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RUCKELSHAUS, BEVERIDGE, FAIRBANKS & DIAMOND

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M E M O R A N D U M

TO

THE SOCIETY OF THE PLASTICS INDUSTRY

RE: THE LEGALITY OF THE STANDARD PROPOSED BY EPA UNDER THE CLEAN AIR ACT TO REGULATE EMISSIONS OF VINYL CHLORIDE INTO THE AMBIENT AIR

January , 1976

Suite 300
One Farragut Square South
Washington, D.C. 20006

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## Introductory Statement

On December 16, 1975 the Environmental Protection Agency proposed regulations for emissions of vinyl chloride into the ambient air under Section 112 of the Clean Air Act of 1970, 42 U.S.C. §1857c-7. The Agency's action results from studies undertaken since early 1974 when the first evidence of the carcinogenicity of vinyl chloride due to occupational exposure was disclosed.

EPA's proposed standards conclude that vinyl chloride is a "hazardous air pollutant" as defined in Section 112(a)(1) of the Clean Air Act, because "in the judgment of the Administrator" it "may cause, or contribute to, an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness." Once a substance is classified as hazardous, the Administrator must publish proposed regulations establishing emission standards within one hundred and eighty days. A notice of public hearing within thirty-days must also be published. Within six months after publication of the proposed regulations, the Administrator must prescribe a final emission standard unless he finds "that such pollutant clearly is not a hazardous air pollutant." Regulations published by the Administrator must establish an emission standard "at the level which in his judgment provides an ample margin of safety to protect the public health." 42 U.S.C. §1857c-7(b)(1)(B).[1/]

The purpose of this memorandum is to analyze whether, assuming EPA's final standard is substantially the same as the proposed one, the industry will have sufficient standing to challenge the final version and whether judicial review will be available. In addition, the memorandum will evaluate the possible bases for an attack on the standard and discuss the manner in which the courts are likely to consider the validity of any challenge. We will first describe in greater detail the nature of the proposed standard and EPA's rationale for it. We will then consider the industry's standing to challenge the proposed regulation and the basis for judicial review. Next we will outline the approach the courts are likely to take in assessing the legality of the EPA standard. Finally, we will discuss specifically the various lines of attack open to the industry and the manner in which we believe the courts will treat them.

In summary of our conclusions, the details of which are set forth more fully below, we believe that the industry will clearly have standing to file a formal legal challenge to the

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1/ Existing sources are accorded ninety-days to achieve compliance. However, the Administrator has authority to grant waivers for up to two years if he finds such a period is necessary for the installation of controls and adequate steps will be taken during the waiver period to protect the health of persons from "imminent endangerment." The President may also issue exemptions from compliance for reasons of national security. 42 U.S.C. §1857c-7(c).

final EPA standard if it chooses to do so. In addition, judicial review of EPA's action is available in the U.S. Court of Appeals for the District of Columbia. The criterion which the court will apply in reviewing the proposed action is whether EPA has acted within the scope of its authority and in a reasonable manner consistent with "principled decision-making." The more stringent substantial evidence test for review is not applicable in this case and thus the Agency will be accorded somewhat more discretion than in other circumstances. Further, although there is some question of the applicability of Section 112 of the Clean Air Act to the problems posed by vinyl chloride, as well as questions over the manner of implementing Section 112 even if applicable, EPA appears to have acted properly and within its discretion in choosing Section 112 and in promulgating specific standards under that Section. We conclude, therefore, that the result of any legal challenge to the proposed standard by the industry is likely to fail or to result in a more stringent requirement.

Background: The Proposed Standard and Its Rationale

In announcing the proposed standard for vinyl chloride, EPA concludes that the problems associated with vinyl chloride place it within the definition of "hazardous air pollutant" in Section 112 of the Clean Air Act. Among the reasons for the Agency's determination is its finding that vinyl chloride has been shown to cause cancer both in workers occupationally exposed to it and in animals.[2/] The Agency further finds that liver cancer has been produced in test animals at exposure levels as low as fifty parts per million, and that there is evidence of a multiple cancer risk in vinyl chloride, namely tumors in a variety of organs other than the liver.[3/]

While conceding that most confirmed cases of liver angiosarcomas among workers involve those engaged directly in polyvinyl chloride production, EPA also suggests that there is evidence that exposure to vinyl chloride at lower levels than usually encountered in production is capable of causing cancer.[4/] Finally, EPA adverts to studies which have shown the potential of vinyl chloride to be a chemical mutagen and teratogen.[5/]

The Agency suggests that these data give rise to concern that the present ambient levels of vinyl chloride may cause or contribute to cancer or other disorders, even though it concedes that the average daily concentration of vinyl chloride in the vicinity of plants is less than one part per million with some twenty four hour averages of one to three parts per million and "some occasional peak concentrations" as high as

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2/ "National Emission Standards for Hazardous Air Pollutants, Proposed Standard for Vinyl Chloride, pp. 4, 5 (hereinafter "Proposed Standard").

3/ Proposed Standard, pp. 4-5.

4/ Proposed Standard, p. 5.

5/ Proposed Standard, p. 6.

33 parts per million.[6/]

In assessing the risk posed to health, EPA states that there is no dose-response data and no absolute proof of adverse affects at the concentrations of vinyl chloride in the atmosphere.[7/] It goes on to assert, however, that for carcinogens there may be no atmospheric concentration which poses absolutely no public health risk because there may be no threshold for a substance with the properties of vinyl chloride below which no risk is encountered. Moreover, there may be a latency period of twenty years or longer between initial exposure and occurrence of disease.[8/]

EPA has determined to act now to reduce exposure on the ground that by so doing it will substantially reduce the potential risk to health. The Agency rejected several alternative courses of action. It refused not to act or to delay, particularly because of the long latency period and the lack of certainty as to whether or when additional data would be available which might change its current conclusions.[9/] EPA rejected regulation under Section 109 applicable to national ambient air standards because of the localized nature of vinyl

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6/ Proposed Standard, pp. 6-7. Of course, this characterization of peak concentrations appears to be erroneous.

7/ Proposed Standard p. 7.

8/ Proposed Standard, p. 7.

9/ Proposed Standard, pp. 10-11.

chloride emissions and the lack of expedited means of control. Finally, it rejected regulating vinyl chloride under Section 111 applicable to stationary sources on the grounds that action would be too long delayed, levels of control might vary from state to state, variances based on cost alone might be granted, and the Federal Government under Section 112 rather than the States under Section 111 should have primary enforcement responsibility.[10/]

In proceeding under Section 112, the Administrator suggests that it is difficult to determine what level of emissions to permit that assures "an ample margin of safety to protect the public health" when dealing with an apparent "non-threshold pollutant that is hazardous at some level."[11/] Vinyl chloride, he concludes, may be hazardous at some level and not others but may create some risk to public health at all levels. Since a threshold cannot be specified, the Administrator believes that he must assume any level of emission may pose a risk and that a zero emissions limitation might therefore be required to offer absolute safety.[12/]

The Administrator rejects the zero emissions approach. He finds that there is no technology to achieve zero emissions. He does not believe that the risk posed to society after requiring the best available control technology is sufficient to warrant

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10/ Proposed Standard, pp. 11-12.

11/ Proposed Standard, p. 12.

12/ Proposed Standard, p. 13.

a ban on production of vinyl chloride and closure of a major industry, with all the attendant social costs. He also remains unsure of substitutes, their expense, their safety, and whether they would have some of the desirable characteristics of polyvinyl chloride.[13/] EPA thus concludes that Section 112, while applicable to the problems posed by vinyl chloride, was drafted by Congress at a time when there was little awareness of the nature of the problems associated with a carcinogen which has no apparent threshold. EPA believes that Section 112 under these circumstances accords the Agency the flexibility to apply a "best available control technology" approach which would produce stringent regulation short of zero emissions or an absolute ban on production.[14/]

## Discussion

The industry has several avenues of possible attack if it elects to challenge the standards promulgated by EPA to control vinyl chloride emissions. (We are assuming, *arguendo*, that the final standard will follow in pertinent part the proposed standards.) They are (1) that EPA has abused its discretion in acting to regulate emissions of vinyl chloride in the ambient

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13/ Proposed Standard, p. 14.

14/ Proposed Standard, p. 15. In further elaboration on all aspects of EPA's decision-making, see the *Standard Support and Environmental Impact Statement*: *Emission Standard for Vinyl Chloride* and the *Scientific and Technical Assessment Report on Vinyl Chloride and Polyvinyl Chloride*.

air at this time. This argument would assert that EPA should take no action or, alternatively, that if any action is necessary it should be deferred until more dispositive monitoring and medical data has been gathered. (2) Next the industry could argue that even if EPA is correct in acting now it has selected the wrong regulatory framework and that some section other than Section 112 of the Clean Air Act is more appropriate, such as Section 109 applicable to national air quality standards or Section 111 applicable to stationary sources. (3) Finally, the industry might argue that even if EPA is assumed to have authority to regulate vinyl chloride under Section 112, it has departed from the requirements of that section in formulating standards.

Before examining each of these lines of attack more specifically, it is necessary to determine whether the industry will have standing to challenge the regulation, whether judicial review is available in the event there is standing, and the principles the courts are likely to apply in reviewing the legality of EPA's action.

## I. Will the Industry Have Standing to Challenge the Administrator's Action and Will Judicial Review of the Final Standard Be Available

There is little doubt that the industry will have standing to challenge the Administrator's final regulations under Section 112 of the Clean Air Act. Under the test enunciated in a number of decisions, where a party alleges that it has suffered an injury in fact, economic or otherwise, is within the "zone of interest" to be protected or regulated by the particular agency, and judicial review is not precluded by statute, standing is accorded the party which alleges injury. Association of Data Processing Service Organizations v. Camp, 397 U.S. 150 (1970); EDF v. Hardin, 428 F.2d 1093, 1096 (D.C. Cir. 1970). Not only would the industry be free to allege that the regulations proposed by EPA have caused it serious economic injury, but it is obvious that it is the industry most affected by the regulations.

Judicial review is clearly authorized in this case, because the Clean Air Act specifically provides for review when the Administrator promulgates regulations under Section 112. Section 307, 42 U.S.C. §1857h-5. (Petitions for review must be filed in the United States Court of Appeals for the District of Columbia.)[15/] Thus, the test for standing can be met and judicial review is available. See Citizens to Preserve Overton Park v. Volpe, 401 U.S. 402 (1971). (The Court reversed a decision by the Secretary of Transportation authorizing use of federal funds to construct a highway through a public park.)

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15/ Even assuming, arguendo, that there was no specific statutory provision authorizing review of EPA's action, the provisions of the Administrative Procedure Act, 5 U.S.C. §§701, et seq. would be applicable to the question whether review was available. Under this test, persons aggrieved by agency action are entitled to review unless a statute precludes review or the action is clearly committed to agency discretion, i.e., involves mere ministerial acts. In this case there is no statutory provision precluding review and EPA is engaged in complex regulation which places its activity well outside the category of ministerial acts. Citizens to Preserve Overton Park v. Volpe, 401 U.S. 402, 410 (1971); Industrial Union Dep't., AFL-CIO v. Hodgson, 499 F.2d 467 (D.C. Cir. 1974).

II. In Reviewing the Legality of EPA's Action in Regulating Vinyl Chloride Will the Courts Examine the Reasonableness of the Agency's Action and Whether There Has Been an Abuse of Discretion or Will They Apply Another Standard of Review

Once it is determined that judicial review is available, the next question is the standard or scope of review. To define the appropriate standard it is necessary first to look at the particular statute involved and its legislative history. If a standard is not set forth then the general provisions of the Administrative Procedure Act are incorporated and govern the scope of review. Citizens to Preserve Overton Park v. Volpe, supra; Amoco Oil Co. v. EPA, 501 F.2d 722, 731 (D.C. Cir. 1974). Since Section 307 of the Clean Air Act provides for judicial review but does not establish its scope, the provisions of Section 706 of the Administrative Procedure Act are applicable, 5 U.S.C. §706.[16/]

Under the APA, the alternatives for scope of review are (1) that the Agency's decision must be based upon substantial evidence; (2) aggrieved parties are entitled to a de novo hearing on the merits; or (3) the agency must simply have acted reasonably

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16/ Section 307 of the Act emerged during conference. The House had no provision to govern judicial review but in Section 308 of its proposed bill, S.4358, the Senate provided for judicial review and a presumption that a determination by the Administrator (then referred to as the Secretary of HEW in the absence of the yet-formed EPA) would be correct. The presumption would be rebuttable if a decision was not supported by a preponderance of the evidence. The presumption was dropped during conference. See S.Rep. 91-1196, 91st Cong. 2d Sess., p. 41.

and not arbitrarily or capriciously. 5 U.S.C. §706. Legal precedents indicate that in the present context, the reasonableness standard would be applied. Citizens to Preserve Overton Park v. Volpe, supra; Amoco Oil Co. v. EPA, supra, 501 F.2d at 731-732; Delaware Citizens for Clean Air, Inc. v. Administrator, U.S. EPA, 480 F.2d 972 (3rd Cir. 1973).

A. Are the Substantial Evidence and De Novo Theories of Review Available in the Present Case

The stringent substantial evidence test is applicable only when the statute under which review is sought expressly requires that an adjudicatory-type hearing be held in reaching agency decisions, in short, that there be rulemaking "on the record," and after notice and opportunity for an agency hearing. Citizens to Preserve Overton Park v. Volpe, supra; U.S. v. Fla. East Coast Ry. Co., 410 U.S. 224 (1973); Amoco Oil Co. v. EPA, supra, 501 F.2d at 732, fn. 25. Since regulation of air pollutants under Section 112 does not require "on the record" hearings, but merely a public hearing, the courts will not apply a substantial evidence test. Id. See also International Harvester v. Ruckelshaus, 478 F.2d 615, 629 (D.C. Cir. 1973).

The Administrative Procedure Act does not provide recourse for attempting to hold EPA to the substantial evidence test. The provisions of the Act which require adjudicatory-type hearings in rule-making under Sections 556 and 557 of the Act, 5 U.S.C.

§§556, 557, and substantial evidence review, are not triggered unless the particular rulemaking is required by statute to be "on the record after opportunity for an agency hearing." 5 U.S. 553(c), 706(2)(E). There being no such requirement in Section 112 of the Clean Air Act, the substantial evidence test cannot apply. Citizens to Preserve Overton Park v. Volpe, supra, 401 U.S. at 414-415.

The same reasoning eliminates the possibility that challengers to EPA's action would be entitled to a "de novo" hearing in the courts. Here, also, unless a statute expressly provides that an adjudicatory hearing be held by an agency, with a right of a de novo hearing on review, a party seeking to appeal agency action is not entitled to such review. Id.

B. Under the Reasonableness Standard of Review Will the Courts Generally Defer to the Expertise of the Agency and Will They Especially Do So When Public Health and Safety Are Involved

With the unavailability of substantial evidence or de novo review, the courts will determine whether agency action should be set aside as "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. §706(2)(A). While the courts will make a "substantial inquiry" and subject the agency's action to "a thorough, probing, in-depth review," the basic test is the reasonableness of agency action. Moreover, the decision of the agency is generally entitled to deference and to a "presumption of regularity." Assuming the agency has acted reasonably within the permissible range of choices available to it, has not made a clear error of judgment, and has complied with the procedural requirements of the statute, its action will be upheld. Citizens to Preserve Overton Park v. Volpe, supra, 401 U.S. at 415, 416-417, Delaware Citizens for Clean Air Inc. v. Administrator, supra.

The deference generally accorded administrative agencies when the reasonableness of their actions is reviewed has been often stated. In Udall v. Tallman, 380 U.S. 1 (1965), the Supreme Court reviewed the decision of the Secretary of the Department of the Interior rejecting certain applications for oil and gas leases. In upholding his action as reasonable, the Court commented that "The Secretary's interpretation may not be the only one permitted . . . but it is quite clearly a reasonable interpretation; courts must therefore respect it." 380 U.S. at 4. The Court defined the degree to which it defers to the judgment of an administrative agency:

> When faced with a problem of statutory construction, this Court shows great deference to the interpretation given the statute by the officers or agency charged with its administration . . . . "Particularly is this respect due when the administrative practice at stake 'involves a contemporaneous construction of a statute by the men charged with the responsibility of setting its machinery in motion, of making the parts work efficiently and smoothly while they are yet untried and new.'"

380 U.S. at 16, quoting from Power Reactor Co. v. International Union of Electrical, 367 U.S. 396 (1961). See similarly U.S. v. Shimer, 367 U.S. 374 (1961). (The Supreme Court affirmed the Veterans

Administration's interpretation of the requirements of the Servicemen's Readjustment Act on the ground that where an agency must exercise its judgment and discretion, its action will not be overturned unless the agency has exceeded its authority or its action was clearly wrong. 367 U.S. at 381-382.)

Where, as in the present case, regulation is "on the frontiers of scientific knowledge," involves considerable technological complexity, health considerations are paramount, and the administrative agency must make legislative-type judgments, the agency has especially wide latitude in formulating a regulatory system. The Society of the Plastics Industry v. OSHA, 509 F.2d 1301, 1304 (2nd Cir, 1975), cert. den. sub nom Firestone Plastics Co. v. U.S. Dep't of Labor, 43 U.S.L.W. 3623 (1975); Industrial Union Dep't, AFL-CIO v. Hodgson, 499 F.2d 467 (D.C. Cir.1974); Essex Chemical Corporation v. Ruckelshaus, 486 F.2d 427 (D.C. Cir 1973) cert. den. 416 U.S. 969.

One of the earliest decisions enunciating the principle that administrative agencies enjoy extra discretion in regulating to protect public health is U.S. v. Dotterweich, 320 U.S. 277 (1943). There the Court reviewed a court of appeals judgment reversing a conviction for violation of the 1938 Federal Food, Drug, and Cosmetic Act. The Supreme Court reinstated the conviction after examining the agency's construction of regulations requiring that adulterated and impure food and drugs be kept out of commerce. In measuring the regularity of Agency action, the Court commented:

> The purposes of this legislation . . . touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words.

320 U.S. at 280. Later, the Seventh Circuit enunciated similar principles in affirming another conviction under the Food and Drug Act. U.S. v. Kordel, 164 F.2d 913 (7th Cir. 1947), aff'd 335 U.S. 348 (1948). In response to the argument that the statute should have been more strictly construed, the court held:

> Courts for a long time have been committed to the doctrine of giving statutes intended to protect the public health a very liberal construction . . . . "The public and social purposes served by such legislation greatly exceed the inconvenience and hardship imposed upon the individual, and therefore the former is given greater emphasis in the problems of interpretation. Therefore the courts are inclined to give health statutes a liberal interpretation despite the fact that such statutes are primarily penal in nature and frequently impose criminal penalties."

164 F.2d at 917, quoting Sutherland on Statutory Construction, and referring to U.S. v. Dotterweich, supra.

In recent years agencies have found it necessary to act in areas affecting health in spite of the fact that existing methodology and medical data may not be complete. Often an agency must make difficult technical judgments. Under these circumstances the latitude accorded the agency is considerable.

In Industrial Union Department, AFL-CIO v. Hodgson, supra, the court affirmed in principal part the Department of Labor's regulations promulgated under the Occupational Safety and Health Act to control atmospheric concentrations of asbestos dust in the workplace. In doing so the court stressed that some regulations affecting health in the workplace are "on the frontiers of scientific knowledge, and consequently as to them insufficient data is presently available to make a fully informed factual determination." 499 F.2d at 474. In such circumstances, it ratified decision making which depended "to a greater extent upon policy judgments and less upon purely factual analysis." Id. The court reasoned that formulating standards in such cases therefore involved basically "legislative" determinations rather than resolution of purely factual issues and that judicial review was necessarily more limited: "Policy choices of this sort are not susceptible to the same type of verification or refutation by reference to the record as are some factual questions." 499 F.2d at 475.

Particularly when "existing methodology or research in a new area of regulation is deficient, the agency necessarily enjoys broad discretion to attempt to formulate a solution to the best of its ability on the basis of available information." 499 F.2d at 474-475, fn. 18. In spite of the absence of data measuring "precisely predictible health effects of various levels of exposure," the agency is nonetheless obligated to act. 499 F.2d at 475. So long as its action is not arbitrary or irrational, it will be upheld. Id. The same rationale has been applied to action regulating vinyl chloride. The Society of the Plastics Industry v. OSHA, supra. See also Reserve Mining Co. v. Environmental Protection Agency, 514 F.2d 492 (7th Cir. 1975), discussed infra, pp. 24-25.

C. Will the Courts Defer to EPA's Exercise of Discretion in Matters Affecting Public Health and Safety Provided the Agency Has Acted Reasonably and Demonstrated Principled Decision-Making

The general principles of review discussed above have been applied with special care in the context of EPA regulation. Courts reviewing EPA action regulating threats to the environment and health will affirm EPA decisions if the record shows that the Agency has exercised "principled decision-making." Environmental Defense Fund, Inc. v. Ruckelshaus, 439 F.2d 584 (D.C. Cir 1971). (In that case the court reviewed the Secretary of Agriculture's refusal to issue certain notices of cancellation or suspension of federal registration of DDT under the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §135, and remanded for further action.)

The court elaborated on the "principled decision-making" standard in Essex Chemical Corp. v. Ruckelshaus, supra. There, in upholding in principle part EPA action establishing standards of performance for new or modified stationary sources under Section 111 of the Clean Air Act, 42 U.S.C. §1857c-6, the court stated that in subjecting the Administrator's actions to review, "we apply a test of reasonableness, wherein we are not empowered to substitute [our] judgment for that of the Agency but must consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." 486 F.2d at 434, quoting Citizens to Preserve Overton Park v. Volpe, supra. The court then elaborated:

> The judgment of the Administrator is to be weighed against his statutory function and limitations, the record searched to determine if indeed his decisions and reasons therefore are themselves reasoned, and at that point our function terminates. Our "expertise" is not in setting standards for emission control but in determining if the standards as set are the result of reasoned decision-making . . . even this limited function requires that we foray into the technical world to the extent necessary to ascertain if the administrator's decision is reasoned. While we must bow to the acknowledged expertise of the Administrator in matters technical we should not automatically succumb thereto, overwhelmed as it were by the utter "scientificity" of the expedition.

486 F.2d at 434. See also, International Harvester v. Ruckelshaus, 478 F.2d 615, 641 (D.C. Cir. 1973) and U.S. v. Big Chief, 7 ERC 1840 (E.D. La. 4/23/75).

Measuring EPA's action in regulating vinyl chloride by these standards suggests the difficulty of sustaining any challenge which might be raised. There is at the outset judicial deference to the Agency seeking to ensure that it has the necessary latitude to protect the public health. In addition, the courts accord wide latitude to agency's attempting to frame regulations to meet not simply proven health threats but also those that are merely potential. That the courts allow for stringent agency action may perhaps be best summarized by reference to EDF v. EPA, 465 F.2d 528 (D.C. Cir. 1972). There the court reviewed the failure of EPA to suspend registration of aldrin and dieldrin while it was initiating proceedings to cancel their registrations. In remanding to the Agency for further action the court said:

> Environmental law marks out a domain where knowledge is hard to obtain and appraise, even in the administrative corridors; in the courtrooms, difficulties of understanding are multiplied. But there is a will in the courts to study and understand what the agency puts before us. And there is a will to respect the agency's choices if it has taken a hard look at its hard problems. We emphasize again the judicial toleration of wide flexibility for response to developing situations . . . the court's concern is for elucidation of basis, not for restriction of EPA's latitude.

465 F.2d at 541.[17/]

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17/ The skepticism with which the courts view agency action which fails to acknowledge fully threats to public safety is highlighted by the very recent comment of the Chief Judge of the U.S. Circuit Court of Appeals for the District of Columbia:

> Science believes that it can quantify and understand the danger posed to organisms and the environment by those undisputed levels [of radiation]. The risk at issue herein is the risk that such present scientific knowledge is simply wrong or blind in such degree that after the passage of time and further study, the danger to society will be seen as greater than expected by orders of magnitude. Said differently, the twin risks are that either science is ignorant of entire categories of harm, or that rule-permitted quantities of radiation do the type of damage they are thought to, but to a far greater extent, or in a cumulative fashion with other factors so as to render difference in degree

con't.

It is in this context that we must turn to a specific examination of the likelihood of success for the avenues of attack which appear to be open to the industry.

III. Under the Standards of Review Applicable to EPA's Action on Vinyl Chloride Will the Courts Approve the Agency's Proposed Regulations as Principled Decision-Making

Theoretically the industry has a number of lines of attack against EPA assuming the regulations proposed on December 16 become final. It can argue (1) that EPA has abused its discretion in acting at all or in refusing to delay action until there is more convincing monitoring and medical data showing a causal effect between the ambient amounts of vinyl chloride and adverse health effects. In an attempt to buttress this argument, the industry could argue that there is insufficient

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17/ Continued:

> a difference in kind. These risks are hardest to calculate because they surpass the problems posed by mere ignorance of a new technology. The scientists and decision-makers are asked to assess and make allowance for the probabilities that present scientific understanding is itself terribly wrong.

Citizens for Safe Power, Inc. v. NRC, ___ F.2d ___, (D.C. Cir. No. 74-1186, 12/22/75 (Bazelon, C. J.), Slip Op. p. 640. (The court affirmed an order of the Atomic Safety and Licensing Appeal Board authorizing issuance of an operating license for a constructed commercial power reactor, finding that the facility "fully complies" with "unchallenged safety and health regulations." Slip Op. at 630.)

data showing exposure to the minimal amounts of vinyl chloride in the ambient air is harmful; that there is inadequate medical evidence that vinyl chloride is carcinogenic to man except when there is exposure to huge doses in the workplace; and that extrapolation to humans of data showing a carcinogenic effect of vinyl chloride in animals at 50 parts per million is speculation. (2) The industry can argue that even if EPA was required to act under the circumstances, it was incorrect to choose Section 112 as the regulatory framework and that some other section, such as 109 or 111, would have been more pertinent. Here the argument would be that for reasons outlined in (1) vinyl chloride cannot meet the definition of hazardous pollutant since EPA admits the substance may only be hazardous at some levels and merely a potential risk at all levels. Once EPA concedes that it lacks sufficient data to determine adequately the threat of vinyl chloride at very low ambient amounts, it either must proceed under some other section of the Act or it must seek an amendment to the legislation to permit it to deal with this sui generis problem. Finally, (3) even assuming that Section 112 was a proper vehicle for regulation, the industry can argue that EPA has improperly construed the section and has abused its discretion and acted outside the scope of its authority. It would argue that a "design" or "process" standard, which constitutes a part of the proposed regulation, is impermissible under Section 112. It could also argue that EPA's reliance on technology and cost in attempting to set standards under Section 112 is impermissible and proves the inapplicability of that Section. The industry would conclude that the emission limits established in the proposed standard are completely arbitrary and without sound basis.

In short, the industry would attack the standard as having been the result of arbitrary and capricious action, unsupported by the record, and in violation of the requirement that EPA's actions be the result of principled decision-making.

Upon close scrutiny, these arguments, however tempting, fail to offer a reasonable chance of success.

### A. Is EPA Authorized to Act to Regulate the Ambient Amounts of Vinyl Chloride Under Present Circumstances

The case authority is ample that based strictly upon the amount of information currently available to EPA, the Agency is acting well within its authority in issuing regulations and may even be under an absolute obligation to act to control the dangers posed by vinyl chloride in the ambient air. This is true even though other federal agencies may also be regulating vinyl chloride.

Generally, the courts have required EPA to act whenever there is any risk to public health. "This agency," commented the U.S. Court of Appeals for the District of Columbia, "particularly when its decisions can literally mean survival of persons or property, has a continuing duty to take a 'hard look' at the problems involved in its regulatory task, . . . " Portland Cement Association v. Ruckelshaus, 486 F.2d 375, 394 (D.C. Cir. 1973), cert. den. 417 U.S. 921. (The court remanded for further consideration standards promulgated under Section 111 of the Act.) This requirement of action pertains even in the absence of clear medical evidence as to the magnitude of the risk or of the probability of adverse health consequences. See, EDF v. HEW, 428 F.2d 1083, 1085, 1088-1090 (D.C. Cir. 1970) and EDF v. Hardin 428 F.2d 1093 (D.C. Cir 1970) requiring the Secretaries of Agriculture and HEW to take action to regulate the dangers of DDT. The courts have emphasized that the unavailability of reliable data with respect to "precisely predictable health effects of various levels of exposure" to suspected pollutants does not absolve an agency from the obligation "to establish some specific" standards. There need be no factual determination, per se. Industrial Union Department, AFL-CIO v. Hodgson, supra, 499 F.2d at 475.

The requirement of some specific agency action in this case is predicated on the fact, among others, that vinyl chloride is a known human carcinogen in certain cases of occupational exposure and there is proof of carcinogenicity in animals. When attempting to regulate such a pollutant in other contexts, such as ambient exposure, EPA need not have data showing with certainty that is is harmful in such other situations so long as there is some evidence to support the reasonableness of the Agency's action. For this purpose, EPA is authorized to rely on extrapolation of data from animals to man, to take notice of the long latency period before cancer or other harm may be detectable and the possibility of irreversible disease, and to act on the assumption that there may be no threshold below which the pollutant is safe. The courts have approved action by many agencies—including EPA—regulating suspected carcinogens on this basis; and the approach has been specifically followed in a case involving vinyl chloride.

In Reserve Mining Co. v. EPA, 514 F.2d 492 (8th Cir. 1975), the Eighth Circuit evaluated the problems posed by Reserve Mining's iron ore processing activities near Lake Superior which resulted in emissions of asbestos-like fibers. In considering remedies available under federal statutory (Rivers and Harbors Act of 1899, 33 U.S.C. §407, the pre-1972 Federal Water Pollution Control Act, 33 U.S.C. §1160), state, and common law theories, the Court elaborated on the duty imposed on administrative agencies to act in cases affecting public health and the flexibility allowed to them in developing specific remedies. In doing so, the court commenced by stating that once it was conceded that there were emissions of asbestos into the ambient air this raised "an immediate health issue, since inhalation of asbestos at occupational levels of exposure is associated with an increased incidence of various forms of cancer." 514 F.2d at 501. It then pointed out that the health consequences of asbestos in the ambient air could not be scientifically predicted on the basis of existing medical knowledge because there was insufficient data to base an opinion on the magnitude of the risk associated with the exposure.

514 F.2d at 506. The court ruled that under such circumstances, where a matter is clearly "on the frontiers of scientific knowledge" and there is no proof yet of actual harm, the agency is obligated to weigh the probabilities of harm and the consequences, if any, should harm actually occur. Even where a probability of harm is not more likely than not, and there can be no clear predictions of adverse health effects, there can still be some risk and consequently a reasonable medical concern for the public health. When that occurs, regulation is appropriate and the "contaminant should be removed." 514 F.2d at 520.

The court in Reserve Mining authorized stringent remedial action in light of the circumstances described above. Although it reversed the lower court order requiring the company to close down its facilities entirely, it nonetheless mandated that specific, severe enforcement steps be required of Reserve, including moving the site for depositing industrial wastes from water to land; expending $243 million in plant alterations and construction to halt pollution; and using available technology to reduce the asbestos fiber count in the ambient air "below a medically significant level." 514 F.2d at 537-538. See discussion infra, pp. 50-53 concerning the reasoning of the court in reversing the lower court order totally closing down Reserve's operations.

Thus, the fact that there may be uncertainty as to levels of exposure in regulating ambient emissions of vinyl chloride; difficulty in quantifying those levels in terms of a demonstrable health hazard; inability to predict scientifically adverse health consequences; insufficient knowledge upon which to base an opinion as to the magnitude of the risk associated with the exposure; and less ambient emissions than the factory exposures which have been linked to disease (514 F.2d at 511) still gives rise to a duty to act but simply broadens the discretion available to the agency. 514 F.2d at 506. See also, Amoco Oil Co. v. Environmental Protection Agency, 501 F.2d 722, 740-741 (D.C. Cir 1974) and Industrial Union Dep't, AFL-CIO v. Hodgson, supra.

The standards outlined in Reserve Mining have been applied with specificity in requiring EPA to regulate environmental hazards posed by substances similar to asbestos. See generally the discussion supra, pp. 17ff.

In the recent case of Environmental Defense Fund v. EPA, 510 F.2d 1292 (D.C. Cir. 1975), the court affirmed in principal part as "a rational exercise of discretion, rather than arbitrary agency action," an order issued by EPA suspending the registration and prohibiting the manufacture and sale of the pesticides aldrin and dieldrin. 510 F.2d at 1297. The court ruled that even though the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. §135, requires that there be an "imminent hazard" to man before suspension, that concept does not require crisis but embraces a situation where there is simply a "substantial likelihood that serious harm will be experienced." Id. Although under FIFRA the standard of review is the stringent substantial evidence test, the court ruled that where the administrative record contains "respectable scientific authority supporting the Administrator," his decision will be upheld, even if there is similar respectable authority controverting his findings. 510 F.2d at 1298. The court particularly emphasized the fact that the inability of EPA to determine a safe threshold of exposure did not render the Agency's determination improper. It approved EPA's conclusion that the concept of threshold has no practical significance for carcinogens. The court enunciated the following standard as applicable under the circumstances.

> Where the matter involved is as sensitive and fright-laden as cancer, and the statute places the burden on the registrant to establish the

> safety of his product, we shall not, assuming a substantial showing of danger, require the Administrator to make impossible proofs. In reviewing Administrative actions, courts "cannot fairly demand the perfect at the expense of the achievable." The Administrator's conclusion is within the scientific expertise of the agency and is not infected by error of law.

510 F.2d at 1298-99.[18/] The court also specifically upheld the extrapolation to humans of data derived from tests on animals as well with the discretion of the Agency even though it might be quantitatively imprecise. Such extrapolation, particularly in light of long latency periods for carcinogens, is not simply speculative but is sufficient to establish "a substantial likelihood that harm will result." 510 F.2d at 1299.[19/] See Amoco Oil Co. v. Environmental Protection Agency, supra.

That the emission of vinyl chloride into the ambient air is a proper subject of EPA action under the authorities discussed above seems indisputable. The fact that there has already been court scrutiny of the vinyl chloride problem and ratification of stringent agency action to meet suspected problems is further proof.

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18/ Of course, under Section 112 the producer of a pollutant has no "burden to establish the safety of his product." However, the requirement of action under Section 112 is at least as stringent as under FIFRA, and since vinyl chloride is a suspected carcinogen it poses certain health risks similar to the suspected carcinogens subject to regulation under FIFRA. See further discussion, infra, pp. 30ff.

19/ In a two to one decision last year the U.S. Court of Appeals for the District of Columbia ruled that under Section 211 of the Clean Air Act, 42 U.S.C. §1857f-6c, applicable to fuels and fuel additives, EPA had to prove not merely

con't.

In The Society of the Plastics Industry, Inc. v. OSHA, 509 F.2d 1301 (2nd Cir. 1975), cert. den. sub nom Firestone Plastics Co. v. U.S. Department of Labor, __ U.S. __, 43 U.S.L.W. 3623 (1975), the Second Circuit considered various arguments that there was insubstantial evidence to support a proposed OSHA standard for vinyl chloride under the Occupational Safety and Health Act, 29 U.S.C. §655. Under OSHA, the Secretary of Labor is required to promulgate a standard which "most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life." 29 U.S.C.

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19/ Continued:

a risk to health but an actual causal connection between increments of lead in the air and health hazards before regulating lead emissions. Ethyl Corporation v. EPA, 1 PCG 15811 (D.C. Cir. 1/28/75). Relying on the standards of review elaborated in Citizens to Preserve Overton Park v. Volpe, supra, the majority nonetheless concluded that EPA had made "clear errors of judgment" in evaluating the evidence and could not prove the statutory requirement that increments of lead in the air "will" endanger health. It essentially found the Agency's action so "one-sided" and "flawed," so arbitrary, capricious, and lacking in factual basis, that it had to be overturned, 1 PCG at 15832ff. It recognized, however, that other sections of the Clean Air Act accorded EPA more discretion than the "will endanger" standard of Section 211, such as sections which permit the Administrator to set standards according to his "judgment." Id. at 15819. Of course, Section 112 falls into this category. The majority decision was vacated on March 17, 1975 for rehearing en banc.

§655(b)(5). Although the standard must attain "the highest degree of health and safety protection for the employee," a number of considerations including feasibility and cost must be taken into account in setting the standard.

The court approved very stringent agency action. It found that there was "conclusive proof" of the carcinogenicity of vinyl chloride as well as mounting evidence of its dangers through identification of a cancer causing effect of 50 parts per million in test animals. Precisely because "the question of a safe level of exposure for humans cannot be determined at this time, and may continue as a matter of scientific deliberation for many years," OSHA was authorized to set a standard at "as low a level as can be detected." 509 F.2d at 1307. Where there is uncertainty that exposure to vinyl chloride at very low levels is unsafe, but human lives are at stake and deaths are already shown to have been caused by the substance to be regulated; animal data indicates there can be cancer in test animals at relatively low levels; a safe level cannot be identified; and the chemical involved is a "very virulent" carcinogen; then there is little margin of safety and the Agency faced with regulation must act "even in circumstances where existing methodology or research is deficient." 509 F.2d at 1308. Concluded the court, "The Secretary, in extrapolating . . . from mouse to man, has chosen to reduce the permissible level to the lowest detectable one. We find no error in this respect." Id.

Another argument that might be available to oppose EPA's action on vinyl chloride is that since other federal agencies, principally OSHA, have already acted against the apparent dangers of the substance, and imposed stringent standards, there is neither need nor justification for EPA action. Upon examination, however, this argument is of no apparent help.

The courts have long held that different agencies, when they have separate statutory mandates to act, are entitled and, in some cases obligated, to undertake simultaneous enforcement action even against the same exact parties involving the same issues. For example, in the area of price fixing, the Federal Trade Commission is authorized to act under Section 5 of the Federal Trade Commission Act (15 USC §45) and the Department of Justice is authorized to act under Section 1 of the Sherman Act (15 USC §1). The Supreme Court held in Federal Trade Commission v. Cement Institute, 333 U.S. 683, 693-4 (1948) that an FTC order to cease and desist from price fixing was proper even though the Justice Department had subsequently filed an injunction suit under Section 1 of the Sherman Act on the same facts and against the same parties. The Court took special note of the fact that dual enforcement was also justified because different violations may arise under each Act. See also, U.S. v. W. T. Grant Co., 345 U.S. 629, 631-32 (1953), and Warner-Lambert Co. v. Federal Trade Commission, 361 F. Supp. 948, 952-3 (D.D.C. 1973).

As discussed earlier, the courts have specifically applied the rule authorizing separate, simultaneous enforcement action by different agencies in the environmental area where a threat to public health is at issue. EDF v. HEW, supra, arose under the Food, Drug, and Cosmetic Act, 21 U.S.C. §301 prior to the transfer of the authority to regulate pesticides to EPA. The Secretary of HEW was obligated to regulate the residue of a pesticide which could safety remain on raw agricultural products and the Secretary of Agriculture was required to regulate the registration of a pesticide. The case concerned DDT. The court rejected HEW's argument that it must defer action until the Department of Agriculture itself had acted on registration:

> While it is obvious that the responsibilities of the two Secretaries are interrelated and ought to be coordinated, we think their individual responsibilities are quite clear and quite separate . . . . In our judgment, the Act's language requires that HEW make its own independent judgment . . . and not abdicate its responsibility to the Department of Agriculture.

428 F.2d at 1087. HEW was required to act on the petitioner's request for control of DDT and start the informal and formal administrative studies and hearings required by law.

These cases are strong authority that EPA is required to initiate regulatory action when it perceives a threat to public health that falls within its jurisdiction, even though other agencies may also be taking action. Particularly is this the case when EPA must regulate an aspect of a problem (ambient air) not necessarily covered by another agency's regulation of a different aspect (OSHA relative to the workplace). See Standard Support document, *supra*, pp. 2-7 and 9-5, 9-6 for the interrelationship of OSHA and EPA regulation.

The authorities cited in this section show that if EPA was not actually under statutory mandate to act to regulate ambient concentrations of vinyl chloride the Agency at least has acted well within the scope of its authority in asserting its powers. It cannot be shown that EPA acted arbitrarily or unreasonably even conceding that the Agency lacks information upon which to make definitive judgments. Moreover, under the circumstances of this case EPA is not required to delay action until more evidence is available; nor is it authorized to decline to act because other agencies may also be regulating vinyl chloride.

B. Did EPA Abuse Its Discretion In Selecting Section 112 for Regulation of Vinyl Chloride Emissions into the Ambient Air

The argument that EPA incorrectly selected Section 112 for regulating emissions of vinyl chloride into the ambient air appears to offer little chance of success based upon the authorities discussed in the preceding sections. When EPA is faced with regulating a carcinogen with no known threshold below which safety to public health can be assured, and when there is a long latency period between exposure and disease as well as increasing evidence of carcinogenicity, there appears to be the kind of hazard to the public which the Congress seemed to authorize the Administrator to regulate, in his judgment, under Section 112. This is so even conceding the problems of quantifying the dangers involved.

Unfortunately, the legislative history of Section 112 is unclear. The Section emerged from conference and was not, in its present form, contained in either the House or Senate bills, HR 17255 and S.4358, respectively. It appears that Section 112 originated as Section 115 of the proposed 1970 Senate Amendments, S.4358. The Senate proposal required that EPA list hazardous air pollutants, characterized as those whose presence in the air, chronically or intermittently, alone or combined with other agents, "causes or will cause, or contribute to, an increase in mortality or an increase in serious irreversible or incapacitating reversible damage to health." Section 115(b), S.4358 as reported in S.Rep. No. 91-1196, 91st Cong. 2d Sess. (1970), p. 96. This definition is almost identical to present Section 112, with the significant difference that the enacted provision accords more discretion to the Agency by providing for regulation simply if a hazardous pollutant "may" cause the damage. A timetable for regulation followed that was also similar to current Section 112. The Senate proposal called for prohibition or specific emission standards. In its report, the Senate stated that Section 115 was intended to encompass a limited number of pollutants, including asbestos, cadmium, mercury, and beryllium. S.Rep. at p. 20. Because vinyl chloride has carcinogenic properties and "may" pose a threat similar to those pollutants, the application by the Administrator of the standards of Section 112 in regulating it seems appropriate.

An argument can be made that Section 114 of the proposed Senate bill provided a more appropriate vehicle for regulating a substance like vinyl chloride. That section proposed to regulate through emission limitations agents which have "or may be expected to have an adverse effect on public health." Section 114(a)(1), S.Rep. at p. 93. Included under this section, for example, would be arsenic, chlorine gas, manganese, barium, and hydrogen chloride. S.Rep. at p. 18. Compliance could be waived based upon technological feasibility. Section 114(c)(4), S.Rep. at p. 94. This Section appears to have been enacted into law as part of Section 111 of the current Act, which permits costs to be taken into account in setting standards. The Senate contemplated that some agents originally designated under Section 114 would eventually be regulated under Section 115, as well as the converse. S.Rep. at pp. 19-20.

According to the Senate Report, proposed Section 114 was designed to regulate:

> [T]hose agents which are not emitted in such quantities or are not of such a character as to be widely present or readily detectable on a continuous basis with available technology in the ambient air. The presence of these agents is generally confined, at least for detection purposes, to the area of the emission source.

S.Rep. at p. 18. The ambient concentrations of vinyl chloride arguably fall within this definition.[20/]

Summarizing the implicatons of these various provisions, Section 115 as proposed was the most stringent, authorizing no consideration of cost in setting standards and no waiver of compliance. Section 112 as enacted is the next most stringent, appearing to authorize no cost considerations in setting standards[21/] and authorizing only a two year waiver of compliance due to technological infeasibility of meeting the standards.

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20/ The House Bill, H.R. 17255, had no similar provisions. The closest was Section 112 of the bill applicable to new stationary sources, which provided for the regulation of emissions which "may contribute substantially to endangerment of the public health." Section 112(a) as reported in H.Rep. 91-1146, 91st Cong. 2d Sess., p. 35. No new source could be constructed or operated, unless exempted, if emissions were "extremely hazardous to health." Section 112(b)(1). This section of the House bill was enacted as part of Section 111 of the Act.

21/ But see discussion *infra*, pp. 41ff.

Proposed Section 114 was somewhat less stringent than the aforementioned in that while costs could not be taken into account in setting standards there could be waivers of compliance without time limits taking feasibility into account. Finally, Section 111 as enacted is the least stringent, authorizing costs to be taken into account in setting standards.

It is tempting to argue that once it is conceded that vinyl chloride may not be hazardous at some levels it is necessary for EPA to regulate under less stringent standards than those imposed in Section 112. Section 111 as enacted, and reflecting the criteria in proposed Section 114 of the Senate bill, seems a logical route. Yet this line of reasoning is not likely to prevail. Based upon the nature of the authority possessed by the Administrator under Section 112, the few cases which have arisen interpreting that Section, and case authority generally, it seems more reasonable to conclude, as EPA has, that once a substance is found to be hazardous as defined in Section 112 of the Act at some levels, Congress contemplated that it would be regulated under that Section and at the very least authorized such regulation.

The authority of the Administrator to classify a substance as "hazardous" within the definition of Section 112 is very broad. He may act whenever he believes that an air pollutant merely "may" cause or contribute to mortality or serious disease, 42 U.S.C. §1857c-7(a)(1). There is no requirement that there be certainty or even probability. Moreover the basis of this decision is simply his "judgment." While his judgment will be subject to the standards of review discussed in previous sections, as we have seen he has fairly wide discretion. Moreover, once he classifies a substance as "hazardous" he is obligated to promulgate standards to regulate it unless it is shown "clearly" not to be hazardous; 22/ this requirement imposes a difficult burden of proof. Finally, the regulations promulgated must provide an "ample margin of safety" to protect the public health, not merely an "adequate" margin and whether the margin is "ample" or not depends again on the Administrator's "judgment." Id. These are words of broad statutory discretion and authority. 23/ Thus, whether the Administrator *might* have selected another section to regulate vinyl chloride, it is hard to conclude that he acted outside the scope of his authority by choosing Section 112.

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22/ See Conference Report, 91-1783, as reported in U.S. Code Cong. and Admin. News, 91st Cong. 2d Sess., p. 5379. (Section 112 "requires the Administrator . . . to publish a list of hazardous pollutants, to issue proposed emission standards . . . and to finalize such standards . . . .")

23/ That the Administrator under Section 112 was apparently accorded broad authority by the Congress is evident in the brief legislative history accompanying that Section. See, e.g., Remarks of Rep. Hechler, 116 Cong. Rec. 42521, 91st Cong., 2d Sess., Dec. 18, 1970. ("The Administrator has been given wide discretion in dealing with the emissions of highly hazardous substances.") Unfortunately, however, the legislative history is largely silent on the meaning of the term "ample margin of safety." One of the few times Congress even addressed the question of "margin of safety" specifically was in the Senate Report accompanying the Senate version of the 1970 Amendments:

> In setting . . . standards, the Secretary [now Administrator] should consider and incorporate not

con't.

Support for this interpretation appears in International Harvester Co. v. Ruckelshaus, supra, considering the legality of EPA's denial of a one-year suspension of emission standards under Section 202 of the Act, 42 U.S.C. §1857f-1. Discussing the absence of clear statutory direction or legislative history on aspects of the regulatory requirements, the court stated:

> As we see it the issue must be viewed as one of legislative intent. And since there is neither express wording or legislative history on the precise issue, the intent must be imputed. The court must seek to discern and reconstruct what the legislature that enacted the statute would have contemplated for the court's action if it could have been able to foresee the precise situation.

478 F.2d at 649.

Few cases have been decided under Section 112. All of them involve the sole question of whether EPA has authority to promulgate "design" or "process" rather than numerical

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23/ Continued:

> only the research . . . but also the need for margins of safety. Margins of safety are essential to any health-related environmental standards if a reasonable degree of protection is to be provided against hazards which research has not yet identified.

S.Rep, supra, at pp. 9-10. Since other parts of the Act merely require "adequate" margins of safety, see, e.g., Section 109, 42 U.S.C. §1857c-4(b)(1), the plain meaning of the words suggests that more stringent standards must be set when the margin must be "ample." Use of the term "ample" combined with the authority of the Administrator under Section 112 to use his "judgment" as to what constitutes such a margin maximizes his discretion in enunciating specific standards and makes it more difficult to prove he has exceeded his authority.

standards under that Section[24/] (See 40 C.F.R. 61.22(d). None, however, challenges the legality of Section 112 to regulate substances, like vinyl chloride, that are suspected carcinogens but whose ambient concentrations are hard to quantify and whose dangers to health are difficult to measure precisely.

The two cases which were accompanied by lengthy written opinions were U.S. v. Adamo Wrecking Co., supra, and U.S. v. Big Chief, supra. They reached different conclusions on the question of the legality of process or design standards under Section 112. Both suggested, however, that EPA had correctly characterized asbestos as "hazardous" within the definition of that Section. Commented the court in Adamo: ". . . this Court is fully convinced that the Administrator has appropriately characterized asbestos emissions . . . " Slip. Op. at 39. And in Big Chief the court commented on the "uncontradicted scientific evidence that ambient asbestos poses a significant health hazard, related to the causation through inhalation of various diseases."

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24/ The issue has been faced in six lower court criminal cases brought to enforce the EPA standards applicable to the demolition of buildings suspected of containing asbestos. The standards are set in terms of work processes. In U.S. v. Adamo Wrecking Co., CR No. 5-80297 (E.D. Mich. 6/6/75), U.S. v. Harvey Wrecking Co., 74 CR 758 (N.D. Ill. 1975), U.S. v. Brandenberg Demolition Co., 74 CR 757 (N.D. Ill. 1975), U.S. v. Nardi Wrecking Co., 74 CR 756 (N.D. Ill. 1975), and U.S. v. National Wrecking Co., 75 CR 755 (N.D. Ill. 1975) criminal indictments or informations for violation of asbestos demolition regulations were dismissed on the ground that EPA is limited to establishing strictly numerical emission limits in implementing Section 112. Contra: U.S. v. Big Chief, 7 ERC 1840 (E.D. La. 4/23/75). See discussion, infra, pp. 38ff.

7 ERC at 1842. The court also cited to the findings in Reserve Mining, supra, on the need to act against such a hazardous pollutant.

The legislative history of Section 112, the cases to date which have arisen under that section, and the large body of authority considering problems posed by carcinogens lead to the conclusion that the courts would approve EPA's attempt to regulate vinyl chloride under Section 112 of the Clean Air Act. Even if other sections of the Act might be available to regulate vinyl chloride emissions, if the justification EPA sets forth for selecting Section 112 instead of other sections is rational and not arbitrary, the Agency's exercise of discretion is unlikely to be overturned.[25/]

C. Are the Courts Likely to Conclude That the Standards EPA Has Proposed Under Section 112 to Govern the Emission of Vinyl Chloride Into the Ambient Air Are Reasonable and Within the Scope of Its Authority

If EPA has authority to regulate vinyl chloride emissions under Section 112, the main question becomes whether the Administrator has abused his discretion or acted outside the scope of his authority in promulgating specific regulatory provisions. For the reasons discussed earlier, he has wide discretion under Section 112 to meet the hazards posed by carcinogens.

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25/ See, also, Proposed Standard, pp. 11-12 and Standard Support and Environmental Impact Statement: Emission Standard for Vinyl Chloride, EPA, pp. 2-1ff generally and pp. 2-7ff specifically.

The main challenges that can be raised to the proposed regulations are (1) that the Administrator had no authority to set "process" or "design" standards on the industry and (2) that the agency exceeded its authority by taking into account, and setting the standards based upon, costs and technology.

1. Are the Courts Likely to Overturn the Specific Standards EPA Has Set Under Section 112 on the Ground That They Constitute Illegal Process or Design Standards

On the first point, while it is true that the proposed standard sets many "design" requirements on the industry, it is important to note that the Agency has largely avoided the problems considered in the six lower court decisions on demolition of buildings[26/] which have arisen under Section 112, discussed below, in that emissions limitations are established throughout the proposed standards and the process requirements are couched in "emission level" terms. In the asbestos regulations applicable to demolition, there are no numerical standards or references. See 40 C.F.R. 61.22(d). Thus, while there is a dispute of authority on whether design standards are permitted under Section 112,[27/] it appears that in proposing



26/ See footnote 24, supra, p. 36. As decisions issued from lower courts in criminal cases and not yet subject to appellate review, these cases are of limited precedential value in the vinyl chloride case.

27/ The Administrator seems to acknowledge this problem in requesting specific authority from Congress to set design standards under Section 112. See Letter from Russell E. Train to Hon. Jennings Randolph, February 2, 1975, p. 3. This letter, of course, is of no particular probative value on the legal issues.

regulations for vinyl chloride emissions EPA may have avoided for the most part the problem considered in those cases.

Turning specifically to the U.S. v. Adamo, supra, and U.S. v. Big Chief, supra, cases, which are the only ones accompanied by lengthy opinions, there is a split between the two cases. Adamo holds that "an emission standard . . . must establish a set, measurable level of emissions . . . [A] methodology for emission control is not a "standard," . . ." U.S. v. Adamo, Slip. Op. at p. 31. Although recognizing the motive of EPA in trying to control a hazardous pollutant, the court there held that in spite of its "deference" to EPA's interpretation, it could not accept EPA's conclusion. Id. at p. 40. That court concluded that if EPA could not easily measure concentrations of asbestos and therefore set numerical emission standards, it was necessary to seek an amendment of the Act to authorize design standards. It found no authority in the Act for EPA's demolition standards. 28/

To the contrary, Big Chief ruled that the provision in the demolition regulations for design standards was well within the discretion of the Administrator. After discussing

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28/ Recently the Supreme Court stated in a case construing a portion of Section 110 of the Clean Air Act that "emissions limitations . . . are regulations of the composition of substances emitted into the ambient air . . . " Train v. NRDC, 421 U.S. 60, 78 (1975). This definition is so vague it is impossible to generalize from it how the Court would interpret the obligations of EPA under Section 112 in the circumstances which prevail in the asbestos and vinyl chloride cases.

EPA's admission that there were inadequate measurement techniques and insufficient data to show a "quantitative relationship" between asbestos exposure and disease, the court commented:

> Thus, given the extreme options of either ignoring a known health hazard or flatly imposing an absolute ban on any and all asbestos emissions, the agency adopted a pragmatic approach. It arrived at a standard of emission control, not by means of a maximum quantitative level but by means of a work procedure.

7 ERC at 1842. The court, placing "great deference" in administrative rulings of this nature reasoned that the evidence demonstrated that "control of asbestos emission through a work standard was the most, perhaps the only practical means of combating a recognized health hazard." 7 ERC at 1843. Being guided by "principles of liberal construction which govern statutes protective of public health and safety," the court refused to dismiss a criminal charge of a violation of Section 112 standards, declining to take action having "the effect of frustrating statutory purpose by making the regulatory control of hazardous asbestos emissions virtually impossible." Id. It concluded that a work procedure controlling emissions was an "emission standard":

> There appears no justification for restrictively definining "emission standard" so as to exclude standards such as this, which undeniably control the amount of ambient emissions. It is most significant that Congress elected not to limit the term to numerical standards.

7 ERC at 1843. This interpretation of EPA's discretion seems more consistent with the powers accorded the Agency under Section 112 than Adamo's construction. See discussion, *supra*, pp. 33-34.

Even assuming the applicability of these cases to the present situation, EPA seems to have avoided the problems inherent in the asbestos demolition regulations by not only establishing certain emissions limitations but also by couching design standards in an emissions limitation context. The courts are likely, therefore, to uphold EPA's action as reasonable and not arbitrary or capricious. Should the courts, on the other hand, conclude that the proposed standards are simply design requirements, the interpretation of the court in *Big Chief*, in light of the intent of Section 112 to control hazardous emissions, seems more likely to prevail.

2. Are the Courts Likely to Overturn EPA's Standards Because the Agency Took Costs and Technology Into Account in Setting Them

The next important question is whether EPA has improperly utilized cost and technology considerations in promulgating the proposed standards. At the outset, it certainly can be argued that when Congress wanted costs and technology taken into account in promulgating regulations under the Clean Air Act it specifically so provided. See, e.g., Sections 111, 202, and 210 of the Act, 42 U.S.C. §§1857c-7, 1857f-1, and 1857f-6b, respectively. Applying the usual rules of statutory construction, the absence of a specific allowance for costs and technology in other sections, such as Section 112, implies that Congress did not want them taken into account.

This is an argument somewhat dangerous to the industry— as well as the public interest. If this theory prevails the result would presumably cut against the industry's position, for it is precisely because the Agency took cost and technology into account—and went even further to apply a limited cost-risk-benefit analysis—that standards resulted which can presumably be attained. Moreover, by use of this methodology EPA was able to take into account a variety of factors affecting the public interest which resulted in proposed regulations best serving that interest.

On the merits, the weight of authority considering the question of whether EPA under the circumstances of this case has the discretion to apply cost-risk-benefit methodology even in the absence of statutory authorization is favorable to the Agency.

The theory of cost-risk-benefit analysis is that regulation of suspected harmful activity must be accomplished by weighing the risks to society of certain substances against the benefits they confer and the costs of controlling them to various safe levels. Regulation of alleged hazardous pollutants under Section 112 is especially complicated because of the fact that they can include substances which have known thresholds and those that do not, substances that are acutely dangerous and those that are of limited or only potential danger, substances with short persistence and those with long persistence, and substances that have great mobility and those that have no significant mobility. At the same time, the products which pose these varying degrees of danger to public health may have important uses to our society as a whole for which there are no known or safe substitutes, and often thousands if not millions of jobs may be involved in production.

In light of these conflicting pressures, which our society has repeatedly been called upon to measure, EPA has taken the view, supported by many in the scientific community,[29/] that each case requires some balancing of pertinent factors in determining what constitutes the safest course for society to take. Among the risk factors to be considered in a cost-risk-benefit analysis is what the available medical data shows the harm of exposure to a pollutant—or various levels of a pollutant—to be. In addition, are health dangers limited primarily to the workplace; controlled through other government regulations; posed in areas outside plants; widespread geographically; or exacerbated by persistence or mobility. Dose-response studies may be attempted to determine the extent of risk at different levels of exposure. Other studies consider the potential risks posed to health by increased use

29/ See, for example, "Perspectives on Benefit-Risk Decision Making." National Academy of Engineering, April 26-27, 1971 and "Decision Making for Regulating Chemicals in the Environment," National Academy of Science, 1975.

of substitute products.

The Agency then attempts to weigh these risks against any benefits that may be conferred upon society by the products involved. Included are questions such as: How important to society as a whole or parts of society are particular substances and the products derived from them? What impact does the product to be regulated have on jobs, the economy, ecology, national security, and aesthetic demands? What benefit, if any, is derived by those outside the work context? Do we need and are there adequate and safe substitutes if production is halted?

Finally, there is an evaluation of cost factors. What will it cost industry—and ultimately the consumer—to control products to particular levels of safety? What effect will different levels of control have on unemployment, inflation, and market structure, ranging from national productivity to balance of trade?

Although it has not done so intricately, EPA has essentially attempted to weigh risk factors of vinyl chloride against the benefits and costs of control in proposing regulations. The question is whether Section 112 of the Clean Air Act permits it to do so.

The legislative history of Section 112, previously discussed, <ins>supra</ins>, pp. 30ff, is not especially helpful on this question, and the inquiry is shrouded by the fact that in promulgating the 1970 Amendments Congress did not appear to consider specifically the problem of potential non-threshold pollutants whose concentrations might be minimal or even immeasurable. However, as earlier discussed, under such circumstances EPA and the courts must act as they believe the legislature would have intended had it foreseen "the precise situation." International Harvester v. Ruckelshaus, supra, 478 F.2d at 648.

While Senate supporters of Section 112 indicated hypothetically that regulation under the Section "could mean . . . that a plant would be required to close," 116 Cong. Rec. 42385 91st Cong. 2d Sess., Dec. 18, 1970, there is no evidence Congress ever contemplated that Section 112 would require the closing down of an entire industry in circumstances where available data left the question of the degree of risk partly unanswered and at least temporarily unanswerable.[30/]

Although in the Senate version of what became Section 112 there was no provision authorizing consideration of cost factors, there is still some ambiguity in how the Senate wished substances like vinyl chloride to be regulated thereunder. See generally, discussion, supra, pp. 30-34. For example, substances with potential health effects covered by proposed Section

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30/ See Remarks of Sen. Young, 116 Cong. Rec. 33114, 91st Cong. 2d Sess., Sept. 22, 1970 ("It was not intended by the committee that a technically unachieveable zero emission level be set unless the substance is so dangerous that any emissions endanger health. Only in that case would emissions be prohibited, a step which conceivably could force plants to suspend operations."

115[31/] could also have properties described in proposed Section 114 applicable to agents which merely had "or may be expected to have an adverse effect on public health," but "which are not emitted in such quantities or are not of such a character as to be widely present or readily detectable on a continuous basis with available technology in the ambient air," and whose "presence . . . is generally confined, at least for detection purposes, to the area of the emission source." S.Rep., p. 18.

The threat to health posed by vinyl chloride appears to fit Section 115 but the substance's ambient properties Section 114. While Section 114 did not authorize costs to be taken into account in setting standards, compliance could be waived for technological reasons without time limitations. Also, the standard to be set under Section 114—that emissions "not endanger the public health" was less stringent than the "ample margin of safety" standard enacted in Section 112.[32/]

Attempting to reconcile these provisions suggests that it is not inconsistent with congressional intent under Section 112, where emissions of hazardous pollutants may not be widely

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31/ As discussed, supra, pp. 30-31, Section 115 was applicable to hazardous pollutants whose presence in the air "causes or will cause, or contribute to, an increase in mortality or an increase in serious irreversible or incapacitating reversible damage to health." S.4358, as reported in S.Rep. 91-1196, 91st Cong. 2d Sess. (1970), p. 96.

32/ See discussion, supra, pp. 33-35.

present or readily detectable, and the degree of risk is difficult to quantify, to take some cost considerations into account. This, of course, is precisely how EPA has chosen to proceed.33/

Because the legislative history seems not to answer definitively the inquiry whether EPA has abused its discretion or acted outside the scope of its authority in considering, even on an admittedly limited basis, cost-risk-benefit factors in setting standards under Section 112, the answer will no doubt turn on how the courts are likely to scrutinize EPA's decision in this connection. Here the weight of authority seems on EPA's side.

As discussed previously, supra, pp. 39-41, the few cases decided under Section 112 involve the narrow question whether EPA has authority to promulgate "design" or "process" rather than numerical standards. These rulings do not provide specific guidance on whether the Administrator has authority to utilize cost-risk-benefit methodology in promulgating a set of regulations under Section 112. In the absence of clear legislative history applicable to, or case law construing, the statutory provision in question, it is necessary to turn for guidance to the general body of case law.

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33/ As discussed earlier, the House had no provision specifically discussing regulation of hazardous pollutants. In its only proposed section mentioning hazardous emissions, Section 112 applicable to stationary sources, costs and feasibility could be taken into account in setting standards. H.R.17255, as reported in H.Rep. 91-1146, 91st Cong. 2d Sess., p. 35. This lends some support to the above analysis.

Often in circumstances such as those faced by EPA in regulating vinyl chloride, there are no guidelines clearly enunciating the standards to be applied. When the issues are complex—involving factors of health, the economy, jobs, and related social concerns—agency officials have often carefully balanced these factors, or been required by the courts to balance them when they have failed to do so, in determining an appropriate regulatory framework. This approach has been sanctioned even in the absence of express statutory authorization for it.

In a number of environmental areas the courts have applied cost-risk-benefit analysis in evaluating the propriety or government action. Before turning specifically to these cases, it is helpful to remember the basic approach the courts take in reviewing the reasonableness of federal regulatory action aimed at remedying specific problems. The Supreme Court has enunciated standards which are particularly applicable in the complex situation of environmental regulation.

In N.L.R.B. v. Seven-Up Bottling Co., 344 U.S. 344 (1953) the Court upheld the N.L.R.B.'s interpretation of statutory back-pay awards in a discrimination suit. The Court first acknowledged the right of the Board to change interpretative rulings whenever "cumulative experience of many years discloses that [the] remedial provision falls short of effectuating the basic purposes and policies of the Act." 344 U.S. at 347. In examining the Board's attempt to balance various employee rights and interests of the company, the Court commented:

> As is true of many comparable judgments by those who are steeped in the actual workings of these specialized matters, the Board's conclusions may express an intuition of experience which outruns analysis and sums up many unnamed and tangled impressions . . . ; and they are none the worse for it. . . [t]he board was created for the purpose of using its judgment and its knowledge. . . . It is the business of the Board to give coordinated effect to the policies of the Act.

344 U.S. at 348. The Court concluded this discussion by adding:

> [I]n devising a remedy the Board is not confined to the record of a particular proceeding. Cumulative experience begets understanding and insight by which judgments not objectively demonstrable are validated or qualified or invalidated. The constant process of trial and error, on a wider and fuller scale than a single adversary litigation permits, differentiates perhaps more than anything else the administative from the judicial process. [T]he relation of remedy to policy is peculiarly a matter for administrative competence . . . .

344 U.S. at 349.

The Court has suggested that the latitude accorded an agency in interpretating its remedial powers may have special applicability in environmental matters. For example, in Train v. NRDC, 421 U.S. 60 (1975), the Court upheld EPA's interpretation of the variance provisions of Section 110 of the Clean Air Act, 42 U.S.C. §1857c-5. In doing so it held:

> We therefore conclude that the Agency's interpretation . . . was "correct" to the extent that it can be said with complete assurance that any particular interpretation of a complex statute such as this is the "correct" one. Given this conclusion, as well as the facts that the Agency is charged with administration of the Act, and that there has undoubtedly been reliance upon

> its interpretation by the States and other parties affected by the Act, we have no doubt whatever that its construction was sufficiently reasonable to preclude the Court of Appeals from substituting its judgment for that of the Agency.

421 U.S. at 87. See also Udall v. Tallman, supra, 380 U.S. at 16-18.

The rationale underlying this deference to agency interpretation of statutory responsibilities in matters affecting the environment has served to buttress resort to cost-risk-benefit methodology in framing remedies even in the absense of specific authorization for it. See, Reserve Mining Co. v. EPA, supra.

There, in evaluating the nature of the relief which was required to control Reserve Mining's iron ore processing activities near Lake Superior, the court took specific note of the fact that Reserve's operation employed 3,000 workers and was "central to the economic livelihood of Silver Bay and surrounding communities." 514 F.2d at 500 fn. 4,536. Yet nothing in the statutory scheme specifically requires such an evaluation.

Violations of the Rivers and Harbors Act of 1899, 33 U.S.C. §407, the pre-1972 Federal Water Pollution Control Act (FWPCA), 33 U.S.C. §1160, and the federal common law of nuisance were alleged against Reserve. The Rivers and Harbors Act barred (without consideration of cost) the discharge of waste into navigable waters. Under FWPCA, pollution of interstate or navigable waters "which endangers the health or welfare of any persons" was subject to abatement. 33 U.S.C. §1160(a). Standards established to meet this requirement had to take into consideration the use and value of the waters as a public supply, and for propagation of wildlife, recreation, agriculture, industrial and other "legitimate" uses. 31 U.S.C. §1160(c)(3). The "physical and economic feasibility" of complying with the standards were a proper subject of inquiry only during judicial review of agency action to enforce previously established standards. 33 U.S.C. §1160(c)(5).

In spite of the clear health risk perceived by the court, See supra, pp. 24-25, and the absence of statutory authorization for consideration of cost factors in framing remedies, the court narrowed the lower court's order requiring that Reserve close its facility. After extensive analysis of the possible carcinogenicity of asbestos and its danger to man, the Court of Appeals held that remedial action was clearly called for in the case because of the risk posed by asbestos but it narrowed the lower court injunction because of the "uncertainties in plaintiffs' theory of harm . . . particularly the uncertainty as to present levels of exposure and the difficulty in attempting to quantify those uncertain levels in terms of a demonstrable health hazard." 514 F.2d at 506. In attempting to determine the appropriate relief, the court specifically noted the lower level of general public exposure compared to exposure at the factory. 514 F.2d at 511.

Thus, the twin problems of measuring the reliability of the health data and the extent of exposure, true also for regulation of ambient amounts of vinyl chloride, were persuasive with the court in limiting the remedial action undertaken. The Eighth Circuit, as EPA has done, specifically balanced various factors, including the health risk and the benefits to society conferred by Reserve Mining's work in terms of products and jobs: "In fashioning relief in a case such as this," the court reasoned, "a court should strike a proper balance between the benefits conferred and the hazards created by Reserve's facility." 514 F.2d at 535. Specifically to be included in this balancing were:

> a) the nature of the anticipated harm, b) the burden on Reserve and its employees from the issuance of the injunction, c) the financial ability of Reserve to convert to other methods of waste disposal, and d) a margin of safety for the public.

514 F.2d at p. 536.

After acknowledging its inability to quantify satisfactorily all the factors to be weighed, the Eighth Circuit rejected closing down the plant because of the "unpredictable" health effects and the clearly predictable social and economic consequences that would follow the plant closing. The Court then summed up the basis for its decision modifying the injunctive relief against Reserve:

> Congress has generally geared its national environmental policy to allowing polluting industries a reasonable period of time to make adjustments in their efforts to conform to federal standards. See, e.g., Federal Water Pollution Control Act, 33 U.S.C. §1160 (1970); Clean Air Act, 42

> U.S.C. §§1857c-5 to 8 (1970),[34/] National Environmental Policy Act, 42 U.S.C. §4331 (1970). In the absence of an imminent hazard to health or welfare, any other program for abatement of pollution would be inherently unreasonable and invite great economic and social disruption. Some pollution and ensuing environmental damage are, unfortunately, an inevitable concomitant of a heavily industrialized economy. In the absence of proof of a reasonable risk of imminent or actual harm, a legal standard requiring immediate cessation of industrial operations will cause unnecessary economic loss, including unemployment, and, in a case such as this, jeopardize a continuing domestic source of critical metals without conferring adequate countervailing benefits.
>
> We believe that on this record the district court abused its discretion by immediately closing this major industrial plant. In this case, the risk of harm to the public is potential, not imminent or certain, . . . A remedy should be fashioned which will serve the ultimate public weal by ensuring clean air, clean water, and continued jobs in an industry vital to the nation's welfare.

514 F.2d at 537.

Because in many respects the dangers of vinyl chloride may be similar to, but are less proven than, asbestos, the reasoning of Reserve Mining suggests that while EPA may act to control vinyl chloride as a hazardous pollutant it must apply the kind of balancing approach it has utilized in setting standards in light of the difficulty of quantifying the risks. That Reserve did so without the specific authorization of a statute is suggestive of the approach the courts will take in reviewing EPA's action.

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34/ Note that the Eighth Circuit here included Section 112 of the Clean Air Act, 42 U.S.C. 1857c-7.

The considerations which guided the court in Reserve can be found in the opinions of courts in other contexts involving serious risk to society which may be difficult to measure. For example, few environmental problems have been of more immediate concern to the courts than the control of pesticides, poisons which are capable of seriously and immediately endangering human health if improperly regulated. Yet, cost-risk-benefit analysis has been carefully undertaken in pesticide cases under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. §135 et seq., even though until the 1972 Amendments, 7 U.S.C. §136, there was no express authorization for this approach. Rather, pesticides were required to carry labels which, when complied with, were "adequate for the protection of the public" and "adequate to prevent injury to living man" and other life. 7 U.S.C. §135(z)(2).

In Stearns Electric Paste Co. v. EPA, 461 F.2d 293 (7th Cir. 1972), arising under the old law, the Seventh Circuit set aside an order of EPA cancelling a manufacturer's registration of a pesticide designed for home use. Because deaths had been caused when children ingested the pesticide, the Administrator had concluded that the manufacturer's product, even if properly labeled, was not safe for use in the home.

The statute did not then authorize consideration of cost factors in determining whether to cancel registration of a pesticide deemed to be unsafe. Nonetheless, the court ruled that in considering remedial action the Agency should evaluate the benefits to society conferred by the product. The court cautioned against permitting "emotionalism" to infuse the debate on regulating hazardous products because human fatalities had occurred and might occur again even after regulation. 461 F.2d at 298-9, 307-8.

The court elaborated that an "intricate" or "delicate" balancing of costs, risks, and benefits was required in the case of a pesticide that is potentially dangerous even when used properly. Another example it found of a pesticide in this category was DDT, a suspected carcinogen. 461 F.2d at 306-308. The court approved EPA's explanation of the test the Agency normally applied:

> [T]he final decision with respect to initial or continued registration of a product depends on the intricate balance struck between the benefits and dangers to the public health and welfare resulting from its use. More specifically, the Administrator must determine and weigh (1) the nature and magnitude of the foreseeable hazards associated with use . . . against (2) the nature of the benefit conferred . . . or, put another way, against the magnitude of the social cost of foregoing the use of the product.

461 F.2d at 306-7. EPA conceded that there was no statutory basis for this methodology:

> The FIFRA . . . does not explicitly provide that, prior to a cancellation or suspension, the Administrator must or should consider the benefits derived from use of a pesticide. It would, however, be unreasonable to ban the . . . pesticide on grounds of hazard to public health or the environment if in fact such a ban would itself cause the greater hazards . . . [EPA]

> has now unequivocably taken the position that Congress has, in the Act, granted the Agency sufficient discretion to weigh the hazards and benefits from use of a pesticide in making a final cancellation determination.

461 F.2d at 307, fn. 15.

This Agency determination to interpret its powers more flexibly than specifically set forth in the statute had also been approved in Environmental Defense Fund v. Ruckelshaus, 439 F.2d 584 (D.C. Cir. 1971), involving federal registration of DDT. The court held that the Secretary of Agriculture had acted properly in issuing notices of cancellation and initiating related administrative procedures upon determining that there was a substantial question about the safety of the pesticide for certain uses. But it further held that once a substantial question of safety arose the Secretary was obligated to issue notices of cancellation as to all uses of DDT on which he had not acted, and it entered an order to that effect, 439 F.2d at 595. Because the Secretary found that DDT in large doses had produced cancer in test animals and various injuries in man but in small doses its effect on man was unknown, and that the pesticide had important beneficial uses, the cancellation decision could

> . . . 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 . . . There may well be countervailing factors that would justify an administrative decision . . . to continue a registration despite a substantial degree of risk . . . 439 F.2d at 594.

The court also reviewed the Secretary's continued refusal to order an interim summary suspension and remanded for a statement of reasons justifying the refusal. 439 F.2d at 596. In order to determine whether an imminent hazard to the public would be posed during the conduct of further administrative proceedings, thus meeting the statutory test for suspension, the Secretary must establish the degree of harm posed and the likelihood of its occurrence. He had a heavy burden if he wished to permit continued use of known carcinogens. 439 F.2d at 596, fn. 41. Nonetheless, the court supported a balancing test in determining the legality of the Agency's ultimate disposition. See also, EDF v. EPA, 465 F.2d 528 (D.C. Cir. 1972) (There the court reached a similar result in reviewing EPA's action concerning registration of aldrin and dieldrin: "We are clear that the statute empowers the Administrator to take account of benefits or their absence as affecting imminency of hazard," 465 F.2d at 538); and EDF v. EPA, 510 F.2d 1292, 1302 (D.C. Cir. 1975).

Turning specifically to the Clean Air Act, certain portions of the 1970 Act require that costs be taken into account in establishing standards regulating emissions of pollutants into the ambient air (e.g., Sections 111 and 202(a)(2)), while other parts make no reference to cost factors (e.g., Sections 109 and 112). Notwithstanding the absence of express statutory language, the courts have utilized some cost-risk-benefit concepts in assessing the validity of EPA action under the Act.

In International Harvester Company v. Ruckelshaus, 478 F.2d 615 (D.C. Cir. 1973) the court reviewed EPA's action denying certain automobile manufacturers a one-year suspension of 1975 emission requirements. Under the Act, the Administrator was authorized to grant the delay only if (1) suspension was essential to the public interest or health and welfare, (2) all good faith efforts had been made to meet established standards, (3) effective technology was unavailable or was not available for sufficient time, and (4) National Academy of Sciences' studies showed an unavailability of processes necessary for compliance with the standards. 42 U.S.C. §1857f-1(b)(5)(D). EPA, after notice and public hearings, ruled against the manufacturers on all but the second ground.

In reviewing this action the court considered factors outside the strict requirements set forth in the statute. To begin with, it emphasized that EPA has the burden of proving the reasonableness and reliability of its methodology. 478 F.2d at 632, 643. Once it has done so, it must balance competing interests in determining an appropriate standard:

> On the one hand, if suspension is not granted, and the prediction of the EPA Administrator that effective technology will be available is proven incorrect, grave economic consequences could ensue . . . On the other hand, if suspension is granted, and it later be shown that the Administrator's prediction of feasibility was achievable in 1975 there may be irretrievable ecological costs.

478 F.2d at 633.

The court clearly perceived complicated issues involving the economy, competition, the environment, and the consumer in weighing the legality of EPA's action. In such circumstances, it held that the advantages of a cost-risk-benefit methodology in deciding the correct policy to follow should be utilized:

> This case inevitably presents, to the court as to the Administrator, the need for a perspective on the suspension that is informed by an analysis which balances the costs of a "wrong decision" on feasibility against the gains of a correct one. These costs include the risks of grave maladjustments for the technological leader from the eleventh-hour grant of a suspension, and the impact on jobs and the economy from a decision which is only partially accurate, allowing companies to produce cars but at a significantly reduced level of output. Against this must be weighed the environmental savings from denial of suspension. The record indicates that these will be relatively modest...

478 F.2d at 641. The court readily acknowledged the extraordinary complexity of the issues. As quoted earlier, <u>supra</u>, p. 35, where there is no legislative provision or interpretative history on how to resolve them, the agency and the courts must act as they believe Congress would have had the problem anticipated. Doing so, the court said:

> [W]e have not flinched from our discussion of the economic and ecological risks inherent in a "wrong decision" by the Administrator. We . . . [take] into account that the risk of an "erroneous" denial of suspension outweighed the risk of an "erroneous" grant of suspension.

478 F.2d at 648. The court concluded that in its view "the overall legislative firmness does not necessarily require a

"hard-nosed" approach . . . and may indeed be furthered by our more moderate view . . ." 478 F.2d at 649.

The International Harvester case lends support to the approach taken by EPA in attempting to regulate a suspected carcinogen where there is a known but unquantifiable health risk and important economic and other interests are at stake. The most reasoned approach is to evaluate carefully the costs, risks, and benefits in choosing the most valid control. 35/

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35/ Under Section 109-110 of the Clean Air Act, 42 U.S.C. §§1857c-4,5, EPA is accorded no authority to take costs into account in establishing ambient air standards or in determining the acceptability of mandatory State implementation plans. Nonetheless, the majority of courts have required that costs be taken into account in evaluating the implementation plans. See, e.g., St. Joe Minerals v. EPA, 508 7.2d 743 (3rd Cir. 1975), State of Texas v. EPA, 499 F.2d 289 (5th Cir. 1974), Buckeye Power Co., Inc. v. EPA, 481 F.2d 162 (6th Cir. 1973), and Appalachian Power Co. v. EPA, 477 F.2d 495 (4th Cir. 1973). These courts have ruled that where Congress does not make its intention to exclude costs clear the Administrator retains authority to consider them. Moreover, they interpret "costs" to include jobs, competition in the marketplace, and other socio-economic factors. Contra: Union Electric v. EPA, 515 F.2d 206 (8th Cir. 1975).

Support for the application of cost-risk-benefit principles is fairly widespread. Indeed, in their effort to resolve difficult policy questions involving competing public interests—such as health and safety, jobs, economic interests, and national security—the courts have often resorted to cost-risk-benefit analysis and they have done so notwithstanding the lack of specific statutory authorization.

In Industrial Union Department, AFL-CIO v Hodgson, 499 F.2d 467 (D.C. Cir. 1974), for example, discussed, supra, pp. 16-17, the court reviewed standards promulgated by OSHA to regulate atmospheric concentrations of asbestos dust in industrial workplaces. Recognizing that regulation of suspected carcinogens was a new agency responsibility, and that it was difficult or impossible to quantify health risks, the court reaffirmed that the agency would have to make essentially policy judgments and that it "necessarily enjoys broad discretion to attempt to formulate a solution to the best of its ability on the basis of available information." 499 F.2d 474-75, fn. 18. Its action would be upheld if not irrational or arbitrary. 499 F.2d at 475.

Of particular significance in weighing how the courts are likely to approach the vinyl chloride regulations is the manner in which the court in Hodgson interpreted the "feasibility" standard in the Occupational Safety and Health Act, 29 U.S.C. §655. The court upheld the Secretary's two-year delay of more stringent standards under the Act as consistent with the Secretary's right to consider "feasibility." However, the provision for feasibility was interpreted far more broadly than the brief legislative history behind the term suggests it should have been. The requirement for feasibility was added simply so that existing technology could be taken into account in setting standards. See S.Rep. No. 91-1282, 91st Cong. 2d Sess., 1970, U.S. Code Cong. & Admin. News, pp. 5183, 5222, and Conf. Rep. 91-1765. *Id.* at p. 5231. Yet the court went considerably further, holding not only that technological considerations must be taken into account in establishing standards but that competition within the industry and other factors not related to technological "feasibility" must be as well:

> For example, if the standard requires changes that only a few leading firms could quickly achieve, delay might be necessary to avoid increasing the concentration of the industry. Similarly, if the competitive structure or posture of the industry would be otherwise adversely affected—perhaps rendered unable to compete with imports or with suitable products—the Secretary could properly consider that factor.

499 F.2d at 478. This degree of cost-benefit analysis simply finds no basis in the Act or legislative history, yet the court

did not hesitate to find that the Secretary had authority to apply such a methodology.

In other instances involving threats to public health, the courts have applied cost-risk-benefit analysis in evaluating the propriety of agency action. United States v. Goodman, 486 F.2d 847 (7th Cir. 1973), involved the question whether injunctive relief could be obtained under the Food, Drug, and Cosmetic Act against distribution of suspected contaminated fish. The district court, noting that EPA had established no tolerance for DDT, had granted an order permanently enjoining five distributors from shipping fish in which the total amount of DDT exceeded five parts per million, a limit established by the FDA under its authority to prohibit the sale of food containing a pesticide which is "unsafe," i.e., "not generally recognized, among experts . . . as safe for use . . . " 486 F.2d at 850.

The court of appeals upheld the issuance of injunctive relief. Although the standards to be set under the Food and Drug Act for use of pesticides must take into account "the necessity for the production of an adequate, wholesome and economical food supply," 21 U.S.C. 436a(b), the establishment of standards for pesticides which may be carcinogenic to man presents special problems. The court directed its attention to the fact that there may be no safe level of exposure:

> Although the cancer aspects of DDT are frightening, the obvious solution to that problem, that is, a total ban on foods containing DDT, is not available.

> Virtually, every food contains some DDT. The Administrator is required by Section 346a(b)(1) to consider "the necessity for the production of an adequate, wholesome and economical food supply . . . " in setting tolerances. DDT has presented, and apparently will continue to present, a massive dilemma both for EPA and for society. Since there is no tolerance or exemption for DDT in fish, any amount of this poisonous pesticide chemical must be deemed unsafe and result in an adulterated product under a literal interpretation of the statute. Yet it is obvious that at the present time all fish cannot be banned inasmuch as it would seriously affect the total food supply.

486 F.2d at 855. (Emphasis supplied) The considerations which impelled the Seventh Circuit to recognize that five ppm of DDT in food was acceptable—even though it knew there might be no level of safety—evidences the court's willingness to balance society's legitimate competing needs in determining the legality of agency action in setting regulatory standards for the control of potentially harmful products.

Another situation in which the courts have relied on a form of cost-risk-benefit analysis has occurred under the Atomic Energy Act, 42 U.S.C. §2011 et seq. Under Section 182a of the Act, 42 U.S.C. §2232(a), applications for licenses to operate atomic facilities may not be granted unless procedures are established which will be in accord with defense needs and which, in mandatory terms, "will provide adequate protection to the health and safety of the public." In Power Reactor Development Co. v. Electrical Workers, Int'l, 367 U.S. 396 (1961), the Supreme Court ruled that the statutory mandate that a facility "will provide adequate protection" is satisfied if there is "reasonable assurance" the facility will be adequate to protect the public. Such a standard "comports with the requirements" for issuing licenses. 367 U.S. at 406-407. In explaining its holding the Court reasoned:

> [N]uclear reactors are fast-developing and fast-changing. What is up to date now may not, probably will not, be as acceptable tomorrow. Problems which seem insuperable now may be solved tomorrow . . . We see no reason why we should not accord to the Commission's interpretation of its own regulation and governing statute that respect which is customarily given to practical administrative construction of a disputed provision. Particularly is the respect due when the administrative practice at stake "involves a contemporaneous construction of a statute by the men charged with the responsibility of setting its machinery in motion, of making the parts work efficiently and smoothly while they are yet untried and new." 367 U.S. at 408.

Thus, the Supreme Court read into the otherwise unambiguous statutory language a less stringent "reasonable assurance" standard as sufficient to protect public health. See also Nader v. Nuclear Regulatory Commission, 513 F.2d 1045 (D.C. Cir. 1975). (The court denied requests for emergency shutdown or derating of twenty nuclear power plants on assertions of danger to public safety. It approved the AEC's decision which stated that "Neither the statute nor the Commission regulations in issue . . . require such an unattainable guarantee of risk-free operation . . . We do not live in a risk-less society, nor could modern technological societies exist on that basis . . . The regulatory process turns upon the concept of 'reasonable

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assurance' to public health and safety." 513 F.2d at 1050.

In the situation facing EPA regulation of vinyl chloride, of course, if the industry chooses to defend the fairness of the Agency's reliance in setting standards on a limited cost-risk-benefit methodology it would obviously not also argue that the AEC cases suggest that the Agency should—or would be authorized to—establish a less stringent health standard than the "ample margin of safety" required in Section 112. What it would argue is that language like that in Power Reactor acknowledges some flexibility in the agency charged with protecting the public health. Thus, when EPA measures the risk posed to society by vinyl chloride against the benefits its uses confer and the cost of controlling its emissions, the Agency is not reducing the severity of the standard but engaging in a difficult attempt to decide the most acceptable basis for regulation. In this attempt, Power Reactor and similar cases lend credibility to the kind of decision-making undertaken by EPA, because in the nuclear cases the courts have permitted the AEC to go further, i.e., to the point of actually reducing the severity of the statutory command.

The willingness of the courts to balance safety considerations against countervailing public interests is further shown in Nader v. Federal Aviation Administration, 440 F.2d 292 (D.C. Cir. 1971). There the D.C. Circuit was asked to overturn the FAA's refusal to impose an emergency ban on smoking on commercial aircraft. Danger to safe flight was alleged to be posed by fire and smoke. The standard to which aircraft carriers are held under the Federal Aviation Act is performance of service "with the highest possible degree of safety in the public interest." 440 F.2d at 294, citing 49 U.S.C. §1421(a)(6)(b). Nothing in the statute authorized the FAA to consider factors extraneous to safety and the court acknowledged that smoking on aircraft could be hazardous. 440 F.2d at 293-4. Nonetheless, in upholding the FAA's refusal to order an immediate ban on smoking, the court applied traditional cost-benefit analysis:

> [T]he suggestion of any safety hazard does not automatically require the Administrator to act. The Administrator is given some power to measure the suggested hazard. The Administrator has done that measuring in this case, and we cannot say that his measurements are unreasonable . . .

Id. The court affirmed the FAA's action on the ground that the "freedom to smoke" was enjoyed by millions and should not be abrogated when the agency charged with regulation does not find the magnitude of risk to be too great. 440 F.2d at 294-5. The court relied for this holding on Environmental Defense Fund v. Ruckelshaus, supra. Arguably, the "freedom" to smoke is not entitled to greater consideration than are important cost-risk-benefit factors—including jobs—in other contexts.

In summary, legal precedent suggests EPA has authority to balance costs, risks, and benefits in setting health standards to control substances whose threat to public health may be high but is still not precisely quantifiable and upon which society is to varying degrees dependent. The courts have adopted this methodology repeatedly in areas involving the gravest threats to public health and safety, and even when the substance to be regulated is a suspected carcinogen. They have specifically approved agency action which permits continued use of no-threshold or highly dangerous products because, on balance, the overall interests of the public are best served. This has often been done without express statutory sanction.

It is probable, therefore, that the courts would approve EPA's regulation of vinyl chloride under Section 112 of the Clean Air Act through utilization of a limited cost-risk-benefit analysis. In the event the courts did not approve, the likely reason would be that the Agency improperly weakened the regulatory framework by resorting to extraneous factors not set forth in the statute. The courts might compel EPA to require zero emissions or ban vinyl chloride.

## Conclusion

In developing an appropriate regulatory framework to govern emissions of vinyl chloride into the ambient air, EPA has taken into account the properties of vinyl chloride, the quantity of medical data on the risks it poses to public health, the various statutory avenues available in selecting a mechanism for regulation, and the conflicting public interests at stake in deciding upon any particular control strategy. In attempting to do this, the Agency has concluded that vinyl chloride production should not be terminated, that Section 112 of the Clean Air Act is the appropriate section of the Act under which to promulgate regulations, and that while there may be no threshold below which there is no public health risk, the Agency's standard as proposed will nonetheless provide "an ample margin of safety" to the public.

A court called upon to review EPA's action will look to the reasonableness of the Agency's response to the vinyl chloride problem. It will accord the Agency considerable discretion in analyzing the nature of the risk and the remedies called for under the circumstances. Unless the Agency can be shown to have abused its discretion or acted outside the scope of its authority—in short, arbitrarily and irrationally—or unless it can be shown that EPA has simply failed to employ "principled decision-making" in promulgating regulations, its action is likely to be upheld.

Analyzing all the factors which entered into EPA's decision-making process on regulating vinyl chloride emissions, it is difficult to argue with the basic rationale it applied in developing a regulatory framework. While there are parts of the Agency's analysis with which fault can be found, as well as aspects of its decisions and process which may be inaccurate (all of which can and should be corrected specifically on the public record), the entirety of the EPA response appears to constitute the kind of principled decision-making that the courts have repeatedly looked for in reviewing the sufficiency of agency action. It is, therefore, probable that a reviewing court will find that EPA has acted within its authority in regulating vinyl chloride emissions into the ambient air, that its selection of Section 112 to accomplish regulation is authorized and that in implementing that Section the Agency has not exceeded its authority. Of the alternative rulings possible—that the Agency did not go far enough in controlling vinyl chloride or that it went too far—neither seems sensible under the circumstances or consistent with either the industry's commitment to assuring public safety or with the public interest in assuring that adequate health and safety precautions are undertaken where their may be unacceptable risk.