The "Shotgun Wedding" of Science and Law: Risk Assessment and Judicial Review

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During its environmental heyday, Congress passed a number of laws which may be thought of as "basic science-forcing." Including the Clean Air Act Amendments of 1970[1] and the Federal Water Pollution Control Act Amendments of 1972,[2] these laws authorize agencies to take regulatory action on the basis of agency findings made at the very frontiers of scientific inquiry.[3] To make such findings, public administrators increasingly rely on

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1. Clean Air Amendments of 1970, Pub. L. No. 91-604, 84 Stat. 1676 (1970), codified at 42 U.S.C. §§ 7401-7642 (1982).

2. Federal Water Pollution Control Act Amendments of 1972, Pub. L. No. 92-500, 86 Stat. 816 (1972) (amending 33 U.S.C. §§ 1251-1376 (1982)).

3. *See, e.g.*, 33 U.S.C. §§ 1251(d), 1252, 1254, 1361 (1982); 42 U.S.C. §§ 7403(b), 7404(b), 7407(c), 7408, 7601 (1982). For a summary of provisions in the major environmental statutes which authorize agencies to regulate at the frontiers of scientific knowledge, see *infra* Appendix I, Environmental Protection Agency, *Chemical Substances Designation* (1981).

a variety of scientific techniques for assessing risks to human health.[4] Many risk assessment techniques are highly speculative, and almost all rely upon multiple assumptions of fact, some of which may be entirely untestable.[5]

The administrative agencies' reliance on risk assessment engenders a fragile and uneasy partnership[6] between science and law,[7]—a veritable "shotgun wedding" according to former EPA Administrator William Ruckelshaus.[8] Administrative agencies are committed to the traditional scientific paradigm as the basis for finding facts, but cannot rely on it to select the best regulatory action. Questions of fact may be stated in the language of science, but administrative decisions based on "fact" demand the exercise of judgment and discretion. Thus, agencies repeatedly find themselves forced to resolve scientific questions to which the scientific community has only incomplete answers.

To the consternation of both scientists and judges, not science but the judiciary must rule on the "correctness" of an administrative agency's resolution of questions lying at the frontiers of science.[9] The proof of "correctness" required by a reviewing court differs both qualitatively and quantitatively from that which would be demanded in a scientific forum.[10] Regardless of the applicable

4. The agencies' use of risk assessment in regulatory decisionmaking has been the subject of considerable commentary by both scientists and legal scholars. *See generally*, QUANTITATIVE RISK ASSESSMENT IN REGULATION (1982); NATIONAL RESEARCH COUNCIL, RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS (1983).

5. *But see infra*, note 196 (proposed guidelines for the uniform application of risk assessment techniques to agency decisionmaking).

6. The term "uneasy parnership" originated with Judge Friendly, who used it to describe the relationship between administrative agencies to which Congress has delegated decisionmaking of a legislative character, and the federal courts, which Congress has charged with the task of reviewing agency exercise of the delegated power. Associated Indus. of N.Y.S. v. U. S. Dep't of Labor, 487 F.2d 342, 354 (2d Cir. 1973). The term is equally appropriate as a description of the relationship between science and law.

7. Alvin Weinberg has coined the term "trans-science" to describe the interface between these divergent sectors. Weinberg, *Science and Trans-Science*, MINERVA, April 1972, 209.

8. W. Ruckelshaus, Science, Risk and Public Policy, Speech at National Academy of Sciences 3, (June 22, 1983) (available in office of Columbia Journal of Environmental Law).

9. *See, e.g.*, Lead Industries Ass'n v. EPA, 647 F.2d 1130 (D.C. Cir. 1980), *cert. denied*, 449 U.S. 1042 (1982) (noting that the task of review in a case involving complicated scientific questions is difficult for the court).

10. *See infra* notes 22-32 and accompanying text for discussion of the standards of judicial review. Scientists develop statements of probability at specified levels of statistical significance that a particular fact is likely to be true. Many toxicological studies set the level of statistical significance as that at which there are only five chances out of one hundred that a particular finding occurred due to chance.

standard of review, judges often find themselves engaged in a hands-on examination of incomplete scientific data regarding risks to human health. Not surprisingly, review of agency action under science-forcing laws has strained judicial expertise, and created a bull market, in certain courts, for law clerks with training in the sciences.[11]

This article will examine how courts have faced the "shotgun wedding" of science and the law when reviewing agency decisions based on risk assessments.[12] In particular, this article will examine whether courts have applied standards of judicial review in risk assessment cases in a consistent fashion. Cases involving agency regulations of asbestos, polyvinyl chlorides, benzene, formaldehyde, leaded gasoline, ozone, taconite ore, and dioxin will be discussed in detail. The discussion will highlight some major policy questions involving the "shotgun wedding": What proof of harm must the agency provide to support its regulation? Given that science can provide only probabilities of harm, how much certainty of risk can a reviewing court demand? And when must politically based policy decisions replace scientifically based risk assessments?

Section I of the article will review basic risk assessment methodologies. Section II will introduce the scope of judicial review under the "substantial evidence" and "arbitrary and capricious" standards. Section III will examine cases involving risk assessments subject to the substantial evidence and arbitrary and capricious standards of review. Section IV will examine how courts have reviewed risk assessments which have not been used by an agency to promulgate a regulation, but which are presented as

11. The late Judge Leventhal of the United States Court of Appeals for the District of Columbia Circuit suggested in an informal conference sponsored by the Environmental Law Institute in 1978, that judges should have specially-designated science clerks to assist them with technical matters lying beyond the bounds of traditional legal training. Judge Leventhal believed that the courts have a "central role in ensuring the principled integration and balanced assessment of both environmental and nonenvironmental considerations in federal agency decisionmaking." Leventhal, *Environmental Decisionmaking and the Role of the Courts*, 122 U. PA. L. REV. 509, 555 (1974). He subscribed to the talmudic notion that judges should have some competence with which to review results. His colleagues, Judges Bazelon and Wright, disagree with this view. Judge Bazelon maintains that the very complexity of the evidence submitted makes it dangerously unreliable to involve " illiterate judges" in the review process. Ethyl Corp. v. EPA, 541 F.2d 1, (D.C. Cir.) (en banc) (Bazelon, J., concurring), *cert. denied*, 426 U.S. 941 (1976).

12. *See also* McGarity, *Judicial Review of Scientific Rulemaking*, 9 SCIENCE, TECHNOLOGY AND HUMAN VALUES 97 (1984).

evidence by plaintiffs seeking to enjoin a particular polluting activity.

I. RISK ASSESSMENT TECHNIQUES

Toxicology, epidemiology and clinical research are the basic tools employed in assessing risks to human health.[13] Toxicology attempts to predict future risks to humans by measuring the effects of exposure to a suspect substance on test mammals such as mice and rats. Because toxicological research is conducted through controlled experiments, it produces findings, such as dose-response curves which are, in and of themselves, relatively precise. Extrapolating from animals to humans is more problematic.[14] Epidemiologic research documents past risks in human populations exposed to toxic substances under "natural conditions." A major defect of epidemiological research is that it can rarely determine the precise level or "dose" to which a given population has been exposed.[15] In theory, clinical research on human subjects would solve many of the problems encountered in both toxicology and epidemiology, but for obvious ethical and practical reasons, clinical tests are of limited use. Faulty design or sloppy implementation of all these investigative approaches can invalidate expensive and time-consuming studies. Finally, risk assessment models apply mathematical formulae to the raw data produced by toxicological, epidemiological and clinical research, in order to answer the question typically posed by the regulatory agency: What are the potential consequences of exposure at different levels?

II. THE SCOPE OF JUDICIAL REVIEW

Environmental and health statutes generally confer broad discretion on agencies to choose the means for determining the existence of hazards which would trigger regulatory action.[16] Statutory descriptions of those triggering points may, themselves, be sufficiently broad to afford agencies wide discretion to make

13. *See, e.g.*, NATIONAL RESEARCH COUNCIL, *supra* note 4.

14. *See generally* J. DOULL, C.D. KLAASSEN & M.O. AMDUR, CASARETT AND DOULL'S TOXICOLOGY: THE BASIC SCIENCE OF POISONS (2d ed. 1980).

15. *See generally* A. M. LILIENFELD & D.E. LILIENFELD, FOUNDATIONS OF EPIDEMIOLOGY (1980); J.S. MAUSNER & A.K. BAHN, EPIDEMIOLOGY: AN INTRODUCTORY TEXT (1974); B. MACMAHON & T.F. PUGH, EPIDEMIOLOGY: PRINCIPLES AND METHODS (1970).

16. *See, e.g.*, Occupational Safety and Health Act of 1970, 29 U.S.C. § 655(b)(5) (1982).

the determination. For example, section 6(a) of the Toxic Substances Control Act requires the EPA to regulate chemicals when necessary to "adequately" protect against any "unreasonable risk of injury to health or the environment" posed by the chemical's manufacture, processing, use or disposal.[17]

The extent of an agency's discretion depends on the applicable scope of judicial review. Review may be specified either in the statute authorizing the particular agency action at issue,[18] or in the Administrative Procedure Act ("APA").[19] Under the APA, agency decisions made after "formal" or trial-type proceedings[20] must be supported by "substantial evidence in the record."[21] This standard has been defined as "more than a mere scintilla. It means such relevant evidence that a reasonable mind might accept as adequate to support a conclusion."[22] "Informal" agency decisions, those not required by statute to be made on the record after a formal agency hearing, are set aside by a reviewing court if found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."[23] This standard is intended, in the abstract, to be more deferential than the substantial evidence standard, but, as applied, may involve just as rigorous an inquiry by reviewing judges. According to the Supreme Court's decision in *Citizens To Preserve Overton Park v. Volpe*,[24] a court applying the arbitrary and capricious standard must make a searching and careful "substantial inquiry" into the facts presented to the agency to determine whether the agency

17. Toxic Substances Control Act § 6(a), 15 U.S.C. § 2605(a) (1982).

18. *See, e.g.*, Clean Air Act § 307(d)(9), 42 U.S.C. § 7607(d)(9) (1982).

19. Administrative Procedure Act, 5 U.S.C. §§ 551-559; 701-706 (1982).

20. 5 U.S.C. §§ 556, 557 (1982). Section 556 refers to hearings in front of an administrative law judge, where interested parties may be present, have the right to submit evidence, and cross-examine witnesses; the transcript in the proceeding is the "exclusive record for decision." Section 557 provides that the agency must consider findings and conclusions proposed by interested parties, and rule on the proposals "on the record." All decisions including initial, recommended and tentative decisions are a part of the record and must include a statement of findings and conclusions, and the reasons or basis therefor.

21. 5 U.S.C. § 706(2)(e) (1982).

22. Consolidated Edison Co. v. NLRB, 305 U.S. 197, 229 (1938). This definition was adopted prior to the APA, but has been held to apply to the substantial evidence standard under the APA, with the additional requirement that "substantial evidence" must be based on all the evidence in the record. *See* Universal Camera Corp. v. NLRB, 340 U.S. 474, 477 (1951).

23. 5 U.S.C. § 706(2)(a) (1982).

24. 401 U.S. 402 (1971).

considered all the relevant factors, or made a "clear error of judgment."[25]

Whether the substantial evidence and arbitrary and capricious standards, as defined above, require reviewing courts to engage in different inquiries, at least, in the context of agency regulations based on risk assessments, is questionable. To determine whether an agency made "a clear error of judgment," a reviewing court essentially determines whether the agency had an adequate factual basis for its decision. This inquiry is not far removed from that which lies at the heart of substantial evidence review: was the agency's decision based on evidence that a reasonable mind might accept as sufficient to support a conclusion?[26] Moreover, given the increased complexity of modern environmental decisionmaking, the record in an informal proceeding may be as extensive as that generated under the requirements of formal rulemaking.[27] In an attempt to subject agency proceedings to greater and more uniform scrutiny, some major environmental statutes provide explicitly for substantial evidence review of agency decisions which are arrived at on the basis of proceedings which, under the APA, would be reviewed under the "arbitrary and capricious" test.[28]

A recent decision by the Supreme Court in *Chevron v. United States*,[29] may set a precedent for greater deferential judicial review of all agency decisions.[30] The Supreme Court in *Chevron* held that an agency's regulation—subject to arbitrary and capricious review—which is based on a "reasonable" interpretation of statutory language should be upheld by a reviewing court absent

25. *Id.* at 415-16.

26. *See also Associated Industries*, 487 F.2d at 349-50 ("[I]n the class of cases in which the ground for challenging the agency action is the inadequacy of its evidentiary basis, it is difficult to imagine a decision having no substantial evidence to support it which is not 'arbitrary', or a decision struck down as arbitrary which is in fact supported by 'substantial evidence,' " citing Scalia & Goodman, *Procedural Aspects of the Consumer Product Safety Act*, 20 U.C.L.A. L. REV. 899, 935 n.138 (1973).

27. *See, e.g.*, Lead Industries Ass'n v. EPA, 647 F.2d 1130, 1181 (D.C. Cir. 1980); Industrial Union Dep't, AFL-CIO v. Hodgson, 499 F.2d 467, 474 (D.C. Cir. 1974).

28. *See, e.g.*, Occupational Safety and Health Act of 1970, 29 U.S.C. § 655 (1982); Consumer Product Safety Act, 15 U.S.C. § 2501 (1982). Such statutes have been referred to as "hybrid" statutes. *See, Industrial Union*, 499 F.2d at 473.

29. — U.S. —, 104 S. Ct. 2778 (1984).

30. *See, e.g.*, Wald, *Negotiation of Environmental Disputes: A New Role for the Courts?* 10 COLUM. J. ENVTL. L. 1 (1985); *and* Reed, *Three Strikes and the Umpire is Out: The Supreme Court Throws the D.C. Circuit Out of the Bubble Review Game*, 14 ENVTL. L. REP. (ENVTL. L. INST.) 10,338 (1984).

evidence of Congress' specific intent on the meaning of such language, and given evidence of conflicting policies which the regulation is directed to promote.[31] The regulation at issue in *Chevron* was an interpretation of the Clean Air Act's definition of a polluting "source" as constituting an entire industrial plant, rather than each pollution-emitting unit within the plant.[32] What impact the Court's holding will have on judicial review of agency regulations based on risk assessments is uncertain. If nothing else, the Court's emphasis on the *reasonableness* of an agency's decision reinforces the point made above that the arbitrary and capricious and substantial evidence standards often require a reviewing court to undertake the same kind of inquiry.

III. Case Law on Risk Assessment

A. *Regulating Hazards in the Home and the Workplace; the Substantial Evidence Test*

The Occupational Safety and Health Act of 1970[33] delegates broad authority to the Secretary of Labor and, through the Secretary, to the Occupational Safety and Health Administration ("OSHA"), to promulgate "occupational safety and health standards" to protect American workers.[34] The Act defines such standards as those required to establish working conditions and practices that are "reasonably necessary or appropriate to provide safe or healthful" places of employment.[35] The Act further directs that, when promulgating standards for "toxic materials" or "harmful physical" agents, the Secretary must "set the standard which most adequately assures, to the extent feasible, and on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity."[36] These standards are to be developed on the basis of research, demonstrations, experiments and other "appropriate" information.[37] In setting the standard, the Secretary is to consider the Act's goal of attaining the highest degree of workplace safety and health, the

31. *Chevron*, 104 S. Ct. at 2783.
32. *Chevron*, 104 S. Ct. at 2782-83; Reed, *supra* note 30 at 10,338-40.
33. Occupational Safety and Health Act of 1970, 29 U.S.C. §§ 651-678 (1982).
34. 29 U.S.C. § 655(a) (1982).
35. *Id.* § 652(8) (1982).
36. *Id.* § 655(b)(5) (1982).
37. *Id.*

latest available scientific data in the field, the feasibility of the standards, and experience gained under health and safety laws generally.[38] Although the procedures required for the promulgation of OSHA standards fall short of those required for "formal" rulemaking under the APA,[39] the Act directs courts of appeals to apply a substantial evidence test in reviewing the Secretary's standards.[40]

In *Industrial Union Dep't, A.F.L.-C.I.O. v. Hodgson*,[41] unions whose members were affected by the health hazards of exposure to asbestos dust challenged OSHA regulations of the atmospheric concentration of asbestos dust in the workplace. The health hazards posed by asbestos were a matter of concern even before OSHA came into being, and one of the agency's first acts was to establish an emergency standard to control atmospheric concentrations of asbestos.[42] Under that standard, the maximum permissible eight hour time-weighted average airborne concentration of asbestos dust had been limited to five fibers greater than five microns in length per milliliter of air.[43] For its permanent standard, the Secretary reduced the permissible concentration to two fibers, but retained the five-fiber limit for four years in order to give employers a grace period in which to meet the stricter limit. The unions challenged the four-year delay on two grounds: that the five-fiber standard endangered the health of employees and that the employers did not need four years to comply with the more protective standard.[44]

In assessing the health impacts of the Secretary's decision to allow four years before imposing the lower two-fiber standard, the court drew attention to the widely disparate conclusions from risk assessments conducted by experts with whom the Secretary had consulted.[45] The then Assistant Surgeon General of the

38. *Id.*

39. These procedures are detailed in 29 U.S.C. § 655(b)(1)-(4). *See* Synthetic Organic Chem. Mfrs. Ass'n v. Brennan, 503 F.2d 1155, 1160 (3d Cir. 1974)(discussing the scope of judicial review of OSHA regulation limiting employee exposure to ethyleneimine); *Industrial Union*, 499 F.2d at 474-75 (comparing "substantial evidence" review to review of a "legislative policy determination").

40. 29 U.S.C. § 665(f), 667(g) (1982).

41. 499 F.2d 467.

42. *Id.* at 471.

43. 36 Fed. Reg. 23,207-08 (1971).

44. 499 F.2d at 479.

45. *Id.* ("The experts differed sharply in some of their opinions, but their responses are generally cautious and reflect deficiencies in available data.").

United States had stated that some not significant increase in the effects of asbestosis could be expected from the delay in implementing the two-fiber standard.[46] The chief of medical research at St. Luke's Hospital in Cleveland had stated that no evidence supported the proposition that asbestos is *per se* carcinogenic.[47] Conversely, a research professor at Mount Sinai School of Medicine in New York had indicated that any concentration higher than two fibers could not be justified.[48]

Judge McGowan of the District of Columbia Circuit described the problems facing the court under the Act's substantial evidence standard of review. According to Judge McGowan, the agency's determination could not be reviewed under a substantial evidence standard as traditionally applied, because sufficient data had not been available upon which the agency could make a "fully informed factual determination."[49] Because "no precise prediction of increased harm can be made at this time," Judge McGowan could not conclude whether the Secretary had erred in determining that the imposition of the two-fiber standard could safely be delayed for four years, or whether employees would be subject to an additional risk from continued exposure to the five-fiber concentration.[50] Moreover, the agency had been forced to make an "essentially legislative policy judgment" in the face of conflicting and inconclusive evidence.[51] Accordingly, the court's task was to determine not whether substantial factual evidence supported the agency's decision, but whether the agency had carried out its job "in a manner calculated to negate the dangers of arbitrariness and irrationality in the formulation of rules for general application in the future."[52]

Such a test required, at a minimum, that the agency provide a careful identification of the policy considerations which affected its choices.[53] The Secretary's consideration of the *chance* that health hazards would result from continued exposure to the higher standard, and of the Act's "overriding concern" for the

46. *Id.* at 479 n.27.
47. *Id.*
48. *Id.*
49. *Id.* at 474.
50. *Id.* at 479.
51. *Id.* at 474.
52. *Id.* at 475, citing Automotive Parts & Accessories Ass'n v. Boyd, 407 F.2d 330, 338 (D.C. Cir. 1968).
53. 499 F.2d at 475-76.

protection of employees' health, were deemed by the court to have been a sufficient indication of the policies supporting the Secretary's choice of a two-fiber standard.[54] However, the court found that the Secretary's decision to allow a four-year delay for all industries, regardless of the capacity of each industry to implement the two-fiber standard immediately, was not supported by sufficient policy considerations. Rather, the record left "nagging questions—even for the inexpert observer" as to the reason and rationale for the agency's decision.[55]

Industrial Union highlights the problem of judicial review which is presented when experts in a medical or scientific field draw sharply conflicting conclusions from risk assessment analyses. The District of Columbia Circuit's solution was a practical one and one which respected the agency's legislative role: having determined that the factual evidence was conflicting, the District of Columbia Circuit upheld those parts of the Secretary's decision which were sufficiently supported by policy considerations.[56]

In *Society of the Plastics Industry, Inc. v. Occupational Health and Safety Administration*,[57] the Second Circuit accorded similar deference to OSHA regulations of employers producing vinyl chloride monomer (VCM) and its products, notably polyvinyl chloride (PVC). By the time the case was decided, thirteen workers exposed to VCM had died from angiosarcoma, a rare form of cancer.[58] Thus, the workers' deaths lent a sense of urgency to the court's decision.

Retired Supreme Court Justice Clark, sitting by designation, wrote the opinion for the Second Circuit, which upheld the regulation. At the outset, Justice Clark noted his agreement with Judge McGowan of the District of Columbia Circuit that "the traditional 'substantial evidence' test is almost impossible of application where, as here, the Secretary's decision is essentially leg-

54. *Id.* at 474.

55. *Id.* at 488.

56. *See also* Merrill, *The Legal System's Response to Scientific Uncertainty: The Role of Judicial Review*, 4 FUNDAMENTAL AND APPLIED TOXICOLOGY S418 (1984). Merrill describes *Industrial Union* as characteristic of an era of "judicial reticence" to review agency decisions on health risks. *Id.* at S522. Merrill applauds the court's review in *Industrial Union* as a "frank recognition that where facts do not carry you all the way, judgment is needed, and that reviewing courts cannot expect certainty where science cannot provide definitive answers." *Id.* at S423.

57. 509 F.2d 1301 (2d Cir. 1975), *stay denied*, 420 U.S. 1002 (1975).

58. *Id.* at 1306.

islative in character."[59] Justice Clark explained that, where agency decisions are based on evidence lying at the frontiers of scientific inquiry, the court must essentially apply an arbitrary and capricious standard of review.[60]

As background, the court detailed the "morbid chronology" of events associated with vinyl chloride.[61] A study conducted in the Soviet Union in 1949 had first found liver irregularities in rats and rabbits subjected to VCM at a concentration of 100 parts per million (ppm). Recurring reports of the softening of the fingertips and bone of VCM/PVC workers prompted the Manufacturing Chemists Association ("MCA") to sponsor a study, but the results were inconclusive as to the exact cause of the malady. Further toxicological studies continued to show that VCM exposure caused cancer in rats.[62] The first death of an American worker exposed to VCM was reported in 1971; on March 30, 1972, MCA financed an epidemiological study; by 1974, thirteen workers in the PVC and fabricating industries had died from angiosarcoma.[63]

In response to these developments, the Secretary promulgated an emergency standard of fifty ppm time-weighted average to replace the 500 ppm standard then prevailing in the industry. Four days after a hearing was held on this standard, it was discovered that angiosarcoma of the liver had been produced in mice at a level of fifty ppm of VCM. OSHA abandoned the fifty ppm standard in favor of a one ppm standard, the so-called "no detectable" level. The agency's permanent standard was one ppm averaged over an eight-hour period, but allowing for peaks of up to five ppm during periods of not longer than fifteen minutes.[64]

That thirteen human lives had already been lost as a result of inadequate regulation of VCM greatly affected Justice Clark's decision.[65] The Society of the Plastics Industries and members of

59. *Id.* at 1304.

60. *Id.*

61. *Id.* at 1305-06. "We need not outline in detail the morbid 'Vinyl Chloride Chronology,' published by an industry spokesman . . . in order to illustrate the mounting evidence of VCM's carcinogenity. Indeed, the record shows what can only be described as a course of procrastination on the part of the industry to protect the lives of its employees."

62. *Id.*

63. *Id.* at 1306.

64. *Id.* at 1307.

65. *See, e.g., id.* at 1308 ("[I]t must be remembered that we are dealing here with human lives, and the record reveals that eleven manufacturing plant workers and two fabrication plant workers have already died from the effects of this potent chemical.").

the vinyl chloride industry argued that the one ppm standard was not justified by the available scientific evidence because none of the expert witnesses who testified at the agency's rulemaking hearing could say with certainty that exposure to VCM at levels lower than fifty ppm was unsafe.[66] Justice Clark, however, pointed to evidence including a toxicology study conducted by the industry's trade association, and the recommendation of "expert after expert" that exposure to the carcinogen be restricted to the "lowest detectable level." Given the Secretary's role under OSHA to protect employees, and that the Secretary's decision was at the "frontiers of scientific knowledge," Justice Clark found the evidence "quite sufficient" to support the Secretary's decision.[67]

OSHA's effort in 1978 to reduce exposure to benzene met with less judicial sanction than its efforts in the *Society of Plastics* case. In what has come to be known as the "Benzene Case,"[68] industry representatives challenged the Secretary's proposed permanent standard for this known carcinogen. The standard would have lowered the permissible level for airborne concentrations of benzene from ten ppm to one ppm. The Secretary based the lower standard on a combination of epidemiological data and recent toxicological studies showing that exposure to benzene caused leukemia, chronic nonmalignant blood disorders, chromosomal aberrations and other long-term health effects in humans.[69] Because no level of exposure of benzene had been shown by these studies to be safe, the agency reduced permissible exposure to 1 ppm on the basis of its general policy of reducing exposure to all carcinogens to the "lowest feasible level."[70]

In the court's view, the primary inquiry was whether the agency acted within the bounds of its statutory authority.[71] According to the court, for a standard to be "reasonably necessary" to provide a safe and healthful place of employment, as required by the Act, the Secretary had to provide substantial evidence showing that the the benefits of lowering the standard bore a reasonable rela-

66. *Id.*

67. *Id.*

68. American Petroleum Inst. v. OSHA, 581 F.2d 493 (5th Cir. 1978), *aff'd* , 448 U.S. 607 (1980).

69. 581 F.2d at 498 & n.10.

70. *Id.* at 501.

71. *Id.* at 497.

tionship to the costs imposed upon industry of complying with the standard.[72] In this case, the estimated dollar costs of compliance were quite high,[73] while the benefit to workers was indeterminable. The Secretary argued that it was sufficient to assume, on the basis of scientific hypothesis, that those benefits "may be appreciable,"[74] but that it was impossible to estimate such benefits because there was a lack of knowledge on the effects of low-level exposure to benzene.[75] The Fifth Circuit disagreed with the Secretary's claim that estimates could not be based on the existing level of scientific knowledge.[76] The court also felt that the agency's estimation of benefits could not be supported by substantial evidence simply because it was based on a rational hypothesis.[77] Rather, the Secretary had to provide "some factual basis for an estimate of expected benefits" to show that the standard was reasonably necessary.[78] The court distinguished the *Industrial Union* and *Society of Plastics* decisions as not having considered the "reasonably necessary" statutory requirement.[79]

By a plurality vote,[80] the Supreme Court affirmed the Fifth Circuit's decision to invalidate the 1 ppm standard, but did not address whether the Act required that OSHA standards be supported by a reasonable correlation between costs and benefits.[81] Instead, the Court construed the "necessary and appropriate" language of the Act[82] to contain a threshold requirement for revising health and safety standards: the Secretary had to show, on the basis of substantial evidence, that the existing standard

72. *Id.* at 502-05.

73. *Id.* at 503. According to OSHA's estimates, first-year operating costs for all affected industries would be $187 to 205 million; engineering control costs would be $266 million, and recurring annual costs would be $34 million.

74. *Id.*

75. *Id.* at 504.

76. *Id.*

77. *Id.* at 503.

78. *Id.* at 504.

79. *Id.* at 505.

80. Justice Stevens wrote the opinion for the Court; the Chief Justice and Justice Stewart joined in the opinion and Justice Powell joined it in part. Justice Rehnquist concurred in the judgment; Justice Marshall, joined by Justices Brennan, White and Blackmun, dissented.

81. 448 U.S. at 639-40. That question was later resolved in American Textile Mfrs. Inst. v. Donovan, 452 U.S. 490 (1981), where the Court held that the Act does not require the Secretary of Labor to determine that the costs imposed by a health and safety standard bear a reasonable relationship to its benefits for workers.

82. 29 U.S.C. § 652(8) (1982).

"more likely than not" posed a "significant risk of material health impairment" such that lowering the exposure limit would significantly increase worker health.[83]

As in the Fifth Circuit case cited below, the Secretary's policy of reducing exposures to the "lowest feasible level" failed to pass the Court's substantial evidence standard of review. The Court argued that the policy placed the burden on industry of proving a "safe" level of exposure, while the Act imposed a burden on the Secretary to establish a need for stricter standards.[84] The Secretary had found that exposures to between twenty-five and forty ppm of benzene indisputably caused nonmalignant blood disorders; but it had not provided "direct support" that such disorders occured at exposures below ten ppm.[85] The Secretary had not estimated the risk of contracting nonmalignant disease from exposures below ten ppm, because, the Secretary argued, the data linking low-level exposures and blood abnormalities was inadequate to construct a dose-response curve at such levels.[86] The evidence that low-level exposure to benzene caused leukemia was "even sketchier," according to the Court. Only one epidemiological study supported such a conclusion, and its authors had expressly stated that the study was not conclusive because workers' deaths might have been caused by other carcinogens.[87]

In the Secretary's view, the policy was justified lest the agency be forced to wait for deaths to occur before it could regulate to prevent them.[88] The Court denied that its new threshold requirement put the agency in such an untenable position. The agency could still determine what constituted a "significant" risk, a test which was not intended to impose a "mathematical straitjacket" on the agency to calculate the exact probability of harm.[89]

However, the court at one point urged the agency to use mathematical methods of calculating risk, and to extrapolate from toxicological and epidemiological evidence to show that it would be "more likely than not" that a significant risk exists under the prevailing standard.[90] The Court also seemed to be promoting a so-

83. 448 U.S. at 653.
84. *Id.* at 659.
85. *Id.* at 631.
86. *Id.* at 631-32.
87. *Id.* at 633.
88. *Id.* at 652.
89. *Id.* at 655.
90. *Id.*

called "reasonableness" standard for determining significance: a one in one thousand chance of death from exposure might appear significant to a "reasonable person," a one in one billion chance would not.[91] Despite the Court's assurances to the contrary, the very choice of a reasonableness test for estimating "significance" reveals a reflexive, unthinking reliance on mathematical assessments.[92] For example, the Court's set of reasonably significant and insignificant numerical risks ignores the frequency of exposure. Yet it is essential that a probable frequency of the event be incorporated in any calculation of risk. Risk assessment requires two distinct estimations: toxicity and exposure. For example, it is conceivable that of 240 million persons experiencing a *daily* risk of one in a million from drinking water, 87,600 would die each year. But if 1,000 persons experienced a cumulative *lifetime* risk of only one in a thousand from exposure to a rare airborne contaminant, only one person would die in seventy-three years. The Court's numerical examples only indicate toxicity, but suitable risk assessments must also reflect exposure, that is, they must be restricted to doses over time in specific populations.

In his dissent, Justice Marshall decried the reliance on quantification of risks which the plurality opinion seemed to foster. Justice Marshall explained that, for carcinogens, the assumptions required for quantification are "necessarily arbitrary." Regulatory action based on quantification, therefore, would "deceive the public . . . [that] realistic assessments of the relevant risks" were being made.[93]

The plurality assured the Secretary that "substantial evidence" did not mean "scientific certainty" but simply "best available evidence."[94] The Court cited the District of Columbia and Second

91. *Id.* at 656, 657 n.64.

92. Merrill describes the *Benzene* case as marking the "hard look" era of judicial review, *supra* note 48, at S423-24. Merrill criticizes the Court's review in this case as "betray[ing] little recognition of the limits of scientific certainty." *Id.* at S424.

93. *Id.* at 716. *See also* Ruckelshaus, *Risk in a Free Society*, 14 ENVTL. L. REP. (ENVTL. L. INST.) 10,190, 10,193 (1984) ("[W]e should understand the limits of quantification; there are some cherished values that will resist being squeezed into a benefits column, but are no less real because of it. Walter Lippman once pointed out that in a democracy "the people" as in "We the people," refers not only to the working majority that actually makes current decisions, and not only to the whole living population, but to those who came before us, who provided our traditions and our physical patrimony as a nation, and to those who will come after us, and inherit. Many of the major decisions we make on environmental affairs touch on this broader sense of public responsibility.")

94. *Id.* at 656.

Circuits, and stated that "the Agency is free to use conservative assumptions interpreting the data with respect to carcinogens, risking error on the side of over-protection rather than under-protection," in construing the evidence, "so long as those assumptions are supported by a body of reputable scientific thought."[95] In this case, however, the plurality felt that the Secretary had not used all the scientific techniques currently available for assessing risks.[96] The Court attributed the Secretary's refusal to make a dose-response estimate not to a lack of data to make a meaningful estimate, but—"at least in part"—to the Secretary's view that "nothing less than absolute safety would suffice."[97]

It is difficult to reconcile the Court's assurances that the Secretary retained substantial discretion with the Court's actual decision in the Benzene case. The plurality denied having made its own fact findings, or having rejected those made by the Secretary.[98] But the Court's assumption that certain kinds of scientific evidence must be employed is, nevertheless, an intrusion on the Secretary's role of determining risks at the frontiers of scientific knowledge. Because the Benzene decision provides no uniform criteria for evaluating exposure standards promulgated pursuant to the Act, it is uncertain how meaningful the Court's assurances will be.

A more recent decision in the Fifth Circuit, *Gulf South Insulation v. Consumer Product Safety Commission*,[99] adds to the confusion over judicial review of risk assessment. A markedly activist Fifth Circuit rejected a risk assessment of the adverse health effects of urea-formaldehyde foam insulation (UFFI), which was used by the Consumer Product Safety Commission (CPSC) as a basis for regulation under the Consumer Product Safety Act.[100] In *Gulf South*, manufacturers sought to overturn the Consumer Product Safety Commission's ban on the use of UFFI in schools and residences. The Commission supported the ban with a finding, as required under the Act, that UFFI presented an unreasonable risk of injury to human health, and that no feasible product standard could be

95. *Id.*

96. *Id.* "[T]he record . . . and OSHA's own rulings on other carcinogens indicate that there are a number of ways in which the Agency can make a rational judgment about the relative significance of the risks associated with exposure to a particular carcinogen."

97. *Id.* at 656 n.63.

98. *Id.* at 659.

99. 701 F.2d 1137 (5th Cir. 1983).

100. Consumer Product Safety Act, 15 U.S.C. § 2057 (1982).

devised that would adequately protect the public.[101] Petitioners challenged that finding under Section 2060(a) of the Act, which provides for review of the Commission's action in the courts of appeals according to a substantial evidence standard.[102]

The court's opinion began by reviewing the agency's investigations into the health effects of UFFI, specifically, those effects caused by the substance's propensity to emit formaldehyde gas. The agency had first undertaken a three-year investigation of 350 UFFI homes in which residents had complained of acute irritant symptoms such as nausea, headaches, respiratory distress and skin irritation. The agency then commissioned the National Academy of Sciences to determine whether there was a threshold level of formaldehyde exposure below which no acute symptoms will be experienced. The Academy found, on the basis of available scientific literature, that no such threshold existed. From the Academy's finding, the Commission concluded that formaldehyde gas released from UFFI posed an unreasonable risk of acute irritant effects.[103]

The Commission had also received data from UFFI manufacturers linking nasal cancer in rats to high levels of formaldehyde exposure. The Commission assembled a sixteen-member panel of government scientists to study the data. The panel concluded that the data were valid and that "formaldehyde should be presumed to pose a carcinogenic risk to humans."[104] The Commission then extrapolated from the high-dose animal studies to quantify the human cancer risk posed by low levels of exposure to UFFI. Using a computerized mathematical risk assessment model called Global 79, the agency predicted that it was 95% possible that the increased risk of cancer to a person living in a UFFI home for his or her lifetime would range from zero to fifty-one in 1,000,000. From this prediction, the Commission concluded that UFFI posed an unreasonable risk of cancer to humans. The Comission's subsequent ban was based on its findings with respect to both acute irritation and carcinogenicity.[105]

The UFFI manufacturers alleged that the Commission's carcinogenicity findings were unconvincing, primarily because of inad-

101. *Id.*
102. *Id.* § 2060(a).
103. 701 F.2d 1141.
104. *Id.*
105. *Id.* at 1142.

equacies in the data base that had produced the Global 79 prediction. One of the assumptions underlying that prediction was that the level of formaldehyde present in a UFFI home averaged .08 ppm over nine years. The Commission had derived this average from tests taken in 1,164 homes, and from laboratory tests conducted under simulated conditions. Petitioners argued that the 1,164 sample homes were not selected randomly, that the tests were not conducted consistently or, in some cases, accurately, and that the laboratory tests were conducted under conditions that did not resemble those in the average home.[106]

The Fifth Circuit found that the studies relied on by the Commission did "suggest" that UFFI appreciably raises in-home formaldehyde levels. However, the court felt that the Commission had erred by incorporating its data into "an exacting, precise and extremely complicated risk assessment model."[107] The court considered the model useless without reliable data on what constituted an average UFFI home.[108] The court also faulted the model for relying on empirical data on formaldehyde carcinogenicity derived from a single study involving only 240 rats. The court noted that if twenty fewer or twenty more rats had been used, the risks predicted by the model might have been drastically altered.[109]

The court also criticized the Commission's conclusion regarding the acute irritant effects produced by UFFI, because the Commission's study of 350 homes did not indicate the degree of likelihood that such symptoms would occur. Without determining the degree of risk involved, in the court's view, the Commission could not make a finding of "unreasonable risk of injury." The Commission had relied on the degree of risk posited in the National Academy of Sciences study, that "somewhat less than 20% of healthy adults may respond to the irritant effects of formaldehyde at 25 ppm." But as the court pointed out, 25 ppm was considerably greater than what the Commission had concluded to be the formaldehyde level in the average UFFI home; moreover, the NAS study had not indicated whether the predicted responses were severe or slight. In view of these shortcomings, the court concluded that substantial evidence did not support the Commis-

106. *Id.* at 1143-44.
107. *Id.* at 1145.
108. *Id.*
109. *Id.* at 1146.

sion's finding of "unreasonable risk" of injury from acute irritant effects.[110]

The reviewing court's determination to undertake a scientific re-analysis of the reliability of the CPSC's risk assessment in *Gulf South* is cause for concern. For sound reasons the decision leaves legal analysts troubled.[111] Of the many issues in the case, the court concentrated on a scientific re-analysis of the agency's risk assessment. The court provided a footnote criticizing the agency's assumption that human beings are at least as vulnerable as rodents, and its use of conservative assumptions for developing standards.[112] The court also chided the agency for failing to consider the absence of evidence on human harm.[113] Merrill correctly describes this decision as the first to embody even greater uncertainty than that associated with the risk assessments themselves.[114] As McGarity cautions, such decisions will find the courts inheriting the kind of unpleasant attention previously reserved to the agencies.[115] The decision stands simply as a remarkable judicial probe of an agency's record on a narrow question. It is unlikely to set an important precedent.[116]

The above analysis indicates the erratic application of the substantial evidence review to agency risk assessments.[117] The courts in *Industrial Union* and *Society of Plastics* deferred to the agency's policy choices based on the limitations of those assessments. The

110. *Id.* at 1148.

111. *See, e.g.*, Merrill, *supra* note 56, at S424-25; McGarity, *supra* note 12, at 103.

112. 701 F.2d 1145-46.

113. *Id.*

114. Merrill, *supra* note 56, at S425. "The opinion's close scrutiny of an exercise that is fraught with uncertainty, but yet promises improvement in regulation of health hazards, is disconcerting." *Id.* Merrill cautions that the *Gulf South* decision may discourage agencies from using risk assessments without data which is usually not available, and may lead agencies to conclude that risk assessments are simply not a sufficient legal basis for regulating. *Id.*

115. McGarity, *supra* note 12 at 103.

116. *But see* Merrill, *supra* note 56, at S424-25 (noting that *Gulf South* marks a new era of increased judicial scrutiny over agency decisions based on risk assessments).

117. Merrill breaks the courts' decisions down into four eras of judicial review. Cases in the first era—"forced deliberation"—marked courts' willingness to review agency inaction. Merrill, *supra* note 56, at S421-22. In the second era of "judicial reticence," as exemplified by *Industrial Union*, the courts gave agencies broad discretion to find facts and make policy decisions related to health risks. *Id.* at S422. The third era— "hard look"— includes the *Benzene* case and reflects courts' "aggressive scrutiny" of agencies' fact-findings. *Id.* at S423-24. The fourth era, which Merrill labels "substituted judgment," consists solely of ;the *Gulf South* decision and represents an even closer judicial scrutiny of agency decisions based, in part, on risk assessments. *Id.* at S424-25.

courts in the Benzene case and *Gulf South*, on the other hand, closely scrutinized the agencies' risk assessment methods. Such scrutiny, itself, led to possibly inconsistent results. The Supreme Court in the Benzene case urged the agency to quantify its risk assessments, despite inadequacies in the data base for such quantification; the Fifth Circuit in *Gulf South* chastised the agency for over-relying on quantification of risks when the underlying data was weak. Given that risk assessments are conducted at the forefront of scientific knowledge, courts cannot routinely scrutinize agencies' methodologies in order to fine-tune such methods, and provide a clear course for agencies to follow.

2. *Controlling Air Pollution: The Arbitrary and Capricious Test*

In *Ethyl Corporation v. EPA*,[118] manufacturers of lead additives and refiners of gasoline sought review under the Clean Air Act (CAA)[119] of the EPA's regulation requiring a reduction of lead in all gasoline to an average of 0.5 grams per gallon.[120] Section 211(c)(1)(A) of the CAA authorizes the Administrator of the EPA to promulgate regulations prohibiting the use of fuel additives if emission products of fuel or fuel additives "endanger the public health or welfare."[121] Because the Clean Air Act did not prescribe a standard of review for emissions regulations, the District of Columbia Circuit applied the APA's prescription that "informal" rulemaking procedures must not be "arbitrary, capricious, or an abuse of discretion."[122] A division of the Court found the regulation to be arbitrary and capricious but, in a rehearing *en banc*, the full Court vacated its decision. Judge Skelly Wright, who had filed a vigorous dissent when the case was first decided, wrote the majority opinion for a sharply divided court.

The focus of the *en banc* court's inquiry was the level of proof required under the CAA for a finding of "endangerment" to the public health or welfare. The majority held that the standard did not require proof of actual harm, but only proof of a "significant risk of harm."[123] Indeed, the agency was not even required to

118. Ethyl Corp. v. EPA, 541 F.2d 1 (D.C. Cir.) (en banc), *cert. denied*, 426 U.S. 941 (1976).

119. 42 U.S.C. § 7401 and scattered sections of Title 42 (1982).

120. 541 F.2d at 9-10.

121. 42 U.S.C. § 7401 (1982).

122. 5 U.S.C. § 706(2)(A) (1982).

123. 541 F.2d at 13.

prove that harm is "probable," if a probability could not be determined from the available evidence.[124] According to the majority, because the standard is essentially precautionary and preventive, it requires the Administrator to assess risks without relying solely on facts and, where necessary, to make "an essentially legislative policy judgment, rather than a factual determination, concerning the relative risks of underprotection as compared to overprotection."[125] Its own task, the court emphasized, was not to decide whether the agency's finding was based on substantial evidence in the record, or even on a preponderance of the evidence, but rather to determine whether that finding had a "rational basis" in the evidence.[126]

To make such a determination, the court waded through the massive record generated by the rule-making process. The record revealed that the EPA had relied on three types of evidence in establishing the new standard for lead in gasoline: theoretical work on lead dust-fall, epidemiological studies of exposed populations, and clinical studies of exposed individuals. A number of laboratory studies had established that young animals were more susceptible than adults to the effects of lead. Molecular biochemistry analysis showed that animals deficient in zinc, calcium and iron—a condition very common among children in poor families—absorb lead much more readily than other animals.[127]

After immersion in the record which contained over 10,000 pages, and which all parties agreed was incomplete, the court admitted that the evidence was so inconclusive that it could as easily have upheld a decision not to regulate lead as a decision to require phased-in elimination of lead in gasoline.[128]

Under the applicable standard of review, however, EPA's action was upheld. The agency's reliance on the best available estimate of the risks of lead to the health of children was within the deference afforded by the "will endanger" standard, and its handling of the risk assessment process was entirely rational.[129] Central to the court's decision was its own risk assessment formula: the magnitude of the risk sufficient to justify regulation is inversely pro-

124. *Id.* at 18.
125. *See id.* at 13-18.
126. *See id.* at 33-37.
127. *See id.* at 37-48.
128. *Id.* at 37.
129. *See id.* at 47-48.

portional to the harm to be avoided.[130] In the court's view, the severity of harm threatened was of great importance in judging the rationality of the agency's conclusions.[131] In this case, the potential harm was severe, particularly in relation to the most vulnerable sector of the population—inner-city children. This potential made it less significant that the agency could not conclusively prove the degree to which emissions from leaded gasoline, as opposed to exposure from other lead sources, caused the reported damage to human health.[132]

Judge Wright's formula translated into legal doctrine an eminently sound value judgment with which most scientists in the public health field readily agree: It is better to prevent disease, rather than try to cure it. The court's review in *Ethyl Corp.* was both exhaustive and deferential. The court considered every study in the record and the objections made to them. Yet the court was equally impressed by the agency's thorough assessment and handling of a "complicated problem with great ease and candor," and respectful of the "flexibility" afforded the agency's assessments by the "will endanger" standard in the CAA.[133]

Perhaps the best example of the exhaustive evidentiary review under the arbitrary and capricious standard which courts have made in the past decade is *Lead Industries Ass'n. v. EPA*[134] In *Lead Industries*, the District of Columbia Circuit upheld EPA's national ambient air quality standards for lead, which were promulgated under Section 109(a)(2) of the Clean Air Act.[135] As in *Ethyl Corp.*, the primary evidentiary issue arose from the problems inherent in determining the health effects of low-level, cumulative exposure to lead.

As required by statute, EPA had prepared a "criteria document" to support its ambient air quality standards for lead.[136]

130. *See id.* at 19.

131. *See id.*

132. *See id.* at 13.

133. *See id.* at 47.

134. 647 F.2d 1130 (D.C. Cir. 1980), *cert. denied*, 449 U.S. 1042 (1982).

135. 42 U.S.C. § 7409 (1982). EPA plans to issue final regulations to eliminate lead from gasoline by 1990. The Federal Centers for Disease Control of the Department of Health and Human Services is recommending that the action level for blood lead be set at 25 micrograms per decileter.

136. 42 U.S.C. § 7408(a)(2) (1982) provides that criteria documents "shall accurately reflect the latest scientific knowledge useful in indicating the kind and extents of all identifiable effects on public health and welfare which may be expected from the presence of such pollutants in the ambient air in varying quantities."

The document considered a range of health effects related to lead, and concluded that children with more than forty micrograms of lead per liter of blood risked developing anemia. A range of subclinical effects on the blood forming system were also noted, including elevation of erythrocyte protoprophyrin (EP), which impairs functioning at the subcellular level of the blood.[137] Preschool children and pregnant women were found to be particularly susceptible to adverse health effects of lead exposure.[138]

In addition to considering the qualitative health effects of exposure to lead, the criteria document laid the groundwork for quantifying a relationship between air lead levels and blood lead levels. After a detailed examination of relevant studies, the criteria document concluded that air lead/blood lead ratios encountered in the general population fell within a range of 1:1 to 1:2 (micrograms of lead per cubic meter of air to micrograms of lead per deciliter of blood). No safe level for lead in the blood was identified.[139]

The existence of a hypersusceptible population of children and pregnant women was central to the development of the final ambient air standards for lead. The proposed standards were specifically designed to prevent the elevation of EP and the resulting effects on cellular functions in children. Thus a target mean population blood lead level was selected as the lowest reported threshold of lead levels for EP elevation in children. On the basis of the information in the criteria document, the EPA selected a ratio of 1:2 to calculate the effect of air lead exposure on blood lead levels and arrived at the final standard of 1.5 micrograms of lead per cubic meter of air.[140]

Petitioners contended that nothing in the record supported the Administrator's choice of the level of thirty micrograms lead per deciliter of blood, particularly since no adverse health effects had been shown to occur at that level. Under the APA's "arbitrary and capricious" standard of review, however, the court found the record "adequate" to support the EPA's decision.[141] The EPA had relied primarily upon the findings contained in its criteria document which, the court noted, was the product of a process

137. 647 F.2d at 1138-40.
138. *Id.*
139. *Id.* at 1140-41.
140. *Id.* at 1143-44.
141. *Id.* at 1156-60.

that allowed for rigorous scientific and public review.[142] It was significant that various experts who testified at the rulemaking proceedings supported the Administrator's choice of a target blood lead level. The court also found that the agency's reliance on the practices of the Centers for Disease Control was well-placed.[143] According to the court, because "there is evidence" in the record to support the agency's judgment, and because the agency had properly explained both the factual and policy bases for its decision, the selection of a target blood lead level must be upheld.[144]

The court in *Lead Industries* was also forced to grapple with methodological challenges to the agency's use of three studies in establishing an air lead/blood lead ratio of 1:2. The studies involved both children and adults; since the standards were designed to protect children, petitioners contended, only studies focussing on children should have been used. The court dismissed this argument on the basis of the criteria document which cited studies reporting ratios for children at 1:1.2 to 1:2.3.[145] Petitioners also argued that the agency's use of these studies was "inconsistent and designed solely" to support EPA's predetermined choice of an air quality standard for lead. The court rejected this characterization and accepted EPA's explanation that differences in its approaches to these studies were warranted by apparent errors in the studies themselves. The court noted that the criteria document had treated these studies as reliable, that the agency's choice of a ratio was endorsed by several experts, and that the entire issue of air lead/blood lead ratios had been the subject of extensive discussion in the rulemaking process.[146]

Ethyl Corp. and *Lead Industries* reveal the mixed nature of review which courts undertake pursuant to the arbitrary and capricious standard. The District of Columbia Circuit in *Lead Industries* cited *Ethyl Corp.* to justify its "substantial inquiry" into the facts (which in a case such as this will consist primarily of a body of scientific

142. The Administrator had found that the initial adverse health effects of lead exposure occurred at the thirty microgram level in children, and that the thirty microgram level provided a margin of safety to protect children against more serious consequences of lead exposure. *Id.* at 1144.

143. *Id.* at 1157-58.

144. *Id.* at 1158.

145. *Id.* at 1162-63.

146. *Id.*

literature).[147] In *Ethyl Corp.* the court's perusal of the record was equally as rigorous. Yet in both cases the court of appeals placed less weight on the existence of conflicting evidence which its vigorous inquiry revealed than on the existence of some evidence to provide a rational basis for the agency's decision. The purpose of the court's "substantial inquiry" was to "educate" the court, not so that it could second-guess the agency's conclusions and methods, but merely to adequately assess whether such conclusions and methods were rational and within the discretion afforded by Congress.[148]

The flexibility with which the arbitrary and capricious standard may be applied is also illustrated by the District of Columbia Circuit's opinion in *American Petroleum Inst. v. Costle*.[149] At issue were EPA's revised national ambient air quality standards for ozone. In revising its prior standard of 0.08 ppm to 0.12 ppm, the EPA had relied on a mix of scientific evidence, including clinical studies of healthy subjects exposed to ozone, toxicological studies, and an environmental model of the formation of ozone. In addition, a risk assessment study summarized medical opinions regarding the dose-response relationship between ozone and chronic diseases such as emphysema.[150]

Among the ten petitioners, the Natural Resources Defense Council contended that the revised regulation was too lenient. Challenging the regulation as too stringent, the American Petroleum Institute ("API") presented the now familiar argument that because no adverse health effects had been proven below 0.25 ppm, the 0.12 standard was irrational.[151] The API also cited EPA's admission that its own risk assessment was not completely reliable.[152]

Under the arbitrary and capricious standard of review,[153] the court considered its "proper function . . . not to weigh the evidence anew and make technical judgments; . . . but to determin[e] if the Administrator made a rational judgment."[154]

147. *Id.* at 1145-46.

148. *Id.*

149. 665 F.2d 1176 (D.C. Cir. 1981), *cert. denied*, 455 U.S. 1034 (1982).

150. Revisions to the National Air Quality Standards for Photochemical Oxidants, 44 Fed. Reg. 8202-17 (1979).

151. 665 F.2d at 1184-85.

152. *Id.* at 1185.

153. 42 U.S.C. § 7607(d)(9)(A) (1982). *See* 665 F.2d at 1184.

154. 665 F.2d at 1185.

To make such a finding, the court did not consider itself obligated to determine that each study relied on by the EPA was accurate. Numerous studies showed disruption of normal body functions at "low" (0.15 to 0.39 ppm) ozone levels, and the court saw no reason to second-guess the Administrator's reliance on the studies, "even given the acknowledged uncertainties in some of the conclusions."[155]

The District of Columbia's Circuit's approach in *American Petroleum* seems hardly consistent with the court's painstaking inquiries in *Ethyl Corp.* and *Lead Industries* under the same standard of review. Analysis of judicial review under the arbitrary and capricious standard also reveals that such review is not fundamentally different from review of agency risk assessments at the forefront of scientific knowledge when the substantial evidence standard applies. Under both standards, review is limited to the rationality or reasonableness of the agencies' conclusions. How deeply the reviewing court will delve into the record to make such a determination seems more a function of that court's predilections than of the applicable standard of review.

IV. THE COURT AS AGENCY: THE ENDANGERMENT STANDARD

Several environmental statutes provide that the United States and private individuals may bring actions in the federal district courts to enjoin unlawful polluting activities.[156] A court called upon to grant relief under such provisions often finds itself in the same position as an administrative agency with basic science-forcing authority — both are confronted with inconclusive risk assessments on which some decisive action must be taken.

Reserve Mining Co. v. EPA[157] is a classic illustration of the courts' role as an independent assessor of uncertain scientific evidence. The EPA had sought an injunction ordering Reserve Mining a taconite processing company, to cease discharging taconite tailings from its facility into the waters of Lake Superior and the air surrounding the community of Silver Bay, Minnesota. Taconite tailings, which result when taconite (low-grade iron) ore is processed into iron-rich pellets, were being released into the waters of Lake Superior at the rate of 67,000 tons daily when the suit

155. *Id.*

156. *See, e.g.*, Federal Water Pollution Control Act, 33 U.S.C. §§ 1319(b), § 1365(a)(1) (1982); Clean Air Act, 42 U.S.C. § 7604(a)(1) (1982).

157. 514 F.2d 492 (8th Cir. 1975) (en banc).

was commenced in 1972.[158] The EPA, joined by three states and several environmental groups, charged that Reserve was violating a number of federal and state environmental laws and regulations.[159] The trial court concluded that Reserve's air and water discharges were unlawful and posed a "substantial danger" to public health. The court granted an injunction, and ordered the Silver Bay facility to be closed immediately.[160]

Reserve appealed the order and the Eighth Circuit granted a stay of the injunction pending the appeal.[161] After further proceedings in the district court, the case was decided by the court of appeals sitting *en banc*. Judge Bright, in an elaborate opinion, concluded that Reserve's discharges did so endanger the public health as to require abatement. However, the endangerment had not been shown to be so substantial as to justify the immediate shut-down of the facility.[162]

Factual disputes dominated every aspect of this complex case,[163] including the central issue of whether the discharges posed a "substantial endangerment" to the public. Studies demonstrating the health damage caused by inhalation of asbestos fibers provided one of the sources of contention. Most of the studies were conducted among workers in asbestos mills and mines at exposures much higher than that presumed to face Silver Bay residents.[164] A few of the studies showed that low level exposure to asbestos fibers might result in mesothelioma, but because the level of exposure was not quantified in those studies, and because the concentration of particles in the air around Reserve's processing facility could not be precisely measured, the trial court had found it impossible to draw firm conclusions from these studies.[165]

158. *Id.* at 500.

159. *Id.* at 501.

160. United States v. Reserve Mining Co., 380 F. Supp. 11 (D. Minn. 1974).

161. Reserve Mining Co. v. EPA, 498 F.2d 1073 (8th Cir. 1974).

162. 514 F.2d at 500.

163. A threshold question was whether the particular ore mined by Reserve contained amosite asbestos, a material with a demonstrated capacity to endanger human health. At trial, the evidence did not show conclusively that Reserve's tailings contained asbestos, but only that a "portion of" the cummingtonite-grunerite contained in the ore could not be meaningfully distinguished from amosite asbestos. 380 F. Supp. at 33 (summarized by the court of appeals at 514 F.2d at 510).

164. 514 F.2d at 510.

165. *Id.* at 510-12.

Assessing the danger posed by the discharge of tailings into waters which were the source of the Silver Bay public drinking water system raised even more difficult questions of proof. Reliable evidence as to whether the ingestion, as opposed to inhalation, of asbestiform particles could cause damage to human health was limited to studies based on experimentation with animals, and studies of gastrointestinal effects in workers exposed to high levels of asbestos. These studies could not be applied to the Silver Bay community with any degree of precision to draw conclusions other than that the ingestion of asbestos fibers posed some undetermined health risk.[166]

The trial court had heard testimony from over 100 witnesses in the course of a 139-day trial which generated 18,000 pages of transcript.[167] The court of appeals, in turn, scrutinized this numbing record. It was obvious that the medical and scientific questions in dispute lay at the frontiers of scientific knowledge: the very nature of the pollutant could not be conclusively established; there was no proof that actual harm to human health would result if Silver Bay residents continued to be exposed to taconite tailings in the air and water; indeed, the court of appeals could not say that the probability of harm from continued discharge was more likely than not.[168]

Although the *Reserve* case involved a request for injunctive relief, the court of appeals viewed its function as similar to one of reviewing an agency regulation based on the same evidence. The court cited *Industrial Union* in indicating that its evidence was "clearly . . . on the frontiers of scientific knowledge."[169] Next the court invoked *Ethyl Corp.* where the court used the same "endangerment" threshold as a basis for taking preventive measures. Under the "endangerment" test, the court reasoned that *potential* harm must be considered.[170] Following Judge Wright's formula in his dissent in the first *Ethyl Corp.* decision,[171] the Eighth Circuit saw the severity of potential harm as a crucial element in its determination of endangerment.[172] The EPA's purported hazards were

166. *Id.* at 520. The opinion summarizes the available information on ingestion of asbestos fibers at 514-19.

167. 380 F. Supp. at 15.

168. 514 F.2d at 520.

169. *Id.* at 519.

170. *Id.* at 519-20.

171. *See supra* text accompanying notes 112-126.

172. 514 F.2d at 519-20.

not based on proven scientific facts but on a medical theory (essentially, that the pollutant was a form of asbestos which endangered the public health even at low levels of exposure), but the consequences that could result if the theory proved true would be severe. The court concluded that the existence of a public health risk justified an injunctive decree requiring abatement of the hazard "on reasonable terms as a precautionary and preventive measure to protect the public health."[173] Although the district court's order for an immediate shut-down of the taconite facility was reversed as an abuse of discretion,[174] the court of appeals gave detailed directions for the formulation of an order on remand requiring Reserve Mining to take immediate action to abate its discharges.[175]

Similar problems of proof and an even more toxic substance were at issue in *United States v. Vertac Chemical Corp.*, decided by the District Court for the Eastern District of Arkansas in 1980.[176] The United States sought injunctive relief under the Resource Conservation and Recovery Act,[177] Federal Water Pollution Control Act,[178] and Refuse Act[179] requiring Vertac to cease discharging toxic chemicals, including dioxin,[180] into the air, water, and soil surrounding its Jacksonville, Arkansas, chemical manufacturing plant. Vertac had undertaken considerable effort in cooperation with federal and state authorities to control releases of toxic wastes from its 92-acre site. Nevertheless, at the time the suit was brought, dioxin persisted at the parts per billion level in the soil and sediment surrounding the plant, in the cooling pond, and in the Jacksonville sewage treatment plant.[181] The sediments of Rocky Branch Creek at the plant contained 1090 parts per billion of dioxin. The question for the court was whether the presence of such quantities of dioxin constituted an "imminent and sub-

173. *Id.* at 520.

174. *Id.* at 537.

175. *Id.* at 538-40.

176. 489 F. Supp. 870 (E.D. Ark. 1980).

177. 33 U.S.C. § 1364 (1982).

178. 42 U.S.C. § 6973 (1982).

179. 33 U.S.C. § 407 (1982). The court rejected this claim because Vertac had ceased producing dioxin. 489 F. Supp. at 876-77.

180. The district court referred to dioxin as "the most acutely toxic substance yet synthesized by man." 489 F. Supp. at 876.

181. *Id.* at 876-77.

stantial endangerment" to human health for purposes of the applicable federal statutory injunction provisions.[182]

The twin elements of endangerment—the severity of harm and the probability of its occurence—were as difficult to quantify here as they had been in *Ethyl Corp.* and *Reserve Mining*. The dioxin concentrations present at the Vertac site were "far below the threshold for acute or single-dose toxic effects" of dioxin, but the United States contended that the long-term effects of chronic exposure to low levels of dioxin could be severe.[183] Toxicity studies demonstrated that harmful effects could be produced in animals exposed to dioxin at low levels. No safe detectable level of dioxin in the environment was known to exist.[184]

The district court granted a preliminary injunction and required Vertac to undertake specified abatement measures.[185] As justification for its decision, the court cited evidence from 1971 EPA hearings on the dioxin-containing chemicals 2-4-5-T and TCDD, after which the EPA canceled its registration of the chemicals under the Federal Insecticide, Fungicide and Rodenticide Act.[186] Such evidence included epidemiological data from Oregon and Vietnam which showed an increased incidence of miscarriage and birth defects in populations exposed to dioxin in defoliant sprays.[187] The evidence also included laboratory studies showing that dioxin caused birth defects in mice and rats.[188]

The district court acknowledged that "while there may be low probability of harm from dioxin as defendants contend, there is a serious and dire risk from exposure to dioxin should the hypothesis advanced by the plaintiff prove to be valid."[189] Citing *Reserve Mining*, the court acknowledged that "endangerment" need not be proven with certainty, but merely as a probability. Moreover, because the evidence gave rise to a "reasonable medical concern for the public health," the court found such evidence of risk to present an "imminent and substantial endangerment."[190]

182. *Id.* at 884-85.
183. *Id.* at 876.
184. *Id.*
185. *Id.* at 888-89.
186. *Id.* at 881 n.7.
187. *Id.* at 880-81, 884.
188. *Id.*
189. *Id.* at 885.
190. *Id.* (quoting 33 U.S.C. § 1364 (1976) and 42 U.S.C. § 6973 (1972)).

From the above discussion, it appears that judicial review of risk assessments, presented in actions for injunctive relief under the endangerment standard, is quite similar to the review conducted in the two other contexts discussed earlier. The reviewing court is faced with inherently inconclusive evidence, and a statutory policy dictating what consequences should follow from an apparent—albeit highly uncertain—risk of harm. The policy in *Reserve Mining* and *Vertac* of, essentially, erring on the side of precaution or prevention, was derived from the District of Columbia Circuit's formula in *Ethyl Corp.* for assessing the rationality of an agency's decision. The policy also appears more deferential to the proponent of the requested protective action than that which the Supreme Court drew from OSHA, in the *Benzene* case.

Conclusions

According to a major school of the philosophy of science, scientific evidence cannot "prove" anything, but can only establish the probability that something is likely to be true.[191] A proposition can be falsified, that is, disproved, but can never be confirmed. According to one author, the level of proof required to convince a reviewing court that a regulatory action was supported by substantial evidence, or was not arbitrary and capricious, would demonstrate to a scientist only that the proposition had a forty and thirty percent chance, respectively, of being true.[192] Recognizing the impossibility of proving certain scientific propositions even under the less rigorous legal standards, the Supreme Court and most federal courts have demanded that agencies provide neither rigorous step-by-step proof of cause and effect, nor scientific consensus, to support agencies' efforts to protect the public health. Confronted with issues on the frontiers of science, and regardless of the applicable standard of review, courts have granted considerable weight to experimental or animal evidence, and to efforts by experts to estimate risks from such evidence. This is especially true where evidence of human harm, albeit incomplete, supplements experimental evidence.[193]

191. K. Popper, The Logic of Scientific Discovery (1959).

192. Hills, *Legal Decisions and Opinions in Pollution Cases*, 10 Envtl. Sci. and Tech. 234-35 (1976).

193. Agency and judicial approval of risk assessment techniques remains a source of public debate. In one debate, ex-EPA Administrator William Ruckelshaus argues that risk assessment is necessary to direct agencies' attention toward "significant problems" to help

Analysis of judicial review of risk assessments under the substantial evidence, arbitrary and capricious, and endangerment standards reveals that the applicable standard does not strictly determine the scrutiny which such review will entail.[194]

Professor Rodgers views the uneven application of standards of judicial review on environmental matters as grounds for suspecting that "whether the court will dig deeply or bow cursorily depends exclusively on whether the judge agrees with the result of the administrative decision."[195] This cynicism does not seem completely justified, the Fifth Circuit notwithstanding. Uneven application of standards of review by the courts may simply be a consequence of the inherently imprecise nature of the risk assessment process, and of the varied circumstances in which that process is presented to the courts. As a basic example, judicial acceptance of the agencies' reliance on tentative findings, extrapolations, and experimental models, appears much more likely when such evidence is supplemented by the actual occurence of human harm from exposure to the chemical at issue.[196]

A risk assessment is hardly the linchpin in the disposition of an issue of such widespread public concern as the effects on children

agencies prioritize public resources for the protection of public health. Ruckelshaus, *supra* note 93, at 10,190-93. Ruckelshaus cautions, however, against over-reliance on risk assessments because of their uncertainties, and urges that the public be educated as to the uncertainties and the policy assumptions underlying the risk estimates. *Id.* at 10,190-191.

David Doniger, a senior attorney with the Natural Resources Defense Council, argues that reliance on risk assessments even to the extent urged by Ruckelshaus is unwarranted. According to Doniger, risk assessments are simply "too uncertain and fragile" to be a basis for agency regulations in all but a few limited circumstances. Doniger, *The Gospel of Risk Management: Should We be Converted?*, 14 ENVTL. L. REP. (ENVTL. L. INST.) 10,222, 10,223 (1984).

194. Whether the strong pronouncements by the Supreme Court in *Chevron*, 104 S. Ct. 2778, on deference to agencies' choice among conflicting statutory policies will lead to a more consistent review of agency's policy choices remains to be seen.

195. Rodgers, *Judicial Review of Risk Assessment: The Role of Decision Theory in Unscrambling the* Benzene *Decision*, 11 ENVTL. L. 301, 302 (1981).

The EPA recently proposed guidelines for the uniform application of risk assessment techniques to agency decision-making. *See* N.Y. Times, Nov. 20, 1984, at A21, col. 1. Adoption of uniform guidelines by administrative agencies may, in turn, lead to a more uniform judicial review of agency decisions based on risk assessments.

196. The lesson of the *Society of Plastics Industry*, 509 F.2d 1301, where the deaths of thirteen workers exposed to vinyl chloride preceded the court's consideration of OSHA's strict regulatory standard for the substance, remains striking in this regard.

The EPA recently proposed guidelines for the uniform application of risk assessment techniques to agency decision-making. *See* 49 Fed. Reg. 46,294-46,331 (1984). Adoption of uniform guidelines by administrative agencies may, in turn, lead to a more uniform judicial review of agency decisions based on risk assessments.

of flaking asbestos insulation in schools. However, while it is convenient to differentiate between the political management and the scientific assessment of risk, the latter cannot be removed from politics. The very decision to assess the risk associated with a particular product or activity can derive from public pressure. Some years ago, Max Weber aptly characterized this dilemma: "Strictly speaking, objectivity cannot be applied to the selection of problems, but only to their solutions. What a society deems worth resolution becomes the measure of that society, but this worth cannot be scientifically demonstrated."[197]

Moreover, risk assessment techniques, themselves, are artful constructions, based on science but entailing numerous assumptions of fact which are based on politically derived policy choices. For example, the choice of a margin of safety—which is a component of risk assessments—is also a keenly political question. Science alone cannot rationalize a regulatory standard which is a 10th, 100th, or 1000th of the level at which no effect has been observed. As ex-EPA Administrator Ruckelshaus cautions, "We should remember that risk assessment data can be like a captured spy: if you torture it long enough, it will tell you anything you want to know."[198]

The cases examined above all attest to this problem. No readily discernible logic yet allows regulatory agencies to anticipate future risks. The agencies continue to mount a reactive response to externally generated pressures. This often leaves them short on science and long on speculation. Yet to delay occupational or environmental regulation in the name of better science because no human harm has yet been detected makes experimental subjects of those exposed in the meantime. To the fore comes risk assessment, garbed as the neutral arbiter.

With the exception of *Gulf South*, the cases discussed illustrate judicial tolerance for risk assessment as an aid to agencies struggling with an imperfect data base. In the face of scientific uncertainty regarding the effects of highly toxic substances, courts are willing to concede that prevention of future harm demands inferences and leaps of faith. Unwavering scientific consensus is not a prerequisite to regulatory action. What remains largely undecided among Congress, agencies and the courts is just how far

197. M. WEBER, THE METHODOLOGY OF THE SOCIAL SCIENCES (1949).

198. Ruckelshaus, *supra* note 93, at 10,190. *See id.* at 10,190-01 for a brief discussion of policy based assumptions.

such inferences should be tolerated as a basis for regulatory action. At a minimum, courts can be expected to continue to require not certain evidence, but the best available evidence. Agencies must marshall the best science, rationally and systematically. Limitations on judicial review are imposed both by courts' lack of expertise and by the agencies' assigned role of protecting the public health in the face of scientific uncertainty.

APPENDIX I

RISK RATIONALE FOR DESIGNATION/REGULATION

Statutory Provision	Mandate or Authority	Certainty/Causality/Probability	Severity of Hazard (w/Risk)	Type of Harm
*TSCA § 4(a) (1)	EPA "may" issue a testing standard if a chemical substance of (sic) mixture	(A) "may present" or (B) "is or will be" produced in substantial quantities and (i) "enters or may reasonably be anticipated to enter" or (ii) "there is or may be"	"an unreasonable risk of"	"injury to health or the environment" "the environment in substantial quantities" "significant or substantial human exposure"
TSCA § 4(f)	EPA must "find" that the risk is "not reasonable" or initiate action under §§ 5, 6, 7, if	"there may be a reasonable basis to conclude that a chemical substance or mixture presents or will present"	"a significant risk of"	"serious, widespread harm to human beings from cancer, gene mutations, or birth defects"
TSCA § 5(b) (4) (A)	EPA "may" compile and keep current a list of chemical substances that	"presents or may present"	"an unreasonable risk of"	"injury to health or the environment"
TSCA § 5(f) [§ 6(a)]	EPA "shall" issue a rule to limit or prohibit [for § 6(a)] the use of a chemical substance [or mixture] if	"there is reasonable basis to conclude" that it "presents or will present"	"an unreasonable risk of"	"injury to health or the environment"
**CWA § 311(b) (2) (A)	EPA "shall" designate "elements and	"present"	"an imminent and substantial danger"	"danger to the public health or

* [Toxic Substances Control Act, Ed.]
** [Clean Water Act, Ed.]

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	compounds which"			welfare, including, but not limited to, fish, shellfish, wildlife, shorelines, and beaches"
CWA § 311(b) (4)	EPA "shall" designate "those quantities of 'hazardous substances' the discharge of which"	"may be"	"harmful to"	"the public health or welfare of the United States, including, but not limited to fish, shellfish, wildlife, and private property, shorelines and beaches"
CWA § 307(a)	EPA "may" revise list of designated toxic pollutants to include substances which	"will cause"	—	"death, disease, behavioral abnormalities, cancer, mutations, physiological malfunctions in reproduction, or physical deformations in organisms or their offspring"

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*SDWA § 1401(1)	EPA "may" revise and "must" issue primary drinking water regulations for contaminants which	"may have"	—	"any adverse effect on the health of persons"
SDWA § 1412(b)(1)(B)	EPA "shall" by rule establish maximum levels for each contaminant which	"may have"	—	"any adverse effect on the health of persons"
SDWA § 1421(a)(1), (d)	EPA "shall" publish regulations for underground injection control if			
	such injection	"may" result in	—	"the presence of any contaminant"
	and			
	if the presence of such contaminant	"may affect adversely"		"the health of persons"
**MPRSA § 102(a)	Dumping permits "may" be issued where dumping	"will not"	"unreasonably degrade or endanger"	"degrade or endanger human health, welfare, or amenities, or the marine environment, ecological systems,

* [Safe Drinking Water Act, Ed.]
** [Marine Protection, Research, and Sanctuaries Act, Ed.]

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				or economic potentialities"
*RCRA § 3001, § 1004(5)	EPA "shall" promulgate criteria and regulations identifying the characteristics of listing particular hazardous wastes which	(A) "may cause or contribute to" OR	"an increase in"	"mortality" or "serious irreversible, or incapacitating reversible, illness"
		(B) "may pose" [when "improperly" managed]	"a substantial present or potential hazard to"	"human health or the environment"
RCRA § 3002, § 3003, § 3004	EPA "shall" promulgate regulations applicable to generators, transporters, and owners or operators of facilities for listed or identified hazardous wastes as	"may be necessary to protect"	—	"human health and the environment"
**FIFRA § 3(c)(5)(C)	EPA "shall" register a pesticide if	(C) "[it] will perform its intended function without" [and(D)] "will not generally cause" ["when used in accordance with widespread and commonly recognized practice" or as directed]	—	"unreasonable adverse effects on the environment"

* [Resource Conservation and Recovery Act, Ed.]
** [Federal Insecticide, Fungicide and Rodenticide Act, Ed.]

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Statutory Provision	Mandate or Authority	Certainty/Causality/Probability	Severity of Hazard (w/Risk)	Type of Harm
FIFRA § 3(c)(7)(A)	EPA "may" conditionally register or amend registration of identical and substantially similar pesticides if that	"would not significantly increase"	"the risk of"	"unreasonable adverse effects on the environment"
FIFRA § 3(c)(7)(B)	EPA "may" conditionally amend registration to permit additional uses of a pesticide, except where risk criteria for human dietary exposure have been met or exceeded and the use involves a major food or feed crop or the use involves minor food/feed crop and an effective alternative is available if that	"would not significantly increase"	"the risk of"	"any unreasonable adverse effects on the environment"
FIFRA § 3(c)(7)(C)	EPA "may" conditionally register a pesticide containing any unregistered active ingredient if its use	"will not cause"	—	"any unreasonable adverse effects on the environment" during the time period covered by such registration
FIFRA § 3(d)(1)(B)	EPA "will" classify a pesticide for general use if its use	"will not generally cause" [same condition as below]	—	"unreasonable adverse effects on the environment"

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FIFRA § 3(d)(1)(C)	EPA "shall" classify a pesticide for restricted use if, otherwise, its use	"may generally cause" without additional regulatory restrictions in accordance with directions for use warnings, cautions, and for the uses for which it is registered ["when used in accordance with widespread and commonly recognized practice" or as directed] or when applied	—	"unreasonable adverse effects on the environment, including injury to the applicator"
FIFRA § 6(b)	EPA "may" commence proceedings to cancel or change the classification of a pesticide if its use	"generally causes" if it appears that a pesticide or its labeling or other material required to be submitted does not comply with the provisions of the Act or when used in accordance with widespread and commonly recognized practice	—	"unreasonable adverse effects on the environment"
FIFRA § 25(c)(3)	EPA "may" establish packaging standards	"in order to protect children and adults"	—	"[against] serious injury or illness resulting from accidental ingestion or contact"
*CAA § 108(a)(1)	EPA "shall" list each air pollutant which	"causes or contributes to air pollution which may reasonably be anticipated to"	"endanger public health or welfare"	—

* [Clean Air Act, Ed.]

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CAA § 109	EPA "shall" establish air quality standards which	"are requisite to protect the public health"	—	—
CAA § 111(b)(1)(A)	EPA "shall" list a category of new sources of pollution if it	"causes, or contributes significantly to, air pollution which may reasonably be anticipated to"	"endager public health or welfare"	—
CAA § 112	EPA "shall" list as a "hazardous air pollutant" any air pollutant which	"may reasonably be anticipated to result in"	"an increase in"	"mortality or serious irreversible, or incapacitating reversible, illness"
CAA § 157(b)	EPA "shall" regulate "any substance, practice, process, or activity" which	"may reasonably be anticipated to affect the stratosphere, especially ozone, if such effect" "may reasonably be anticipated to"	"endager public health or welfare"	—
CAA § 202(a)	EPA "shall" regulate any air emissions from new motor vehicles and engines which	"cause, or contribute to, air pollution which may reasonably be anticipated to"	"endanger public health or welfare"	—
CAA § 211	EPA "may" control or prohibit the manufacture, sale, or use of a fuel or fuel additive if any emission product	"causes or contributes to air pollution which may reasonably be anticipated to"	"endanger the public health or welfare"	—
CAA § 231	EPA "shall" issue standards for any aircraft emission which	"causes, or contributes to, air pollution which may reasonably be anticipated to"	"endanger public health or welfare"	—

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Statutory Provision	Mandate or Authority	Certainty/Causality/Probability	Severity of Hazard (w/Risk)	Type of Harm
*CERCLA § 102	EPA "shall" designate as "hazardous substances" "such elements, compounds, mixtures, solutions, and substances which"	"may present" ["when released into the environment"]	"substantial danger to the public health or welfare or the environment"	—
CERCLA § 104(a)(2)	The phrase "pollutant or contaminant" "shall include, but not be limited to, any element, substance, compound, or mixture, including disease-producing agents, which"	"will or may reasonably be anticipated to cause" ["directly...or indirectly" after "release into the environment"]	—	"death, disease, behavioral abnormalities, cancer, genetic mutation, physiological malfunction including malfunctions in reproduction) (sic)" in "organisms or their offspring"

* [Comprehensive Environmental Response, Compensation and Liability Act, Ed.]

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CERCLA 105(3)	EPA shall establish procedures and standards for responding to releases of hazardous substances, pollutants and contaminants, which shall include methods and criteria for determining the appropriate extent removal or remedy.	not specified by statute	not specified by statute	—
CERCLA 105(8)(A)	EPA shall establish procedures and standards for responding to releases of hazardous substances, pollutants and contaminants, which shall include methods and criteria for determining priorities for remedial and removal actions.	not specified by statute	not specified by statute	—