# Risk and Benefit in Environmental Law

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*Summary.* Judicial review establishes whether the mandate of Congress is observed by an agency's rule-making mechanisms for setting environmental standards or other regulations. Central issues in risk assessment now include whether a risk is significant, what the burden of proof for significance is, how to resolve the tension between the effort to reduce hazardous exposures and the goal of efficient regulation, and precisely how and in what detail the costs of regulation must be measured. Under current regulatory statutes, there are several paradigms for balancing costs and benefits.

Currently, more than ten federal statutes contain statements about risk and benefit assessment; the process of setting environmental standards increasingly rests on the analysis of risk. The courts have made numerous references to risk-benefit analysis in reviewing the actions of regulatory agencies. Yet the issue of what role risk-benefit assessment should have in energy or environmental policy is neither clear nor settled. One reason is that many of the questions that arise in attempting to evaluate risk are what Weinberg (*1*) has called "questions which can be asked of science and yet which cannot be answered by science . . . they transcend science." Another is that decisions on how to measure or reduce risk are not purely scientific ones; they are policy choices as well, enveloped in the controversy that usually accompanies policy disagreements.

In carrying out this rule-making function, regulatory agencies are frequently required to postulate answers to transscientific questions. These include the extrapolation to low doses of results obtained at high doses of a substance; the interpretation of carcinogenic potencies measured in different animal species to infer possible effects on humans; the meaning of benign tumors; the use of epidemiologic, in vivo, and in vitro studies as evidence for establishing health effects; the choice of a dose-response model.

Regulatory agencies, such as the Environmental Protection Agency (EPA) and the Occupational Safety and Health Administration (OSHA), promulgate standards that reflect their policies on health risk. In doing so, they must consider the enabling statute, the intent of Congress, and the procedural requirements of the Administrative Procedure Act. The statutes vary greatly in their description of the risk analysis that the agency must perform. Because of the frequent ambiguity of the statutory language and the discretion given to agencies in choosing objectives and methods of implementation, litigation and judicial review are often the ultimate source of regulatory policy.

The statutes have thus created an "uneasy partnership" (*2*) between administrative agencies and the U.S. Courts of Appeal. The courts must scrutinize the procedures used by the agencies in forming regulations and also examine the substance of the agency policy. Agency findings of fact must be supported by evidence in the record. Environmental regulation is a difficult area for courts to oversee because of its technical content, and judges do not agree on the role of the courts in reviewing energy or environmental decisions. The positions of two judicial scholars of administrative law illustrate this. The late Judge Leventhal of the D.C. Circuit Court of Appeals believed that the courts have a "central role of ensuring the principled integration and balanced assessment of both environmental and non-environmental considerations in federal agency decision-making" (*3*). In his view, the decisions taken by the agency are reviewed by competent judges, who apply uniform standards of review, thus limiting the dependence of results on the court that hears the case. A different view was expressed by Judge Bazelon, also of the D.C. Circuit, who stated: "Because substantive review of mathematical and scientific evidence by technically illiterate judges is dangerously unreliable, I continue to believe we will do more to improve administrative decision-making by concentrating our efforts on strengthening administrative procedures" (*4*).

Considering the technical complexity of the assessment of health risks, it is understandable that courts would be cautious about interposing their judgments on these issues. Nevertheless, the last decade has brought closer judicial scrutiny of environmental policy, as courts have required more formal and rigorous administrative proceedings. Under the "hard look" doctrine of administrative law, the agency must analyze the evidence, describe its methodology, and explain the rationale for its decision (*5*).

In this article we discuss the treatment in law of several key issues in risk assessment: the meaning of the 1980 Supreme Court ruling that OSHA must demonstrate that a standard is needed to remedy a "significant risk," the burden of proof of the significance of risk under conditions of scientific uncertainty, and the resolution of the conflict between the desire for accuracy and the need to reduce hazardous exposures. We then review approaches that have been taken in balancing the economic costs against the benefits of risk reduction.

## Significance and Risk

In the 1980 Supreme Court ruling in *Industrial Union* v. *American Petroleum Institute* (*6*), the court required OSHA to demonstrate, before it issues a standard, that "it is reasonably necessary and appropriate to remedy a significant risk of material health impairment." Lower courts had recognized that not all risks can be eliminated by regulation; some are too slight (*de minimis*) to be considered.

In a case involving the use of acrylonitrile in beverage containers (*7*), the court interpreted the legal definition of additive as requiring that a substance migrate into food "in more than insignificant amounts." Although the court said the

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second law of thermodynamics guarantees that some acrylonitrile will enter the beverage, it decided that this fact alone does not make acrylonitrile an additive.

In cases under the Clean Air Act and the Toxic Substances Control Act the courts recognized that the regulatory agency has the power, "inherent in most statutory schemes, to overlook circumstances that in context may fairly be considered *de minimis*" (*8*). However, if the EPA wishes to ignore low levels of a substance, it must find "the concentration at which there are only trivial benefits to be derived from regulation"(*9*).

In previous OSHA cases the lower courts did not apply close scrutiny to agency regulation of uncertain risks. For example, in a 1975 case the court upheld a reduction in the standard for workplace exposure to vinyl chloride from 50 to 1 part per million. It did not request that OSHA calculate the number of cancers to be expected from either exposure level or adopt a model of carcinogenesis; the opinion does not mention the problem of extrapolation from animal tests (*10*). Another court in 1978 upheld the standard for coke oven emissions, acknowledging that no safe level of exposure could be shown (*11*). A strong expression of this approach came in a 1976 opinion by J. Skelly Wright, now Chief Judge of the D.C. Circuit, upholding an EPA regulation restricting lead as a gasoline additive. He said that "a determination of endangerment to public health is necessarily a question of policy that is to be based on an assessment of risks and that should not be bound by either the procedural or the substantive rigor proper for questions of fact" (*12*). The agency was left free to adopt risk-averse regulations.

In contrast, the Supreme Court ruling in *Industrial Union* (*6*) requires OSHA to develop better evidence of the risks of exposure. The Occupational Safety and Health Act calls for safe employment, and the court noted that " 'safe' is not the equivalent of 'risk-free.' There are many activities that we engage in every day—such as driving a car or even breathing city air—that entail some risk . . . nevertheless, few people would consider these activities 'unsafe.' Similarly, a workplace can hardly be considered 'unsafe' unless it threatens the workers with a significant risk of harm."

The court based its decision primarily on economic considerations, that is, a recognition that regulation of low-level exposures is very costly. It pointed out that under OSHA's rules, once a substance was determined by specific evidence to induce cancer in animals, or in humans who experienced extremely high exposures, it must be regulated. Since the National Institute of Occupational Safety and Health (NIOSH) had 2415 substances on its list of suspected carcinogens and OSHA listed 269 of them as carcinogens subject to regulation, following this course "would give OSHA power to impose enormous costs that might produce little, if any, discernible benefit." The court concluded that Congress did not intend to give OSHA such broad power. After a review of the legislative history of the Occupational Safety and Health Act, the court rejected the view that "the mere possibility that some employee somewhere in the country may confront some risk of cancer is a sufficient basis for . . . the expenditure of hundreds of millions of dollars to minimize that risk." It then proceeded further: if OSHA were correct in arguing that it need not characterize a risk as significant, the statute might be unconstitutional as an overly "sweeping delegation of legislative power" (*13*).

Conclusively showing the significance of risks from low-level exposures would require resolution of issues that range from the choice of a dose-response model to the definition of "acceptable" risk. OSHA's rule-making allowed it to avoid this problem; it did not establish a safe exposure level of a substance. OSHA required standards to be set at the lowest level feasible. But this approach incorporated other assumptions about carcinogenesis, such as the no-threshold hypothesis. The extent to which a finding of significance may rest on such assumptions is unclear. The Supreme Court refused to consider what factual findings are necessary to establish significance. In footnotes to its opinion (*6*), it stated that animal studies could support "a conclusion on the significance of the risk" and that epidemiologic evidence, even if insufficient to generate a dose-response model, "would at least be helpful" in deciding whether a risk is significant.

However, with animal studies there are still the questions of extrapolation and interspecies comparison, and appropriate epidemiologic studies may be nonexistent, so the evidence suggested by the court may still not resolve the controversy.

On some occasions, however, OSHA regulates a well-defined risk. The Supreme Court considered what level of known risk is significant by bounding the concept. It noted that a one per billion risk of cancer from chlorinated water would not be significant, while a one per thousand risk of death from inhaling gasoline vapor would be. Somewhere in between lies significance; where that point lies must require case-by-case determination.

Under other statutes, courts confronted with a known risk have often ruled that if the probability or severity of harm is very low, the risk should not be regulated. In nuclear power plant licensing, the courts have noted that there is a small probability of a major accident from a meltdown, but because the chance of such an occurrence is so low, it need not be factored into the environmental impact statement (*14*). Similarly, a nuclear plant exposes some persons to low-level radiation; this guarantees that some risk exists, but it is of such low severity that courts and agencies have found it "clearly acceptable under existing conditions" (*15*). The D.C. Circuit acknowledged that this risk might at some future time be proved severe, but did not find that possibility sufficient to justify refusing a license. As the court added in a later case, "even the absolute certainty of *de minimis* harm might not justify government action . . . whether a particular combination of slight risk and great harm, or great risk and slight harm, constitutes a danger must depend on the facts of each case" (*16*).

### Burden of Proof

When the risk is uncertain, what is the burden of proof that an agency must satisfy to demonstrate significance? The law usually requires that a fact or an overall finding (such as civil liability) be supported by a "preponderance of the evidence" or "more likely than not" (51 percent). The normal rule of administrative law is that "it is the proponent of a rule or order who has the burden of proof in administrative proceedings" (*6*). With the exception of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), which places the burden on the registrant to prove that a pesticide is safe, environmental statutes follow this principle. In earlier cases OSHA was not required to demonstrate the significance of a risk. But in the benzene case the Supreme Court held that "the burden was on the agency to show, on the basis of substantial evidence, that it is at least more likely than not that long-term exposure to 10 ppm of benzene presents a significant risk of material health impairment" (*6*).

While this principle applies to the overall finding of significance, it does not apply to the components of the analysis. The basic principles of scientific proof

must be followed wherever there is a consensus among scientists. For a specific piece of evidence to be valid, such as the induction of tumors in mice by chemical X ingested under conditions Y, the findings must be replicable and be statistically significant at commonly prescribed levels. A finding of carcinogenesis must be "proven" with 95 percent confidence or greater. However, there are some issues in the measurement of risk about which there is no scientific consensus. Here the agency is held to a lower burden of proof than "a preponderance of the evidence."

The Supreme Court ruling allowed OSHA to adopt conservative assumptions about carcinogenesis "so long as they are supported by a body of reputable scientific thought" (*6*). It also stated that the agency has no duty to calculate the exact probability of harm. Therefore OSHA may regulate carcinogens by estimating the risk, and characterizing it as significant, on the basis of the most conservative dose-response models. Allowing the agency to choose answers to transscientific questions that are not necessarily the most popular or most logical, but are supported by some experts, would allow OSHA to assume significance even where a preponderance of the evidence does not support such a finding.

### Factual Accuracy

Risk assessment by regulatory agencies reflects a tension between two basic goals of regulation. McGarity (*17*) has described these as factual accuracy and result orientation. To achieve the first goal, the agency should wait until sufficient data have been accumulated before imposing regulations. The second goal requires agencies to implement policies that Congress considers socially desirable. An agency may choose to endorse a particular result and acknowledge that factual accuracy is impossible, or it may regulate only where it can be accurate. To avoid this choice, an agency faced with a risk of uncertain magnitude may choose to defer regulatory action until more studies are completed that will better define the risk. If the agency has underestimated the risk, delay will prove to have unnecessarily injured some; if it has overestimated it, delay will avert the imposition of excessive costs. In a case where the agency lacked complete evidence of the environmental impact of its action, the D.C. Circuit held that the agency must give "full and careful consideration" to delay, but may proceed if it decides that delay "is outweighed by the benefits of proceeding" (*18*).

When further research is unlikely to produce additional knowledge, delay is inappropriate. Thus a court contemplating the risks of low-level radiation from a nuclear plant refused to consider that the exposure might be proved hazardous because "There is no indication that either possibility could be rendered other than speculative during the foreseeable future" (*18*).

Sometimes delay is inappropriate because Congress has clearly chosen the result-oriented approach in the relevant statute. The EPA must establish ambient air quality standards for pollutants even where the current state of knowledge makes this difficult; it must make do with the best information available (*19*). But in other cases, such as occupational exposure to suspected carcinogens about which little research has been done, it is difficult to decide whether to delay. Thus far, the courts have given no clear guidance.

The Supreme Court appeared to endorse both factual accuracy and result orientation in the benzene case. As described in the opinion, if the agency is explicit in its choice of models, it may attempt to eliminate almost all cancer risks by adopting a "one-hit" theory of carcinogenesis. But the court has also called for stronger evidence, better documentation, and clearer proof that a risk exists; it found the evidence of low-dose benzene carcinogenicity inadequate (*20*).

### Balancing

A critical question is the extent to which economic costs should be weighed against the benefits of risk reduction. Statutes dealing with the environment and energy differ in their approach to this issue, and the courts are wrestling with it. There are four types of statutory frameworks, as described below.

1) One class of statutes requires that the agency balance cost and benefits. Some statutes explicitly require cost-benefit analysis. The most important example is the National Environmental Policy Act (NEPA), which mandates "balancing of the environmental costs of a project against its economic and technological benefits"; a numerical cost-benefit analysis is required in cases where other methods provide inadequate detail. More recently, the Outer Continental Shelf Lands Act, amended in 1978, requires offshore drilling to be done with the safest technology, except when "the incremental benefits are clearly insufficient to justify the incremental costs of using such technologies" (*21*). Similarly, FIFRA requires suspension of pesticides when there is "unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits" of the pesticide. Similar language appears in the Toxic Substances Control Act (*22*).

When the "unreasonable risk" language appears, the courts have imposed balancing as a prerequisite to regulation. Under the Consumer Products Safety Act (CPSA) and the Federal Hazardous Substances Act (FHSA), the courts have held that such language "necessarily involves a balancing test like that familiar in tort law" (*23*). This balancing formula, called "Learned Hand's algebra" after the great jurist of the 1920's, has three components: the burden of the regulations, the probability of harm occurring from the product or conduct at issue, and the severity of the harm if it occurs. A regulation is valid if the severity of the injury, factored by its probability, outweighs the burden of regulation. This allows the courts to make a subjective assessment of the imposition on the consumer.

2) A second approach to balancing costs and benefits appears in the Clean Water Act. The EPA must consider costs, but they are much less central to the decision than under the first approach. In establishing phase I (1977) effluent standards, the agency must consider the total cost of standards, including potential unemployment and dislocation. It need not make a quantitative comparison of cost and benefit, and it is to impose the standard unless the marginal level of effluent reduction is "wholly out of proportion" to the cost. For phase II (1987) standards, the total cost need not be compared to benefit, but only considered. One court of appeal has required a cost-effectiveness analysis of alternative strategies to implement phase II controls.

When an individual polluter wishes a variance from the effluent standards, the result is different. The U.S. Supreme Court ruled in 1980 that the economic capability of an individual plant to bear the costs of a phase I standard may not be considered (*24*). But under phase II individual economic hardship will justify a variance. The reasoning is that phase I standards already incorporate costs, because they are calculated on the basis of the best control system now in use; segments of industry that have not attained this level should be required to do so. Individual consideration is appropri-

ate for phase II because such cost analysis has not yet been performed.

3) A third approach is to ignore costs and focus on the issue of health risk. The Delaney clause of the federal Food, Drug, and Cosmetic Act, which provides that no additive can be approved "if it is found to induce cancer," is an example. In theory, once tests demonstrate the carcinogenicity of a substance, no consideration of its benefits or the costs of its removal is relevant; the additive is banned. This approach is used in other statutes, although not with the same clean-cut rejection of balancing. For instance, the Clean Air Act requires the establishment of primary national ambient air quality standards solely as a function of health risk. Considerations of economic or technological infeasibility cannot be used in formulating these standards (*25*).

4) It is the Occupational Safety and Health Act that has been the main focus of the debate over balancing. Regulation under this act raises very difficult questions about the assessment and acceptability of health risk, and the answers to the problems of low-level occupational exposure to toxic substances will influence policies in many other areas. Section 6(b)(5) of the statute provides that standards must assure "to the extent feasible" that "no employee will suffer material impairment of health." The Courts of Appeal had interpreted the word "feasible" to require only that the technology existed and could be installed without destroying the industry. In 1974 the D.C. Circuit ruled that standards were feasible even though they were financially burdensome to the employer and reduced his profit margin; even a standard that bankrupted some individual employers could be feasible (*26*). But in a groundbreaking 1978 ruling on OSHA's benzene standard, the Fifth Circuit endorsed cost-benefit balancing (*27*). It held that the benefits of a standard must bear a "reasonable relationship" to its costs, because the statutory definition of health standards as "processes reasonably necessary to provide safe or healthful employment" implied a balancing of costs and benefits. However, in other contexts the phrase "reasonably necessary" only requires that the agency action bear a rational relationship to the statutory purpose (*28*). In 1979 the D.C. Circuit upheld OSHA's cotton dust standard and held that OSHA need not balance costs and benefits (*29*).

When the benzene case reached the Supreme Court in 1980, the main opinion avoided the issue of balancing. Then in 1981 the court ruled in *American Textile Manufacturers Institute (ATMI)* that balancing was inappropriate under its reading of the legislative history of the Occupational Safety and Health Act. The court held that Congress had performed balancing and intended to place "the 'benefit' of worker health above all other considerations save those making attainment of this 'benefit' unachievable. Any standard based on a balancing of costs and benefits by the Secretary that strikes a different balance than that struck by Congress would be inconsistent with the command set forth in §6(b)(5)" (*30*). The court also held that interpretation of the phrase "reasonably necessary" to require balancing of costs and benefits "would eviscerate the to the extent feasible requirement."

The court ruled that feasibility, not cost-benefit consideration, is the only factor that takes precedence over worker health. It defined feasible as "capable of being done." It refined the definition of economic feasibility, but still left some aspects uncertain. For instance, OSHA conducted studies to estimate the cost of complying with the new standards and concluded that the cost would not seriously threaten the textile industry and that the industry would maintain "long-term profitability and competitiveness." The court refused to decide whether a standard that threatens this status is feasible.

Obviously, an analysis of these economic questions requires estimates of costs. The precision needed for these estimates is not certain. In *ATMI*, the cost studies were based on a hypothetical dust standard that was less strict than the one actually adopted; thus the cost estimates were too low. The studies also overestimated the cost by miscalculating the amount of synthetic fibers used. OSHA claimed it could not generate more precise figures unless industry was willing to release proprietary data. It then assumed that the overestimate of cost roughly equaled the underestimate due to the hypothetical standard. The court admitted that a cost estimate based on the actual standard "surely would be preferable," but held that the lower court had the power to accept OSHA's estimate under the circumstances. The court concluded that OSHA "acted reasonably" and that the lower court had not "misapprehended or grossly misapplied" the test for substantial evidence.

The *ATMI* case should resolve the meaning of "to the extent feasible" for this issue, but feasible has a different meaning in other contexts. The feasibility of a standard, as just discussed, is not the same as the feasibility of various methods employed to achieve the standard. Two Courts of Appeal implied that this provision necessitates a cost-effectiveness analysis of possible solutions. Thus the employer might avoid expensive engineering controls by demonstrating that they are not feasible because they are not cost-effective (*31*). In *ATMI* the Supreme Court noted that if two methods that achieved the same reduction of health risk were both feasible, the more burdensome method might not be "reasonably necessary." So it appears that cost-effectiveness is needed for OSHA standards.

The *ATMI* decision also implied that the "reasonably necessary" language might require cost-benefit balancing for other hazards. The feasibility principle of section 6(b)(5) only reflects the intent of Congress to regulate toxic materials as much as possible; it does not necessarily apply to safety or noise standards, for example. Therefore standards in those areas might require "some form of cost-benefit analysis." Again, the court did not decide this issue.

However the problems are resolved, if balancing is to play a role in environmental law, some attempt must be made to value human life and health. Society, either implicitly or explicitly, places a dollar value on the preservation or saving of a life. The most dramatic example is the jury award. Juries make death awards in auto accidents, product liability suits, and medical malpractice cases. Statutory compensation systems such as the federal black lung disease program or state workers' compensation also put a price on injury or death. Legislative decisions to finance programs whose effects are documented also value life because they expect to save a certain number of lives for a certain number of dollars. Examples are mobile cardiac emergency units and drinking water treatment plants (*32*). Human life is not the only aspect that is difficult to evaluate, and balancing under environmental statutes often involves comparing intangible costs and benefits. It is through balancing that the courts attempt to weigh such factors as scenic beauty, preservation of animal life, and quality of life.

### Prospects for Risk Assessment

There is no doubt that agencies and courts will continue to be troubled by risk questions. The easiest administrative policy—eradication of risk to the greatest extent possible—has been declining in popularity as we have become

aware of the finite nature of our resources. The costs of environmental regulation seemed less burdensome at a time when the United States had greater economic advantages. Yet the calculus of risk involves basic values that will always be weighted differently by different individuals. Decision-makers select a policy that implicitly weighs health, quality of life, economic opportunity, and environmental amenities. Consensus is almost impossible, yet we have no alternative but to seek increasingly rational approaches (*33*).

Risk-benefit assessment is still in development. Better methodology and better procedures in the agencies and courts are urgently needed. The distributive effects of regulation (which groups are benefited and burdened by a policy), and the trade-offs between present and future generations should be considered. Recent articles have called for new procedures in policy-making: generic rulemaking on transscientific issues, full disclosure of the uncertainties contained in all risk decisions, and the use of permanent special masters to advise appellate courts in these cases (*34*). More accurate and just results may be possible in the future.

### References and Notes


1. A. Weinberg, *Minerva* **10**, 209 (1972).
2. This phrase originated with Judge H. Friendly in *Associated Industries of New York State* v. *Department of Labor*, 487 Fed. Rep., 2nd ser. 341, 354 (2nd Cir., 1973). The partnership is designed to "check extravagant exercises of the agency's authority to regulate risk" (*29*, p. 649).
3. H. Leventhal, *Univ. Pa. Law Rev.* **122**, 509 (1974), p. 555.
4. D. Bazelon, *Ethyl Corp.* v. *Environmental Protection Agency*, 541 Fed. Rep., 2nd ser. 1, 67 (D.C. Cir. 1976) (Bazelon, Circuit Judge concurring).
5. For a description of the history of standards of review, see *National Lime Association* v. *Environmental Protection Agency*, 627 Fed. Rep., 2nd ser. 416, 451 (D.C. Cir., 1980). The phrase "hard look" originated with Judge Leventhal in *Greater Boston Television Corp.* v. *Federal Communications Commission* (FCC), 444 Fed. Rep., 2nd ser. 841 (D.C. Cir., 1970) and *Pikes Peak Broadcasting Co.* v. *FCC*, 422 Fed. Rep., 2nd ser. 671 (D.C. Cir., 1969). The doctrine is defined and described in detail in W. Rodgers, *Geo. Law J.* **67**, 699 (1979), pp. 705–707.
6. *Industrial Union Department, AFL-CIO* v. *American Petroleum Institute*, 100 S. Ct. 2844, 66 L.Ed., 2nd 268 (1980).
7. *Monsanto* v. *Kennedy*, 613 Fed. Rep., 2nd ser. 947, 955 (D.C. Cir., 1979).
8. *Environmental Defense Fund* v. *EPA*, 636 Fed. Rep., 2nd ser. 1267, 1283 (D.C. Cir., 1980).
9. *Ibid.*, p. 1284.
10. *Society of the Plastics Industry* v. *OSHA*, 509 Fed. Rep., 2nd ser. 1301 (2nd Cir., 1975).
11. *American Iron and Steel Institute* v. *OSHA*, 577 Fed. Rep., 2nd ser. 825 (3rd Cir., 1978).
12. *Ethyl Corp.* v. *EPA*, 541 Fed. Rep., 2nd ser. 1, 24 (D.C. Cir., 1976).
13. The delegation doctrine is a basic principle of constitutional law that blocks Congress from delegating too much of its authority to other branches of government. Key New Deal legislation was invalidated by the courts because it gave the executive too much authority. *Schechter Poultry Corp.* v. *United States*, 295 U.S. 495 (1935) (National Industrial Recovery Act unconstitutional). In general, courts interpret a statute narrowly if this will avoid a finding of unconstitutionality. Justice J. P. Stevens' plurality opinion in the benzene case raised the possibility that an open-ended grant of authority to OSHA might violate the nondelegation principle. Limiting OSHA's authority avoided the issue.
14. *Carolina Environmental Study Group* v. *United States*, 510 Fed. Rep., 2nd ser. 796 (D.C. Cir., 1975) (class 9 reactor accidents "almost totally unworthy of consideration" in environmental impact statement).
15. *Citizens for Safe Power* v. *Nuclear Regulatory Commission* (NRC), 524 Fed. Rep., 2nd ser. 1291, 1300 (D.C. Cir., 1975) (low-level radiation from Maine Yankee plant acceptable).
16. *Ethyl Corp.* v. *EPA*, 541 Fed. Rep. 2nd ser. 1, 18 (D.C. Cir., 1976).
17. T. McGarity, *Geo. Law J.* **67**, 729 (1979).
18. *Alaska* v. *Andrus*, 580 Fed. Rep., 2nd ser. 465, 473 (D.C. Cir., 1978) (cost of proceeding without more data may be outweighed by benefits: National Environmental Policy Act fails to specify level of certainty needed for environmental estimates); *Citizens for Safe Power* v. *NRC*, 524 Fed. Rep., 2nd ser. 1291, 1300 (D.C. Cir., 1975) (halting plant until studies settle issue would "bring essential economic development to a standstill").
19. *Natural Resources Defense Council* v. *Train*, 545 Fed. Rep., 2nd ser. 320 (2nd Cir., 1976). The fact that current knowledge makes this difficult is "irrelevant." See note 5 in the court's opinion.
20. The Supreme Court examined the record in detail. Studies of U.S. rubber workers exposed to pure benzene as a solvent in the 1940's and 1950's showed a ninefold increase in leukemia. A NIOSH study of workers at two plants in Ohio in the 1940's showed a significantly higher incidence of leukemia. However, exposures were usually in excess of 100 parts per million, and OSHA concluded that no dose-response relation could be determined. Only one study of low-level exposure was found, a Dow Chemical study that showed three leukemia deaths in the work force (0.2 expected). The three had been exposed to 2 to 9 parts per million benzene. Because the three workers were probably exposed to other occupational carcinogens and no leukemia deaths appeared in other groups of workers with higher exposures, OSHA did not claim that this study demonstrated cause and effect. The Supreme Court concluded that evidence in the record of "adverse effects of benzene exposure at 10 parts per million is sketchy at best" and said OSHA had not shown significant risk.
21. *Columbia Basin Land Protection Association* v. *Schlesinger*, 643 Fed. Rep., 2nd ser. 585, 594 (9th Cir., 1981); *Outer Continental Shelf* Lands Act, 43 U.S. Code, sect. 1347(b).
22. FIFRA, 7 U.S. Code, sect. 136(bb); Toxic Substances Control Act, 15 U.S. Code, sect. 2605(a).
23. The quotation is from *Forester* v. *Consumer Products Safety Commission* (CPSC), 559 Fed. Rep., 2nd ser. 774, 789 (D.C. Cir., 1977) (FHSA); see *Aqua Slide "N" Dive* v. *CPSC*, 569 Fed. Rep., 2nd ser. 831 (5th Cir., 1978) (CPSA).
24. The "wholly out of proportion" phrase originated with Senator Muskie [*A Legislative History of the Water Pollution Control Act Amendments of 1972* (93rd Congress, 1st Session), p. 170]; *EPA* v. *National Crushed Stone Association*, 49 U.S. Law Week 4008 (1980). The case dealt only with variances from phase I standards; however, the court indicated (note 10 of Justice White's opinion) that it supported the view that cost-benefit analysis is unnecessary for phase II.
25. In construing the National Ambient Air Quality Standards provision, the Supreme Court held that "claims of economic or technological infeasibility may not be considered by the Administrator in evaluating a state requirement that primary ambient air quality standards be met in the mandatory three years" [*Union Electric Co.* v. *EPA*, 427 U.S. 246, 265 (1976)].
26. *Industrial Union Department, AFL-CIO* v. *Hodgson*, 499 Fed. Rep., 2nd ser. 467 (D.C. Cir., 1974). A later court expanded on this, noting that massive dislocation or "crippling" of an industry would be unacceptable, but it upheld coke oven regulations estimated to cause a 13 percent drop in earnings for industry [*American Iron and Steel Institute* v. *OSHA*, 577 Fed. Rep., 2nd ser. 825 (3rd Cir., 1978).
27. *American Petroleum Institute* v. *OSHA*, 581 Fed. Rep., 2nd ser. 493 (5th Cir., 1978) affirmed on other grounds, sub nom. *Industrial Union Department, AFL-CIO* v. *American Petroleum Institute* (*6*).
28. Means-end analysis is common in judging the constitutionality or validity of regulations. The Supreme Court held (in a case under the Truth-in-Lending Act) that a statute allowing such rules "as may be necessary" only requires that the means chosen by the agency reasonably relate to the purpose of the statute [*Mourning* v. *Family Publications Service*, 411 U.S. 356, 369 (1972)]. Whether in the Consumer Products Safety Commission or Occupational Safety and Health Administration, "reasonably necessary" probably was not intended to limit agency authority.
29. *AFL-CIO* v. *Marshall*, 617 Fed. Rep., 2nd ser. 636, 665 (D.C. Cir., 1979).
30. *American Textile Manufacturers Association* v. *Donovan*, 49 U.S. Law Week 4720 (1981).
31. *International Harvester* v. *Occupational Safety and Health Review Commission*, 628 Fed. Rep., 2nd ser. 982, 988 (7th Cir., 1980), citing *Turner* v. *Secretary of Labor*, 561 Fed. Rep., 2nd ser. 82 (7th Cir., 1977); *RMI Co.* v. *Secretary of Labor*, 594 Fed. Rep., 2nd ser. 566 (6th Cir., 1979) requires ad hoc balancing to determine whether the means selected to meet the standard is feasible.
32. For examples of the costs per life saved of these and other funding decisions, see W. Rodgers, *Harvard Environ. Law Rev.* 4, 191 (1980), pp. 194–195.
33. Executive Order 12291, signed by President Reagan in early 1981, is intended, among other things, to "reduce the burdens of existing and future regulations, increase agency accountability for regulatory actions," with certain specific exclusions, through regulatory impact analysis. Such impact analysis should contain information on potential net benefits to include "evaluation of effects that cannot be quantified in monetary terms" and the identification of distributional effects.
34. T. McGarity (*17*); D. L. Bazelon, *Science* **211**, 792 (1981); J. Yellin, *Harvard Law Rev.* **94**, 489 (1981).


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