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February 13, 1976

Mr. Ralph L. Harding
The Society of the Plastics
Industry, Inc.
250 Park Avenue
New York, New York 10017

Dear Ralph:

Attached is a draft of a legal memorandum which we propose that you submit to EPA along with the other comments in preparation on the proposed vinyl chloride standard.

Please note that the memorandum, although intended for filing with EPA, is addressed to SPI. The reason for this is two-fold:

1. Because the legal position adopted by the Society is essentially supportive of the approach EPA has taken in proposing a standard, we believe it would be inappropriate for our legal document to be addressed directly to the Agency. It might appear that the industry is merely being self-serving, and we want to avoid that. On the other hand, as we have discussed, we do want to place in EPA's hands a document which provides support for the legal approach the Agency has taken.

2. We do not wish to preclude individual companies from filing their own separate comments on legal issues if they wish to do so, or to foreclose legal challenge by an individual company. Accordingly, by your submission to EPA of a legal analysis which is addressed to SPI by its special counsel, you are able to lend support to the Agency without appearing to be filing an official SPI position which could be construed as binding on all its members.

Please let me know if you have any questions about this approach.

Sincerely,

Bill
William D. Ruckelshaus

WDR/ap
Attachment

AP00053853

DRAFT
2/10/76

M E M O R A N D U M

TO

THE SOCIETY OF THE PLASTICS INDUSTRY, INC.

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

February, 1976

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Washington, D.C. 20006

AP00053854

TABLE OF CONTENTS

	<u>Page</u>
Table of Cases.....	ii
Introductory Statement.....	1
Discussion.....	2
I. Are the Courts Likely to Overturn the Standard EPA Has Proposed Under Section 112 on the Ground That It Constitutes An Illegal Design or Process Standard.....	7
II. Are the Courts Likely to Overturn EPA's Standard Because the Agency Took Costs and Technology Into Account in Setting It.....	11
A. Cost-Risk-Benefit Methodology.....	12
B. Legislative History.....	15
C. Application of Cost-Risk-Benefit Method- ology by EPA.....	17
D. Application of Cost-Risk-Benefit Method- ology by Other Federal Agencies.....	32
Conclusion.....	42

TABLE OF CASES

	<u>Pages</u>
<u>Amoco Oil Co. v. EPA</u> , 501 F.2d 722 (D.C. Cir. 1974).....	3,4,6
<u>Appalachian Power Co. v. EPA</u> , 477 F.2d 495 (4th Cir. 1973).....	33
<u>Association of Data Processing Service Organizations v. Camp</u> , 397 U.S. 150 (1970).....	3
<u>Buckeye Power Co., Inc. v. EPA</u> , 481 F.2d 162 (6th Cir. 1973).....	33
<u>Citizens for Safe Power, Inc. v. NRC</u> , ____ F.2d ____, D.C. Cir. No. 74-1186 (12/22/75).....	39
<u>Citizens To Preserve Overton Park v. Volpe</u> , 401 U.S. 402 (1971).....	3,4
<u>Delaware Citizens for Clean Air, Inc. v. U.S. EPA</u> , 480 F.2d 1972 (3rd Cir. 1973).....	3,4
<u>EDF v. EPA</u> , 465 F.2d 528 (D.C. Cir. 1972).....	6,29
<u>Environmental Defense Fund v. EPA</u> , 489 F.2d 1247 D.C. Cir. 1973).....	13
<u>Environmental Defense Fund v. EPA</u> , 510 F.2d 1292 (D.C. Cir. 1975).....	7,29
<u>EDF v. Hardin</u> , 428 F.2d 1093 (D.C. Cir. 1970).....	3,6
<u>EDF v. HEW</u> , 428 F.2d 1083 (D.C. Cir. 1970).....	6
<u>Environmental Defense Fund, Inc. v. Ruckelshaus</u> , 439 F.2d 584 (D.C. Cir. 1971).....	5,28
<u>Essex Chemical Corporation v. Ruckelshaus</u> , 486 F.2d 427 (D.C. Cir. 1973), <u>cert. den.</u> 416 U.S. 969 (1973).....	5,6
<u>Federal Trade Commission v. Cement Institute</u> , 333 U.S. 683 (1948).....	6

TABLE OF CASES

	<u>Pages</u>
<u>Industrial Union Dep't., AFL-CIO v. Hodgson,</u> 499 F.2d 467 (D.C. Cir. 1974).....	3,5,33
<u>International Harvester v. Ruckelshaus, 478 F.2d</u> 615 (D.C. Cir. 1973).....	4,6,18,29
<u>Nader v. Federal Aviation Administration, 440</u> F.2d 292 (D.C. Cir. 1971).....	40
<u>Nader v. Nuclear Regulatory Commission, 513</u> F.2d 1045 (D.C. Cir. 1975).....	38
<u>NRBB v. Seven-Up Bottling Co., 344 U.S. 344</u> (1953).....	19
<u>Power Reactor Development Co. v. Electrical</u> <u>Workers, Int'l., 367 U.S. 396 (1961).....</u>	37
<u>Reserve Mining Co. v. Environmental Protection</u> <u>Agency, 514 F.2d 492 (8th Cir. 1975).....</u>	5,6,21
<u>St. Joe Minerals v. EPA, 508 F.2d 743 (3rd Cir.</u> 1975).....	33
<u>State of Texas v. EPA, 499 F.2d 289 (5th Cir.</u> 1974).....	33
<u>Stearns Electric Paste Co. v. EPA, 461 F.2d</u> 293 (7th Cir. 1972).....	26
<u>The Society of the Plastics Industry v. OSHA,</u> 509 F.2d 1301 (2d Cir. 1975), cert. den. sub nom <u>Firestone Plastics Co. v. U.S. Dep't. of Labor,</u> 43 U.S.L.W. 3623 (1975).....	5,7
<u>Train v. NRDC, 421 U.S. 60 (1975).....</u>	10,20
<u>Udall v. Tallman, 380 U.S. 1 (1965).....</u>	4,20

TABLE OF CASES

	<u>Pages</u>
<u>Union Electric v. EPA</u> , 515 F.2d 206 (8th Cir. 1975).....	33
<u>U.S. v. Adamo Wrecking Co.</u> , CR No. 5-80297 (E.D. Mich. 6/6/75).....	8
<u>U.S. v. Big Chief</u> , 7 ERC 1840 (E.D. La. 4/23/75)...	8,9
<u>U.S. v. Brandenburg Demolition Co.</u> , No. 74 CR 757 (N.D. Ill. 1975).....	8
<u>U.S. v. Dotterweich</u> , 320 U.S. 277 (1943).....	5
<u>U.S. v. Fla. East Coast Ry. Co.</u> , 410 U.S. 224 (1973).....	4
<u>United States v. Goodman</u> , 486 F.2d 847 (7th Cir. 1973).....	35
<u>U.S. v. Harvey Wrecking Co.</u> , No. 74 CR 758 (N.D. Ill. 1975).....	8
<u>U.S. v. Nardi Wrecking Co.</u> , No. 74 CR 756 (N.D. Ill. 1975).....	8
<u>U.S. v. National Wrecking Co.</u> , No. 74 CR 755 (N.D. Ill. 1975).....	8

Introductory Statement

This memorandum follows up our earlier analyses of issues involved in the Environmental Protection Agency's issuance of a proposed standard regulating vinyl chloride emissions into the ambient air. See, "National Emission Standards for Hazardous Air Pollutants, Proposed Standard for Vinyl Chloride," 40 Fed. Reg. 59532 (December 24, 1975). It is intended to consider two legal questions: (1) whether EPA, in implementing the mandate that it set an "emission standard" under Section 112 of the Clean Air Act, has abused its discretion or acted outside the scope of its authority in ordering certain "design" or "process" changes; and (2) whether it has acted illegally in applying a cost and technology methodology in determining an appropriate standard.

In summary of our conclusions, the details of which are set forth more fully below, we conclude that the courts would hold EPA has set a valid emission standard under Section 112. First, the Agency seems to have imposed the kind of numerical limitations which the majority of the lower courts believe to be required by the Act. Second, to the extent the Agency has ordered certain design modifications, we believe the courts would conclude that such modifications are authorized under Section 112.

We have also concluded that the courts would rule EPA is authorized to take costs and technology into account in

establishing a standard under Section 112 when regulating a suspected carcinogen with no known threshold. However, the levels of vinyl chloride which exist in the ambient air are extremely low. There is no demonstrated human health risk associated with the substance at these levels. In addition, there are important uses for vinyl chloride in our society, as well as a large number of jobs involved in its production and end use. Accordingly, while EPA's decision not to order zero emissions, currently unachievable based upon technology, or a total ban, seems clearly correct and consistent with the public interest, the Agency can be challenged for not having applied a rigorous cost-benefit methodology carefully balancing the costs of particular control requirements against the benefits likely to be achieved in protecting public health. The Agency's resort to cost considerations only where they are "grossly disproportionate" to the emission reduction achieved, and its rejection of a "fine balancing of costs against benefits . . . " ^{1/} seems to fall short of the methodology required.

Discussion

Before turning to the specific issues under consideration, we thought it would be helpful to recapitulate a number of our earlier conclusions. We have previously shown that there is

^{1/} Proposed Standard, 40 Fed. Reg. at 59536. See also, Standard Support and Environmental Impact Statement: Emission Standard for Vinyl Chloride, EPA, October 1975, pp. 2-24 — 2-26.

no doubt of the availability of judicial review of final EPA action under Section 112. See, Section 307 of the Clean Air Act, 42 U.S.C. §1857h-5. (Petitions for review must be filed in the United States Court of Appeals for the District of Columbia.)^{2/} Nor is there doubt that the industry would have standing if it chose to seek review of final vinyl chloride regulations. -It is within the zone of interests to be regulated, would be most affected by the regulations, and would suffer injury in fact if the regulations become final.

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).

Because the statute does not specify the scope of judicial review of EPA's action, the applicable standard is established by the Administrative Procedure Act, namely, whether Agency action is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. §706(2)(A); Citizens to Preserve Overton Park v. Volpe, *supra*, Amoco Oil Co. v. EPA, 501 F.2d 722, 731 (D.C. Cir. 1974); Delaware Citizens for Clean Air, Inc. v. Administrator, U.S. EPA, 480 F.2d 972 (3rd Cir. 1973). The more stringent substantial evidence and de novo theories of review are unavailable because

^{2/} As we have discussed, in the event review were not expressly authorized in the Clean Air Act, applicable provisions of the Administrative Procedure Act would provide for review. 5 U.S.C. §§701 et seq.; Citizens to Preserve Overton Park v. Volpe, 401 U.S. 402, 410 (1970); Industrial Union Dep't., AFL-CIO v. Hodgson, 499 F.2d 467 (D.C. Cir. 1974).

of the absence of a statutory provision requiring either an on-the-record, adjudicatory-type hearing in promulgating regulations under Section 112 or a right to de novo review. 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 731-2 (D.C. Cir. 1974); International Harvester v. Ruckelshaus, 478 F.2d 615, 629 (D.C. Cir 1973).

While the standard of "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" is difficult to define precisely, a set of guiding principles for review of agency action under this standard has emerged. The courts will make a "substantial inquiry" and subject the agency's action to "a thorough, probing, in-depth review." However, deference and a "presumption of regularity" will be accorded an agency decision. If 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; Udall v. Tallman, 380 U.S. 1, 16 (1965); Delaware Citizens for Clean Air Inc. v. Administrator, *supra*.

An agency is granted especially wide latitude in formulating a regulatory system where, as in the present case, regulation is "on the frontiers of scientific knowledge," involves considerable technological complexity, and health

considerations are paramount, forcing the agency to make policy or legislative-type judgments. U.S. v. Dotterweich, 320 U.S. 277, 280 (1943). 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 (1973). There is particularly wide latitude in framing regulations where existing methodology and medical data for measuring the degree of threat to public health may be incomplete. Under these circumstances, because pure factual analysis cannot be dispositive, the courts have permitted agencies to rely to a greater extent on policy judgments and have limited their own review. They will uphold agency action if it is rational and not arbitrary. Reserve Mining Co. v. EPA, 514 F.2d 492 (8th Cir. 1975); The Society of the Plastics Industry v. OSHA, supra; Industrial Union Department, AFL-CIO v. Hodgson, supra.

These principles have been applied frequently in the context of EPA regulation. The United States Court of Appeals for the District of Columbia, which by law reviews any challenge to regulations promulgated under Section 112 of the Clean Air Act (supra, p. 3) has distilled its interpretation of what constitutes reasonable, rational and non-arbitrary agency action into the phrase "principled decision-making." Environmental Defense Fund v. Ruckelshaus, 439 F.2d 584 (D.C.

Cir. 1971). Where EPA shows that its decisions are reasoned and based upon relevant factors without clear error of judgment, the Court will not substitute its judgment for the Agency's and will tolerate "wide flexibility" in the establishment of a regulatory framework. Environmental Defense Fund v. EPA, 465 F.2d 528, 541 (D.C. Cir. 1972); Essex Chemical Corporation v. Ruckelshaus, supra, 486 F.2d at 434; International Harvester v. Ruckelshaus, supra, 478 F.2d at 641.

Reviewing EPA's action in the present case under the "principled decision-making" standard, we have previously concluded that the courts would likely hold the Agency has acted within the scope of its authority in attempting at this time to regulate the ambient amounts of vinyl chloride. See, for example, Reserve Mining Co. v. EPA, supra, 514 F.2d at 501, 506, 520; Amoco Oil Co. v. EPA, supra, 501 F.2d at 740-741; Environmental Defense Fund v. HEW, 423 F.2d 1083, 1085, 1088-90 (D.C. Cir. 1970); and Environmental Defense Fund v. Hardin, 428 F.2d 1093 (D.C. Cir. 1970). This is so even though other federal agencies, such as OSHA or FDA, have acted or may have jurisdiction to act on other problems associated with vinyl chloride. See Federal Trade Commission v. Cement Institute, 333 U.S. 683 (1948) and EDF v. HEW, 423 F.2d 1083 (D.C. Cir. 1970).

As we have also discussed earlier, we believe the courts would hold that EPA has acted within its authority in categorizing vinyl chloride as a "hazardous air pollutant" within

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the meaning of Section 112.^{3/} See, Environmental Defense Fund v. EPA, 510 F.2d 1292 (D.C. Cir. 1975); The Society of the Plastics Industry v. OSHA, supra. We have seen that the argument that (1) vinyl chloride is properly categorized as hazardous within the definition of Section 112 at high occupational exposure levels, (2) but not at the extremely low levels found in the ambient air, and consequently (3) should not be subject to emission limitations is unlikely to succeed in the courts. Once a substance is properly classified as hazardous at some levels the statute requires the establishment of emission limitations unless the substance is shown "clearly" not to be hazardous. } NO

The question remains whether in the manner of implementing Section 112, EPA has acted lawfully.

I. Are the Courts Likely to Overturn the Standard EPA Has Proposed Under Section 112 on the Ground That It Constitutes An Illegal Design or Process Standard?

One of the main challenges to EPA's proposed vinyl chloride standard is that it is invalid because it basically establishes design or process requirements and fails to set the kind of numerical emission limitations required by Section 112. We believe the courts would disagree.

^{3/} A substance is hazardous if "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." This definition accords the Administrator considerable discretion in deciding if a pollutant is "hazardous."

The question of what constitutes an emission limitation—and whether process requirements are valid—is not addressed in the legislative history. The issue has been the subject of six lower court decisions reviewing indictments or informations charging violations of EPA regulations under Section 112 applicable to the demolition of buildings suspected of containing asbestos. The demolition standards were set exclusively in terms of work processes without any numerical limitations being established. See 40 C.F.R. 61.22(d).^{4/}

The U.S. v. Adamo, supra, and U.S. v. Big Chief, supra, cases are the only ones accompanied by lengthy opinions. There is a split between the two cases.^{5/} 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.

4/ In U.S. v. Adamo Wrecking Co., CR No. 5-80297 (E. D. Mich. 6/6/75), U.S. v. Harvey Wrecking Co., No. 74 CR 758 (N.D. Ill. 1975), U.S. v. Brandenburg Demolition Co., No. 74 CR 757 (N.D. Ill. 1975), U.S. v. Nardi Wrecking Co., No. 74 CR 756 (N.D. Ill. 1975), and U.S. v. National Wrecking Co., No. 75 CR 755 (N.D. Ill. 1975) criminal actions 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). 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.

5/ The Administrator anticipated the problem caused by the split by 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.

Although recognizing the difficulty facing EPA in trying to control a hazardous pollutant, the court held that in spite of its "deference" to EPA's interpretation, it could not accept EPA's conclusion. Id. at p. 40. The court reasoned that if EPA could not adequately measure concentrations of asbestos and therefore set numerical standards, it was necessary to seek an amendment of the Act to authorize design requirements. It found no authority in the Act for EPA's demolition standards.

To the contrary, the Louisiana court in Big Chief ruled that the establishment of design requirements was well within the Administrator's discretion under Section 112. Discussing EPA's conclusion 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 Louisiana

court refused to dismiss criminal charges 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 defining "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.^{6/}

^{7/}
7 ERC at 1843.

The courts are likely to find the demolition cases inapposite in reviewing the vinyl chloride standard. In its proposed standard, EPA has set basically numerical emission levels. See, e.g., Proposed Standard, §§61.62-66.65(a), 40 Fed. Reg. 59545. Those requirements applicable to process are couched in numerical terms and are keyed to technology. See, e.g., Proposed Standard, §61.65(b), 40 Fed. Reg. 59546. In the event the courts conclude that the proposed controls are simply design requirements, we believe the United States

^{6/} Although the court did not allude to this provision, it might be noted that Section 112 specifically requires the Administrator to "issue information on pollution control techniques for air pollutants subject to the provisions of [the] section." 42 U.S.C. §1157c-7(b)(2).

^{7/} 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.

Court of Appeals for the District of Columbia is more likely to adopt the reasoning in Big Chief than Adamo, particularly in light of the broad authority of the Administrator to control hazardous pollutants under Section 112. 

II. Are the Courts Likely to Overturn EPA's Standard Because the Agency Took Costs and Technology into Account in Setting It?

The most important question in reviewing EPA's action under Section 112 is whether the Agency has improperly utilized cost and technology considerations in promulgating the proposed standard. We have concluded that under the circumstances of this case it is likely the courts would find the Administrator is acting reasonably and within the scope of his authority under Section 112 in applying a best available control technology methodology with some consideration of costs.

In addition, we believe there is authority to support the argument that the Agency should undertake "a fine balancing" of the costs of each prescribed control requirement against the benefits likely to be achieved in protecting the public health rather than merely evaluating whether certain costs would be "grossly disproportionate" to the benefits achieved.^{8/}

^{8/} The Environmental Defense Fund, in its presentation at the EPA Hearing on February 3, 1976, suggested that the Administrator under Section 112 should consider banning certain uses of vinyl chloride. In doing so, it conceded that it was unclear about the legal authority for this proposition. This concession did not go far enough. There is no authority in Section 112 for the Administrator to act in this fashion. He is limited to setting emission standards, i.e., standards applicable to sources. See, e.g., 42 U.S.C. §1857c-7(a)(2) and (3), (b)(1)(B), (c)(1)(A), (B). Nothing in the legislative history contradicts this conclusion.

The basic reason for this conclusion is that while vinyl chloride is a human carcinogen at high occupational exposure levels, and a carcinogen at lower exposure levels in test animals, there is no demonstrable health effect at the extremely low levels found in the ambient air. In addition, the substance has many beneficial uses to society and its production and further use involve over two million jobs. Once EPA concedes a ban of the product is inappropriate, only a fine-tuned cost-benefit approach can arrive at an appropriate regulation.

At the outset, it 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 rule 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.

Notwithstanding this rule, the weight of authority is that EPA under the circumstances of this case has the discretion to apply a cost-risk-benefit methodology even in the absence of express statutory authorization.

A. Cost-Risk-Benefit Methodology

The theory of cost-risk-benefit analysis is that regulation of suspected harmful substances must be accomplished by

weighing the health risks to society of certain products against the benefits they confer and the costs of controlling them to various safe levels or, optimally, a threshold level. Regulation of alleged hazardous pollutants under Section 112 is especially complicated because such pollutants may or may not have known thresholds; may be acutely dangerous or of limited or only potential danger; may have short or long persistence; may be present in the ambient environment in large amounts or only at extremely low levels; and may have great mobility or no significant mobility at all.^{9/} 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 available or safe substitutes, and often thousands if not millions of jobs may be involved.

While vinyl chloride appears to be a carcinogen with no known threshold, it also appears to be present in the ambient air at extremely low levels, to have short persistence, to have no significant mobility, and to pose no demonstrable threat to the public living within the vicinity of its manufacture or production.

Our society has increasingly been called upon to regulate substances which pose problems like vinyl chloride. A

^{9/} See the discussion in Environmental Defense Fund v. EPA, 489 F.2d 1247, 1250-1254 (D.C. Cir. 1973) (The Court approved EPA's decision to ban most uses of DDT.)

methodology often adopted, supported by many in the scientific community,^{10/} is to attempt through a cost-risk-benefit analysis to balance a number of pertinent factors in determining what constitutes the safest course for society to take. Among the risk factors to be considered is what the available medical data shows the harm of exposure to 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 exposure levels. Extrapolation to humans of data on animals is attempted. Other studies consider the potential risks posed to health by increased use of available 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

^{10/} 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.

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 are the costs of specific control requirements? How much emission reduction will they achieve? What effect might control costs have on unemployment, inflation, and market structure, ranging from national productivity to balance of trade?

Although it has done so in only a rudimentary way, EPA has undertaken in proposing regulations to weigh health risk factors of vinyl chloride against its benefits and the costs of control. The question is whether Section 112 of the Clean Air Act permits it to do so.

B. Legislative History

When a statute is silent on the methodology to be applied in regulating a particular problem, it is necessary to examine the statute's legislative history. The history of Section 112 is not especially helpful, and the inquiry is shrouded by the failure of Congress in promulgating the 1970 Amendments to the Clean Air Act to consider specifically the problem of potential non-threshold carcinogens whose concentrations might be so minimal as to pose no significant threat to public health.

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., December 18, 1970. There is no evidence Congress ever contemplated that Section 112 would require an absolute ban of a product—and the consequent closing down of an entire industry—in circumstances where available data leaves the question of the degree of risk partly unanswered and at least temporarily unanswerable and there are counter-^{11/}vailing benefits to society.

In the Senate version of what became Section 112 there was no express provision authorizing consideration of cost factors.^{12/} Yet ambiguity remains as to how the Senate wished substances like vinyl chloride to be regulated thereunder. For example, substances with the potential health effects described in Section 112 also have properties the Senate intended to cover in another section of its bill applicable to "selected" air pollution agents.^{13/}

^{11/} 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 unachievable 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." (Emphasis supplied). EPA has not suggested, nor does the record show, that vinyl chloride falls within this description.

^{12/} Section 115, S.4358, S.Rep. No. 91-1196, 91st Cong. 2d Sess. (1970), p. 95.

^{13/} Namely, they "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 their "presence . . . is generally confined, at least for detection purposes, to the area of the emission source." S. Rep., p. 18, describing proposed section 114. This section was dropped without explanation during conference.

Thus, the nature of the threat to health posed by vinyl chloride appears to fit Section 112 but the substance's ambient properties do not. In addition, EPA is unable to measure the degree to which the levels of vinyl chloride in the ambient air pose a risk to public health. Attempting to reconcile this conflict suggests that it is not inconsistent with congressional intent under Section 112, where emissions of hazardous pollutants may not be widely present or readily detectable, and the degree of risk is difficult to quantify, to take some cost considerations into account.^{14/} This, of course, is precisely how EPA has chosen to proceed.^{15/}

C. Application of Cost-Risk-Benefit Methodology
by EPA

In the absence of both statutory direction and definitive legislative history on aspects of regulatory requirements, EPA

^{14/} This conclusion is bolstered by the fact that Congress apparently contemplated that substances with ambient properties like vinyl chloride would be regulated more flexibly than required by the terms of Section 112. While proposed section 114 itself did not provide explicitly for consideration of costs, it authorized waivers of compliance for technological reasons without time limits and provided for less stringent controls than Section 112's "ample margin of safety," namely, that emissions "not endanger the public health." See further, Conf. Rep. 91-1783, as reported in U.S. Code Cong. and Admin. News, 91st Cong. 2d Sess., p. 5379; S.Rep., *supra*, pp. 9-10; Remarks of Rep. Hechler, 110 Cong. Reg. 42521, 91st Cong. 2d Sess., Dec. 18, 1970.

^{15/} As we have discussed on previous occasions, the House bill proposed no separate section for regulation of hazardous pollutants. In its only section mentioning "hazardous" emissions, section 112 applicable to stationary sources, costs and feasibility could be taken into account in setting standards. Section 112, H.R. 17255, as reported in H.Rep. 91-1146, 91st Cong. 2d Sess., p. 35.

and the courts must act as they believe Congress would have intended. In International Harvester v. Ruckelshaus, *supra*, the United States Court of Appeals for the District of Columbia considered the legality of EPA's denial of a one-year suspension of emission standards under Section 202 of the Clean Air Act, 42 U.S.C. §1857f-1. Faced with a problem not clearly governed by statute or legislative history, the court commented:

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.

The problems faced by EPA in regulating vinyl chloride are not unique nor is the solution chosen by the Agency. Frequently in situations similar to 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 cost-risk-benefit methodology has been sanctioned even in the absence of express statutory authorization for it.

Before turning specifically to cases where the courts have approved such a methodology in evaluating the propriety

of government action, 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 against 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 administrative from the judicial process. [T]he relation of remedy to policy is peculiarly a matter for administrative competence

344 U.S. at 349.

The Supreme Court has suggested that this latitude accorded an agency in interpreting 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:

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.

In recent years the courts have increasingly been required to review agency action aimed at remedying threats to public health posed by carcinogens with no known thresholds or by similar substances. They have repeatedly sanctioned application

of a cost-risk-benefit methodology in framing appropriate remedies even absent statutory authorization for it.

In Reserve Mining Co. v. EPA, supra, the Eighth Circuit evaluated the nature of the relief ordered to control Reserve Mining's iron ore processing activities near Lake Superior which resulted in emissions of asbestos-like fibers into the water and ambient air.^{16/} 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 (FWPCA), 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 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 required such an evaluation.

The Rivers and Harbors Act bars (without a statutory provision for consideration of cost) the discharge of waste into navigable waters. Under the old FWPCA, pollution of interstate or navigable waters "which endangers the health or

^{16/} Abatement efforts undertaken at the request of the Federal and State governments had produced few results. Eventually the United States, joined by Minnesota, Wisconsin, Michigan, and various environmental groups, filed suit against Reserve.

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, however, were a proper subject of inquiry only during judicial review of agency action to enforce previously established standards. There was no specific statutory authorization for EPA to consider such factors in promulgating regulations. 33 U.S.C. §1160(c)(5).

In spite of the clear health risk perceived by the Eighth Circuit because of the threat to public health posed by asbestos—like vinyl chloride a carcinogen with no established threshold—^{17/} and the absence of express statutory authorization for consideration of cost factors in framing remedies, the court of appeals 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

^{17/} See generally 514 F.2d at 501, 506, 520.

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, concluding that "exposure [to the public] cannot be equated with the factory exposures which have been clearly linked to excess cancer and asbestosis." 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 to some degree, 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."^{18/} 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),^{19/} 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.

^{18/} It is instructive to note the court's concern over the possible closing of simply one plant. Compare the 58 plants and 28 companies that produce vinyl chloride and polyvinyl chloride, "Environmental News," EPA, Tuesday, December 16, 1975. See also Standard Support and Environmental Impact Statement: Emission Standard for Vinyl Chloride, EPA, October 1975, pp. 7-66, 67.

^{19/} Note that the Eighth Circuit here included Section 112 of the Clean Air Act, 42 U.S.C. 1857c-7.

514 F.2d at 537.

Although the court rejected closure, it nonetheless authorized stringent remedial action against Reserve, including requirements that it move the site for depositing its industrial wastes from water to land; expend \$243 million in plant alterations and construction to halt pollution; and use available technology to reduce the asbestos fiber count in the ambient air "below a medically significant level." 514 F.2d at 537-538.

Because in many respects the dangers of vinyl chloride may be similar to, but perhaps 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, in light of the difficulty of quantifying the risks, apply at a minimum the kind of partial cost-benefit approach it has utilized in setting a standard and at most a careful, precise cost-benefit methodology as to each required control.

The considerations which guided the court in Reserve can be found in other opinions reviewing the legality of EPA action regulating threats to public health where the degree of risk is difficult to measure. For example, few environmental problems have been of more immediate concern to the courts than pesticides, poisons which are capable of seriously and immediately endangering human health if inadequately controlled. Yet, cost-risk-benefit analysis has been carefully undertaken by EPA in regulating pesticides 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.^{20/} The courts have sanctioned EPA's action.

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.

^{20/} 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. §136(z)(2). Now pesticides are to be approved if, inter alia, they have no "unreasonable adverse effects on the environment," defined to mean no "unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." 7 U.S.C. §§136a(c), 136(bb).

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. An 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 in determining the safety of a pesticide:

[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 PIFRA . . . 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 unequivocally 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. 45.

This Agency determination to interpret its powers more flexibly than specifically set forth in the statute had previously

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 had to 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 remanding for further action EPA's refusal to suspend registration of aldrin and dieldrin pending hearings pursuant to notices of cancellation: "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 of 1970, certain portions of the 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 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

is required to prescribe standards controlling emissions of pollutants which endanger the public health or welfare. Costs and technology can be taken into account in setting standards. 42 U.S.C. §1857f-1(a). Once regulations are final the Agency is authorized to grant a delay in compliance only if (1) it is essential to the public interest or health and welfare, (2) all good faith efforts have been made to meet established standards, (3) effective technology is unavailable or has not been available for sufficient time, and (4) National Academy of Sciences' studies show 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 and ordering a remand for further proceedings, 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. After analyzing the threat to the environment

posed by a one-year delay, the Court held that that cost must be balanced against both the costs to the consumer of buying cars with devices that the evidence suggested could cause poor auto performance and the danger that the consumer might keep driving older cars with worse pollution problems. 478 F.2d at 634-636.

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 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, supra, p. 18, where there is no legislative provision or definitive interpretative history on how to resolve them, the agency and the courts must act as they believe Congress would have, had it anticipated the problem. 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.^{21/}

D. Application of Cost-Risk-Benefit Methodology
by Other Federal Agencies

Support for the application of cost-risk-benefit principles has been expressed in a number of cases not involving EPA although concerning problems similar to those faced by that Agency. Indeed, in their effort to resolve difficult policy questions involving competing public interests—such as health and safety, jobs, economic interests, and national

^{21/} Under Section 109-110 of the Clean Air Act, 42 U.S.C. §§1857c-4, 5, EPA is accorded no express 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

Cont'd.

security—the courts have resorted to cost-risk-benefit analysis in a variety of contexts without specific statutory authorization. They have done so in cases involving carcinogens and other serious threats to health.

In Industrial Union Department, AFL-CIO v. Hodgson, 499 F.2d 467 (D.C. Cir. 1974), the court reviewed standards promulgated by OSHA to regulate atmospheric concentrations of asbestos dust in industrial workplaces. The Occupational Safety and Health Act requires the Secretary of Labor to set the 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." 29 U.S.C. §655(b)(5). In upholding in principal part the action of the Secretary in promulgating asbestos regulations the Court acknowledged that regulation of a suspected carcinogen like asbestos was "on the frontiers of scientific knowledge" and accordingly it was impossible "to make a fully informed factual determination." 499 F.2d at 474. As a result, it reaffirmed the general rule that "Decision-making must in that circumstance depend to a greater

21/ Continued:

into account in evaluating the implementation plans. See, e.g., St. Joe Minerals v. EPA, 508 F.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).

extent upon policy judgments and less upon purely factual analysis." Id. The Court reasoned that:

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 474-75, fn. 18.

Reliable data was not available with respect to the "precisely predictable health effects" of various exposures to asbestos, yet the Secretary must still set a specific level of exposure. 499 F.2d at 475. He may set a "relatively low limit" but the decision must rest on "essentially legislative policy judgment[s]" and not a factual determination. Id. The test to be applied in evaluating agency action in these circumstances should be:

Whether the agency, given an essentially legislative task to perform, has carried it out in a manner calculated to negate the dangers of arbitrariness and irrationality in the formulation of rules for general application in the future.

Id.

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. 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. The court went considerably further, holding not only that technological considerations must be evaluated 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.

Similarly, 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. (Emphasis in original)

486 F.2d at 855. 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, including a carcinogen with no established threshold.

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.

Similarly, while acknowledging the potentially "acute" danger posed when reactors are located near large cities, the Court ratified the AEC's approval of a site between Detroit and Toledo: "the Commission found reasonable assurances . . . that the reactor could be safely operated . . . and that is enough to satisfy the statute." 367 U.S. at 414. Thus the Supreme Court read into the otherwise unambiguous statutory language a less stringent "reasonable assurance" standard as sufficient to protect public health.

Very recently this standard became the direct issue in another AEC case, Nader v. Nuclear Regulatory Commission, 513 F.2d 1045 (D.C. Cir. 1975). Petitioners sought emergency review of an AEC order denying their request for shutdown or derating of twenty nuclear plants. The request was based upon the assertion that interim standards applicable to cooling systems were inadequate to assure safe equipment and the plants posed immediate dangers to the public health and safety. The AEC, involved at the time in a rulemaking proceeding on permanent standards, denied the request and the Court affirmed.

In rejecting petitioners' original request for relief the AEC had stated:

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. We are, of course, aware of the potential risks in nuclear matters if safety is not given the very close attention it deserves However we cannot—and do not—claim "assurance" as an absolute.

Rather the regulatory process turns upon the concept of 'reasonable assurance' to public health and safety.

513 F.2d at 1050. The Court reviewed this long-standing AEC practice of interpreting the statutory command that a licensed facility "will" afford adequate protection of health and safety as requiring only a "reasonable assurance" of protection. It relied on the Supreme Court's decision in the Power Reactor case, and endorsed the AEC's practice. 513 F.2d at 1052.

The Court explained that the "reasonable assurance standard" was the "hallmark of many of the Commission's regulations." The adoption of safety standards that were flexible was necessary, in spite of the awesome dangers posed by nuclear accidents, because criteria for the development of practices necessary to protect the public "will be augmented and changed from time to time as important new requirements . . . are developed." Id. See also, Citizens for Safe Power, Inc. v. NRC, ___ F.2d ___, (D.C. Cir. No. 74-1186, December 22, 1975).

The AEC cases do not mean that in regulating vinyl chloride EPA should—or would be authorized to—establish a less stringent health standard than the "ample margin of safety"

required in Section 112. What the line of authority begun by Power Reactor acknowledges, however, is some flexibility in an agency charged with protecting the public health. 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 what constitutes an "ample margin of safety." In this attempt, Power Reactor and similar cases lend support 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 reducing to some extent 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). In considering the request for a ban, no statutory provision authorized FAA to evaluate factors extraneous to safety. 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" in commercial aircraft 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. 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 a substance which may pose a threat to public health that is not precisely quantifiable, where society is to varying degrees dependent upon it. 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 with no known threshold. They have specifically approved agency action which permits continued use—in whole or in part—of no-threshold or highly dangerous products when, on balance, the overall interests of the public are best served. This approval has often occurred 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. Conceivably it would also hold that EPA should have undertaken a more intricate balancing than it has.

Conclusion

In developing an appropriate regulatory framework to govern emissions of vinyl chloride into the ambient air, EPA has attempted to measure the properties of vinyl chloride, the quality 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. The Agency has concluded that vinyl chloride and polyvinyl 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.

In reviewing EPA's action, the courts will look to the reasonableness of the Agency's response. They 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, the Agency's action is likely to be upheld.

Analyzing all the factors which entered into EPA's decision-making process on regulating vinyl chloride emissions, the courts are likely to accept the basic rationale it applied in developing a regulatory framework. With the exception of its refusal to undertake an intricate cost-risk-benefit analysis for each proposed control requirement,^{22/} EPA's 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 with the exception mentioned 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 abused its discretion.

^{22/} In addition, of course, there are a number of inaccuracies, mistakes, and misstatements in the Agency's proposed standard and supporting documents. These will be corrected—and requests for changes in aspects of the standard will be made—in other documents submitted by SPI by February 23, 1976.