Vanderbilt Law Review

Volume 30
Issue 6 *Issue 6 - November 1977*

Article 2

11-1977

The Toxic Substances Control Act: A Regulatory Morass

Kevin Gaynor

The Toxic Substances Control Act: A Regulatory Morass

*Kevin Gaynor**

TABLE OF CONTENTS

I. INTRODUCTION

The Toxic Substances Control Act (TSCA or the Act),[1] which was signed into law in October of 1976, originated in a 1971 report by the Council of Environment Quality (CEQ). The CEQ report reviewed the problems presented by toxic chemicals and concluded

* Private Practice, Washington, D.C. Formerly staff attorney with the Environmental Protection Agency, Office of Legislation. B.A., University of Connecticut, 1970; J.D., University of Virginia School of Law, 1973.

1. Toxic Substances Control Act, Pub. L. No. 94-469, 90 Stat. 2003 (1976) (codified at 15 U.S.C.A. §§ 2601-2629 (Supp. 1977)) [hereinafter cited as TSCA].

that existing regulation was fragmented and inadequate.[2] The report pointed out the need for authority requiring the testing of chemicals to determine their health and environmental effects, restricting the use and distribution of some chemicals when necessary to protect human health and the environment, and providing for development of adequate data on the environmental and health effects of chemicals. During the Ninety-second and Ninety-third Congresses, the Senate and House each passed toxic substances legislation[3] based upon the CEQ report. The Senate and House could not work out differences between the two bills, however, and the legislation died at the conclusion of each session. The major point of contention concerned controls upon the entry into commerce of new chemicals.[4] A reading of section 5 of the TSCA,[5] which deals with new chemicals, reveals the tortured compromise the conferees developed to reconcile the two houses' views.

The legislation finally enacted by the Ninety-fourth Congress grants to the Administrator of the Environmental Protection Agency (EPA) broad authority to regulate the manufacture, processing, distribution in commerce, use, and disposal of chemical substances and mixtures. Because of the expansiveness of the term "chemical substance"[6] and the Administrator's broad regulatory authority, TSCA will affect the entire business community and most of the general public. Manufacturers, processors, and distribu-

2. The report is set forth in the legislative history of TSCA. LEGISLATIVE HISTORY OF THE TOXIC SUBSTANCES CONTROL ACT 757 (1976) [hereinafter cited as LEGISLATIVE HISTORY].

3. The present law had its beginnings in the Ninety-second Congress with Senate Bill 1478. The Senate passed the bill on May 30, 1972, but given the delay of passage in the House, the differences between the two bills were not reconciled in conference. The same scene reproduced itself in the Ninety-third Congress as Senate Bill 426 was passed by both the House and the Senate, but the conference committee was unable to resolve the differences. The Ninety-fourth Congress passed the present law.

4. The Senate favored a restricted approach that was analogous to the premarket registration required for pesticides under the Federal Insecticide, Fungicide and Rodenticide Act. 7 U.S.C. § 136a (Supp. V 1975). The House favored the marketing of all new chemicals without premarket notification unless the Administration had the foresight to place the new chemical on a list, in which case premarket notification would be required. LEGISLATIVE HISTORY 529-41 (House debate) (particular attention should be paid to remarks of Congressmen Collins, Ashbrook, and Eckhardt).

5. TSCA § 5, 15 U.S.C.A. § 2604 (Supp. 1977).

6. A chemical substance is defined as being any organic or inorganic substance of a particular molecular identity, including any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and any element or uncombined radical. Listed in the Act, however, are several exclusions from the term "chemical substance." The most significant of these are pesticides, mixtures, and items covered by the Food, Drug and Cosmetic Act. *Id.* § 3(2)(B), 15 U.S.C.A. § 2602(2)(B) (Supp. 1977).

tors of chemical substances and mixtures will be the most extensively regulated.

An examination of some of TSCA's provisions demonstrates its breadth. For example, under TSCA the Administrator may require the testing of any chemical substance that "may present" an "unreasonable risk" to health or the environment.[7] If the tests reveal an unreasonable risk, the Administrator must act to reduce it. The options available to him range from prohibiting manufacture of the harmful chemical to requiring that it be labeled.[8] In addition, the Administrator is empowered to evaluate the potential hazards of new chemical substances before they are manufactured or processed for commercial purposes.[9] Manufacturers and processors must give to the Administrator premarket notification of their intent to commence manufacturing or processing for commercial purposes.[10] If the Administrator fails to take regulatory action within ninety days, manufacturing or processing of the new chemical substance may begin. Any chemical substance not appearing on the inventory of existing chemical substances to be published by the Administrator no later than November 11, 1977, will be considered a new chemical substance.[11] In passing TSCA Congress recognized the necessity of developing adequate data on the effects of chemical substances and mixtures upon health and the environment. The Act places the burden of developing this data upon the chemical industry. Pursuant to broad statutory authority, the Administrator may order compilation of reports on chemical substances, retention of records concerning the adverse effects of chemical substances and mixtures, and submission of health and safety studies relating to chemical substances or mixtures.[12]

Several attributes of TSCA may hinder effective implementation of its provisions. First, the Administrator's monetary resources[13] are insufficient to cover the costs of effective implementa-

7. *Id.* § 4(a), 15 U.S.C.A. § 2603(a) (Supp. 1977).

8. *Id.* § 6(a), 15 U.S.C.A. § 2605(a) (Supp. 1977).

9. *Id.* § 5(a), 15 U.S.C.A. § 2604(a) (Supp. 1977).

10. Premarket notification requirements also are applicable to significant new uses of existing chemicals. *Id.* The Administrator is given authority to determine what is a significant new use. This determination is to be based on factors such as changes in human exposure or volume of production. *See id.* § 5(a)(2), 15 U.S.C.A. § 2604(a)(2) (Supp. 1977).

11. *See id.* §§ 3(9), 8(b), 15 U.S.C.A. §§ 2602(9), 2607(b) (Supp. 1977). Delays in promulgating inventory reporting regnlations caused the EPA to delay publication of the initial inventory list until July, 1978. *See* letter from Douglas M. Costle to Senator Warren Magnuson (June 20, 1977). Premarket notification requirements for new chemical substances concomitantly will be delayed.

12. TSCA § 8(a), (c), (d); 15 U.S.C.A. § 2607(a), (c), (d) (Supp. 1977).

13. The Act authorizes $10.1 million for 1977, $12.6 million in 1978, and $16.2 million

tion of this complex legislation. Second, even if sufficient funding were available, assembling a staff in the immediate future with the expertise necessary to administer the statute might be impossible.[14] Third, administration of the Act will be very cumbersome. With two exceptions,[15] the Administrator can impose regulatory and information-gathering requirements only through rulemaking proceedings that comply with the Administrative Procedure Act (APA).[16] Under the APA, an informal hearing must precede substantive rulemaking.[17] Although this procedure provides the public, and especially industry, with an opportunity to influence much of the action that the Administrator will take under the Act, it is time-consuming and resource-intensive.

This Article will examine the attributes of TSCA mentioned above and, in addition, will attempt to provide a detailed analysis of this complex legislation. In particular, the Article will guide the reader through the Act's provisions from the initial determination that a new or existing chemical creates an unreasonable risk (a determination that triggers the Administrator's regulatory authority) to the criminal and civil penalties that may be imposed for noncompliance with statutory requirements. This analysis will include inquiry into the nature of the Act's judicial review provisions, the concept of data development, the various regulatory options and requirements of TSCA, its enforcement provisions, and finally, the relationship of TSCA to other laws.

II. The Concept of Unreasonable Risk

Because Congress realized that a risk-free society is unattainable, TSCA regulates only conduct that creates unreasonable risks.[18] The term "unreasonable risk" is not defined by TSCA, however, because a determination of its presence necessarily involves an examination of the probability of harm, the potential severity of

in 1979. *Id.* § 29, 15 U.S.C.A. § 2628 (Supp. 1977). S. 1531 a proposal that would raise these authorization levels to $50 million in 1978 and to $100 million in 1979 was passed by the Senate on October 31, 1977.

14. *See* 7 Envt'l Rep. (BNA) 1190. For example, Steven D. Jellinek, the first permanent head of the TSCA program, was not chosen until August, 1977, and did not assume his position officially until October, 1977. *See* 123 Cong. Rec. S17,112 (daily ed. Oct. 12, 1977).

15. The exceptions are the ninety-day notice requirement for intended marketing of new chemicals and the § 8(e) notice to the Administrator of substantial risks. TSCA §§ 5(a), 8(e), 15 U.S.C.A. §§ 2604(a), 2607(e) (Supp. 1977).

16. TSCA § 6(c)(2), 15 U.S.C.A. § 2605(c)(2) (Supp. 1977).

17. 5 U.S.C. § 553 (1970 & Supp. V 1975).

18. Legislative History 423 (House report), 742 (House consideration of the conference report).

that harm, and similar considerations that cannot be defined in precise terms, but rather require the exercise of discretion.[19] The determination of unreasonable risk, which triggers regulatory action under TSCA, involves a two-tiered analysis.[20] The first tier assesses the risk of a substance or mixture by considering the effect or severity of the harm, and the exposure, or probability of harm.[21] The second tier involves a determination of reasonableness by balancing the risk against the benefits society would lose through regulation of the substance or mixture.[22] The balancing process is not a formal cost-benefit analysis because human health and environmental values cannot be quantified in monetary terms. It does require, however, that whenever a rule is promulgated the Administrator publish a succinct and precise statement of findings regarding the effects, exposure, and benefits of the substance, and the economic consequences of restricting the substance.[23]

The Administrator properly may find an unreasonable risk when the probability of exposure is small, but the potential adverse effect is great, or when the probability of exposure is great and the potential adverse effect is small.[24] Case law establishes, however, that this proposition is not without limits. For example, in *Carolina Environmental Study Group v. United States,*[25] the court found the possibility of a severe nuclear disaster to be so low that the Atomic Energy Commission's minimal consideration in an environmental impact statement of such a disaster's effects was sufficient. The severity of risk necessary to justify regulatory action varies with the kind of action being contemplated. Because few benefits are lost if the EPA orders testing, and all benefits are lost if the EPA bans a substance, a more severe risk must be shown to justify a total ban. In addition to these differences in risk-benefit analysis, the statutory requirements for issuing a testing rule are less stringent than the requirements for issuing a substantive regulation. A testing rule must be issued if a substance "may present" an unreasonable risk while a substantive regulation may be issued only if there is a "reasonable basis to conclude" that the substance "will present or

19. *Id.* at 421-23 (House report).
20. *Id.* at 422.
21. *Id.*
22. *Id.*
23. *See* TSCA § 6(c), 15 U.S.C.A. § 2605(c) (Supp. 1977); LEGISLATIVE HISTORY 688 (conference report); Green, *The Risk-Benefit Calculus in Safety Determinations*, 43 GEO. WASH. L. REV. 791 (1975).
24. LEGISLATIVE HISTORY 422 (House report).
25. 510 F.2d 796 (D.C. Cir. 1975).

presents" an unreasonable risk.[26]

When potential for substantial human exposure to a chemical substance exists, testing is required if available data or past experience is insufficient to support a determination of the chemical's effect on health or the environment.[27] The "may present" requirement, coupled with the minimal losses caused by a testing rule, creates a standard so low that a positive result in a simple Ames test[28] might trigger testing.[29] Although more is required to support the determination of risk preceding issuance of substantive regulations, the standard is not difficult to meet, especially if the EPA seeks to impose less than a total ban.[30] Congress recognized that factual certainty may not be possible in this area because of the complexity in identifying the long-range toxicological effects of a given substance[31] and, therefore, required only a "reasonable basis to conclude" that an unreasonable risk exists.[32] The Administrator's judgment may be based upon toxicological, epidemiological, or statistical studies or upon scientific theories or trends projected from available data. The Administrator must set forth adequate reasons for and explanations of his conclusions, but the factual certainty that normally must be demonstrated in civil litigation is not necessary.[33] The minimal showing necessary under the Act to support a determination that an unreasonable risk is present has led one commentator to conclude that the term "risk" is used in its lay rather than scientific sense. "Risk," as the term is used scientifically, assumes that a quantified prediction can be made. This clearly is not Congress' intent.[34]

The conferees emphasized that the term "presents" in section

26. *Compare* TSCA §§ 4(a), 5(e), 15 U.S.C.A. §§ 2603(a), 2604(e) (Supp. 1977) *with id.* §§ 5(f), 6(a), 15 U.S.C.A. §§ 2604(f), 2605(a) (Supp. 1977).

27. *Id.* § 4(a)(1)(A)(ii), 15 U.S.C.A. § 2603(a)(1)(A)(ii) (Supp. 1977).

28. The Ames assay, developed by Dr. Ames of tbe University of California, Berkeley, employs yeast cells and an activator from human liver cells designed to approximate human metabolic conditions. *See* note 125 *infra.*

29. *See From Microbes to Men: The New Toxic Substances and Bacterial Mutagenicity/Carcinogenicity Tests,* 6 ENVT'L L. REP. 10,248, 10,250 (1976) [hereinafter cited as *From Microbes to Men*].

30. Of the following restrictions, the Administrator may apply the least burdensome requirement that adequately protects against the risk: (1) prohibition of manufacture; (2) limitations on the amount manufactured; (3) limitations on use; (4) labeling; (5) notice; and (6) regnlation of disposal and repurchase of adulterated substances. *See* TSCA § 6(a), (b), 15 U.S.C.A. § 2605(a), (b) (Supp. 1977).

31. LEGISLATIVE HISTORY 257-62 (Senate debate), 439 (House report), 685-87 (conference report).

32. TSCA § 6(a), 15 U.S.C.A. § 2605(a) (Supp. 1977).

33. LEGISLATIVE HISTORY 439 (House report).

34. *From Microbes to Men, supra* note 29, at 10,251.

6 of TSCA was intended to allow the Administrator to regulate substances and mixtures indirectly presenting unreasonable risks. Furthermore, the substance or mixture alone need not create the risk. A risk arising from the interrelationship or cumulative impact of several substances or mixtures could be sufficient.[35] This mandate enables the Administrator to find that a substance presents an unreasonable risk upon meeting fairly lenient standards. Although the conference report does not clearly state that a substance's contribution to the risk must be significant,[36] any other reading would permit the regnlation of substances with only a de minimis contribution to an unreasonable risk.

III. JUDICIAL REVIEW

Section 19 of TSCA provides for judicial review in the United States courts of appeals of rules promulgated under the Act. No later than sixty days after a rule or order is promulgated pursuant to section 4(a), 5(a)(2), 5(b)(4), 6(a), 6(e), or 8, any person may file a petition for judicial review in the appropriate court of appeals or in the District of Columbia Circuit Court.[37] The courts of appeals also have exclusive jurisdiction over orders issued pursuant to section 6(b).[38] This section specifically requires that the rulemaking record include the rule being reviewed,[39] any required transcript of an oral presentation, any written submission of interested parties, and any other information that the Administrator considers relevant to the rule.[40] In addition, certain required findings and statements regarding specific rules also must be included in the rulemaking record.[41]

The usual standard for judicial review, which is found in section 706 of the Administrative Procedure Act,[42] is the arbitrary and capricious standard and applies to review under TSCA.[43] With regard

35. LEGISLATIVE HISTORY 673-74 (conference report).

36. *Id.* at 176 (Senate report), 440 (House report), 673-74 (conference report).

37. TSCA § 19(a)(1), 15 U.S.C.A. § 2618(a)(1) (Supp. 1977).

38. The United States district courts review the enforcement of rules but the legality of the rule itself cannot be raised in this forum. *Id. See also* E.I. DuPont de Nemours & Co. v. Train, 430 U.S. 112 (1977).

39. The rulemaking record would include a statement of basis and purpose pursuant to 5 U.S.C. § 553(c) (1970 & Supp. V 1975).

40. The Administrator also must publish a notice in the *Federal Register* on or before the date the rule is promulgated identifying the information included in the rulemaking record. TSCA § 19(a)(3), 15 U.S.C.A. § 2618(a)(3) (Supp. 1977).

41. These include the findings described in §§ 4(a), 5(b)(4), 6(a) and 5(f) and the § 6(c) statement. *Id.* E.I. Dupont de Nemours & Co. v. Train, 430 U.S. 112 (1977).

42. 5 U.S.C. § 706 (1970).

43. TSCA § 19(c), 15 U.S.C.A. § 2618(c) (Supp. 1977).

to review of a rule promulgated pursuant to section 4(a), 5(b)(4), 6(a), or 6(e),[44] however, the Act provides for a standard for review more stringent than the normal standard. Rules promulgated under these sections will be held unlawful if the court finds them unsupported by substantial evidence on the rulemaking record. The conferees expressed their intent as follows:

> [T]he traditional presumption of validity of an agency rule is to remain in effect. The conferees recognize that in rulemaking proceedings such as those contained in this bill, which are essentially informal and which involve both determinable facts and policy judgments derived therefrom, the traditional standard for review is that of "arbitrary and capricious." However, the conferees have adopted the "substantial evidence" test because they intend that the reviewing court focus on the rulemaking record to see if the Administrator's action is supported by that record. Of course, the conferees do not intend that the Court substitute its judgment for that of the Administrator.[45]

Whether the distinction intended by the conferees between the two review standards will be followed by courts reviewing the Administrator's actions under TSCA is questionable.[46] Commentators have

---

44. The Senate and House bills both provided that rules promulgated pursuant to certain subsections of § 5 would be reviewed by a substantial evidence standard. The conferees did not explain why only § 5(b)(4) rules were retained in this group. The exclusion of §§ 5(e) and 5(f) rules is understandable since these rules arguably are promulgated under §§ 4(a) and 6(a), respectively, so they would be reviewed by the substantial evidence standard. A § 5(a)(2) rule designating a siguificant new use, however, is now subject to the usual arbitrary and capricious standard. *See* LEGISLATIVE HISTORY 80 (Senate bill), 189 (House bill), 708 (conference report). In light of the effect of such rules and the importance that significant new-use determinations are afforded in the Act, reviewing them under the more lenient standard is an anomaly.

45. LEGISLATIVE HISTORY 709 (conference report). The conferees' desire that a reviewing court focus on the adequacy of the record may be inconsistent with their recognition that factual certainty is not required for the Administrator to make an unreasonable-risk finding. *See* text accompanying notes 31-34 *supra.*

46. Historically, the substantial evidence test afforded more generous judicial review than the arbitrary and capricious test. A third standard, the clearly erroneous test, gave the reviewing court broader powers than the substantial evidence test. *See, e.g.,* Abbott Laboratories v. Gardner, 387 U.S. 136, 143 (1967). Since the Supreme Court decided Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402 (1971), however, the differences among the standards have all but disappeared in the environmental and health areas. In *Overton Park* the Court was considering the standard by which it should review the Secretary of Transportation's approval of construction of a highway through a park. After concluding that the substantial evidence test was not applicable, the Court noted:

> Section 706(2)(A) requires a finding that the actual choice made was not "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." To make this finding the court must consider whether the decision was based on a consideration of the relevant factors and whether there has been *clear error of judgment.* Although this inquiry into the facts is to be searching and careful, the ultimate standard of review is a narrow one. The court is not empowered to substitute its judgment for that of the agency.

Id. at 416 (emphasis supplied). If "clear error in judgment" is the same as "clearly erroneous," then the Court has treated the arbitrary and capricious and clearly erroneous standards as equivalents. *See* K. DAVIS, ADMINISTRATIVE LAW OF THE SEVENTIES § 29.00 (1976). Subsequent

suggested that the different standards of review have no discernible effect upon the manner in which courts review agency decisions.[47] When a judge is impressed that an agency has made its decision carefully, great deference will be accorded. When the agency has made decisions in a slovenly fashion, however, the review will be more penetrating,[48] regardless of the standard under which the court proceeds. This common sense prediction of judicial review standards should be heeded by attorneys seeking review under TSCA.[49]

The courts are recognizing the difficulty of applying either the substantial evidence standard or the arbitrary and capricious test to decisions made at the frontiers of scientific knowledge.[50] Because evidence of a chemical substance's toxicity often cannot be interpreted empirically, the term "evidence" as used in TSCA refers to any material in the rulemaking record.[51] This definition flows from a congressional recognition that the evidence supporting the Administrator's findings often would be speculative. For example, the section 5 premarket review of new chemicals forces the Administrator to balance the risks of possible injury against uncertain projections of the benefits that would accrue if the chemical were marketed. Since the evidence of risk and the evidence of benefit would be equally speculative, reviewing courts should not be biased in requiring concrete facts.[52] The major issue relating to judicial review of environmental agency determinations revolves around the quality of the evidence and the degree to which a reviewing court will allow the Administrator to draw inferences from concrete facts. The leading case in this area is *Ethyl Corp. v. Environmental Protection Agency*.[53] Ethyl sought review of EPA regulations requiring phased reductions in gasoline lead additives. In a five to four decision, the court, applying an arbitrary and capricious standard, issued an opinion typifying judicial response to the kind of administrative action aimed at potential threats to human health and the environment that undoubtedly will arise under TSCA. In *Ethyl* the majority and minority disagreed over the meaning of the arbitrary and

decisions indicate that the Court does not regard the standards as equivalent, but the distinction between the standards remains unclear. *Id.*

47. *See* DAVIS, *supra* note 46, § 29.00.

48. *Id.* § 29.01.

49. It is also an excellent reason to take advantage of the opportunity afforded in § 19 to forum shop. *See* TSCA § 19(a), 15 U.S.C. § 2618(a) (Supp. 1977).

50. *See* Industrial Union v. Hodgson, 499 F.2d 467 (D.C. Cir. 1974); Amoco Oil Co. v. EPA, 501 F.2d 722 (D.C. Cir. 1974).

51. TSCA § 19(b), 15 U.S.C.A. § 2618(b) (Supp. 1977).

52. *See From Microbes to Men, supra* note 29, at 10,249.

53. 541 F.2d 1 (D.C. Cir), *cert. denied,* 426 U.S. 941 (1976).

capricious standard, particularly because the Supreme Court in *Citizens to Preserve Overton Park, Inc. v. Volpe* seemed to indicate that the arbitrary and capricious standard requires a finding that the agency has made a "clear error of judgment."[54] The *Ethyl* court agreed, however, that the reviewing court had an obligation to engage in a searching and complete review of the facts. The majority believed that the purpose of a searching review was to educate the court so that it could determine whether the Administrator took all relevant factors into account in making his decision and whether those factors supported his decision.[55] The majority described its interpretation of the phrase "clear error in judgment" as follows:

> Post-*Overton Park* decisions, as well as the internal evidence in *Overton Park* itself, . . . have made clear that the Court does not intend the "clear error of judgment" phrase to sanction review more intrusive than traditional "arbitrary and capricious" review; rather, the Court has reaffirmed that the reviewing court must defer if the agency has a rational basis for its decision. Thus it is important that courts not think themselves licensed to embark upon wide-ranging searches for "clear errors of judgment." Such searches can only distort the established appellate role in reviewing informal agency action. Rather, we think *Overton Park's* troublesome phrase is best read as no more than an affirmation of the traditional standard of review. Accordingly, in the context of "arbitrary and capricious" review, we shall reverse for a "clear error of judgment" only if the error is so clear as to deprive the agency's decision of a rational basis.[56]

To the majority, review under the arbitrary and capricious standard remained unchanged by *Overton Park*. The minority, however, felt that a searching review encompasses a careful scrutiny of the entire record to determine if the Administrator has made any errors in judgment. An error in judgment occurs, the dissent maintained, if the Administrator reaches his conclusions through arbitrary jumps in logic.[57] The dissent's standard of review was more demanding than the majority's and necessitated a detailed examination of the analytical bases of an agency's decision.[58]

Another issue over which the court split was the effect of the "precautionary" nature of some statutes on the factual basis upon which the court would allow the Administrator to base his actions. Section 211 of the Clean Air Act authorized the Administrator to take action against fuel additives that "will endanger" human health. The "will endanger" language is comparable to the "may

54. *See* note 46 *supra*.
55. 541 F.2d at 36.
56. *Id.* at 34 n.74.
57. *Id.* at 100.
58. *Id.* at 111.

present," "presents," and "will present" language in TSCA. The *Ethyl* court accepted the Administrator's interpretation of "will endanger" to mean "presents a significant risk of harm,"[59] and the majority concluded that the statute was precautionary because of this language. In the court's opinion, regulatory action is appropriate under a precautionary statute without a showing of actual harm.[60] This permits the Administrator to assess risks by making policy judgments rather than by making factual determinations.[61] On this point the court observed:

> Where a statute is precautionary in nature, the evidence [is] difficult to come by, uncertain, or conflicting because it is on the frontiers of scientific knowledge, the regulations desigued to protect the public health, and the decision that of an expert administrator, we will not demand rigorous step-by-step proof of cause and effect. Such proof may be impossible to obtain if the precautionary purpose of the statute is to be served. Of course, we are not suggesting that the Administrator has the power to act on hunches or wild guesses. *Amoco* makes it quite clear that his conclusions must be rationally justified. . . . However, we do hold that in such cases the Administrator may assess risks. He must take account of available facts, of course, but his inquiry does not end there. The Administrator may apply his expertise to draw conclusions from suspected, but not completely substantiated, relationships between facts, from trends among facts, from theoretical projections from imperfect data, from probative preliminary data not yet certifiable as "fact," and the like. We believe that a conclusion so drawn—a risk assessment—may, if rational, form the basis for health-related regulations under the "will endanger" language of Section 211.[62]

The dissent rejected the conclusion that the Administrator has the authority to make legislative policy decisions under section 211. Based upon its reading of congressional intent, the dissent interpreted section 211 as requiring reasoned, factual determinations based solely upon medical and scientific evidence.[63] The legislative history of TSCA, however, establishes that TSCA is a precautionary statute and, therefore, Congress must have intended to give the Administrator the power the majority found under section 211.[64]

Both the majority and the dissent agreed that the studies relied upon in *Ethyl* were inconclusive because of difficulties in gathering human exposure and effects data.[65] The majority, however, permit-

59. *Id.* at 17-18.

60. *Id.*

61. *Id.* at 20. Congress clearly intended to enable the Administrator to make policy judgments, interpolating from available facts or drawing conclusions from trends. *See* text accompanying notes 27-36 *supra.*

62. 541 F.2d at 28 (citations omitted).

63. *Id.* at 94-96.

64. *See* text accompanying notes 31-36 *supra.*

65. *Compare* 451 F.2d at 28 *with id.* at 102.

ted the Administrator to extrapolate from studies indicating that urban children and occupational groups exposed to high levels of automobile emissions have unusually high levels of lead in their bodies. In contrast, the dissent claimed that these studies covered too insignificant a portion of the population to be considered persuasive;[66] inferences based upon these studies would not be supported by sufficient underlying factual findings.

Several conclusions in *Ethyl* are applicable to the standard of judicial review under TSCA. Although the judges disagreed on the degree of judicial scrutiny required by *Overton Park,* more basic, philosophical differences underlay their contrary conclusions concerning the sufficiency of the Administrator's regulatory action. The majority recognized that in the health and environmental field conclusive factual evidence of a cause and effect relationship between the industrial activities of a manufacturer and effects on health and the environment are not available. Consequently, if health and the environment are to be protected, regnlatory decision makers must be permitted to draw inferences from available data. The dissenting judges, on the other hand, adopted the traditional view of regulatory action and demanded that decisions be supported by a firm factual basis. Because of this philosophical viewpoint, even if the dissenters had accepted the majority's reading of *Overton Park,* they probably would not have agreed with the majority's conclusions. Unlike the legislative history of the Clean Air Act, which does not address the problem of inadequate data, Congress went to great lengths to explain that under TSCA the Administrator could overcome the problem through reasoned speculation and extrapolation from existing data.[67] In light of this intent, courts, in reviewing regulatory actions of the TSCA Administrator, probably will follow a review procedure similar to that adopted by the *Ethyl* majority. As a result, reviewing courts should uphold most TSCA regulations. This conclusion is supported by the affirmation of numerous regnlatory actions taken pursuant to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).[68] In *Environmental Defense Fund v. EPA*[69] the court concluded that evidence in the record showing potential danger in the continued use of DDT justified cancellation of DDT registrations:

66. *Compare id.* at 28 *with id.* at 102.

67. *See* text accompanying notes 27-36 *supra.*

68. *See, e.g.,* Environmental Defense Fund v. EPA, 489 F.2d 1247 (D.C. Cir. 1973) (cancellation of DDT). Like TSCA, FIFRA requires the reviewing court to apply the substantial evidence test to most regulatory actions taken pursuant to the statute. *See* 7 U.S.C. § 136(h) (Supp. V 1975).

69. 489 F.2d 1247 (D.C. Cir. 1973).

> Considering the evidence in the record as a whole, we cannot say that the Administrator's decision was not based on substantial evidence, even if the hazardous nature of DDT has not been proved beyond a reasonable doubt. Sufficient evidence has been adduced to show potentially great dangers from DDT, and the Administrator's decision to cancel the DDT registrations is well within his statutory authority.[70]

The court reached this conclusion in spite of its admissions that the evidence in the record was sufficient to support a contrary decision. The case demonstrates the court's reluctance to second-guess an agency that is acting to protect public health.[71]

To summarize, courts are recognizing that governmental regulation has entered a new era in which definitive evidence establishing a direct correlation between a chemical and adverse effects to human health and the environment is not available. For this reason, reviewing courts are deferring to the Administrator's judgment when he acts to protect public health, regardless of whether they are applying an arbitrary or capricious standard or a substantial evidence standard. In light of the legislative history of TSCA, reviewing courts likely will construe the term "evidence" to include speculations and extrapolations based upon available knowledge. As long as the Administrator's regulatory actions are supported by clearly enunciated reasoning, they will be affirmed. The anticipated extreme reluctance of reviewing courts to reverse these regulatory decisions makes citizen participation in the EPA decision-making process imperative.[72]

IV. DATA DEVELOPMENT

A. The Burdens Information Gathering Imposes on Industry

A stated purpose of TSCA is the development of adequate data concerning the effects of chemical substances and mixtures on the environment and human health.[73] The burden of developing such data falls upon those parties manufacturing and processing chemical substances and mixtures.[74] The Act makes available to the Ad-

70. *Id.* at 1252.

71. *See also* Environmental Defense Fund v. EPA, 548 F.2d 998 (D.C. Cir. 1976) (suspension of Heptaclor and Chlordane); E.I. Dupont de Nemours & Co. v. Train, 430 U.S. 112 (1977).

72. A common prerequisite to judicial review is exhaustion of administrative remedies. To avoid problems with this doctrine, one should participate in the agency rulemaking process. *See* DAVIS, *supra* note 46, § 20.01. When agency recourse is futile, however, as when the agency's position is firmly established, a court might not require exhaustion of administrative remedies. *See* National Resources Defense Council v. Train, 510 F.2d 692 (D.C. Cir. 1975).

73. TSCA § 2(b)(1), 15 U.S.C.A. § 2601(b)(1) (Supp. 1977).

74. *Id.*

ministrator a wide variety of mechanisms for gathering data from industry. Congress was aware of the potential burden on industry and sought to mitigate it by providing partial exemptions from reporting and other data requirements for small business,[75] mixture manufacturers and processors,[76] and manufacturers and processors of small quantities of research chemicals.[77] In addition, the Administrator must seek information from federal entities before seeking it from the private sector[78] in order to avoid duplication of data. He also must exempt manufacturers and processors from submitting duplicative testing data.[79]

The major data gathering provisions in TSCA are sections 4, 5, 6, and 8. Under sections 4, 5(e), 5(f), and 6, the Administrator's regulatory actions against specific chemical substances will generate data. In contrast, under section 5(d) (premarket notice), section 8(a) (maintenance of records and reports), section 8(c) (record retention), and section 8(d) (health studies), the Administrator by general rules can require industry to produce great amounts of data.[80] The data that may be required under sections 8(a) and 5(d) insofar as it is "reasonably ascertainable"[81] may include:[82]

> (a) The common or trade name, the chemical identity and the molecular structure of each chemical substance or mixture for which such a report is required.
> (b) The categories or proposed categories of use of each such substance or mixture.
> (c) The total amount of each such substance and mixture manufactured or processed, reasonable estimates of the total amount to be manufactured or processed, the amount manufactured or processed for each of its categories of

75. *Id.* §§ 8(a)(1),(3), 15 U.S.C.A. §§ 2607(a)(1),(3) (Supp. 1977).

76. *Id.* §§ 8(a)(1)(B), 4(a)(2), 5(a), 15 U.S.C.A. §§ 2607(a)(1)(B), 2603(a)(2), 2604(a) (Supp. 1977).

77. *Id.* §§ 8(a)(1)(B), (b)(1), 5(b)(3), 15 U.S.C.A. §§ 2607 (a)(1)(B), (b)(1), 2604(h)(3) (Supp. 1977).

78. *See* LEGISLATIVE HISTORY 449 (House report).

79. TSCA §§ 4(c), 5(h)(2), 15 U.S.C.A. §§ 2603(c), 2604(h)(2) (Supp. 1977).

80. Any person manufacturing and processing a chemical or mixture or proposing to do the same must comply with § 8(a) rules. Any person manufacturing, processing, or distributing in commerce a chemical substance or mixture must comply with § 8(c) rules. Any person manufacturing, processing, or distributing in commerce a chemical substance or mixture or proposing to do the same must comply with § 8(d) rules. Processors or manufacturers must comply with § 5(d) premarket notice requirements.

81. The reasonable ascertainable standard is an objective, not a subjective, standard. Thus, the manufacturer or processor must provide information of which a reasonable person similarly situated might be expected to have knowledge. *See* LEGISLATIVE HISTORY 693 (conference report).

82. Neither § 8 nor § 5 applies to a chemical unless it is being processed or manufactured for commercial purposes. *See* TSCA §§ 5(i), 8(f), 15 U.S.C.A. §§ 2604(i), 2607(f) (Supp. 1977).

use, and reasonable estimates of the amount to be manufactured or processed for each of its categories of use or proposed categories of use.
(d) A description of the byproducts resulting from the manufacture, processing, use, or disposal of each such substance or mixture.
(e) All existing data concerning the environmental and health effects of such substance or mixture.
(f) The number of individuals exposed, and reasonable estimates of the number who will be exposed, to such substance or mixture in their places of employment and the duration of such exposure.
(g) In the initial report under paragraph (1) of section 8(a) on such substance or mixture, the manner or method of its disposal, and in any subsequent report on such substance or mixture, any change in such manner or method.[83]

These data requirements obviously are extensive.[84] Sections 8(c) and 8(e) are troubling because they present manufacturers, processors, and distributors with subjective decisions. Under section 8(c) any person who manufactures, processes, or distributes in commerce any chemical substance or mixture must maintain records of "significant adverse reactions" to health or the environment. Employee records must be maintained for a period of thirty years and other records for a period of five years.[85] The obvious dilemma is determining the existence of a "significant adverse reaction." The Administrator by rule will offer guidance on this question.[86] The conferees expected that manufacturers would err on the side of safety in retaining records. In discussing what constitutes a significant adverse reaction, they observed:

The seriousness, duration, and the frequency of reactions should be taken into account in establishing what constitutes a significant adverse reaction. For example, if an individual reports that a chemical substance causes his or her eyes to become inflamed and to tear, such reaction may be attributed to an isolated allergic reaction. However, if several persons report a similar reaction, then the reaction may indeed be significant. Because the ultimate significance of adverse reactions is difficult to predict, the conferees intend that the re-

83. *Id.* §§ 8(a)(2)(A)-8(a)(2)(G), 15 U.S.C.A. §§ 2607(a)(2)(A)-2607(a)(2)(G) (Supp. 1977). A § 5(d) notice also includes a description of the data concerning environmental and health effects of the chemical substance that is in the possession of the manufacturer or processor. *Id.* § 5(d)(1)(C), 15 U.S.C.A. § 2604(d)(1)(C) (Supp. 1977).

84. The EPA announced a three phase strategy for implementing its authority under § 8(a). The first of the three phases is to develop an inventory of chemical substances for the § 8(b) inventory list. Reproposed reporting regulations for this list have been published. *See* 42 Fed. Reg. 39,182 (1977). The second phase would commence in the fall of 1977 and will be directed towards a substantial number of chemical substances because of their priority to the EPA and other federal agencies. The third phase would commence sometime in 1978 and would require reporting on selected chemical substances that have relatively higb production volumes. *See* letter from Douglas M. Costle (Administrator of EPA) to Senator Warren C. Magnuson (June 20, 1977).

85. EPA may inspect the records upon request. TSCA § 8(c), 15 U.S.C.A. § 2607(c) (Supp. 1977).

86. *Id.*

quirement 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.[87]

Section 8(e) presents even greater problems than section 8(c) because the section has been in effect since January 1, 1977, and noncompliance with its provisions constitutes a violation of the Act.[88] Unlike section 8(c), the legislative history provides no guidelines for determining when a chemical substance or mixture complies with the section. Section 8(e) requires a "person" who "obtains" information that "reasonably supports the conclusion" that a chemical substance or mixture presents a "substantial risk" of injury to health or the environment to inform the Administrator.[89] The terms "reasonably supports the conclusion" and "substantial risk" are not found elsewhere in the Act, and they are subject to numerous interpretations. The term "obtains" is at least in the present tense, indicating that information obtained prior to the effective date of TSCA[90] does not fall within section 8(e).[91]

Like much of TSCA, all the information provisions with the exception of section 8(e) are triggered by the Administrator's promulgation of rules. The Administrator will determine by exercise of his rulemaking authority what burden will be imposed upon industry by these information sections. Because the potential burden is great, industry should follow carefully the EPA rulemaking activities in this area and attempt through full participation in the rulemaking process to educate the Administrator of the effect the rules will have upon them.

B. Protection of Trade Secrets and Other Confidential Data

Through the Freedom of Information Act (FOIA)[92] and specific

87. LEGISLATIVE HISTORY 694 (conference report).

88. TSCA § 15(3), 15 U.S.C.A. § 2614(3) (Supp. 1977). Violation of TSCA exposes a person to severe civil and criminal penalties. *See id.* § 16, 15 U.S.C.A. § 2615 (Supp. 1977). *See* part VII and Appendix A of this Article.

89. This requirement does not apply if such person has actual knowledge that the Administrator has been informed adequately of such information. *Id.* § 8(e), 15 U.S.C.A. § 2607(e) (Supp. 1977).

90. TSCA became effective on January 1, 1977. *See id.* § 31, 15 U.S.C.A. § 30 (Supp. 1977).

91. Until the EPA by a public notice makes known its expectations under § 8(e), advising manufacturers, processors, and distributors of their duties will be difficult. The EPA recently proposed guidance on § 8(e). 42 Fed. Reg. 45,362 (1977). The term "person" was interpreted expansively to include a corporate entity as well as any employee with knowledge of a substantial risk. *Id.* at 45,364. Thus an employee is liable for failing to report information that ascribes serious risk to a chemical, even when the information was received before the effective date of the Act. *Id.* at 45,363.

92. 5 U.S.C. § 552 (1970).

mechanisms in TSCA, Congress contemplated that the information gathered by the Administrator would be accessible to the general public to inform them of the risks associated with toxic substances and to facilitate public enforcement of the Act.[93] The unrestricted dissemination of information, however, would conflict directly with a stated purpose of the Act of controlling toxic substances without stifling technological innovation.[94] Section 14 of TSCA attempts to strike a compromise between these competing policies. Section 14(a) requires the EPA to maintain as confidential[95] that information falling within the fourth exemption to the FOIA.[96] This exemption protects trade secrets and privileged or confidential financial or commercial information. The confidentiality requirement of section 14 is subject to four exceptions. The Administrator may disclose confidential information: (1) to federal employees on official business; (2) to federal contractors under conditions of confidentiality; (3) to participants or to the public in a TSCA enforcement proceeding, but only in compliance with protective orders; and (4) to the public when the EPA has determined that disclosure is necessary "to protect health or the environment against an unreasonable risk of injury."[97] The section 14(a) prohibition generally does not apply to health and safety studies submitted to the Administrator.[98] Manufacturers, however, may segregate from these studies and appropriately mark as confidential information concerning a secret process for manufacturing the chemical and information concerning the percentage composition of mixtures.[99] A manufacturer, processor, or distributor in commerce, however, has an affirmative duty to mark as confidential the data submitted to the EPA.[100] If the

93. *See* part VI(A) of this Article in which public enforcement is discussed.

94. TSCA § 2(b)(3), 15 U.S.C.A. § 1(b)(3) (Supp. 1977).

95. Under the FOIA, exemptions are permissive and each agency is empowered to disclose information that it is technically entitled to withhold. 5 U.S.C. § 552(9)(b) (1970). The Administrator, however, does not have this discretion under TSCA. He must withhold the information if it is exempt. LEGISLATIVE HISTORY 703 (conference report).

96. An advantage of tying determinations of confidentiality to the fourth exemption of the FOIA is the existence of an extensive body of law interpreting the exemption. The leading case construing the fourth exemption is National Parks and Conservation Ass'n v. Morton, 498 F.2d 765 (D.C. Cir. 1974), which established two considerations for determining the applicability of the exemptions:

(1) the likelihood that the disclosure of the particular documents at issue would impair the Government's ability to obtain necessary information in the future; and

(2) the likelihood that the disclosure would cause substantial harm to the competitive position of the person from whom the information is obtained.

97. TSCA §§ 14(a)(1)-14(a)(4), 15 U.S.C.A. §§ 2613(a)(1)-2613(a)(4) (Supp. 1977).

98. *Id.* § 14(b), 15 U.S.C.A. § 2613(b) (Supp. 1977).

99. *Id.*

100. *Id.* § 14(c)(1), 15 U.S.C.A. § 2613(c)(1) (Supp. 1977). While it may be possible for

Administrator feels the data should not be confidential, he may release it after giving the manufacturer the advance notice required by statute. Thirty days notice usually is required,[101] but the period is shortened to fifteen days when "necessary to protect health or the environment against an unreasonable risk of injury."[102] Notice can be given as late as twenty-four hours before disclosure if immediate disclosure is necessary to prevent an imminent and unreasonable risk of injury. Once the notice is received, the federal courts can restrain disclosure until they have had an opportunity to determine the validity of the Administrator's proposed release. Penalties for wrongful disclosure of information are severe, and the EPA, therefore, should exercise great care with confidential information.[103]

Although the EPA has general regulations relating to confidentiality, they are wholly inadequate to deal with the unique problems posed by the conflict between public dissemination and confidentiality.[104] Two situations in which the confiict has become apparent illustrate the difficulty that the EPA faces.[105] In the first situation, if a manufacturer claims that the chemical name of a particular chemical substance is a trade secret, the EPA would be confronted with conflicting statutory provisions. Section 8(b) apparently requires the EPA to place the chemical name on the inventory list. Section 14 appears to require the EPA to keep the name confidential, at least until a final determination is made by either the EPA or the courts. In addition, the FOIA directs the EPA either to release information in response to a request or to provide reasons for its refusal to do so. If, however, the request is for disclosure of the

a manufacturer to make a request for confidentiality after information is submitted, a safer course is to make confidentiality determinations prior to submitting the data, as a later determination may raise EPA's suspicions as to the veracity of the claim or may violate EPA confidentiality regulations. *See* Nichols v. United States, 460 F.2d 671 (10th Cir. 1972); 40 C.F.R. §§ 2.101, 2.103 (1976).

101. The notice period does not begin to run until the party actually has received a notice that usually will be given by certified mail. *See* LEGISLATIVE HISTORY 703.

102. TSCA § 14(a)(3), 15 U.S.C.A. § 2613(a)(3) (Supp. 1977).

103. Present and former EPA employees and contractor employees are prohibited from disclosing confidential TSCA material to any person not entitled to receive it. Violations are punishable by a $5,000 fine and imprisonment for one year. These sanctions supplement agency internal-security regulations and employee disciplinary proceedings for breaches of security. *Id.* § 14(d), 15 U.S.C.A. § 2613(d) (Supp. 1977).

104. The EPA originally indicated that it would treat claims of confidentiality under TSCA under its general confidentiality regulations found in 40 C.F.R. §§ 2.100-.121 (1976). 42 Fed. Reg. 13,136 (1977). The EPA apparently now will add a new section to its confidentiality regulations to govern claims asserted under TSCA. *Id.* at 39,188 (1977). The exact form these regulations will take is unknown. *Id.* at 39,188-89.

105. These two problems are discussed in the preamble to the reproposed inventory reporting regulations. 42 Fed. Reg. 39,188 (1977).

identity of a chemical substance that is allegedly a trade secret, an EPA reply that a record exists, but will not be released, would inform the party making the request that such a substance is being manufactured, imported, or processed for commercial purposes. The trade secret would be revealed by the denial of the request. Second, assertions of confidentiality pose an additional problem under section 5 of TSCA. This section requires anyone who proposes to manufacture a new chemical substance to furnish the EPA with a ninety-day premarket notice during which the person may not begin manufacturing the substance. This delay may be even longer if a section 4 testing rule requires the manufacturer to develop and submit certain test data. If the chemical substance is on the section 8(b) inventory list, however, it is not a "new substance," and the section 5 notice need not be given. If a company asserts that the name or specific identity of a chemical substance is confidential, however, the EPA may not be able to place it on the inventory list, and all other manufacturers would be required to give premarket notification.

If a manufacturer feels that the information it is submitting to the EPA is important and should be considered confidential, it should not hesitate to designate the information as confidential. In making the designation, however, the manufacturer should be prepared to justify its position in court. The EPA's inability to disclose to the public any information that is classified as confidential is contrary to the general policy encouraging public enforcement and awareness. Thus, the more extensive industry's claims of confidentiality are, the more pressure the EPA will feel to contest these claims.

V. Regulatory Requirements

A. New Chemicals and Section 5 Requirements

The notification and data submission requirements of section 5, which apply to new chemical substances and to significant new uses of existing chemical substances, can be burdensome and may delay manufacturing and processing for months or even years. The application of the section, however, is limited to new chemical substances manufactured or processed for commercial purposes.[106] It does not apply to mixtures. Changes in the inert ingredients of a substance, therefore, are not covered because they create new mix-

106. TSCA § 5(a),(i), 15 U.S.C.A. § 2604(a),(i) (Supp. 1977).

tures, not new chemicals.[107] New chemical substances are those substances not on the inventory list that the EPA must publish under the Act.[108] If a substance is neither an existing chemical nor a mixture, it still might qualify for an exemption from premarket notification. The Administrator has the discretionary power to grant exemptions to new chemical substances manufactured for test marketing purposes, to benign new chemical substances, and to benign intermediates.[109] Small quantities of chemical substances manufactured or processed for research purposes are automatically exempt.[110] If a substance falling within none of the exemptions is classified as a new chemical substance, the manufacturer must give

107. *Id.* § 3(8), 15 U.S.C.A. § 2602(8) (Supp. 1977); LEGISLATIVE HISTORY 685 (conference report).

108 TSCA § 3(9), 15 U.S.C.A. § 2602(9) (Supp. 1977). The Act requires the EPA to publish regulations governing reporting of chemical substances in an initial inventory list by June 29, 1977, and to publish the list by November 11, 1977. *Id.* §§ 8(a),(b), 15 U.S.C.A. §§ 2607(a),(b) (Supp. 1977). The EPA published proposed regulations governing inventory reporting on March 9, 1977. 42 Fed. Reg. 13,030 (1977). Because of the comments on these regulations, the EPA reproposed them on August 2, 1977. *Id.* at 39,182 (1977). As a result of this delay, the EPA has announced that the initial inventory will not be published until July 1978. *See* letter from Douglas Costle (Administrator of the EPA) to Senator Warren G. Magnuson (June 20, 1977).

Any chemical substance processed or manufactured within three years from the date of the promulgation of § 8(a) inventory reporting rules is eligible for the list. TSCA § 8(b), 15 U.S.C.A. § 2607(b) (Supp. 1977). Industry through the comment process should encourage the Administrator to use categories of chemical substances. Under § 26(c) the Administrator must use categories whenever possible. *Id.* § 26(c), 15 U.S.C.A. § 2625(c) (Supp. 1977). Section 8(b)(2) specifically authorizes him to use categories in formulating the inventory. *Id.* § 8(b)(2), 15 U.S.C.A. § 2607(b)(2) (Supp. 1977). Congress intended that the use of categories would prevent subjecting every insignificant change in a chemical to the burden of the premarket notification requirements of § 5. *See* LEGISLATIVE HISTORY 451 (House report).

109. TSCA §§ 5(h)(1), (4), (5), 15 U.S.C.A. §§ 2604(h)(1), (4), (5) (Supp. 1977). Because "test marketing" is not defined in TSCA, the point at which a new chemical passes from the developmental to the test marketing stage will be determined by the Administrator. In the reproposed inventory reporting regulations, test marketing was defined as:

> the distribution of no more than a predetermined amount of a chemical suhstance, or mixture or article containing that chemical substance, by a manufacturer or processor to no more than a defined number of potential customers to explore market capability in a competitive situation during a predetermined testing period prior to the broader distribution in commerce.

42 Fed. Reg. 39,191 (1977).

110. TSCA § 5(h)(3), 15 U.S.C.A. § 2604(h)(3) (Supp. 1977). What constitutes a small quantity will not be determined absolutely. The term's meaning will differ from chemical to chemical depending upon the properties of the chemical and the research being performed. *See* LEGISLATIVE HISTORY 437 (House report). "Small quantities" has been defined in the reproposed inventory reporting regulations to mean:

> Quantities of a chemical substance manufactured or processed or proposed to be manufactured or processed that (a) are no greater than reasonably necessary for such purposes and (b) after (the effective date of premanufacture notification requirements), are used by, or directly under the supervision of, a technically qualified individual(s).

42 Fed. Reg. 39,191 (1977).

notice of his intent to manufacture ninety days prior to manufacturing.[111] At a minimum, this entails submitting information in compliance with the section 5(d) notice requirement.[112] The data requirements, however, may be far greater. If the new chemical appears on the section 5(b)(4) risk list, or is subject to a section 4 testing rule, data requirements will be considerable.[113] If the Administrator places a category of substances on the section 5(b)(4) risk list or subjects a category of chemicals to a section 4 testing rule, a new chemical falling within the category must comply with the data requirements promulgated for the category.[114] In addition, the ninety-day period does not begin to run until the manufacturer complies with these requirements.[115] The EPA can extend the premarket period for an additional ninety days upon a showing of good cause. Although the extension is a final agency action, whether a court will have the opportunity to review the extension before the additional ninety days have expired is questionable.

The EPA also can delay manufacture by following the complex procedures contained in two sections of TSCA that were developed to accommodate differences between the House and Senate bills. The Senate desired to grant the Administrator the authority to issue immediately effective rules restricting manufacture when the Administrator could make an unreasonable risk determination or when available information was inadequate to evaluate risks.[116] The House, on the other hand, wanted the Administrator to seek a court injunction when information was inadequate and to follow normal section 6(a) rulemaking procedures whenever information was adequate to make a determination of unreasonable risk.[117] The compromise now is contained in section 5(e), which pertains to insufficiency of information, and section 5(f), which sets forth the action that should be taken when the Administrator has sufficient infor-

111. TSCA § 5(a), 15 U.S.C.A. § 2604(a) (Supp. 1977). This provision also applies to new uses of existing chemicals that the Administrator determines to be significant. *Id.* § 5(a)(2), 15 U.S.C.A. § 2604(a)(2) (Supp. 1977).

112. Because the Administrator must publish the information received in the notice, questions arise concerning its confidential nature. *See* part IV(B) of this Article.

113. TSCA § 5(b), 15 U.S.C.A. § 2604(b) (Supp. 1977).

114. Any action the Administrator takes against a chemical substance or mixture under any provision of the Act may be taken against a category of chemical substances or mixtures. *Id.* § 26(c), 15 U.S.C.A. § 2625(c) (Supp. 1977).

115. *Id.* § 5(a)(1), 15 U.S.C.A. § 2604(a)(1) (Supp. 1977).

116. S. 3149, 94th Cong., 2d Sess. 27-29 (1976), *reprinted in* LEGISLATIVE HISTORY 83-85.

117. H.R. 14032, 94th Cong., 2d Sess. 187-89 (1976), *reprinted in* LEGISLATIVE HISTORY 134-35.

mation to determine unreasonable risk. Under section 5(e), if the Administrator determines that available information is insufficient to evaluate the health and environmental effects of a chemical substance and that (1) the substance may present an unreasonable risk; (2) the substance will be produced in substantial quantities; or (3) a substantial number of persons will be exposed to the substance, the Administrator may propose an order restricting the substance.[118] Written notice of the order must be given to the manufacturer forty-five days prior to the expiration of the premarket notification period.[119]

Because the House was concerned with preventing the Administrator from taking unilateral action without adequate basis, manufacturers were given thirty days to file objections stating specific grounds.[120] If the Administrator does not accept the objections, he must seek an injunction in district court.[121] To mollify the Senate, the conferees replaced the elements a party ordinarily must show to receive an injunction with a two-part standard. If the court finds: (1) that information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of the substance; and (2) that either (A) in the absence of such information, the substance may present an unreasonable risk or (B) such substance is being or will be produced in substantial quantities, creating substantial human exposure, the court must grant an injunction. The Administrator should be able to meet the requirements of this two-part standard easily. If, however, the manufacturer or processor successfully contests the injunction, the notification period will almost certainly have expired by the time the proceeding is completed,[122] enabling the manufacturer to market the

118. Although not specified in § 5(e), the conferees obviously intended the order to remain in effect until the information insufficiency is overcome. For example, the title of § 5(e) is "Regulation Pending Development of Information."

119. The question whether notice is timely certainly will arise. The Administrator may claim that the notice provision is satisfied upon the postmarking of a letter. The intent of the conferees, however, was that the notice requirement would not be considered satisfied until the manufacturer in fact had received the notice. LEGISLATIVE HISTORY 681 (conference report).

120. *Id.*

121. Although the issuance of a proposed rule is discretionary under § 5(e), once the rule is issued the Administrator must seek an injunction unless he accepts the objections. TSCA § 5(e)(2), 15 U.S.C.A. § 2604(e)(2) (Supp. 1977). Either the United States District Court for the District of Columbia or the United States district court in the judicial district where the manufacturer or processor is found, resides, or does business is an appropriate forum. *Id.* § 5(e)(2)(A)(i), 15 U.S.C.A. § 2604(e)(2)(A)(i) (Supp. 1977).

122. The Administrator can seek a temporary restraining order to prevent manufacture, processing, distribution, use, and disposal pending the completion of the injunction proceeding. *Id.* § 5(e)(2)(C), 15 U.S.C.A. § 2604(e)(2)(C) (Supp. 1977).

substance. Should an injunction issue, it remains effective until sufficient test data on the effects of the substance are submitted to and evaluated by the Administrator.[123] If, however, the Administrator has initiated a proceeding for a section 6(a) rule, the injunction remains in force until the rule becomes effective.[124]

A section 5(e) action would delay the manufacture of a substance for a substantial length of time. The EPA, however, does not have sufficient resources to conduct many section 5(e) actions.[125] The section, therefore, will serve only as a deterrent to manufacturers that might be inclined to submit incomplete data with their premarket notices. A manufacturer or processor should be able to avoid section 5(e) by supplying enough data to comply with section 5(d) and any additional data that demonstrates the absence of an unreasonable risk.[126]

A problem arises under section 5(f) when a manufacturer accompanies his 5(d) notice with complete data in order to avoid section 5(e), but simultaneously provides the EPA with sufficient information to commence a section 5(f) action. The problem has been resolved as follows: unless the Administrator seeks to ban the substance in the section 5(f) action, manufacturing, processing, distribution, use, and disposal can commence subject to restrictions he imposes. This solution is preferable to a section 5(e) action in which no manufacturing can take place until the requisite data is supplied. Because the EPA does not have sufficient resources, it will press few section 5(f) actions. The resources committed to a section 5(f) action result in the regulation of only one chemical substance.[127]

123. No time limitation is placed upon the EPA evaluation by the statute. The district court, however, retains jurisdiction during the pendency of the injunction and thus may expedite the EPA's evaluation.

124. TSCA § 5(e)(2)(D), 15 U.S.C.A. § 2604(e)(2)(D) (Supp. 1977).

125. It is estimated that 1000 new chemicals are introduced yearly. This means the EPA will receive an average of four premarket notices each business day. It is inconceivable that the EPA will be able to review these notices completely, at least during the initial three or four years of TSCA. The EPA may require the results of certain microbial tests such as an Ames assay to accompany the premarket notice. These tests are relatively quick and inexpensive and provide indications of whether the tested chemical is mutagenic or carcinogenic to humans. The EPA may consider a positive result on an Ames assay to be sufficient reason to order the manufacturer to conduct further testing. *See* note 28 *supra*. The EPA has indicated recently that it will review strictly certain categories of new chemicals while screening all other new chemicals for possible in-depth review. *See* U.S. ENVIRONMENTAL PROTECTION AGENCY, ASSESSMENT AND CONTROL OF CHEMICAL PROBLEMS 32 (1977).

126. When a manufacturer is unsure what kinds of data the EPA will consider adequate under § 5(e), a possible source of guidance is § 4(g), which permits petitioning of the Administrator to prescribe standards for the development of test data. TSCA § 4(g), 15 U.S.C.A. § 2603(g) (Supp. 1977).

127. One may argue forcefully that the regulation of new chemicals before they enter

To conserve resources, the EPA can choose to maintain a section 6(a) action and through the use of categories promulgate regulations reaching numerous chemicals. In addition, the time constraints of a section 5(f) action render it an unattractive regulatory tool. Because the decision to proceed under section 5 must be made before the ninety-day premarket period expires, the EPA has little time to evaluate the data to find the requisite unreasonable risk.

Section 5(f) incorporates the Senate's provisions by giving the Administrator authority to act immediately against new chemicals posing unreasonable risks. Once the Administrator has found an unreasonable risk, he must protect against it by issuing a proposed rule restricting the substance. The proposed rule is effective immediately unless it bans a chemical substance.[128] The Administrator then must proceed expeditiously under the section 6(a) rulemaking procedures. During the pendency of this rulemaking, the chemical substance can be marketed subject to the restrictions of the proposed rule. Unlike a section 5(e) action, the manufacturer has no procedure by which it can object before the proposed rule takes effect. Unlike the procedures associated with regulation of existing chemicals, the proposed rule becomes effective immediately without an administrative finding that serious and widespread injury may result during the promulgation of a final rule.[129] To ban a new chemical substance, the Administrator may seek either a court injunction or follow the objection procedure outlined in section 5(e). Before the court can issue an injunction, however, it must find that the substance presents or will present an unreasonable risk before a section 6(a) rule could become effective.[130] In contrast to a proposed ban of an existing chemical, which will not become effective immediately unless the Administrator has found that serious or widespread injury would result and a district court has found an immi-

---

the environment minimizes environmental damage and creates less economic dislocation than later regulation. *See* LEGISLATIVE HISTORY 411-15 (House report).

128. When issuing a proposed rule to restrict a suhstance, the Administrator cannot restrict use of a new chemical in such a manner that his action is tantamount to a han. *See id.* at 683 (conference report).

129. *Compare* TSCA § 5(f), 15 U.S.C.A. § 2604(f) (Supp. 1977) *with id.* § 6(d), 15 U.S.C.A. § 2605(d) (Supp. 1977).

130. The Act and the legislative history are silent on the subject of what happens once a court has issued the injunction. Since the rule is a proposed rule, the obvious conclusion would be that the Administrator must proceed expeditiously to rulemaking as he must do if a rule other than to ban is made effective immediately. *Compare id.* § 5(f)(2), 15 U.S.C.A. § 2604(f)(2) (Supp. 1977) *with id.* § 5(f)(3), 15 U.S.C.A. § 2604(f)(3) (Supp. 1977). There also is not a procedure specified for dissolving the injunction. The procedure for filing a petition for dissolution under § 5(e) offers guidance and should be followed. *See id.* § 5(e)(2)(D), 15 U.S.C.A. § 2604(e)(2)(D) (Supp. 1977).

nent and unreasonable risk under section 7, a ban of a new chemical can be obtained more easily.

In summary, if avoidance of premarket notification is impossible, a manufacturer should submit complete data with its premarket notice of the new chemical substance. If this is done, the new chemical substance should not become subject to a section 5(e) order, and thus, even if the Administrator initiates action under section 5(f), manufacture, processing, and distribution can commence subject to the restrictions he imposes unless he attempts to ban the substance. If the restrictions are onerous, the manufacturer will have an opportunity to persuade the Administrator to modify them during the rulemaking proceeding, and the final rule will be subject to judicial review. The Administrator's resources will allow only a few section 5(e) and 5(f) actions, and as a result most new chemical substances will proceed to market upon expiration of the ninety-day notice period.

B. Substantive Regulation of Chemical Substances and Mixtures[131]

(1) Regulatory Options and Procedures

A variety of substantive regulatory options are available to the Administrator for use against a chemical substance or mixture.[132] Section 7 allows the Administrator to act promptly against imminent hazards. Its importance, however, is reduced by the Administrator's ability to issue immediately effective proposed rules under section 6.[133] Because of the severity of a ban, a proposed rule banning a chemical substance or mixture is not effective unless a court previously has granted section 7 relief against the risk of the chemical substance or mixture.[134] Section 7 does provide the Administrator with a regulatory option not found in section 6(a), and to the extent that this option is more suitable to address a risk, the Administrator

131. The Administrator has commenced § 6 regulatory action against chlorofluorocarbons (aerosols) and polychlorinated biphenyls (PCB's). *See* 42 Fed. Reg. 24,542 (1977); *id.* at 26,564.

132. These options are contained in §§ 5(f), 6(a), and 7. Section 5(f) was discussed in part VA of this Article and thus will not be addressed below.

133. TSCA § 6(d)(2)(A), 15 U.S.C.A. § 2605(d)(2)(A) (Supp. 1977). Earlier versions of § 6 did not empower the Administrator to make a rule effective immediately; the Administrator would have to follow normal rulemaking procedures. Section 7 was thought to give the Administrator sufficient authority to deal with risks posed by a chemical substance or mixture pending the completion of rulemaking. *See, e.g.*, H.R. 664, 94th Cong., 1st Sess. (1975) (sponsored by Congressman McCollister).

134. TSCA § 6(d)(2)(B), 15 U.S.C.A. § 2605(d)(2)(B) (Supp. 1977).

can be expected to use section 7. Section 7 permits the Administrator to commence an action in a United States district court against an imminently hazardous chemical substance or mixture or any article containing such substance or mixture. The court is empowered to order seizure of these items.[135] The seizure procedure is to conform with the libel process in an admiralty proceeding in rem.[136] The court also may order whatever temporary or permanent relief is necessary to protect health and the environment. Such relief may include an order: (1) to give notice to purchasers of risks associated with the product; (2) to recall the product; (3) to replace or repurchase the product; or (4) any combination of these actions.[137] These remedies, however, also are available to the Administrator under section 6(a).[138]

Several disadvantages accompany use of section 7 rather than section 6(a). These disadvantages are (1) the greater difficulty in showing the imminent hazard[139] required by section 7, rather than the unreasonable risk required by section 6(a), (2) the necessity of going to court under section 7, rather than merely commencing rulemaking under section 6(a), and (3) the requirement that the Administrator commence a section 6(a) rulemaking concurrently with the filing of a section 7 action.[140] Thus the Administrator likely will use section 6(a) except in those situations in which seizure is necessary or in which the Administrator seeks an immediately effective ban.

Under section 6(a), the Administrator must take regulatory action if he finds a reasonable basis for concluding that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture presents or will present an unreasonable risk.[141] A section 6(a) rule may consist of any one or more of the following:

(1) A prohibition of manufacturing, processing, or distribution in commerce;

---

135. *Id.* § 7(a), 15 U.S.C.A. § 2606(a) (Supp. 1977).

136. *Id.* § 7(b)(3), 15 U.S.C.A. § 2606(b)(3) (Supp. 1977). Under admiralty law, the rem is considered to be tbe tortfeasor and action can be taken directly against it without regard to who owns it.

137. *Id.* § 7(b)(2), 15 U.S.C.A. § 2606(b)(2) (Supp. 1977).

138. *Id.* § 6(a)(7), 15 U.S.C.A. § 2605(a)(7) (Supp. 1977).

139. An imminent hazard is defined as "a chemical substance or mixture which presents an imminent and unreasonable risk of serious or widespread injury" before a § 6 rule can be promulgated. *Id.* § 7(f), 15 U.S.C.A. § 2606(f) (Supp. 1977).

140. *Id.* §§ 7(a),(d), 15 U.S.C.A. §§ 2606(a), (d) (Supp. 1977).

141. *Id.* § 6(a), 15 U.S.C.A. § 2605(a) (Supp. 1977).

(2) The limitation of the amount manufactured, processed, or distributed in commerce;
(3) A prohibition on manufacturing, processing, or distribution in commerce for a particular use or in concentrations in excess of levels set by the Administrator;
(4) A labeling requirement;
(5) A requirement that the manufacturers and processors of the substance or mixture make and retain records of the processes used to manufacture or process the substance or mixture;
(6) A prohibition or otherwise a regulation of any manner or method of commercial use;
(7) A requirement regulating disposal by any commercial user;
(8) A direction to manufacturers or processors of such substance or mixture to notify purchasers of the substance and/or the general public of its risks;
(9) A requirement to replace or repurchase such substance or mixture as elected by the person to which the requirement is directed.

In addition to the section 6(a) requirements outlined above, the Administrator may order a manufacturer or processor to change quality control procedures when unintentional contamination of a chemical substance or mixture is attributable to the method of manufacturing or processing.[142] The Administrator is constricted in his choice among the above restrictions because he must choose the least burdensome alternative that adequately will protect against the risk.[143] In practice, however, this constraint probably will have only a minor effect. Congress, in imposing this limitation, did not intend to require the Administrator to delay regulation to develop quantitative data comparing the costs of various possible control methods.[144] A more effective constraint on the Administrator's promulgation of rules containing restrictions exceeding those required to control the risk adequately is the increased difficulty he will face in finding an unreasonable risk.[145]

Two limitations are placed upon the Administrator's exercise of his section 6(a) authority by other legislation. Although the Administrator is empowered to prohibit or limit the distribution in commerce of substances or mixtures and to prohibit or limit the

142. *Id.* § 6(b), 15 U.S.C.A. § 2605(b) (Supp. 1977).
143. *Id.* § 6(a), 15 U.S.C.A. § 2605(a) (Supp. 1977).
144. LEGISLATIVE HISTORY 441 (House report), 688 (conference report).
145. *See* text accompanying notes 18-36 *supra.*

distribution in commerce of a substance or mixture for a particular use, this authority does not reach the manner or method of transporting hazardous chemical substances or mixtures or the storage of such substances.[146] Similarly, the Administrator cannot use TSCA to issue work-place standards. The issuance of these standards is governed by the Occupational Safety and Health Act of 1970.[147] Furthermore, the Administrator must consider several enumerated factors[148] and publish a statement of his determinations in the *Federal Register* whenever he promulgates a section 6(a) rule.[149] These are the key elements that should be considered in the course of the typical risk-benefit analysis necessary to determine if the risk is unreasonable. A succinct and precise statement of the Administrator's considerations will suffice to fulfill this requirement.[150]

Rulemaking under section 6 follows the informal rulemaking procedures of the APA[151] with the addition of an opportunity for an oral hearing and for limited cross-examination.[152] The Administrator has great control over the hearings; although any person can submit written views on the proposed rulemaking, rebuttal submissions and cross-examination are limited to those disputed issues that the Administrator determines are material. Furthermore, cross-examination is limited to persons the Administrator deems appropriate and necessary for full disclosure of the facts surrounding the issues in dispute.[153] The Administrator also has the authority to appoint a single representative to conduct cross-examination on behalf of a group of persons with similar interests.[154] Frequent public

146. *See* LEGISLATIVE HISTORY 441 (House report). Transportation, storage, loading, and unloading of a hazardous material is governed by the Hazardous Materials Transportation Act. 49 U.S.C. §§ 1801-1812 (Supp. V 1975).

147. *See* LEGISLATIVE HISTORY 441 (House report).

148. These factors include: the effects of such substance or mixture on health and the environment; the magnitude of human exposure and exposure to the environment; the benefits of the substance for various uses; the availability of substitutes and the economic consequences. TSCA § 6(c), 15 U.S.C.A. § 2605(c) (Supp. 1977).

149. Section 6(c) also requires that, if the Administrator determines that a risk could be eliminated or reduced under another law he administers he shall not use TSCA unless it is in the public interest to protect against the risk under TSCA. This requirement contains so many loopholes that it might not constrict the Administrator's actions.

150. LEGISLATIVE HISTORY 688-89 (conference report).

151. 5 U.S.C. § 553 (1970 & Supp. V 1975).

152. TSCA §§ 6(c)(2)-6(c)(3), 15 U.S.C.A. §§ 2605(c)(2)-2605(c)(3)(Supp. 1977). The rulemaking provisions of § 6 are patterned after § 18 of the Magnuson-Moss Warranty—Federal Trade Commission Improvement Act. *Compare id.* §§ 6(c)(2)-6(c)(3), 15 U.S.C.A. §§ 2605(c)(2)-2605(c)(3) (Supp. 1977) *with* 15 U.S.C. § 57a (Supp. V 1975).

153. TSCA § 6(c)(3)(C)(i), 15 U.S.C.A. § 2605(c)(3)(C)(i) (Supp. 1977).

154. *Id.* § 6(c)(3)(C)(i), 15 U.S.C.A. § 2605(c)(3)(C)(i) (Supp. 1977). A person seeking to conduct cross-examination independent of the group representative must show a good faith

interest group participation in section 6(a) rulemaking can be expected because participation is unrestricted and because the statute provides for the award of reasonable attorney fees and costs.[155] In light of the availability of reimbursement for expenses and the open invitation that any person may participate in the rulemaking proceedings, the informal hearing has the potential of becoming an unmanageable donnybrook. The Administrator should exercise his authority and control over the hearing procedure to avoid such a situation while simultaneously allowing the parties an opportunity to present their views. Industrial groups attempting to argue for a less restrictive rule or no rule at all will have the most to lose if the hearing is not managed well because they, as the parties most directly affected by the rule, will be missing a valuable opportunity to convince the EPA that an alternative course of action is appropriate. Additionally, participation in the rulemaking proceeding is critical to preserve rights of judicial review. Exhaustion of administrative remedies often is a prerequisite for obtaining judicial review.[156] Interested parties should take care to raise all issues at the agency level in order to build an adequate record. Failure to raise an issue at the agency level normally will foreclose consideration of the issue on review.[157] Once promulgated, a section 6 rule takes effect on a date specified by the Administrator.[158] The Administrator may make a proposed rule effective upon publication if prompt action is necessary to protect the public from an unreasonable risk of immediate, serious, and widespread harm.[159] If a proposed rule bans a chemical substance or mixture, however, a court must previously have granted section 7 relief against the risk before a rule can be made immediately effective.[160] As a concession to affected parties, if a proposed rule is made effective immediately, the Administrator

effort to agree on group representation and the Administrator must determine that suhstantial and relevant issues will not be presented adequately without independent cross-examination. *Id.* § 6(c)(3)(C)(ii), 15 U.S.C.A. § 2605(c)(3)(C)(ii) (Supp. 1977).

155. A person requesting reimbursement must demonstrate, among other things, insufficient resources to participate in the proceeding without compensation. *Id.* § 6(c)(4)(A), 15 U.S.C.A. § 2605(c)(4)(A) (Supp. 1977).

156. DAVIS, *supra* note 46, § 20.01.

157. First Nat'l Bank v. Board of Governors of the Fed. Reserve Sys., 509 F.2d 1004 (8th Cir. 1975).

158. TSCA § 6(d), 15 U.S.C.A. § 2605(d) (Supp. 1977).

159. *Id.* § 6(d)(2)(A), 15 U.S.C.A. § 2605(d)(2)(A) (Supp. 1977).

160. *Id.* The imposition of this additional requirement when the Administrator proposes to ban a substance is a congressional recognition of the severity of hanning a substance. *See* LEGISLATIVE HISTORY 446 (House report). It also is consistent with the treatment of new chemicals. *See* TSCA § 5(f), 15 U.S.C.A. § 2604(f) (Supp. 1977).

must commence rulemaking proceedings promptly and hold a hearing within five days after a request is made.[161]

The manner and frequency of the Administrator's use of substantive regulatory authority largely will be shaped by the availability of resources and evidence to support necessary findings of risk. Whether section 5(f), section 6(a), or section 7 is used, substantive regulatory actions will be resource intensive. Section 5(f) relating to new chemicals, however, is far more resource intensive than section 6(a) because only one chemical at a time can be regulated under section 5(f). The seizure provision of section 7 is also resource intensive since the substance must in fact be seized, a procedure that may require action in each of the different judicial districts in which quantities of the substance are found. Under section 7 the Administrator also must make the more difficult showing of imminent hazard. For these reasons, the Administrator should rely primarily upon section 6(a). By proceeding under section 6(a) and directing regulatory activity at categories of chemicals, resources expended to regulate toxic substances are minimized. The less restrictive nature of section 6(a) will reduce the difficulty of showing unreasonable risk and will minimize data deficiencies.[162] Whether the Administrator will use his regulatory authority in the manner suggested above is uncertain, but whatever course he follows, the Administrator will be forced by citizens' petitions to adopt an aggressive regulatory posture.[163]

(2) Research Chemicals and Mixtures

A chemical substance produced in small quantities[164] solely for scientific experimentation or analysis or for chemical research is exempt from premarket notification and generally excluded from the reporting requirements of section 8 if all persons engaged in the experiment or research are notified of any health risk.[165] Once granted, the exemption continues even if the manufacturer uses an outside laboratory for testing or makes the chemical available to potential industrial users in order to complete experimentation.[166] Similarly, the exemption is not lost if the chemical is sold to other

161. TSCA § 6(d)(2)(B), 15 U.S.C.A. § 2605(d)(2)(B) (Supp. 1977).

162. *See* text accompanying notes 18-36 *supra.*

163. *See* part VI of this Article.

164. *See* note 110 *supra.*

165. TSCA §§ 5(h)(3), 8(a)(1)(B), 8(c), 15 U.S.C.A. §§ 2604(h)(3), 2607(a)(1)(B), 2607(c) (Supp. 1977).

166. *See* LEGISLATIVE HISTORY 437 (House report).

persons, provided that it continues to be used only for research purposes.[167]

The section 8(a) reporting and record retention requirements apply only to the extent the Administrator determines is necessary for the effective enforcement of the Act. Although a research chemical remains subject to section 4 testing rules and section 6(a) regulation, the Administrator probably will not attempt to regulate any but the most toxic research chemicals under either section because they will not be produced in quantities that pose an environmental threat sufficient to warrant regulatory action.

A mixture is afforded far less stringent treatment under TSCA than is a chemical substance. This distinction is drawn because a mixture is as safe or as unsafe as its chemical components, so testing and reporting the components should provide information adequate for evaluating the mixture.[168] Mixtures are exempt from premarket notification under section 5 and generally will not be subject to testing under section 4 or record retention and reporting under section 8.[169] A mixture is defined as

> any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in 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 the combination could have been manufactured for commercial purposes without a chemical reaction at the time the chemical substances comprising the combination were combined.[170]

The exception results in inclusion of certain combinations of chemical substances in the definition of "mixtures." The definition includes combinations produced by chemical reaction to prevent disparate treatment of identical combinations simply because of the number of steps involved in producing the combination. An example contained in the House report explains the problem succinctly:

> For example, a soap product may be manufactured by combining coconut oil soap, sodium tripoly phosphate, sodium sulphate, and sodium bicarbonate. When combined, these four ingredients do not react chemically. Thus if a manufacturer combined the four ingredients, the resulting combination would clearly be considered a mixture. However, if another manufacturer simultaneously mixed two substances which react to form coconut oil soap, the first ingredient, together with the latter three ingredients, the resulting combination would have been produced in part by a chemical reaction. The two end

167. *Id.* at 575 (remarks of Congressman Murphy in the House debate).
168. *See, e.g., id.* at 448 (House report).
169. TSCA §§ 4(a)(2), 8(a), 15 U.S.C.A. §§ 2603(a)(2), 2607(a) (Supp. 1977).
170. *Id.* § 3(8), 15 U.S.C.A. § 2602(8) (Supp. 1977).

products would be identical, and they should be subject to identical treatment under the bill. The Committee definition assures that they will be.[171]

(3) Remarks on Testing

A unique feature of TSCA is that it empowers an administrative agency to order a manufacturer or processor to test the effect of a substance on health and the environment.[172] This section of the Act may be the most difficult to implement because of the volume of chemicals in existence and being produced annually and because of the scientific uncertainties surrounding the efficacy of various test protocols as predictors of health effects on humans. When data are insufficient to predict reasonably the effects of a chemical, the Administrator may require testing by rule if he finds (1) that the manufacture, processing, distribution, use, or disposal of the chemical may present an unreasonable risk or (2) that the chemical will be produced and enter the environment in substantial quantities, or (3) that significant or substantial human exposure is possible.[173] Before ordering testing of a mixture, the Administrator must find further that the mixture's effect on the environment cannot be determined more reasonably and efficiently by testing the component chemical substances.[174] A rule must include testing standards that specify test protocols and methodologies[175] and a reasonable time period in which the results may be submitted to the Administrator.[176] Test protocols should be scrutinized closely because courts will defer to conclusions and interpolations concerning human health that the Administrator draws from data generated under a particular protocol.[177] Substantial scientific debate exists concerning the efficacy of microbial tests and animal tests as accurate predictors of health effect in humans.[178] In addition, the great dispara-

171. LEGISLATIVE HISTORY 420 (House report).

172. TSCA § 4(a), 15 U.S.C.A. § 2603(a) (Supp. 1977).

173. *Id.* § 4(a)(1), 15 U.S.C.A. § 2603(a)(1) (Supp. 1977).

174. *Id.* § 4(a)(2), 15 U.S.C.A. § 2603(a)(2) (Supp. 1977). *See* text accompanying notes 26-34 *supra* for a discussion of the sufficiency of evidence justifying a finding necessary to trigger a testing rule. Rules requiring testing may only be adopted after notice is published in the *Federal Register* and opportunity is provided for public comment. TSCA § 4(b)(5), 15 U.S.C.A. § 2603(b)(5) (Supp. 1977).

175. *Id.* § 3(12), 15 U.S.C.A. § 2602(12) (Supp. 1977).

176. *Id.* § 4(b)(1), 15 U.S.C.A. § 2603(b)(1) (Supp. 1977).

177. *See* Ethyl Corp. v. EPA, 541 F.2d 1 (D.C. Cir.), *cert. denied*, 426 U.S. 941 (1976). *See* part III of this Article on judicial review.

178. *See* NATIONAL ACADEMY OF SCIENCES, PRINCIPLES FOR EVALUATING CHEMICALS IN THE ENVIRONMENT 93-155 (1975); Kraus, *Environmental Carcinogenesis: Regulation on the Frontiers of Science*, 7 ENVT'L LAW 83, 95-96 (1976); *From Microbes to Men*, *supra* note 29, at 10,250.

ties in costs between different protocols will be considered by the Administrator.[179]

Whether the EPA has the resources and expertise to carry out a quality testing program is questionable. The EPA will be unable to test all 30,000 existing chemicals and the 1,000 new chemicals introduced annually. Establishing effective criteria for choosing priorities among chemicals will be equally difficult. Questions also arise whether the EPA has the expertise to evaluate critically the test data it receives or to ensure that industry is submitting accurate, quality data. Unless the EPA is able to set up a priority system of chemicals to be tested, the federal interagency committee,[180] created under section 4 to make recommendations on chemicals for testing, will set the agency's testing priorities. This committee must publish a list of chemical substances or mixtures in order of importance, giving priority to those chemicals suspected of causing cancer, gene mutations, or birth defects.[181] The committee must state the reasons for inclusion of each substance or mixture on this list. The interagency committee also is required to designate up to fifty substances or mixtures per year as testing priorities for the following twelve-month period.[182] Although the Administrator need not follow the committee's recommendations, he must state reasons for not testing any chemical recommended by the committee.[183] In the absence of alternative candidates for testing, however, the Administrator may be unable to explain his failure to follow the committee's recommendations.

Two provisions within section 4 are particularly beneficial to industry. One provides for exemptions from the testing requirements, and the other permits a manufacturer to petition for development of testing standards. The Administrator may grant exemptions to chemical substances or mixtures that are equivalent to chemical substances or mixtures for which data has been submitted

179. TSCA § 4(b)(1), 15 U.S.C.A. § 2603(b)(1) (Supp. 1977). The simplest microbial test takes two weeks and costs less than $1,000 whereas an animal test may take two years and cost $200,000. *From Microbes to Men*, *supra* note 29, at 10,250. *See generally* NATIONAL ACADEMY OF SCIENCES, PRINCIPLES FOR EVALUATING CHEMICALS IN THE ENVIRONMENT 134-54 (1975).

180. The Committee will be composed of representatives from the following federal agencies: EPA; Occupational Safety and Health Administration; National Institute of Occupational Safety and Health; Council on Environmental Quality, Department of Commerce; the National Science Foundation; the National Cancer Institute; and the National Institute of Environmental Health Sciences. TSCA § 4(e)(2)(A), 15 U.S.C.A. § 2603(e)(2)(A) (Supp. 1977).

181. The Committee has made its initial recommendations. *See* 42 Fed. Reg. 55,026-79 (1977).

182. TSCA § 4(e)(1)(A), 15 U.S.C.A. § 2603(e)(1)(A) (Supp. 1977).

183. *See* LEGISLATIVE HISTORY 675 (conference report).

or is being developed.[184] Companies producing the exempted substances, however, must share costs for at least five years with any company that has borne the initial testing expense.[185] If the parties are unable to agree upon reimbursement, the Administrator must determine a "fair and equitable" allocation of costs.[186]

A company intending to manufacture new chemical substances for which no testing rule has been published may petition the Administrator for proposed standards to guide the development of test data. The Administrator has sixty days to act on the petition. If the petition is granted, standards must be prescribed within seventy-five days and if denied, the reasons for denial must be published in the *Federal Register*.[187] This petitioning procedure forces the EPA to specify the type of data required. By following the EPA standards and supporting the premarket notice with the resulting data, a manufacturer can avoid an EPA-imposed delay in marketing the chemical.

VI. ENFORCEMENT

A. Public Enforcement

The passage of TSCA affords the public an opportunity to participate in the regulation and control of toxic substances. The EPA must disseminate information[188] through public notices that must include: descriptions of test data received on a chemical substance;[189] the lists of chemicals identified by the interagency committee for testing;[190] the reasons for failure by the Administrator to initiate testing of any of the listed chemical substances;[191] the reasons for extending the ninety-day premarket period;[192] and summa-

184. TSCA § 4(c)(2), 15 U.S.C.A. § 2603(c)(2) (Supp. 1977). In determining equivalency, the Administrator must consider whether either of the chemical substances contain contaminants that would alter test data. *See* LEGISLATIVE HISTORY 674 (conference report).

185. TSCA § 4(c)(3), 15 U.S.C.A. § 2603(c)(3) (Supp. 1977).

186. *Id.* § 4(c)(4)(A), 15 U.S.C.A. § 2603(c)(4)(A) (Supp. 1977). The EPA has encountered difficulty in implementing a "similar data reimbursement" clause of the Federal Insecticide, Fungicide and Rodenticide Act, §§ 3(c)(1)(D), 10(b), 7 U.S.C.A. §§ 136a(c)(1)(D), 136h(b) (Supp. 1977). *See* Dow Chemical Co. v. Train, 423 F. Supp. 1359 (E.D. Mich. 1976); *FIFRA Amendments, Getting the Pesticide Program Moving*, 7 ENVT'L L. REP. 10,141-44 (1977).

187. TSCA § 4(g), 15 U.S.C.A. § 2603(g) (Supp. 1977).

188. *See* part IV of this Article for a discussion of the information gathering sections of TSCA and the questions that the dissemination of information raise regarding confidentiality.

189. TSCA § 4(d), 15 U.S.C.A. § 2603(d) (Supp. 1977).

190. *Id.* § 4(e)(1)(B), 15 U.S.C.A. § 2603(e)(1)(B) (Supp. 1977).

191. *Id.*

192. *Id.* § 5(c), 15 U.S.C.A. § 2604(c) (Supp. 1977).

ries of information contained in premarket notices.[193] In addition, the Administrator in most instances must act by rule, which requires public notice and publication of certain findings. Through FOIA requests, the public also can gain access to the data the EPA collects under the information gathering sections of TSCA subject only to confidentiality restrictions.

An informed public can effectuate toxic substances control by bringing market pressures upon manufacturers through product liability suits or through refusal to purchase products containing toxic substances. TSCA provides the general public with two other avenues, citizens' suits[194] and citizens' petitions. Any person[195] may commence a citizens' suit in United States district court against any person violating the Act or any rule promulgated under section 4, 5, or 6 or against the Administrator to compel him to perform a nondiscretionary action.[196] The citizens' petition provision permits any persons to petition the Administrator for issuance, amendment, or repeal of any rule promulgated under section 4, 6, or 8 or for issuance, amendment, or repeal of any order issued under section 5(e) or 6(b)(2).[197] Its use as a vehicle for relief from an onerous rule or order is limited to those instances in which a manufacturer has discovered new information.[198] In contrast, a petition for issuance of a rule is an effective device for forcing the Administrator to take regulatory action.[199] If the Administrator denies the petition, the petitioner may seek de novo review in a United States district court. The court must order the Administrator to initiate the requested action if the petitioner demonstrates by a preponderance of the evidence that the statutory standard for issuing the requested rule is met.[200] The requested action, however, will be deferred to a time

193. *Id.* § 5(d)(2), 15 U.S.C.A. § 2604(d)(2) (Supp. 1977).

194. Citizens' suits provisions commonly are found in environmental legislation. *See, e.g.*, Clean Air Act, 42 U.S.C. § 1857h-2 (1970).

195. Standing to bring a citizens' suit is discussed in part VI of this Article.

196. TSCA § 20(a), 15 U.S.C.A. § 2619(a) (Supp. 1977). What constitutes a discretionary action is not as clear as may appear upon a first reading of a statute. *See* National Resources Defense Council v. Train, 545 F.2d 320 (2d Cir. 1976).

197. The Consumer Product Safety Act provides some precedent for citizens' petition procedures. *See* 15 U.S.C. § 2059 (1970).

198. The failure to provide new information is an adequate ground for denying the petition. *See* LEGISLATIVE HISTORY 464-65 (House report). Although a person may seek review of the denial of a petition, the standard of review for the denial of a petition for repeal or amendment of a rule or order is the arbitrary and capricious standard. *Id.* at 712 (conference report).

199. This certainly was Congress' intent. *See* LEGISLATIVE HISTORY 168-69 (Senate report).

200. TSCA § 21(b)(4)(B), 15 U.S.C.A. § 2620(b)(4)(B) (Supp. 1977).

prescribed by the court if more pressing actions are pending and insufficient resources prevent the Administrator from taking the action requested by the petitioner. To prevent petitioners and courts from dictating the actions he will take and when, the Administrator is forced by section 21 to take a number of regulatory actions and to maintain an aggressive regulatory posture.[201] This gives the Administrator grounds for arguing that a court should defer the action requested by the petitioner.[202]

B. Standing

A party has standing to obtain review of federal agency action under section 10 of the Administrative Procedure Act if he establishes that the challenged action has caused him an "injury in fact" and that the injury was to an interest "arguably within the zone of interests to be protected or regulated" by the statute the agency allegedly violated.[203] In environmental cases, courts have been liberal in finding that a party has fulfilled these necessities of standing.[204] The specific statutory authorization in TSCA for "any person" to sue for enforcement of the Act or to seek review of agency actions minimizes the necessity of meeting standing requirements.[205] The term "any person," which only appears in the citizens' suit provision of the Clean Air Act,[206] has been interpreted by two circuit courts to mean that any person may bring a citizens' suit regardless of whether that person has alleged some personal in-

201. The Administrator already has commenced regulatory action against PCB's and chlorofluorocarbons. The Administrator also has received his first petition, filed by the National Resources Defense Council, regarding chlorofluorocarbons.

202. The court may award reasonable attorneys' fees for action taken under §§ 20 or 21. TSCA §§ 20(c)(2), 21(b)(4)(C), 15 U.S.C.A. §§ 2619(c)(2), 2620(b)(4)(C) (Supp. 1977). This should encourage the public to use both these sections. In addition, the Administrator is authorized to award attorneys' fees and other expenses to participants in the informal rulemaking proceedings of § 6, which should encourage public participation in these proceedings. *Id.* § 6(c)(4)(A), 15 U.S.C.A. § 2605(c)(4)(A) (Supp. 1977).

203. United States v. Students Challenging Regulatory Agency Procedures, 412 U.S. 669, 686 (1973).

204. *See, e.g.*, National Forest Preservation Group v. Butz, 485 F.2d 408, 410 (9th Cir. 1973); *cf. The Revival of the Standing Defense in Environmental Litigation*, 7 ENVT'L L. REP. 10,031 (1977) (examining recent judicial challenges to environmental litigation on standing grounds).

205. TSCA § 19(a), 15 U.S.C.A. § 2618(a) (Supp. 1977) (judicial review); *id.* § 20(a), 15 U.S.C.A. § 2619(a) (Supp. 1977) (citizens' civil actions).

206. 42 U.S.C. § 1857h-2 (1970). Senator Hart quoted former Attorney General Ramsey Clark during a discussion of the citizens' suit provision as stating "we must give the individuals affected by, or *concerned about* pollution . . . the power to stop [it] through legal process." LEGISLATIVE HISTORY OF THE 1970 CLEAN AIR AMENDMENTS 355 (1974) (emphasis added).

jury.[207] TSCA is the first environmental legislation, however, to use the term "any person" in setting forth those who may seek judicial review. Other environmental acts, including the Clean Air Act, either are silent on this question or limit petitioners to interested persons. One circuit court reviewing the judicial review provisions of the Clean Air Act[208] held that petitioners must demonstrate the traditional elements of standing.[209] The courts appear to have no reason, however, to interpret the "any person" language of section 19(a) of TSCA inconsistently with the term "any person" in the citizens' suit provision. This interpretation would allow any person to petition for review of an agency rule or order, and would create a convenient avenue for environmental groups to challenge agency rules and orders they find lenient.

VII. Relationship to Other Laws

To avoid duplication of regulatory activity against a toxic substance, the Administrator, if he determines that the risk presented by a toxic substance may be handled adequately by another agency, must give that agency an opportunity to act.[210] If the other agency initiates action within ninety days, the Administrator is precluded from acting under TSCA.[211] Section 9(a) gives the Administrator discretion to select the risks, if any, he wishes to defer to other agencies. The sole restraint upon his exercise of discretion is legislative history stating that Congress did not intend the Administrator to infringe upon the Occupational Safety and Health Administration by using TSCA to set work-place standards or to infringe upon the Hazardous Materials Transportation Act[212] by regulating the manner of transporting hazardous chemicals in commerce or their storage.[213] The Administrator's major coordination problems are not with other agencies but within his own agency.[214] There are potential

207. *See* National Resources Defense Council v. EPA, 489 F.2d 390 (5th Cir. 1974), *rev'd on other grounds,* 421 U.S. 60 (1975); National Resources Defense Council v. EPA, 484 F.2d 1331 (1st Cir. 1973). The unrestricted use of the term "any person" in the Clean Air Act and TSCA should he contrasted to the citizens' suit provision of the Federal Water Pollution Control Act in which only persons having an interest that is or may be affected adversely are able to commence suit. 33 U.S.C. § 1365(g) (Supp. V 1975).

208. *See* 42 U.S.C. § 1857h-5(b)(1) (1970).

209. National Resources Defense Council v. EPA, 481 F.2d 116 (10th Cir. 1973).

210. TSCA § 9(a)(1), 15 U.S.C.A. § 2608(a)(1) (Supp. 1977).

211. *Id.* § 9(a)(2), 15 U.S.C.A. § 2608(a)(2) (Supp. 1977).

212. 49 U.S.C. §§ 1801-1812 (Supp. V 1975).

213. *See, e.g.,* Legislative History 441 (House report).

214. The Administrator recently has entered into an agreement with several other federal agencies that are concerned with the regulation of toxic and hazardous substances. The

conflicts between the Clean Air Act, the Federal Water Pollution Control Act (FWPCA), and the newly enacted Resource Conservation and Recovery Act (RCRA).[215] Although the Administrator is encouraged to use authorities contained in these other federal laws, he has wide discretion to take action under TSCA rather than under the other acts.[216] In many cases TSCA will present a better vehicle for controlling a risk presented by a toxic substance because with one regulatory action he can reach the air, water, and solid waste problems caused by a single harmful chemical. The Administrator operates under TSCA's lenient standard of proof that enables him to act against a risk absent a showing of demonstrable harm to health or the environment. This showing often is required under other environmental laws.[217] Another major advantage of TSCA is the direct control that can be imposed on a harmful chemical before it reaches the environment, a characteristic not present in other statutes, which in most cases provide regulatory authority for controlling a harmful chemical only after human and environmental exposure has occurred. This is not to say that TSCA will replace these other acts. On the contrary, they give the Administrator ongoing authority to issue permits that is effective in controlling a wide range of environmental hazards in particular mediums. The Administrator's use of TSCA will be limited to risks associated with an identifiable chemical substance or mixture or category of chemical substances or mixtures that transcends one medium and to situations in which the environment cannot be protected sufficiently unless the entry of chemical substances, mixtures, or categories of chemical substances or mixtures is restricted or eliminated.

---

signatories agreed to cooperate in the regulation of these substances by establishing interagency communications for the exchange of data and the development of consistent testing procedures and enforcement policies. 42 Fed. Reg. 54,856 (1977).

215. *See* Clean Air Amendments of 1970, § 112, 42 U.S.C. § 1857c-7 (1970) (hazardous pollutants); Federal Water Pollution Control Act Amendments of 1972, § 504, 33 U.S.C. § 1364 (Supp. V 1975) (emergency powers); Resource Conservation and Recovery Act of 1976, §§ 3001-3007, 15 U.S.C.A. §§ 6921-6931 (Supp. 1977) (hazardous waste management).

216. TSCA § 9(b), 15 U.S.C.A. § 2608(b) (Supp. 1977).

217. *See* parts II and III of this Article. The clearest illustration of the courts' reluctance to curtail the actions of a polluter absent a showing of demonstrable harm to public health is Reserve Mining Co. v. United States, 498 F.2d 1073 (8th Cir. 1974). In that case, which was brought under several environmental laws including the Federal Water Pollution Control Act, the court of appeals stayed an immediate injunction preventing the company from dumping tons of taconite tailings into Lake Superior because, while conceding that evidence presented by the government may have indicated a risk, the court found that the government failed to sustain its burden of showing a demonstrable harm to public health. *Id.* at 1084.

VIII. Criminal and Civil Penalties

A number of possible violations of TSCA will result in criminal and civil penalties. Over forty possible violations are listed in Appendix A on a section-by-section basis. Most of these violations result from failure to comply with section 15 of TSCA, entitled "Prohibited Acts." This section specifies a number of actions that constitute violations of the Act. In addition to section 15 violations, failure to comply with a court order or injunction and failure to comply with specific sections of the Act, such as the confidentiality requirements, the general administrative rules, and the sections protecting employees from employer harassment, also constitute violations. Section 15 is drafted in an unusual manner by listing unlawful acts with specificity rather than by setting forth a blanket prohibition against violations of the Act. In general, the section makes unlawful any failure or refusal to comply with any section of the Act, or with any rule, order, or requirement promulgated under the Act. Section 15 also forbids the use for commercial purposes of a chemical substance or mixture that the person knew or had reason to know was manufactured, processed, or distributed in violation of the Act. In addition, failure to comply with the Act's record-keeping and reporting requirements is unlawful under section 15.

One aspect of section 15 that causes concern is the prohibition of the use for commercial purposes of a chemical substance or mixture where the user "knew" or "had reason to know" the substance or mixture was manufactured in violation of the Act. Although the obvious purpose of this requirement is to ensure effective compliance with the Act by depriving the manufacturers of illegally produced chemicals of a market for their products, it may place a great burden upon users of chemicals and mixtures. The "knew" or "had reason to know" language is perilously close to the requirement that a user "knowingly" violate the Act, which triggers the Act's criminal penalty provision. Unfortunately, what constitutes "knew" or "had reason to know" is not discussed in the legislative history or defined in the Act. Because definitional guidance is lacking, a situation could arise in which a *Federal Register* notice announcing a section 6 restriction on the manufacture of a chemical substance could be held to constitute "reason to know." If, for example, a labeling requirement on a particular chemical was announced in a *Federal Register* notice and a user received the chemical without labeling, his commercial use of the chemical would constitute use of a chemical manufactured in violation of a section 6 rule. Because the *Federal Register* notice would have been a public announcement,

any user of the chemical would have reason to know of the announcement, and upon seeing that the chemical was not labeled, would know or have reason to know that the chemical was manufactured in violation of the section 6 rule. Hence, the user's action would violate section 15.[218]

Section 16 of TSCA subjects violators of section 15 to both criminal and civil penalties.[219] The civil penalties for violating section 15 are potentially heavy. Fines may rise as high as 25,000 dollars for each violation, with each day the violation continues considered a separate violation. The Administrator assesses civil penalties by an order made on the record after an opportunity for a hearing has been afforded to the alleged violator.[220] The hearing, however, is not automatic. After a person receives written notice of the Administrator's intent to assess a civil penalty, he must request a hearing within 15 days of receipt of the notice.[221] Because the Administrator's discretion to determine the amount of a civil penalty is broad, the hearing affords the violator an excellent opportunity to bargain with the EPA over the size of the fine. In assessing the penalty, the Administrator may take into account considerations such as the nature of the violation, the financial condition of the violator, the violator's past record, and the degree of culpability of the violator. The Administrator also may compromise, modify, or remit a civil penalty with or without conditions.[222] A person requesting a hearing before the assessment of the civil penalty or disagreeing with the order assessing the civil penalty may file a petition for judicial review in the United States Court of Appeals for the District of Columbia or in any circuit in which such person resides or transacts business.[223] The petition for review must be filed within thirty days of the date the order assessing the civil penalty was issued. Because a person may file a petition for judicial review in any one of several circuits, forum shopping is possible. The constitutionality of an administrative agency's power to assess civil penalties similar

218. In an effort to avoid liability, several users of chemicals have requested their suppliers to execute a warranty providing that the supplied product conforms with all TSCA regulations, particularly the inventory reporting regulations. In most instances, however, these requests are an overreaction because standard purchasing agreements contain a compliance-of-laws clause that serves the same function. Although these requests do alert suppliers to their responsibilities under TSCA, a letter would serve this purpose without the commercial disruptions that often are caused by requests for warranties.

219. TSCA § 16(a), (b), 15 U.S.C.A. § 2614(a), (b) (Supp. 1977).

220. *See* 5 U.S.C. § 554 (1970).

221. TSCA § 16(a)(2)(A), 15 U.S.C.A. § 2615(a)(2)(A) (Supp. 1977).

222. *Id.* § 16(a)(2)(B), (C), 15 U.S.C.A. § 2615(a)(2)(B), (C) (Supp. 1977).

223. *Id.* § 16(a)(3), 15 U.S.C.A. § 2615(a)(3) (Supp. 1977).

to those contained in section 16 of the TSCA has been questioned in a number of cases.[224] Recently, however, the Supreme Court upheld the civil penalty authority of the Occupational Safety and Health Act (OSHA), which is similar to the Administrator's authority in TSCA.[225] In light of the Court's decision, section 16 probably would withstand a constitutional challenge.

In addition to civil penalties, violators of section 15 may be subject to criminal penalties. The criminal penalty section is applicable to any person who "knowingly" or "willfully" violates any provision of section 15. The criminal penalty of imprisonment for up to one year may be imposed in addition to or in lieu of any civil penalty.[226] The Act also gives United States district courts the injunctive authority to compel compliance with the Act and to restrain violators. An important power granted to the court by TSCA is the authority to order manufacturers and processors to give notice of an illegally manufactured or processed chemical to persons in the chain of distribution and to order the repurchase or replacement of the chemical. Actions may be brought in district court for seizure and condemnation of any chemical substance or mixture manufactured, processed, or distributed in commerce in violation of the Act or of any article containing such a substance or mixture.[227]

IX. CONCLUSION

As the problems created by our technological society become increasingly complex, the legislation enacted by Congress to deal with them necessarily becomes more complicated. The Toxic Substances Control Act evidences this trend. While TSCA provides the Administrator with ample authority to deal with toxic substances, problems such as data deficiencies, resource deficiencies, lack of staff expertise, and the Act's cumbersome procedures undoubtedly will hamstring his efforts to exercise his authority effectively. Whether the Administrator can overcome these obstacles and exert meaningful control over toxic substances without severely damaging the innovative initiative and abilities of the chemical industry remains an open question. Inordinate delays encountered in the appointment of an Assistant Administrator for the TSCA program and in the promulgation of inventory reporting regulations, how-

224. *See, e.g.*, Frank Ivey, Jr., Inc. v. OSHA, 519 F.2d 1200 (3d Cir. 1974).
225. Atlas Roofing Co. v. OSHA, 430 U.S. 442 (1977) (companion case to *Frank Ivey*).
226. TSCA § 16(b), 15 U.S.C.A. § 2615(b) (Supp. 1977).
227. *Id.* § 17(b), 15 U.S.C.A. § 2616(b) (Supp. 1977).

ever, augur ill.[228] The answer will have a profound effect, not only upon the future environmental condition of this country, but upon its economic health as well.

228. *See* New York Times, Oct. 30, 1977, § 1, at 1, col. 4.

APPENDIX A

Possible Violations of TSCA

In general, section 15 of TSCA, "Prohibited Acts," specifies a number of actions that constitute violations of the Act. Sections 16 and 17 provide basic enforcement authority for EPA action against violators.[229] Various actions that may violate TSCA are listed below on a section-by-section basis, and the relevant subsections of section 15 are noted in brackets.

(1) Section 4 — Testing

Violation of a section 4 testing rule [15(1)(A)].
Violation of a section 4(c)(3) or 4(c)(4) reimbursement order [15(1)(A)].

(2) Section 5 — Premarket Notification

Failure to submit a section 5(a) notice [15(1)(B)].
Failure to submit the proper information and data required by sections 5(d), 5(b)(1), and 5(b)(2) with the section 5(a) notice [15(1)(B)].
Commencing manufacture or processing prior to the expiration of the section 5(a) or 5(c) notice periods [15(1)(B)].
Violation of a section 5(e) administrative order [15(1)(C)].
Violation of a section 5(e) court injunction [15(2)].
Violation of a proposed section 6(a) rule proposed pursuant to section 5(f) [15(1)(c)].
Violation of a section 5(f) administrative order [15(1)(c)].
Violation of a section 5(f) court injunction [15(2)].
Noncompliance with section 5(h)(1)(B) exemption restrictions [15(1)(B)].
Violation of a section 5(h)(2)(B) reimbursement order [15(1)(C)].
Violation of a section 5(h)(4) exemption rule [15(1)(C)].

(3) Section 6 — Regulation of Hazardous Substances and Mixtures

Violation of a section 6(a) rule [15(1)(C)].
Violation of a section 6(b) order [15(1)(C)].

229. *See, e.g.*, TSCA §§ 16(a)(1), 16(b), 17(a)(1), 17(b), 15 U.S.C.A. §§ 2615(a)(1), 2615(b), 2616(a)(1), 2616(b) (Supp. 1977).

Violation of a proposed section 6(a) rule that is immediately effective pursuant to section 6(d) [15(1)(C)].
Noncompliance with section 6(e)(2) [15(1)(B)].
Noncompliance with section 6(e)(3) [15(1)(B)].
Violation of section 6(e)(3)(B) exemption terms and conditions [15(1)(C)].

(4) Section 7 — Imminent Hazards

Violation of section 7 court orders and injunctions [15(2)].

(5) Section 8 — Reporting and Recordkeeping

Violation of a section 8(a) rule [15(3)(A) & (B)].
Violation of a section 8(c) rule [15(3)(A)].
Failure to permit a section 8(c) inspection of records [15(3)(C)].
Failure to submit records pursuant to section 8(c) [15(3)(B)].
Violation of a section 8(d) rule [15(3)(B)].
Noncompliance with section 8(e) [15(3)(B)].

(6) Section 11 — Inspections

Failure to allow a section 11(a) inspection [15(4)].
Failure to comply with a section 11(c) subpoena.

(7) Section 12 — Exports

Violation of TSCA by one incorrectly believing that section 12(a) applies.
Failure to submit a section 12(b) notice [15(3)(B)].

(8) Section 13 — Imports (administered by the Secretary of the Treasury)

Noncompliance with section 13(a).
Failure of a consignee to return a substance or mixture to the United States pursuant to section 13(b).

(9) Section 14 — Disclosure of Data

Wrongful disclosure of material by government employees in violation of section 14(a). *See also* section 14(d).

(10) Section 15 — Prohibited Acts

Violation of section 15(2).

(11) Section 16 — Penalties

Failure to pay a final assessment of a section 16(a) civil penalty. *See also* section 16(a)(4).

(12) Section 17 — Specific Enforcement and Seizure

Violation of a section 17 court order regarding specific enforcement and seizure.

(13) Section 23 — Employee Protection (administered by the Secretary of Labor)

Violation of a section 23(b) administrative order. *See also* section 23(d).
Violation of a section 23(d) court order.

(14) Section 24 — Employment Effects

Failure to present information pursuant to section 24(b)(2)(B)(iii) [15(3)(B)].

(15) Section 26 — Administration of the Act

Violation of section 26(b) rule regarding payment of fees.
Noncompliance with section 26(e)(1) requirements concerning financial disclosure. *See also* section 26(e)(5).

APPENDIX B

The EPA's Implementation Schedule

The EPA has instituted a number of activities to implement critical sections of the Act. The following is a summary of these activities:

1. The EPA currently is developing regulations to control polychlorinated biphenyls (PCB's) and chloroflurocarbons. Proposed regulations on each substance were published in May 1977,[230] with final regulations for disposal and labelling of PCB's and chlorofluroalkanes to be published in December 1977. In addition, on October 13, 1977, the EPA announced the formation of a work group to consider the possible regulation of polybrominated biphenyls (PBB's).[231] The EPA is considering the initiation over the next few months of several more regulatory actions against chemicals not yet named.
2. Inventory reporting regulations were proposed on March 9, 1977,[232] and reproposed on August 2, 1977.[233] Publication of final regulations is scheduled for the fall of 1977.
3. Regulations on testing are being prepared.
4. The section 4 Interagency Testing Committee made initial recommendations on October 2, 1977.[234]
5. The members of the Advisory Committee to the Administrator, consisting of representatives of industry, labor, and other interested groups have been announced.[235]
6. Regulations on sections 8(c) and (d) are being prepared. Formal guidance on section 8(e) was proposed September 9, 1977,[236] and proposed regulations under section 8(c) and 8(d) are expected in the fall of 1977.
7. A technical assistance office has been created in the EPA, Washington.
8. The EPA's Office of Toxic Substances is setting up procedures to give states grants for toxic substances programs and developing a data processing system for handling in-

230. 42 Fed. Reg. 26,546, 24,542 (1977).
231. *Id.* at 55,134.
232. *Id.* at 13,130.
233. *Id.* at 39,182.
234. *Id.* at 55,026.
235. *Id.* at 58,779.
236. *Id.* at 45,362.

formation gathered under the Act.

9. Regulations setting up section 6(a) hearing procedures were proposed on April 21, 1977.[237]

237. *Id.* at 20,640.