NOTES

The Toxic Substances Control Act of 1976: An Introductory Background and Analysis

I. INTRODUCTION

Federal legislation dedicated specifically to the regulation of toxic metals and synthetic organic chemicals did not exist prior to January, 1977. Though some degree of control had been exercised in a limited number of instances, it was accomplished only through provisions of statutes[1] directed to other environmental concerns, at a date subsequent to manufacture, distribution and widespread use of the substance, and in many cases, under pressure of public outcry stemming from discovery after the fact of the irreversible and tragic effects of the substance. This absence of specific toxic substances control authority could not be dismissed as insignificant in view of the increasing pervasiveness of such substances in our society.[2] Nor could it be attributed to lack of notice of the potential risks which many of them present given the substantial documenta-

1. *See* note 10 *infra*.

2. Federal agency reports confirm this trend: approximately 3.5 million chemical compounds are presently known to exist, [1976] COUNCIL OF ENVIRONMENTAL QUALITY ANN. REP. 29, with over 250,000 new compounds discovered each year, COUNCIL OF ENVIRONMENTAL QUALITY, TOXIC SUBSTANCES 3 (1971) [hereinafter cited as TOXIC SUBSTANCES]; over 9,000 synthetic organic compounds are now in commercial use, each in excess of 1,000 pounds, and 300 to 500 new chemical compounds are introduced annually into commercial use, *id.*; in 1973, production of the top fifty chemicals alone totalled 410 billion pounds, U.S. ENVIRONMENTAL PROTECTION AGENCY (E.P.A.), ACTIVITIES OF FEDERAL AGENCIES CONCERNING SELECTED HIGH VOLUME CHEMICALS ii (1975); and since 1966, production of synthetic organic chemicals has expanded by 255 percent, [1975] COUNCIL OF ENVIRONMENTAL QUALITY ANN. REP. 23.

tion of health danger.[3] Prompted by such reports, both the 92d and 93d Congresses considered a number of toxic substances proposals, but the members' inability to resolve differences between House and Senate versions prevented final approval of the legislation during either term. Not until the waning days of the 94th Congress were both chambers able to reach agreement, and in October, 1976, the Toxic Substances Control Act[4] was signed into law by the President.

In its final form, the Act is preeminently a compromise, the product of numerous factors and pressures. Intense lobbying through three Congresses by public interest, labor, and industry groups; a belief of legislators in an election year that debate had continued long enough and that action was necessary now; a feeling among manufacturers that no more lenient bill was likely, particularly in view of the seemingly imminent election of a Democratic President who had made the need for environmental protection a campaign issue of importance; the disinclination of the President to veto less than one month prior to election day a bill actively supported by labor unions and public interest groups—these factors and others contributed to passage of the Act in 1976. And, as with most compromises, no one was entirely satisfied. Opponents would have preferred more limited controls, if any at all, but could take satisfaction in the relatively cautious approach of many provisions in comparison to stricter measures which might have been agreed to; supporters were relieved that some comprehensive legislation had after so many years become law, but lamented that the administering agency had not been given a stronger mandate both in terms of regulatory power and monetary authorization. More generally, however, the attitude appeared to be one of pragmatic resignation: that, under the circumstances, the Act as finally approved was the best that could be achieved.

3. Approximately 60 to 90% of all cancer is believed to be environmentally caused, *id.* at 17; 20% of all birth defects are caused by environmental influences, and another 60% of birth defects are believed to stem from a combination of environmental and hereditary factors, CONGRESSIONAL RESEARCH SERVICE, EFFECTS OF CHRONIC EXPOSURE TO LOW-LEVEL POLLUTANTS IN THE ENVIRONMENT 135 (1975); and such commonly used and widely dispersed substances as lead, cadmium, mercury, polychlorinated-biphenyls (PCB's), asbestos, polyvinyl-chloride (PVC), bischloromethyl-ether (BCME), and fluorocarbons have been cited in recent studies as posing significant health dangers of cancer, birth defects, genetic mutations, or other serious diseases, TOXIC SUBSTANCES, *supra* note 2, at 8-14.

4. Pub. L. No. 94-469, 90 Stat. 2003, (*codified at* 15 U.S.C.A. § 2601 *et seq.* (West Supp. 1977)) [hereinafter cited as the Act.]

The discussion which follows is divided into two parts. First, the legislative background of the Act and the development of its major provisions are traced from the Act's origins in 1971 through passage five years later. With regard to the proposals of the 92d and 93d Congresses, the discussion is cursory; as to those of the 94th Congress, its scope is broadened to include recommendations and activities of principal toxic substances lobbying interests during 1975 and 1976 and the influence of the Ford Administration on the legislation. Second, key sections of the Act are analyzed. In several instances, this consists of a summary of a particular provision; in others, some interpretive discussion based on the legislative history is included. It must be emphasized, however, that this analysis is neither a thorough critique of the Act nor a definitive resolution of its interpretive difficulties. It is intended solely as an introduction to issues much debated in the past which may arise again in the course of future litigation.

II. BACKGROUND

A. *Council on Environmental Quality (CEQ) Report on Toxic Substances*

When the CEQ was established in early 1970 with Russell Train as its chairman, one of the first projects undertaken was the development of effective legislation to deal generally—rather than on a case-by-case basis—with the problem of toxic substances.[5] Though the need for new controls seemed probable, the scope of the problem, the lack of a central source of knowledge to deal with questions raised, and great uncertainties about toxic substances generally required that a study be conducted prior to formulation of legislative proposals. In April, 1971, the results of that study were published in a report entitled "Toxic Substances."[6] This report—which became the primary impetus for the original Toxic Substances Control Act legislation introduced in the 92d Congress[7] —contained four basic findings: first, that production and use of potentially toxic metals and synthetic organic compounds—such as

5. *Hearings on S. 776 Before the Subcomm. on the Environment of the Senate Comm. on Commerce*, 94th Cong., 1st Sess. 202 (1975) [hereinafter cited as S. HEAR., 94TH CONG.].

6. TOXIC SUBSTANCES, *supra* note 2.

7. S. REP. NO. 94-698, 94th Cong., 2d Sess. 3 (1976) [hereinafter cited as S. REP., 94TH CONG.].

dyes, plastics and rubber products—were widespread and rapidly increasing in this country;[8] second, that data indicated the potential or actual danger of many of them;[9] third, that existing authorities were inadequate to assure their control;[10] and fourth, that comprehensive new legal authority was essential for the testing and regulation of such substances.[11] Concluding that "we need no

8. "These substances enter man's environment—and man himself—through complex and inter-related pathways. Present in air, water, soil, consumer products, and food, they pervade our environment. . . . Increasingly, all forms of life are being exposed to potentially toxic substances." *Id.* at iv.

9. The Council noted that the environmental effects of most chemical substances were not well understood—particularly the long-term effects. However, it cited numerous substances known or strongly believed to pose health risks and stated:

> Many serious effects, including those resulting in cancer (carcinogenicity), genetic mutations which cause permanent and transmissable change in the genes of offspring from those of the parent (mutagenicity), and production of physical or biochemical defects in an offspring (teratogenicity) can occur from metals, their compounds, and synthetic organic compounds.

Id.

10. The Council surveyed the major regulatory statutes applicable to toxic substances and concluded that only a small portion of the total number of potentially hazardous substances could adequately be controlled under the limited foci of existing authorities. Statutes directed toward control of manufacture and distribution—the Federal Insecticide, Fungicide, and Rodenticide Act (F.I.F.R.A.), 7 U.S.C. § 136 *et seq.* (Supp. V 1975), and the Federal Food, Drug, and Cosmetic Act (F.F.D.C.A.), 21 U.S.C. § 301 *et seq.* (1970)—though potentially effective, could be applied only to a limited range of substances. Acts regulating the interstate transport of hazardous substances—the Department of Transportation Act, 49 U.S.C. § 1651 *et seq.* (1970), the Transportation of Explosives Act, 18 U.S.C. §§ 831-36 (1970), and the Hazardous Cargo Act, 46 U.S.C. § 170 (1970)—were directed primarily against hazards involved in the transportation and accidental spillage of chemicals. Similarly, emission and effluent control authorities—the Clean Air Act (C.A.A.), 42 U.S.C. §§ 1857-571 (1970), *as amended* (Supp. IV 1974), and the Federal Water Pollution Control Act (F.W.P.C.A.), 33 U.S.C. § 1151 *et seq.* (1970), *as amended in 1972*, 33 U.S.C. §§ 1251-1376 (Supp. III 1973)—which enable the regulation of pollutants introduced in relatively large quantities directly into the environment, were limited in their effective application against minute quantities of dangerous substances which are found not only in air and water, but in soil, food, and industrial and consumer products as well. More importantly, though, the Council emphasized that such authorities were untimely: "The obvious limitation of controls over effluents is that they generally deal with a problem only *after* it is manifest. They do not provide for obtaining information on potential pollutants before widespread damage has occurred." *Id.* at 20. *See generally id.* at iv, v, 15-20.

For a list of 27 existing statutes compiled by Dow Chemical Co. in support of its contention that no further toxic substances legislation was necessary, *see Hearings on H.R. 7229, H.R. 7548, and H.R. 7664 Before the Subcomm. on Consumer Protection and Finance of the House Comm. on Interstate and Foreign Commerce*, 94th Cong., 1st Sess. 325-326 (1975) [hereinafter cited as H.R. HEAR., 94TH CONG.].

11. TOXIC SUBSTANCES, *supra* note 2, at v-vi.

longer remain in a purely reactive posture with respect to chemical hazards,"[12] the Council recommended immediate adoption of legislation designed to restrict or prohibit use or distribution of a chemical before its hazardous effects could be realized.[13]

In accord with CEQ's recommendation, President Nixon, in his environmental message to Congress on February 2, 1971,[14] called for legislation to establish a federal regulatory system to protect the public and the environment from potentially hazardous chemicals. Specifically, the President proposed:

> [T]hat the Administrator of EPA be empowered to restrict the use or distribution of any substance which he finds is a hazard to human health or the environment;
>
> . . . that the Administrator be authorized to stop the sale or use of any substance that violates the provisions of the legislation and to seek immediate injunctive relief when use or distribution of a substance presents an imminent hazard to health or the environment;
>
> . . . that the Administrator be authorized to prescribe minimum standard tests to be performed on substances.[15]

12. The Council continued:

> We need no longer be limited to repairing the damage after it has been done; nor should we allow the general population to be used as a laboratory for discovering adverse health effects. There is no longer any valid reason for continued failure to develop and exercise reasonable controls over toxic substances in the environment.

Id. at 21.

13. *Id.* at 21-22.

14. The President proposed the Toxic Substances Control Act of 1971 prior to publication of the CEQ study on which it was based because writing of the study was not concluded until after his legislative proposals had been formulated. The Council's findings, however, were substantially complete by December, 1970. *Id.* at preface.

15. 7 WEEKLY COMP. OF PRES. DOC. 194 (Feb. 15, 1971). In addition to these regulatory, imminent hazard, and testing authorities, other notable provisions proposed by the Administration included authority for the Administrator to conduct necessary research and monitorings, execute reasonable inspections of industry facilities based on judicially issued warrants, develop an information system and prediction capability, and require submission of information by chemical manufacturers and processors concerning the name, composition, production level, uses, and test results of any substance produced by them; civil and criminal penalties for violation of the Act; exemption from all requirements of the Act for substances produced solely for export and for pesticides, food, drugs, cosmetics, and other substances and articles regulated under existing federal statutes; and broad preemption of state authority to test or regulate substance subject to such a rule under the federal Act, unless the state regulation is a total ban of a particular use or uses. *See* TOXIC SUBSTANCES, *supra* note 2, at vi and S. 1478, 92d Cong., 1st Sess. (1971).

One week later, a bill incorporating these authorities and entitled the Toxic Substances Control Act of 1971 was transmitted by EPA Administrator William Ruckleshaus through Executive Message to the President of the Senate and the Speaker of the House of Representatives.[16]

B. *Congressional Action*

Both chambers approved versions of toxic substances legislation during the 92d Congress,[17] but only after significant changes were made in the President's proposals. Most important of these—and the provision which became the major stumbling block to House and Senate accord on the legislation during the succeeding five years—was the inclusion of EPA authority to screen new chemicals prior to marketing. The Senate provision, adopted in lieu of a proposal for pre-market certification of new chemicals,[18] required manufacturers to submit test results on all new chemical substances produced by them—except those exempted by the Administrator—at least 90 days prior to commercial production, and authorized the Administrator, where warranted by the test data or lack of them, to restrict the use or distribution of a substance at the end of the 90 day period, pending the outcome of administrative proceedings on the restriction. The House bill contained a pre-market screening provision substantially less universal in application, lim-

16. H.R. REP. NO. 92-1477, 92d Cong., 2d Sess. 21 (1972) [hereinafter cited as H.R. REP., 92D CONG.].

17. Principal toxic substances legislation of the 92d Congress included: S. 1478—introduced on Apr. 1, 1971 by Senators Hart (D. Mich.), Magnuson (D. Wash.), and Tunney (D. Cal.), by request of the Nixon administration; *Hearings on S. 1478 Before the Subcomm. on the Environment of the Senate Comm. on Commerce*, 92d Cong., 2d Sess. (1972); reported by the Commerce Committee on May 5, 1972, together with S. Rep. No. 92-783, 92d Cong., 2d Sess. (1972); Senate debate, amendments, and passage on May 30, 1972, 118 CONG. REC. 19156-74 (1972); Senate reconsideration of House amendments on Oct. 14, 1972, 118 CONG. REC. 36252-61 (1972); H.R. 5276—introduced on Mar. 1, 1971 by Reps. Staggers (D. W. Va.) and Springer (R. Ill.), by request of the Nixon administration; *Hearings on H.R. 5276 and H.R. 10840 (and identical bills) Before the Subcomm. on Commerce and Finance of the House Comm. on Interstate and Foreign Commerce*, 92d Cong., 2d Sess. (1972); reported as S. 1478 on Sept. 28, 1972, together with H.R. REP., 92D CONG., *supra* note 16; House debate, amendments, and passage on Oct. 13, 1972, 118 CONG. REC. 36054-65 (1972).

18. Senator Spong (D. Va.) introduced an amendment which provided for mandatory pre-market certification by EPA of compliance with testing requirements as to all new chemical substances. *See* Amend. No. 338 to S. 1478, 92d Cong., 2d Sess. (1972). The amendment was rejected by the committee.

ited to substances designated in advance by the Administrator as likely to pose substantial danger to health or the environment.[19] Because the House did not approve its version of the legislation until the final week of the session, adjournment prevented both appointment of a conference committee to resolve this and other differences and reconsideration of the legislation by both chambers. Consequently, Congress failed to complete action on the legislation during the 92d Congress.

The innovation necessary to bridge the gap existing at the end of the previous session did not emerge during the 93d Congress,[20] as the bills introduced in both the House and Senate were essentially recycled versions of proposals of the 92d Congress.[21] To insure that

19. Other notable additions to House and Senate legislation were an extension of the Administrator's regulatory authority to existing chemical substances; inclusion of authority for citizen civil actions against alleged violators of the Act; and, in the House version only, a nullification of the Administrator's authority to regulate a substance where an unreasonable risk posed by that substance could be prevented or sufficiently reduced by actions taken under existing federal statutes. During the 92d and succeeding Congresses, this provision describing the relationship of the act to existing federal laws remained a major point of controversy between Senate and House sponsors.

20. Principal toxic substances legislation of the 93d Congress included: S. 426—introduced on Jan. 18, 1973 by Senators Byrd (D. W. Va.), Magnuson, Hart and Tunney; *Hearings on S. 426, S. 888, and Amends. 1, 8 and 9 Before the Subcomm. on the Environment of the Senate Comm. on Commerce*, 93d Cong., 1st Sess. (1973); reported by the Commerce Committee on June 26, 1973, together with S. REP. NO. 93-254, 93d Cong., 1st Sess. (1973); Senate debate, amendments and passage on July 18, 1973, 119 CONG. REC. 24485-501 (1973); H.R. 5356—introduced on Mar. 7, 1973 by Reps. Moss (D. Cal.), Stuckey (D. Ga.), Eckhardt (D. Tex.) and Helstoski (D. N.J.); *Hearings on H.R. 5087, H.R. 5356 and H.R. 1014 Before the Subcomm. on Commerce and Finance of the House Comm. on Interstate and Foreign Commerce*, 93d Cong., 1st Sess. (1973); reported from committee on June 29, 1973, together with H.R. REP. NO. 93-360, 93d Cong., 1st Sess. (1973); House debate, amendments and passage on July 23, 1973, 119 CONG. REC. 25431-76 (1973).

S. 888 and H.R. 5087 were introduced by request of the Nixon administration and differed only slightly from the administration proposal of the 92d Congress.

21. Aside from drafting refinements, important changes were few. However, a number of amendments were offered in committee or on the floor of either chamber to slow the regulatory mechanisms of the Act and reduce its burden on the chemical industry. For example, the pre-market screening section of S. 426 was expanded to include exemption and reimbursement provisions for industry in certain circumstances, and the Administrator was authorized to reduce the period during which production was barred where, in his judgment, a substance posed no unreasonable threat to health or the environment. Similarly, H.R. 5356 contained a comparable reimbursement provision, an exemption for small businesses from many of the Act's reporting and recordkeeping requirements, and a provision directing the Administrator to prepare a detailed economic impact statement at the time he promulgates a final rule.

toxic substances legislation would not again be doomed by adjournment, both houses acted quickly and a conference committee was appointed in July, 1973, to work out differences between House and Senate approved versions. However, months of effort by the committee proved unavailing: Senate conferees refused to compromise on the issues of pre-market screening and discretion of the Administrator to utilize the regulatory authorities of the proposed legislation in preference to existing statutes; similarly, the House conferees—under heavy pressure from industry lobbies—would not acquiesce to the Senate language. When the 93d Congress adjourned more than one year after the committee was formed, no accord had been reached.

No fewer than nine toxic substances bills were introduced during the 94th Congress in an effort to create a compromise that would break the deadlock of the previous four years and clear the way for final approval of the Act. The first of these—S. 776—was introduced on February 20, 1975, by Senator Tunney (D. Cal.), for himself and Senators Magnuson (D. Wash.) and Hart (D. Mich.). Though generally similar in content to Senate passed legislation of previous sessions, the bill broadened the Administrator's authority and foreshadowed the increasing complexity that would characterize much of the 94th Congress toxic substances legislation.[22] After subcommittee hearings in early spring,[23] a staff working draft was released in June and was received with strong criticism by some members of the chemical industry who feared what they considered to be the potentially prohibitive cost of the bill.[24] This

22. Most notable of the changes were these: pre-market screening requirements, previously applicable only to new chemical substances, were extended to include "significant new uses" of existing substances; the reporting section was strengthened by requiring industry to submit all health and safety studies to EPA and to maintain records of adverse reactions to human health or the environment alleged to have resulted from exposure to a chemical substance; the Administrator was empowered to authorize reasonable inspections of industry facilities, a power which previously had been conditioned on a judicially issued warrant; the Administrator's authority to disclose information submitted under the Act was broadened by a provision requiring only his determination that disclosure is "necessary to protect health or the environment"; the determination whether a risk can be sufficiently reduced by actions taken under existing federal laws became discretionary, thereby increasing the Administrator's freedom to utilize this Act; and an employee protection section was added to prevent retaliatory discharge of workers based on actions taken to carry out the purposes of the Act. S. 776, 94th Cong., 1st Sess. (1975).

23. S. HEAR., 94TH CONG., *supra* note 5, at pts. 1 and 2.

24. *See* notes 63-65 and accompanying text *infra*.

fear—also shared by some members of the subcommittee—and memories of past unwillingness of the House to support similarly stringent Senate measures contributed to a decision by its sponsors, after one day of additional hearings on the cost issue in October, to postpone further action on S. 776.

In the House, three toxic substances bills were introduced in early 1975: H.R. 7229, by Rep. Eckhardt (D. Tex.), on May 21; H.R. 7548, by Rep. Brodhead (D. Mich.), on June 3; and H.R. 7664, by Rep. McCollister (R. Neb.), on June 5. These proposals embodied a wide range of viewpoints respecting the appropriate level of toxic substances regulation—as described by Rep. Van Deerlin (D. Cal.), chairman of the subcommittee to which they were referred for hearings,[25] they represented a range of "two to ten on the Richter scale."[26] Rep. McCollister's H.R. 7664 deferred in large part to the viewpoint of the chemical industry and most resembled the generally unrestrictive House legislation of preceding Congresses; Rep. Eckhardt's H.R. 7229 struck a middle ground between House and Senate bills approved in 1972 and 1973, though it retained a limited pre-market screening provision similar to those previously adopted by the House and rejected by the Senate; and Rep. Brodhead's H.R. 7548 most nearly approximated the degree of stringency considered necessary by environmental lobbies.[27]

In an effort to resolve the vast differences between these three versions of the Act and to alleviate the paramount concern of industry over potential scope, scale, and cost of the testing and screening programs, Rep. Eckhardt introduced a fourth bill—H.R. 10318—on October 22, for himself and Rep. Van Deerlin. The critical elements of this compromise were the inclusion of universal pre-market screening of all new chemical substances and significant new uses of existing chemical substances, and the explicit exclusion of chemical mixtures from the statutory definition of chemical substance. Thus, the regulatory powers of the Administrator were augmented to a level similar to that contained in Senate approved legislation, but the number of chemicals subject to those powers and the economic burden on the chemical industry were limited by

25. H.R. HEAR., 94TH CONG., *supra* note 10.

26. [1975] 6 ENVIR. REP. (BNA) 480.

27. For a comparison of major provisions of these bills, see notes 124 and 144 *infra*.

the inapplicability of the pre-market screening provisions to mixtures and by the inclusion of partial exemptions for mixtures in the testing and reporting sections. With these and other innovative provisions,[28] H.R. 10318 was approved by the subcommittee in early December after minor amendment, and was reintroduced in the House on January 28, 1976, as H.R. 11576 in order to accommodate fourteen other members who wished to be included, along with the three original sponsors, as co-sponsors of the legislation.[29]

These developments seemed to indicate a growing consensus in the House in support of a single draft of the Act, but agreement was still far from unanimous. On March 4, Rep. McCollister, for himself and Rep. Broyhill (R. NC) and at the request of the Ford Administration, introduced H.R. 12336—an amended version of his previously offered H.R. 7664—"in the spirit of compromise" and in an attempt to "strike a balance between the ill-conceived approach of H.R. 10318 and the more careful and selective approach of H.R. 7664."[30] Though H.R. 12336 did indeed have the outward appearance of compromise, containing as it did a mix of provisions drawn from earlier bills, the primary reliance by its drafters on H.R. 7664 and H.R. 7229 gave McCollister's proposal a conservative, industry-oriented character.[31] The bill was referred to the House Interstate

28. Another obvious compromise was the bifurcation of the much disputed section concerning the relationship of the Act to existing federal laws: where a risk could be sufficiently reduced pursuant to an existing law not administered by the Administrator, the Administrator was required to notify the other agency and defer to its jurisdiction; where the risk could be dealt with under existing laws administered in whole or in part by the Administrator, those laws were to be utilized unless the risk could be "more appropriately protected against" under the Toxic Substances Control Act. In addition to inspection and reporting provisions similar to those of S. 776, H.R. 10318 created authority for citizen petitions to the Administrator for issuance of a rule and established a seven-member inter-agency advisory committee to compile a priority listing for testing chemicals and mixtures. If the Administrator initiated no rulemaking with respect to a substance within twelve months after inclusion on the list, he was required to publish in the *Federal Register* his reasons for inaction.

29. In addition to Reps. Eckhardt, Van Deerlin (D. Cal.), and Brodhead (D. Mich.), H.R. 11576 was co-sponsored by Reps. Metcalfe (D. Ill.), Scheuer (D. N.Y.), Ottinger (D. N.Y.), Edgar (D. Pa.), Edwards (D. Cal.), Eilberg (D. Pa.), Harrington (D. Mass.), Hechler (D. W. Va.), Holtzman (D. N.Y.), Koch (D. N.Y.), Nix (D. Pa.), Richmond (D. N.Y.), Studds (D. Mass.), and Zefferetti (D. N.Y.).

30. 122 CONG. REC. E1070-71 (daily ed. Mar. 4, 1976).

31. Aside from increased reporting requirements for large manufacturers and a provision similar to that in H.R. 10318 concerning the relationship of the Act to existing laws, the substance of H.R. 7664 remained largely intact: the Administrator was given discretion whether to require testing of substances found to be potentially hazardous; pre-market screening was included only in limited form; rules regulating

and Foreign Commerce Committee, where a compromise between H.R. 11576[32] and H.R. 12336 was not achieved until June.

In contrast to the numerous House versions, S. 776 remained throughout the first session the only toxic substances bill before the Senate. By February, 1976, however, members of the Senate Commerce Subcommittee on the Environment still had not resolved their doubts about the potential costs of S. 776 and the likelihood of its approval by both chambers and the executive branch. Therefore, in executive session meetings of the Commerce Committee on February 3, 4, and 17, Senator Hartke (D. Ind.) proposed and urged adoption of a substituted text derived substantially from H.R. 11576.[33] After several days of markup and some further amendment directed primarily toward increased public disclosure of the reasons for administrative action or inaction under the Act, the substitute—S. 3149—was accepted. One month later, on March 16, it was reported out of committee and introduced in the Senate[34] by Senator Tunney, for himself and Senator Hartke.[35] As reported, the bill conformed closely to the substance and the language of H.R. 11576. In comparison to the myriad differences existing between S. 776 and earlier House bills, the characteristics of S. 3149 which materially distinguished it from H.R. 11576 were relatively few.[36] On March 26, without significant amendment of

substances could not be made immediately effective by the Administrator except through court action under the imminent hazard authority; inspections were conditioned on judicially issued warrants; no citizen civil action or petition authority was included; and the bulk of reporting and recordkeeping requirements was made inapplicable to small businesses.

32. The bill number H.R. 11576 will be used here in the interest of clarity to designate the version of H.R. 10318 approved by the House subcommittee. However, even after H.R. 10318 was amended and reintroduced as H.R. 11576, it was generally known by its original number.

33. *See* note 29 and accompanying text *supra*.

34. S. REP., 94TH CONG., *supra* note 7.

35. On Mar. 17, 1976, additional co-sponsors were added: Senators Magnuson, Pearson (R. Kan.), Durkin (D. N.H.), Hart, Moss (D. Utah), Stevens (R. Ala.), Stevenson (D. Ill.), and Weicker (R. Conn.).

36. The major difference was the requirement in S. 3149 that the Administrator publicly account for his failure to initiate authorized actions. For example, the Administrator was required prior to expiration of the 90 day notice period to publish in the *Federal Register* his reasons for failure to take action against a new chemical substance after notification of its intended production. Where test data indicated the potential of a substance to induce cancer, gene mutations, or birth defects in humans, the Administrator was required—not merely authorized—to take "appropriate" regulatory action or publish in the *Federal Register* his reasons for determining that no unreasonable risk is presented.

its major provisions, the bill was overwhelmingly approved in the Senate by a vote of 60 to 13.[37]

Not until May, 1976, did the House committee reach a preliminary accommodation between the majority and minority forces on a draft of the House bill. On May 26, Rep. Eckhardt introduced H.R. 14032[38] as legislation carefully drafted to meet "the urgent need for an effective means of controlling toxic chemicals . . . [without] an undue regulatory burden placed on the chemical industry."[39] The effect of this accommodation was to cast in doubt once again the likelihood of House and Senate accord on toxic substances legislation, an accord which, based on the close similarities of H.R. 11576 and S. 3149, had seemed imminent. Important changes were made in the subcommittee bill, most of which were intended to mollify the chemical industry and neutralize or dilute the regulatory authority of the Administrator. This was effected not simply by obvious amendment of key provisions, but by numerous, seemingly minor, drafting alterations as well.[40] Most crucial, how-

Other additions to S. 3149 were more elaborate specification of rulemaking procedures; expansion of the employee protection provision; and authority of the Administrator to impose production, distribution, and use quotas in certain instances, subpoena documents and witnesses, and award attorneys fees where equitable.

37. Two notable amendments to § 6 of S. 3149, concerning regulation of substances found to pose an unreasonable risk, were adopted prior to Senate passage of the bill. First, Senator Nelson (D. Wisc.) proposed that PCB's be singled out for immediate regulation and, two years after enactment, total ban, subject to exceptions deemed non-hazardous by the Administrator. Second, Senator Cannon (R. Nev.) offered an amendment limiting the Administrator's authority to make immediately effective a proposed rule regulating an existing chemical substance. For debate, amendments, and passage of S. 3149, see 122 CONG. REC. S4379-S4420 (daily ed. Mar. 26, 1976).

38. H.R. 14032 was a product of committee members' belief that legislation could be drafted "which would be satisfactory to all of us." 122 CONG. REC. E2914 (daily ed. May 26, 1976) (statement by Rep. Eckhardt). Based on an amended version of H.R. 11576, the bill was drafted and sponsored principally by Reps. Eckhardt and Broyhill (R. N.C.). Other co-sponsors were Reps. Murphy (D. N.Y.), Van Deerlin, Moss, Rooney (D. Pa.), Scheuer, Carney (D. Ohio), Moffett (D. Conn.), Rinaldo (R. N.J.), and Lent (R. N.Y.).

39. *Id.*

40. For example, throughout the bill the threshold standard for justifying regulatory action was changed from "cause or contribute to an unreasonable risk" to "cause or significantly contribute to" such a risk; in the testing section, a cost factor was added to the relevant considerations in promulgating a testing rule and a representative of the Commerce Department was included in the inter-agency committee which recommends testing priorities; in the imminent hazard section, the definition of such a hazard as a substance "which causes or contributes to an imminent and unreasonable risk to health or the environment," became a substance "which causes

ever, were amendments to the enforcement provisions of the bill. Under H.R. 11576, the Administrator could, based on a specified finding, make a proposed rule immediately effective to hold off the market or otherwise regulate a new chemical substance. However, under H.R. 14032, the Administrator could effect such results only through court action, a much slower and more cumbersome process. When House and Senate versions of the legislation were sent to conference committee later in the year, that provision became the point most difficult to resolve.

According to Rep. McCollister, H.R. 14032, as introduced and presented to the committee, constituted "a very delicate balance . . . that [could] be destroyed rather readily."[41] Not surprisingly, then, the committee was unreceptive to further adjustment of that balance. With several non-substantive exceptions, all amendments were rejected, and, on June 9, the bill was favorably reported by the committee.[42] On August 23, after lengthy floor debate, the

or significantly contributes to an imminent and unreasonable risk of sèrious widespread harm to health or the environment"; and in the section concerning relationship of the Act to existing laws, the authority of the Administrator to disregard other laws administered by him which might be utilized to reduce a risk was conditioned not on a finding of appropriateness, but on a determination that use of the Act is "in the public interest."

Other notable changes were the inclusion of an exemption for small businesses from most of the reporting and recordkeeping requirements; an extension of the scope of federal preemption so that all state regulation of a substance regulated under the federal Act is prohibited; and further limitations on disclosure of information submitted pursuant to the Act with specification of criminal penalties for knowing violation.

41. 122 CONG. REC. H8810 (daily ed. Aug. 23, 1976).

42. H.R. REP. NO. 94-1341, 94th Cong., 2d Sess. (1976) [hereinafter cited as H.R. REP., 94TH CONG.]. Dissension on the part of some members of the committee is evidenced by the supplementary statements which accompanied the Report. Reps. Collins (R. Tex.) and Devine (R. Ohio) charged that the bill would prove "ruinous" to much of the chemical industry and specifically criticized the inclusion of citizen civil action, citizen petition, and employee protection provisions. Rep. Dingell (D. Mich.) called for authority directed explicitly to the regulation of PCB's, and joined in a minority statement with Reps. Moss, Metcalfe, Brodhead, Moffett, and Maguire (D. N.J.) which listed eight major inadequacies of the legislation as reported. Specifically, the statement criticized (1) the failure to require that the Administrator act on the recommendations of the inter-agency testing priority committee or explain his inaction; (2) the requirement that the Administrator seek a court injunction to prevent marketing of a new substance after the 90 day notice period where information is insufficient to determine a risk; (3) the failure to require that the Administrator explain why a new substance was permitted to be marketed without regulation; (4) the requirement that the Administrator seek a court injunction to immediately regulate a chemical determined to pose an unreasonable risk; (5) the requirement that the

House approved H.R. 14032 by a vote of 319 to 45. Particularly notable among the amendments[43] approved was a proposal by Rep. Moore (R. La.) to permit either chamber of the Congress to invalidate EPA-approved toxic substances regulations within 60 days after promulgation. Inclusion of such a provision by the House was tantamount to a request that the President veto the entire bill in light of his recent veto of pesticide legislation based on constitutional objections to just such a provision.[44]

After amending S. 3149 to contain the language of the H.R. 14032 as finally passed, the House requested a conference with the Senate; on August 31, the request was agreed to, and the conference committee meetings commenced on September 1.[45] The issue

Administrator make a "cumbersome and time consuming" determination of the public interest where a risk can be regulated by other laws under his authority; (6) the preemption of state authority to regulate toxic substances, thus precluding states from taking stronger action; (7) the failure to provide the Administrator with subpoena power for information gathering purposes; and (8) the failure to provide EPA with a firm mandate supported by adequate funding and time-phased enforcement requirements. *Id.* at 135-38.

43. Also agreed to was an amendment offered by Reps. Dingell and Gude (R. Md.) to regulate and eventually ban PCB's. For debate, amendments, and passage, see 122 CONG. REC. H8803-66 (daily ed. Aug. 23, 1976).

44. To infer that Rep. Moore may have intended by this amendment to inject a fatal flaw into the legislation is not unreasonable in view of the fact that he voted against the bill despite adoption by the House of his amendment as § 32 of the House bill. Subsequently, Senate conferees refused to accept this provision, and it was omitted from the conference agreement. Had it been included, the Act almost certainly would have been vetoed by the President, whose constitutional objections to such a procedure were well-known to the Congress. On August 13, 1976, President Ford vetoed an extension of F.I.F.R.A., 7 U.S.C. § 136 *et seq.* (Supp. V 1975), solely because a similar section had been included, and, in so doing, he explained his objections:

> [Such provisions] are contrary to the general principle of separation of power whereby Congress enacts laws but the President and the agencies of government execute them. Furthermore, they violate Article I, section 7 which requires that resolutions having the force of law be sent to the President for his signature or veto. There is no provision in the Constitution for the procedure contemplated by this bill.

122 CONG. REC. H8787 (daily ed. Aug. 23, 1976). Thus, adoption by the conference committee of § 32 of the House bill would have supplied a constitutional basis for veto of the legislation, a basis entirely unrelated to issues of toxic substances control.

See Rep. Broyhill's defense—in the face of strong criticism from Reps. Moore and Levitas (R. Ga.)—of the House conferees' decision to accede to the objections of the Senate conferees on this issue. 122 CONG. REC. H11345 (daily ed. Sept. 28, 1976).

45. House conferees were Reps. Staggers, Murphy, Stuckey, Eckhardt, Broyhill, McCollister, Brodhead, Scheuer, and Rinaldo. Subsequently appointed was Rep. Devine, to replace Rep. McCollister who resigned in order to devote time to his Senate

most responsible for the toxic substances deadlock in the 92d and 93d Congresses—the scope of pre-market screening—was not a problem in this conference, having been largely resolved during the preceding several months. Instead, the committee was faced with the closely related and equally difficult question of how much authority the Administrator should have to hold new chemicals off the market once notified of intended manufacture. As previously noted, the Senate version of S. 3149 authorized the Administrator to make immediately effective a proposed rule upon termination of the 90 day notice period, pending completion of administrative hearings on the rule. The House amendment, on the other hand, required the Administrator first to seek a court injunction. The greater part of conference deliberations was directed toward resolution of this issue as, once again, irreconcilable viewpoints on a single dominant issue threatened to stall the legislation in the final weeks of the session.

Resolved with comparatively little difficulty were other points of controversy, such as whether the Administrator should be required to publish in the *Federal Register* his reasons for failure to (1) take regulatory action against a new chemical substance prior to expiration of the notice period and (2) require testing of a substance within one year after its inclusion on the interagency advisory committee's testing priority list.[46] Also disputed—as they had been during each Congress considering this legislation—were the relationship of the Act to existing federal laws and the authority of the Administrator to utilize the regulatory provisions of this Act against a risk which is subject to provisions of other laws administered by him. The ultimate resolution of these and other issues by the conference committee was substantially a product of the urgent need for control of hazardous chemicals, concession by industry that some increase in regulation was inevitable, and a strong desire on the part of the legislation's sponsors to achieve some constructive, tangible results and to prevent the recurrence of stalemate. Though not willing to concede unilaterally on key provisions in order to reach an agreement, the conferees were more amenable during this Congress to accommodation and settlement. Consequently, the bill

campaign. Senate conferees were Senators Magnuson, Hartke, Hart, Durkin, Tunney, Baker, and Stevens.

46. In both instances, the Senate bill required publication and the House amendment did not.

that emerged from conference was a lengthy, complex, and, at times, convoluted compromise, particularly with respect to the authority of the Administrator to screen new chemical substances.[47]

On September 14, agreement among the conferees was reached[48] and two weeks later, on September 28, S. 3149 was approved by both chambers without amendment.[49] Because the Ford administration favored a less stringent version of the legislation forwarded to the White House for his signature, there was, even at that late date, some expectation that President Ford might veto the Act after adjournment of Congress on October 2, thereby precluding any possibility of congressional override. In fact, that expectation was not discredited until the final day before a pocket veto would have become effective, and on October 11, S. 3149 was signed into law.[50]

C. *Lobbying and Pressure Groups*

The effects of multifarious public interest, labor, industry, and government groups on the development of the Toxic Substances Control Act are not easily overestimated. Since its inception in 1971, the Act has been the focus of substantial lobbying activity, and its final form is in no small measure the result of that activity.[51] Particularly during the 94th Congress, the Act became the

47. Its provisions will be discussed in Part III *infra*.

48. Nine days thereafter the committee filed its report. H.R. REP. NO. 94-1679, 94th Cong., 2d Sess. (1976) [hereinafter cited as CONF. REP., 94TH CONG.].

49. S. 3149 passed the Senate by a vote of 73 to 6 and the House by a vote of 360 to 35. For debate and final passage, see 122 CONG. REC. S16802-09, H11343-48 (daily ed. Sept. 28, 1976).

50. For discussion of the role of the Ford Administration with regard to toxic substances legislation during the 94th Congress, see notes 75-86 and accompanying text *infra*.

51. Introducing S. 3149 in the Senate on March 26, 1976, Senator Tunney described industry's efforts to defeat the legislation:

> It is indeed unfortunate that while the record of chemical dangers continues to grow, segments of the chemical industry have presented roadblocks at every juncture of this bill's development. There is no question in my mind that a statute would now be on the books providing effective protection against chemical hazards had it not been for the concerted effort of certain segments of the chemical industry to gut the essential provisons of this legislation. . . .
>
> . . . .
>
> I must say that I have never seen such an effective lobbying effort as was done against this legislation.

122 CONG. REC. S4397-98 (daily ed. Mar. 26, 1976).

object of intense lobbying activity as the various interests sensed that 1976 would be a year in which elected officials would be most sensitive to public concern for protection from the dangers of toxic chemicals and that, after five years of debate over legislation the need of which had been widely acknowledged in 1971, congressional inaction had continued long enough. These efforts took many forms, ranging from informal meetings with legislators to public action campaigns on a far grander scale.[52] Though dollar estimates of resources expended by interest groups with respect to this legislation are difficult to determine,[53] it seems probable that the amounts may have been substantial, particularly on the part of industry.

52. Other lobbying activities included subsidizing cost analysis studies (see notes 63-65 and accompanying text *infra*), arranging briefings for legislators, funding congressional breakfasts, motivating public sentiment through periodical publications, and initiating and stimulating public letter writing campaigns. A striking illustration of this last activity is a letter, signed by Dow Chemical Co. President, Earle B. Barnes, which describes a planned campaign in opposition to toxic substances bills of the 94th Congress:

> Before long we will want to encourage the broadest and strongest possible grass roots political action campaign in opposition to Toxic Substances legislation. Hopefully, it will be based on mail to and calls on Senators and Representatives from employees, relatives, friends, distributors, vendors, customers, state organizations, etc. The objectives are to kill the bills or to register a minority vote sufficient to sustain a hoped-for veto or, as a last resort, to get the bills moderated significantly through floor amendments in the House. . . .
>
> . . . .
>
> Now, the time is near for our big push. We are not alone in this effort. Numerous other companies are also rallying grass roots campaigns. . . .

122 CONG. REC. S4401-02 (daily ed. Mar. 26, 1976). The letter included summaries of the legislation, lists of Representatives and Senators, and tips on how best to correspond with them, and concluded with an offer of prepared paragraphs and sentences "which people may wish to draw upon in framing their own letters on their own (non-Dow) stationery." *Id.*

53. Aside from difficulties inherent in quantifying in terms of dollars the resources directed toward support of or opposition to a particular piece of legislation, lobbying groups often prefer that such financial information not become a matter of public record. From a public relations standpoint, this is understandable considering the detrimental publicity which a particular group or company is likely to receive if it is known to be spending large amounts of money to defeat legislation intended to control dangerous chemicals. Financial reporting mandated by the Federal Regulation of Lobbying Act, 2 U.S.C. §§ 261-70 (1970), is of little use because the information required to be submitted by lobbyists is general in nature and because the statute does not preclude an organization from masking its accounting by filing through a number of individuals rather than as a single entity. For reports submitted pertaining to a period of heavy lobbying with respect to this Act during 1976, see 122 CONG. REC. pt. II (daily ed. Aug. 10, 1976).

Because of its tremendous size and resources,[54] the chemical industry—more than any other interest group—was equipped to initiate and maintain a prolonged and extensive campaign. Not surprisingly, however, manufacturers did not in all cases present a consistent viewpoint, and some were more amenable than others to the prospect of stricter regulation. In testimony before the House subcommittee, Dow Chemical Co. General Counsel James H. Hanes characterized the early House bills as the "Chemical Industry Control Act"[55] and expressed Dow's complete opposition to any increase in control because "from both the public's and the industry's standpoint a law is not needed and should not be passed."[56] According to Dow, new legislation would further constrict an already overregulated industry, causing inflation and unemployment and stifling necessary creativity.[57] On the other hand, Rohm and Haas Co. President Vincent Gregory, Jr., announced his company's early support for the relatively stringent S. 776 and the "philosophy and reasoning behind it."[58]

A more moderate approach—most representative of the views of the industry as a whole—was advocated by the two organizations most active in lobbying during the 94th Congress: the Manufacturing Chemists Association (M.C.A.)[59] and the Synthetic Organic Chemical Manufacturers Association (S.O.C.M.A.).[60] Though conceding the necessity of some new authority, these groups em-

54. Annual sales of the chemical industry now exceed $100 billion annually. S. REP., 94TH CONG., *supra* note 7, at 3.

55. H.R. HEAR., 94TH CONG., *supra* note 10, at 322.

56. *Id.* This viewpoint was expressed also by Elmer Fike, President of Fike Chemical Co. and chairman of the legislative committee of the Chemical and Specialties Management Council, a group of small eastern chemical manufacturers. Citing excessive regulatory legislation as the primary reason for the rise of the national debt to $500 billion, Fike, on behalf of small manufacturers, deprecated the value of federal regulatory agencies, any one of which "has such broad and loosely defined powers that they can, by legal means or by pure harassment, force us into bankruptcy at any time they choose." A better alternative, he suggested, would be "voluntarism." *Id.* at 94-102.

57. *Id.* at 323 (statement by Dow General Counsel Hanes).

58. S. HEAR., 94TH CONG., *supra* note 5, at 69. The Rohm and Haas Co. was at that time involved in litigation stemming from 20 to 25 employee deaths since 1962, allegedly from lung cancer resulting from exposure to BCME, a chemical treatment for fabrics.

59. M.C.A. is a non-profit trade organization having 184 U.S. company members representing 90% of the production capacity of industrial chemicals in the U.S.

60. S.O.C.M.A. is a non-profit trade association of 74 manufacturers of organic chemicals.

phasized that "selectivity should be the key feature of the thrust of any new law" since sweeping, duplicative controls intended to do more than close the gaps in existing laws would have detrimental effects on the industry and, as a consequence, on the entire economy.[61] Similarly, they considered careful, reasoned administration essential: "Any law, however carefully drafted, must be administered reasonably and prudently, and all aspects of its potential impact on productivity and technology must be evaluated carefully."[62]

The paramount concern of all segments of the chemical industry with respect to this legislation was undoubtedly its potential cost. To alleviate uncertainty as to precisely what that would be, Dow Chemical Co., M.C.A., and the EPA conducted independent cost analysis studies which attempted to project, based on the provisions of S. 776, costs of screening, testing, delays, bans and restrictions, and any other costs. Instead of resolving the issue, however, the inconsistent conclusions of the studies only heightened the controversy: Dow estimated an overall annual cost to industry of $2 billion; M.C.A. projected a range from $358 million to $1.325 billion, depending on the degree of testing needed; and EPA predicted a range of $78.5 million to $141.5 million. By request of Senator Hart, the General Accounting Office (G.A.O.) reviewed

61. S. HEAR., 94TH CONG., *supra* note 5, at 124-25 (statement by M.C.A. representative Dr. C. Boyd Shaffer).

62. *Id.* With regard to specific provisions of the bills before the 94th Congress, industry representatives recommended that the subcommittee: condition testing rules on a finding that the chemical substance is likely to pose a *substantial* unreasonable risk to health or the environment; adopt the limited pre-market screening procedure included in H.R. 7664; exempt mixtures, catalysts, research and laboratory chemicals, and test-marketing chemicals from the scope of the Act; delete authority of the Administrator to make immediately effective a proposed regulatory rule, and require in all rulemaking advance notice of proposed rules, right to comment, and an opportunity for public hearing with cross-examination of witnesses; provide less stringent requirements for small businesses; permit the Administrator to take action pursuant to the Act only upon a finding that the risks involved cannot be dealt with under existing law; limit retention of health and safety studies to ten years; delete authority for citizen civil actions against the Administrator as to performance of discretionary duties; and provide for total pre-emption of state regulatory authority over a chemical substance already subject to federal controls. For these and other recommendations, *see* H.R. HEAR., 94TH CONG., *supra* note 10, at 284-93, 313-23, 391-96; S. HEAR., 94TH CONG., *supra* note 5, at 123-37, 328-33.

For an exchange of views between an executive of E.I. DuPont de Nemours and Co. and principal Senate sponsors of the Act, see Heckert, *Toxic Substances: A Case for Common Sense*, 8 NAT'L J. 462, (1976); and Tunney, Hartke & Hart, *S3149: The Toxic Substances Control Act*, *id.*, at 834-35.

each study to determine the cause of the vast variation in appraisal. In a report[63] submitted to the Senate subcommittee, the G.A.O. emphasized that, because of the numerous variables involved, any prediction would be uncertain; nevertheless, it concluded cautiously that it would "feel least uncomfortable" with an estimate within the range of $100 million to $200 million per year.[64] The G.A.O. noted as a final caveat that none of the studies had considered benefits and that, whatever the costs, the benefits to society as a whole might still exceed them, particularly where chemicals banned were dangerous to health.[65]

Public interest organizations, such as the Sierra Club, the Environmental Defense Fund (E.D.F.), the Natural Resources Defense Council (N.R.D.C.), and Ralph Nader's Public Citizens' Health Group, utilized many of the traditional lobbying methods noted earlier.[66] Undoubtedly, though, the greatest impetus to legislative concern were events over which those groups had no direct control: the recent disasters associated with such substances as mercury, B.C.M.E., vinyl chloride, arsenic, and asbestos, and the press reports of them.[67] Such events lent credibility to the view

63. S. HEAR., 94TH CONG., *supra* note 5 at pt. 2 (U.S. GENERAL ACCOUNTING OFFICE, A COMPARISON OF THREE ESTIMATES OF COSTS OF THE PROPOSED TOXIC SUBSTANCES CONTROL ACT, and accompanying testimony by Harry S. Havens, Director, Office of Program Analysis, General Accounting Office (G.A.O.) at 82-98).

64. *Id.* at 97-98. In his testimony before the Senate subcommittee, Harry S. Havens, the Director of the Office of Program Analysis of the G.A.O. reviewed briefly the basis for the G.A.O.'s conclusions. He characterized the Dow study as the "least reliable" and stated that the $2 billion estimate was "highly questionable" because based on a greatly overstated estimate of costs. *Id.* at 84-85. As to the M.C.A. study—also known as the Snell report—he cited several defects, the most significant of which was the inclusion of questionable "maintenance of innovation" costs, consisting largely of an exaggerated increase in research and development costs. *Id.* Havens described the EPA study as "closer than the industry studies to an accurate picture of what the legislation will entail," *id.* at 84, but he commented that certain of its assumptions and statements were inadequately documented. *Id.* at 88.

65. This is precisely the view advocated by Sierra Club representative Linda Billings with respect to the cost issue in testimony before the House subcommittee: that the costs of regulation "should be balanced by also considering the cost to society of not doing so." H.R. HEAR., 94TH CONG., *supra* note 10, at 161. Among those costs she included losses in labor productivity due to illness, losses in lifetime earnings to those seriously disabled, costs of treating diseases, and, most importantly, "the incalculable cost in human suffering, not to mention serious environmental costs . . . ." *Id.* She suggested that manufacturers would be more prudent to "spend money in testing . . . than to later be required to put out even more money in the event of damage suits." *Id.*

66. *See* note 52 *supra*.

67. The widely acclaimed CBS news documentary entitled *The American Way of*

of these groups that toxic substances legislation was necessary not simply as a "gap-filler" between existing laws, but as authority for a comprehensive system of federal control over the introduction of hazardous substances into the environment.[68] According to E.D.F. counsel Jacqueline Warren, the three essential elements of such legislation were (1) reporting and recordkeeping requirements to assure dissemination of information, (2) mandatory pre-screening of all chemicals in order to detect harmful substances before health disasters occur, and (3) adequate administrative authority to act

Cancer was shown specially for House and Senate members, and Sen. Tunney commented in subcommittee hearings that it "presented an excellent case for the Toxic Substances Control Act." S. HEAR., 94TH CONG., *supra* note 5, pt. 1, at 1-2. Throughout the 94th Congress, accounts of chemical dangers were drawn from newspapers around the nation and introduced into the *Congressional Record* in support of the Act. As much as any direct lobbying activity, such reports argued persuasively in favor of stringent regulation and gave credence to the contentions of consumer and environmental advocates. *See* 122 CONG. REC. H1206-08 (daily ed. Feb. 19, 1976), E1449-50 (daily ed. Mar. 22, 1976), S4005-07, E1487-89 (daily ed. Mar. 23, 1976), S4142 (daily ed. Mar. 24, 1976), S4239-40, E1544-45, E1554-56 (daily ed. Mar. 25, 1976), E1649-51, E1676-78 (daily ed. Mar. 30, 1976), E1710-11, E1714-16 (daily ed. Mar. 31, 1976), E1725-26 (daily ed. Apr. 1, 1976), E1847-48 (daily ed. Apr. 6, 1976), E1879 (daily ed. Apr. 7, 1976), E1942 (daily ed. Apr. 9, 1976), E2016-18 (daily ed. Apr. 13, 1976), S10145-46 (daily ed. June 22, 1976), S13666-67 (daily ed. Aug. 5, 1976).

68. Specifically, public interest advocates recommended to House and Senate panels that they: require the manufacturer to carry the burden of proof concerning the safety of a chemical which may pose a risk or about which insufficient information exists to make a determination; require pre-market certification by the Administrator of all new chemical substances; require the Administrator to issue temporary restrictions where the outcome of testing is pending or issue immediately effective rules where data is insufficient to determine absence of risk, where a chemical is determined to pose a risk, or where a substance is found to present an imminent hazard; delete any exemption for test-marketing of chemicals; provide for broad reporting and retention of data requirements, particularly respecting health and safety studies; delete provisions depriving the Administrator of authority under the Act where a risk might be dealt with pursuant to other laws and provide instead that nothing in this Act shall be construed to limit the authority and responsibility of the Administrator or other federal officials under any other federal law; delete the exemption for exports; authorize the Administrator to disclose information submitted pursuant to the Act where the interest of public health and safety is served thereby; permit states to regulate toxic substances at any level equal to or more stringent than the federal regulations; provide for citizen civil actions by "interested or aggrieved persons" where there is a failure of the Administrator to perform any non-discretionary duty under the Act; and provide adequate authorization to assure that EPA is well staffed and well funded. For these and other recommendations, see H.R. HEAR., 94TH CONG., *supra* note 10, at 157-200; S. HEAR., 94TH CONG., *supra* note 5, at 137-76.

See discussion of the cost issue by Sierra Club representative Linda Billings, at note 65 *supra*.

quickly and decisively against potential or actual hazards.[69] N.R.D.C. representative J.G. Speth warned, however, that the existence, without more, of discretionary EPA authority to test, screen, and regulate would not be enough:

> The legislation should require EPA in mandatory terms to regulate substances that pose an unreasonable risk; otherwise you run the risk that EPA will not act. . . . And the legislation should have careful deadlines for EPA action; otherwise you run the risk of prolonged delay and repeated postponements. Give EPA a discretionary framework for aggressive action but no mandate to act aggressively . . . and you will get some regulation of toxic substances but not much.[70]

Public interest advocates were not alone in their efforts to get stringent toxic substances legislation approved by the 94th Congress. An important factor in the success of that body in finalizing the Act in 1976 was the heightened level of activity by labor groups toward that end. Though several union representatives testified during the 92d Congress,[71] not until 1975 did a concerted effort materialize in support of stricter controls.[72] In testimony before House and Senate subcommittees, labor representatives voiced general sympathy with the concerns raised by public interest groups, but directed their testimony more particularly to the failure of existing laws—specifically, the Occupational Safety and Health Act (O.S.H.A.)—to adequately protect the worker until after the toxic substance and its attendant hazards have been introduced into the workplace. The Toxic Substances Control Act was characterized as an urgently needed remedy to the existing "body in the morgue" system which uses workers as guinea pigs to determine the toxicity of inadequately tested chemicals.[73] Thus, union representatives made recommendations pertaining primarily to provisions intended to supplement O.S.H.A., coordinate with

69. H.R. HEAR., 94TH CONG., *supra* note 10, at 175-76.

70. *Id.* at 193-94.

71. *See Hearings on S. 1478 Before the Subcomm. on the Environment of the Senate Comm. on Commerce*, 92d Cong., 2d Sess. (1972).

72. Labor groups represented at hearings during the 94th Congress included the Oil, Chemical and Atomic Workers International Union, AFL-CIO; the United Steelworkers of America; the United Paper Workers International Union; the Textile Workers Union of America, AFL-CIO; and various departments of the AFL-CIO.

73. H.R. HEAR., 94TH CONG., *supra* note 10, at 87 (statement of Anthony Mazzocchi, Citizenship-Legislative Director, Oil, Chemical and Atomic Workers International Union, AFL-CIO).

the National Institute for Occupational Safety and Health (N.I.O.S.H.) and the Occupational Safety and Health Administration (O.S.H. Adm'n), and prohibit employer discrimination.[74]

The role of the Ford Administration with respect to this legislation resembled in many ways that of the interest groups discussed above, as officials sought, primarily through testimony, to influence its development. During the early months of 1975, the President's top environmental advisors—EPA Administrator Russell Train and CEQ Chairman Russell Peterson—actively urged that "a systematic and comprehensive approach to the control of toxic substances be provided,"[75] and announced Administration support for regulatory authorities significantly more stringent than those advocated by the Nixon Administration during either of the previous two Congresses. In testimony before the Senate subcommittee in March, 1973, Train described the elements which he considered critical to an effective program,[76] and gave a qualified endorsement to S. 776:

> First, the legislation would provide authority to collect necessary information about the chemicals now in production. . . .
>
> Second, pre-market notification would be required for new chemicals and significant new uses of existing chemicals. . . .
>
> Third, one of the key provisions . . . is the development of the standards for test protocols, . . . to insure that the environment does not become the testing laboratory and the general public the test species for chemicals with uncertain effects.
>
> Finally, the proposed legislation would provide for appropriate legal, administrative, and enforcement tools such as civil,

74. Specifically, they urged that the bill: provide for high priority testing by EPA of those substances known to present occupational hazards; direct the Administrator to inform both O.S.H. Adm'n and N.I.O.S.H. and provide them with all relevent data where he determines that a chemical substance poses an unreasonable risk; contain specific language to preclude possible conflict of authority between O.S.H. Adm'n and EPA; establish a permanent inter-agency advisory committee made up of representatives of the federal agencies concerned; prohibit employer discrimination and use of threat by management of job losses resulting from actions by the employee or the EPA pursuant to the Act; and establish special financial assistance programs—i.e., economic dislocation assistance and retraining and relocation aid for workers displaced by EPA actions. For these and other recommendations, see *id.* at 85-94; S. HEAR., 94TH CONG., *supra* note 5, at 246-89.

75. *Id.* at 212.

76. The close similarity between the program outlined by Train and that proposed by E.D.F. counsel Jacqueline M. Warren is striking and suggests that the Administration's traditional sympathy for the interests of the chemical industry had lost some ground—at least for the moment—to the environmentalist viewpoint. For Warren's testimony, see note 65 and accompanying text *supra*.

> criminal, and injunctive relief provisions; citizen suit provisions; and appropriate inspection authority.
>
> . . . .
>
> With regard to S.776, . . . I am pleased to note that it contains the authorities I believe are essential for effective toxic substances control legislation and we are in accord with many of its provisions.[77]

The most basic change in the Administration's position was a clear recognition of the concept of pre-market screening of *all* new chemicals as essential to effective regulation. In reference to the provision of H.R. 7229 incorporating the more limited approach advocated by the previous Administration,[78] CEQ Chairman Peterson expressed the Council's primary concern that it would not "ensure that the impact of any new chemical substance is adequately assessed and prepared for before commercial production begins."[79] He characterized as "essential," therefore, the inclusion of language clearly indicating that "pre-market notification can be required of *all* new chemical substances."[80] Commenting on that same provision of H.R. 7229, Deputy EPA Administrator John Quarles expressed emphatic agreement:

> We feel very strongly that that provision would hobble the administration of this program and would essentially prohibit any effective application of the pre-market notification provision. . . . Therefore, if you are serious about pre-market notification, and we are serious about that, because we feel it is one of the key provisions of the bill—then the provision requiring the Administrator to publish a list before that whole mechanism is activated is going to be very self-defeating. In our judgment that is the single most offensive feature of any of the bills under consideration.[81]

77. S. HEAR., 94TH CONG., *supra* note 5, at 212.

78. *See* notes 18 & 19 and accompanying text *supra* and notes 144-46 and accompanying text *infra*. This limited approach subjected to pre-market screening requirements only those substances included by the EPA Administrator on a list of substances likely to pose a substantial risk. In effect, such approach required near-clairvoyant powers on the part of the Administrator to predict, without benefit of notification by the manufacturer, which substances would be marketed and the risks which they might pose. According to Deputy EPA Administrator John R. Quarles: "It would be very difficult or virtually impossible for any administrator or his staff to be able to anticipate all the new chemicals that might be developed or all the significant uses for which existing chemicals might be applied . . . ." H.R. HEAR., 94TH CONG., *supra* note 10, at 212.

79. *Id.*

80. *Id.*

81. Two other provisions found in several of the bills were singled out for particular criticism in testimony by Train and Quarles. First, Senator Tunney's "watch-

In November, 1975, however, the Ford Administration suddenly abandoned its stated position and endorsed the concept of limited pre-market screening and a modified version of Rep. McCollister's first bill H.R. 7664. This reversal in attitude in the area of toxic substances control came as a great surprise to many, including, no doubt, the administration's environmental spokesmen Train, Quarles, and Peterson. The turnaround stemmed not from a scientific re-evaluation of the issues, but from a determination by Office of Management and Budget (OMB) Director James Lynn that pre-market notification as to all new substances "could be overly burdensome" to manufacturers and the government's regulatory workload.[82] Accordingly, Lynn advised Rep. McCollister in a letter of November 13 that "the Administration had reassessed its previous position with regard to toxic substances control legislation and would support H.R. 7664 with some modification."[83] This amended version was introduced in March, 1976, by Reps. McCollister and Broyhill as H.R. 12336.[84]

Despite continued opposition by the Administration to major aspects of both House and Senate majority bills throughout the sec-

dog" provision, precluding the Administrator from forwarding any budget estimates, legislative proposals, comments on legislation, or testimony to the Office of Management and Budget (OMB) for review without also transmitting those materials to Congress, was criticized as "not a toxic substance provision" and likely, if included in the bill, to cause a veto of the entire Act. Second, authority of the Administrator to make immediately effective any rule proposed during the 90 day pre-market review period, was characterized as an unnecessary and undesirable abridgment of the well-established procedure of rulemaking. Train and Quarles urged deletion of both provisions. *Id.* at 211-12; S. HEAR., 94TH CONG., *supra* note 5, at 202-03. For these and more specific criticisms of S. 776, see *id.* at 73-88, letter from Quarles to Sen. Magnuson.

82. According to the *National Journal* and congressional subcommittee staff involved with the legislation, early endorsements of universal pre-market screening had been approved at relatively low levels of Lynn's OMB office, and not by Lynn himself. One week prior to the letter to McCollister detailing the reversal, chemical industry representatives met with top OMB staff for purposes which are not known, though it seems probable that the Toxic Substances Control Act would have been discussed. Lynn, who had vigorously opposed the concept of pre-market screening when he served as General Counsel to the Commerce Department in 1971, then met to discuss the bills with President Ford, who decided during the course of the meeting to overrule his top environmental advisors. Neither Train nor Peterson was invited to the meeting. Magida, *Environment Report/Toxic substances debate focuses on notification and testing*, 8 NAT'L J. 206, 207 (1976).

83. This description of Lynn's letter to McCollister and an explanation of the recommended modifications of H.R. 7664 were contained in a Feb. 5, 1976, letter from EPA Administrator Train to Rep. Staggers. H.R. REP., 94TH CONG., *supra* note 42, at 81-95.

84. *See* notes 30 & 31 and accompanying text *supra*.

ond session of the 94th Congress, President Ford signed S. 3149 without apparent misgivings, calling it "one of the most important pieces of environmental legislation that has been enacted by the Congress."[85] His brief statement upon signing the Act emphasized congressional intent to fill gaps between existing statutes, and concluded with the following caveat concerning proper administration of its provisions:

> This bill provides broad discretionary authority to protect the health and environment. It is critical, however, that the legislation be administered in a manner so as not to duplicate existing regulatory and enforcement authorities. . . . I am certain that the Environmental Protection Agency realizes that it must carefully exercise its discretionary authority so as to minimize the regulatory burden consistent with the effective protection of the health and environment.[86]

President Ford's cautious explanation of the Act's intended purpose and proper administration is an analysis with which many might disagree. It is incongruous that the President, after praising the significance of the legislation, should adopt an interpretation of it most characteristic of the viewpoint of the chemical industry, which for years had fought to prevent its enactment.

III. ANALYSIS[87]

Section 2—Findings, Policy, and Intent[88]

The basis of the Act is set forth in *subsection (a)* and consists of three congressional findings: first, that humans and the environ-

85. 12 WEEKLY COMP. OF PRES. DOC. 1489 (Oct. 18, 1976).

86. *Id.*

87. Some sections of the Act are more administrative than substantive in content and are, therefore, less controversial. In the interest of brevity, they will not be considered in this analysis. Such sections include (citations to 15 U.S.C.A. (West Supp. 1977) are noted in brackets): § 10 [§ 2609]—*Research, Development, Collection, Dissemination, and Utilization of Data;* § 11 [§ 2610]—*Inspections and Subpoenas;* § 12 [§ 2611]—*Exports;* § 13 [§ 2612]—*Entry into Customs Territory of the United States;* § 15 [§ 2614]—*Prohibited Acts;* § 16 [§ 2615]—*Penalties;* § 22 [§ 2621]—*National Defense Waiver;* § 23 [§ 2622]—*Employee Protection;* § 24 [§ 2623]—*Employment Effects;* § 25 [§ 2624]—*Studies;* § 26 [§ 2625]—*Administration of the Act;* § 27 [§ 2626]—*Development and Evaluation of Test Methods;* § 28 [§ 2627]—*State Programs;* § 29 [§ 2628]—*Authorization for Appropriations;* § 30 [§ 2629]—*Annual Report;* § 31 [§ 2630]—*Effective Date.*

For a discussion of the constitutionality of an inspection provision substantially similar to that adopted in § 11 of the Act, *see* Comment, *The Constitutionality of General Inspections Under the Occupational Health and Safety Act of 1970*, in this issue *infra*.

88. 15 U.S.C.A. § 2601 (West Supp. 1977).

ment are exposed to a large number of chemical substances and mixtures; second, that some of those substances "may present an unreasonable risk of injury to health or the environment;"[89] and third, that there is a need to regulate intrastate commerce of such substances if interstate commerce is to be regulated effectively. In this subsection and throughout the Act, the central concern is the "*unreasonable* risk"—not risks generally—which may arise from exposure to chemical substances and mixtures. Thus, Congress did not intend through this Act to achieve a zero-risk environment.[90]

The statement of policy in *subsection (b)* is balanced: that data development respecting chemical substances and mixtures is needed and is the responsibility of industry; that adequate authority should exist to regulate substances "which present an unreasonable risk" and to act with respect to imminent hazards; and that the authority should be exercised so as not to stifle technological innovation "while fulfilling the primary purpose of this Chapter to assure that such innovation and commerce . . . do not present an unreasonable risk of injury to health or the environment."[91]

The declaration of congressional intent in *subsection (c)* is a note of caution to the Administrator: he shall carry out the Act in a "reasonable and prudent manner, and . . . shall consider the environmental, economic, and social impact of any action" taken or proposed.[92] The House Committee Report notes, however, that this subsection is intended only as guidance for the Administrator and is not to involve him in any "cost-benefit justifications."[93]

Though Section 2 was the focus of relatively little controversy, resolution by the conference committee of two differences between the Senate bill and the House amendment is notable here. First, the basic standard of "presents" or "may present" found throughout the section is a compromise between narrower House language ("may cause or significantly contribute to"[94]) and broader Senate

89. 15 U.S.C.A. § 2601(a)(2) (West Supp. 1977).

90. Rep. Broyhill, one of the chief sponsors of the Act, explained:

> The general standard for taking action under the legislation is that the substance may present an unreasonable risk. The conferees intend to limit the Administrator to taking action only against unreasonable risks because to do otherwise assumes that a risk-free society is attainable, an assumption that Congress does not make.

122 CONG. REC. H11344 (daily ed. Sept. 28, 1976).

91. 15 U.S.C.A. § 2601(b)(3) (West Supp. 1977).

92. 15 U.S.C.A. § 2601(c) (West Supp. 1977).

93. H.R. REP., 94TH CONG., *supra* note 42, at 9.

94. H.R. 14032, § 2, 122 CONG. REC. H8849 (daily ed. Aug. 23, 1976).

wording ("may cause or contribute to"[95]). Second, whereas the House amendment confined its data development mandate to "hazardous and potentially hazardous"[96] substances, the final Act adopted the Senate bill's more inclusive mandate with respect to all substances, regardless of hazard.

Section 3—Definitions[97]

Of the fourteen terms[98] defined by this section, four are considered here:

(1) "chemical substance"[99]—This definition is important primarily because it excludes from the regulatory reach of the Act (a) mixtures (except where explicitly included); (b) pesticides;[100] (c) tobacco or any tobacco products; (d) source material, special nuclear material, or byproduct material;[101] (e) any food, food additive, drug, cosmetic, or device,[102] and (f) any article the sale of which is

95. S. 3149, § 2, 122 CONG. REC. S4420 (daily ed. Mar. 26, 1976).

96. H.R. 14032, § 2(b)(1), 122 CONG. REC. H8849 (daily ed. Aug. 23, 1976).

97. 15 U.S.C.A. § 2602 (West Supp. 1977).

98. These terms are: Administrator, chemical substance, commerce, distribution in commerce, environment, health and safety study, manufacture, mixture, new chemical substance, process, processor, standards for the development of test data, State, and United States.

99. "Except as provided in subparagraph (B) [which lists exemptions from this definition], the term 'chemical substance' means any organic or inorganic substance of a particular molecular identity, including—(i) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and (ii) any element or uncombined radical." 15 U.S.C.A. § 2602(2)(A) (West Supp. 1977).

100. This term is defined in the F.I.F.R.A., 7 U.S.C. § 136 (Supp. V 1975). With regard to that definition the House Report states:

> [T]he F.I.F.R.A. defines "pesticide" to include "(1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, and (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant." Thus the definition in that Act would include chemical substances on which research is being performed with the intent that the substance being used for any of the purposes be subject to regulation under that Act and, by virtue of the exemption for pesticides, are exempted from regulation under this bill.

H.R. REP., 94TH CONG., *supra* note 42, at 11.

101. These terms are defined in the Atomic Energy Act of 1954, 42 U.S.C. § 2011 *et seq.* (1970), and regulations issued thereunder.

102. These terms are defined in the F.F.D.C.A., 21 U.S.C. § 321 *et seq.* (1970). With regard to those definitions the House Report states:

> The definition of "drug" in the [F.F.D.C.A.] includes "articles intended for use as a component" of substances included in the definition of "drug". As used in that Act, the term "component" does not mean only an item which may be identified as an ingredient of a drug in its final dosage form. Thus, precursors,

subject to the tax imposed by § 4181 of the Internal Revenue Code.[103] Exclusions (b) and (e) are conditioned on manufacture and distribution in commerce of the substance or object for use specifically as a pesticide, food, food additive, drug, cosmetic, or device. To the extent that it can be used for other purposes, the item is subject to regulation under this Act.[104]

The Senate Committee Report cautions that these exemptions are to be narrowly drawn in order to prevent a situation where "new unpredictable uses . . . may not be properly controlled under the provisions of this Act because of the existence of an exclusion."[105] Because they were intended to avoid jurisdictional overlap between existing regulatory statutes and this Act, such exclusions are specific and are applicable only where an item is defined in accord with the relevant statutory definition.

Consistent with this restrictive interpretation of exemptions is a broad reading of the term "chemical substance." According to the Conference Committee Report, "any reference to a chemical substance includes all impurities and concomitant products, including incidental reaction products, contaminants, co-products, and trace materials."[106] Thus, a regulating rule applied to a particular substance would likewise apply to any impurities without specifically identifying them.

(2) "mixture"[107]—Early versions of the legislation drew no dis-

intermediates, and catalysts intended for use in the production of drugs in their final dosage form are "drugs" within the meaning of the [F.F.D.C.A.].

Further, the [F.F.D.C.A.] clearly covers drugs during the "investigation" or research stage. Consequently, the definition of "drug" in that Act includes chemical substances used for drug research and development. The same is true of the definitions of food, food additives, and cosmetics.

H.R. REP., 94TH CONG., *supra* note 42, at 11.

The term "food" also includes poultry and poultry products under the Poultry Products Inspection Act, 21 U.S.C. § 453 (1970), meat and meat products under the Federal Meat Inspection Act, 21 U.S.C. § 601 (1970), and eggs and egg products under the Egg Products Inspection Act, 21 U.S.C. § 1033 (1970).

103. Among such articles are pistols, firearms, revolvers, shells, and cartridges. 26 U.S.C. § 4181 (1970).

104. H.R. REP., 94TH CONG., *supra* note 42, at 11-12.

105. S. REP., 94TH CONG., *supra* note 7, at 15.

106. CONF. REP., 94TH CONG., *supra* note 48, at 57.

107. "The term 'mixture' means any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or part, the result of a chemical reaction; except that such term does include any combination which occurs, in whole or in part, as a result of a chemical reaction if none of the chemical substances comprising the combination is a new chemical substance and if

tinction between mixtures and other chemical substances and subjected them to equal requirements under the Act. To alleviate industry fears that each slight change in formulation or physical blend would constitute a different chemical substance subject individually to the Act's provisions, Rep. Eckhardt's compromise bill H.R. 10318 introduced such a distinction and limited the applicability of key sections of the Act in the case of mixtures.[108] This concept is maintained in the final version: mixtures are not subject to pre-market screening under § 5[109] and special findings are necessary before testing of them may be required under § 4[110] or before they can be subjected to reporting and recordkeeping rules under § 8.[111]

Though the Senate bill contained this distinction, it defined "mixture" narrowly to include only combinations of substances which do not react chemically with each other. The conference committee adopted the broader House amendment definition which included combinations resulting from reactions of existing substances where the combination could also have been produced by non-reactive means. As explained in the House Report, "[t]he two end products would be identical, and they should be subject to identical treatment under the bill."[112]

(3) "manufacture"[113]—The Act defines this term to mean "import into the customs territory of the United States . . ., produce or manufacture," thus subjecting imported chemicals to the same requirements as domestically produced substances. The Senate bill limited the term's scope to such activities done "for commercial purposes." Where this qualification is intended under the final Act, it is explicitly stated within the section to which it is applicable.[114]

(4) "health and safety study"[115]—This term denotes information basic to the reporting provisions of § 8,[116] and by its terms it is liberally defined to include "any study of any effect of a chemical sub-

the combination could have been manufactured for commercial purposes without a chemical reaction at the time the chemical substances comprising the combination were combined." 15 U.S.C.A. § 2602(8) (West Supp. 1977).

108. *See* notes 28 & 29 and accompanying text *supra*.

109. By its terms, § 5 applies only to chemical substances. 15 U.S.C.A. § 2604(a) (West Supp. 1977).

110. 15 U.S.C.A. § 2603(a)(2) (West Supp. 1977).

111. 15 U.S.C.A. § 2607(a)(1)(B) (West Supp. 1977).

112. H.R. REP., 94TH CONG., *supra* note 42, at 12.

113. 15 U.S.C.A. § 2602(7) (West Supp. 1977).

114. *See* 15 U.S.C.A. § 2604(i) (West Supp. 1977).

115. 15 U.S.C.A. § 2602(6) (West Supp. 1977).

116. 15 U.S.C.A. § 2607 (West Supp. 1977).

stance or mixture on health or the environment or both . . . ."[117] The Conference Report emphasizes its broad scope:

> It is intended that the term be interpreted broadly. Not only is information which arises as a result of a formal, disciplined study included, but other information relating to the effects of a chemical substance or mixture on health and the environment is also included. Any data which bears on the effects of a chemical substance on health or the environment would be included.[118]

The most basic term—"unreasonable risk"—is not defined by the Act. The House committee had earlier considered inclusion of such a definition, but rejected it because the committee felt such a determination to be incapable of sufficiently precise definition.[119] The conference committee omitted a related provision of the Senate bill which defined "unreasonable adverse effects on the environment" as "any unreasonable risk to man or to the environment taking into account the economic, social, and environmental costs and benefits of the use of any chemical substance."[120] Though "unreasonable risk" is not explicitly defined by the Act, it appears, based on these sources, that a balancing-of-factors approach to determine existence of such a risk was intended by the drafters. This analysis is supported by the language of § 2(c) of the Act.[121]

117. This includes "underlying data and epidemiological studies, studies of occupational exposure to a chemical substance or mixture, toxicological, clinical, and ecological studies of a chemical substance or mixture, and any test performed pursuant to this chapter." 15 U.S.C.A. § 2602(6) (West Supp. 1977).

118. CONF. REP., 94TH CONG., *supra* note 48, at 58.

119. *See* H.R. REP., 94TH CONG., *supra* note 42, at 14. The House committee continued:

> In general, a determination that a risk associated with a chemical substance or mixture is unreasonable involves balancing the probability that harm will occur and the magnitude and severity of that harm against the effect of proposed regulatory action on the availability to society of the benefits of the substance or mixture, taking into account the availability of substitutes for the substance or mixture which do not require regulation, and other adverse effects which such proposed action may have on society.

Id.

120. S. 3149, § 3(a)(15), 122 CONG. REC. S4420 (daily ed. Mar. 26, 1976). This definition was included in the Senate bill through a floor amendment offered by Senator Allen (D. Ala.). Its purpose was to define "unreasonable risk" and "imminent hazard" in a manner consistent with those terms as defined under F.I.F.R.A., 7 U.S.C. § 136 *et seq.* (Supp. V 1975). Introducing the amendment, Allen stated: "My amendment would provide that whenever the term 'unreasonable risk' is used it will be in accord with the meaning of 'unreasonable adverse effect' as defined in my amendment and as defined in the [F.I.F.R.A.]." 122 CONG. REC. S4407 (daily ed. Mar. 26, 1976).

121. *See* notes 92-96 and accompanying text *supra*.

A prima facie finding of unreasonable risk is, in effect, established under § 4(f) where information indicates to the Administrator a reasonable basis to conclude that

Section 4—Testing of Chemical Substances and Mixtures[122]

Subsection (a) mandates that the Administrator require testing, if, with regard to a chemical substance or mixture, he makes one of several enumerated findings. The most important of these are: that it "may present an unreasonable risk of injury to health or the environment," or that it "is or will be produced in substantial quantities;" and, in the case of a mixture, that its effects may not be "more reasonably and more efficiently determined" by testing the components of the mixture.[123] Though several early bills had given the Administrator whole or partial discretion whether to require testing based on similar findings,[124] both the Senate bill and the House amendment prescribed mandatory testing, as does the final Act.

With respect to the findings which the Administrator must make, the House and Senate versions were similar in substance except that the House amendment necessitated a finding that the substance "cause or significantly contribute to" an unreasonable risk. The conference committee adopted the House language for subsection (a) generally, but substituted the Senate bill standard—"presents or may present"—for the narrower standard of the House amendment. That phrase, the committee explained, is to be liberally construed and should enable the Administrator to address sub-

a substance "presents or will present a significant risk of serious or widespread harm to human beings from cancer, gene mutations, or birth defects." 15 U.S.C.A. § 2603(f) (West Supp. 1977). See notes 137 & 38 and accompanying text *infra*.

122. 15 U.S.C.A. § 2603 (West Supp. 1977).

123. 15 U.S.C.A. § 2603(a) (West Supp. 1977).

124. Three early House bills of the 94th Congress—H.R. 7664, H.R. 7229, and H.R. 7548—illustrate widely varying approaches to this testing authority. H.R. 7664 provided that the Administrator "may" prescribe testing of a chemical substance where he finds it "necessary to protect against an unreasonable risk to health or the environment." H.R. 7229 stated that the Administrator "shall" prescribe testing where he determines that a substance "presents an unreasonable risk . . . ," and "may" take such action where insufficient data exists to make such a determination. Substantially more inclusive than either of these was H.R. 7548 which provided that the Administrator "shall" prescribe testing where a substance "may possibly present an unreasonable risk" and insufficient data exists to conclude that such risk does or does not exist, or "is produced in substantial quantities, or enters the environment in substantial quantities, or will result . . . in substantial exposure . . . , or is closely related to chemicals known to be hazardous, or is listed by another Federal agency as carcinogenic, teratogenic, or mutagenic. . . ."

Though § 4(a) as enacted adopts a fully mandatory approach, the partial exemption for mixtures is a significant limitation on the number of chemicals potentially subject to a testing rule.

stances which "indirectly present unreasonable risks, as well as those which directly present such risks."[125] This interpretation was confirmed by Rep. Murphy, House Manager of the legislation, who suggested, through specific examples, that very slight evidence of a hazard might be enough to trigger the testing authority.[126]

The finding with respect to production or exposure of a substance is intended to reflect a need for testing even if no information exists indicating that the substance may be *per se* hazardous. According to the House Report, a finding of substantial exposure is not an inflexible standard, and, in addition to volume of production or exposure at a given time, the Administrator should consider such factors as the duration, intensity, and extent of human and environmental exposure.[127]

Subsection (b) sets forth various procedural details of the testing authority. Among these are the contents of a testing rule,[128] factors to be considered by the Administrator in prescribing test standards, a requirement that he occasionally review and revise those standards, a requirement that manufacturers of a substance conduct testing and submit data on such substance, and the procedure for issuance of a testing rule.[129]

Subsection (c) is intended to prevent duplication of data and needless expense to manufacturers by permitting the Administrator

125. CONF. REP., 94TH CONG., *supra* note 48, at 60. The committee continued: "Further, the conferees do not intend that a substance or mixture must be the single factor which results in the presentation of the risk. Oftentimes an unreasonable risk will be presented because of the interrelationship or cumulative impact of a number of different substances or mixtures." *Id.* at 60-61.

126. For example, if one substance is structurally similar to a second chemical with known adverse health or environmental effects, the Administrator could reasonably conclude that the first chemical may present an unreasonable risk and therefore require testing of it to determine its health and environmental effects. Or if there is reliable preliminary data indicating that a substance may be dangerous, again it would be reasonable to conclude that the chemical may present an unreasonable risk and that additional testing should be done.
122 CONG. REC. H11346 (daily ed. Sept. 28, 1976).

127. H.R. REP., 94TH CONG., *supra* note 42, at 18.

128. A subsection (a) rule shall include the name of the substance, standards for development of test data, and the time period for submission of results. 15 U.S.C.A. § 2603(b)(1) (West Supp. 1977).

129. This procedure is drawn from the Administrative Procedure Act (A.P.A.), 5 U.S.C. § 553 (1977), except that interested persons shall have opportunity to give oral argument in addition to written submissions, and the Administrator must publish in the *Federal Register* his justification for the rule. 15 U.S.C.A. § 2603(b)(5) (West Supp. 1977).

to grant exemptions from testing requirements and to order reimbursement by one manufacturer to another for testing costs.[130] If on application the Administrator determines that a substance is equivalent to another substance for which data has been or is being submitted and that submission of test data by the applicant would be duplicative, the Administrator must grant an exemption to the applicant. If an exemption is granted, the Administrator shall order the person exempted to provide "fair and equitable reimbursement" for a portion of the testing costs to the persons who previously submitted or are submitting test data on the substance. Absent agreement among the parties, the Administrator is to determine the proper amount of reimbursement, considering "all relevant factors including the relative competitive positions" of the parties involved to insure that small businesses are not assessed an undue percentage of the testing costs.

Subsection (d) assures public access to test data submitted pursuant to this section by requiring the Administrator to publish in the *Federal Register* within 15 days of receipt of any test data the name of the substance, a list of intended uses, and a description of the test data. It further provides that the test data shall be made available to anyone, except as otherwise provided in § 14 of the Act[131] concerning disclosure of data.

Subsection (e) establishes an interagency advisory committee[132] to make recommendations to the Administrator regarding the substances to be given top priority consideration for a testing rule. It requires that the committee compile a "priority list"[133] of 50 substances and periodically publish that list in the *Federal Register*, and it directs that within two months of inclusion of a substance on

130. S. REP., 94TH CONG., *supra* note 7, at 16.

131. 15 U.S.C.A. § 2613 (West Supp. 1977).

132. One member is to be appointed by each of the following: the Administrator of EPA, the Secretary of Labor, the Chairman of CEQ, the Director of the National Institute for Occupational Safety and Health (N.I.O.S.H.), the Director of the National Institute of Environmental Health Sciences (N.I.E.H.S.), the Director of the National Cancer Institute, the Director of the National Science Foundation, and the Secretary of Commerce. *Id.* § 2603(e)(2)(A).

133. In compiling this list, the committee shall consider such factors as the quantities in which a substance will be manufactured, the quantities in which it will enter the environment, the number of individuals likely to be exposed in their places of employment, the likely extent of human exposure, the extent it is related to a substance known to be hazardous, the existence of data concerning its effects, the probable success of testing to determine its effects, and the reasonably foreseeable availability of facilities and personnel for performing testing. *Id.* § 2603(c)(1)(A).

the list, the Administrator either initiate a rulemaking proceeding to establish a testing rule or publish in the *Federal Register* his reasons for inaction.

The language of this subsection is adopted primarily from the Senate bill, though the House amendment did not differ significantly. Most notable variations were the absence in the latter of any provision for publication by the committee of its priority list or for explanation by the Administrator of his failure to act with respect to a listed substance. As to the requisite specificity of the Administrator's explanation, the legislative history is inconclusive. According to the Senate committee, his statement should be "specific and . . . explain in some detail why the conditions for testing under subsection (a) are absent."[134] The conference committee, on the other hand, indicated that the Administrator should not "divert from the regulatory activities of the Agency an inordinate amount of resources to justify the failure to require testing."[135] By holding the Administrator accountable to the committee, at least insofar as he must respond to its recommendations, this provision gives the committee more than the purely advisory function delegated to it by the House amendment. The Conference Report makes clear, however, that though the interagency committee recommendations shall be given "great weight . . . , the decision to require testing rests with the Administrator."[136]

Subsection (f)[137] requires that the Administrator, within 180 days of receipt of information indicating ". . . there may be a reasonable basis to conclude that a chemical substance or mixture presents or will present a significant risk of serious or widespread harm to human beings from cancer, gene mutations, or birth defects," either (1) take action under the Act against the substance to prevent or reduce the risk or (2) publish in the *Federal Register* a finding that such risk is not unreasonable. This subsection is a modified version of a similar but more broadly applicable Senate bill provision which required only that the information indicate that a substance "has the potential . . . to induce in human beings (1) cancer, (2) gene mutations, or (3) birth defects. . . ."[138]

134. S. REP., 94TH CONG., *supra* note 7, at 17.

135. CONF. REP., 94TH CONG., *supra* note 48, at 62.

136. *Id.*

137. This subsection takes effect two years after date of enactment. 15 U.S.C.A. § 2603(f)(2) (West Supp. 1977).

138. S. 3149, § 4(f), 122 CONG. REC. S4420 (daily ed. Mar. 26, 1976). The House amendment contained no equivalent authority.

Subsection (g)—drawn from § 5(h) of the House amendment—authorizes any person intending to manufacture or process a substance not subject to a testing rule to petition the Administrator to prescribe standards, and sets time limitations for the procedure. According to the House Report, this petition procedure is intended for use only after informal consultation with appropriate EPA officials fails to provide guidance.[139]

Section 5—Manufacturing and Processing Notices[140]

This section is the heart of the Act. In conference committee, where much of the language was drafted, it was the center of contention,[141] and as enacted it represents more clearly than any other section the compromise necessary to finalize this legislation. The primary purpose of § 5 is to insure review and evaluation of chemical substances to determine whether regulation of their manufacture, processing, distribution, use or disposal is appropriate.[142] Its basic premise is that "the most desirable time to determine the health and environmental effects of a substance, and to take action to protect against any potential adverse effects, occurs before commercial production begins."[143]

The principal stumbling block to final approval in previous years—whether to require universal or limited pre-market notification of new chemical substances—was substantially resolved prior to conference.[144] Universal notification was finalized in *subsection*

139. H.R. REP., 94TH CONG., *supra* note 42, at 62.

140. 15 U.S.C.A. § 2604 (West Supp. 1977).

141. *See* note 45 and accompanying text *supra*.

142. CONF. REP., 94TH CONG., *supra* note 48, at 65.

143. *Id.*

144. During the 94th Congress, a wide range of pre-market notification proposals were devised. H.R. 7664 contained the most limited version, requiring prior notification only for those new chemical substances listed in advance by the Administrator as "likely to pose substantial danger to health or the environment," defined as "an unreasonable risk of death, of widespread or severe personal injury or illness, or of widespread or severe harm to the environment." An amended but similarly restricted procedure was incorporated in the House amendment—H.R. 14032—which applied notification requirements to a new substance (not a mixture) listed in advance by the Administrator as one which he finds "causes or significantly contributes to or may cause or significantly contribute to an unreasonable risk to health or the environment." Uses of existing substances found by the Administrator to be "significant new uses" were also subject to the requirements.

At the opposite extreme, H.R. 7548 dispensed with the prior listing, applied notification requirements to all new chemical substances, and required that the Administrator explicitly certify each substance before marketing was permitted. Universal

(a), which prohibits any person from manufacturing a new chemical substance[145] or manufacturing or processing an existing chemical substance for a use determined by the Administrator to be a "significant new use" without giving notice to the Administrator at least 90 days before commencing production. Where the Senate bill also mandated notification for significant new distributions or disposals, the final Act instead requires only that the Administrator consider those factors, in addition to others, in determining that a use is a significant new use.[146]

Subsections (b) through *(d)* detail the elements of the notification process. These include a description of the instances in which a person required to give notice must submit test data before production may begin, a requirement that data submitted be made available to interested persons, authority for the Administrator by rule to compile a list of substances which he finds "present . . . or may present" an unreasonable risk,[147] authority for the Administrator, upon good cause, to extend for up to 90 additional days the period of notification, and a description of the contents of a subsection (a) notice and of various publications to be made by the Administrator upon receipt of such notice.

Subsections (e) and *(f)*—the most controversial provisions of § 5—prescribe the authority of the Administrator to screen new chem-

notification was adopted by S. 776, H.R. 10318, H.R. 11576, S. 3149, and the Act as finally enacted, and was extended in each of these to include "significant new uses" of existing substances. To reduce the burden on industry and EPA, mixtures were excluded, first in part, then entirely. The certification procedure of H.R. 7548 was never seriously considered by the 94th Congress because, in view of the large number of new chemical substances introduced each year, it was promptly dismissed as administratively infeasible and prohibitively expensive.

145. "New chemical substance" denotes a substance not included on the inventory of all chemicals manufactured or processed in the United States which the Administrator is required by § 8(b) of the Act to publish. *See* notes 192-94 and accompanying text *infra*.

146. A use is designated a "significant new use" by the Administrator based on consideration of factors listed in § 5(a)(2) of the Act: the projected volume of manufacturing and processing, the extent to which the use changes the type or form of human or environmental exposure, the extent to which a use increases the duration of exposure, and the reasonably anticipated manner and methods of manufacturing, processing, distribution, and disposal of the substance.

147. Inclusion of a substance on this list increases the data submission requirements with which a manufacturer or processor of such substance must comply prior to commencement of production. 15 U.S.C.A. § 2604(b)(2) (West Supp. 1977). The significance of this authority is doubtful, however, because of the requirement that a substance can be listed only by full compliance with the rulemaking procedure described at note 129 *supra*. 15 U.S.C.A. § 2604(b)(4) (West Supp. 1977).

ical substances and significant new uses upon expiration of the notification period.[148] The Senate bill provided broad and immediate regulatory powers,[149] while the House amendment contained a far more cumbersome mechanism.[150] Drawing in part from § 701 of the F.F.D.C.A., the conference committee devised a hybrid substitute which "represents a melding of the Senate bill and the House amendment."[151] Essentially, this compromise pre-

148. Subsection (e) provides that if the Administrator finds (1) that insufficient information exists to evaluate the effects of a new chemical and (2) that, absent such data, it "may present an unreasonable risk" or that it will be produced in substantial quantity with significant environmental or human exposure, he may—though he is not required to—issue an order effective on expiration of the notice period to prohibit or limit the manufacture, processing, distribution, use, or disposal of the substance. The manufacturer may prevent that order from becoming effective by filing, within stated time limits, an objection "specifying with particularity the provision of the order deemed objectionable." The Administrator must then either withdraw the order or apply to a District Court to enforce it through an injunction which shall issue if the court makes findings identical to those made by the Administrator. The court is authorized to issue a temporary injunction if it determines that the notification period may expire prior to completion of the proceeding.

Under subsection (f), if the Administrator finds reasonable basis to conclude that a new chemical substance "presents or will present" an unreasonable risk before a regulation can become effective under § 6 of the Act, the Administrator is required to take one of the following actions: (1) issue a proposed rule under § 6(a) to limit—but not prohibit—the manufacture, processing, distribution, use, or disposal of the substance, and publish it in the *Federal Register*, at which time it becomes immediately effective; (2) issue a proposed order prohibiting such activities, but which is subject to the elaborate procedures described in subsection (e); or (3) apply to a District Court for a prohibitory injunction which shall issue if the court makes a finding identical to that made by the Administrator. The requirements which may be adopted under the first of these actions range from labeling or recordkeeping to prohibition of a particular use or limitation of the amount which can be produced. However, prohibition of a particular use may not be promulgated unless there is more than one practical use of the substance. CONF. REP., 94TH CONG., *supra* note 48, at 70-71. Prohibition of the *only* use of a substance would effectively prohibit *all* uses of the substance. Such an action is permitted only upon compliance by the Administrator with the procedures applicable to alternatives (2) and (3) above.

149. The Senate bill directed the Administrator to issue an immediately effective rule halting or limiting the manufacture, processing, distribution, use, or disposal of a new chemical substance if he found either (1) that a testing rule under § 4 should be promulgated or modified, or (2) that the substance "presents or is likely to present" an unreasonable risk. S. 3149, § 5(e), 122 CONG. REC. S4423 (daily ed. Mar. 26, 1976).

150. The House amendment authorized the Administrator to apply to a District Court for an injunction which could be granted only upon a finding by the court that insufficient data existed to evaluate the effects of the chemical substance and that, absent such data, the substance "may cause or significantly contribute to" an unreasonable risk. H.R. 14032, § 5(g), 122 CONG. REC. H8852 (daily ed. Aug. 23, 1976).

151. CONF. REP., 94TH CONG., *supra* note 48, at 68.

serves the Senate bill's grant of authority to the Administrator to issue a regulatory rule or order effective immediately upon expiration of the notification period. However, "to protect against unilateral action by the Administrator without an adequate basis for action,"[152] it provides that the manufacturer of the substance at issue may file timely objections and thereby prevent that rule or order from becoming effective. If objections are filed—and in cases of significance it seems probable that they would be—the Administrator must apply to a District Court for enforcement of the regulation, in accord with the House amendment procedure.

The crucial element of this conference substitute is the provision for objection by a manufacturer or processor. As noted, the statute provides that a proposed order will not take effect if objections are filed "specifying with particularity the provisions of the order deemed objectionable."[153] However, it is unclear—and the legislative history is divided—on the question of whether the Administrator may refuse to recognize an inadequately stated objection. In a House speech, Rep. Broyhill stated the purpose of the provision as one only of notice to the Administrator that the order is objectionable, implying no power by him to scrutinize the sufficiency of the complaint.[154] Senator Magnuson, on the other hand, advanced a significantly different interpretation in the Senate, where he cited legal precedent construing the analogous provision in § 701 of the F.F.D.C.A. to permit the designated Agency official to disregard objections not supported by reasonable grounds.[155] The Confer-

152. *Id.*

153. 15 U.S.C.A. § 2604(e)(1)(C) (West Supp. 1977).

154. The purpose of this provision is to put the Administrator on notice as to the objections of the manufacturer or processor. However, the Administrator could not put the proposed order into effect because he determined that the objections of the manufacturer were either unmeritorious or not of sufficient specificity. It is enough that the Administrator be on notice that objections do lie against the proposed order.

122 CONG. REC. H11344 (daily ed. Sept. 28, 1976).

155. Senator Magnuson explained:

As the entire procedure is similar to that contained under section 701(e) of the Federal Food, Drug and Cosmetic Act, the provision will operate in the same manner.

For example, under the case law developed pursuant to that section—*Pfizer, Inc. v. Richardson*, C.A.2, 1970, 434 F.2d 536—as it applies to this act, the Administrator may require that reasonable grounds be stated by a manufacturer or processor as a condition for recognizing that objections have been filed. Thus, under the procedure adopted by the conference, the Administrator may indeed

ence Report does not explicitly resolve this disagreement. However, it does note that the "conference substitute borrows the procedure from section 701(e) of the [F.F.D.C.A.] . . . ,"[156] thus seeming, by implication at least, to lay a basis for Magnuson's not unreasonable conclusion that case law interpretation of the existing statute should be applicable to a similar provision in the new Act. Furthermore, Broyhill's contention that the Administrator has no authority to question the sufficiency of objections would effectively make surplusage of the statutory requirements of specificity and particularity.

Subsection (g), adopted from the Senate bill,[157] directs the Administrator, if he has initiated no action within the notification period against a substance with respect to which notification was given, to publish in the *Federal Register* a statement of his reasons for not acting. The Senate provision, known as the Durkin amendment, specified no exceptions, while the House amendment contained no comparable requirement. Because both House and Senate conferees considered this an issue of some importance, a compromise was devised by the conference committee limiting the applicability of the provision. As enacted, the chemical substances for which such a statement is required are those subject to a testing rule under § 4, those listed under § 5(b) as potentially hazardous, and those for which notification is required as a significant new use. With respect to the content of the Administrator's publication, Senator Magnuson stated the appropriate response: "that the Administrator's response must be . . . that no unreasonable risk exists or that a testing need does not exist."[158] His explanation is confirmed by the Senate Report.[159]

exercise flexibility in determining whether or not objections have been filed and thus whether or not his order is rendered ineffective.

If the Administrator determines that valid objections have been filed, then he is required either to seek an injunction or to dismiss the order. If he decides the objections are not reasonable, then the proposed order becomes effective upon the expiration of the pre-market notification. Any manufacturer who disagrees with the Administrator's determination that the grounds are not reasonable is entitled to judicial review under chapter 7 of title 5, United States Code.

Id. at S16803.

156. CONF. REP., 94TH CONG., *supra* note 48, at 68.

157. S. 3149, § 5(f), 122 CONG. REC. S4423 (daily ed. Mar. 26, 1976).

158. 122 CONG. REC. S16803 (daily ed. Sept. 28, 1976).

159. "It is anticipated that the Administrator's statement in the *Federal Register* will be specific and contain sufficient information explaining why there are no unreasonable risks which should have been protected against or a need for more test data." S. REP., 94TH CONG., *supra* note 7, at 18.

Subsection (h) authorizes the Administrator to grant certain exemptions[160] from the provisions of § 5 of the Act and directs that he publish a notice of all applications for exemptions and of their dispositions.[161]

Section 6—Regulation of Hazardous Chemical Substances and Mixtures[162]

Subsection (a) directs the Administrator to take regulatory action by rule against an existing chemical substance or mixture for which he finds there is reasonable basis to conclude that the manufacture, processing, distribution, use, or disposal "presents or will present" an unreasonable risk. This basic finding was adopted in lieu of a narrower House standard ("causes or significantly contributes to"[163]) and a broader Senate test ("presents or is likely to present."[164]) Subsection (a) further provides that such action shall consist of the least burdensome yet effective of several enumerated requirements ranging from total prohibition of the substance to mere notice of potential risk. Both the House and Senate Reports suggest that this authority is to be interpreted broadly and should extend to situations where absolute certainty of causality and of the existence of an unreasonable risk is impossible, as is likely to occur with respect to chronic and synergistic effects of a substance.[165]

160. The following exemptions are authorized: (1) from the notification requirements where a substance is intended for test-marketing purposes, upon a showing of no unreasonable risk and under such restrictions as the Administrator considers appropriate; (2) from the data submission requirements where submission would be duplicative; (3) from the notification requirements where a substance is intended for scientific experimentation if all persons engaged in such activities are notified of the risks; (4) from any or all § 5 requirements where a new chemical substance is determined by rule not to present an unreasonable risk; and (5) from the notification and data submission requirements where a substance which exists only temporarily as a result of a chemical reaction will cause no human or environmental exposure.

161. Omitted from § 5 of the Act was a Senate bill provision authorizing the Administrator to "specify any mixture which shall be subject to the provisions of this section." S. 3149, § 5(j), 122 CONG. REC. S4424 (daily ed. Mar. 26, 1976). As enacted, § 5 is inapplicable to mixtures.

162. 15 U.S.C.A. § 2605 (West Supp. 1977).

163. H.R. 14032, § 6(a), 122 CONG. REC. H8854 (daily ed. Aug. 23, 1976).

164. S. 3149, § 6(a), 122 CONG. REC. S4424 (daily ed. Mar. 26, 1976).

165. The authority of section 6(a) is broad enough to authorize the control of those chemical substances or mixtures which may not be the sole cause of an unreasonable risk . . . The authority is also broad enough to reach those chemical substances which may enhance the toxic properties of other substances or mixtures through the processes known as synergism or potentiation.

S. REP., 94TH CONG., *supra* note 7, at 20.

This standard for taking action recognizes that factual certainty respecting the

However, this subsection does not grant authority either to regulate the transportation of hazardous substances or to promulgate work place standards.[166]

Subsection (b) authorizes the Administrator to review and revise a manufacturer's quality control procedures where the Administrator has reasonable basis to conclude that the manufacturing is being conducted in a manner which unintentionally causes a substance to present an unreasonable risk. A Senate bill provision granting authority to assign production, distribution, and use quotas was omitted in conference because of its potential effect on the competitive position of a manufacturer.[167]

Outlined in *subsection (c)* are provisions relevant to promulgation of a subsection (a) rule. The Administrator is directed to "consider and publish a statement with respect to" the effects of a substance on the environment and humans, the magnitude of exposure, the benefits of its use, and the "reasonably ascertainable economic consequences of the rule . . . ."[168] According to the Senate Report, consideration of this economic factor should insure that benefits are balanced against costs incurred, but it must not be permitted to overshadow non-quantitative concerns.[169] This subsection also requires that the Administrator use other federal regulatory statutes administered in whole or in part by him if he finds that a risk can be eliminated or sufficiently reduced by actions

existence of an unreasonable risk of a particular harm may not be possible and the bill does not require it. Such uncertainty is particularly likely to occur true when dealing with the long term or chronic effects of a substance or mixture . . . When, as here, regulatory action is intended to be taken to prevent the occurrence of harm in the future as well as protect against presently visible harm, such action often must be based not only on consideration of facts but also on consideration of scientific theories, projections of trends from currently available data, modeling using reasonable assumptions, and extrapolations from limited data. Further, regulatory action may be taken even though there are uncertainties as to the threshold levels of causation.

H.R. REP., 94TH CONG., *supra* note 42, at 32.

166. *Id.* at 34. *See also* 122 CONG. REC. E5585 (daily ed. Oct. 1, 1976) (statement by Rep. Murphy of New York).

167. S. 3149, § 6(a)(2), 122 CONG. REC. S4424 (daily ed. Mar. 26, 1976).

168. 15 U.S.C.A. § 2605(c)(1) (West Supp. 1977).

169. The Report states:

In comparing risks, costs, and benefits, however, it is important to recognize that one is weighing noncommensurates, and it is not feasible to reach a decision just on the basis of quantitative comparisons. The burdens of human suffering and premature death are extraordinary and must be given full consideration in such decisions.

S. REP., 94TH CONG., *supra* note 7, at 13.

taken under them, unless he finds also that it is in the "public interest" to utilize § 6 of this Act. The finding of "public interest" is explicitly committed to the discretion of the Administrator and, according to the Conference Report, is not subject to judicial review.[170] A similar deferral provision appears in § 9 of the Act.[171] Finally, subsection (c) describes the rulemaking procedure applicable to § 6(a) rules[172] and provides authority to the Administrator to grant fees for attorneys and experts where, in light of enumerated criteria, such an award is appropriate.[173]

Subsection (d) directs the Administrator to specify the date on which a rule shall become effective, "which date shall be as soon as feasible." It further provides discretionary authority to make a proposed rule immediately effective upon publication in the *Federal Register* if the Administrator determines that a substance is "likely to result in an unreasonable risk of serious and widespread injury . . . ," early effectiveness is "necessary to protect the public interest," and, in the case of a proposed rule of prohibition, judicial

170. CONF. REP., 94TH CONG., *supra* note 48, at 76.

171. *See* notes 200-05 and accompanying text *infra*.

172. The procedure set forth in the A.P.A., 5 U.S.C. § 553 (1977), is modified to include, *inter alia*, opportunity for an informal hearing with cross-examination and verbatim transcripts for public scrutiny. Elements of the hearing procedure are also specified.

173. 15 U.S.C.A. § 2605(c)(4) (West Supp. 1977). This attorney's fees provision is based upon statutory authority regarding participation in rulemaking proceedings before the Federal Trade Commission (FTC), 15 U.S.C. § 57(a)-(h) (Supp. V 1975). The FTC has adopted implementing regulations, 16 C.F.R. § 1.17 (1977), which may provide the basis for similar EPA regulations. An extensive legislative history to aid in the interpretation of the provision enacted here appears in H.R. REP., 94TH CONG., *supra* note 42, at 37-39. To insure legislative consistency, that section of the House Report was introduced verbatim into the *Congressional Record* by Senator Magnuson. Only a small portion of it is included here:

> Such fees and costs may be provided to any person who represents an interest which will substantially contribute to a fair determination of the issues to be resolved in the proceeding if the economic interest of the person is small in comparison to the costs of effective participation by that person in the proceeding or if the person demonstrates to the satisfaction of the Administrator that the person does not have sufficient resources to participate in the proceeding in the absence of compensation. In determining if a person represents an interest which will substantially contribute to a fair determination of the issues, the Administrator is to take into account the number and complexity of the issues and whether representation of such interest will contribute to widespread public participation and to representation of a fair balance of interest for the resolution of the issues.

122 CONG. REC. S16804-05 (daily ed. Sept. 28, 1976).

relief under § 7[174] of the Act concerning imminent hazards has been granted with respect to the substance. Where a proposed rule is made effective upon publication, a specified expedited rulemaking procedure is to be utilized promptly.[175]

Subsection (e) sets forth special, time-phased requirements for PCB's, the only substance which is explicitly regulated by the Act. That this subsection was added to both Senate and House versions of the Act by floor amendment despite opposition to singling out one substance to the exclusion of others, is a reflection of the extremely hazardous nature of PCB's.[176] This subsection outlines a phased withdrawal of PCB's: within six months from date of enactment, rules must be promulgated to regulate disposal and labeling; after one year, manufacturing, processing, or distribution in other than totally enclosed systems is prohibited; after two years, all manufacture is prohibited; after two and one-half years, all processing or distribution is prohibited. Exemptions can be granted by the Administrator where, pursuant to a petition, he finds no unreasonable risk will result and good faith efforts have been made to develop a substitute.[177]

Paragraph (5) of subsection (e) explicitly states that inclusion of special provisions for regulation of PCB's does not in any way limit the authority of the Administrator to take action respecting PCB's under any other provision of the Act or any other Federal statute.

Section 7—Imminent Hazards[178]

Subsection (a) authorizes the Administrator to initiate a District Court proceeding for seizure or other relief against an imminently

174. 15 U.S.C.A. § 2606 (West Supp. 1977).

175. 15 U.S.C.A. § 2605(d)(2)(B) (West Supp. 1977). This subsection was drawn from the House amendment. H.R. 14032, § 6(d), 122 CONG. REC. H8849 (daily ed. Aug. 23, 1976). The Senate version differed significantly only in the authority of the Administrator to make immediately effective a proposed rule of prohibition, without first securing judicial relief under the imminent hazard authority. S. 3149, § 6(d), 122 CONG. REC. S4420 (daily ed. Mar. 26, 1976).

176. During debate in the House, Rep. Leggett (D. Cal.) quoted EPA Administrator Train: "So far as I am concerned, there is absolutely no disagreement whatsoever that PCB's should be eliminated, all uses should be gotten rid of just as rapidly as we can." 122 CONG. REC. H8832 (daily ed. Aug. 23, 1976).

177. According to Rep. Broyhill, PCB's already in existence are also exempted: "Equipment now in existence containing PCB's is clearly exempted from this ban. Similarly, any PCB substance in existence would also be exempted from the ban on processing and distributing in commerce if sold or used to maintain existing equipment or transported for purposes of disposal." 122 CONG. REC. H11344 (daily ed. Sept. 28, 1976).

178. 15 U.S.C.A. § 2606 (West Supp. 1977).

hazardous substance or an article containing the substance, or against any person who manufactures, processes, distributes, or disposes of it. To insure that this authority is utilized, § 7(a) action is mandatory if a regulatory rule has not been made immediately effective under § 6(d) with respect to the imminent hazard. *Subsection (b)* grants jurisdiction to the court to adopt "such temporary or permanent relief as may be necessary to protect" against unreasonable risk. Relief against a person may include requirements of notification to customers of the risk, notice to the public of the risk, recall or replacement of the substance, or any combination of these.

This authority drew criticism from environmentalists who urged that the Administrator be authorized to take all necessary action—including prohibition and seizure—against imminent hazards without first having to secure a court order.[179] According to this view, the judicially-triggered mechanism is too cumbersome to effectively control substances posing imminent danger, and, therefore, the probable consequence of the inclusion of such a procedure in § 7 of the Act is virtual assurance that the imminent hazard authority will seldom be utilized. If past experience is any indication of future conduct, this analysis is not unfounded.[180] Further, because all restrictions short of prohibition or seizure can be made immediately effective against an imminent hazard pursuant to § 6(d) of the Act without resort to the courts, it is unlikely that EPA—already "overcommitted, understaffed, and battle-weary"[181]—will expend its limited resources in initiation of a potentially time-consuming and costly court action to achieve prohibition of the substance, however justified that final measure of protection may be.[182]

Subsections (c), (d), and *(e)* outline provisions relating to concurrent promulgation of a rule under § 6(a) of the Act and to pro-

179. H.R. HEAR., 94TH CONG., *supra* note 10, at 177.

180. Existing statutes incorporating a procedure which does not require court action are F.I.F.R.A., 7 U.S.C. § 136 *et seq.* (Supp. V 1975), and the F.F.D.C.A., 21 U.S.C. § 301 *et seq.* (1970). According to E.D.F. counsel Warren, "a bit of research into recent cases will indicate that the ony [*sic*] actions that are ever taken in case of imminent hazard are under those acts." H.R. HEAR., 94TH CONG., *supra* note 10, at 178.

181. *Id.* at 193 (statement by N.R.D.C. representative Speth).

182. By entrusting the final decision to individual judges—some of whom may be unsympathetic to environmental concerns or unable to comprehend the often technical problems—rather than the agency of the government whose function it is to protect the environment, the possibility is increased that a prohibition, even where justified, will be denied based on whim or an insufficient understanding of the problems involved.

cedural aspects of imminent hazard litigation under § 7(a), such as venue, consolidation, and representation of the Administrator.

The term "imminently hazardous chemical substance or mixture" is defined in *subsection (f)* as "a chemical substance or mixture which presents an imminent and unreasonable risk of serious or widespread injury to health or the environment." A risk is "imminent" if production, distribution, or use of the chemical "is likely to result in such injury to health or the environment before a final rule under [§ 6] can protect against such risk."[183] According to the Conference Report, the phrase "widespread injury" is intended to denote not merely geographically widespread injury, but "an unreasonable risk of harm affecting a substantial number of people, even though it is within a rather limited geographic area . . . ."[184] With respect to the relation of physical harm to the imminent risk concept, the Report states clearly that it is the risk which must be imminent and not the actual injury or its physical manifestations.[185] Recognition of this distinction and of the fundamental importance of "risk" independent of "actual injury" is crucial if the intent of the conferees is to be realized: that "action under the imminent hazard section be able to occur early enough to prevent the final injury from materializing."[186]

Section 8—Reporting and Retention of Information[187]

Subsection (a) mandates that the Administrator issue rules requiring manufacturers and processors (other than those considered small businesses) to maintain and submit such records as the Administrator "may reasonably require," or, in the case of mixtures or

183. 15 U.S.C.A. § 2606(f) (West Supp. 1977). Section 7 of the Senate bill defined an imminent hazard as existing where "continued use of a chemical substance would be likely to result in unreasonable adverse effects on the environment or will involve an unreasonable hazard to the survival of a species declared endangered . . ." S. 3149, § 7(a), 122 CONG. REC. S4420 (daily ed. Mar. 26, 1976). *See* notes 120 & 121 and accompanying text *supra*.

184. CONF. REP., 94TH CONG., *supra* note 48, at 78.

185. The Report states:

> The conferees wish to note that while the unreasonable risk of injury must be imminent, the physical manifestations of the injury itself need not be. Rather, an imminent hazard may be found at any point in the chain of events which may ultimately result in injury to health or the environment. The observance of actual injury is not essential to establish that an imminent hazard exists.

Id.

186. *Id.*

187. 15 U.S.C.A. § 2607 (West Supp. 1977).

chemical substances for research, as determined by the Administrator to be "necessary for the effective enforcement of this Act."[188] Along with a caveat that the Administrator shall not require any unnecessary or duplicative reporting, a list is provided illustrative of the kinds of information with respect to which recordkeeping and reporting may be required "insofar as known to the person making the report or insofar as reasonably ascertainable."[189]

The potentially discriminatory effect of regulation on small manufacturers and processors was a major concern of industry throughout the development of the Act. To alleviate this concern, less demanding provisions were added to this subsection to protect small businesses from "unreasonably burdensome reporting requirements."[190] As enacted, § 8(a) authorizes the Administrator to require reporting from small manufacturers only under certain specified circumstances.[191]

Subsection (b) directs the Administrator to compile, keep current, and publish an inventory of each chemical substance manufactured or processed in the United States. Because it is this inventory which determines whether a particular substance is a "new chemical substance" for purposes of pre-market notification pursuant to § 5 of the Act, it is critical that existing substances be precisely defined to include only the particular substance and variations of it which do not affect its toxicity.[192] On the other hand,

188. Regarding interpretation of this phrase, Senator Magnuson stated:

> [T]he phrase "effective enforcement of this [A]ct" . . . should be used broadly. It is not meant to imply that such records and reports may only be required in order to effectively bring an enforcement action under section 16 [of the Act]. Rather it should be interpreted to mean requiring records and gathering reports so that the authorities of the act may be indeed invoked, if necessary.

122 CONG. REC. S16804 (daily ed. Sept. 28, 1976).

189. The list includes: (1) the trade name, chemical identity, and molecular structure; (2) the categories of use; (3) the amounts; (4) a description of byproducts; (5) all existing data concerning the environmental and health effects; (6) the number of individuals exposed or who will be exposed; and (7) the method of disposal.

190. CONF. REP., 94TH CONG., *supra* note 48, at 80.

191. The Administrator may by rule require reporting by a small manufacturer with respect to substances subject to a testing rule under § 4, a rule under § 5(b)(4) including the substance on a list of potentially hazardous substances, a regulatory rule under § 6, a regulatory order under § 5(e), or with respect to which relief has been granted pursuant to a civil action under § 5 or § 7. 15 U.S.C.A. § 2607(a)(3)(A) (West Supp. 1977).

192. Senator Magnuson emphasized the importance of narrow definition:

> With respect to the 8(b) inventory and its relationship to pre-market notification, EPA must be careful not to define contaminants too broadly with respect to substances on the section 8(b) inventory. If EPA were to do so, then there would be

it would be pointless and administratively infeasible to list as a unique chemical substance each slight modification in formulation. Accordingly, § 8(b)(2) of the Act authorizes the Administrator, in lieu of individual listings, to "list a category of chemical substances" in which a particular chemical substance is included. The House Report explains that this provision is intended to relieve chemical companies, particularly small ones, from an "extremely burdensome" situation where every insignificant change in a chemical's structure—no matter how innocuous its effects on health or the environment—would automatically be subject to the notification requirements of § 5.[193] The committee cautioned, however, that categories should be utilized only where the modification is understood to have an insubstantial effect on the toxicity of a substance.[194]

Section (c) requires any manufacturer, processor, or distributor of a chemical substance or mixture to maintain records of "significant adverse reactions"[195] to health or the environment alleged to have been caused by any substance or mixture. Duration of retention of these records is specified[196] and inspection by a representative of the Administrator is authorized. Among the records which shall be retained are "consumer allegations of personal injury or harm to health, reports of occupational disease or injury, and reports or complaints of injury to the environment. . . ."

Subsection (d) provides that the Administrator shall promulgate rules which require any manufacturer, processor, or distributor of a chemical substance or mixture to submit lists of health and safety studies conducted or initiated by or for them, known to them, or reasonably ascertainable by them, except that the Administrator

no pre-market notification for chemical substances with new or different contaminants than those which appear on the section 8(b) inventory.

122 CONG. REC. S16803 (daily ed. Sept. 28, 1976).

193. H.R. REP., 94TH CONG., *supra* note 42, at 44.

194. *Id.*

195. As to definition of a "significant adverse reaction," the Conference Report states:

> The seriousness, duration, and the frequency of reaction should be taken into account . . . . Because the ultimate significance of adverse reactions is difficult to predict, the conferees intend that the requirement to retain records err on the side of safety. Some very serious neurological disorders, for instance, at first present what appear to be trifling symptoms.

CONF. REP., 94TH CONG., *supra* note 48, at 81.

196. The periods are thirty years from discovery for reports of occupational effects and five years from discovery for other reports.

may exclude certain types where submission is unnecessary to carry out the purposes of the Act. Though the Act also states that the Administrator "shall require" submission of copies of the listed studies, the House Report interprets identical language in the House amendment to mean that copies "may" be required,[197] and the Senate bill explicitly adopted that approach.[198] Because of the potential volume and number of such studies, this interpretation seems preferable to a literal reading of the mandatory language of the Act.

Subsection (e) directs any manufacturer, processor, or distributor to notify the Administrator immediately of any information which "supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the enivronment . . . ," unless the person has actual knowledge that the Administrator already possesses the information. The Senate Report emphasizes that any such information must be given proper attention by the EPA in order to avoid a recurrence of tragedy similar to that which occurred at the Kepone plant in Hopewell, Virginia, after an employee complaint submitted to the Department of Labor was inadequately dealt with.[199]

Section 9—Relationship To Other Federal Laws[200]

During the six year history of the Act, this section was debated extensively: industry sought to limit the Administrator's regulatory authority to that of a gapfiller in order to avoid duplicative or overlapping regulation, while environmentalists urged that the Administrator be free to utilize whatever authority would provide the greatest measure of protection to health and the environment under all circumstances. As enacted, § 9 is a bifurcated compromise, distinguishing laws not administered by the Administrator from those in whole or in part under his authority. The section is complex and presents potential for much litigation.

Subsection (a) provides that if the Administrator has a reasonable basis to conclude that a substance "presents or will present" an unreasonable risk, and if, in his discretion,[201] he determines that

197. H.R. REP., 94TH CONG., *supra* note 42, at 45.

198. S. 3149, § 8(d)(2), 122 CONG. REC. S4420 (daily ed. Mar. 26, 1976).

199. S. REP., 94TH CONG., *supra* note 7, at 22.

200. 15 U.S.C.A. § 2608 (West Supp. 1977).

201. Under the House amendment, this determination was not committed to the Administrator's discretion and was, therefore, subject to judicial review. H.R. 14032, § 9(a), 122 CONG. REC. H8849 (daily ed. Aug. 23, 1976).

the risk may be "prevented or reduced to a sufficient extent" by action taken under a Federal law not administered by him, he shall request the administering agency to determine if such risk can be adequately addressed under its authority. Thereafter, the Administrator is prohibited from acting under § 6 or 7 of the Act with respect to the substance if the other agency either issues an order declaring that no risk is presented or within 90 days of its response initiates an action under its authority to prevent the risk.

Subsection (b) directs the Administrator to coordinate actions taken under this Act with those taken under other laws administered in whole or in part by him. If he makes findings similar to those made by him under subsection (a) but with respect to other statutes administered by him, he is required to use those other authorities to protect against the risk unless he determines, in his discretion, that "it is in the public interest to protect against such risk by actions taken under this [Act]."[202] With regard to that determination, the Conference Report states that, though it is discretionary and, therefore, not reviewable, the Administrator should review the other authorities and present his findings at the time he takes action under the Act.[203] Similarly, a reviewing court is "expected to require that the Administrator have examined the other authorities and present the results of that examination" when making his findings as to the public interest.[204]

Subsections (c) and *(d)* relate specifically to coordination with other agencies and the submission to Congress by the Administrator of an annual report on any coordination actions.[205]

202. 15 U.S.C.A. § 2608(b) (West Supp. 1977). The finding of "public interest"—drawn from the House amendment—was adopted in preference to the seemingly broader, yet equally amorphous, Senate bill language that a risk "may be more appropriately protected against" under the Act. S. 3149, § 9(b), 122 CONG. REC. S4420 (daily ed. Mar. 26, 1976).

203. CONF. REP., 94TH CONG., *supra* note 48, at 85.

204. *Id.*

205. Omitted was a Senate bill provision that "[n]othing contained in this section shall limit any requirement of section 4, 5 (other than section 5(e)(2)), or 8, or rules promulgated thereunder." S. 3149, § 9(e), 122 CONG. REC. S4420 (daily ed. Mar. 26, 1976). The Conference report noted, however, with regard to subsection (b) that:

> [T]he requirement to examine other EPA laws and to make determinations applies only when the Administrator takes regulatory action to protect against an unreasonable risk under this Act. It does not apply when the Administrator takes action necessary for the administration or enforcement of the Act, such as issuing recordkeeping requirements.

CONF. REP., 94TH CONG., *supra* note 48, at 85.

Subsection (a), by its terms, only restricts the Administrator's authority to act against an unreasonable risk under § 6 or § 7.

Section 14—Disclosure of Data[206]

Industry's principal objection to this section stemmed from a fear that trade secrets or confidential financial information would be publicly disclosed.[207] Accordingly, *subsection (a)* was drafted to explicitly prohibit disclosure by the Administrator of information which falls within the trade secrets and commercial or financial information exemption of the Freedom of Information Act (F.O.I.A.).[208] Such information must be disclosed, however, to officers or employees of the United States in connection with their official duties, to contractors with the United States where determined by the Administrator to be necessary for the satisfactory performance of a contract, or where the Administrator determines that disclosure is "necessary to protect health or the environment against an unreasonable risk." Further, such information "may be disclosed when relevant in any proceeding under this Act. . . ."

By particular reference to only one of the eight exemptions from disclosure listed under the F.O.I.A., the drafters have created an ambiguity as to whether the other seven were intended, for purposes of this Act, to be nullified by implication. Though this inference draws support from some rather obfuscatory discussion of the subsection by the conference committee,[209] other language of the Report seems to suggest more clearly that, though exemption (b)(4) is emphasized, all other exemptions are applicable as well.[210] The

206. 15 U.S.C.A. § 2613 (West Supp. 1977).

207. S. HEAR., 94TH CONG., *supra* note 5, at 127.

208. 5 U.S.C. § 552 (1977). § 552(b)(4) provides: "(b) This section does not apply to matters that are—(4) trade secrets and commercial or financial information obtained from a person and privileged or confidential."

209. In any proceeding under section 552(a) of title 5 to obtain information which the Administrator has refused to release on the basis that disclosure is prohibited by section 14(a) of this Act, the Administrator may not rely on section 552(b)(3) of title 5 to sustain the refusal to disclose the information. Thus the Administrator will have to show that the information falls within section 552(b)(4) of title 5. Of course, section 552 of title 5 is the vehicle through which the public can obtain information from the Federal government, and all the provisions of that section will apply to requests for information obtained under this Act.

CONF. REP., 94TH CONG., *supra* note 48, at 90-91.

210. In reference to disclosure of health and safety studies, the Report states:

[T]he Administrator may not deny a request under section 552 of title 5, United States Code, on the basis that such information is included in the exceptions to mandatory disclosure enumerated in subsection (b)(3) or (b)(4) of such section. It is also intended that the Administrator not use exception (b)(7) of section 552 of title 5, relating to matters under investigation, in an excessive manner as a device for withholding information submitted under this Act. In order to be with-

committee's discussion of other exemptions would be unnecessary if all exemptions other than that for trade secrets and commercial information were intended to be inapplicable to the disclosure provisions of this Act. Thus, one might reasonably conclude that the Administrator can deny requests for information on the basis of each 552(b) exemption unless it is within one of the three provisions of mandatory disclosure described in subsection (a).

Subsection (b) exempts health and safety studies from the prohibition in subsection (a).

Except in case of data required to be disclosed under subsection (a), *subsection (c)* permits a manufacturer, processor, or distributor to designate and submit separately data which he or she believes is entitled to confidential treatment, and, thereafter, requires that the Administrator notify such person of intended release of the data 30 days prior to release. Where disclosure of data is necessary to protect health or the environment, the notice period is 15 days; where release is necessary to protect against an imminent hazard, the period is 24 hours.

Subsection (d) specifies criminal penalties for wrongful disclosure (defined as knowing and willful): up to $5,000 or imprisonment for up to one year, or both. *Subsection (e)* mandates disclosure of any information to a congressional committee if requested in writing.[211]

Section 17—Specific Enforcement and Seizure[212]

This section grants jurisdiction over civil actions to District Courts on application by the Administrator or the Attorney General to restrain any violation of the Act, or of any regulations or orders issued under it, and to compel the taking of any action required by or under the Act. It further authorizes those officials to require violators to give notice of their illegal acts—both to the general public and to those in possession of violating substances—and to replace or repurchase such substances. *Subsection (b)* authorizes actions against a substance for seizure or condemnation.

During Senate Commerce Committee consideration of S. 3149,

held under that exception, the information must be the subject of an ongoing, active investigation.

Id. at 91.

211. Subsections (b) through (e) were drawn with minor modification from the House amendment. H.R. 14032, § 14(b)-(e), 122 CONG. REC. H8849 (daily ed. Aug. 23, 1976). The Senate bill contained no equivalent provisions.

212. 15 U.S.C.A. § 2616 (West Supp. 1977).

an amendment was introduced which was intended to overrule for purposes of this Act the controversial decision of the Eighth Circuit Court of Appeals in *Reserve Mining Co. v. United States*,[213] as it related to the issue of the burden of proof that a plaintiff must sustain in order to gain judicial relief. In an attempt to insure that "proof of demonstrable hazard to the public health" would not be deemed a prerequisite to relief by courts under § 17 of the Act, amendment # 21 was introduced in committee to prohibit a court from denying equitable relief under any statute administered by the EPA where a risk to public health is alleged and established.[214] This amendment was directed to situations in which evidence of a serious potential hazard exists though evidence is inconclusive. Because the Senate Committee felt that United States Court of Appeals decisions since *Reserve Mining* had clarified the standard in accord with the intention of the amendment, it was not included in S. 3149 as reported to the full Senate.[215] During Senate debate on the legislation in March, 1976, Senator Nelson introduced into the Congressional Record a Library of Congress American Law Division opinion in support of the conclusion reached by the Senate Committee.[216]

Section 18—Preemption[217]

This section describes the relationship between state and federal laws for the regulation of chemical substances and mixtures. *Subsection (a)* asserts the right of a state to regulate, except in two instances: first, a state may not establish or enforce a requirement for testing of a substance "for purposes similar to those for which testing" has been required by the Administrator under § 4 of the Act; and second, a state may not establish or enforce a requirement applicable to a substance and designed to protect against a risk if the Administrator has, pursuant to §§ 5 or 6 of the Act, prescribed a

213. 498 F.2d 1073 (8th Cir. 1974). In that decision, a three-judge panel denied a request for an injunction against the dumping of mining wastes into Lake Superior by the Reserve Mining Co. because the plaintiff had failed to establish a demonstrable hazard to the public health. Specifically, the court stated: "[W]e are a court of law, governed by rules of proof, and unknowns may not be substituted for proof of a demonstrable hazard to the public health." *Id.* at 1084.

214. S. REP., 94TH CONG., *supra* note 7, at 26.

215. *Id.*

216. 122 CONG. REC. S4418-19 (daily ed. Mar. 26, 1976).

217. 15 U.S.C.A. § 2617 (West Supp. 1977).

requirement applicable to that same substance and designed to protect against the same risk.

Preemption in the second instance is nullified, however, if the state requirement is identical to that prescribed by the Administrator, is adopted under the authority of another federal law, or is a total prohibition of the use of a substance. The provision regarding state requirements adopted under the authority of another federal law is explained more fully in the House Report. That Report cites "state emission standards, effluent limitations, or other regulatory requirements adopted under the Clean Air Act or Federal Water Pollution Control Act" as examples of state or local requirements which would not be preempted, even though they might be more stringent than the federal requirements.[218] The theory of the exception for state regulations which totally prohibit use of a substance within its boundaries is that the interest of a state in adequately protecting its citizens is preserved thereby, without significantly interfering with the interstate commerce of chemical substances and mixtures.[219] Though it does maintain one element of the state's prerogative, the drastic, "all-or-nothing" nature of the exception severely limits its utility in all but the most extreme situations. For that reason, its practical value may be minimal.

Subsection (b) authorizes the Administrator, upon application from a state, to exempt by rule from subsection (a)(2) a state requirement if compliance with it would not be in violation of the applicable federal requirement prescribed under the Act; if it provides a "significantly higher degree of protection" from a risk than does the federal requirement; and if it does not unduly burden interstate commerce.

218. Other illustrations included:

> [T]his would be the case if a State limitation, standard or requirement were adopted, submitted, and approved as part of a State implementation plan required under Federal law. Similarly, the preemption would not apply to a State or local limitation, standard, or requirement if it were adopted under the State or local government's authority which is preserved by a provision of Federal law, such as section 116 of the Clean Air Act or sections 1414(e) or 1424(c) of the Public Health Service Act (relating to safe drinking water).

H.R. REP., 94TH CONG., *supra* note 42, at 54. *See also* 122 CONG. REC. S4416 (daily ed. Mar. 26, 1976) (statement by Senator Tunney).

219. In a House speech, Rep. Murphy of N.Y. cited the following example:

> For instances (*sic*), a State could totally prohibit the use within its boundaries of a detergent containing a particular chemical substance. However, the State could not prohibit the manufacture or processing within the State of either the substance or the detergent, nor could it prohibit or limit interstate distribution of the substance. . . .

122 CONG. REC. H11346 (daily ed. Sept. 28, 1976).

Section 19—Judicial Review[220]

Subsection (a) authorizes "any person" to file, not later than 60 days after the promulgation of a rule under specified sections of the Act,[221] a petition for judicial review of such rule with a United States Circuit Court of Appeals, and elaborately defines the elements of the "rulemaking record." *Subsection (b)* empowers the court to order the Administrator to provide opportunity to make additional submissions and presentations for the record, on the basis of which the Administrator may modify or set aside the rule under review.

Subsection (c) provides that 5 U.S.C. § 706, concerning judicial review of administrative agency actions, shall apply to review of a rule under this section, with several enumerated exceptions, two of which are noted here. First, in the case of review of a rule under §§ 4(a), 5(b)(4), 6(a), or 6(e),[222] the court shall set aside the rule if it finds the rule is not supported by substantial evidence in the rulemaking record. Second, in the case of review of a rule under § 6(a), the court shall set aside a rule if it finds that a denial or limitation by the Administrator of cross-examination or of presentation by the petitioner of rebuttal submissions has precluded disclosure of disputed material facts necessary to a fair determination by the Administrator.

The traditional standard of review in essentially informal rulemaking proceedings such as those contained in the Act is that of "arbitrary and capricious, an abuse of discretion, or otherwise not in accordance with law."[223] This relatively relaxed test has been replaced under the Act, however, by the substantial evidence standard in order to focus the attention of the reviewing court on the rulemaking record "to see if the Administrator's action is supported by that record."[224] Adoption of this latter standard was the subject of criticism at congressional hearings[225] because it may se-

220. 15 U.S.C.A. § 2618 (West Supp. 1977).

221. The following sections, as codified in 15 U.S.C.A. (West Supp. 1977), are specified: § 2603(a)—testing rule; § 2604(a)(2)—rule determining significant new uses; § 2604(b)(4)—rule listing chemical substances that present or may present an unreasonable risk; § 2605(a)—rule imposing requirements on chemical substances or mixtures in order to protect against unreasonable health or environmental risks; § 2605(e)—rule regulating PCB's; § 2607—rule requiring recordkeeping or reporting.

222. *See* note 221 *supra*.

223. CONF. REP., 94TH CONG., *supra* note 48, at 96. *See generally* Citizens to Preserve Overton Park v. Volpe, 401 U.S. 402 (1971).

224. CONF. REP., 94TH CONG., *supra* note 48, at 96.

225. H.R. HEAR., 94TH CONG., *supra* note 10, at 179-80.

verely impair the Administrator's ability to take prompt action under key provisions of the Act. Some of the principal rulemaking provisions in §§ 4 or 5 are triggered by a finding of insufficiency of information and are intended to generate precisely the kind of clear evidence necessary to satisfy the standard. To require, then, that all such rules be supported by substantial evidence in the rulemaking record seems paradoxical. Indeed, this difficulty in establishing a substantial evidence basis for administrative agency determinations in an area of much scientific uncertainty has been recognized in decisions of several United States Circuit Courts of Appeals.[226]

Senator Magnuson was not unaware of the dilemma which this presents to the Administrator. In a Senate floor speech subsequent to conference, he suggested that the standard should not be strictly applied with respect to administrative agency determinations which, by nature, cannot be based on a solid factual foundation demonstrable in the record. Explaining that "it is not anticipated that this review standard will unduly hinder the Administrator," Magnuson stated that with respect to testing requirements based on an insufficiency of data under § 4 "it would not ordinarily be appropriate for the Administrator to develop 'substantial evidence' of that insufficiency."[227] To satisfy the statutory standard, he con-

226. Associated Industries of N.Y. State, Inc. v. United States Dep't of Labor, 487 F.2d 342, 354 (2d Cir. 1973) (Friendly, J.); Industrial Union Dep't, AFL-CIO v. Hodgson, 499 F.2d 467, 473-76 (D.C. Cir. 1974) (McGowan, J.); Synthetic Organic Chem. Mfrs. Ass'n v. Brennan, 503 F.2d 1155, 1157 (3d Cir. 1974); and Florida Peach Growers' Ass'n v. United States Dep't of Labor, 489 F.2d 120, 127 (5th Cir. 1974).

As explained by J. McGowan in *Hodgson*:

> [S]ome of the questions involved . . . are on the frontiers of scientific knowledge, and consequently as to them insufficient data is presently available to make a fully informed factual determination. Decision making must in that circumstance depend to a greater extent upon policy judgments and less upon purely factual analysis. . . . Judicial review of inherently legislative decisions of this sort is obviously an undertaking of different dimensions.
>
> . . . .
>
> The paramount objective is to see whether the agency, given an essentially legislative task to perform, has carried it out in a manner calculated to negate the dangers of arbitrariness and irrationality in the formulation of rules for general application in the future. Automotive Parts & Accessories Ass'n v. Boyd, 132 U.S. App. D.C. 200, 407 F.2d 330, 338 (1968).

499 F.2d at 474-75.

For further discussion of this issue under the Act and the potential use of *in vitro* tests to evaluate quickly the long-term effects of a substance, see *In Anticipation: Comparing the 1976 Toxic Substances Control Bills*, 6 ELR 10138, 10140-41 (1976); and *From Microbes to Men: The New Toxic Substances Control Act and Bacterial Mutagenicity/Carcinogenicity Tests*, *id.* at 10248.

227. 122 CONG. REC. S16804 (daily ed. Sept. 28, 1976). Though the Conference

tinued, the Administrator need only have made "a reasonable effort to find data . . . ," and, with respect to substances for which premarket notification is required, he "should not be required to look beyond the notification documents."[228]

Subsection (d) authorizes the court to include as part of its decision an award of costs and fees for attorneys and expert witnesses if the court "determines that such an award is appropriate."[229] *Subsection (e)* provides that the remedies set forth in this section shall be in addition to, not in lieu of, other penalties provided by law.

Section 20—Citizens' Civil Actions[230]

Ample precedent for a citizen civil action provision had been established by similar authorities in existing environmental statutes.[231] Though some legislators feared its potentially burdensome impact on EPA, the courts, and the chemical industry,[232] public interest groups lobbied strongly for its inclusion, and identical Senate bill and House amendments were finalized by the conference committee in this section. *Subsection (a)* authorizes any per-

Report does not explicitly consider these potential difficulties, the intent of the conferees is clearly expressed that a court shall not substitute its judgment for that of the Administrator. CONF. REP., 94TH CONG., *supra* note 48, at 96.

228. 122 CONG. REC. S16804 (daily ed. Sept. 28, 1976).

229. An extensive legislative history to aid in interpretation of this and similar attorney's fees provisions appearing later in the statute was read into the *Congressional Record* by Senator Tunney and again later by Senator Magnuson. That history reads in part:

> [I]n typical circumstances, the court should follow prevailing case law which holds that a successful plaintiff "should ordinarily recover an attorneys' fee unless special circumstances would render such an award unjust."
>
> . . ."Plaintiff" in this sense is used to mean the parties seeking to enforce the rights granted by this section and can include an intervenor, or a defendant in some cases. . . .
>
> . . . .
>
> For purposes of the award of fees and costs, it is "appropriate" to make awards where the parties have vindicated rights through a consent judgment, or without formally obtaining relief, or where such award is in the public interest without regard to the outcome of the litigation. . . .

122 CONG. REC. S4416-17 (daily ed. Mar. 26, 1976) and S16804 (daily ed. Sept. 28, 1976).

230. 15 U.S.C.A. § 2619 (West Supp. 1977).

231. Such provisions appear in § 304 of the C.A.A., 42 U.S.C. § 1857h-z (1970), *as amended* (Supp. IV 1974); § 505 of the F.W.P.C.A., 33 U.S.C. § 1365 (Supp. III 1973); and § 12 of the Noise Control Act, 42 U.S.C. § 4911 (Supp. V 1975). *See* H.R. REP., 94TH CONG., *supra* note 42, at 56. *See generally* Note, *Judicial Review of EPA Action Under the Citizen Suit Provision*, 3 COLUM. J. ENVT'L L. 262 (1977).

232. H.R. REP., 94TH CONG., *supra* note 42, at 139-41.

son to commence an action in a District Court against any person or government agency alleged to be in violation of the Act, of any rule promulgated under §§ 4, 5 or 6, or of any order issued under § 5. It further authorizes such an action against the Administrator to compel any duty under the Act which is not discretionary. *Subsection (b)* limits this right by providing that no action may be commenced until 60 days have expired after notification of the defendant,[233] or if the Administrator or Attorney General has already commenced and is "diligently prosecuting" an action to require compliance. *Subsections (c)* and *(d)* describe aspects of the litigation, such as intervention, consolidation, preemption of remedies, and authority for the court to award costs and reasonable fees for attorneys and experts where it "determines that such an award is appropriate."[234]

Though subsection (a) provides that an action may be commenced to compel the Administrator to perform "any act or duty under this Act which is not discretionary," neither the words of the statute nor its legislative history explicitly specify—except in a very few instances[235]—how such an act or duty is to be distinguished from one that is discretionary. Use of the verb "shall" rather than "may" in particular provisions of the Act may have been intended to designate non-discretionary powers subject to review; however, at least one decision of the District of Columbia Circuit Court of Appeals has held that ". . . preclusion of judicial review cannot be found in the mere fact that a statute is drafted in permissive rather than mandatory terms."[236] Thus, though the statutory phrasing is persuasive as to legislative intent, it is not by itself determinative and must be considered in light of its context and relevant history.

233. In the case of an action for failure of the Administrator to file an imminent hazard action, the 60 day period is reduced to 10 days.

234. *See* note 229 *supra*.

235. For example, 15 U.S.C.A. §§ 2605(c)(1) and 2608(b) (West Supp. 1977).

236. In Environmental Defense Fund v. Hardin, 428 F.2d 1093, 1096-97 (D.C. Cir. 1970), the court stated:

> Related to the question of standing is respondents' argument that the decision to suspend the registration of a pesticide as an "imminent hazard" is committed by statute to unreviewable administrative discretion . . . . Preclusion of judicial review is not lightly to be inferred, however; it requires a strong showing of clear evidence of legislative intent. That evidence cannot be found in the mere fact that a statute is drafted in permissive rather than mandatory terms. Although the F.I.F.R.A. provides that the Secretary "may" suspend the registration of an economic poison that creates an imminent hazard to the public, we conclude that his decision is not thereby placed beyond judicial scrutiny.

This holding—together with the inference which might be drawn from the drafters' explicit designation of discretionary powers in several provisions—provides the basis for an argument that acts or duties of the Administrator which are phrased in permissive terms, in addition to those in mandatory terms, should be subject to judicial scrutiny.

Section 21—Citizens' Petitions[237]

The Senate bill and the House amendment differed in a subtle yet significant way with respect to the scope of this section: S. 3149 authorized petitions only for issuance of a restrictive rule or order, while H.R. 14032 permitted petitions for issuance, repeal, or modification of such a rule or order. By increasing the actions which a petitioner may request under this provision, the House amendment provided a means apart from the rulemaking procedure itself whereby all regulatory rules may be challenged. Though on its face more neutral than the Senate provision, the House language posed an added danger that EPA's regulatory efforts would be hampered by vexatious litigation intended to divert the limited resources of the agency from promulgation of stricter controls to defense of existing controls. The Senate version, on the other hand, served to reinforce and direct the agency's enforcement efforts under the Act because it limited petitions to requests for increased regulation.[238]

As enacted, § 21 adopts the House approach and *subsection (a)* authorizes "any person" to petition the Administrator to initiate a proceeding for the issuance, amendment, or repeal of a rule or order pursuant to specified provisions of the Act.[239] *Subsection (b)* outlines the procedures attendant to a petition: within 90 days after filing, the Administrator must either grant or deny the petition; if he denies it, he must publish in the *Federal Register* his reasons; within 60 days after denial, the petitioner may commence a civil

237. 15 U.S.C.A. § 2620 (West Supp. 1977).

238. The ability of a petitioner to "direct" the efforts of EPA is limited under the final Act by a provision in subsection (b): if a court determines, after finding in favor of the petitioner seeking to initiate rulemaking, that the extent of the risk alleged by the petitioner is less than the extent of risks with respect to which the Administrator is already taking action and there are insufficient resources to act against both, the court may permit deferral of action on the petition until such time as the court prescribes. 15 U.S.C.A. § 2620(b)(4)(B) (West Supp. 1977).

239. A petition under this section may be used to initiate a proceeding under § 5(f) since a proceeding under that section is for the issuance of a rule under § 6(a). CONF. REP., 94TH CONG., *supra* note 48, at 98.

action in a District Court to compel the Administrator to take the desired action.

Thereafter, subsection (b) provides different types of review for petitions seeking to initiate rulemaking and those seeking to amend an existing rule or order. With respect to the former, the petitioner is entitled to have his or her petition considered in a *de novo* proceeding. If the petitioner demonstrates by a preponderance of the evidence that there is an adequate basis as prescribed in the Act for the issuance of the rule or order, the court shall order that the petition be granted. If, however, the petition seeks to amend an existing rule or order, no special provisions are specified and, according to the Conference Report, court review of denial of a petition is permitted only as prescribed in the A.P.A.[240] The provision of greater rights to a person seeking a new rule is based on the conferrees' belief that only such requests will not have been previously addressed by the Administrator. As to requests for amendment or repeal of an existing rule, the conferees' main concern was to make certain that "any such petitioner receive timely consideration of such petition."[241]

Subsection (b) provides further that the court may award costs and fees for attorneys and experts if it "determines that such an award is appropriate,"[242] and that the remedies under this section are in addition to, and not in lieu of, other remedies provided by law.

IV. CONCLUSION

The Toxic Substances Control Act has repeatedly been hailed as the most important environmental legislation to come before the 94th Congress.[243] A more realistic appraisal, perhaps, is that its true importance is as yet undetermined. To be sure, it creates valuable and needed authorities for testing, screening, regulation, and

240. *Id.* at 99.

241. *Id.* at 98-99. Regarding the substance of a petition to amend, the Report continued: "The conferees believe that a petition for amendment or repeal . . . should contain newly discovered, noncumulative material which was not presented for the Administrator's consideration in promulgating the rule or order. Failure to include such information would be an adequate basis for denying the petition." *Id.*

242. *See* note 229 *supra*.

243. Statement by President Ford, note 85 and accompanying text *supra*; statement by CEQ Chairman Peterson, H.R. HEAR., 94TH CONG., *supra* note 10, at 69; statement by Senator Magnuson, 122 CONG. REC. S16802 (daily ed. Sept. 28, 1976); statement by Rep. Murphy (of N.Y.), *id.* at H11345.

reporting with respect to chemical substances and mixtures; it empowers the EPA for the first time to control a chemical in a comprehensive rather than a piecemeal manner; and it places the burden of research and testing upon the chemical industry where it rightly belongs. Yet, it is far from perfect. The Act is a compromise with the economic realities of our time—or, more skeptically, with what the chemical industry would have us believe them to be. Further, it does not recognize as an attainable goal a zero-risk environment, but is directed solely to the amorphous, litigable, and more easily circumvented concept of "unreasonable risk." More specifically, it provides no time-phased schedule for the testing and regulation of existing chemicals, rejects pre-market certification of all new chemicals as a viable regulatory tool, and creates enforcement mechanisms which, because of their complexity, may hinder EPA's efforts to screen harmful substances from the market. Finally, it fails to authorize sufficient funds to assure full and successful implementation of its provisions.[244]

The crucial cause of uncertainty in predicting the future success or failure of the Act, however, is the tremendous discretion which it vests in the Administrator of the EPA to determine risks, to promulgate rules, to issue orders and initiate court actions, to grant exemptions, and, of course, to take no action at all. This element of discretion places a heavy burden on the Administrator to insure that the provisions of the Act are effectively utilized. Should he fail to adequately exercise his powers, the judicial review and citizen action provisions in §§ 19 through 21 provide means to compel him to do so. Ultimately, however, such mechanisms cannot assure the successful implementation of this Act; as it is drafted, only the Administrator can accomplish that.[245]

244. Authorization for appropriations to carry out the Act is as follows: $10.1 million for the fiscal year ending September 30, 1977; $12.625 million for the fiscal year ending September 30, 1978; and $16.2 million for the fiscal year ending September 30, 1979. 15 U.S.C.A. § 2628 (West Supp. 1977). Given the complexity of the toxic substances problem, this authorization is surprisingly low, and the Act is subject to valid criticism on that basis. However, EPA budget requests called for an amount even less than that ultimately approved because, as Acting EPA Administrator Quarles explained, EPA budget requests for previous years had included funds to handle work anticipated to be required should toxic substances legislation be approved. H.R. REP., 94TH CONG., *supra* note 42, at 71. It seems probable that the agency's recommendations for authorization were more an estimate of what OMB determined the President's budget would permit than of the amount reasonably necessary to appropriately carry out the broad purposes of the Act.

245. Early indications are not encouraging as administrative difficulties have hin-

At the least, the Toxic Substances Control Act of 1976 is a beginning, representing years of effort by legislators and lobbyists to obtain the strongest possible reform. Given the intense and prolonged opposition of the chemical industry and the high probability of veto by Presidents more sympathetic to the concerns of manufacturers than to the pleas of environmentalists, this initial legislation should not, because of its inadequacies, be dismissed as insignificant. Authority now exists pursuant to which the Administrator can act, by regulation, order, and court action, "to assure that . . . innovation and commerce in . . . chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment."[246] Should this authority prove insufficient to effect that broad purpose of the Act, then it is the responsibility of Congress swiftly and finally to remedy that insufficiency through stronger legislative measures.

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dered implementation of the Act since its effective date on January 1, 1977. On February 17, 1977, the Office of Toxic Substances issued a draft implementation plan suggesting priorities to be given to the various authorities and outlining proposed timetables applicable to such authorities. U.S. ENVIRONMENTAL PROTECTION AGENCY, ASSESSMENT AND CONTROL OF CHEMICAL PROBLEMS: AN APPROACH TO IMPLEMENTING THE TOXIC SUBSTANCES CONTROL ACT, Draft #3 (1977). Thus far, that timetable has not been followed, and as of December 31, 1977, only one set of final rules had been promulgated pursuant to the Act. These rules define inventory reporting procedures under § 8(a). 42 *Fed. Reg.* 64572 (1977). Proposed regulations with respect to the following areas have also been published: procedures for rulemaking under § 6, *id.* at 20640; reporting procedures for chlorofluorocarbons under § 6(a), *id.* at 24542; and marking and disposal of PCB's under § 6(e), *id.* at 26563. In addition, numerous miscellaneous notices have been published, including the following: guidance on notification of substantial risk under § 8(e), *id.* at 45362; Interagency Toxic Substances Strategy Committee work plan pertaining to data collection and research, *id.* at 57866; and temporary rules concerning compensation for public participation in rulemaking under § 6, *id.* at 60911.

For a recent newspaper report of the administrative problems which have complicated initial efforts by EPA to implement the Act, see Vinocur, *Major Enforcement Gaps Hobble Law to Control Toxic Substances*, N.Y. Times, Oct. 30, 1977, at 1, col. 4.

246. 15 U.S.C.A. § 2601(b)(3) (West Supp. 1977).