TSSC directives.

(EPA, June 1976, p. 36; Environment Reporter, 17 August 1979, p. 1014).

The Interagency Regulatory Liaison Group (IRLG) was formed in August 1977 by the agreement of EPA, CPSC, FDA, and OSHA. The formal agreement states that the agencies:

> "as the principal regulatory agencies charged with protection of the public and the environment from adverse effects of toxic and hazardous substances, agree to increase ongoing efforts to cooperate as much as possible, to make the most efficient use of resources, achieve consistent policy, and improve protection of public health and the environment..." (Federal Register, 11 October 1977, p. 54856).

The Food Safety and Quality Service, of the Department of Agriculture, joined IRLG in December 1978.

The Interagency Toxic Substances Strategy Committee (TSSC) was established in response to President Carter's environmental message of 23 May 1977. The purpose of the Committee is to advise, consult with, and make recommendations to EPA on policy, technical and procedural matters which are related to the impacts of actions considered

under TSCA. The committee is composed of representatives of eighteen Federal agencies which have research, regulatory, or other control over toxic substances. TSSC activities include:

- Review and assessment of Federal activities relating to planning, management, and analysis of research;
- Data and information gathering and utilization;
- Toxic substances problem identification and prediction; and
- Regulatory and non-regulatory measures for prevention and correction of problems

(Federal Register, 31 January 1977, p. 5746; 4 November 1977, p. 57866; Environment Reporter, 17 August 1979, p. 1014).

The Administrator's Toxic Substances Advisory Committee (ATSAC) was authorized under TSCA and is supported by EPA. Its members come from government, industry, labor, public interest groups, academe, and the public at large. The committee consults with and makes recommendations to EPA on policy, technical and procedural matters related to environmental, economic, social, and legal impacts of actions considered under TSCA. It also comments on proposed rules and regulations and assesses the likely impacts of these (EPA,

June 1979, p. 2).

To minimize the burdens of TSCA and of the regulation of toxic substances as a whole, as well as increasing the effectiveness of such regulations, EPA is expending considerable effort to make regulations under TSCA consistent with the regulations under other laws dealing with chemical substances:

> "...OTE is devoting substantial time in attempting to harmonize its test standards with those under consideration or adopted by EPA's pesticide program, FDA, the Interagency Regulatory Liaison Group, and other nations and international organizations. EPA is committed to adopting consistent standards for both pesticides and toxic substances to the extent permitted by the different laws. This effort is designed to reduce the burden on the regulated public which could arise from conflicting requirements; however, major expenditures of time go into the process of taking into account the needs of the two statutory programs. (Many chemicals are regulated under other statutes in addition to TSCA because of their multiple uses, e.g., as a pesticide and industrial chemical.) In addition to this intra-agency effort, EPA is working with the IRLG to develop testing protocols for human health and environmental effects which would be acceptable to all the member agencies.
>
> EPA is also attempting to harmonize its standards internationally, through participation in a major program of the Organization for Economic Cooperation and Development (OECD). This effort is intended to reduce international trade and regulatory barriers, ensure that the international chemical industry is not unnecessarily hampered by inconsistent requirements, and that data developed in one country are acceptable elsewhere. (Under TSCA, importers are generally treated like domestic manufacturers.) While all these coordination activities are being given high priority by the U. S. agencies and international community, the process is extremely slow because of the time and effort required to take into account the very different

> needs, concerns, and practices of the various agencies and countries (as well as those of the chemical industry)" (U. S. District Court, 11 July 1979, p. 6).

The ban on chlorofluorocarbons as propellants in aerosols provides an example of interagency coordinative efforts to provide consistent regulations of a hazardous substance. Products in aerosol containers are under the regulatory authority of FDA if they are food, drug, or cosmetic products such as hairsprays, deodorants, and food items. The remaining aerosol products -- household cleaners, laundry sprays, pesticides, and some industrial products fall under the jurisdiction of EPA and CPSC. When the potential threat of CFCs to the ozone layer became known, these three agencies worked together to coordinate their regulatory rule-making After several different labeling requirements were made, EPA, FDA, and CPSC, in May 1977, jointly proposed plans to phase out CFCs in non-essential aerosol uses. These joint proposals were promulgated in March 1978 (Federal Register, 13 May 1977; p. 24536; 17 March 1978, p. 11301). FDA acted under the authority of the Food, Drug and Cosmetic Act. EPA's authority came under Section 6 of TSCA. CPSC acted jointly with FDA and EPA, but action on its part was made unnecessary by EPA's action. This was one of the first coordinative efforts of the newly organized IRLG, one of the main purposes of the group being to promote common, consistent,

compatible regulations. As a result of this effort to achieve consistency, the regulations provided for the same requirements for all non-essential CFC aerosol uses, and they were phased out uniformly.

The Interagency Testing Committee has initiated the regulatory process leading to Section 4 testing rules. Using a multi-step screening procedure, substances likely to require testing are determined and presented to EPA for priority consideration. This procedure consisted of the preparation of an initial listing of chemicals which included about 3,650 substances. A master file of 1,700 substances and categories of substances subject to TSCA was created from this. Next, a preliminary list of 330 substances and categories for further consideration was developed from the master file, and published in July, 1977. After consideration of possible hazards, 80 substances and categories were selected for detailed review. Finally, from these, four chemical substances and six categories of substances were selected for inclusion in ITC's initial recommendations to EPA, published in October, 1977 (EPA, January 1978, p. iii, 5).

ITC revised this list in April 1978, adding four chemicals and four categories for which EPA must initiate

testing rules in the following twelve months. One substance and two categories were added when the list was revised in October 1978. Eleven chemicals and one category were added in the ITC report of 1 June 1979. In the latest revision, made in November 1979, two chemicals and three categories were added, bringing the total to 38 chemicals and categories designated for EPA consideration. (Federal Register, 7 December, p. 70664).

The EPA has not come close to meeting the requirement of initiating Section 4(a) testing requirements within twelve months of when ITC designates a chemical on the priority list. The first proposed rule package for testing chemicals on the ITC list was released to EPA's Science Advisory Board in March 1980, and OTS expects these proposed rules to be published in June 1980, although the rules for the first designated list were due in October 1978 (U. S. District Court, 4 March 1980, p. 4, 41).

"Start-up" problems --organizational and staffing problems and the settling of "generic" issues -- have occupied much of the early energy within the Office of Testing and Evaluation (OTE) in OTS, the office charged with implementing Section 4 of TSCA. These problems were initially cited as the main impedant to developing testing rules on time. Dr. Warren Muir, DAA for Testing and Evaluation, stated that he anticipated

that after the precedent-setting work was completed on generic test rules, and the staff was more experienced, the Agency would be able to "routinely propose Section 4(a) rules within twelve months of a chemical's designation by ITC" (U.S. District Court, 11 July 1979, p. 8). But, more recently, Mr. Steven Jellinek, Assistant Administrator for Toxic Substances, has expressed doubt that the twelve-month deadline can regularly be met:

> "To my profound frustration, we did not come close to achieving our goal for any of the chemicals recommended on the first three ITC lists. Simply put, we seriously under-estimated the immense amount of work that goes into developing a new organization, the time that it takes a new office and new employees to gain regulatory expertise, the effort that it takes to review scientific literature and decide whether testing is necessary, and the time needed for resolving issues and developing the documentation to support our decisions...We have evaluated the status of each of the chemicals recommended by the ITC to date. Even though substantial efforts have been expended on most of them, I am forced to conclude on the basis of experience that it is unlikely that we would be able to issue proposed rules for most of them within the next year. Further, our experience indicates that even if this large backlog did not exist, EPA ordinarily will not be able to publish rules within 12 months of future ITC designations." (U. S. District Court, 4 March 1980, p. 5).

It is the statutory responsibility of ITC to decide which chemicals should have priority in EPA's consideration of substances for required testing. In conjunction with the designation of chemicals, ITC makes recommendations to EPA about the kind of testing that may be needed of the chemicals,

and provides EPA with the data these recommendations are based on as well as other information gathered in its review process. But for several different reasons, the input of ITC has not aided EPA, to any extent, in making decisions about the test rules it must issue. Addressing this, Dr. Muir said,

> "While a great deal of time and effort went into the ITC's deliberations and recommendations, much work remains to be done by EPA. Because of its quite different statutory mandate, time constraints, and limited resources, the ITC did not address many of the issues that EPA is required to address, or explore those issues it did consider to the degree that EPA must in order to have scientifically and legally sound test rules. In effect, the ITC's broad survey of thousands of chemicals currently in commerce served the function of attempting to identify those substances most likely to be hazardous and about which least is known. It is EPA's responsibility to do a more refined analysis of the data concerning the smaller number of chemicals singled out by the ITC, to evaluate a broader range of factors than those considered by the ITC and to make regulatory decisions..." (U. S. District Court, 11 July 1979, p. 17).

EPA is required to act upon ITC recommendations, but since ITC is an independent body, EPA has little say or control over the recommendations, and thus the demands upon the Agency, that ITC makes. In making its analysis of the environmental and health effects of suspect chemicals, the ITC does not have to consider the same criteria that EPA must. ITC

> "is not required to take economics into account, to conclude whether an unreasonable risk is present or to decide what form of the chemical should be tested

> and by whom" (U. S. District Court, 11 July 1979, p. 18).

ITC's literature searches have not included some significant information sources. This has necessitated intensive data gathering efforts by EPA. The dossiers of data ITC based its recommendations on were not even available to EPA until four months after the first ITC report and three months after the second. (U. S. District Court, 11 July, 1979, p. 18).

ITC included categories of chemicals in its designated list, covering from four chemicals to 500 different chemical substances. EPA is left to resolve the issue of how to make testing rules that will properly assess the hazards of large groups of chemicals that are structurally similar, but may have quite different effects on the environment or health.

ITC does provide a forum outside of EPA for setting priorities on chemical substances. This helps to assure that EPA remains responsive to external influences. Nevertheless, ITC, in fulfilling its own statutory obligations through its independent role, can place demands upon EPA that, realistically, under the requirements of the Act, are impossible to meet. ITC may have up to fifty chemicals designated for EPA consideration at any one time; yet Mr. Jellinek has recently stated that

> "In view of our other major TSCA responsibilities,

> we have determined that OTE (Office of Testing and Evaluation) can handle only 15-20 ITC chemicals per year that require substantial in-house analysis and decisionmaking" (U.S. District Court, 4 March 1980, p. 43).

In its initial report ITC included an evaluation of the availability of testing facilities for the testing of its recommendations. Based on surveys done by HEW Committee on Coordinate Toxicology Related programs and the Society of Toxicology, and by its own review, ITC concluded that

> "there are sufficient toxicology testing capabilities in the U. S. to carry out the health effects testing recommended by the Committee."

With respect to environmental or ecological testing, however, ITC was not certain of the national capability to conduct long term tests of chemical pollution on the environment. The nation's capability to meet testing requirements would not be known

> "until the test standards and protocols have been defined through the rulemaking process." (EPA, January 1978, p. 15-16.)

The possibility exists, therefore, that sufficient testing facilities do not exist in the United States to do the testing that might be recommended by ITC.

IV. EXTRA-AGENCY COORDINATION

A. Environmental Groups

Environmental public interest groups have contributed

significantly to the development of toxic substances control. These groups provided substantial input into the development of toxics legislation. Lobbying done by the Environmental Defense Fund (EDF), the Natural Resources Defense Council (NRDC), the Sierra Club, the Public Citizen's Health Research Group, and others, was instrumental in preserving the strength of TSCA as it moved through Congress.

Two sections in the Act provide environmental and other groups with powerful inputs into the administration of TSCA:

(1) Section 20 authorizes private citizens to sue companies for violations of the Act and to sue the EPA for failure to carry out mandatory provisions.

(2) Section 21 allows citizens to petition the EPA to initiate proceedings to issue, amend or repeal any of the toxic substances regulations developed through Sections 4, 6, 8, or 5(e) (Congressional Quarterly Almanac, 1976, p. 122).

Environmental groups are well organized to take advantage of these provisions, and through them, to influence EPA in its handling of the Act. Proceedings initiated under Section 21 can provide a forum for review of poorly done regulations. Under Section 20, if EPA is acting slowly in

developing regulations and failing to meet its deadlines -- as has often been the case thus far -- the agency can be forced by civil action in district court to meet the deadlines set by the Act. The impact of such action may be positive or negative. On one hand, a court order may force EPA to fulfill its statutory responsibiliites; in so doing, however, the Agency may act hastily and develop ineffective regulations that will have to be revised later.

Because of EPA's failure to meet the deadlines for setting testing rules for ITC designated chemicals, the Natural Resources Defense Council (NRDC) filed suit against the agency on May 8, 1979, under the provisions of Section 20 of TSCA. According to Edward Shaw, attorney for NRDC, "The EPA Administrator comes close to rendering TSCA totally ineffectual" by failing to develop testing rules on even the first ten substances EPA has acknowledged as priority chemicals. In taking EPA to court, NRDC demanded that EPA undertake actions mandated by Congress, and begin on testing rules and the development of testing standards. The NRDC stated that EPA is overly cautious in its rule-making under TSCA, and expressed its hope that the suit would "get the Agency going on TSCA in general" (Environment Reporter, 18 May 1979, p. 83).

B. EPA-Industry Relations

One of the major issues surrounding TSCA is its impact upon the chemical industry. The Act has been called by some in the industry the "Chemical Industry Control Act" (House, 1975, p. 322) because of the extent of the requirements placed on the industry, and the numbers of chemical producers potentially affected. An estimated 115,000 chemical companies in the U.S. are currently in operation.

A positive, working relationship between EPA and chemical producers would reduce the problems of both. If EPA can initially develop regulations which are acceptable to industry, the job of developing and defending subsequent regulations will be eased. Correspondingly, if industry can be involved in the rule-making process then effective regulations can be developed which minimize the burden placed on industry.

There are several forums available to industry by which to provide input into EPA. The comment period after regulations are proposed allows industry to comment directly to EPA about an Agency proposal. EPA considers and replies to these comments, and incorporates ones of sufficient merit into reproposed or final regulations.

Rules for the initial inventory reporting under Section 8 of TSCA, for example, were proposed three separate times and

subsequently revised after consideration of comments received, and before the final rules were finally promulgated (Federal Register, 23 December 1977, p. 645800). In developing Premanufacture Notification (PMN) requirements, EPA delayed the promulgation of the final regulations because of "the number and nature of comments" (EPA, September 1979).

Comments which EPA receives concerning proposed rules allows for desirable external input, but also slows the rule-making process. For example, interim, rather than final, PMN procedures had to be published when they were due on July 1, 1979; the final regulations were not complete because of the time it took to assess the comments received.

Regardless of industry's input into EPA's rulemaking, the requirements of TSCA will have significant impacts upon the chemical industry. As discussed in previous chapters, the economic costs of reporting, recordkeeping, and testing requirements will make it difficult for many small companies to stay in business. Mr. Monte Throdahl, Senior Vice President of Monsanto, stated, "The little guy is going to get a terrible clobbering. He simply doesn't have the resources." Companies with sales of less than $100 million annually are going to have a very hard time introducing new products (Monte Throdahl, 29 January 1980).

The ultimate effect of TSCA on innovation is impossible to determine. It should be noted that a large number of the new chemicals previously entering the market were merely substitutes for existing products and offered relatively little social value other than the fact that they were "new."

On the positive side, TSCA may be a catalyst to the chemical industry. According to Mr. Throdahl, "This law has the potential of improving profits, of rewarding innovation, of promoting progress." TSCA is, he says, "making us pay stricter attention to what products are likely to survive and under what conditions. The law is forcing us... to find out what the effects of that product are on society." In addition, "TSCA could benefit research in that it could enhance our development and understanding of testing procedures." (Throdahl, 22 November 1977, p. 1-2.)

According to A.S. West, of Rohm and Haas, Co., speaking for the American Institute of Chemical Engineers (AIChE), TSCA will bring about improved process technology, extension of product life cycles, upgraded equipment design and plant layout, and "improvements in safety and environmental integrity of the industry and its products." (West, 1979, p. 26-30.)

V. INTERGOVERNMENTAL RELATIONS: STATE-EPA RELATIONS

Under Section 28 of TSCA, the EPA "may make grants to States for the establishment and operation of programs to prevent or eliminate unreasonable risks within the States to health or the environment which are associated with a chemical substance and with respect to which the Administrator (of EPA) is unable or is not likely to take action..." Such State action has the purpose of complementing EPA authority under TSCA rather than replacing it.

EPA announced in August 1978 the availability of approximately $3 million to fund a limited number of toxic substances control cooperative agreements. (Federal Register, 28 August 1978, p. 38466.) States must furnish at least 25 percent of the fund for these agreements. The first of these grants through TSCA were awarded in 1979 to fund programs in five states; among the grants were those given to:

- The Michigan Department of Natural Resources -- awarded $504,500 to develop the "Critical Materials Program" of toxic substances control (Environment Midwest, May 1979, p. 20);
- The State of Wisconsin -- awarded $202,847 for an environmental epidemilogical study (Environment Midwest, June 1979, p. 22).

State programs are instrumental in handling environmental concerns, although there are fewer state programs for toxic substances management than for water, air, and waste management. "State and local folk," says EPA's Assistant Administrator for Planning, William Drayton Jr., "provide 85 to 90 percent of the environmental control " (Drayton, January 1980). EPA is trying to implement joint planning with States. Under the Intergovernmental Personnel Act, EPA is seeking to arrange for 25 to 30 percent of its regional offices personnel to work for the States. An idea being considered by the EPA Planning Office is to reward states with good environmental programs by loaning them more regional personnel (Drayton, January 1980).

A major coordinative effort between EPA and the states is the State/EPA Agreement (SEA) process. These agreements coordinate State and EPA environmental programs through the ten EPA regional offices. Thirty-two states executed State/EPA Agreements for FY1979. These were almost totally associated with water programs. For FY1980, SEAs were made mandatory, and the scope of the agreements was expanded to include programs under the Clean Water Act, Safe Drinking Water Act, and Resource Conservation and Recovery Act. Many SEAs also include air programs and a few include toxics programs (EPA, October 1979, p. i).

Among the goals set in the first Annual State/EPA Agreement Report is that "future State/EPA Agreement Policy and Guidance must include all EPA media programs -- that is, the programs under the Offices of Enforcement, Air, Noise and Radiation, and Toxic Substances as well as those programs under the Office of Water and Waste Management" (EPA, October 1979, p. ii).

For FY1979, the New York SEA was the most comprehensive of the Agreements. It covered all the program elements in CWA, RCRA, SDWA, and TSCA. The FY1980 California SEA includes an integrated toxics program cross-cutting five media-related categories. Washington and Kansas have also incorporated toxics management and control programs into their SEAs for 1980.

The major successes of the State/EPA Agreements have been:

- Better communication and coordination between State agencies and the respective EPA Regional Office, resulting in more interaction and contact between personnel from separate programs;
- Better communication between State agencies;
- Better resource allocation in the Regional Offices;
- The possibility of a net reduction in paperwork, once the initial preparation of SEAs is completed.

As the State/EPA Agreement process becomes more established many of the difficulties may be worked out. To effectively coordinate toxic substances control into SEAs, though, the Agreements need to be restructured. Overall, the State/EPA Agreements are largely program or process oriented. They must evolve in the direction of program integration if the SEA process is to be a success (EPA, October 1979, p. iii).

VI. SCIENTIFIC COMMUNITY

Input into EPA from the scientific community comes both from within government and from the private sector. Much of the scientific data on chemical substances and their environmental and health effects reaches EPA from the chemical industry through section 5 and section 8 reporting requirements. NIOSH, NIEHS, NCI, and NSF all have scientists studying toxic and hazardous chemical substances. These government organizations provide input through ITC and through development of scientific data that will be readily accessable when the interagency data network is complete.

The Science Advisory Board (SAB) in EPA consists of eighty scientists, representing various disciplines, who serve as consultants to EPA. SAB authority comes from the

Environmental Development and Demonstration Act of 1977. The Board reports directly to the EPA Administrator. SAB scientists review and render opinions on issues considered relevant by the Agency (EPA, June 1979).

VII. CONCLUSIONS

As EPA implements the Toxic Substances Control Act, participation is needed by all those involved or affected by toxic substances regulation. The Office of Toxic Substances in EPA has provided adequate channels for input into this implementation process. Much effort has gone into coordinating toxics programs with other related programs.

An unfortunate result of this effort is that OTS has not been able to meet some of the requirements and deadlines of the Act. Internal problems in developing a new organization are partly to blame, but the large amount of work devoted to coordination and review of inputs of interested parties has also been a factor.

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Chapter 5

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CHAPTER 6

IMPLEMENTATION OF THE TOXIC SUBSTANCES CONTROL ACT: ADMINISTRATIVE ISSUES

I. INTRODUCTION

In 1976, Congress passed the complex Toxic Substances Control Act (TSCA), which,

> establishes a program with the objective of insuring that adequate data are developed with respect to the effects of chemical substances and mixtures on health and the environment and that those chemicals which present an unreasonable risk of injury to health or the environment are regulated to reduce that risk.
>
> (EPA 1980 Budget Publication)

During the Congressional hearings on TSCA, one representative of the chemical industry testifed that passage of such a complex and highly technical act would result in total confusion, both in the regulating government agency and in the regulated chemical industry (U.S., House, 1972). It has now been more than three years since TSCA was enacted, but the implementation of TSCA has neither been met with total confusion nor total success. To analyze the success or failure in the implementation of TSCA is essentially to gauge the degree of success or failure of the Environmental Protection Agency's (EPA's) TSCA program, since that agency is delegated the authority to implement TSCA. This analysis specifically deals with EPA's implementation of TSCA with regard to new

chemicals, as opposed to provisions of TSCA relating to the "existing inventory." However, to ignore the impacts of duties relating to existing chemicals on the new chemical review processes would be fallacious, as the two efforts are intricately interrelated. Therefore, the impact of the existing inventory (Sec. 4) provision will be noted, but in the context of their relation to the implementation efforts with regard to new chemicals (Sec.5). The existing inventory was published in May 1979; therefore, the new chemical provisions of TSCA began 30 days later on July 1, 1979.

This analysis is divided into two sections. The first section examines the organizational structure established by EPA to implement TSCA, to determine whether the capabilities of that structure are consistent with the required actions prescribed under TSCA. Section two focuses on the actual implementation efforts thus far, and attempts to coordinate the fundamental issues from section one with the detailed activities currently underway at EPA.

II. THE ADMINISTRATIVE STRUCTURE OF OPTS

A. Organization

Meeting the requirements of the Toxic Substances Control Act requires an extensive organization. The reporting provisions of TSCA for existing and new chemicals require massive paper shuffling capabilities, both in the regulating agency and in the affected industries. The technical provisions depend upon enormous numbers of scientists to examine the complex scientific issues confronting TSCA's implementation. How these personnel and responsibilities are organized into a functional structural arrangement significantly impacts the efficiency of implementation of the Act.

Because the nature of the Federal Insecticide, Fungicide, Rodenticide Act (FIFRA) and TSCA are similar, EPA has joined the offices charged with these Acts' implementation. The Office of Pesticides and Toxic Substances (OPTS) is headed by an Assistant Administrator (AA) who is the principal advisor to the administrator of EPA; the AA is responsible for the strategies, duties, and actions relating to FIFRA and TSCA. The Office of OPTS is currently (April 1, 1980) subdivided into four sections, with each headed by a Deputy Assistant Administrator (DAA). The Pesticide Program is headed by one DAA, while the responsibilities under TSCA

are organized as follows:

Assistant Administrator

Office of Pesticides Programs: in charge of FIFRA programs.

Office of Chemical Control (OCC): determines and implements regulatory control actions -- new and existing chemicals.

Office of Testing and Evaluation (OTE): prescribes test standards, determines what tests need to be done, and assesses data.

Office of Program Integration and Information (PII): responsible for information gathering and processing, integration with other agencies and programs, international coordination.

The extent of the administrative actions required by TSCA is not the only factor impacting an efficient implementation of the law. Other factors must also be considered:

(1) TSCA differs from most environmental legislation in that it is intended to be a preventative, precautionary piece of legislation. Because of the unique activities to be performed under TSCA, there was no prior legislation that could provide insight into an optional structural arrangement for EPA to conduct its TSCA program. After four years, hindsight can identify some of these structural inefficiencies. A number of deadlines are written

into the law. The framers of the legislation may have viewed these deadlines as forcing actions out of the bureaucracy, but without an extremely efficient structural mechanism, these deadlines may force a quantity of action, but at the expense of quality.

(2) The "least burdensome" provisions of TSCA require extensive economic analyses, and the integration of a multi-disciplinary information, involving administrators, lawyers, economists, and scientists, places additional pressures on the structural framework.

Overall, the alignment of divisions and branches beneath three Deputy Assistant Administrators requires a concerted effort to coordinate the vertical movement under each DAA with the horizontal movements between the different DAA subdivisions. For example, the Assessment Division of OPTS is directed by the Office of Testing and Evaluation, while the Premanufacturing Review Division is directed by the Office of Chemical Control. The responsibilities of these two divisions are directly intertwined, and any lack of coordination or communication between the two could severely constrain implementation efforts.

The scientific expertise of the toxic substances program is located in the Office of Testing and Evaluation (Jellinek affidavit, p. 27). However, current scientific priorities include responsibilities under Section 4 of TSCA (prescribing ITC testing rules), and Section 5 (new chemical reviews). Therefore, any bottleneck resulting from dealys or overloads in this shop may prevent the performance of other activities dependent upon the results from OTE.

Current reorganization efforts within OPTS are aimed at resolving some of these structural inefficiencies that constrain implementation of TSCA. A reorganization proposal dated March, 1980, states that:

> Presently the various steps in the exposure assessment process are performed in *eight different branches*, which are located in *five different Divisions*, which report to *three different Deputy Assistant Administrators*. This arrangement has proven to be *unwieldy and very inefficient*, especially since the various technical steps in the exposure assessment process are by nature, highly interactive.

B. Personnel and Staffing

A common accusation from industry charges that key personnel charged with implementing EPA's TSCA program are inexperienced and in some cases, unqualified to direct a program that impacts private industry with the magnitude of

TSCA. Such a charge may be hard to refute, but alternatives are lacking. TSCA requires new and massive start-up procedures, and the experienced personnel to deal with key issues will be developed over time. The lack of experience in the administrative positions of OPTS has limited an overall effective management system, which is essential to a productive implementation process. Two particular problems have emerged in the start-up activities relating to administrative personnel:

(1) Inexperienced personnel pulled from other EPA programs, other agencies, and outside the government must first become acquainted with the complex requirements of TSCA in order to propose feasible policies. According to Mr. Steven Jellinek, Assistant Administrator of OPTS:

> Finally--and this is a very significant, although more intangible factor--the fact that so many of our employees are new and inexperienced has meant they have tended to underestimate the amount of time and work it takes to analyze and resolve issues and to develop rationales for decisions that allow meaningful public notice and comment.
>
> (Jellinek affidavit, p. 13-14)

(2) The establishment of a new program with new personnel has intensified "turf problems," i.e., the establishment of lines of responsibility and authority within OPTS. The reasons for these problems are essentially

> related to establishing territory in a new program, but personalities and pressures relating to proposed time guidelines also have added to these problems.
>
> (The Law, TSCA, Aidala p. 15)

The major personnel problems in OPTS have not been in the administrative, managerial positions; the real problems lie in the staffing of the scientific offices. The assessment activities of new and existing chemicals require the services of many scientists from the general fields of toxicology, chemistry, and engineering, and even more refined fields, such as teratology and epidemiology. Although the staff in OPTS increased from 72 to 176 persons between October 1978 and March 1980, hiring problems prevented the filling of 54 authorized permanent positions in fiscal year 1979 (Jellinek affidavit, p. 13). A lack of a full complement of scientists to perform the technical duties under TSCA has had a critical impact on the pace of implementation. For example, the Agency employs only one teratologist, who must divide his time between the development of a teratology test standard under Section 4, testing guidance under Section 5, evaluation of the ITC's commendations for teratology testing, the development of OTE policy on teratology under Section 4, and reviews of other chemicals which may cause birth defects (Muir affidavit, p. 9). This reshuffling of personnel among

high priority projects is extremely counter-productive, but there has been no alternative with the present shortage of personnel in these areas. The resulting backlog of work compounds the problems, as substantial ground must be made up before new activities can be initiated.

The Civil Service System of hiring is cited as one hiring constraint as the amount of paperwork and delays involved in the process discourages applicants. The Civil Service System also utilizes a register of qualified personnel for certain positions, but many of the vacancies in OPTS require such refined expertise that the listings in the register will not reflect the true available personnel in these detailed areas. For example, toxicologists are listed under the Civil Service biology register, but recently enough non-toxicologist biologists were listed to fill the register; as a result, few toxicologists were even listed on the register from which EPA must hire (Muir affidavit, p. 10).

The governmental hiring freeze imposed from October 29, 1979, to January 29, 1980, also cost the Agency some recruits who could not afford to wait out the four month-delay (Muir, p. 10).

Competition with industry for the scientific personnel will be another factor hindering EPA's recruiting efforts. Generally, private sector chemical firms can offer more money, better working conditions, and better benefit

packages than offered by EPA. Dr. Warren Muir, Deputy Assistant Administrator of the Office of Testing and Evaluation, recently offered this example of OPTS's ability to compete with the private sector:

> For example, EPA has intensely recruited veterinary pathologists over the last year. After three separate attempts using Civil Service procedures, advertising the opening in professional journals, and sending recruitment letters to approximately 100 veterinary pathologists, no qualified applicants responded.
>
> (Muir, p. 10)

C. Space

> It's amazing to me that something like a lack of space should be the reason we can't move faster.
>
> (U.S., Senate, 1979, p. 8)

While the issue of office space may seem trivial in terms of TSCA's implementation, this problem has been a surprisingly troublesome aspect to EPA in implementing TSCA. While every other environmental law passed in the previous decade required additional staff at EPA, it is doubtful that any approach the rapid increase of personnel in a wide variety of job areas needed to implement TSCA. In 1976, when TSCA was enacted, the Office of Toxic Substances employed 45 people; the estimated total for 1980 is 557. But Mr. Jellinek has remarked that the problem has not been one of hiring personnel,

"But it's been our ability to find space to put them in. We are extremely crowded. In many cases we have people sitting in areas where they have 50, 60, 75 square feet, which is less than half of the G.S.A. allotment. We just can't squeeze them any more." (U.S., Senate, 1979, p. 11).

The EPA did acquire some additional office space in the Washington D.C. area in 1979, but as of April 1980, the problem of overcrowding was ever present in the OPTS offices. An inspection of the Washington EPA offices at 401 M Street, S.W. reveals extensive use of metal partitions to subdivide offices into smaller components. The effect of space problems on morale and general productivity within OPTS may be minimal, but the impact on hiring is significant. Several of the divisions in OPTS could use scientific and engineering personnel who have experience in private industry. These personnel would be extremely valuable to EPA as they could provide perspectives from the private sector from a knowledgeable point of view. However, these personnel, who are likely to be accustomed to a high salary, comfortable offices, and good working conditions, are not likely to be enthralled with the prospects of working in a small partitioned area, for probably less money, and in a city noted for its high cost of living (Smith, 3/28/80).

III. STRATEGICAL CONSIDERATIONS

A. Determining Unreasonable Risk

A standard procedure to avoid ambiguities in the interpretation of a piece of legislation is to include specific definitions for terms used in the Act. In section 3 of TSCA, Congress carefully defines such terms as chemical substance, food, commerce, environment, and a health and safety study. However, several phrases which appear in the law are left undefined by Congress; EPA must determine its regulatory policies from more broad legislative mandates. For example, members of Congress did not choose to define "unreasonable risk" because it is the intention of the Act that EPA should decide on the exact criteria which constitute reasonable or unreasonable risk. But has EPA been able to define "unreasonable risk?" When asked that question by a Senate subcommittee, the agency issued the following response:

> The Agency does not believe that it is possible to have explicit criteria by which the risk associated with environmental or human exposure to a chemical can readily be identified as unreasonable or not unreasonable.
>
> (U.S., Senate, 1979)

Although clouded in bureaucratic legalese, the statement expresses the basic idea that EPA has not defined what

constitutes unreasonable risk; but if that definition occupies such a key position in the implementation of TSCA, why not?

The procedure to define unreasonable risk can be broken down into a three-step framework for analysis. First, the testing and toxicity data about a specific chemical must be established by the scientific community. Second, EPA must establish a reporting mechanism through which toxicity data will be transferred from the chemical manufacturers to the EPA. And last, EPA must decide what level of risk will classify a chemical as acceptable or unacceptable, and how to best regulate the chemicals that exceed the established guidelines.

Examining step one, the important question is whether the scientific methods for the determination of toxicity are consistent and reliable enough for EPA to make a reasonable, rational decision in its evaluative process. The answer at this time is no, as state-of-the-art toxicological procedures do not produce a high level of certainty. Because the health and environmental effects from toxic chemical low-level exposure are usually chronic, identification of a clear-cut threshold level for hazardous effects may be impossible. All testing techniques are fraught with inconsistency, uncertainty, and subjectivity. (Chapter 3 of this report analyzes risk assessment and testing procedures in greater detail.)

The administrative impacts of these issues delay the implementation of TSCA. As an illustration, EPA had until September 80, 1977 to choose ten existing chemicals from the existing inventory of more than 77,000 chemicals for priority testing. These chemicals were to be those believed to present the most serious threats. The list was announced October 12, 1977; by law, EPA had one year from that date to begin testing or to publish reasons for not doing so. However, because of a prolonged controversy over testing standards, EPA had not fulfilled either of its duties as of August 1979, two years after the original group was selected for testing (Washington Monthly, 1979a).

At this time, testing and risk assessment procedures are not sufficiently developed to provide a consistent reliable data base for EPA to base its decisions. Yet EPA must decide, as reflected in the comments made by Mr. Jellinek:

> I think the testing provisions of TSCA are designed to fill the gap in scientific information on the assessment of chemical hazards. There is a lack of information now. It is a serious lack of information... In most cases the data that we have available on chemicals that we feel we have to take some action on, or make decisions on, is not adequate. We may have fragments of information when we really need full information. Yet we are forced by our public responsibility to make a decision on the basis of uncertainty... I think we are really at the frontier of knowledge in taking information from

> experimental animals and predicting human health effects. I might add that a major part of our effort in the Office of Toxic Substances is to push the science of assessment as hard as we can... I would be remiss, though, if I didn't acknowledge that this is not going to happen overnight. It's a process that is going to take years before it begins to bear real fruit.
>
> (U.S., Senate, 1978)

B. Judicial Review

Provisions relating to judicial review have also lengthened the implementation process. If a manufacturer disagrees with an EPA decision to obtain further information, or a decision to regulate the chemical, the manufacturer can take EPA to court to contest their actions. Thus an ironic turn of events has brought the court system back into a decision-making process that was originally created to bypass the courts. A strategy of the New Deal in the 1930's was to create regulatory agencies because the court system was viewed as unsympathetic and inefficient with regard to the interpretation of New Deal legislation. TSCA has reintroduced the court system in an oversight capacity with the authority to rule to prevent any over-zealous regulatory actions (Washington Monthly, 1979b). As one analysis states:

> Where the New Dealers had hoped to replace the inefficient courts with efficient agencies, we now

> have inefficient agencies and inefficient courts struggling (inefficiently) with each other.
>
> (Washington Monthly, 1979b)

An article in Science magazine in January 1979 noted that EPA was currently defending itself against more than seventy legal challenges to its regulations. In the context of the total number of regulatory decisions, seventy may be an insignificant number, but the precedents established in these cases may have far-reaching effects on other decisions by EPA. The possibility also exists that legal challenges could be utilized as delay strategy to stall and obstruct EPA's enforcement of TSCA.

Private industries' utilization of the courts may act as a delay strategy with regard to EPA's implementation efforts, but EPA's efforts to avoid litigation may cause slower action in many phases of TSCA activities. The Office of General Counsel has considerable input into virtually all regulatory decisions, in order to avoid litigation and to insure a sound legal base for the decision should it be contested in court. Some groups have charged that this continual referral to the Agency's lawyers results in delayed implementation and distorted regulatory decisions based on the legal, procedural issues, rather than rational, scientific considerations (U.S., House, 1976, p. 10).

The court, in theory, will not decide evaluative regulatory actions delegated to the EPA by TSCA. The court is to decide if EPA's decision is "arbitrary or capricious," or whether EPA has considered all relevant factors in making its decisions. A widely held opinion is that a federal judge will not have enough understanding of the relevant issues to make a fair determination of an EPA regulatory action. If a second opinion is needed to guard against biased action by EPA, the establishment of a science court has been suggested. No court decision, either legal or science, can free itself from all sympathies or biases, as the information on which EPA's regulatory decisions are based will contain a certain degree of uncertainty.

One consequence of TSCA's judicial review provisions has been the practice of "judge-shopping." For example, suppose a chemical firm in Illinois chooses to take EPA to court over a regulatory decision. That case may not necessarily be heard in an Illinois Court, the case is heard in the court where the complaint is filed, and there are no restrictions on where a case can be filed in the federal court system. The case will be heard in the court where it is filed <u>first</u>. An excellent example can be found in the case relating to an EPA decision to regulate aldrin/dieldrin. The EPA decision left both the Environmental Defense Fund and Shell Oil Company dissatisfied, and the EDF logged an appeal at the District of

Columbia court. The obvious strategy of the chemical industry has been to file for court cases in districts where the judges have proven to be more sympathetic to their interests. Should the EPA lose the decision, the effort to propose and rewrite those provisions can take years, particularly if the new provisions must be passed by Congress (Science, January 1979, p. 32). Two consequences of the legal challenges allowed under TSCA are inefficiency, which hurts all parties, and delays, which are often beneficial to industry.

C. Economic Considerations

With the current economic conditions and the concern that government regulation hinders private sector productivity, economic considerations are playing an increasing role in all phases of TSCA implementation. The law's specific requirements that regulatory actions be "least burdensome" to industry are considered in another section of this report, but other factors also affect the implementation process. The Agency has adopted a so-called "open door" policy in implementing TSCA. Former Director of OPTS Glenn Schweitzer stated, "Before we do anything, we will take a couple of months to consult with everybody." (Business Week, 1976.) The result is endless meetings with environmentalists, industry representatives, and lawyers, whose inputs must be combined with the Agency's in-house analysis of complex judicial and

economic factors to produce final policy decisions. For example, when OPTS proposed health effects standards for testing, EPA received 200 public comments amounting to approximately 4,000 pages, challenging every scientific and legal aspect of the proposal (Jellinek affidavit, p. 24). The costs of these in-depth analyses may actually cost more than the cost of implementing a particular policy decision. The most critical cost to the implementation of TSCA is probably the time lost because of the staff commitment to analysis projects. The consequence of court action over the failure to consider virtually any viable factors has resulted in an extremely cautious flow of movement throughout OPTS. The overlap with other environmental laws and required cross-agency coordination further complicate efforts to produce timely, decisive policy decisions out of OPTS.

IV. THE REGULATION OF NEW CHEMICAL SUBSTANCES

A fundamental purpose of the Toxic Substances Control Act was to fill the gaps in toxics control left by other legislation; TSCA would be able to provide a basis for regulatory action for toxic substances that would not have been possible under existing environmental laws such as the Clean Air or Clean Water Acts. A second function of TSCA was to establish a screening mechanism for new chemicals that were not part of an existing chemical inventory published by EPA in May 1979. Chemical manufacturers wishing to produce a new chemical substance after that date would be required by Section 5 of TSCA to file a pre-manufacturing notification form (PMN), which would include basic testing information about the chemical's potential hazards. This information would then be evaluated by EPA within a 90-day time period to determine if the chemical presents an unreasonable risk of injury to health or the environment. Chemicals found to exceed the unreasonable risk criteria established by EPA would then be subject to a number of alternative regulatory actions, from restrictions requiring labeling to controls of production quantities, use restrictions, or an out-right ban of the substance.

Establishing consistent reliable testing information is plagued by uncertainty. However, for the purposes of this

analysis, suppose consistent reliable information on low-level, long-term toxic effects has been developed by industry, as they hold the burden of proof with regard to the safety of their products. A problem arises with regard to reporting mechanisms: are there sufficient reporting mechanisms in TSCA to encourage full disclosure of testing information to EPA for their evaluation procedures? A loophole in that mechanism can be illustrated by examining the exact phrasing by which EPA is authorized to take action--"If the Administrator finds..." The determination of whether a chemical does present an unreasonable risk relies on an efficient transfer of data from industry to EPA. As a compromise to one of the controversies preventing TSCA's passage for five years, Congress did not give EPA the authority to require testing of all new chemicals coming onto the market. The burden to decide what tests to perform, or even whether to perform any tests, falls upon industry. However, if EPA decides it does not have sufficient information to evaluate a chemical's safety, it can prohibit production of the chemical pending submission of further data. In essence, reporting of information is voluntary if, in the manufacturer's opinion, the chemical is safe and does not merit close scrutiny by EPA, but mandatory if EPA decides the chemical does warrant a close examination of its toxic effects. EPA, then, is left in the tenuous position of publishing guidelines so industry will know what information

EPA is likely to view as adequate, at the same time balancing those guidelines with the non-mandatory provisions to avoid breaking the law. The intricacies involved in this process cause slower movement in EPA in interpreting the law; EPA must choose approaches that will encourage, but not require, full disclosure of information by the chemical industry (Science, Nov. 1979).

Given the ambiguous requirements of the law, what are the incentives for industry to disclose information to EPA about the toxicity of their chemicals? Obviously, the chemical manufacturer would like EPA to make a reasonable decision without the inconveniences of a court injunction or other consequences of non-disclosure. By law, the manufacturer must report all data pertaining to the chemical's toxicity, but EPA has no mechanism to discover hidden or unreported information. If the manufacturer realized that EPA would accept certain minimum requirements, some manufacturers could omit, alter, and report fraudulent data in order to pass EPA's evaluative process. Two emerging issues that may have to be resolved in court illustrate how the reporting requirements have confounded EPA's efforts to comply with the 90-day time constraint for its evaluation of new chemical substances.

First, the question has arisen as to whether a manufacturer must submit all of its own evaluative information about a new chemical, or only basic raw scientific data. For

example, suppose one scientist of a manufacturer has some doubts about the toxicity of a new substance, and he expresses concern by memo to an executive in charge of new chemical production. On the basis of other tests, the other scientists of that manufacturer conclude the substance is safe. The question is whether any or all of the scientist's evaluative conclusions and memos should be submitted to EPA. Some manufacturers have contended these in-house evaluations are not subject to TSCA reporting requirements, as long as all raw data about the chemical is submitted (Selig, 3/25/80). It is conceivable that a manufacturer's scientists could become aware of hazards presented by a new chemical substance which might not be apparent from examining the results of test data by itself.

A second issue currently impeding a timely evaluation procedure results from the 90-day response provision. In practice, a manufacturer can submit a brief, incomplete PMN form, and say to EPA, "Start the 90-day evaluation period." Should valuable time be lost in obtaining further information from the manufacturer, the 90-day clock may expire, allowing production of the chemical by the manufacturer to proceed. EPA does have an available mechanism to require further information from the manufacturer before beginning evaluation procedures. Under Section 5(e), EPA can take a

manufacturer to court to obtain further information and can even obtain an injunction preventing production of the chemical pending submission of required data. However, the 5(e) approach is not an attractive alternative; the process is made much simpler if EPA can decide that the information in the PMN form is insufficient, and refuse to begin the 90-day time period until the required data is submitted. The settlement of this issue will likely be made in court, as the intent of the Law is not clear, and the problem has proven to be a major thorn in the side of EPA's evaluation processes (Selig, 3/25/80; Smith, 3/28/80).

Two additional problems hampering the information reporting mechanism should be resolved in 1980. Before reorganization at OPTS, the Chemical Information Reporting Branch was not a part of the Assessment Division, which caused the inefficient process of:

> one Division trying to determine and justify the information needs of another Division, and, with less than complete understanding, potentially placing unnecessary requirements on industry without fully meeting chemical assessment information needs.
>
> (EPA Reorganization, March 1980)

A second factor hampering consistent interpretation of EPA's policies has been the failure by the Agency to promulgate final rules on the PMN form requirements. Proposed rules were issued January 10, 1979, but the Agency has not decided on a final format as of April 1980. These rules should

be published in 1980, and some of industry's questions about the data submittal process will be resolved at that time.

An article in the Harvard Journal on Legislation summed up the reporting mechanism of TSCA this way:

> Since the data compiled under TSCA will be used for regulatory decision-making, TSCA casts manufacturers and the EPA in adversarial roles. Historically, similarly situated regulatory agencies have become the pawns of the industry they are commissioned to oversee. Even if that result does not obtain, no one expects industry to undertake experiments, testing, and reporting simply to further the statutory intent of Congress. Without an incentive for the full disclosure and discovery of data, industry will routinely and half-heartedly file the appropriate forms as required, but will do little more.
>
> (U.S., Senate, 1978)

At this time, the half-hearted description of industry's efforts to submit test data is an accurate one. The Premanufacturing Review Division has received about seventy PMN forms from January 1 to April 1, 1980, and approximately 50 percent of those have left out important testing information that will be required by the Assessment Division of EPA (Smith, 3/28/80).

The fact that so many questions have arisen with regard to submission of data emphasizes that at least one step in the

five-step pre-manufacture review process envisioned by EPA has not functioned according to expectation. The first stage of the process clearly allows for negotiations between the manufacturer and the EPA to ensure that sufficient testing will be done to avoid the consequences of a 5(e) ruling by EPA. Questions of exemptions, confidentiality, whether the chemical should be considered new or existing, and proper testing data submitted could be resolved in the Prenotice Communication stage if the manufacturer chose to do so. The Prenotice Communication Process depends on the initiative of the manufacturer to communicate with the offices at EPA; if EPA is given no opportunity to respond to these questions before the 90-day evaluation period begins, their efforts will continually be obstructed and the 90-day deadline will become more critical than with a functional Prenotice Communication Process.

Various decision-making frameworks have been suggested as solutions to the problems of risk assessment and the ensuing regulatory decision, but no one technique of analysis can objectively weigh all of the variables EPA must consider in its evaluation processes.

Cost-benefit analysis is limited in its capacity to quantify the social costs and benefits resulting from toxic substances pollution. Cost-effectiveness analysis may provide more useful information, and according to one EPA official, increased economic analyses will be necessary to justify EPA's regulatory decisions to the public, the Congress, and the court system (Smith, 1/28/80).

The current evaluation process utilized by EPA is described in a budgeting publication of OPTS:

> Chemicals of concern identified through review of substantial risk notifications and other sources will be entered into a multi-stage hazard evaluation process, with a decision being made at the end of each stage of evaluation.
>
> (1980 EPA Budgeting Publication)

EPA's 1980 budget estimates that 400 PMN forms will be received during the year; that estimate appears accurate after the first quarter of 1980. With the 90-day time constraint for evaluation and a shortage of personnel on hand to assess new chemical substances, the Agency would be hard pressed to perform detailed assessments at the rate of one per day in fiscal year 1980. However, the initial screening stage of evaluation is designed to weed out low-risk chemicals that do not warrant the thorough evaluation

procedures that will be utilized for certain new chemical substances. As of April 1980, approximately 15 percent of the received PMNs have undergone the detailed review process. Only in the detailed reviews will a chemical be considered for any of the regulatory options provided for by TSCA.

The PMN review process is one of the most recently implemented programs under TSCA. The existing inventory was published in May 1979, and the PMN process was begun July 1, 1979. Therefore, some of the problems besetting the evaluation process may be resolved once the mechanism gets beyond the difficult start-up phase it is facing now. However, the start-up processes have identified areas of potential inefficiency for the Agency to consider.

Two perspectives relating to personnel currently aggravate the timely, efficient assessment of new chemical substances. Although the PMN Division of EPA is currently "on target" in its hiring schedule for fiscal year 1980, the office is operating with 60 percent of the staff that are budgeted for the year (Smith, 3/28/80). Given the overcrowded conditions at EPA and the competitive position with private industry for the chemists and engineers employed by this Division, the hiring problem may become critical, both for fiscal year 1980, and the further expansion planned for 1981.

A second personnel problem relating to the assessment process has been the adjustment in the nature of duties performed by the scientists in the review process. This adjustment has been described as "making a regulatory scientist out of a bench scientist," involving an incorporation of the uncertainties and lack of information in the evaluation process into the scientists regulatory policy recommendation (Aidala, The Law, 1979). A usual response by newly hired scientific personnel faced with a lack of information is to look for additional information. However, regulatory policies at OPTS will be continually plagued by a lack of information, and the scientists' reluctance to make decisions based on incomplete or uncertain information has caused continual underestimates in the time allocated for policy decisions in OPTS.

Organizational structure has also impacted the assessment of new chemical substances, as the review procedures must move within the 90-day period to various branches and divisions in each of the three major subdivisions in OPTS. As discussed earlier in this chapter, the availability of qualified personnel, space problems, and determinations of program priorities in OPTS can make this administrative structure crucial to the 90-day disposition of PMN notices.

Congress established the 90-day time limit for new chemical evaluations to prevent bureaucratic inaction. In

cases where a detailed review process is not required, 90 days has proven to be ample, as the initial screening process usually takes about 30 days. However, for chemicals thought to present higher risks, 90 days may not be enough time to insure a quality evaluation program, given the current state of affairs in OPTS (Smith, 3/28/80). The analysis of alternative regulatory and control options includes not only scientists' recommendations, but feasibility inputs from the Office of General Counsel and the enforcement offices charged with insuring compliance. These offices recommend whether the proposed regulatory response will stand in a court of law, and whether the action can be practically implemented by the chemical industries.

It also has been rumored that the number of PMNs received for evaluation could greatly exceed the magic 400 figure estimated by the Agency. Should that event occur, the time for the Agency to respond with additional personnel and facilities will lag behind the time period when they will first be needed. Ordinarily, the backlog of excess work could be made up once the hiring and staffing caught up to the necessary level. However, with a 90-day time constraint, a sudden surge in the number of PMN forms could result in a process of rubber-stamp approval by OPTS, as they would not have sufficient time to handle an increased volume of evaluations.

V. ISSUES AND CONCLUSIONS

Issue: Organizational Structure

Background: The organization of responsibilities and activities in the administrative framework has been one stumbling block in the way of an efficient TSCA implementation process.

Conclusion: Current reorganization efforts at EPA are aimed at more efficient structuring of duties related to implementing TSCA. Extensive start-up procedures have complicated this process, particularly prioritizing work under Sections 4 and 5 of TSCA. However, the structural arrangement in OPTS is not the most critical problem limiting implementation efforts, and experience combined with the capacity to make structural adjustments should be sufficient to make OPTS a workable bureaucracy.

Issue: Personnel

Background: Staffing, particularly in the "science shop," has proven to be the most pervasive problem hampering smooth implementation of TSCA.

Conclusion: In the past twenty years, rapid development of the space program and of computer applications

has caused shortages in personnel with expertise in specific areas. However, the high salaries and job security benefits spawned the development of educational and training programs in universities and technical schools, and eventually attracted the increased pool of personnel required in those industries. In theory, supply and demand will equilibriate in a similar manner with regard to the specialized science professions needed by the TSCA program.

The formation of the National Toxicology Program in 1978 will yield some beneficial results to the advancement of Toxicology in several areas. The goals of the program are to improve and step up the pace of research, detection, and control activities relating to toxicology. The program will be funded by four agencies -- the National Cancer Institute, the National Institute of Environmental Sciences, the National Institute of Occupational Safety and Health, and the Food and Drug Administration (Science, February 1979).

Issue: Space

Background: The current overcrowded conditions in the Washington D.C. EPA offices greatly affect attempts to hire qualified personnel. These conditions may also affect productivity, as morale and office efficiency are reduced by the poor working conditions.

Conclusion: As stated by Senator Riegle, it is inconceivable why space has been such a continuing problem for the EPA. TSCA was enacted over four years ago, and the number of personnel required for its implementation required little foresight. The Agency has plans to expand further in 1981, yet office space still proves to be a crucial problem. This could be a classic example of bureaucratic confusion between the planning divisions at GSA and the administrators at EPA. As start-up procedures get under way, space might be an expected consideration, but approaching five years from enactment, why space remains to be a problem cannot be explained in this analysis.

Issue: Unreasonable Risk

Background: The continual reliance of TSCA on the undefined term of unreasonable risk has created many problems in interpreting and implementing the law by the EPA.

Conclusion: Some adjustment to the exact working might prove to be helpful, but basically TSCA intended for the EPA to determine at what level of risk a chemical would either be regulated or not regulated. This is the primary function of TSCA, and controversy will continue to surround EPA's evaluative decisions which are necessarily based on a lack of information. From an administrative point of view, to prove a chemical substance presents unreasonable risk may be more difficult than showing the chemical presents a significant risk (Aidala, Problems, 1979), but the detailed wording by itself should not prove to be the reason why TSCA is successful or unsuccessful in controlling toxic substances.

Issue: Judicial Review

Background: The introduction of due process into several provisions of TSCA may cause excessive caution

in policy decisions out of OPTS, and reliance on the federal court system may not be a rational alternative to evaluate the basis for EPA's regulatory decisions.

Conclusion: The minuses of utilizing a federal court system to evaluate policy decisions from EPA greatly outweigh the plusses resulting from a third party opinion. If an alternative opinion is required, either a mediation process or a review board consisting of represented parties could make such a determination. The consequence of court action over EPA's decisions has caused that Agency to rely extensively on its legal counselors to avoid litigation. The excessive analysis and continual consultations with lawyers costs the Agency time and money, and the resulting policies may be based more on a lawyer's point of view of regulation rather than on scientific and economic criteria.

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Chapter 6

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APPENDIX I

ECONOMICS AND POLLUTION

I. INTRODUCTION

Environmental economics has become an important information base for facing the conflicting assertions about the incompatibility of environmental quality with other important social goals. Economics can be viewed as a necessary tool for evaluating the decision-making process in the regulation of pollutants and for measuring the impacts that are reflected in society once a regulatory action is implemented.

Within the context of pollution control, several approaches have emerged. Among the literature concerning this problem, one can distinguish two general approaches: the market system approach and the direct regulation approach (the latter corresponding to TSCA). The objective of this section is to provide some insight into the theoretical background which has motivated these two conflicting approaches and to identify their points of coincidence and other alternatives which have recently appeared in this area. This background will allow in the next section an evaluation of the U.S. approach to toxic substances control: TSCA.

II. MAIN CONCEPTS AND THEORETICAL BACKGROUND

The importance of economics in environmental pollution is supported by most authors:

> The key to understand the problems of practical decision making (regarding environmental pollution) lies in a recognition of the economics of the issue. Economists classify the inputs into the production system according to their availability to producers. Resources that are scarce, or exist in limited quantity relative to demand, are defined as economic goods and can be acquired only by paying a price. Other inputs, such as air and water, are not scarce in that they are provided without charge by nature. This type of resource is defined as a free good. (Duncan, 1973, p. 59.)

However, it is recognized that we are living in a finite world where all resources are limited in quantity. Therefore the problem of how to efficiently manage these resources has arisen.

It is unanimously agreed that the problems we face today arise essentially from "market failures," i.e., the market mechanisms for allocating resources are only partially operative. That is why, when an environmental effect is not automatically taken into account by the price mechanism because it remains "outside," it is called an "external effect."

Classical economic theory states that every economic agent seeks to maximize his (or her) profit by some socially useful activity. In such a situation we can expect a harmony of interest between the producer and the community; this is

reflected in the identity between private cost and social cost. In the case that the producer activity is accompanied by certain disutilities affecting one or more economic agents, a discrepancy arises between the private cost of the activity and the corresponding social cost. The effect which causes this discrepancy is called an "external diseconomy," or negative external effect. Misallocation of resources results from the existence of such effects. The only way to correct the misallocation, and at the same time ensure rational management of resources, is to include the effects in the economic calculation, i.e., internalization of external effects (OECD in U. S., Senate, 1977, p. 253).

As a result of this misallocation of resources it is important to recognize that some pollution is an inevitable byproduct of production and consumption. Also, it should be recognized that pollution presents a cost dilemma for decision-makers and society. When a society pollutes, it experiences costs in the form of property damage and a diminished quality of human health. On the other hand, if pollution is reduced, costs take the form of capital investment in anti-pollution meansures; this diverts resources from "more productive" uses and eventually may retard economic growth (Duncan, 1973, p. 62).

Since many externalities involve degradation of the environment, internalizing external effects implies: (1) ensuring better management of natural resources; and (2) maximizing welfare by optimum cost allocation. There are several methods for internalization of external effects:

(a) One could imagine that the polluting agent and the victim(s) might negotiate in order to fix the best cost allocation between them.

(b) One could also levy a tax on the polluter equal to the value of damage caused and reimburse the victims using the proceeds.

(c) Generally speaking, one can imagine a whole range of instruments which would ensure the internalization of an external effect. Economic theory states that in this case, regardless of the instruments used, the optimum is attained at the point where the gap between social cost and private cost is closed.

The Pareto optimum requires fulfillment of certain assumptions: (a) a state of pure and perfect competition; and (b) a complete knowledge of the "damage function" which enables the discrepancy between private cost and social cost to be exactly offset. Viewed less statically, an environmental policy will

attain the optimum at a point where its marginal social cost and marginal social benefit meet; this assumes a knowledge of the two functions (EOCS in U. S., Senate, 1977, p. 254).

The idea of marginalism has been treated as the most important economic idea in controlling the level of economic activity. The application of this idea is theoretically simple, but the major difficulty lies in determining the costs and benefits of pollution control activities (Ruff in U. S., Senate, 1977, p. 14).

Another concept of a self-regulating economic system is that if pollution affects others, the social cost is not zero; this divergence is the fundamental cause of all pollution (Ruff in U. S., Senate, 1977, p. 14).

In different situations the responsibility for pollution is not clearly identified. However, there are cases where the coincidence between physical and economic responsibility is quite clear (e.g., industrial pollution, air pollution from domestic heating). It should be pointed out that determining the identity of the polluter may be a delicate matter and that in some cases it would be wrong to charge the cost merely to the physical polluters.

Apart from responsibility, one must find out who has the effective economic and technical power to combat pollution.

Action should be taken against the agent who has the most effective power to abate pollution, so that it may lead to a prevention of the disutility, rather than seeking merely to compensate the victims (OECD in U. S., Senate, 1977, p. 256).

If a polluter causes damage, it is logical to make him (or her) pay for it. However, this solution is unsatisfactory and even dangerous for several reasons: (1) restoration of damage is meaningless in the case of serious irreversible effects which do not admit of true compensation; (2) the assessment of damage is beset with well-known difficulties (e.g., ignorance of long-term effects, tracing indirect effects); (3) one usually has to make do with approximating the monetary cost of damage as cost of restoring it; and (4) restoring damage is often economically wasteful -- prevention is better than cure.

Apart from these particular measures, pollution control involves other costs such as the cost of implementing an anti-pollution policy, the cost of research and development in anti-pollution technology, and grants for modernizing out-of-date plants. (The latter problem concerns the eventual impact of the cost of pollution control.)

Depending on the market structure (monopoly, oligopoly, free competition) and on the price elasticity of demand,

the repercussion of the cost on the consumer will be null, partial, or total. To say that the polluter shall be the payer is, in fact, to stipulate that he shall be the first payer, or that he is the stage at which external effects are internalized (OECD in U. S., Senate, 1977, pp. 256-7).

III. ALTERNATIVES FOR POLLUTION CONTROL

In environmental policy several strategies of pollution control are available, each having relative merits with respect to the sector concerned, the objectives, and the efficiency and equity criteria. This section deals first with the direct control alternative which corresponds to TSCA, then describes other approaches. which emerge from economic considerations.

The direct regulation of toxic substances under TSCA operates under a preventive mode of performance. This characteristic could lead to the conclusion that other economic approaches are not useful in this area. However, it is important to mention that other approaches can provide a point of reference to evaluate the effectiveness of TSCA.

The problem of assessing the economic validity of any mechanism of pollution control such as information on total social costs and benefits as well as total private costs and benefits is common to the different approaches.

The macroeconomic and microeconomic impacts of pollution control and abatement have been quantified, but the crucial question of combining these data into a critical perspective has not been resolved.

A. Direct Controls

Direct controls are based on the principle of an absolute obligation to comply with the standards fixed by law at the national, regional, or local level. This means that all polluting activity must comply with regulations directly enforceable by means of legal measures and not through the operation of economic instruments. The standards may concern rates of effluent emission, the average quality of the receptor body, or the characteristics of the finished product (OECD in U. S., Senate, 1977, pp. 258-9). Standards may be designed as either post-market or pre-market controls.

The direct control method, represented by TSCA (pre-market) in the case of toxic substances, is of definite advantage to the environment, since it directly determines the objectives and means without being dependent on the play of economic mechanisms. Direct controls are the surest means of preventing irreversible effects or unacceptable pollution. However, the method has certain drawbacks.

> "It is cumbersome to administer and the arrangements for checking, sanctions, and measuring are expensive.
>
> Economic efficiency is reduced, since no economic mechanism operates to enable the standards to be attained at least cost. (EPA's new "bubble policy" may inject a degree of market freedom into direct controls regulation.)
>
> In addition, direct controls are hardly incentives, since each transactor, is content to do neither more nor less than comply with the regulations, having no incentive to surpass the standard, such as he might have if he were actuated by economic stimuli." (OECD in U. S., Senate, 1977, p.259 ; refer to EPA's controlled trading [offset and banking] policies.)

It should be noted that direct controls are often preferred by government authorities and by industrialists; to the former they are a clearcut concept within an already existing administrative and legal framework; to the latter they open the way to bargaining and compromise regarding the fixing of differentiated waste discharge standards. Furthermore, once

a polluter has complied with the regulations, he has no further charges to pay. Although economists generally prefer pollution taxes, some have specified conditions where regulations are more applicable (Ruff in U. S., Senate, 1977, p. 22).

The question remains: to what extent is regulation the most effective means of controlling toxic substances? Even though regulation does not consider economic mechanisms, the requirements imposed by regulation have economic implications.

B. Market Alternatives

Many argue that in the process of setting standards, the quality of information is still inferior to that provided by a free competitive market. Thus, one increasingly popular policy alternative that could have serious implications for decision-makers in affected industries would be the incorporation of the pollution control problem into the existing price system (Duncan, 1973, p. 66). This is the standard economic approach to the correction of pollution.

In a market-type price system, factors of production move responsively and rapidly to small differences in prices. However, in the case of environmental degradation, the lack of prices for the use of air and water results in market failure. The phenomenon of environmental degradation is

not within the market system (Ruff in U. S., Senate, 1977, p. 18).

Economists argue that the costs of damages imposed on society by pollution are a direct result of the failure of markets to reflect the full costs of production. These damages can be incorporated into the market system by imposing a pollution tax. On the other hand, although taxation plans have possibilities, they usually lack the quality of information necessary to establish precise relationships between actual charges and desired pollution levels and as a result are more negative or punitive than positive.

A commonly proposed market solution suggests selling right to use commonly owned properties, such as public lands, rivers, and air; thereby bringing the costs of resource misuse to producers, and ultimately to consumers. The rights are allowed to fluctuate in value depending upon supply and demand factors. Although the process is somewhat complicated, it is important to note that this market alternative deviates substantially in philosophy and conduct from the legislative approach.

When the acceptable pollution level is determined and the appropriate prices are assigned to the rights to

air and water, these resources become "economic" in character, and the waste of resources becomes a real private cost (Duncan, 1973, p. 66).

The relationship between risk assessment and market considerations is expressed by Doniger in the following words:

> In defining a socially acceptable risk several approaches have emerged, but ...the approach currently in favor among economists and policy analysts focuses on the fact that while people are unwilling to name a dollar sum worth their own death, they apparently are willing to trade economic benefits for increases or decreases in the risk of death for each individual to a large group.
>
> In other words, ...the benefits and costs of risk-bearing must be considered in deciding the amount of risk society should be willing to take.
>
> (1978, p. 518)

-- See Chapter 4 for references.