(i) Compliance Orders

It is clear from sponsors' statements that the Senate intended to preclude considerations of economic feasibility in the issuance of compliance orders. Senator Muskie, in presenting the conference report on H.R. 6161 stated:

> Cost of compliance does not serve as a basis for an exemption. It is recognized that the purpose of the noncompliance penalty itself is to capture the financial savings that are presently realized from delayed compliance. However, when the civil and criminal penalties are considered in addition to the noncompliance penalty, the act will have eliminated incentives to delay compliance and there will be positive incentives to come into compliance. The owner or operator of a major emitting source will no longer have anything to gain from delayed compliance but will have a lot to lose. Senate consideration of conference report and cont. comm. on H.R. 6161, 95th Cong., 1st Sess Aug. 4, 1977 at 3 L.H. 346, (1977).

Any discussion of exemption from compliance on the basis of cost is absent from the House report on H.R. 6161.

The 1977 amendments added a new section to the act authorizing delayed compliance orders (DCO's) to existing stationary sources who are "unable to comply" or required delays for new means of emissions controls. The report on HR. 6161 fails to mention economic cost as one of the factors the Administrator may consider in granting a DCO although it does mention shortage of the means of emission limitation "such as shortages of low-sulfur coal and technological infeasibility." See H.R. Report No. 294, 95th Cong., 1st Sess. 59-60 at 4 L.H. 2526-27. In approving a DCO for an innovative technology, it is clear, however, that Congress intended both reduced cost of equivalent emissions control and the cost of its installation and operation to be relevant factors in the Administrator's decision. Id. at 60-1, 4 L.H. 2527-8.

In addition, the delayed compliance exemption under section (d) for smelter recognizes unique compliance problems within that industry. The Congressional intent was, however, that such an exemption provision could not be construed as providing leeway for economic considerations within other industries. The Senate consideration of

H.R. 6101 states that:

> By permitting this interim relief measure for smelters, there is no implied intent to relax the Clean Air Act's long-standing prohibition against the use of dispersion technology as a means of meeting ambient standards. Nor is there any intent to permit similar relief to other industries or sources, irrespective of cost considerations. Senate consideration of conf. rep. op. cit. at 3 L.H. 348, (1977).

(ii) Civil Penalties

The legislative history of section 113(b) is not extensive, but suggests that Congress intended to make mandatory civil actions for injunctions for major source violators, but that EPA was not required to seek penalties. Section 113(b) came from the Senate bill. In explaining that bill on the Senate floor, Senator Muskie stated:

> If a State has not issued a delayed compliance order with a new time schedule, the Administrator is required to seek an injunction against the noncomplying source and is authorized to seek [§120] civil penalties for noncompliance. In addition, the Administrator is authorized to seek additional [§113] penalties against sources which are subject to the delayed compliance penalty. 3 Legislative History 734 (statement of Senator Muskie).

This suggests that both sections 113(b) and 120 were to be utilized at the discretion of the Administrator. However, in introducing the Conference bill on the Senate floor, the Senator stated:

> The bill also requires the States and/or Administrator of the Environmental Protection Agency to assess and collect noncompliance penalties. 3 Legislative History (statement of Senator Muskie).

The legislative history of section 120 makes clear that Congress intended to recoup the full economic benefit of noncompliance. Senator Muskie explained the proposition in introducing the Conference Report on the Senate floor:

> The purpose of the penalties is to capture these economic savings and remove any advantage of delay. In other words, the noncompliance penalty will eliminate any economic advantage that delayed compliance will confer on a noncomplying firm relative to a firm that complies in a timely manner. 3 Legislative History (statement of Senator Muskie).

He went on to emphasize that economic hardship was not a ground for exemption from the penalties.

> Cost of compliance does not serve as a basis for an exemption. It is recognized that the purpose of the non-compliance penalty is to capture the financial savings that are presently realized from delayed compliance. 3 Legislative History 347 (statement of Senator Muskie).

The legislative history does not discuss the bases on which the civil penalties under section 113 were to be calculated.

(iii) Criminal Sanctions

There is no revelant legislative history on criminal sanctions.

(iv) Mobile Source Enforcement Program

There is no relevant legislative history on this issue.

(v) Economic Studies

There is little direct discussion in the 1977 amendments legislative history of the economic studies mandated under section 405. The Senate Report on the conference committee agreement states that the bill is to be conducted by EPA (and the Council of Economic Advisers) instead of CEQ. One of Congress' main interests was a study and report to Congress on the relative advantages and disadvantages of establishing a system of penalties for stationary sources on NO_x emissions in order to aid the development of effective new control systems and technologies. S. Rep. No. 95-564, 95th Cong., 1st Sess. at 4 L.H. 567 (1977).

c. Case Law

The bulk of the Court's statements regarding the Agency's duty to weigh defenses of the economic or technological infeasibility of compliance are dicta. The most influential of these court statements on factors to be considered by EPA in fashioning compliance orders appeared in the Supreme Court's 1976 Union Electric Co. v. EPA opinion (dismissing the utility's claims that the Administrator erred in approving the Missouri SIP without considering sources' ability to comply). 427 U.S. 246 (1976). The opinion observed that economic factors are relevant in the Agency's choice of enforcement tool:

> Technological and economic factors may be considered in at least one other circumstance. When a source is found to be in violation of the state implementation plan, the Administrator may, after a conference with the operator, issue a compliance order rather than seek civil or criminal enforcement. Such an order must specify a "reasonable" time for compliance with the relevant standard, taking into account the seriousness of the violation and "any good faith efforts to comply with applicable requirements." §113(a)(4) of the Clean Air Act, as added, 84 Stat 1686, 42 U.S.C. §1857c-8(a)(4) §42 U.S.C. §1857c-8(a)(4)]. Claims of technological or economic infeasibility, the Administrator agrees, are relevant to fashioning an appropriate compliance order under §113(a)(4). Brief for Respondent 36 n 34. Id. at 268.

See also, Union Electric Co. v. EPA, 593 F.2d 299 (8th Cir. 1979), cert. den'd 444 U.S. 839 (1980); Indiana Michigan Electric Co. v. EPA, 500 F.2d 839, (7th Cir. 1975); U.S. v. West Penn Power, 460 F. Supp. 1305 (W.D. Pa. 1978); Lloyd A. Fry Rooting Co. v. EPA, 415 F. Supp. 799 (W.D. Mo. 1976) affd 554 F.2d 885 (8th Cir. 1976).

For instance in Indiana & Michigan Electric Co. v. EPA, supra, the Seventh Circuit observed:

> Under Section 113(a)(4), any order issued by the Administrator directing compliance with the provisions of an implementation plan must "specify a time for compliance which the Administrator determines is reasonable, taking into account the seriousness of the violation and any good faith efforts to comply with applicable requirements." 42 U.S.C. §1857c-8(a)(4). This language . . . reflects Congressional intent that serious violations be corrected expeditiously, and yet recognizes that compliance may in some instances border on

> the impossible, despite the good faith efforts of a party subject to regulation. Where such is the case, the good faith efforts of that party are worthy of consideration in terms of compliance schedules as well as the imposition of penalties . . . . In view of the clear purpose behind enactment of the Clean Air Act Amendments of 1970, the absence of demonstrable good faith efforts toward compliance should serve to dampen any enthusiasm for technological and economic arguments advanced in defense of a claimed violation. Id. at 845.

(i) Compliance Orders

The Third Circuit Court of Appeals ruled on the factors that must be considered in the Administrator's decision to grant an application for a delayed compliance order for "new means" of emission limitation under Section 113(4) in Bethlehem Steel v. EPA, 651 F.2d 861 (3rd Cir. 1981). EPA rejected the foundry's petition because it concluded that the particulate control system Bethlehem had installed did not qualify as a "new means of control" since it lacked technological novelty and the Agency considered the controls to be "state-of-the-art." Bethlehem Steel argued that it was the first blast furnace cast house control system of its kind and also the first system retrofitted to a previously operating cast house. The court found for the steel company and held in its opinion that EPA must consider the cost to the company of applying technolgies in new circumstances in deciding whether to issue a delayed compliance order. Id. at 873. The court explained its reasoning:

> In framing the statutory standard, Congress did not intend that the inquiry should be limited only to a performance comparison without consideration of relevant costs. While subsection (i) authorizes new means treatment for those technologies which achieve greater emission reduction than the subject of comparison, subsection (ii) requires only equivalent reduction if accomplished at lower energy, economic or other environmental costs and was obviously inserted to broaden the range of technologies which would be accorded such treatment. It is also significant that Congress did not limit new means treatment to the best available option. If there is more than one option, any control system which meets the statutory standard will qualify for new means treatment. Id. at 873-4.

In a related case brought by the Kennecott Corporation challenging EPA's regulations for approval of delayed compliance orders for nonferrous smelters, the D.C.

Circuit ruled that EPA must weigh both the economic impact of delayed compliance and economic and technological feasibility on the company under section 119 of the Act. Kennecott Corp. v. EPA, 684 F.2d 1007 (D.C. Cir. 1982). The regulation struck down by the court had established closure of the plant as the sole criteria for granting a company's petition for a compliance extension.

(ii) Civil Penalties

The courts have addressed some of the issues concerning econoinic analysis and the civil penalties of the Clean Air Act. While some courts have indicated that EPA has a mandatory duty to bring a civil action against a major source violator under section 113(b) (see e.g., Luckie v. Gorsuch, 13 ELR 20400, 20402 (D. Ariz., Feb. 25, 1983)), research uncovered no decisions requiring EPA to seek penalties (not a surprising result since it has been EPA's policy to seek penalties in all SIP enforcement cases over the last six years).

The courts have not considered whether EPA has a nondiscretionary duty to impose noncompliance penalties. In its section 120 regulations, the agency maintained that it had discretion in not issuing noncompliance notices to all potential recipients as a result of the overwhelming administrative consequences of doing so. (45 Fed. Reg. 50088 (July 28, 1980).) This portion of the regulations was not challenged in the major case on the section 120 regulations, however. (See, Dusquesne Light Co. v. Environmental Protection Agency, 13 ELR 20251 (D.C. Cir. Jan. 7, 1983).)

Turning to the question of the appropriate standards for setting penalties, there has been some judicial approval for the concept of using penalties to eliminate the economic benefit of delayed compliance. In Dusquesne Light, supra, the D.C. Circuit held EPA's noncompliance penalty regulations on virtually all challenged points, denying claims that, among other things, the Act required exemptions for economic inability to comply with the Act. (See Reed, EPA Noncompliance Penalty Regulations Upheld, But

Will They Be Applied?, 13 ELR 10104 (1983).) Moreover, the only court to address the issue upheld EPA's policy of seeking penalties based on the economic benefit of non-compliance under section 113(b) for sources not subject to section 120 liability. State ex rel Brown v. Dayton Malleable, Inc., 12 ELR 21146 (Ohio, 1982).

In Duquesne Light, the court upheld EPA's regulations implementing section 120(d) of the Act which included a model for estimating the economic benefit of continued non-compliance with the Air Act. The court agreed certain assumptions EPA used in the model would lead to the overassessment of the penalty such as industry-wide rather than company specific data on the rate of return of equity and the use of an average debt-equity ratio over the past five years instead of a long-term debt-equity ratio. Id. 265-256. In addition, it ruled that EPA could prorate expenditures used for the purpose of bringing sources into compliance which Congress directed EPA to subtract from the calculated penalty. Id. at 20266. On that issue, the D.C. Circuit rejected petitioners' arguments that the statute mandated subtraction from the penalty of interim control devices, and it held:

> EPA's argument that the statute assesses penalties for benefits derived from the failure to meet legal pollution standards enumerated in the statute is well-taken. Increasing stack heights and dispersion techniques, while costly, do not reduce emissions levels and should not be credited. The main focus of the Act is to ensure swift and steady movement towards meeting federal and state standards that have been honed through the regulatory process. It is not to encourage self-determination in the process of pollution control. EPA's refusal to give credits for interim or extra expenditures that do not reduce emissions levels is in complete accord with the statute.
>
> The question arises, however, as to the proper treatment of interim control devices that do reduce the economic value of noncompliance. EPA has said that expenditures for such devices will lower the penalty assessment. See 45 Fed. Reg. 50,109 (1980). We believe that this is the proper treatment and hold EPA to this reading of the statute. With this in mind, we affirm EPA's treatment of expenditures that reduce the economic value of noncompliance. Id.

Concerning the application of mandatory exemptions from assessment of civil penalties under section 120, petitioners in the Duquesne Light case argued that EPA failed to include technological infeasibility as a factor it would consider, as "beyond the control of a source." EPA's list implementing this section included such bases for exemptions as an act of God, fire, embargo, failure of equipment to perform as designed, assuming expectations about performance were reasonable, and the inability to obtain capital, if that inability is the result of temporary market conditions. The D.C. Circuit agreed with EPA that it was reasonable to exclude technological impossibility from the inability to comply exemption and held:

> At no time during the debates did Congress consider enumerating technological impossibility as one of the factors triggering the exemption, nor did Congress move towards the more flexible formulation of the exemption in order to incorporate technological impossibility. Indeed, Senator Muskie's explanation of the version of section 120 that emerged from the Senate and House conference stated explicitly that the exemption was not intended to cover a claim that needed technology is unavailable. 3 1977 Legislative History at 347. Congress' emphasis that exemptions should be contrued narrowly, to avoid diluting incentives created by the penalty provision, was repeated. Id.

Finally the court also rejected petitioners claims that the courts could fashion relief from the Agency's assessment of civil penalties through case-by-case variances. Such a result, according to the opinion would completely undercut the statute which Congress generously supplied with exemptions and opportunities for readjustment of the levied noncompliance penalty. Id. 20267.

(iii) Criminal Sanctions

There is no relevant case law on this issue.

(iv) Mobil Source Enforcement Program

In Hudson Stations v. EPA, 642 F.2d 261 (8th Cir. 1981) the court examined the basis for EPA's calculation of a civil penalty under Section 211(d) of the Act and the Agency's regulations. The court upheld EPA's assumptions is calculating the penalty which included valuing the "corporate assets" by examining the family assets of an interlocking directorate owning and operating 16 retail service stations under the same name. Id. at 263-264. The court also rejected the petitioners claim of economic hardship, and held that was not an abuse of discretion in light of testimony that although the penalty was burdensome, its assessment would not adversely affect Hudson Stations ability to continue in business. Id. at 264-265.

(v) Enforcement Studies

No case law is relevant on this issue.

I. RESOURCE CONSERVATION AND RECOVERY ACT OF 1976 (42 U.S.C. Section 6901-6987, as amended by the Solid Waste Disposal Act Amendments of 1980)

A. Summary of Act

The Resource Conservation and Recovery Act (RCRA) establishes a comprehensive regulatory and enforcement framework for the control of hazardous and other solid wastes, and for the promotion of resource conservation and recovery. RCRA amended the Solid Waste Disposal Act of 1965 (Pub. L. 89-272), and has subsequently been amended several times. (Pub. L. 91-512; Pub. L. 94580; Pub. L. 96-46; Pub. L. 96-482). The basic law was enacted to "eliminate the last remaining loophole in environmental law, that of unregulated land disposal of discarded materials and hazardous wastes."

Subtitle C of RCRA controls hazardous wastes. RCRA treats hazardous wastes differently than solid wastes, requiring stricter control of hazardous wastes.

It incorporates at least five major emphases:

1) federal identification and listing of hazardous wastes;

2) standards for persons who generate, transport, treat, store, or dispose of hazardous wastes;

3) use of a manifest system to track hazardous wastes;

4) a permitting system for treatment, storage, and disposal facilities; and

5) eventual state responsibility for implementing RCRA according to federal standards.

Subtitle D of RCRA, which controls nonhazardous wastes, establishes criteria for distinguishing acceptable "sanitary landfills" from unacceptable "open dumps." As a condition for receipt of federal assistance in solid waste management, Subtitle D requires states to develop solid waste management plans pursuant to federal guidelines. Among other things, these plans must:

1) identify the responsible state, regional, and local authorities for implementing the plan, distributing federal funds, and coordinating regional planning;

2) prohibit new open dumps;

3) require eventual upgrading or closure of existing dumps; and

4) contain resource conservation and solid waste disposal requirements.

Subtitle C of RCRA is generally silent on the issue of economic considerations during regulatory development. In some cases, the meaning of this silence is somewhat clarified by the legislative history. Congress deleted certain language during the RCRA debate specifically authorizing costs to be considered in developing the regulatory program. The final intent of Congress in deleting the language is open to debate. RCRA's legislative history contains no statements of why the language calling for consideration of the costs and benefits of achieving protection standards, or for the development of regulations that "reasonably protect" human health and the environment were omitted from the final text. Two interpretations of this statutory "silence" are possible. First, that Congress intended to leave the decision of whether to consider costs within EPA's discretion. The second and more likely interpretation is that the deletion of such balancing language evidences Congressional intent to preclude EPA from such balancing in setting protection goals. This is corroborated by the EPA construction of Congressional intent on the matter.

> The silence of the statute itself appears especially significant because earlier drafts of the legislation had contained language which either explicitly called for considerations of cost or implicitly sanctioned such consideration. A draft bill for use by the relevant House Subcommittee would have required that hazardous waste regulations "shall be such as will minimize the risk of adverse effects on human health while taking to the greatest extent possible, into account the economic costs and benefits of achieving such standards." Section 351(e), Subcommittee on Transportation and Commerce, Draft of the Solid Waste Utilization Act (December 8, 1975). When this bill was redrafted for introduction to the House of Representatives as H.R. 14496, this provision calling for consideration of costs and benefits had been deleted. The House bill, however, required that hazardous waste

> regulations "reasonably protect" human health and the environment. H.R. 14496, 94th Cong., 2d Sess., section 306 (1976). The legislative materials accompanying H.R. 14496 provided no guidance on what effect if any, the draftsman intended the potentially moderating phrase "reasonably protect" should have on the development of regulations. In the compromise bill reconciling the differences between the Senate and House bills, the adverb "reasonably" was deleted. In the debate in the House prior to the Act's passage there was no discussion of the effect of this deletion on the intended operation of the Act.
>
> Congress was aware that the hazardous waste regulation would impose substantial costs on the regulated community. See, e.g., H.R. Rep. at 4. Despite this recognition, Congress deliberately rejected provisions that would require consideration of cost burden on industry or to moderate the Act's environmental objectives. For these reasons, the Agency concludes that the Act prohibits it from considering such costs in the development of Subtitle C regulations as a basis for lessening the standards it considers necessary to ensure protection of human health or the environment.
>
> 45 Fed. Reg. 33089 (May 19, 1980) (emphasis added).

EPA's comments on the RCRA regulations were made in May of 1980, three years and some months after Congress enacted RCRA. These regulations, reflecting EPA construction of the RCRA legislative history, have been in place since May of 1980. How much weight a court would give to EPA's construction of the legislative history given the lapse of time between enactment of the Act and promulgation of the regulations and the relatively short history of implementation is unclear. The key to such a determination will be the reasonableness of the Agency's interpretation.

While RCRA's legislative history implies that EPA may not consider the cost burden on industry in choosing the level of its protection standards, this history says nothing that would imply a Congressional intent to discourage consideration of cost-effectiveness in choosing among regulatory alternatives. The implication is that EPA has the discretionary authority to develop the most cost-effective regulations and to use economic analyses as a guide in the promulgation of regulations.

Again EPA's interpretation of its statutory mandate under RCRA corroborates this conclusion. The Agency states:

> The Agency has, however, considered cost-effectiveness in choosing among alternatives that meet the requirements of the statute. In addition, the Administrator may refer to other considerations such as energy or environmental impacts, and implementation and enforcement burdens. For instance the information received or developed in the course of rulemaking on the cost implications of its proposed regulations may be used by EPA to determine the relative cost-effectiveness of various methods to implement a particular requirement. Information on economic impacts may also be useful in informing Congress about the implementation of the hazardous waste program, developing new legislative or Agency initiatives which might affect the regulatory program, and advising the public about the project impacts of the program. See, Hercules, Inc. v. Environmental Protection Agency, 598 F. 2d 91, 113 (B.C. Cir. 1978). EPA has prepared an economic impact analysis on the entire Subtitle C regulatory program. This analysis provides detailed information on the projected economic impacts of these regulations. The report should facilitate public understanding of the task that the Agency is undertaking.
>
> Id. (emphasis added).

Depending on the requirement of specific sections this flexibility seems to allow cost-effectiveness analyses as well as the consideration of economic based standards. Further, there are a number of provisions where balancing health/environmental risks and economics plays an implicit role in regulatory decisionmaking.

B. Regulatory Activities

1. Identification and Listing of Hazardous Wastes-Section 3001

a Statutory Directive

Section 3001 of RCRA, 42 U.S.C. 6921, requires EPA to identify the criteria for determining the characteristics of hazardous wastes, and to identify criteria for listing hazardous wastes. Wastes may be classified as hazardous if they meet the characteristics or if they are specifically listed as hazardous wastes. Hazardous waste is defined in the Act as:

> . . . a solid waste, or combination of solid wastes, which because of its quantity, concentration, or physical, chemical, or infectious characteristics may--
>
> (A) cause, or significantly contribute to an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness; or
>
> (B) pose a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, or disposed of, or otherwise managed.
>
> RCRA, section 1004(5), 42 U.S.C. 6903

In identifying the criteria for determining characteristics of hazardous wastes, and for listing wastes as hazardous, EPA is to consider: toxicity, persistence, and degradability in nature, potential for accumulation in tissue, and other related factors such as flammability, corrosiveness, and other hazardous characteristics. 42 U.S.C. 6921.

Nothing in this provision of the Act suggests that EPA should consider economic tradeoffs in identifying criteria for determining characteristics of hazardous wastes or in listing hazardous wastes.

b. Legislative. History

The legislative history of this and related sections of RCRA contains no evidence of an affirmative legislative intent to allow economics to factor explicitly in EPA's decision on identifying or listing hazardous wastes. See, HR 14496, 94th Cong. 2d Sess., Section 301, and House Rep. No. 94-1491, pp. 25-26 (1976). For example, there is nothing in the various definitions of "hazardous waste" proposed during the legislative debate over RCRA indicating that costs were to be considered in determining whether a waste is hazardous. See, e.g., S. 2150, section 6, amending section 203 of the Solid Waste Disposal Act, 94th Cong., 1st sess (1975); H.R. 14496, section 104(5), 94th Cong., 2d Sess. (1976). All the definitions of hazardous waste relate to the magnitude and probability of harm

such wastes could cause, rather than the economic values associated with waste-producing activities. As indicated by the Senate Committee on Environment and Public Works:

> The bill defines the term "hazardous waste" to mean any waste or combination of wastes which pose a substantial, present or potential hazard to health or living organisms because such wastes are lethal, non-degradable, or persistent in nature; or because such wastes may be biologically magnified or may otherwise cause or tend to cause detrimental cumulative effects. These adverse public health and environmental impacts may be acute (short-range or immediate) or chronic (long-range) effects.
>
> U.S. Senate, Rep. No. 988, 94th Cong., 2d Sess., p. 26 (1976).

This requirement for decisionmaking based primarily on risks was reiterated by the House Interstate and Foreign Commerce Committee. See U.S. House, Rep. 94-1491, 94th Cong., 2d Sess., pp. 25 (1976).

In fact, references to economic considerations were deleted from earlier versions of the bill. The House bill contained language authorizing designation of hazardous wastes upon petition by State Governors. EPA's refusal to designate such wastes would have been permissible "because of financial considerations." Id. This language concerning financial constraints was not incorporated in RCRA, again suggesting that economics was not to play a significant role in defining hazardous wastes.

The joint committee report implies that only human health impacts and to a lesser extent environmental impacts are to be considered in developing hazardous waste identification criteria. The discussion focuses on characteristics of toxicity, persistence, and degradability. (H.R. No. 94-1491, p. 25.)

c. Relevant Case Law

None

2. Standards Applicable to Generators of Hazardous Wastes - Section 3002

a. Statutory Directive

Section 3002 of RCRA, 42 U.S.C. 6922, governing hazardous waste generators, requires EPA, inter alia, to develop requirements concerning:

> use of a manifest system (42 U.S.C. 6903(12)) and any other reasonable means necessary to assure that all such hazardous wastes generated is designated for (permitted treatment, storage, or disposal facilities). (emphasis added).

The specific type of manifest system contemplated by the Act is not explicitly prescribed; however, EPA would seem to be authorized to select a cost-effective system from among the alternatives meeting the overall statutory goals.

b. Legislative History

The standards applicable to generators of hazardous waste in proposed legislation originally contained language indicating that such standards should "reasonably protect human health and the environment." See H.R. 14496, section 302, 94th Cong., 2d Sess. (1976). The House Committee noted its concern with regulatory burdens on generators:

> Rather than place restrictions on the generation of hazardous waste, which in many instances would amount to interference with the productive process itself, the Committee has limited the responsibility of the generator for hazardous waste to one of providing information.
>
> U.S. House, Rep. 1491, 94th Cong. 2d. Sess., p. 26 (1976).

However, the language regarding "reasonably protect" was subsequently deleted in the final Act, suggesting that these standards for generators should not be based on compliance costs.

The statutory language on use of "reasonable means" for tracking wastes was inserted in the 1980 amendments to the Solid Waste Disposal Act. See, Pub. L. 96-482, Section 8. In commenting on this additional language, the Senate Report noted:

> the term the use of “other reasonable means" is intended to codify the responsibility of the generator under existing common law. It is recognized that generators frequently utilize independent contractors to transport or dispose of waste and these additional requirements are not intended to change or limit this practice. Use of due care (as understood under the principles of nuisance and negligence law) in the selection of an independent contractor would be a factor in meeting the requirement for “other reasonable means” as contemplated by this amendment.
>
> U.S. Senate, Rep. No. 172, 96th Cong., 1st Sess., p. 3 (1979).

Congress intended, based on this statement, that in addition to requiring hazardous waste generators to adopt the manifest system, EPA may require supplemental controls to track wastes. Such supplemental controls are permissible as long as these additional requirements are "reasonable" and embody “due care” under common law principles. Such common law principles, however, historically and explicitly have incorporated cost-benefit balancing. See, e.g., W. Presser, The Law of Torts, pp. 143-145 (1971) (negligence); Restatement (Second) of Torts, Section 291, , comment a (negligence); W. Rodgers, Environmental Law, pp. 116-121 (1977) (nuisance). Thus, any supplemental waste tracking system regulations likely would need to be justified by weighing the costs and benefits of such regulations.

c. Relevant Case Law

None

3. Standards Applicable to Transporters of Hazardous Wastes - Section 3003

a. Statutory Directive

Section 3003 of RCRA, 42 U.S.C. 6923, requires EPA to issue standards for hazardous waste transporters. Such standards must be developed in consultation and coordination with the Department of Transportation (DOT).

b. Legislative History

The legislative history of transporter standards essentially parallels that of generators. Early versions of RCRA required such standards to "reasonably protect" human health and the environment. H.R. 14496, Section 303(a), 94th Cong. 2d Sess. (1976). The House Interstate and Foreign Commerce Committee noted that it was not its intent to "interfere with the transportation of waste." U.S. House, Rep. 1491, 94th Cong., 2d Sess., p. 27 (1983). However, the "reasonably protect" language was subsequently deleted in the Act, although coordination with DOT was still retained.

c. Relevant Case Law

None

4. Standards Applicable to Owners and Operators of Hazardous Wastes Treatment, Storage and Disposal Facilities - Section 3004

a Statutory Directive

Section 3004 of RCRA, 42 U.S.C. 6924, requires EPA to issue regulations establishing performance standards for hazardous waste treatment, storage and disposal (TSD) facilities. These regulations must be "necessary to protect human health and the environment." Such standards must include but need not be limited to, requirements concerning: (1) recordkeeping; (2) reporting, monitoring, and inspection and compliance with the manifest system; (3) treatment, storage, or disposal methods, techniques, and practices; (4) location, design and construction of facilities; (5) contingency plans for unexpected damage caused by waste-related activities; (6) maintenance of operation and any necessary requirements governing continuity of operation, personnel training, and financial responsibility; and (7) permit compliance. See, RCRA section 3004(1)-(7), 42 U.S.C. 6924(l)-(7). This language appears to limit trade-offs between costs and benefits. Yet, significantly, EPA is authorized to distinguish between new and existing TSD facilities in setting standards.

b. Legislative History

The legislative history of this provision reinforces EPA's determination that costs are not to be weighed against benefits under RCRA, at least in setting standards for new TSD facilities. Some early bills to control solid and hazardous wastes incorporated provisions for balancing costs and benefits in setting standards for TSD facilities and in connection with hazardous wastes activities. See e.g., S. 2753, Section 403, 93rd Cong., 1st Sess. (1973) (focusing on "unreasonable burdens and risks"); H.R. 13176, Section 2, amending Section 219(c) of the Solid Waste Disposal Act, 93rd Cong, 2d Sess. (1974), (requiring EPA to consider the "economic and social costs and benefits of achieving such standard"); Subcommitee Draft of the Solid Waste Utilization Act of 1975, Section 351, Subc. on Trans. and Commerce, Comm. on Interest and Foreign Commerce (1975). Other early bills eschewed (or were silent on) economic and risk balancing. See, H.R. 4873, Sections 4 and 5, 93rd Cong., 1st Sess. (1973); S. 1086, Sections 4 and 5, 93rd Cong., 1st Sess. (1973).

As introduced in the 94th Congress, H.R. 14496 (the immediate predecessor to RCRA) stated that standards for TSD facilities must be "necessary to reasonably protect human health and the environment." H.R. 14496, Section 304, 94th Cong. 2d Sess. (1976). This language remained in the version of H.R. 14496 ultimately reported out of the House Committee on Interstate and Foreign Commerce, although the Committee did not elaborate upon its meaning. See, U.S. House, Rep. No. 1491, 94th Cong. 2d Sess., pp. 27-28 (1976).

However, before the bill was considered by the full House, a compromise bill was drafted after consultation with the Senate. The compromise version deleted the word "reasonably" and required that standards for TSD facilities be simply "necessary to protect human health and the environment." See, 122 Cong. Rec. H. 3261, Sept. 27, 1976. This legislation was passed by the House as an amendment to H.R. 14496 in the

nature of a substitute, resulting in the current version of this statutory language. The implication of the substitute is that Congress intended to restrict the authority of EPA to consider factors other than impacts on health..

The 1980 amendments to RCRA changed Section 3004, however, to allow EPA to distinguish between new and existing TSD facilities. The reasons for this were primarily economic in nature, as explained by the House Conference Committee:

> In including this amendment in the conference bill the conferees are concerend (sic) primarily with two key factors which distinguish existing facilities from new facilities. First, existing facilities are already committed to particular sites, and thus relocation especially where the facility is directly connected to a manufacturing operation (like a wastewater treatment impoundment), is usually not a feasible alternative. Second, existing facilities have made substantial commitments to the design and construction of the facility.
>
> * * *
>
> The Administrator should exercise discretion with regard to the standards set forth for existing as differentiated from new facilities, including establishment of separate requirements for new and existing facilities where necessary taking into considerations the factors noted above. Regulations issued under Section 3004 should provide sufficient flexibility to allow different designs and locations for existing facilities, can and should, be made without compromising on the level of protection necessary to protect public health and the environment.
>
> U.S. House, Rep. No. 1444, 96th Cong., 2d. Sess., pp. 29-30 (1980) (emphasis added).

Thus, with respect to existing TSD facilities, EPA appears to have the discretion to consider the economic feasibility and practicality of its regulations.

c. Relevant Case Law

None

5. Authorized State Hazardous Waste Programs- Section 3006

a Statutory Directive

RCRA is essentially intended to be administered by the states pursuant to federal authorization. Interim federal authorization of state programs may be provided for a period of up to two years following the development of federal standards for hazardous wastes generators, transporters, and TSD facilities. Section 3006(c), 42 U.S.C. 6926(c). Application for final authorization may be made after such standards are promulgated. Section 3006(b), 42 U.S.C. 6926(b) The federal government will enforce federal RCRA standards in any state that does not wish to run its own program and does not apply for federal authorization.

To receive interim federal authorization a state program must be "substantially equivalent" to the federal program. To obtain final authorization, a state program must: (1) be "equivalent to" the federal program; (2) "consistent with" the federal program and other state programs, and (3) "provide adequate enforcement of compliance." Section 3006(b), 42 U.S.C. 6926(b). These terms (i.e., "consistency," "substantially equivalent" and possibly even "equivalent") are sufficiently flexible to allow administrative deference to economic analysis and to the implementation of alternative regulatory approaches meeting the goals of the Act. However, nothing in this language suggests that significant cost-benefit balancing was intended or sanctioned under the Act in the process of state assumption of primacy over RCRA implementation.

b. Legislative History

The legislative history of RCRA indicates that EPA may be able to accord some limited weight to economic factors in authorizing state programs, at least during the interim authorization process. H.R. 14496, as introduced in the 94th Congress, provided for "temporary authorization" of state hazardous wastes programs pending "authorization." See, H.R. 14496, Section 306, 94th Cong. 2d Sess. (1976). Temporary

authorization was to be granted if the state program was “reasonably in conformance with the purpose of (the) Act.” "Authorization” would have been granted where a state program "complies" with the federal program. This language was changed in the House Committee on Interstate and Foreign Commerce to read essentially as it does today. As stated by the House Commerce Committee, the reasons for interim authorization of state programs are:

> (1) so that existing progress in the area of state hazardous waste law does not come to an abrupt halt, as has been the situation with the passage of other environmental jaws, and (2) to give such states that have begun developing or implementing a hazardous waste program sufficient time to bring such program into conformity with federal minimum standards.
> U.S. House, Rep. No. 1491, 94th Cong. 2d. Sess., p. 29 (1976),

The House Commerce Committee report suggests that economic factors were among the driving forces in the entire authorization process. Viewed in this light, EPA may be able to accord limited weight to cost considerations in authorizing state programs under RCRA:

> The general purpose of having federal minimum standards for hazardous wastes disposal, with the option of state implementation of state programs equivalent to the federal program, is (1) it provides uniformity among the states as to how hazardous wastes are regulated; (2) it provides industry and commercial establishments that generate such wastes uniformity among states, (3) by providing such uniformity with environmentally sound laws does not drive business out of the state to a state which, for economic reasons, decides to be a dumping ground for hazardous wastes, and (4) by permitting states to develop and implement hazardous waste programs equivalent to the federal program, the police power of the states are utilized rather than the creation of another federal bureaucracy to implement the act.
>
> U.S. House, Rep. No. 1491, 94th Cong. 2d Sess., p. 30 (emphasis added)

c. Relevant Case law

None

6. Imminent Hazards - Section 7003

a Statutory Directive

Section 7003(a) of RCRA states:

> Authority of Administrator - Notwithstanding any other provisions of this chapter, upon receipt of evidence that the handling, storage, treatment, transportation or disposal of any solid waste or hazardous waste may present an imminent and substantial endangerment to health or the environment, the Administrator may bring suit on behalf of the United States in the appropriate district court to immediately restrain any person contributing to such handling storage, treatment, transportation or disposal to stop such handling, storage, treatment, transportation or disposal or to take such action as may be necessary. 42 U.S. 6973 (emphasis added)

b. Legislative History

In the version of RCRA enacted in 1976, Section 7003 required EPA to show that the activity in question "is presenting an imminent and substantial endangerment." See Pub. L. 94-580, Section 7003. Congress did not elaborate substantially on the meaning of this term, the use of this term, or the use of cost-benefit considerations in identifying or remedying such hazards. The 1980 amendments to RCRA (technically, they amended the Solid Waste Disposal Act) changed the wording "is presenting" to the current "may present."

The Senate Committee on Environment and Public Works, however, had reported the 1980 amendments with language requiring that EPA show only a substantial endangerment to health or the environment" in order to bring suit. The Committee explained its language as follows:

> Section 15 modifies section 7003 to allow the Agency to take enforcement action against any practice -which is presenting a substantial endangerment to health or the environment. At present, EPA is authorized to act only against a practice which is presenting an imminent hazard.
>
> Like other imminent and substantial endangerment provisions in environmental statutes, (e.g., section 504 of the Safe Drinking Water Act), section 7003 is essentially a codification of common law public nuisance remedies.

* * *

> Section 7003, therefore incorporates the legal theories used for centuries to assess liability for creating a public nuisance (including intentional tort, negligence, and strict liability) and to determine appropriate remedies in common law history, attached to terms such as "imminent" and "substantial", as well as more recent legislative history. However, section 7003 should not be construed solely with respect to the common law. Some terms and concepts, such as persons "contributing to "disposal resulting in a substantial endangerment, are meant to be more liberal than their common law counterparts.
>
> US. Senate, Rep. No. 172, 96th Cong., 1st Sess. (1979). (emphasis added).

Although the Senate called for common law balancing of burdens and benefits to weigh in decisions under section 7003, the House language was adopted in conference, essentially reflecting the current wording in RCRA. See, U.S. House, Rep. No. 1444, 96th Cong., 2d Sess., p. 44 (1980). There is little additional explanation of Congressional intent on the need to consider costs and benefits under section 7003.

c. Relevant Case law

It is not clear whether Section 7003 confers a substantive standard of conduct on those persons involved with hazardous wastes, or whether the provision is jurisdictional only. Substantive authority under section 7003 would allow EPA to use this provision to force compliance with certain norms. Jurisdictional authority under section 7003 would merely allow EPA to bring suit in federal court and would not address the actual conduct required of defendants.

Several courts have held that Section 7003 of RCRA is jurisdictional only, and does not prescribe substantive standards to govern conduct. See, U.S. v. Waste Industries, 13 ELR 20286 (E.D.N.C. Dec. 30, 1982); U.S. v. Midwest Solvent Recovery, Inc., 484 F. Supp. 138 (N.D. Ind. 1980); U.S. v. Solvents Recovery Service of New England, 496 F. Supp. 1127 (D. Conn. 1980); U.S. V. Ottati and Goss Inc., C80-225-C (D.N.H. October 1980) (Slip op.)

Under this interpretation, section 7003 authorizes the federal courts to hear the government's case alleging an "imminent annd substantial endangerment," but the government must rely on other substantive authority (e.g., violation of other statutory provisions of RCRA or, arguably, the common law of nuisance) to prove such endangerment.

Other courts have held that Section 7003 does establish substantive standards of conduct. See, U.S. v. Diamond Shamrock Corp., 12 E.L.R. 20819 (N.D. Ohio, May 29, 1981); U.S. v. Reilly Tar and Chemical Corp., 546 F. Supp. 1100 (D. Minn. 1982); U.S. v. Hardage, 13 E.L.R. 20188 (W.D. Okla. 1982) (Section 7003 confers strict liability). However, in cases where courts have held that Section 7003 confers substantive liability on defendants, they have rarely dealt with the need to balance costs and benefits in determining whether an activity constitutes an "imminent and substantial endangerment." Rather, those courts seem to envision these standards as risk-based only. For example, in U.S. v. Vertac, 489 F. Supp. 870, 885 (E.D. Ark. 1980), a federal district court concluded that dioxin escape from a chemical manufacturing plant "gives rise to a reasonable medical concern over the public health" and, under Section 7003 of RCRA, presents an "imminent and substantial endangerment to the health of persons." Id. In fashioning an injunctive remedy, the court noted that it, "must strike a balance between the benefits conferred and the hazards created by Vertac's facility." The four factors considered by the court in striking this balance were:

a. the nature of the anticipated harm;

b. the burden on Vertac and its employees from the issuance of the injunction;

c. the financial ability of Vertac to convert to other methods of waste disposal; and

d. a margin of safety for the public.

Id; See also, U.S. v. Price, 688 F. 2d 204 (3rd Cir. 1982).

However, the issue of judicial balancing of costs and benefits in constructing an equitable remedy for imminent and substantial endangerment is somewhat distinct from the issue of whether EPA must or can consider costs and benefits in its regulatory decisonmaking. EPA's decision to bring suit should be governed by either of two criteria, depending on the interpretation of Section 7003 given to it by the particular court:

1) In courts that hold Section 7003 to be substantive, EPA should have evidence that the defendant's conduct may present an imminent and substantial endangerment without necessarily referring to another specific substantive standard. (e.g., it should give "rise to a reasonable medical concern over public health," as defined by the court in Vertac, supra).

2) In courts that hold Section 7003 to be merely jurisdictional, EPA must find a distinct statutory (or, arguably, common law) basis to support its claim of imminent and substantial endangerment.

In either case, however, court decisions on Section 7003 seem to indicate that this section is primarily health-based; it leaves little latitude for balancing economic effects in regulatory decisionmaking.

7. Additional Provisions

Other statutory provisions in RCRA allow EPA to consider economics in environmental decisionmaking. These statutory provisions are perhaps not as fundamental to achieving RCRA's goals as those analyzed above, but they do indicate some Congressional intent to incorporate economics in EPA's rulemaking. These provisions of RCRA are summarized below:

Solid Waste Management Information and Guidelines. (Section 1008, 42 U.S.C. 6907). Section 1008 of RCRA requires EPA to issue guidelines for solid waste management. These guidelines must contain, inter alia, "a technical and economic description of the level of performance that can be attained by various available solid waste management

practices . . ." These guidelines must be followed by federal agencies, Id., Section 6004, 42 U.S.C. 6964, but are optional for other governmental entities, such as states. In U.S. Brewers Association v. EPA,, 600 F.2d 974 (D.C. Cir 1979), a federal circuit court upheld the validity of federal guidelines requiring a 5 cent refundable deposit on beverage containers sold at federal facilities. The court disagreed with the Brewers' contention that such guidelines amounted to statutorily impermissible regulation of "manufacturing processes" under Section 1008 of RCRA.

Restrictions on Recycled Oil. (Section 3012, 42 U.S.C. 6932). This section allows EPA to issue regulations to protect the public from recycled oil hazards. The statute requires EPA to "conduct an analysis of the economic impact of the regulations on the oil recycling industry." Moreover, such regulations may not "discourage the recovery or recycling of oil."

Federal Guidelines for Solid Waste Plans and Requirements for Approval of Solid Waste Plans. (Sections 4002 and 4003, 42 U.S.C. 6942, 6943). Under Section 4003 of RCRA State solid waste disposal plans must incorporate certain minimum features. When Congress was considering HR 14496, the parallel statutory provision referred to approval of "discarded materials" plans, rather than "solid waste" plans, See HR 14496, 94th Cong., 2d Sess., Sections 104(2), 401-403.

In establishing minimum requirements for discarded materials plans, EPA was to develop guidelines. As ultimately enacted, RCRA requires EPA to issue such guidelines under Section 4002. These guidelines must reflect a variety of environmental factors (e.g., groundwater and surface water quality) as well as "population density, location and transportation within the region the rates of generation of wastes, and political, economic, financial and institutional barriers to the planning processes." See, 42 U.S.C. 6942(c)(1-11); See also, U.S. House, Rep. No. 1491, 94th Cong., 2nd Sess., p. 40 (1976).

Criteria for Sanitary Landfills (Section 4004, 42 U.S.C. 6944). The criteria for distinguishing an “open dump” from a "sanitary landfill" must ensure that “there is no reasonable probability of adverse effects on health or the environment from disposal of solid waste at such facility." The Commerce Committee provided limited elaboration on this term, stating only that “the effects on human health and the environment from real sanitary landfill (sic) should be slight.” U.S. House, Rep. No. 1491, 94th Cong., 2d Sess., p. 37 (1976).

Furthermore, Section 4003(c) of RCRA, 42 U.S.C. 6943(c), allows a state to receive additional federal financial assistance if its solid waste plan provides for, inter alia, analyses of the economic and technical feasibility of resource recovery and conservation.

Employee Protection (Section 70031, 42 U.S.C. 6971). RCRA requires EPA continually to evaluate the "potential loss or shifts of employment" resulting from the administration or enforcement of the Act. Other than using such information in protecting employees from unfair or discriminatory discharges, there is no significant legislative history concerning the substantive effect of such studies.

Special Studies (Section 8003, 42 U.S.C. 6982). Section 8002 of RCRA requires EPA to study the economic and environmental impact of RCRA implementation and selected industries and wastestreams such implementation may affect. These studies are distinct from environmental impact and regulatory impact studies otherwise required of EPA. They were included in the 1980 amendments to RCRA (Pub. L. 96-482, Section 29) when Congress suspended, delayed, and/or modified the regulation of a number of wastestreams. , See, U.S. House, Rep. No. 1444, 96th Cong., 2d Sess., pp. 31-32 (1980).

Full Scale Demonstration Facilities (Section 8004, 42 U.S.C. 6984). EPA may fund waste management demonstration facilities that demonstrate new technologies or processes, or "the technological feasibility and cost-effectiveness of an existing, but unproven technology, process, or practice...."

Special Study and Demonstration Projects, Grants for Resource Recovery (Section 8005, 42 U.S.C. 6985). EPA is required to study the economic, environmental and other aspects of recovering useful energy and materials from solid waste. Grants are available for demonstrating new recovery systems and for constructing new solid waste disposal facilities.

I. THE TOXIC SUBSTANCES CONTROL ACT OF 1976 (TSCA, Pub. L. 94-469, 15 U.S.C. 2601-2629

A. Summary of TSCA

TSCA empowers the EPA Administrator to take a variety of regulatory actions to protect health and the environment from “unreasonable" risks of harm posed by chemicals. Balancing economic, health and environmental concerns plays an important role throughout the Act, especially in determining whether a chemical risk is “unreasonable."

TSCA was enacted “[t]o regulate commerce and protect human health and the environment by requiring testing and necessary use restrictions on certain chemical substances.." (See, Pub. L. No. 94-469). All chemical substances and mixtures are covered by the Act except pesticides, tobacco, nuclear material, goods subject to tax imposed by the Internal Revenue Code of 1954 section 4181 (firearms and ammunition), food, food additives, drugs, and cosmetics. TSCA 53(2)(B).

Probably the most important substantive provisions of TSCA are sections 4, 5, and 6 of the Act that govern testing, premanufacture clearance, and the regulation of chemical production and distribution. Section 4 requires that EPA issue testing rules applicable to chemical manufactures if a finding is made that insufficient data exist on a substance and that the substance may: “present an unreasonable risk” (S4(a)(1)(A)(i)), “enter the environment in substantial quantities*’ (S4(a)(1)(B)(i)(I)), or present a likelihood of “substantial human exposure” (S4(a)(1)(B)(i)(II)). Section 5 requires a chemical manufacturer to give notice to EPA before manufacturing a new substance (S5(a)(1)) or before manufacturing an old substance for "signifciant new use” (S5(a)(1)(B)). Section 6 applies to all chemicals and empowers EPA to use the “least burdensome” of any number of restrictions to adequately protect against unreasonable risks of injury to health or the environment (S6(a)).

B. Regulatory Activities and Policies

1. Section 2: Policies Underlying TSCA

a. Statutory Directive

Subsection 2(b) states the policies of the Toxic Substances Control Act and provides the vantage point from which the Act as a whole must be viewed. Three policies are specified: (1) Data should be developed on the health and environmental effects of chemicals, with principal responsibility for this data development placed on industry; (2) there should be adequate authority for the government to prevent unreasonable risks of injury to health or the environment, particularly with respect to imminent hazards; and (3) this authority should be exercised "so as not to impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose of this Act to assure that . . . such chemical substances . . . do not present an unreasonable risk of injury . . . ." TSCA S2(b)(1)(3), 15 U.S.C. S2601(b)(1)(3) (emphasis added).

TSCA gives the U.S. Environmental Protection Agency (EPA) broad authority to regulate "the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture . . . that . . . presents or will present an unreasonable risk of injury to health or the environment" (15 U.S.C. S2605(a)), and "to take action with respect to chemical substances or mixtures which are imminent hazards" (15 U.S.C. S2601(b)(2)). Thus, the statute covers ongoing chemical manufacturing operations, including manufactured products already distributed in commerce.

TSCA S2(c) explains that "[i]t is the intent of Congress that the Administrator shall carry out this Act in a reasonable and prudent manner, and that the Administrator shall consider the environmental, economic. and social impact of any action the Administrator takes or proposes to take under this Act." 15 U.S.C. S2601(c) (emphasis added).

b. Legislative History

(i) Introduction

Section 2 of the Toxic Substance Control Act sets forth the congressional findings, policies, and intentions that led to the passage of the Act. The exposure of human beings and the environment to a large number of chemicals prompted Congress to enact TSCA in an effort to control both inter- and intra-state commerce in chemicals.

The Senate Commerce Committee Report, (S. Rep. No. 698, 94th Cong., 2d S ess (1976)), accompanied S-3149, the Senate bill on toxic substances regulation. This report states that it is the purpose of TSCA "to prevent unreasonable risks of injury to health or the environment associated with the manufacture, processing, distribution in commerce, use or disposal of chemical substances," and that the Act "is designed to fill a number of regulatory gaps." Id. at 1. It notes that such statutes as the Clean Air and Clean Water Acts, Consumer Product Safety Act, and the Occupational Safety and Health Act "impose restrictions after [chemical) manufacture begins" (Id. at 5, emphasis added), and that TSCA authorizes EPA to take a comprehensive look at the totality of health and environmental hazards associated with a chemical prior to its manufacture and use. This preventive method allows for the direct control of potentially dangerous chemical substances that could be found in consumer and industrial items. The committee report explains:

> The most effective and efficient time to prevent unreasonable risks to public health or the environment is prior to first manufacture. It is at this point that the costs of regulation in terms of human suffering, jobs lost, wasted capital expenditures, and other costs are lowest. Frequently, it is far more painful to take regulatory action after all of these costs have been incurred.
>
> . . . [I]t seems far more prudent to provide authority to limit the amounts of dangerous materials in . . . products than to allow them to escape . . . . A prime purpose of the . . . Toxic Substances Control Act is to provide authority for such regulatory controls.

Id. at 5-6 (emphasis added).

The toxic substances control bill that passed the House of Representatives was H.R. 14032 (94th Cong., 2d S ess (1976)). U.S. House, Rep. No. 1341 (94th Cong., 2d S ess. (1976)) accompanied the House bill and was submitted by the Committee on Interstate and Foreign Commerce to which the original bill was referred. Under subsection 2(c), Congress intended the Administrator and to consider the economic, environmental, and social impacts of proposed actions. The report cautioned, however, that the committee's intent "is not to be construed as a direction to the Administrator to make any statement of findings in addition to those required by specific provisions of the bill or to involve the Administrator in any cost benefit justifications." Id. (emphasis added).

(ii) Unreasonable Risk

The words "unreasonable risk" are not defined in the Act, even though the term appears throughout the statute. The legislative history is helpful in providing definition. It indicates that the costs and benefits should be weighed in developing regulations. Moreover, it notes that although quantitative comparisons of costs and benefits are not feasible, the benefits of a regulations should be of at least the same magnitude as the anticipated costs. As Senate Report No. 698 states:

> [I]n each case where restrictive rules are authorized, the Administrator is required to protect against "unreasonable risks." In determining what is an "unreasonably" risk a balancing of risks and benefits is required.
>
> It is important to note that in the testing and key regulatory provisions of the legislation, it is specifically required that the Administrator evaluate the risks and the benefits of his actions before taking regulatory action. Thus, costs are not to. be incurred unless they are offset by benefits of at least the same magnitude. In comparing risks, costs, and benefits of at least the same is important to recognize that one is weighing noncommensurates, and it is not feasible to reach a decision just on the basis of quantitative comparisons. The burdens of human suffering and premature deathare extraordinary and must be given full consideration in such decisions.
>
> Id. at 12-13 (emphasis added).

On the House side, U.S. House, Rep. No. 1341 (accompanying H.R. 14032) similarly explains the need to weigh regulatory costs and benefits without conducting a formalized cost-benefit analysis.

> Because the determination of unreasonable risk involves a consideration of probability, severity, and similar factors which cannot be defined in precise terms and is not a factual determination bur rather requires the exercise of judgment on the part of the person making it, the Committee did not attempt a definition of such risk. In general, a determination that a risk associated with a chemical . . . is unreasonable involves balancing the probability that harm will occur and the magnitude and severity of that harm against the effect of proposed regulatory action on the availability to society of the benefits of the substance . . ., taking into account the availability of substitutes . . . which do not require regulation, and other adverse effects which such proposed action may have on society.
>
> The balancing process described above does not require a formal benefit-cost analysis under which a monetary value is assigned to the risks associated with a substance and to the cost to society of proposed regulatory action on the availability of such benefits. Because a monetary value often cannot be assigned to a benefit or cost, such an analysis would not be very useful. (Footnote omitted).
>
> Id. at 13-14 (emphasis added).

The committee also cited to a National Academy of Sciences report that stated: "Highly formalized methods of benefit-cost analysis seldom can be used for making decisions about regulating chemicals in the environment. Thus the development of such methods should not have high priority." Id. at 14 n.1.

EPA, therefore, has considerable discretion in weighing costs and benefits under TSCAm and can- consider- both qualitative and quantitative factors in determining whether a chemical persents unreasonable risks as compared to its benefits. However, the Agency does not have to engage in a formal cost/benefit exercise. Although it is not clear whether the Agency is actually precluded from conducting such an analysis the expression of Congressional skepticism over the feasibility of undertaking formalized

cost-benefit analysis in regulating health and environmental risks suggests that the Agency may not be able to do so.

B. Regulatory Activities

1. Section 4: Testing of Chemical Substances and Mixtures

a. Statutory Directive

Section 4 (15 U.S.C. S2603) gives EPA the power to adopt rules requiring manufacturers to test their chemical products for effects on health and the environment. This section applies to existing chemicals that are already in commerce and to new chemicals. Section 4 also provides an exemption procedure to avoid the submission of duplicative data by persons otherwise required to conduct tests (Subsection 4(c)). Cost-sharing procedures are applicable to the exempt manufacturer.

The Administrator has a duty to issue a testing rule when the following determinations are made. (1) A chemical "may present an unreasonable risk of injury to health or the environment . . "; (2) there are insufficient data on the manufacture, use, processing, distribution in commerce, or disposal of such chemical; thus, a reasoned risk assessment cannot be made; and, (3) testing of the chemical is required in order to generate the needed data. 15 U.S.C. S2603(a)(1)(A)(i)-(iii). Alternatively, if EPA finds substantial production of the chemical and the likelihood of significant exposure to humans or the environment, a test rule may be issued if sufficient data are lacking and there is a need for testing. 15 U.S.C. S2603(a)(1)(B)(i)-(iii).

A rule under TSCA S4(a), 15 U.S.C. S2603(a), must include:

> (A) identification of the chemical substance or mixture for which testing is required under the rule,
> (B) standards for the development of test data for such substance or mixture, and
> (C) with respect to chemical substances which are not new chemical substances and to mixtures, a specification of the period (which period may not be of unreasonable duration) within which the persons required to conduct the testing [i.e.,

> manufacturers or processors of existing chemicals] shall submit. to the Administrator data developed in accordance with the standards referred to in . . . (B) [above].
>
> 15 U.S.C. S2603(b)(1)(A)-(C) (emphasis added).

TSCA S4(b)(1), 15 U.S.C. S2603(b)(1), concludes:

> In determining the standards and period to be included, pursuant to subparagraphs (B) and (C), in a rule under subsection (a), the Administrator's considerations shall include the relative cost of the various test protocols and methodologies which may be required under the rule and the reasonably foreseeable availability of the facilities and personnel needed to perform the testing required under the rule.
>
> 15 U.S.C. S2603(b)(1) (emphasis added).

In setting standards for the development of test data under this section, the Administrator is guided by TSCA S3(12), which defines "standards for the development of test data."

The statue and applicable legislative history give the Administrator broad authority to determine the standards for testing. Methodologies may include whole animal tests, in vitro tests, and epidemiological, serial or hierarchical tests. The health and environmental effects to be tested included carcinogenesis, teratogenesis, mutagenesis, synergistic effects and behavioral disorders or any other effect that may present an unreasonable risk of injury. TSCA S4(b)(2)(A). Beyond this, the Act does not specify the particular type of test that EPA may require. The Agency, therefore, apparntly has discretion in formulating appropriate test procedures and protocols.

TSCA S4(c) provides that certain persons obligated "to conduct tests and submit data" pursuant to a rule may apply for an exemption from the requirement. 15 U.S.C. S2603(c)(1). After the application for exemption is received, the Administrator must grant the applicant's request for exemption if two conditions are met: (1) data on a chemical substance equivalent to the one for which the application was submitted has been or is being generated in accordance with a rule; and (2) data if submitted by an

applicant “would be duplicative of data” submitted or in the process of being submitted pursuant to a rule.

b. Legislative History

Section 4 gives the Administrator the authority to achieve one of the objectives of TSCA: to place upon industry the responsibility for adequately testing potentially hazardous substances and to determine their effects on health and the environment. New and existing chemical substances and mixtures are subject to the requirements of this section.

The committee of conference reconciled S. 3149 and H.R. 14032 and unanimously agreed to a compromise between the two bills. House Conference report No. 1679 (94th Cong., 2d Sess. (1976)) accompanied S. 3149. The conferees intended that the Administrator have authority to protect against unreasonable risks posed both directly and indirectly by chemicals either acting alone or in combination. Testing is required in two situations: (1) where “a substance or mixture may present an unreasonable risk,” and (2) where "there may substantial environmental or significant or substantial human exposure to a substance or mixture about which there is inadequate information to predict effects on health or the environment." Id. at 61. The report continues:

> In the first situation, the conferees intend to focus the Administrator's attention on those chemical(s). . . about which there is a basis for concern, but about which there is inadequate information to reasonably predict or determine their effects . . . . The Administrator need not show that the substance or mixture does or will present a risk (emphasis added).
>
> The second situation reflects the conferees' recognition that... testing should be conducted even though there is an absence of information indicating that the substance or mixture per se may be hazardous.
>
> Id.

House Rep. No. 1341 summarizes the interplay between sections 4, 5, and 6 of TSCA, with emphasis on the Administrator's duties with respect to unreasonable risks.

> Although the standard for defining the regulatory authority of the Administrator throughout the bill is "unreasonable risk," the implementation of the standard will of necessity vary depending on the specific regulatory authority which the Administrator seeks to exercise. For example, a testing rule under section 4 will ordinarily not result in depriving the public of the benefits of a substance or mixture subject to the rule. This is because such a rule does not prohibit the manufacture, processing, etc., of existing substances or mixtures. At the most a testing rule may, through section 5(d), delay the commercial availability of new substances and new uses of existing substances subject to the testing rule. Similarly, a requirement imposed under section 5(g) (regulation of new substances and significant new uses of substances pending the development of information) will only delay or restrict the availability of a substance subject to it until adequate health and safety data can be developed and evaluated.
>
> However, this is to be contrasted with the effect of the imposition of a requirement under section 6 on a substance. Such a requirement may remove a substance from the market or impose lesser restrictions on its availability and such a requirement is not of limited duration. Thus, the effect on society nay be far reaching. As a result regulatory effect will be of greater significance in a determination of unreasonable risk for purposes of section 6 than for a determination for purposes of section 4 or 5(g). Conversely, with respect to section 4 or 5(g), because the regulatory effect of action taken under either of those sections is less than that of action taken under section 6, the requirements for a determination of unreasonable risk for purposes of section 4 or 5(g) are less demanding.
>
> The Committee has limited the Administrator to taking action only against unreasonable risks because to do otherwise assumes that a risk-free society is attainable, an assumption that the Committee does not make.
>
> U.S. House Rep. No. 1341 at 14-15.
>
> The conferees do not intend that, in complying with the requirements of the statute, the Administrator divert from the regulatory activities of the Agency an inordinate amount of resources to justify the failure to require testing.
>
> If the Administrator receives information which indicates to the Administrator that there may be a reasonable basis to conclude that a substance or mixture presents or will present a significant risk of serious or widespread harm to human beings from cancer, gene mutations, or birth defects,

> the Administrator shall initiate appropriate action under section 5, 6, or 7 to protect against the risk or publish in the Federal Register a finding that the risk is not unreasonable. Such action must be taken within 180 days of the receipt of the data, except that the Administrator may extend that period for an additional 90 days for good cause. This requirement does not take effect until two years after the date of enactment.
>
> U.S. House Rep. No. 1679 at 62.

c. Relevant Case Law

None

2. Section 5: Manufacturing and Processing Notices

a. Statutory Directive

TSCA S5(a)(1) states that when a manufacturer intends to introduce a chemical substance into the stream of commerce, and that substance is not on the TSCA Inventory (S8(b)), notice must be submitted to the Administrator at least ninety (90) days before commencement of manufacture or import. 15 U.S.C. §2604(a)(i). TSCA S5(d) sets forth the information required to be contained in the notice.

These premanufacturing notification provisions are designed to regulate the introduction into commerce of substances posing unreasonable risks. This is a preventive measure rather than one aimed at controlling chemicals, already produced. The Administrator has broad authority to review and evaluate information on the substance and to prohibit or otherwise restrict manufacture if it is determined that: (1) data are insufficient to evaluate health and environmental effects; or (2) the chemical or new use presents or will present an unreasonable risk.

Under section 5 (15 U.S.C. S2604), manufacturers must give EPA notice 90 days before manufacture or import of a "new chemical substance" (§5(a)(1)(A)), or an old substance for a “significant new use” (S5(a)(1)(B)). For a substance subject to a section 4 testing rule, section 4 test results must accompany the section 5 notice (§5(b)(1)(A)). (It should be noted that there is a special provision, TSCA §5(b)(1)(B), for those persons

exempted from section 4). If a substance is not covered by section 4, the manufacturer must provide data showing absence of unreasonable risk of injury to health or the environment, according to the requirements of TSCA §5(b)(2)(A),(B). This subsection comes into play for chemicals that are new (§5(a)(1)(A)), and for old chemicals intended to be put to a significant new use (§5(a)(1)(B)) if the substance has been listed by the EPA Administrator as one that "presents or may present an unreasonable risk of injury to health or the environment" (§5(b)(4)).

A section 6 (15 U.S.C. 92605) proceeding would normally follow as the next step. However, if EPA determines "that there is a reasonable basis to conclude that . . . an unreasonable risk" may be presented prior to promulgation of a section 6 rule, EPA can seek "an injunction prohibiting the manufacture, processing, or distribution in commerce" of a substance (§5(f)). Or, EPA can issue a proposed section 6(a) rule, or an administrative order (Id.), which are both discussed in the next section of this document.

Chemicals for which EPA has insufficient data to make a "reasoned evaluation" of safety can be regulated under subsection 5(e), "Regulation Pending Development of Information." EPA is authorized by this section to issue an administrative order prohibiting or limiting the manufacture, use, distribution, processing, or disposal of such substance if findings of risk or prevalence (similar to those triggering section 4 testing rules) are made (§5(e)(1)(A)(i), (ii)(I) and (II)). TSCA §5(e) provides that if a manufacturer or processor is potentially subject to a proposed order, he may file timely objections to the order. Should this occur, the proposed order will not take effect and the EPA Administrator must then seek injunctive relief (§5(e)(1)(C),(2)).

Subsection 5(g) provides that when the Administrator takes no action on a chemical for which premanufacturing notification is required, the Administrator must publish in the Federal Register a statement of reasons for not taking action.

TSCA subsection S(h) allows for exemptions from the requirements of subsections 5(a) or (b). Upon application, an exemption may be granted (with appropriate

restrictions) and test marketing permitted if there is a proper showing that the chemical "will not present any unreasonable risk of injury . . . ." §5(h)(1)(A),(B). Furthermore, an applicant may be exempted, upon application, from testing requirernents (§5(b)(2)) if the Administrator finds that: data on an equivalent chemical had been previously submitted (§5(h)(2)(A)(i); and, (2) "submission of data by the applicant . . . would be duplicative of data" previously submitted (§5(h)(2)(A)(ii)). An exempted applicant is under a duty to provide, either by personal agreement or by administrative order, "fair and equitable reimbursement" of a portion of testing costs incurred by the other persons who had previously submitted data (§5(h)(2)(B),(C)). The amount of reimbursement determined by the Administrator is calculated by a method similar to section 4 reimbursement.

Included among the allowable exemptions from the premanufacture notification requirements are chemicals produced:

> only in small quantities (as defined by the Administrator by rule) solely for purposes of (A) scientific experimentation or analysis, or (3) chemical research on, or analysis of such substance or another substance, including [research for product development], if all persons engaged in such . . . research . . . for a manufacturer . . . are notified . . . of any risk to health which [is believed to] be associated with such chemical substance.
>
> TSCA § 15 U.S.C. §2604(h)(3).

b. Legislative History

The conference report, in discussing section 5, explains the reasons for the premanufacturing notification provisions:

> The requirements are intended to provide the Administrator with an opportunity to review and evaluate information with respect to a substance to determine if manufacture . . . should be limited, delayed or prohibited because data is insufficient to evaluate the health and environmental effects or because the substance or the new use presents or will present an unreasonable risk of injury to health or the environment.
>
> The provisions of the section reflect the conferees' recognition that the most desirable time to determine the health and environmental effects of a substance, and to take action

> against any potential adverse effects, occurs before commercial production begins. Not only is human and environmental harm avoided or alleviated, but the cost of any regulatory action in terms of loss of jobs and capital investment is minimized.
>
> U.S. House Rep. No. 1679 at 65.

Subsection 5(b) delineates the situations in which a manufacturer subject to a notice requirement (TSCA S5(a)) must provide EPA with testing data prior to commencement of manufacturing. This provision was designed to ensure "that information respecting the health and environmental effects of any chemical substance which the Administrator has identified as a suspect chemical substance is submitted at the time of notification." Id. at 66.

In circumstances where protection against unreasonable risks is considered necessary after submission of a permanufacture notification, subsection 5(f) comes into play.

Section 5(f) of the conference substitute requires the Administrator to take immediate action

> to prohibit or limit human or environmental exposure to 8 new chemical substance or to an existing chemical substance for a significant new use in certain situations. In section 5(f) the conference substitute authorizes the Administrator to issue a proposed rule under section 6(a), but such rule is to be effective upon its publication in the Federal Register. Such action is authorized in instances in which there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of the substance presents or will present an unreasonable risk of injury to health or the environment before a rule promulgated under section 6(a) could protect against the risk. The conferees recognize, of course, that there is authority in section 6(d) under which the Administrator may make a proposed section 6(a) rule immediately effective. However, to invoke the section 6(d) authority the Administrator must find an imminent, unreasonable risk of serious or widespread injury. With respect to new chemical substances or substances for significant new uses, immediate action is authorized under section 5(f) when there is an

imminent, unreasonable risk of injury, regardless of whether. the injury will be serious or widespread.

Id. at 70.

c. Relevant Case Law

None

3. Section 6: Regulation of Hazardous Chemical Substances and Mixtures

a. Statutory Directive

Pursuant to section 6 of TSCA, the Administrator has a variety of regulatory tools at his disposal in order to take action against hazardous chemicals for which "there is a reasonable basis to conclude" that an unreasonable risk is or will be presented by the manufacture, use or disposal of such chemical. TSCA S6(a). Requirements that range from simple labeling to complete prohibition may be imposed to the extent necessary to protect against the risk. EPA has the discretion to choose among these regulatory alternatives , but must consider factors listed in 6(c), which is discussed below.

Unlike section 5, section 6 of TSCA, 15 U.S.C. S2605, is applicable to all chemicals, not just to new chemicals or significant new uses. Section 6 gives the EPA Administrator power to issue restrictive rules when "necessary to protect adequately against . . . [an unreasonable] risk [of injury to health or the environment] using the least burdensome requirements. . . ." TSCA S6(a). This rulemaking authority is available once a determination is made "that there is a reasonable basis to conclude that . . . a chemical substance . . . presents or will present an unreasonable risk . . . ." Id. A restrictive rule may contain one or more of the following requirements: prohibition or limitation of chemical manufacture, processing, distribution in commerce, use, or disposal; use of adequate warnings and instructions with respect to the chemical; recordkeeping, monitoring, or testing requirements and a requirement directing that a manufacturer or

processor must give proper notice of unreasonable risk of injury to persons in contact with such chemicals." See, S6(a)(1)-(7). Quality control measures may also be required under subsection (5) of section 6.

Subsection (c) of section 6 governs the promulgation of subsection (a) rules. It states that before instituting a rule the Administrator shall publicly identify:

> (A) the effects of such substance or mixture on health and the magnitude of the exposure of human beings to such substance or mixture,
>
> (B) the effects of such substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture
>
> (C) the benefits of such substance or mixture for various uses and the availability of substitutes for such uses, and
>
> (D) the reasonably ascertainable economic consequences of the rule, after consideration of the effect on the national economy, small business, technological innovation, the environment, and public health.
>
> TSCA §6(c)(1), 15 U.S.C. §2605(c)(1).

This requirement is consistent with the policy behind TSCA (§2(b)(3)) that while unreasonable risks should be reduced, technological innovation should not be "unduly" impeded. Thus, before a rule is issued, the Administrator must consider and balance a variety of information about a chemical: (1) risks and benefits (§6(a),(c)(1)(C)); (2) availability of substitutes (§6(c)(1)(C)); and (3) whether a chemical is new or already in production and in commerce (§6(c)(1)(D).

While formal cost-benefit analyses are not required under TSCA, due to difficulties in assigning dollar values to noncommensurates, EPA is directed to consider both risks and benefits before instituting a section 6 rule. A statement of the environmental, health, and economic effects of the rule is to be published in the Federal Register.

Subsection 6(c) generally directs EPA to use its powers under other federal environmental statutes in preference to section 6. However, it is within the Administrator's discretion to use section 6 if the public interest so requires. This

involves consideration by the Administrator of the following factors: "(i) all relevant aspects of the risk, . . . (ii) a comparison of the estimated costs of complying with actions taken under this Act and under such law (or laws), and (iii) the relative efficiency of actions under this Act and under such law (or laws) to protect against such risk of injury." TSCA S6(c)(1).

Subsection (e) of section 6 provides for the regulation of polychlorinated biphenyls (PCBs), effective six months after TSCA's effective date of January 1, 1977. Except in those situations that quality for exemptions (where the Administrator finds that no unreasonable risk of injury is presented by PCBs and that good faith efforts to develop a substitute have been made), PCBs are only to be used in a "totally enclosed manner," to ensure minimal human exposure.

b. Legislative History

The conference committee report emphasizes that according to subsection (a) of section 6, "[t]he requirement, must be the least burdensome feasible for those subject to the requirement and for society while providing for an adequate margin of protection against the unreasonable risk." U.S. House Rep. No. 1579 at 73.

The report from the Committee on Interstate and Foreign Commerce (U.S. House Rep. No. 1341, accompanying H.R. 14032) made similar recommendations.

> The committee intends that any requirement prescribed under section 6(a) be the least burdensome possible for those subject to the requirement and for society while providing an adequate margin of protection against the unreasonable risk . . . . [T]he determination of the least burdensome requirement will be based on information submitted to the Administration during the rulemaking proceeding and other information . . . . The committee does not intend that needed regulation be unreasonably delayed while the Administrator develops quantitative data comparing the costs of control methods.
>
> Id. at 34.

While the Administrator has a discretion in deciding what restrictions to imposed under 6(a) in cases of unreasonable risks, the conferees offered the following guidance with respect to production limits:

> [I]f the Administrator chooses to impose a production limitation . . . such limitation . . . could produce monopoly profits. The conferees believe that the Administrator should consult with the Attorney General and the Federal Trade Commission in order to avoid any anticompetitive consequences.
>
> U.S. House, Rep. No. 1679 at 75.

In promulgating a rule under subsection (a), subsection (c) of section 6 enumerates the factors that the Administrator must consider, including the reasonably ascertainable economic consequences of the rule. This "anticipates that the Administrator's consideration will include, but not be limited to, major effects of the rule on the national economy and the rule's effect on technological innovation, the environment, [small business] and the public health." US. House, Rep. No. 1341 at 35. Industry is expected to provide the data on economic effects of a rule on industry, due to its expertise. Id. U.S. House, Rep. No. 1341, with respect to subsection (c), concludes:

> The economic consequences of a rule should include the positive impact a regulatory limitation or proscription will have on the development and use of substitutes as well as the negative impact on the manufacturer or processor of the regulated substance. Likewise, the economic savings to society resulting from the removal of an unreasonable risk must be a key element in any consideration of economic consequences. The committee does not intend that a chemical which causes . . . an unreasonable risk should be permitted to be marketed solely because it would cause economic costs to producers if it were not permitted to be sold.
>
> Id.

Subsection (c) of section 6 requires an additional finding if the Administrator determines that the unreasonable risk could adequately be dealt with by another EPA-administered statute. The Administrator must find that it is in the public interest to regulate under TSCA rather than such other law. U.S. House, Rep. No. 1341 explains:

> The fact that a risk could be subject to regulation under one of the other Federal laws . . . does not trigger the additional finding requirement. Instead, the Administrator must determine that the risk could be eliminated or reduced to a sufficient extent under the other law before the finding is required . . . . In making the finding, the Administrator is to take into consideration all aspects of the risk, the authorities available to enforce actions under the [TSCA] and such other laws, a comparison of the estimated costs of complying, and the relative efficiency of actions under the respective laws . . [C]onsideration of the time and resources needed to take such actions should also be included.
>
> U.S. House, Rep. No. 1341 at 35-36.

This subsection can be compared with section 9 of TSCA. Section 9 establishes the relationship between the Act and federal laws not administered by EPA. If there is a reasonsable basis to conclude that a chemical presents or will present an unreasonable risk of injury, and if the Administrator makes a discretionary finding that the risk could be prevented or reduced by a law not administered by him, the administering agency must be given the opportunity to protect against the risk before TSCA sections 6 or 7 are invoked.

The Administrator submits a report of his findings to the other agency and may request that agency to decide whether it can protect against the risk and to issue an order declaring whether or not the risk is unreasonable.

Due to widespread concern over several well-publicized incidents of PCB contamination, Congress imposed a set of requirements in TSCA for the control of PCBs. Data on carcinogenic and other effects of PCBs, together with evidence of bioaccumulation in the food chain and presistence in the environment, prompted the adoption of specific provisions for this substance. (See e.g., House consideration of H.R.

14032, 122 Cong. Rec. H8803, (daily ed. Aug. 23, 1976) (amendment offered by Rep. Dingell and his subsequent remarks reprinted in Legislative History of the Toxic Substances Control Act (Comm. Print Dec. 1976) at 580-83); 40 C.F.R. pt. 761 (1979)).

The conference report, US. House, Rep. No. 1679, provided the following summation, noting that TSCA section 6(e) mandates the eventual phase-out of PCB manufacture and distribution:

> Exemption may be granted only if the Administrator finds that there is no unreasonable risk to health or the environment, and that good faith efforts have been made to develop a substitute [for PCBs]. So that existing PCBs may be reused rather than disposed of, the prohibitions do not apply to distributions in commerce of PCBs sold for purposes other than resale before the effective date of the prohibition on distribution of PCBs.
>
> H.R. Rep. No. 1679 at 77.

c. Relevant Case Law

PCB Regulations: Environmental Defense Fund. Inc. v. Environmental Protection Agency, 636 F.2d 1267 (D.C. Cir. 1980). In this case the Environmental Defense Fund (EDF) sought review of three sections of the regulations promulgated by EPA under TSCA section 6(e)(2) and (3) that govern the manufacture and use of PCBs. (See 40 C.F.R. pt. 761 (1979). EDF objected to the provision that certain totally enclosed uses of PCBs, such as use in electromagnets, capacitors, and non-railroad transformers, were permissible due to the exemption granted in section 6(e)(2)(A). Section 6(e)(2)(C) defines "totally enclosed manner" as "any manner which will ensure that any exposure of human beings or the environment to a [PCB] will be insignificant as determined by the Administrator by rule." Because the Administrator had defined "insignificant exposure" as "no exposure" EDF argued, and the court agreed, that EPA had not produced substantial evidence on the record that the totally enclosed use regulations "will ensure that any exposure. . . to a [PCB] will be insignificant." 636 F.2d at 1286.

EDF also challenged the determination by EPA that eleven non-totally enclosed uses of PCBs could continue based on a finding that such uses "will not present an unreasonable risk of injury to health or the environment." TSCA section 6(e)(2)(B). (See 40 C.F.R. pt. 761.30.(1979))

After reviewing EPA's evidence that the Administrator had carefully balanced social and economic impacts of the rule against environmental and health risk (pursuant to 6(c)(1) criteria), the court upheld the regulations. 636 F.2d at 1279.

Regarding EDF's third objection, the court agreed: the record did not contain substantial evidence to support EPA's decision to permit continued manufacture of PCBs in concentrations less than 50 ppm. The court cited evidence of studies that exposure to PCBs in such concentrations could indeed be harmful and cause adverse effects, and held: "EPA made no findings that the cutoff would involve no unreasonable risk to health or the environment." id. at 1232.

4. Section 7: Imminent Hazards

a. Statutory Directive

Section 7 of TSCA gives the Administrator authority to take action against an "imminently hazardous chemical substance or mixture." This is defined in TSCA S7(f) as: "a chemical substance or mixture which presents an imminent and unreasonable risk of serious or widespread injury to health or the environment." A risk "shall be considered imminent if it. . . is likely to result in such injury to health or the environment before a final rule under section 6 can protect against such risk." Subsections (a) and (b) provide for enforcement procedures. The Administrator has the power to bring a civil action in order to seize, recall or replace a hazardous substance and to obtain the relief needed to protect health or the environment from risks associated with such a substance.

b. Legislative History

The conferees imposed a nondiscretionary duty upon the Administrator: if he has not used his authority pursuant to subsection 6(d)(2)(A)(i) to make a section 6(a) rule immediately effective in order to prevent an imminent hazard, a section 7 action must be brought. US. House, Rep. No. 1679 at 78.

The report indicates that it is the intent of the conferees that a section 7 action be brought soon enough to "prevent a final injury from materializing." Id. The term "widespread injury" need not refer to a large geographic occurrence. "Rather, an unreasonable risk of harm affecting a substantial number of people, even though it is within a rather limited geographical area, should be deemed adequate to satisfy the requirement of an unreasonable risk of widespread injury to health. Of course if the risk of injury to health or environment is serious, it need not be widespread." Id.

c. Relevant Case Law

In Rush v. Environmental Protection Agency, No. C81-740 (N.D. Ohio, Complaint filed Apr. 13, 1981), plaintiff brought suit under the citizen suit provision of TSCA, section 20. The complaint alleged that plaintiff was injured from a tear gas explosion while in the US. Air Force. The plaintiff sought a ruling from EPA under TSCA §7 that: (1) tear gas is an imminent hazard; (2) its use for police munitions or personal protection should be prohibited; (3) EPA should notify both buyers of the gas and the public of risks involved in the use of the gas; (4) defendants should be ordered to prove the non-toxicity of tear gas; and (5) defendants should be ordered to recall the gas. The case is still pending.

5. Other Provisions Involving Economic Considerations in Regulatory Decisionmaking

TSCA also contains a full complement of provisions (See, sections 8-30, 15 U.S.C. §§2607-2629) governing such concerns as judicial review, penalties and enforcement, preemption and citizen suits. Economic considerations are a factor in many of these sections, summarized below. Many of these provisions refer to the term "unreasonable risk." Reference should be made, where appropriate, to the explanation of this term under section 4, above.

Section 8: Reporting and Retention of Information

Section 8(a): Reports

Subsection (a) directs that each person (other than small manufacturers who are subject to TSCA §8(a)(3)) shall maintain record and submit reports to the Administrator as he reasonably requires pursuant to a rule. And, "[t]o the extent feasible? the Administrator shall not require . . . any reporting which is unnecessary or duplicative!' (Id.) (emphasis added).

Section 8(e): Notice to Administrator of Substantial Risks

Under subsection 8(e) a person who obtains new information that reasonably supports the conclusion that a substance . . . presents a substantial risk of injury to health or the environment shall immediately inform the Administrator," unless that person "has actual knowledge that the Administrator has been adequately informed (emphasis added). Dow Chemical Co. v. Environmental Protection Agency, 605 F.2d 673 (3rd Cir. 1979).

In Dow Chemical the Third Circuit Court of Appeals held that, pursuant to section

8(d), EPA was authorized to obtain information from a chemical manufacturer about research and development projects expected to result in a profitable product. Even though the company did not intend to offer small quantities of the chemical in commerce, but to use it only for research and development, the court found that Dow's actions were "for commercial purposes" as defined by a EPA-proposed rule.

Companies to whom the rule applied had to submit health and safety studies in their possession on a chemical intended solely for research and development purposes.

Section 9: Relationship to Other Federal Laws

The purpose of section 9, according to the conference committee report (H.R. Rep. No. 1679) is "to assure that overlapping or duplicative regulation is avoided while attempting to provide for the greatest possible measure of protection to health and the enviromment" (Id at 84).

Subsection 9(a): Laws Not Administered By The Administrator

The conference report states that this subsection defines the relationship between TSCA and federal laws not administered by the Administrator.

Once the Administrator finds that another law is adequate for protection against a risk, he is required to submit a detailed report to the administering agency. The report is to contain a description of the risk and related activities causing such risk "which the Administrator has reason to believe so present such risk" (section 9(a)(1)).

Section 9(a)(2) provides that if the other agency, after receiving this report, issues an order stating that an unreasonable risk is not presented, the Administrator may not proceed under section 6 or 7. If, however, an unreasonable risk is found, and the other agency acts upon it, no section 6 or 7 proceeding may be initiated by the Administrator. Note that the Administrator may act pursuant to section 6 or 7 if the other agency failes

to make either determination.

Section 9(b) is similar to subsection 6(c)(1) and mandates that the Administrator coordinate TSCA action with the other laws administered by EPA. If a finding is made that a risk "could be eliminated or reduced to a significant extent" by other authority of the Administrator, such other authority shall be used, unless the discretionary finding is made that it is in the public interest to act pursuant to TSCA.

Section 10: Research, Development, Collection, Dissemination, and Utilization of Data

Subsection (a) authorizes the Administrator to make grants and contracts for "research, development, and monitoring" needed to carry out the purposes of TSCA. This is to be done "in consultation and cooperation with the Secretary of Health, Education, and Welfare" (now DHHS) and with other appropriate agency and department administrators.

U.S. House, Rep. No. 1679 explains the economic considerations that may underlie a subsection (5) action:

> Subsection (5) specifies that an efficient and effective data retrieval system shall be developed. The conferees emphasize that sufficient data is necessary for successful implementation of this Act, yet they also acknowledge the burden dated on industry by excessive or duplicative reporting
>
> The efficient exchange of information among Federal agencies and departments will facilitate implementation of this Act, and every effort should be made to achieve this goal and to avoid duplicative requirements in information-gathering.
>
> Subsections (c), (d), (e), (f), and (g). . . concern research and development in the area of data collection. . . .[S]uch research and development should not duplicate any research and development already being conducted by other Federal agencies and departments. Thus, careful coordination and consultation with such departments and agencies is required.

Id. at 86-87 (emphasis added).

Section 12: Exports

This section governs chemicals exported from the United States.

Subsection (a) provides that:

> Unless the Administrator finds that such substances or mixtures will cause or contribute to an unreasonable risk to the health of persons within the United States or the environment of the United States, such substance are exempt from the Act (other than the reporting requirements or Section 8) if proper labeling shows that they are intended for export use only.
>
> However, subsection (b) allows the Administrator to require testing under section 4 to see if such substance or mixture may cause or contribute to a risk of health within the United States or to the environment of the United States.

Subsection (b) requires that "the Administrator shall furnish to the government of such [foreign] country" relevant information obtained pursuant to sections 4 through 7, "so that such foreign governments can protect their own citizens." U.S. House, Rep. No. 1679 at 88.

Section 14: Disclosure of Data

Subsection (a)(3) provides for mandatory disclosure of data (described in FOIA, 5 U.S.C. §552(b)(4)) obtained under TSCA "if the Administrator determines it necessary to protect health or the environment against an unreasonable risk of injury to health or the environment; . . . (emphasis added)." If environment is to be disclosed under subsection (a)(3) the Administrator is required to notify the person who provided the data at least 15 days prior to disclose, "except that if the Administrator determines that the release of such data is necessary to protect against an imminent. unreasonable risk of injury to health or the environment, such notice may be made by such means as the Administrator determines will provide notice at least 24 hours before such release is made." TSCA §14(c)(2)(B)(i) (emphasis added).

Section 18: Preemption

Under this section, no state or locality may establish a testing rule if one has already been instituted by the Administrator. (TSCA §18(a) (2)(A).) Additionally, if the Administrator has issued a rule pursuant to section 5 or 6 (protecting against risks) a state or locality may not regulate such risk by rule unless that rule: "(A) is identical to that issue[d] under this Act, (B) is adopted under the authority of another Federal law, or (C) prohibits the use of such substance or mixture other than its use in the manufacturing . . . of other chemical substances . . . " H.R. Rep. No. 1679 at 95 (with respect to TSCA §18(a)(2)(B)).

It should be noted that subsection (b) provides that a state or locality may apply for exemption from subsection (a)(2). "The Administrator may, by rule, grant an exemption if compliance . . . will not cause a violation of the applicable requirement under this Act, if the State or local requirement will provide a significantly higher degree of protection from the risk, and if the State or local requirement will not unduly burden interstate commerce." H.R. Rep. No. 1579 at 95 (emphasis added). "This provision was designed to discourage differing State requirements which would put an undue burden on those companies that do business in a number of States" House Consideration of H.R. 14032, 122 Cong. Rec. H8803 (daily ed. Aug. 23, 1976) (remarks of Rep. McCollister).

Section 21: Citizens' Petitions

This section provides that any person may "petition the Administrator to initiate a proceeding for the issuance, amendment or repeal of an action under section 4, 5(e), 6, or 8 of the Act." US. House, Rep. No. 1679 at 98. The refusal to grant the petition is reviewable in court, as explained by the House report, US. House, Rep. No. 1341, accompanying H.R. 14032:

> If the petitioner makes the requisite showing, the court shall order the Administrator to initiate the requested rulemaking action unless the court finds that the failure of the Administrator to initiate such action was not unreasonable. In making the latter determination, the court is to consider the priorities of the Administrator, the resources available to the Administrator to take the action requested by the petitioner, and other relevant factors. The Committee intends that the court carefully review the Administrator's priorities and resources to determine if the failure of the Administrator to initiate the requested action was unreasonable in light of the risk demonstrated by the petitioner.
>
> Id at 58 (emphasis added).

Section 24: Employment Effects

Under this section the Administrator is required to "evaluate on a continuing basis the potential effects on employment (including reductions in employment or loss of employment from threatened plant closures) of-

(1) the issuance of a rule or order under section 4, 5, or 6, or

(2) a requirement of section 5 or 6."

TSCA §24(a) (emphasis added).

Subsection (b) allows any employee to request that the Administrator conduct an investigation if the employee has been discharged, discriminated against or had his employment threatened as a result of a rule, order, or requirement of section 4, 5, or 6. A new hearing may be held on the matter unless the Administrator finds that there are no reasonable grounds for holding a hearing, in which case "the Administrator must so find, by order, within 45 days of the date within which time such hearing is requested." U.S. House, Rep. No. 1679 at 100.

Section 28: State Programs

If the Administrator is unable or unlikely to take action under TSCA to protect against "unreasonable risks to health or the environment, upon application by a state he is authorized to make grants to a state for the purpose of organizing and operating

demonstration programs. The Administrator may approve the application by rule:

> Such rules shall take into consideration the seriousness of the health effects in a State which are associated with chemical substances or mixtures, including cancer, birth defects, and gene mutations, the extent of the exposure in a State of human beings and the environment to chemical substances and mixtures, and the extent to which chemical substances and mixtures are manufactured. processed, used, and disposed of in a State.
>
> TSCA §28(b)(2) (emphasis added).

I. THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT OF 1947 (7 U.S.C. Sections 135-135k, and 136-136y)

A. Summary of Act

1. Statutory Overview

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provides a comprehensive mechanism for the regulation of the use, manufacture, and distribution of pesticides. The keystone of the system is the licensing of pesticide producers and their products. Pesticide production facilities and individual pesticides must be registered by EPA. FIFRA generally prohibits persons from distributing, selling, offering for sale, shipping, delivering for shipment, or receiving pesticides that are not registered with the Administrator. In registering a pesticide, the Administrator can impose restrictions on its use and labeling requirements to insure that the pesticide is properly handled and applied. As part of this process, EPA is required to classify pesticides for either general use, restricted use, or a combination of the two. The classification determines which persons can purchase or apply the pesticide. In general, the law is intended to insure that the pesticides produced and distributed do not have an unreasonable adverse effect on the environment, the driving phrase of the Act.

Pesticides have a long history of governmental regulation beginning with the "Insecticide Act of 1910." The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) was enacted in 1947 and has been amended in 1959, 1964, 1972, 1975, and 1978. The 1972 Amendments, called the Federal Environmental Pesticide Control Act of 1972, completely revised the early FIFRA regulatory scheme by prohibiting the misuse of registered pesticides and by extending the law's jurisdiction to cover the intrastate use of pesticides. In addition to the complex statutory history, the administrative duties under the Act shifted agencies in 1970, from the Department of Agriculture to the EPA. Despite the complex history, the requirements of the present legal structure are relatively straightforward and the role that economic considerations can play are well defined.

Economic considerations explicitly enter into this regulatory process. The basic issue in pesticide registration, reregistration, or classification involves balancing the risks presented by pesticide use against benefits of that use. A registrant has the burden of proving that the pesticide can be used without "unreasonable adverse effects on the environment," pursuant to guidelines that specify types of data required to support registration. Such tests include data on teratogenicity, oncogenicity, reproduction, and general chronic effects of the substance. If the evidence submitted raises prudent concerns of "unreasonable adverse effects on the environment" the EPA may initiate the rebuttable presumption against registration (RPAR) process, which may result in denial or cancellation of registration, or changes in the terms and conditions of the registration. Classification turns on a determination by EPA whether a registered pesticide will "generally cause unreasonable adverse effects on the environment," if applied in accordance with its directions for use. The operative phrase is "unreasonable adverse effects on the environment," defined in the Act to mean "any unreasonable risk to man or the environment taking into account the economic, social, and environmental costs and benefits of the use of any pesticides" (7 U.S.C. §136(bb)). The statute, therefore, clearly requires consideration of economic factors in the registration and classification of pesticides.

The statute also directs EPA to consider economic factors in denying a registration request, or cancelling or changing a registration. An environmental impact analysis must be prepared by the Administrator and published in the Federal Register in each instance. This analysis must take into account the impact of the proposed action on production and prices of agricultural commodities, retail food prices, and the agricultural economy in general.

The Act, of course, contains a number of more specific provisions. There are provisions for conditional registration, protections against disclosure of trade secret data, in addition to a full set of provisions on judicial review, civil and criminal penalties,

inspection of manufacturing establishments, standards for pesticide applicators, recordkeeping, experimental uses, imports and exports, and research and monitoring. Additionally, the Administrator is required to cooperate with appropriate state agencies to carry out the Act and to achieve uniformity in pesticide regulation. States and EPA may enter into cooperative agreements for enforcement of the Act and for administering state programs. These requirements also allow for consideration of economic factors by EPA.

B. Regulatory Activities

1. EPA Administrator's Discretion to Consider Economic Factors in Rulemaking-Section 25

a. Statutory Directive

The statute speaks clearly on the authority of EPA to explicitly consider in developing regulations differences in uses and risks among pesticides in developing regulations. The Administrator is directed to prescribe regulations that "take into account the difference in concept and usage between various classes of pesticides and differences in environmental risk and the appropriate data for evaluating such risk between agricultural and nonagricultural pesticides." Any final action taken by the Administrator in the promulgation of regulations "shall include among those factors to be taken into account the effect of the commodities, retail food prices, and otherwise on the agricultural economy, and the Administrator shall publish in the Federal Register an analysis of such effect."

These directives give the agency direct authority to use economic analyses in promulgating regulations. They do not, however, give the agency clear signals on the weight to give the various factors. This will vary according to the specific regulatory action being taken and on the statutory language authorizing the action.

The statute contains checks and balances on the Administrator's discretion. Any proposed and final regulation must be submitted to the Secretary of the Senate and the Clerk of the House of Representatives for approval, and to a scientific advisory panel and the Secretary of Agriculture for comments. (The Administrator must also submit any action, or notice taken to cancel or change a pesticide classification, or to suspend registration to prevent an imminent hazard.)

b. Legislative History

The 1978 amendments pertaining to section 25(a)(1) required the regulations to "take into account . . . the difference in environmental risk and the appropriate data for evaluating such risk between agricultural and nonagricultural pesticides."

The 1975 Act added 25(a)(2)(A) through (D) and (a)(3). The 1978 Act added the requirements that the Administrator, prior to taking any final action, consider certain factors bearing on the agricultural economy and publish such economic impact statement in the Federal Register.

While the 1975 amendments added subsection (d), the 1978 Act added to that language and required that the Administrator has to solicit operating guidelines from the Scientific Advisory Panel to improve EPA scientific analyses that lead to FIFRA decisions. The amendments also extended the publication requirement to include evaluations and recommendations made by the panel and provided for the establishment of temporary subpanels to accelerate the work of the advisory panel.

These measures were in response to criticisms that EPA was not adequately considering agricultural economics in its decisionmaking.

> The creation of a Scientific Advisory Panel and notification of this panel of proposed cancellation or suspension actions and any proposed regulations are intended to further assure balance and objectivity in EPA actions. The purpose of this revision is

> to assure that the EPA obtains unbiased objective scientific opinion in making its decisions.
>
> S. Rep. No. 452, 94th Cong., 1st Sess. 9 (1975).
>
> The substantive amendments to the FIFRA legislation incorporated in the conference version represent an attempt to strike a reasonable balance between the need for food production in a workable situation for farmers who must produce that food and the parallel need to protect human health and the environment from degradation as a result of pesticide usage.
>
> Specifically, the conference version retains the final authority over decisions to cancel or reclassify pesticides or to adopt new administrative regulations in the Administrator of the Environmental Protection Agency, but with provisions to assure that the Secretary of Agriculture is afforded an opportunity for meaningful input into such decisions at an early stage in their consideration. Further, the measure makes explicit that the Administrator of EPA shall consider, analyze, and elaborate the impact on food production of any such decisions, and that a scientific advisory panel also have an input into EPA decisions on pesticides at an early stage.
>
> 121 Cong. Rec. H. 11358 (daily ed. Nov. 18, 1975) (statement of Rep. Vigorito).

c. Relevant Case Law

None

2. The "Unreasonable Adverse Effects on the Environment" Standard -Section 2

a. Statutory Directive

The phrase "unreasonable adverse effects on the environment" was added by the FEPCA Amendment in 1972. This standard is defined as "any unreasonable risk to man or the environment taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." FIFRA Section 2(bb), 7 U.S.C. 136(bb). Thus, this explicitly authorizes the Administrator to engage in risk/benefit balancing in decisionmaking.

The phrase appears in several sections of the law. These include a determination by EPA of: (1) whether to approve or deny an application for registration of a pesticide (section 3(c)(5), (6)); (2) whether a pesticide should be classified for a general or restricted use (section 3(d)(2)); (3) whether to issue a notice of intent to cancel registration or to hold hearings (section 6(b)); (4) whether to suspend a registration pending completion of cancellation procedures (section 6 (c)); (5) whether to issue a final cancellation order (section 6(d)); (6) whether a registrant must submit additional factual information (section 6(a)(2)); and (7) whether the pesticide represents an "imminent hazard" (section 2(1)). The relative weight to be assigned to risk and benefits of a pesticide varies in each section, though there is an overriding concern expressed throughout the Act to prevent risk to public health.

b. Legislative History

The relevant legislative history supports the view that EPA can and should weigh risks and benefits of a pesticide in evaluating a pesticide's effects on the environment. On this point the House Committee on Agriculture stated: "As the Committee labored through months of hearings and discussions, one central legislative philosophy developed. . . the theme of a 'search for balance.'" U.S. House, Rep. No. 511, 92d, Cong., 1st Sess. 5 (1971).

The Committee explained its intent as follows:

> The Congress hereby finds that pesticides are valuable to our Nation's agricultural production and to the protection of man and the environment from insects, rodents, weeds, and other forms of life which may be pests; but it is essential to the public health and welfare that they be regulated closely to prevent adverse effects on human life and the environment, including pollution of interstate and navigable waters; that pesticides are used throughout the Nation and the major portion thereof moves in interstate or foreign commerce; that it is essential in the public interest to protect the public health and welfare from unreasonable adverse effects of pesticide residues on food which is consumed throughout the Nation and which moves in interstate or foreign commerce; and that regulation by the Administrator and cooperation by the States

> and other jurisdictions as contemplated by this Act are appropriate to prevent and eliminate burdens upon interstate or foreign commerce, to effectively regulate such commerce, and to protect the public health and welfare and the environment.
>
> Id. at 13-14.

The Senate Committee on Agriculture and Forestry noted: "Pesticides . . . have important environmental effects, both beneficial and deleterious. Their wise control based on a careful balancing of benefits versus risks to determine what is best for man is essential." U.S. Senate, Rep. No. 838, 92d Cong., 2d Sess. 4 (1972).

A statement in the Senate Commerce Committee report, however, suggests that Congress intended that the benefits of the use of the pesticide must far outweigh the risks, by inserting the phrase "unreasonable adverse effects on the environment" throughout the law. The pertinent paragraph deals specifically with the use of the phrase in the registration section of the Act, Section 3:

> The amendment substitutes the term "unreasonable adverse effects on the environment" for "substantial adverse effects on the environment." As this phrase forms the pivotal criterion for registration of a pesticide and other actions under the Act, the definition is of key importance . . . . Under the definition of "unreasonable adverse effects on the environment" adopted by the Committee on Commerce, the bill on its face would require that EPA make a full weighing of competing interests in making its determinations. Thus, it is intended that any adverse effect ought not to be tolerated unless there are overriding benefits from the use of a pesticide.
>
> U.S. Senate, Rep. No. 970, 92d Cong., 2d Sess. 10-11 (1972) (emphasis added).

c. Relevant Case Law

In Chemical Specialities Manufacturers Association v. EPA, 10 ELR 20432, 489 F.2d 513 (D.C. Cir. 1980), the D.C. Circuit construes the meaning of the phrase "unreasonable adverse effects" to call for the use of benefit-cost analysis by EPA in registering pesticides. In framing the background for its decision, the court points out

that: [T]he regulatory scheme adopted by Congress requires a careful balancing of risks and benefits before allowing the use of pesticides" (Id. at 20430). The court notes that the crucial "risk-benefit balancing approach is embodied...through the phrase 'unreasonable adverse effects on the environment,'" and that though this phrase appears throughout the statute, the principal balancing of risks and benefits is done by the Administrator at the time of registration. Congress, the court notes, recognized that the risk-benefit balance initially performed could change upon reevaluation of the existing information, or as new information is derived. The court's decision construes the phrase "unreasonable adverse effects" in the context of this latter situation, i.e., as the phrase is used in section 6(a)(2) on the submittal by a registrant of new information. The court holds that section 6(a)(2) does not require a registrant to submit new data on the benefits of a pesticide after the initial registration, only new information on the adverse effects. EPA, however, is responsible for determining whether the new information on effects of the pesticide are unreasonable. Id. at 20432. In reaching its decision, the court emphasizes that the phrase "unreasonable adverse effects" must be scrutinized in light of the purposes underlying the specific provision of the Act within which it is found. Id.

3. Registration of Pesticides-Section 3

a Statutory Directive

(i) Registration

Producers, sellers and distributors of pesticides, in general, must register each pesticide with EPA before marketing. As discussed above it is unlawful under FIFRA for a person to "...distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive and (having so received) deliver or offer to deliver, to any person any pesticide which is not registered with the Administrator." Though there are minor exemptions from registration requirements, for the most part any producer must submit an

application for registration. The registration process places the burden on the person desiring to "distribute, sell, offer for sale," etc. the pesticide to obtain the proper forms, and provide the data needed by EPA to evaluate the application. EPA must either approve a registration as expeditiously as possible or deny the request according to a set procedure that gives the applicant an opportunity to appeal. For those pesticides the agency decides to register, it must classify them for either general or restricted use. FIFRA gives the agency ample discretion to consider economic factors during the approval process.

FIFRA section 3(c)(2)(A), as amended in 1978, mandates that "(t)he Administrator shall publish guidelines specifying the kinds of information... required to support the registration of a pesticide...." In cases of minor uses of a pesticide, standards are to be made "commensurate with the anticipated extent of use, and the level of potential exposure of man and the environment to the pesticide (emphasis added)." Furthermore, "(i)n the development of these standards, the Administrator shall consider the economic factors of potential national volume of use, extent of distribution, and the impact of the cost of meeting the requirements on the incentives for any potential registrant to undertake the development of the required data" (emphasis added).

FIFRA section 3(c)(3) directs the Administrator to review the data as expeditiously as possible after receipt of the application and either register the pesticide or deny the registration. The Administrator is empowered by paragraph (5) of this section to register a pesticide if its use and intended function will not cause "unreasonable adverse effects on the environment." If the Administrator determines that the pesticide will cause "unreasonable adverse effects on the environment" he is authorized to deny registration. Applicants whose registrations have been refused can attempt to correct the condition or appeal the decision (see section 6, 7 U.S.C. section 136d).

The Administrator is directed by the statute to consult with other federal agencies during "consideration of any registration or application for registration under this section ..." FIFRA section 3(f)(3), 7 U.S.C. section 136a(f)(3). "The Administrator shall accomplish the reregistration of all pesticides in the most expeditious manner practicable: Provided, that, to the extent appropriate, any pesticide that results in a postharvest residue in or on food or feed crops shall be given priority in the reregistration process" (emphasis added).

EPA may issue a conditional or amended registration if the pesticide is identical to, substantially similar to, or different in environmentally insignificant ways from a registered pesticide, and its use "would not significantly increase the risk of any unreasonable adverse effect on the environment." As prerequisites to granting this status the Administrator must find that sufficient data has been submitted on the additional use and that the additional use "would not significantly increase the risk of any unreasonable adverse effect on the environment." Registration for conditional use, however, is prohibited if

> such pesticide or any ingredient therefrom, meets or exceeds risk criteria associate in whole or in part with human dietary exposure enumerated in regulations issued under this subchapter, and during the pendency of any risk-benefit evaluation initiated by such notice, if (I) the additional use of such pesticide involves a major food or feed crop, or (II) the additional use of such pesticide involves a minor food or feed crop and the Administrator determines, with the concurrence of the Secretary of Agriculture, there is available an effective alternative pesticide that does not meet or exceed such risk criteria. (emphasis added).

Unregistered pesticides may be used for experimental purposes subject to certain requirements. "Experimental use" permits can be issued by EPA for unregistered pesticides "if the Administrator determines that the applicant needs such permit in order to accumulate information necessary to register a pesticide" (section 5, 7 U.S.C. § 136c). The Administrator is authorized to require studies to detect whether the

experimental use causes "unreasonable adverse effects on the environment" and to require the submission of the results of such studies before considering a registration request. In addition, "[i]f the Administrator determines that the use of a pesticide may reasonably be expected to result in any residue on or in food or feed, he may establish a temporary tolerance level for the residue of the pesticide before issuing the experimental use permit" (emphasis added). "The Administrator may revoke any experimental use permit, at any time, if he finds that its terms or conditions are being violated, or that its terms and conditions are inadequate to avoid unreasonable adverse effects on the environment" (emphasis added).

FIFRA also gives the Administrator discretion to promulgate regulations to exempt pesticides from registration requirements which he or she determines "to be of such character which is unnecessary to be subject" to the requirements in order to carry out the purposes of the Act (section 25, 7 U.S.C. §136w).

(ii) Interim Administrative Review

Paragraph 8 of subsection 3(C) authorizes EPA to initiate a "public interim administrative review process to develop a risk-benefit evaluation" where significant evidence comes to its attention that a registered pesticide poses an "unreasonable adverse risk to man or the environment." This process is distinct from more final administrative procedures to cancel or suspend a pesticide registration (discussed below). The statute places limits on the agency's authority to initiate "interim review" prior to one of these more formal actions. The "interim review process" must be based on a validated test or other significant evidence raising concerns of "unreasonable adverse risk to man or the environment."

(iii) Classification

FIFRA section 3(d) provides for the classification of pesticides as part of the registration process based on whether an unreasonable risk is posed by the pesticide. Classification may be for general use, restricted use, or both. (Subparagraphs 3(d)(1)(B) and (C), 7 U.S.C. section 136a(d)(1)(B) and (C).) The pertinent guidance provided by the statute is that, "if the Administrator determines that the pesticide, . . . will not generally cause unreasonable adverse effects on the environment, he will classify the pesticide, . . . for general use." On the other hand, "if the Administrator determines that the pesticide ... may generally cause, without additional regulatory restrictions, unreasonable adverse effects on the environment, including injury to the applicator, he shall classify the pesticide . . . for restricted use."

For those pesticides the Administrator does classify as restricted, the Act provides the following guidance: "if the Administrator classifies a pesticide . . . for restricted use because of a determination that the acute dermal or inhalation toxicity of the pesticide presents a hazard to the applicator or other persons, the pesticide shall be applied . . . only by or under the direct supervision of a certified applicator." Otherwise, "if the Administrator classifies a pesticide, or one or more uses of such pesticide, for restricted use because of a determination that its use without additional regulatory restriction may cause unreasonable adverse effects on the environment, the pesticide shall be applied for any use to which the determination applies only by or under the direct supervision of a certified applicator, or subject to such other restrictions as the Administrator may provide by regulation." This implies that EPA may place as many restrictions on the use of a restricted pesticide as the Administrator deems necessary to protect public health.

FIFRA authorizes the Administrator to change a general use classification to one of restricted use if "necessary to prevent unreasonable adverse effects on the environment" (emphasis added). Also, registrants holding restricted use registrations

may petition for reclassification to general use if it can be established "that restricted use classification is unnecessary because "classification . . . for general use would not cause unreasonable adverse effects on the environment." FIFRA section3(d)(3) (emphasis added).

b. Legislative History

Section 3 of the 1972 amendments added provisions for complete reregistration, classification with respect to degree of potential hazard, and certification of private and commercial applicators of restricted use pesticides. These amendments called for increased protection from adverse environmental effects on the environment by directly controlling their misuse. However, they provided the EPA with broad discretion to balance all factors including economic considerations. The 1975 amendments did not alter any of the parts of section 3 dealing with unreasonable adverse effects on the environment, but the 1978 amendments did add to existing law. Statements found throughout the FIFRA legislative history on these sections provide some insight into how Congress intended EPA to exercise its discretion.

(i) Registration

According to the 1978 legislative history discussing minor uses, this provision requires the Administrator:

> to consider the potential national volume of use, extent of distribution, and impact of the cost of meeting the requirements on the incentives for any potential registrant to develop the required data . . . .
>
> 124 Cong. Rec. S. 15305 (daily ed. Sept. 18, 1978).

Further explanation of the need for the minor use provision was given during House consideration of the 1978 amendments.

> Pesticide registrants are reluctant to register products for control of a pest problem when only a small amount of the product is needed. The small profit realized by the manufacturer is not worth the expense and effort involved in meeting the requirements of registration.
>
> However, the amendments to FIFRA that are being considered here today will provide the flexibility necessary to resolve this very critical problem. I, along with every member of the committee, am sure that with these new amendments the minor uses problem will be resolved in a way that is safe to both man and the environment.
>
> 124 Cong. Rec. H. 10118 (daily ed. Sept. 19, 1978).

Section 3(c)(5), the provision that authorizes the Administrator to approve a pesticide registration if the use and intended function of a pesticide will not cause "unreasonable adverse effects on the environment," was included in the 1972 Act. As noted above, the Commerce Committee report directed that this phrase on its face required EPA to fully weigh competing interests in reviewing registration applications. The Senate report explained:

> The subsection provides that the Administrator shall approve a registration if he determines that, when considered with any section 3(d) restrictions, the pesticide warrants the claims made for it, its labeling complies with the Act, and it will not have unreasonable adverse effects on the environment . . . . Registration may be denied because the pesticide is not effective or because it is dangerous.
>
> Id. at 33.

(ii) Interim Administrative Review

The provision on the interim administrative review process was added by the 1978 amendments to place limits on the use of the rebuttable presumption against the registration process developed by EPA in 1977. The regulations defined various risk triggers which, if found to exist with respect to a pesticide or its use, would establish a

presumption against that pesticide or its use that the registrant had to overcome with evidence to avoid cancellation.

This procedure was the subject of considerable comment during both House and Senate consideration of the amendment.

> The conference bill prohibits the Administrator from initiating a public review process-the RPAR process-unless it is based on validated tests or other significant evidence raising prudent concerns of unreasonable adverse risk to man or to the environment. It also calls on the Administrator to consult with the registrant of a pesticide that is a candidate for RPAR prior to issuing RPAR. This is to afford the registrant opportunity to present evidence to EPA refuting allegations of adverse risk before any unwarranted negative publicity occurs. I wish to stress that this provision is not meant to permit extended private or closed negotiations.
>
> * * *
>
> Therefore, "reasonable" time to respond to a private communication on an impending RPAR must take into account the interest of the public in participating in any risk-benefit evaluations that affect their health, and the need to consider that the public may remain exposed to the hazard the pesticide poses while the RPAR process is underway.
>
> 124 Cong. Rec. S. 15305 (daily ed., Sept. 18, 1978).
>
> To avoid the time-consuming RPAR process, the Administrator is directed to establish suitable scientific protocols for the development of human exposure data; to work cooperatively with the registrants in the assembling and collection of such data; and then to evaluate and weigh such data, prior to initiating an RPAR process. If humans or their environment are not at risk or the potential for exposure is minimal, the Administrator is directed to forego the RPAR process and proceed with the reregistration of the pesticide product.
>
> 124 Cong. Rec. H. 10118-19 (daily ed., Sept. 19, 1978) (statement of Rep. Foley).
>
> The amendment to FIFRA...should be a great improvement in how EPA goes about the business of shortcutting the more formal and lengthy cancellation process.
>
> Id. at 10120-21 (statement of Rep. Wampler).

(iii) Classification

With respect to restricted uses under section 3(d)(1)(C), House Rep. No. 511 stated: The flexibility of these provisions will allow the Administrator, in accordance with the guidelines in the Act, to establish restrictions which are suited to the degree of hazard and adverse environmental effects that could be caused by the misuse of the pesticide." Id. at 15.

The conference committee report discussed section 3(d)(1):

> It makes restricted classification depend in part on the hazards involved in the use of a pesticide in accordance with "widespread and commonly recognized practice" (section 3(d)(1)(B) and (C)).
>
> House Rep. No. 1540, 92d Cong., 2d Sess. 31 (1972).

As to section 3(d)(2) and (3) on changing classifications, this clarification was offered:

> Restrictions imposed by regulation could be changed by the Administrator from time to time as he deemed necessary, relaxing the regulation where that could be safely done so as to make the benefits of the pesticide more easily obtainable, or tightening restrictions where that action appeared necessary to protect health and environment. It is anticipated that only the more damgerous (sic) pesticides would be classified for restricted use.
>
> 118 Cong. Rec. S.15894 (daily ed., Sept. 26, 1972) (statement of Sen. Allen).

c. Relevant Case Law

In the registration cases brought under section 3 of FIFRA, courts have repeatedly held that the burden of establishing the safety of a pesticide (for compliance with labeling requirements) remains on the registrant. The registrant must submit data that convinces the Administrator that the benefits of a pesticide outweigh the risks. EDF v. EPA, 465 F.2d 528, 532 (D.C. Cir. 1972). See also EDF v. Ruckelshaus, 439 F.2d 584, 592 (D.C. Cir. 1971); Dow Chemical Co. v. Ruckelshaus, 477 F.2d 1317, 1324 (8th Cir. 1973);

Southern National Manufacturing Co. v. EPA, 470 F.2d 194, 196-97 (8th Cir. 1973); Continental Chemists Corp. v. Ruckelshaus, 461 F.2d 331, 335 (7th Cir. 1972); and Sterns Electric Paste Co. v. EPA, 461 F.2d 293, 303 17th Cir. 1972).

4. Administrative Review; Cancellation and Suspension - Section 6

a. Statutory Directive

FIFRA requires EPA to balance a number of factors including costs and benefits in cancelling or suspending a registration, or changing the classification of a pesticide.

(i) Cancellations

A pesticide registration can be cancelled either when a pesticide registration lapses, or when the Administrator obtains information that the pesticide poses "unreasonable adverse effects on the environment." Five years after the registration date of a pesticide the Administrator is to cancel such registration unless the registrant requests the continuance of the registration and the Administrator determines that the continued use "will not have unreasonable adverse effects on the environment." As discussed in section 2 above, determining whether a pesticide poses an "unreasonable adverse" threat to the environment or health requires the Administrator to consider a number of factors including economic costs and benefits.

Cancellation is not an action to be taken lightly by the Administrator. The statute requires the Administrator to notify the registrant and public of his intent to cancel the registration. The Act gives the Administrator guidance for determining whether to issue such notice. He or she should take into account the impact of the action to be proposed in the notice "on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy." At least 60 days before issuing the notice, the Administrator must provide the Secretary of Agriculture a copy of the notice and "an analysis of the impact on the agricultural economy." Before taking a final action to cancel a pesticide registration, the

Administrator "shall consider restricting a pesticide's use or uses as an alternative to cancellation...and shall include among those factors to be taken into account the impact of such final action on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy, and he shall publish in the Federal Register an analysis of such impact."

These restrictions place the burden on the Administrator to be very sure of the adverse risks threatened by a pesticide before cancelling registration. The implication of these restrictions is that Congress wanted to protect the variety of parties that come to rely on the availability of a pesticide for specified uses once registered.

(ii) Suspensions

Suspensions are more immediate than cancellations and are followed up on by the more complete cancellation procedures. FIFRA authorizes the Administrator to suspend a pesticide registration once the five-year registration period is up or during change in classification proceedings, if he or she determines immediate suspension is necessary to "prevent an imminent hazard to human health" (subsection (c)(1)). The subsection that details the procedures for cancellation authorizes the Administrator to waive the requirement of notifying and consulting with the Secretary of Agriculture prior to issuing a notice of cancellation if he or she determines that "suspension" is "necessary to prevent an imminent hazard to human health" (subsection b(2)). The term "imminent hazard" is defined to apply to "a situation which exists when the continued use of a pesticide during the time required for cancellation proceedings would be likely to result in unreasonable adverse effects on the environment or will involve unreasonable hazard to the survival of a species declared endangered or threatened" under the Endangered Species Act (section 1361). Given the definition, discussed in section 2 of this paper, of adverse effects on the environment, this directive authorizes EPA to consider economic factors in reaching a decision to suspend registration.

The plain meaning of "imminent hazard" implies, however, that the role economic factors play in the decisionmaking process to suspend will differ from that which it plays in decisions to cancel. The critical factor is whether a hazard exists, threatening human health and which requires an immediate response that cannot wait for the lengthier hearing and review procedures required for cancellation.

b. Legislative History

(i) Introduction

The legislative history of FIFRA conveys the theme that Congress recognized a certain level of risk to be inherent in pesticide use; the presence of risk alone would not support the cancellation or denial of a pesticide registration.

During the 1975 hearings on FIFRA reauthorization it was argued that EPA was not adequately considering agricultural development-that is, the benefits of pesticide use-in its decisions. In addressing this claim the 1975 amendments added several sentences to subsection 6(b) that direct the EPA Administrator to take "into account the impact (of his intent to classify a pesticide, or cancel or suspend a registration) on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy." FIFRA section 6(b), 7 U.S.C. section 136d(b). Moreover, the Administrator must prepare and publish an economic impact statement in cases of final agency action. Id. This subsection also provides for further consideration of economics by giving the USDA a stronger role in the decisionmaking process. Id.

(ii) Cancellation And Changes In Classification

Subsection 6(b) received extensive treatment in the legislative history.

U.S. House, Rep. No. 497 (94th Cong., 1st Sess., 1975), the House Agriculture Committee's report on the bill that become law, H.R. 8841, stated:

> [The subsection] seeks to involve the Department of Agriculture in important phases of the decisionmaking process, in rulemaking and adjudication, and tighten the degree of cooperation between the agencies. By requiring EPA to seek Agriculture's comments, the substitute proposal assures that the impact on the agricultural economy of actions taken by EPA will be fully developed.
>
> Secondly, the substitute assures that EPA takes cognizance of the effect of its actions on the agricultural economy at virtually every step in the decisionmaking process and induces agreement between the two agencies by providing for the Department of Agriculture's comments and EPA's response to be published.
>
> Id. at 6 (emphasis added).

The Senate Committee on Agriculture and Forestry, that amended other provisions of H.R. 8841, included comments on subsection 6(b) governing advance notification to USDA and the public (S. Rep. No. 452 (94th Cong., 1st Sess., 1975):

> . . . The requirement that EPA prepare an analysis of the impact upon agricultural production and prices and the prices of food at retail of any action it takes is a critical feature to assure the fundamental balance that is the intent of this law.
>
> The Committee concurs in the House position that EPA has not always given adequate consideration to agriculture in its decisions. This concern was also voiced by many witnesses appearing before the Committee.
>
> The basic well-being of the American people depends upon adequate supplies of reasonably priced food. Failure to consider carefully the costs, as well as the benefits of pesticide actions, could deprive the Nation of essential food and fiber.
>
> The strength of the Nation's economy is highly dependent on the efficiency of our agricultural economy. During the last fiscal year, agricultural exports made a net contribution of $12 billion to our balance of payment.
>
> Because the basic thrust and principal responsibility of EPA are to protect the environment, the Committee does not see a need to broaden the impact statement to include the environment. There is clearly a need to consider the impact of EPA's decisions on agriculture if balance is to be achieved.
>
> Id. at 8-9 (emphasis added).

(iii) Suspension

The Joint Explanatory Statement of the Conference Committee discussed suspension proceedings in eases of imminent hazards to human health and while concerned with the need to explicitly consider pesticide benefits, also recognized the special consideration needed for human health.

> The Senate conferees conceded to the House on the provision, regarding the waiver of advance notification to the Secretary of Agriculture in cases of "imminent hazard." The House bill limited this waiver to cases of imminent hazard to human health, while the Senate amendment would have allowed the waiver in cases of imminent hazard to the environment and to an endangered species as well as an imminent hazard to human health. The House conferees were adamant on this point, for they felt that the waiver in the Senate amendment was much too broad.
>
> Id. at S. 20460 (statement of Sen. Allen).

c. Relevant Case Law

Case law that interprets EPA's discretion to consider economic factors in cancelling and suspending registrations on the whole interprets the law to give the Agency wide discretion. The decisions turn on whether the Agency applied a rational or reasonable approach in weighing risks and benefits.

(i) The DDT Cases

The first significant pesticide cases involved cancellation of registrations for pesticides containing DDT. In EDF v. Ruckelshaus (439 F.2d 584 (D.C. Cir. 1971), petitioners sought review of the Secretary of Agriculture's decision (required under EDF v. Hardin) not to suspend DDT registration for all uses pending completion of cancellation proceedings. Discussing the 1964 FIFRA amendments that authorized suspension and cancellation procedures when necessary to prevent imminent hazard, the court stated that the "purpose of the amendment was to protect the public by removing

from the market any product whose safety or effectiveness was doubted by the Secretary." Id. at 593. (The 1964 amendments did away with protest registrations that allowed such potentially harmful substances to stay on the market.) The court then engaged in an analysis of cancellation and suspension procedures.

> The cancellation decision does not turn on a scientific assessment of hazard alone. The statute leaves room to balance the benefits of a pesticide against its risks.
>
> The process is a delicate one, in which greater weight should be accorded the value of a pesticide for the control of disease, and less weight should be accorded its value for the protection of a commercial crop. The statutory scheme contemplates that these questions will be explored in the full light of a public hearing and not resolved behind the closed doors of the Secretary. There may well be countervailing factors that would justify an administrative decision, after committee consideration and a public hearing, to continue a registration despite a substantial degree of risk, but those factors cannot justify a refusal to issue the notices that trigger the administrative process.
>
> Id. at 594 (emphasis added).

Because the Secretary's statement in the case clearly indicated "that he found a substantial question concerning the safety of DDT", which was the court's "standard for the issuance of cancellation notices," the court "remanded to the Secretary with instructions to issue notices with respect to the remaining uses of DDT, and thereby commence the administrative process." Id. at 595. The court held that:

> Suspension is designed to protect the public from an "imminent hazard" during the course of further administrative proceedings. In order to decide whether it is warranted in a particular case, the Secretary must first determine what harm, if any, is likely to flow from the use of the product in question during the course of administrative proceedings. He must consider both the magnitude of the anticipated harm, and the likelihood that it will occur. Then, on the basis of that factual determination, he must decide whether the anticipated harm amounts to an "imminent hazard to the public."
>
> Id. (emphasis added).

This process of weighing benefits against risks clearly allows for economic analysis, but the court's holding makes it clear that risks to public health should be given greater weight than benefits derived from the pesticide's use.

(ii) Burden of Proof on Applicant

In a more recent case, EDF v. EPA (510 F.2d 1292 (D.C. Cir. 1975)), the court addressed the issue of burden of proof in pesticide suspension and cancellation cases. The pesticides under attack were aldrin and dieldrin, chlorinated hydrocarbon pesticides. The court decided that EPA properly exercised its discretion to find a "substantial likelihood" that pesticides shown by scientific evidence to have caused cancer in rats and mice present an imminent hazard to human health. 510 F.2d at 1301.

In assessing the risk inherent in the use of aldrin and dieldrin and contrasting that with the benefits derived from their use, in addition to findings of adequate alternatives not possessed of the same carcinogenic potential, EPA acted properly in its suspension of registration. Id. at 1302. FIFRA section 6(c) places the burden of establishing the safety of a product on the applicant and registrant, not on the EPA to establish that it is unsafe. Id.

Similarly, in EDF v. EPA (548 F.2d 998 (D.C. Cir. 1976), cert. denied, sub nom Velsicol Chem. Corp. v. EPA, 431 U.S. 925 (1977)) the court held that the suspension of registrations for the pesticides heptachlor and chlordane for certain uses does not impose upon the Administrator the burden of establishing that the products in question are unsafe. It is the burden of the applicant/registrant to establish the safety of the products. 548 F.2d at 1004. The court held that the risk to humans was properly found by the EPA from substantial evidence of carcinogenic risk to laboratory animals coupled with evidence of widespread residues of heptachlor and chlordane in human diet and human tissues. It is not necessary that a crisis actually exist to establish the requisite "imminent hazard" only that there is a "substantial likelihood" that serious harm will

occur. When this substantial likelihood is shown for one mode of exposure the burden shifts to the applicant/registrant "to rebut the inference that other modes of exposure may also pose a carcinogenic hazard for humans." Id. at 1010. The evidence was sufficient to establish that the benefits of continued use did not outweigh the risks of potential harm. (The evidence also supported the Administrator's decision to refuse the suspension of heptachlor and chlordane for certain uses where the benefit of continuation of such uses did outweigh the human and environmental risks.)

In Cohn v. Flacke, a state case on balancing of risks and benefits, (N.Y. App. Div. Oct. 8, 1981, 12 Envtl. L. Rep. 20212) the New York Court of Appeals upheld the state environmental agency's denial of petitioner's application to lift the prohibition on the use of endrin and to allow restricted use of the pesticide. The court determined that respondents did not act arbitrarily or irrationally in prohibiting its use because the record contained substantial proof that significant risks to humans and the environment would be created by the pesticide. Respondents balanced the evidence on the risks and benefits of endrin use, and in their discretion determined that "the risks so outweighed the benefits as to justify prohibition." 12 Envtl. L. Rep. 20213.

(iii) Factors to Consider in Suspending Pesticides

The issuance of an emergency suspension order to prevent an imminent hazard was contested in Dow Chemical Co. v. Blum (469 F. Supp. 892 (D.C. Mich. 1979)). The Michigan court held that EPA did not make a clear error of judgment in invoking its emergency powers to ban the herbicides 2,4,5-T and Silvex where a rational basis was found that a substantial likelihood of serious harm existed. EPA's rational assessment of the benefits versus the risks of continued use of these herbicides was properly based on the relatively short period the emergency ban was to be in effect and the availability of adequate alternatives. 469 F. Supp. at 907.

In dicta, the court noted that several factors should be considered in determining whether the Administrator made a clear error of judgment in deciding to order the emergency suspension: (1) the seriousness of threatened harm; (2) the immediacy of threatened harm; (3) the probability that threatened harm would result; (4) benefits to the public of continued use of the pesticides in question during the suspension process; and (5) the nature and extent of information before the Administrator at the time he made his decision. Id. at 902. The court stated further that in light of the applicable legislative history, such factors should be applied in the spirit of avoiding delay and in recognition of the broad powers of EPA in regulating pesticides.

4. Protection of Trade Secrets and Other Information - Section 10, Section h

a. Statutory Directive

FIFRA places an obligation on the EPA Administrator not to "make public information which in his judgment contains or relates to trade secrets or commercial or financial information obtained from a person and privileged or confidential." The burden of proof falls to the registrant to show that data submitted with the application includes trade secrets or merits confidential treatment. Registrants mark that material submitted with an application for registration which are believed to be "trade secrets or commercial or financial information." The statute gives the agency the discretion to decide whether the information so marked qualifies as trade secrets or sensitive financial information.

The agency's obligation to protect the information is not absolute. Where the Administrator determines that disclosure is necessary to protect against an "unreasonable risk of injury to health or the environment," "necessary in the public interest," he may authorize the disclosure of information. In addition, any information concerning the production, distribution, sale or inventories of a pesticide otherwise entitled to confidential treatment may be disclosed in a proceeding to determine whether

a pesticide or any ingredient "causes unreasonable adverse effects on health or the environment, if the Administrator determines that public disclosure is necessary in the public interest." (Emphasis added.) These provisions seem to give the Administrator discretion to lift its burden of nondisclosure.

Economic factors are explicitly given a role in the exercise of the Administrator's discretion under the trade secret provisions. As discussed in section 2 above, the phrase "unreasonable adverse effects on the environment" calls for a weighing of health risks against, among other factors, economic costs and benefits of use. The phrases "unreasonable risk", and "necessary in the public interest", however, imply that the potential for economic harm to the registrant should be given less weight than the nature of the risk to health and the environment coupled with the assistance public disclosure will serve in alleviating that risk.

b. Legislative History

The 1978 amendments added subsections (d) to (g) to 1972 FIFRA.

Senator Leahy presented a summary of subsection (d) as provided by the conference substitute on S. 1678. He stated that the purpose of the Amendment to the trade secret provisions of the Act is to:

> (a) Exclude from trade secret protection under the Act data showing test results and information concerning the effects of a pesticide on organisms or the behavior of a pesticide in the environment except that data relating to manufacturing or quality control processes, the identity or percentage quantity of inert ingredients, or details of methods for testing, detecting, or measuring the quantity of any deliberately added inert ingredient could not be made public unless the Administrator determined that disclosure of such information was necessary to protect against an unreasonable risk of injury to health or to the environment;
>
> (b) Authorize the publication of information concerning production, distribution, sale or inventories of a pesticide in connection with a public proceeding to determine whether a pesticide, or an ingredient causes unreasonable adverse effects

> on health or the environment. If the Administrator believed disclosure was necessary in the public interest.
>
> 124 Cong. Rec. S. 15306 (daily ed. Sept. 18, 1978) (emphasis added).

c. Relevant Case Law

None, though a recent decision by the Eastern District Court throws into question the constitutional validity of the FIFRA trade secrets provisions. See Monsanto Co. v. Acting Admin., EPA 13 ELR 20561 (E.D. Mo., Apr. 19, 1983). The issue is likely to be settled by the Supreme Court.

6. State Role in Regulating Pesticides-Sections 23, 24, 26, 27

a. Statutory Directive

The EPA Administrator is authorized to grant states primary enforcement responsibilities for pesticide use violations. After EPA approves the state program, the Administrator and the state sign a cooperative agreement. EPA is authorized by law to enforce the federal requirements in those cases where the state fails to enforce its pesticide regulations.

In addition, states are authorized to regulate the sale or use of any federally registered pesticide subject to specific restrictions. First the state program must not authorize the sale or use of a pesticide prohibited by federal law. Second, states are prohibited from imposing labeling or packaging requirements in addition or different from the federal requirements. States may register pesticides for additional uses to meet "special local needs," as long as the use has not previously been denied, disapproved or cancelled by the Administrator. This latter provision allows for some cost considerations by states. EPA, however, may immediately disapprove the registration where the Administrator determines that the registration issued by the state constitutes an imminent hazard.

b. Legislative History

The grant of authority to states to register pesticides for use to meet special local needs was discussed at some length in the legislative history. The implication of the statements is that cost considerations in terms of potential crop losses, impacts on local economy, etc. can be taken into account by a state in issuing a registration for special local needs; not, however, to the exclusion of health considerations and the overall goals of FIFRA:

> The conference bill also clarifies certain aspects of the State authority to register pesticides for additional uses to meet special local needs. We have retained authority for EPA to suspend the State registration program if EP-4 finds that the State is not exercising adequate control over pesticides. Further, EPA retains the authority that exists in present law for review of individual registrations by States for local uses.
>
> The conference bill, however, removes the requirement that EPA make a determination that there is a special local need. This question is best handled by local officials since EPA often does not have the information to make such a determination.
>
> The conference bill precludes "veto" by the Administrator of State registration of federally registered pesticides if the State registration is for a similar use. In the conference report we give examples of certain uses that are definitely not similar-changes from nonfood to food crops, outdoor to indoor, terrestrial to aquatic, or nondomestic to domestic uses.
>
> Prior to the passage of FIFRA on October 21, 1972, the EPA had authority to register and control only those pesticide products which crossed State lines. The 1972 FIFRA amendments gave EPA the authority over pesticide products manufactured or reformulated and sold solely within one State as well.
>
> ...The Federal oversight responsibility for State registrations has been exercised judiciously, and has operated to protect farmers as well as consumers. However, the conferees felt it was necessary to provide the States (with) the ability to register additional uses to meet special local needs in order to ease the administrative burden and to provide the States with a means of dealing with problems that arise, in part, because of gaps in EPA registrations.
>
> However, this provision is not intended to permit an end run around Federal registration requirements. States must be cognizant of the potential problems in extending; pesticide uses and and Congress is no less determined today that it was in

1972 to protect U.S. citizens and their environment from unreasonable pesticide hazards regardless of State boundaries.

Thus, while the provision is designed to ease the administrative burden for all involved and facilitate availability of pesticides, it is not intended to limit the Administrator's ultimate authority to enforce FIFRA and protect the environment and human health and safety. We expect each "similar use" question to be carefully assessed by EPA.

124 Cong. Rec. S. 15304 (daily ed. Sept. 18, 1978) (statement of Sen. Leahy) (emphasis added).

c. Relevant Case Law

None.

7. Other

a. Indemnities-Section 15

This section authorizes EPA to indemnify persons that suffer "losses by reason of suspension or cancellation" of a registration. The agency is directed to indemnify any person who owned any quantity of the pesticide "immediately" before "suspension or cancellation" unless the Administrator finds that the person had prior knowledge that the pesticide posed unreasonable adverse threats to the environment.

b. Imports and Exports-Section 17

Subsection (c) of this section states that "(t)he Secretary of the Treasury shall notify the Administrator of the arrival of pesticides . . . and shall deliver. . . samples . . . which are being imported into the United States." Furthermore, "(i)f it appears from the examination of a sample that it is adulterated, or misbranded or otherwise violates the provisions set forth in this subchapter or is otherwise injurious to health or the environment, the pesticide or device may be refused admission. . . (emphasis added)."

c. Research and Monitoring--Sections 20, 25

The Administrator is authorized to "undertake research including research by grant or contract with others . . . to carry out the purposes of this subchapter . . . tak(ing) care to insure that such research" is not duplicative, and call for development of a "national pesticide monitoring plant."

In a separate section of the law, the Administrator of EPA is directed to conduct joint studies with the Department of Agriculture of ways to develop and improve the safe use of chemical, biological and alternative pest control.

d. Stop Sale, Use, Removal, and Seizure--Section 13

The EPA Administrator has the authority "to issue a written or printed "stop sale, use, or removal" order to any person who owns, controls, or has custody" of a pesticide in violation of FIFRA provisions. Evidence of such violation must be based on inspection in or tests and the Administrator must have "reason to believe" a violation exists. This authority extends to a pesticide whose registration has been canceled or suspended.

None of these miscellaneous provisions contain specific direction on the role economic considerations are to play, nor do they contain express prohibitions. The Administrator appears to have discretionary authority to" factor in economic considerations where relevant under all three provisions.

1. COMPREHENSIVE ENVIRONMENTAL RESPONSE, COMPENSATION AND LIABILITY ACT (CERCLA, Pub. L. 96-510, 42 U.S.C. 9601 et. seq.)

A. Summary of Act

CERCLA (also known as Superfund) provides a response and liability mechanism for dealing with releases of hazardous substances. CERCLA applies to hazardous waste sites and other sources of toxic substances pollution. In essence, the law authorizes governmental responses to actual and threatened releases of hazardous substances carried out in accordance with a cleanup plan, called the "National Contingency Plan " (NCP). Those parties causing the release of such substances may then be held liable without regard to fault for certain governmental costs incurred and damages resulting from the release, including cleanup, removal, and resource restoration costs.

To ensure that such injuries are redressed, the law establishes a $1.6 billion Hazardous Substances Response Fund, financed jointly by industry and the federal government over a five year period. In those cases where the polluters are unknown, or are unable or unwilling to provide recompense, a claim for response costs may be filed against the fund typically by the federal or state governmental party incurring such costs. Payment of claims by the fund transfer to the fund the right of the claimant to sue the polluter. This makes it possible for fund representatives to attempt to recover the claim payments it has made from the party or parties responsible for the hazardous substance release.

Within this broad statutory outline, the new law establishes various procedures and principles governing response authority, liability, fund administration, and the filing of claims.

In studying CERCLA and the NCP, it is important to realize that the Act is fundamentally different in its approach to environmental pollution than other EPA-administered environmental laws. While most such statutes emphasize regulatory standard-setting to control pollution, CERCLA uses liability for cleanup costs as the primary incentive for environmental protection. Economic analyses, often prominent in

the standard-setting process, play subtler (although essential) roles in the administrative decisions required by CERCLA. EPA most obviously faces cost-effectiveness considerations arising out of its finite fund and administrative resources.

B. Regulatory Activities

2. Revising and Implementing the National Contingency Plan

a. Statutory Directive

Section 105 of CERCLA requires EPA to revise the National Contingency Plan (NCP) originally developed under Section 311 of the Clean Water Act, to incorporate Superfund-related concerns. The revised National Contingency Plan (see 47 Fed. Reg. 31181, July 16, 1982) is the key to understanding the way Superfund works, and is truly the hub of this statute. It governs and constrains response authority, liability actions, and reimbursement of claims for cleanup costs. The NCP emphasizes the need for cost-effectiveness in long-term (i.e., remedial) actions. It is required to include inter alia:

- ... methods for evaluating, including analyses of relative cost, and remedying any releases or threats of releases . . .

- ... methods and criteria for determining the appropriate extent of removal, remedy, and any other measures . . .

* * * *

- ... means of assuring that remedial action measures are cost-effective over the period of potential exposure to the hazardous substances or contaminated materials;

- ... criteria for determining priorities among releases or threatened releases throughout the United States for the purpose of taking remedial action and, to the extent practicable taking into account the potential urgency of such action, for the purpose of taking removal action. Criteria and priorities under this paragraph shall be based upon relative risk or danger to public health or welfare or the environment, in the judgment of the President, taking into account to the extent possible the population at risk, the hazard potential of the hazardous substances at such facilities, the potential for contamination of drinking water supplies, the potential for

> direct human contact, the potential for destruction of sensitive ecosystems, State preparedness to assume State costs and responsibilities, and other appropriate factors; 42 U.S.C. 9605(2), (3), (7), (8)(A) (emphasis added).

The NCP must also specify "procedures, techniques, materials, equipment and methods to be employed in identifying, recovery, or remedying releases of hazardous substances." Id

Although Congress only called specifically for cost-effectiveness in remedial actions under the NCP, it implicitly recognizd the need to weigh both costs and benefits in responding to chemical releases with limited funds. Section 105(2) of CERCLA mandates that the NCP include methods for evaluating and analyzing the relative costs of long-term cleanup. This essentially allows EPA to make cost comparisons between sites. Section 105(3) requires the NCP to include criteria ??? for determining the appropriate extent of remedy, which is equivalent to preselecting desired environmental benefits. Finally section 105(8) requires FPA to develop specific criteria for determining cleanup priorities. This essentially mandates an Agency determination of the relative environmental benefits to be achieved by cleanup actions at each site. Thus, by meeting these three requirements which call for consideration of costs and benefits, EPA can make cost-effective decisions.

Within finite and determinable Agency resource constraints, and facing defined remedial action costs (section 105(2), analyses of relative cost) EPA can: 1) compare the benefits of each Agency remedial action (section 105(8), priority-setting requirement); and preselect the desired environmental benefits at each site (section 105(3), appropriate extent of remedy requirement). Thus development of the revised NCP is the key provision of CERCLA implicitly calling for a balancing of costs and benefits in long-term (i.e., remedial) cleanup actions.

b. Legislative History

The legislative history of CERCLA has a number of references to cost-effectiveness and cost-benefit analyses under the NCP. The legislative history of the NCP is not altogether clear on the need for EPA to engage in formal cost-benefit analysis under CERCLA. However, Congress did indicate that when EPA contemplates fund-financed response actions, the NCP should require EPA to consider costs, available fund resources, and the need to address other releases. Congress was especially concerned with the costs of potentially expensive remedial action measures under the NCP, specifically requiring such actions to be cost-effective. On December 3, 1980, the House of Representatives considered the Senate's modifications of a Superfund bill passed earlier by the House. This new Senate bill would ultimately be enacted by the House that same day, and was identical to the current Superfund. Representative James Florio, sponsor of the initial House bill, noted:

> ... The Senate version contains a number of provisions which have been incorporated directly from the original House bill. These include:
>
> ...A cost-balancing test to determine the appropriate level of response to an individual release incident.
>
> 126 Cong. Rec. H11788, (December 3,1980)

A week earlier, during the Senate debate, Senators Randolph and Stafford engaged in the following colloquy about costs, benefits, and cost-effectiveness under the NCP:

> Mr. Randolph:
>
> In revising the (National Contingency) plan to guide decisions on whether or when to respond and whether particular remedial measures may be cost-effective, it is appropriate, to the extent practicable and with deference to the threat to public health, welfare or the environment, to consider the benefits and to consider the costs of such action. Indeed, this is the purpose of requiring in section 104 that certain decisions strive to strike a balance between considerations of public health and welfare on the one hand and the availability of money from the fund to respond to threats at other sites as well as the particular one under consideration.

This is really only common sense. It is certainly not intended that such considerations of balance be allowed to become cumbersome analytic processes. Formalized benefit-cost analyses would only preclude timely response and would be deceiving, since the current state of science is unable to provide with sufficient certainty much of the necessary information on benefits, not to mention the costs of inaction.

Mr. Stafford:

The Senator is correct. I might add that, as Senator Helms suggested in our earlier colloquy in referring to considerations of public welare" the balancing process is to include not only benefits which are susceptible of easy or exact calculation, but those other considerations which are customarily included when Congress uses the term "welfare." Such intangible or, long-term benefits must be considered in weighing whether a particular response or cost is inappropriate.

In other words, the purpose of this bill and the response plan is to protect the public health and "welfare." in its broadest sense. In protecting those interests, the President is not to be constrained by rigid or inflexible constructions of this language concerning cost effectiveness or considering costs or benefits. 126 Cong. Rec. S16427-28, (Dec. 12, 1980) (emphasis added).

The legislative history also includes discussion of a predecessor Senate bill to CERCLA, which is identical to the final Act in dealing with cost-effectiveness under the NCP.

Mr. Randolph:

* * *

As revised, the (National Contingency) plan will be a comprehensive document detailing emergency response and remedial action procedures, including methods for discovery and investigation, methods for evaluating and remedying environmental emergencies and appropriate roles for governmental and private entities. The plan will contain guidance on cost-effectiveness. Such guidelines are intended to assure that alternative remedial options are considered when planning cleanup actions at a particular site. This guidance will also provide both criteria and procedures for selection of the most cost-effective and environmentally sound alternative for remedying the Site. This selection will require a balancing of a variety of factors, including cost and engineering to achieve the health and environmental goals of the legislation. 126 Cong. Rec. 14965 (November 24, 1980) (emphasis added).

This was followed by a colloquy between Senators Helms and Stafford on the issue of cost-effectiveness and cost-benefit analysis.

> Mr. Helms:
>
> ... My concern is, first, that there be adequate direction in the bill that under the contingency plan cost benefit analysis will be applied to determining whether and when action should be taken to remove hazardous substances or to remedy or otherwise respond to releases. I read section 105 and, particularly, paragraphs (3), (7), and (8) as requiring those charged with developing the national contingency plan to take cost benefit considerations into account, not only in determining whether particular measures are cost-effective given a decision to take action under the act, but also in determining whether and when action should be taken at all. I also read the response authority section (section 104(c)(4) as charging the President to select remedial actions to carry out this section which are cost-effective and provide a balance between considerations of public welfare on the one hand and the availability of money from the Fund to respond to threats at other sites as well as the particular one under consideration.
>
> I ask the chairman of the Environment and Public Works Committee and the ranking minority member of that committee, for the purposes of legislative history, whether my reading of these provisions is correct.
>
> Mr. Stafford:
> The Senator is correct that considerations of the relationship between the costs and the benefits of a particular response action are an essential part of both the national contingency plan to be developed under section 105, and the selection of remedial and response actions under section 104. We intend that priorities be set for expenditures from the fund, and that such expenditures be made in those situations which most present a threat. The fund should not be used to clean up or remedy any and every discharge. 126 Cong. Rec. 15007 (November 24, 1980) (emphasis added)

The bill previously reported out of the Senate Committee on Environment and Public Works was less explicit on the issue of cost-benefit analysis and cost-effectiveness in the NCP. It only contained provisions requiring EPA to specify "methods for evaluating, including analyses of relative cost," of remedying discharges and releases,

and "methods and criteria for determining the appropriate extent" of response. See, S. 1480 as reported, section 3(c)5)(B), (C). See also, U.S. Senate, Rep. No. 848, 96th Cong., 2d Sess., pp. 57-58 (1980).

Similar language was contained in the Administration's early Superfund proposal. See, S. 1341, 96th Cong. 1st Sess, sec. 4 adding sec 603(c) to the Federal Water Pollution Control Act (1979). And, as noted by Representative Florio above, more explicit references to cost-effectiveness and cost benefit analyses under the NCP were made in the original House version of Superfund. See, H.R. 7020, as passed by the House, 96th Cong., 2nd Sess, section 5, adding secs. 3041(d)(e)(7), 3041(a) to the Solid Waste Disposal Act (1980).

c. Relevant Case Law

None

2. Response Authority

a. Statutory Directive

Section 104 of CERCLA authorizes EPA to respond to actual and threatened releases of hazardous substances, pollutants, and contaminants. EPA's response may include both short term "removal" actions, and longer-term "remedial" actions that are consistent with the National Contingency Plan.

EPA should not exercise its own (i.e. Fund-financed) response authority, however, where necessary removal and remedial actions "will be done properly" by others. Id., section 104(a)(1). Furthermore, in the absence of state cost-sharing, EPA's response is limited to $1 million in cleanup costs, or six months of effort, unless there is an emergency. Id., section 104(c)(1).

Under section 101(23) of CERCLA removal actions are primarily short-term, limited responses to chemical threats. Under section 101(24) of CERCLA, remedial actions are primarily longer-term, more permanent (and likely more expensive) responses to such threats. Removal actions include those actions "as may be necessary to prevent, minimize, or mitigate damage to public health or welfare or the environment." CERCLA, section 101(23), 42 U.S.C. 9604(23). Remedial actions are "consistent with permanent remedy" similarly intended "to prevent or minimize the release of hazardous substances." Id., section 101(24).

Read alone, the definitions of "removal" and "remedial" actions may afford EPA some discretion in weighing the costs and benefits of cleanup. Use of statutory language to define such terms as "as may be necessary," "prevent," "mitigate," and "properly" may subtly introduce administrative flexibility and discretion into the Act, allowing EPA to consider costs in responding to releases. Moreover, the definition of remedial action itself includes the costs of relocation of residents, businesses and community facilities where "such relocation is more cost-effective than and environmentally preferable" to offsite disposal. Remedial action explicitly excludes offsite disposal unless such action is, inter alia, "more cost-effective than other remedial action." Id., section 101(24).

Congress was especially clear in its concern that fund-financed, longer-term, and expensive remedial actions be carried out in a cost-effective manner. Although section 105(7) already required EPA to assure that remedial actions are cost-effective, under the NCP. Congress underscored this language in section 104(c)(4), which deals specifically with remedial actions financed by the Fund:

> The President shall select appropriate remedial actions determined to be necessary to carry out this section which are to the extent practicable in accordance with the National Contingency Plan and which provide for that cost-effective response which provides a balance between the need for protection of public health and welfare and the environment at the facility under consideration, and the availability of amounts from the Fund . . . to respond to other sites . . . taking into consideration the need for immediate action. Id., section 104(c)(4)., 42 U.S.C. 9604(c)(4) (emphasis added).

> This section also explicitly requires EPA to consider availale fund resources when the Agency engages in fund-financed remedial actions.

b. Legislative History

The legislative history of EPA's response authority under CERCLA clearly suggests Congressional intent to provide for cost-effectiveness in cleanup actions, particularly long-term remedial actions. While noting the urgent need for chemical cleanups, Senator Dole stated:

> At the same time, Federal action must be responsible and carefully calculated to deal with the immediate problem in a realistic and cost-effective way.
>
> * * *
>
> The compromise package also imposes limits on the discretion of those administering the response mechanism, to insure that reasonably cost-efficient actions are taken, and that the response to a given problem is shaped with regard to the entire range of problems covered by the fund and to the overall limits on the fund. 126 Cong Rec. S14982 (Nov. 24, 1980) (emphasis added)

Authority for cost-effectiveness in response authority, particularly remedial action, evolved in three interrelated ways. These are: (1) in the definitions of removal and, especially, remedial action; (2) in the substantive response authority provisions themselves, by way of provisions applicable to remedial actions; and (3) in the establishment of the NCP. The latter has already been addressed above in part 2, so this section will focus on the evolution of the first two types of statutory language.

Definitions:

The term "removal" was derived primarily from the Senate versions of Superfund as introduced. See, S. 1341 section 3, 96th Cong., 1st Sess., adding section 601 (ff, gg) to the Solid Waste Disposal Act ("removal," "removal costs") (1979); S. 1480, section 2(1) 96th

Cong., 2nd Sess. (referencing the Clean Water Act) and section 2(17) ("removal costs") (1980).

In reporting the bill out of Committee, the Senate Committee on Environment and Public Works formally added the definition and concept of remedial action to the bill. This version of the bill included cost-effectiveness language very similar to that of CERCLA. See, S. 1480 as reported, 96th Cong., 2d Sess, section 2(b)(7)(1980). The Committee provided explanatory remarks on the definition of remedial action and the cost considerations entering into remedial action decisions:

> In order to ensure that the limited moneys made available-under this legislation provide protection from the greatest number of the most serious threats to public health, welfare and the environment, the President must carefully fashion the appropriate remedial action that do not provide a permanent remedy. To assist the President in determining the appropriate remedial action, specific criteria are included in the definition of remedy for three of the most costly possible actions-permanent relocation; pr vision of permanent drinking water supplies; and transport, storage, treatment, destruction cr secure disposition of hazardous substances offsite.
>
> The term "remedy" includes the cost of permanently relocating residences, businesses, or community facilities, when relocation would be more cost-effective than, and environmentally preferable to, other offsite remedial actions.
>
> US. Senate, Rep. No. 848, 96th Cong., 2nd Sess., p. 55 (1980) (emphasis added).

Substantive Response Authority:

The guiding statutory language on cost-effectiveness in fund-financed remedial responses in section 104(c)(4) of CERCLA was taken almost directly from the House version of Superfund, as noted by Representative Florio above (126 Cong. Rec. H 11788, December 3, 1980). It is appropriate, therefore, to track the evolution of both the Senate and House bills to understand the Congressional intent regarding the costs and benefits of response actions in CERCLA. The House bill, as introduced, linked EPA's response authority to those actual and threatened hazardous waste releases presenting an "unreasonable risk to public health or the environment." See, H.R. 7020, as introduced,

section 4 adding section 3041 (a)(1)-(3) to the Solid Waste Disposal Act (1980). Furthermore, the bill limited EPA's authority for offsite remedial action unless such disposal was merited by costs or other considerations:

> The Administrator shall not exercise the authority of this subsection to engage in or order the transportation and offsite disposition of hazardous waste unless the Administrator determines that undertaking such offsite activity is-
>
> (A) less expensive than undertaking such activity onsite; [or]
>
> (B) essential to protect the public health, or safety or the environment due to the seriousness of the danger which may be created by the physical, chemical, or biological properties of the waste and the potential for human exposure, or the unavailability of onsite methods for preventing or minimizing the danger; Id., adding section 3041(a)(4). (emphasis added)

This sentiment regarding the high costs of offsite remedial action was echoed by the Senate in the reported bill. See, S. 1480 as reported, section 2(b)97), 96th Cong. 2d Sess (1980).

As explained by the Senate Environment Committee:

> Typically, it is anticipated that remedial action will be taken onsite. Evidence presented to the Committee on costs of onsite versus offsite remedies suggests that offsite measures may be as much as seven times more expensive and that the somewhat greater protection which may be provided by these more expensive measures does not necessarily justify the huge cost differential or the greatly decreased number of incidents to which the Fund could respond. For these reasons, offsite remedial actions are only authorized if the President determines they cause less environmental impact than onsite actions and they are: (a) more cost-effective, [or] (b) are necessary to protect public health, safety or the environment from the otherwise continued onsite presence of hazardous substances . . . U.S. Senate, Rep. No. 848, 96th Cong. 2d Sess pp. 55-56 (1980) (emphasis added).

As reported out of Committee, however, the House bill only required EPA to weigh cost-benefit considerations at inactive sites. It authorized remedial activity at inactive sites only where there is an "unreasonable risk of harm to public health or the

environment." Other response authority was based on a simple "endangerment" standard, without the need to establish an "unreasonable risk." The Committee on Interstate and Foreign Commerce explained the "unreasonable risk" provision for inactive site remedial action.

> In assessing the appropriate action under this provision, the Administrator must give consideration to such factors as a site's potential for causing chronic adverse health effects. A finding that an "unreasonable risk" may exist does not require an exhaustive cost/benefit analysis that the terms triggers elsewhere in environmental law.
>
> * * *
>
> The Administrator is authorized to relocate, contain, clean up, and take other remedial action with respect to hazardous waste at an inactive site whenever he determines that the site presents or may present an unreasonable risk to public health or the environment.
>
> U.S. House, Rep. No. 1016 Part I, 96th Cong., 2d Sess, p. 28 (1980) (emphasis added).

Additional guidance was also provided on fund-financed response authority (both removal and remedial action) within the reported bill:

> The Administrator shall select appropriate actions determined to be necessary to carry out the provisions of this section. The appropriate actions shall be as nearly in accordance with the National Hazardous Waste Response Plan as possible and shall provide for that cost-effective response which, provides a balance between-
>
> (1) the need for protection of public health and the environment of the site under consideration, [and]
>
> (2) the availability of amounts from the fund established under supbpart D to respond to other sites which present or may present a threat to the public health or the environment. . .
>
> H.R. 7020 as reported, (1980) adding section 3041(d) (emphasis added).

As explained by the Committee:

> The appropriate actions must be nearly in accordance with the National Hazardous Waste Reponse Plan as possible. In addition, action at a given site must be that cost-effective

> response which provides a balance between the need for protection of public health or the environment at the site under consideration and the availability of funds to respond to the other sites which present or may present a threat to public health or the environment In making this determination for emergency situations, the Administrator is directed to take into consideration the need for immediate action. U.S. House, Rep. No. 1016 Part I, 96th Cong., 2d Sess, p. 29 (1980) (emphasis added).

In emergency situations, however, the House Commerce Committee did not require the Administrator to balance costs and benefits:

> The Committee recognizes the need to consider the requirement for immediate action in emergency situation in making the determination of appropriate response. Emergency actions should not be delayed by having to make a cost-balancing determination. U.S. House, Rep. No. 1016, Part I, 96th Cong., 2d Sess, p. 30 (1980) (emphasis added).

As ultimately passed by the House, the bill stated:

> The Administrator shall select appropriate actions determined to be necessary to carry out the provisions of this action. The appropriate actions shall be as nearly in accordance with the National Hazardous Waste Response Plan as possible and shall provide for that cost-effective response which provides a balance between-
>
> (1) the need for protection of public health and the environment at the site under consideration.
>
> (2) the availability of amounts from the fund established under subpart D to respond to other sites which present or may present a threat to public health or the environment; and
>
> (3) in case of an order issued to a responsible party, the technical and financial capabilities of such party to take any action under such order and the reasonableness of such order, taking into consideration the degree to which such party may have caused or contributed to any unreasonable risk.
>
> With respect to actions under paragraphs (1) and (3) of subsection (a) (response authority for imminent and substantial endangerment), the Administrator shall make such determination taking into consideration the need for immediate action.
>
> H.R. 7020, as passed by the House, 96th Cong., 2d Sess., section 4 adding section 3041(d), 3042(e)(7) to the Solid Waste Disposal Act (1980) (emphasis added).