NOTES

THE RISK ASSESSMENT AND COST BENEFIT ACT OF 1995: REGULATORY REFORM AND THE LEGISLATION OF SCIENCE

In 1995, a new Republican majority swept into power in the 104th Congress, due in part to its promise to redefine and reduce the power of the federal government. As part of its proclaimed Contract with America, the Republican majority promised to increase job growth by reducing the burdens and barriers which government places on American businesses. Among the reforms proposed for governmental regulation is a requirement that all federal agencies assess the risks and costs associated with imposed regulations.[1] A major target of this reform is the massive and complex system of environmental statutes and regulations which has evolved over the last three decades.[2]

Following the growth of the environmental movement in the 1960s, Congress enacted a broad range of environmental statutes to address its concerns. Statutes and regulations were promulgated to protect clean air and water, to preserve endangered species and habitats, to regulate the manufacture, transportation, sale, use, and disposal of hazardous materials, and to clean up contaminated sites. The statutes form a broad and interrelated network which, over the past 35 years, have impacted almost every facet of our lives and economic activities.[3] Few rational observers would deny that these laws have had some very beneficial effects. Environmental efforts have achieved dramatic successes in some areas, such as the restoration of water quality in the Great Lakes.[4] Even in areas which have failed to improve, such as air quality in some urban regions, the problem is surely less than it would have been without the mandated reductions in auto emissions.[5]

The complex and pervasive regulations have also entailed costs, in terms of higher consumer prices, expansion of government bureaucracy, shrinkage of jobs in some areas of the economy, and limits on freedom of action. These substantial costs, when compared to benefits that are sometimes obscure and difficult to quantify, have led many to question whether our approach to environmental regulation has been the correct one.[6] Even prior to the current debate in Congress, lawmakers, regulatory

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1. CONTRACT WITH AMERICA 132 (Ed Gillespie & Bob Schellhas eds., 1994).
2. David Clarke, *A Contract Without Green Ink*, ENVTL. F., Jan./Feb. 1995, at 30, 32.
3. *See* WILLIAM H. RODGERS, ENVIRONMENTAL LAW (1994), at viii tbls.1-2, for an indication of the exponential increase in the number of domestic environmental laws and international environmental treaties.
4. 1990 COUNCIL ON ENVTL. QUALITY, TWENTIETH ANN. REPORT 331.
5. *Id.* at 8-9.
6. However, the evidence that environmental regulation has been economically damaging or ruinous to individual companies has frequently been anecdotal. Environmental proponents claim that independent and rigorous economic analyses of the effects of environmental regulation show that they have had little effect on both national and state economies. Stephen M. Meyer, *The Economic Impact of Environmental Regulation*, J. ENVTL. L. & PRAC., Sept./Oct. 1995, at 4, 4.

agencies, and practitioners have devoted a great deal of attention to the principles underlying environmental and health regulation, and have been rethinking what our fundamental approach to regulation should be. Out of this process have come proposals for a restructuring of the regulatory system along different lines.

Several changes in the approach to environmental regulation have been proposed in the Congress, including rewriting major laws, reducing budgets of environmental agencies, and nullifying specific regulations.[7] As a more general overall regulatory reform, bills have been proposed which will require the regulatory bodies to base their actions on reasonable considerations of risks and benefits to human health and safety, and to ensure the scientific soundness of risk assessments and risk management decisions which the agencies undertake. If enacted, these proposals will push risk assessment and risk management techniques to the forefront of environmental policy.

Part I of this note will briefly explore some of the major statutes that have been enacted in the regulatory explosion of the last 35 years and the different approaches they have taken in the protection of human health and safety, including traditional command-and-control regulation, the application of cost-benefit tradeoffs, and the development of economic approaches. Part II will look at some of the results of these approaches which some in Congress find to be unreasonable or misguided when viewed from a risk assessment framework. Part III will describe the methodologies which characterize the current state of the art in risk assessment and risk management techniques, and some of the shortcomings and problems, both scientific and political, in applying these techniques to environmental and safety issues. An example of the application of these methodologies in a particular area of environmental regulation, involving the banning of the pesticide ethylene dibromide, will illustrate some of the benefits, as well as the problems, which can result. Part IV will analyze the congressional proposals embodied in The Comprehensive Risk Assessment and Cost Benefit Act of 1995[8] for expanding the use of risk assessment and risk management in regulatory decision-making. Part V will attempt to analyze how these proposals, if enacted, will affect the functioning of regulatory agencies and the structure of our complex environmental regulatory apparatus. Finally, Part VI will discuss some of the scientific and policy problems which these proposals entail.

I. BACKGROUND IN SIGNIFICANT REGULATION

Governments have long relied on legislation to protect human health and safety from environmental threats.[9] The statutory approach preceded the common law doc-

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7. Dale E. Brooks & Sean D. Bersell, *The Climate for Change in Environmental Policy*, ENVTL. PROGRESS, Nov. 1995, at N5, N5.

8. H.R. 1022, 104th Cong. (1995). This language was also incorporated into the Job Creation and Wage Enhancement Act of 1995, H.R. 9, 104th Cong. H.R. 1022 passed the House on February 28, 1995, and H.R. 9 passed the House on March 3, 1995. Both bills were referred to the Senate Governmental Affairs Committee.

A similar bill, the Comprehensive Regulatory Reform Act of 1995, S. 343, 104th Cong., was introduced and debated in the Senate, but was not brought to a vote. Dale E. Brooks and Sean Bersell, *Congress and the Environment: 1995 in Review*, ENVTL. PROGRESS, Spring 1996, at S7, S8.

9. Statutes to protect water quality date from the fourteenth century reign of Richard II. Statute 12 Rich. 2, ch. 13 (1388) (Eng.), prohibited the disposal of filth or garbage into rivers or waterways near a town. A.S. WISDOM, THE LAW OF THE POLLUTION OF WATERS 3 (1957). Concerning air pollution, a sixteenth century proclamation of Queen Elizabeth I prohibited the burning of sea coal in London during sessions of Parliament. J.F. GARNER & R.S. OFFORD, THE LAW ON THE POLLUTION OF THE AIR AND THE PRACTICE OF ITS PREVENTION 3 (1957).

trines of private and public nuisance which began to take shape in sixteenth century England,[10] and which became the predominant approaches to environmental protection for many years. However, as is true with modern protection efforts, all of these approaches tended to be piecemeal and reactive in nature. With limited exceptions, they were unable to cope effectively with the ravages which the industrial revolution wrought upon human populations and the environment.[11] Their failure was due in part to the limitations of our notions of property and the common nature of environmental resources.[12] In addition, the sheer volume of human activity as populations have increased exponentially and the increase in per capita consumption in industrialized nations have contributed to this failure.[13]

In the late nineteenth century, the scientific study of man in relation to his environment began in Europe with the founding of the ecology movement. The original movement comprised principles of both science and philosophy, including the concepts of limited natural resources and the holistic interrelationship of man with nature.[14] These ideals were influential in the environmental movement which began to flourish in the United States in the 1960s when many scientists became concerned with the effects of pollution on public health and ecological systems and communicated their concerns to the public. The overwhelming public response to these perceived threats moved environmentalism from a fringe doctrine to a mainstream social and political force.[15]

A. Command and Control Regulation

The initial, and so far dominant, approach to environmental and health regulation has been that of command-and-control. Characteristics of this approach are a nationwide system of uniform, technology-based standards and controls, with deadlines for compliance, and which place health and safety concerns above economic considerations.[16] Such standards tend to be complex and rigid. However, flexibility can still be implemented in this approach by allowing regulatory discretion in setting deadlines and issuing variances.

The modern Clean Water Act (originally the Federal Water Pollution Control Act of 1972,[17] or FWPCA) and Clean Air Act of 1970[18] (CAA) embody this approach

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10. RODGERS, *supra* note 3, at 113.

11. *See generally* ROBERT V. PERCIVAL ET AL., ENVIRONMENTAL REGULATION 74-102 (1992) (discussing the shortcomings of public and private nuisance actions in environmental protection).

12. Garret Hardin, *The Tragedy of the Commons,* 162 SCI. 1243, 1245 (1968).

13. AMERICA'S CHANGING ENVIRONMENT, at xi (Roger Revelle & Hans H. Landsberg eds., 1970) ("One [cause of degradation of our surroundings] is undoubtedly rapid population growth, but a good case can be made that two other important villains are the increase in Gross National Product and the changing patterns of our lives.").

14. Michael M. Gemmell and Jay H. Lehr, *Ecology's Ancestry,* THE FREE-MARKET ENVIRONMENTALIST, Dec. 1990, *reprinted in* RATIONAL READINGS ON ENVIRONMENTAL CONCERNS 6, 7 (Jay H. Lehr ed., 1992) [hereinafter RATIONAL READINGS].

15. PERCIVAL, *supra* note 11, at 2.

16. These technology-based standards are often designed to be technology-forcing by setting more demanding standards than can be achieved by current technology, thus forcing industries to invest in technological development and innovation. *See* PERCIVAL, *supra* note 11, at 167. Such technology-forcing implies a certain measure of cost-benefit assessment since a polluter must weigh the expense of implementing the technology to achieve a possible limit against the alternative of ceasing operations and forgoing profits.

17. 33 U.S.C. §§ 1251-1387 (1994).

18. 42 U.S.C. §§ 7401-7671q (1994).

with differing strategies. FWPCA relies on performance and emissions standards which are applied with industry-wide uniformity.[19] The standards applied under FWPCA include both limitations of pollutant levels at point sources of emission ("end-of-pipe" regulations) and ambient water quality goals for the receiving water systems.[20] The statute and its following amendments rely heavily on the concept of "best technology," requiring that limits on emissions be at least as good as what the "best technology" can achieve.[21] The CAA relies more heavily on ambient standards and implements them in more localized attainment zones.[22]

While pollution prevention undeniably adds to the health and well-being of society, some statutes have focused more directly on protecting human health and safety rather than the environment *per se*. In spite of this more directed focus, these acts have not escaped the attention of the regulatory reformers. Increased concern for the health and safety of working people led to the passage of the Occupational Safety and Health Act of 1970[23] (OSHA). While not truly an environmental statute, it has had similar impacts on regulated industries and has been as much criticized. OSHA mandates that each employer shall "furnish to each of his employees employment and a place of employment which are free from recognized hazards . . . ."[24] It is very much in the tradition of command-and control regulation, as it requires that each employer "comply with occupational safety and health standards and all rules, regulations, and orders . . . which are applicable to his own actions and conduct."[25] Under OSHA, while safety standards are subject to a cost-benefit analysis, health standards are not. OSHA needs to show merely that a proposed health standard is technologically feasible and that it will not economically destroy the industry.[26]

Possibly one of the most rigid command-and-control regulations of all is the Endangered Species Act of 1973[27] (ESA), which effectively prohibits activities which lead to the loss of biodiversity without regard to economic considerations.[28] In pass-

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19. PERCIVAL, *supra* note 11, at 880.

20. ROBERT W. FINDLEY & DANIEL A. FARBER, CASES AND MATERIALS ON ENVIRONMENTAL LAW 256 (1991).

21. "Best technology" may take on different connotations for different types of sources or facilities. Under FWPCA, for instance, "best practicable technology" (BPT) was required for all point sources as an interim standard, with "best available technology" (BAT) standards, which are more stringent, to be achieved by the 1983 deadline. *Id.* at 256-57. The 1977 amendments to the Act (renamed the Clean Water Act or CWA) further divided pollutants into toxic, conventional, and non-conventional pollutants, and adopted a new standard of "best conventional technology" (BCT) for the conventional category. *Id.* at 257-58. While the BCT standard allowed for consideration of "economical 'reasonableness'" in setting limitations, the BAT standards were to be based on protection of public health and the provision of an "'ample margin of safety,'" without consideration of economic feasibility. *Id.* (quoting FWPCA § 307(a)(4), 33 U.S.C. § 1317(a)(4)). New or modified sources are generally subject to the stricter standards. *Id.* at 257.

22. PERCIVAL, *supra* note 11, at 768-69.

23. 29 U.S.C. §§ 651-678 (1994).

24. 29 U.S.C. § 654(a)(1) (1994).

25. 29 U.S.C. § 654(b) (1994).

26. David G. Sarvadi, *Workplace Health and Safety Regulation After 25 Years*, J. ENVTL. L. & PRAC., May/June 1995, at 24, 29.

27. 16 U.S.C. §§ 1531-1544 (1994).

28. Tennessee Valley Auth. v. Hill, 437 U.S. 153, 184 (1978) ("The plain intent of Congress in enacting this statute was to halt and reverse the trend toward species extinction, whatever the cost.").

Congress subsequently relaxed the strictures of the ESA by creating an Endangered Species Committee to consider exemptions and reasonable alternatives that are in the public interest. *See* FINDLEY & FARBER, *supra* note 20, at 84. However, it continues to be a powerful and controversial

ing this statute, Congress seemed to be recognizing both the urgency of providing protection to species on the verge of extinction, and the difficulty in quantifying the benefits of preserving biodiversity.[29] The influence of strict ecology principles in this statute is readily apparent.

B. Cost-Benefit Regulation

The use of cost-benefit analysis, while not predominant, was embodied in many early environmental statutes. The most important is the National Environmental Policy Act of 1969[30] (NEPA). It directs agencies of the U.S. Government to give "appropriate consideration" to environmental values as well as economic and technical considerations in planning and decision-making.[31] In contrast to the complex and detailed substantive regulations of the FWPCA and CAA, NEPA is written in terms of general policy goals and is essentially procedural. It has been construed to require the consideration of the environmental risks associated with all reasonable alternatives in a decision-making process.[32] NEPA also sought to improve the scientific underpinnings of environmental policy by establishing a Science Advisory Board[33] (SAB) to review research and regulations promulgated under various statutes. The Environmental Impact Statement (EIS), the methodology which NEPA mandates to accomplish its policy goals, has proved so successful that it has been widely emulated in the environmental laws of other nations.[34] While formal cost-benefit analysis is not a requirement of an EIS, and is even discouraged when important benefits cannot be quantified,[35] the decision-making process which the EIS embodies has been called "the closest thing to a generic cost-benefit rule found in U.S. domestic law."[36]

Another statute aimed directly at protecting public health and safety is the Federal Insecticide, Fungicide, and Rodenticide Act[37] (FIFRA). This is a balancing type of regulation, employing a cost-benefit approach. It bases registration of pesticides for sale and use on the finding that they pose no "unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use . . . ."[38] The Toxic Substances Control Act[39] of 1976 (TSCA) applies similar

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statute. *See* Tom Abate, *A Threatened Statute,* ENVTL. F., Mar./Apr. 1992, at 16, 17-18.

29. In the Endangered Species Act of 1973, § 2(a), 16 U.S.C. § 1531(a), Congress stated its findings that "(2) . . . [S]pecies . . . have been so depleted in numbers that they are in danger of or threatened with extinction;" and "(3) these species . . . are of esthetic, ecological, educational, historic, recreational, and scientific value to the Nation[.]"

30. 42 U.S.C. §§ 4321-4370d (1994).

31. 42 U.S.C. § 4332(B) (1994).

32. Natural Resources Defense Council v. Morton, 458 F.2d 827, 834 (D.C. Cir. 1972).

33. 42 U.S.C. § 4365(a) (1994).

34. RODGERS, *supra* note 3, at 810. The concept of environmental impact assessment has also taken root in international conventions and declarations concerning global environmental protection. *See, e.g.,* UNITED NATIONS CONFERENCE ON ENVIRONMENT AND DEVELOPMENT, RIO DECLARATION ON ENVIRONMENT AND DEVELOPMENT, Principle 17, U.N. Doc. A/C.151/26 (Vol. 1) (1992), *revised by* U.N. Doc. A/C.151/51 Rev. 1 (1992), 31 I.L.M. 874 (1992); Protocol on Environmental Protection to the Antarctic Treaty, Oct. 4, 1991, Art. 8, 30 I.L.M. 1461 (1991).

35. 40 C.F.R. § 1502.23 (1995).

36. RODGERS, *supra* note 3, at 811.

37. 7 U.S.C. §§ 136-136y (1994), (originally the Federal Environmental Pesticide Control Act of 1972).

38. 7 U.S.C. § 136(bb) (1994), *amended by* Food Quality Protection Act of 1996, Pub. L. No. 104-170, §§ 230(a), 304, 110 Stat. 1489, 1508-12 (1996).

39. 15 U.S.C. §§ 2601-2692 (1994).

criteria to the regulation of the manufacture of toxic chemicals, requiring the Environmental Protection Agency (EPA) to consider both the benefits and risks of a chemical in formulating its regulations.[40]

C. Economic Approaches

A later development, intended to overcome the rigidity and economic inefficiency of the command-and-control approach, was the introduction of incentive-based regulation. This approach uses market forces to encourage reductions in pollution by making it more expensive for polluters to continue to discharge. This approach had been considered early in the development of environmental law, with discussions taking place as early as 1965 concerning pollution taxes.[41] Little progress in this area took place, however, until the EPA, forced by non-attainment of air quality standards in many areas, developed an offset program to enable the issuance of new source permits in these areas.[42] Congress adopted this approach legislatively in the 1977 CAA amendments.[43]

The offsets allow a polluter to obtain a permit for a new emissions source in a non-attainment area if it can obtain offsetting emissions reductions from other sources in the same area.[44] The program encouraged the trading of offsets, so that the polluter with the greatest economic incentive could purchase the right to operate a new source.[45] In support of this approach, the EPA believed that the early command-and-control and cost-benefit regulations had been successful in forcing technology and providing rapid progress, but that future regulation should focus more closely on economic efficiency.[46] Congress adopted a similar approach in the emissions allocation and transfer allowances dealing with acid rain, enacted in the 1990 CAA amendments.[47] However, opposition to further expansion of the economic incentive approach has come from both environmental groups and industry.[48]

A more burdensome economic approach, the "polluter pays" principle, is at the heart of the Comprehensive Environmental Response, Compensation, and Liability

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40. 15 U.S.C. § 2605(c)(1) (1994) provides:
> In promulgating any rule . . . with respect to a chemical substance or mixture, the Administrator shall consider and publish a statement with respect to—
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> (A) The effects of such substance or mixture on health and the magnitude of the exposure of human beings to such substance or mixture,
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> (B) The effects of such substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture,
>
> (C) The benefits of such substance or mixture for various uses and the availability of substitutes for such uses, and
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> (D) The reasonably ascertainable economic consequences of the rule, after consideration of the effect on the national economy, small business, technological innovation, the environment, and public health.

41. PERCIVAL, *supra* note 11, at 173.
42. *Id.* at 174.
43. 42 U.S.C. §§ 7501-7505 (1994).
44. 42 U.S.C. § 7503(a)(1)(A) (1994).
45. PERCIVAL, *supra* note 11, at 174.
46. *Id.* (citing *Status of the Programs and Policies of the Environmental protection Agency, Hearing before the Subcomm. on Environmental Pollution of the Senate Comm. on Public Works*, 95th Cong. 9 (1977) (remarks of Russell Train, Administrator, USEPA)).
47. 42 U.S.C.A. §§ 7651-7651o (1994).
48. *See* PERCIVAL, *supra* note 11, at 176.

Act[49] (CERCLA or the Superfund Act), a massive environmental statute designed to repair the effects of past pollution. Its purpose is to designate responsibility for cleanup of severely contaminated sites, implement cleanup programs, and assess liability for the cost of cleanup on parties which are potentially responsible for the environmental damage.[50] Under CERCLA, when the government discovers that a release of contaminants or pollutants has taken place or is imminent, it may undertake the cleanup itself and assess liability on responsible parties.[51] The Act also allows responsible parties which have undertaken a cleanup to recover costs from other responsible parties.[52]

With its strict and broad-based liability, CERCLA has many similarities to the command-and-control approach.[53] At the same time, its site assessment provisions for remedial actions incorporate many of the features of risk analysis. It requires the government, before carrying out a remedial action under § 9604, to "conduct an assessment of permanent solutions and alternative treatment methodologies[,]" which takes into account, among other things, "the persistence, toxicity, mobility, and propensity to bioaccumulate of such hazardous substances and their constituents; . . . [the] short- and long-term potential for adverse health effects from human exposure; . . . [and] long-term maintenance costs . . . ."[54] Recently, the EPA has expanded the scope of risk assessments at Superfund sites to go beyond the risk to human health and to include assessment of ecological risk, such as toxic harm to the environment.[55]

D. Comparison of Regulatory Approaches

Common themes among the proponents of the command-and-control approach are that environmental quality is a public good for its own sake, and that government is most effective as a regulator in an arm's-length or even adversarial relationship with the regulated entities. The initial attraction to the command-and-control approach lay in the belief that uniform, technology-based standards would be easiest for regulators to develop and monitor.[56] The EPA viewed this approach as a way of focusing the efforts of industry and forcing rapid progress in environmental compliance at the cost of some efficiency.[57]

Some critics of coercive regulation, however, perceived this approach as having inevitably grown out of the philosophical roots of the ecology movement. In their view, the holistic concept of man's relationship with nature creates an anti-industry bias

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49. 42 U.S.C. §§ 9601-9675 (1994).

50. Potentially responsible parties include current owners and operators of contaminated sites, persons who were owners or operators at the time hazardous substances were disposed of at the site, persons who arranged for transportation or disposal of the substances, and persons who accepted the substances for transportation or disposal. PERCIVAL, *supra* note 11, at 290-91.

51. 42 U.S.C. § 9604(a) (1994).

52. 42 U.S.C. § 9607(a)(4)(B) (1994).

53. The Superfund Amendments and Reauthorization Act of 1986 (SARA), Pub. L. No. 99-499, 100 Stat. 1613, instituted goals and deadlines to force action on cleanup of listed hazardous waste dumps, similar to the approaches of the early command-and control statutes. SARA also incorporated stricter state standards in states which have more severe standards than the federal government, and it increased civil and criminal penalties for Superfund violations. Charles Davis, *Approaches to the Regulation of Hazardous Waste*, 18 ENVTL. L. 505, 512 (1988).

54. 42 U.S.C. § 9621(b)(1) (1994).

55. Cris Williams, *Using Ecological Risk Assessment Methods*, ENVTL. PROTECTION, Jan. 1994, at 92, 93.

56. PERCIVAL, *supra* note 11, at 161.

57. *Id.* at 173.

which, coupled with the distributional problem of limited resources, favors a forced solution to the pollution problem.[58]

The command-and-control approach has been subject to other criticisms as well. Opponents of technology-based limitations charge that they, in effect, prescribe the use of particular technologies in complying with limitations, and that this inhibits innovation by not providing any incentive for developing more effective technologies.[59] Industrial targets of regulation claim that the uniformity in the regulations and lack of flexibility to individualize them for specific applications cause a great waste of resources in compliance efforts.[60] They also emphasize the lack of realistic priorities and economic efficiency.[61] While industry projections of the cost of compliance with regulations have generally proved to be greatly exaggerated,[62] these criticisms have brought a great deal of pressure for legislation and regulations which respond more favorably to economic concerns.

While the cost-benefit types of statutes still maintain an arm's-length relationship between the regulatory agencies and the regulated entities, they are less adversarial in nature than the command-and-control approach. They allow for more input from the regulated entities into the process, and allow the regulatory bodies wider latitude on issues of reasonableness and feasibility. They also depart further from the principles of the ecology movement by lessening the importance of environmental quality as an end in itself, and treating it more as a means to promote public health and safety.

The approach embodied in the cost-benefit type of statutes involves obvious difficulty in quantifying some environmental benefits. The history of environmental regulation indicates that traditional economic analysis has "systematically undervalued natural resources."[63] It has also been criticized as "single purpose planning"[64] which subordinates important environmental values to economic considerations. This last criticism may be less valid with NEPA due to the broad range of alternatives which the statute forces the regulatory bodies to consider. It is more valid with FIFRA and TSCA, but even here the regulators may be allowed discretion to consider other values by defining what is an "environmental cost" or a "reasonable risk" to the environment.[65] However, to the extent this discretion is implemented, the regulations will

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58. *See* Gemmell & Lehr, *supra* note 14, at 11. The article is strident in tone, comparing the ecology movement to the rise of German Nazism without providing any foundation for the comparison. However, the connection between the principles of the ecology movement and command-and-control regulation is a logical one. The theme that the problem of limited resources requires a coercive solution is also sounded by Hardin, *supra* note 12, at 1248.

59. The argument is that by prescribing specific technologies to be used which are already in existence, a company has no incentive to search for a more effective means of control unless it will be cheaper. PERCIVAL, *supra* note 11, at 166.

60. Bruce Ackerman & Richard Stewart, *Reforming Environmental Law: The Democratic Case for Market Incentives*, 13 COLUM. J. ENVTL. L. 171, 173 (1988).

61. *Id.* at 174-75.

62. PERCIVAL, *supra* note 11, at 167.

63. SCIENCE ADVISORY BD., U.S. EPA, REDUCING RISK: SETTING PRIORITIES AND STRATEGIES FOR ENVIRONMENTAL PROTECTION (1990), *quoted in* Robert F. Blomquist, *The EPA Science Advisory Board's Report on "Reducing Risk": Some Overarching Observations Regarding the Public Interest*, 22 ENVTL. L. 149, 162 (1992).

64. Harold Gilliam, *The Fallacy of Single Purpose Planning*, *in* REVELLE & LANDSBERG, *supra* note 13, at 67, 68.

65. For example, EPA procedures require mitigative measures to be taken, such as limiting application areas, if use of a pesticide jeopardizes an endangered species listed under ESA. U.S. EPA Standard Operating Procedure No. 3065.1.

retain some of the characteristics of the command-and-control approach which led to the original inefficiency. As political pressures grow to increase the reliance on cost-benefit balancing and improve the economic efficiency of regulation, the danger may arise that too little consideration will be given to the broader range of environmental values.

The economic incentive approach to regulation embodied in the offsets programs represents closer cooperation between government and industry than either the command-and-control or the cost-benefit approach. Proposals to broaden this type of regulation include the assessment of charges on polluting activities,[66] the establishment of a market in emissions rights similar to the offsets program,[67] and subsidies, such as tax incentives, for emissions reductions or the installation of pollution control equipment.[68] Their unifying theme is that they would improve the economic efficiency of regulation by directing the resources employed in reducing pollution to the applications in which they are most economically valuable.

This approach also departs further from the ideals of the ecology movement by treating clean air and water as tradeable commodities. The proponents of ecological values see these types of regulations as providing licenses to pollute, and as allowing disparate impacts on different areas by permitting higher emissions in areas where reduction costs would be greater.[69] Beside the basic criticism that market-based incentives may not be entirely effective due to market imperfections,[70] other criticisms have been raised. Some industry representatives oppose such measures because they would reallocate existing emissions rights, creating losers as well as winners. There are further questions as to whether such regulations would be any easier for regulatory bodies to administer than the present approaches.[71]

The present web of environmental laws represents the interaction, conflict and accommodation of different value systems, social goals, and pecuniary interests of the various stakeholders in the regulatory process. So far, no single approach has provided either a totally effective or mutually acceptable solution to the environmental problem, but questions remain as to whether the best approach has been applied in each given situation, and whether a more unified overall approach would lead to greater success.

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66. CHARLES L. SCHULTZE ET AL., SETTING PRIORITIES: THE 1973 NATIONAL BUDGET (1972), *in* FINDLEY & FARBER, *supra* note 20, at 348.

The only "federally imposed pollution tax" so far is the excise tax imposed on chlorofluorocarbons (CFCs) as part of the effort to phase out their manufacture. It may have been enacted as much for revenue production as for its environmental incentive function. *See* Paul Scodari, *Time to Rebuild the Structure,* ENVTL. F., Mar./Apr. 1991, at 18, 19-20.

67. EDWARD I. SELIG, EFFLUENT CHARGES ON AIR AND WATER POLLUTION: A CONFERENCE REPORT OF THE COUNCIL ON LAW RELATED STUDIES (1973), *in* FINDLEY & FARBER, *supra* note 20, at 358.

68. PERCIVAL, *supra* note 11, at 151.

69. *Id.* at 176.

70. For criticism of the incentive-based approach and support for the command-and-control approach, see Sam Hays, *Emissions Trading Mythology,* ENVTL. F., Jan./Feb. 1995, at 14, 20 ("The biologists and geologists are looking for real reductions in emissions and the engineers are offering ways to bring them about. The economists offer cost and income choices that bear only an indirect and often fuzzy relationship with the real world of ecological circumstance.").

71. PERCIVAL, *supra* note 11, at 176.

II. SPECIFIC PROBLEMS GIVING RISE TO THE NEED FOR REGULATORY REFORM

The current state of environmental regulation has led to regulatory decisions and allocation of resources which many find irrational and difficult to understand. Apart from the tremendous cost and complexity, the criticism that has been gaining the most force recently is that our present approach does not set priorities in terms of actual risk to human health or environmental quality, or in terms of the actual benefits produced by a regulation in relation to the expenditure of resources that its implementation requires.[72]

The clamor against present regulatory priorities has grown in response to certain specific examples of the effects of regulation. Among the most highly criticized actions have been cleanup enforcements under the Superfund Act. These actions receive a high profile, both because they often involve a very high cost, and because the Superfund Act is essentially a "no-fault" program which may assess liability regardless of actual responsibility for the contaminated site.[73] However fair or unfair the provisions of Superfund may be on assessing liability, the valid criticism from the risk assessment perspective is that the costs of mandated cleanups are out of all proportion to the actual risk which the sites present to human health.[74]

Another cited instance of regulatory irrationality is the ban on the chemical pesticide and soil fumigant ethylene dibromide (EDB). Use of this chemical was banned when minute residues began to show up in food products.[75] However, many naturally occurring substances in ordinary food products create greater dietary risks than those posed by the EDB residues which led to its ban.[76] Such examples fuel the notion that resources are being wasted by addressing risks that are small, while greater risks are ignored.

A third example involving the growth regulator Alar exemplifies the influence of media attention on risk perception. Critics charge that a media "campaign" greatly overstated the risk from this relatively harmless chemical, and led to an unjustified ban in 1989.[77] The media concentrated its coverage on environmental groups which had an interest in pushing for the ban, and ignored the recommendations of responsible scientists, Congress, the EPA, and the agricultural industry.[78] The distorted public perception which resulted from the media coverage led to a ban which ultimately cost

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72. Scodari, *supra* note 66, at 22.

73. Alfred R. Light, *Déjà Vu All Over Again? A Memoir of Superfund Past*, NAT. RESOURCES & ENV'T., Fall 1995, at 29, 32.

74. In *United States v. Ottati & Goss, Inc.*, 900 F.2d 429 (1st Cir. 1990), the EPA sought to enforce a $9.3 million cleanup to reduce PCB levels from 50 p.p.m. to 20 p.p.m., which was "a very high cost for very little extra safety." *Id.* at 441. Congressional critics point to this as the type of Superfund litigation which cries out for regulatory reform. 141 CONG. REC. H2256 (daily ed. Feb. 27, 1995) (remarks of Rep. Rohrabacher).

75. *See infra* text accompanying notes 133-46 for a description of the regulatory response which led to the banning of EDB.

76. For example, the dietary risk from the levels of the naturally occurring substance aflatoxin that are found in peanut butter is 75 times greater than the risk which led to the EDB ban. 141 CONG. REC. H2278 (daily ed. Feb. 27, 1995) (remarks of Rep. Roberts).

77. Jane S. Shaw, *Is Environmental Press Coverage Biased?*, *in* RATIONAL READINGS, *supra* note 14, at 474, 476.

78. 141 CONG. REC. H2278 (daily ed. Feb. 27, 1995) (remarks of Rep. Roberts).

the industry $400 million.[79]

A fourth example is the ban on asbestos and the removal of asbestos materials from schools.[80] While the removal cost is enormous, there is scientific disagreement as to whether the removal process itself creates a greater risk of exposure than leaving the asbestos in place.[81] The EPA responses to Alar and asbestos were both seen as responses to public pressure rather than reasoned scientific analysis.[82]

Besides these specific examples of flawed regulation, many environmental laws and regulations, arising from different interests and pressures and adopting different approaches, are overlapping, confusing, and conflicting.[83] The result has been a wide variation in the amounts of resources expended, or social costs born, in the regulation of different hazards which provide the same benefits in the reduction of health or ecological risk. For instance, in terms of social costs, the estimated costs in dollar amounts per premature death averted range from a modest $200,000 for the achievement of trihalomethane standards in drinking water to an extreme $5.7 billion for the listing of wood preservative chemicals as hazardous waste.[84] Even given the uncertainty in these estimates, such a disparity indicates an inefficient allocation of scarce resources.

Of course, many additional factors may go into the decision to regulate a particular hazard at a particular time, and it is impossible to say that a disparity between any two specific regulations is the direct result of the factors listed above and no others. It may even be questionable to use such dollar comparisons as a measure of efficiency or value of a regulation. Nevertheless, these types of comparisons solidify the convictions of those who believe that many regulations are unnecessarily burdensome and harmful

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79. *Id.*

80. The Asbestos Hazard Emergency Response Act of 1986, 15 U.S.C. §§ 2641-2656 (1994), requires school administrations to inspect schools for asbestos hazards and develop response plans to mitigate hazards, possibly including removal.

81. Lester B. Lave, *Health and Safety Risk Analyses: Information for Better Decisions*, 236 SCI. 291, 292 (1987).

> The probability of children getting mesothelioma or lung cancer from such asbestos exposure in school is estimated to be about five per million lifetimes, less than 1/5000 the chance of death faced by these children from other current events in their lives. . . . Careless removal of asbestos, however, can pose major risks to the workmen as well as to the children; many experts believe that asbestos in good repair ought to be left in place and removed only when there is a major renovation or a building is demolished.

Id. (footnotes omitted). *See also* Malcolm Ross, *Minerals and Health: The Asbestos Problem*, *in* RATIONAL READINGS, *supra* note 14, at 101, 110.

82. 141 CONG. REC. H2258 (daily ed. Feb. 27, 1995) (remarks of Rep. Brown).

83. An example is the conflict between TSCA and the Resource Conservation and Recovery Act (1976 Amendments to the Solid Waste Disposal Act (SWDA), 42 U.S.C.A. §§ 6901-6992 (West 1995 & Supp. July 1996), also known as RCRA). Congress applied both of these statutes to regulate the disposal of polychlorinated biphenyls (PCBs). However, the statutory schemes have different requirements, which cause administrative difficulties. TSCA regulations established a separate permitting system for incinerators and landfills for PCB disposal. While some RCRA-permitted disposal facilities may have the technological capability to dispose of PCB's in accordance with TSCA requirements, they would have to go through a separate approval process before they could accept PCB's for disposal. This creates greater expense and deterrence to providers of PCB disposal facilities. *See* OFFICE OF TECH. ASSESSMENT, CONGRESS OF THE UNITED STATES, TECHNOLOGIES AND MANAGEMENT STRATEGIES FOR HAZARDOUS WASTE CONTROL 92-93 (1983).

84. Vernon R. Rice, *Regulating Reasonably*, ENVTL. F., May/June 1994, at 16, 23.

to business and the economy.[85]

III. THE CURRENT STATE OF RISK ASSESSMENT AND RISK MANAGEMENT METHODOLOGIES

Risk assessment and risk management are proposed as methods to scientifically evaluate the true nature of potential environmental harms, and rationally and efficiently direct resources to protect the public from the greatest risks to health and welfare. The EPA itself has been a strong proponent of risk assessment in certain areas as a "scientific" way to promote realistic, objective, and balanced regulation.[86] Whether these tools in their present state can effectively achieve these goals in a broader application depends on the applicability of the methodologies which have been developed thus far.

A. Steps in Applying Risk Assessment

Risk assessment methodologies may vary from application to application, but similarities exist. The general methodology is usually described as having four steps, with similar functions in each application. These steps are hazard identification, exposure pathway assessment, dose-response assessment, and risk characterization.[87]

Risk itself is defined generically as a compound measure of the probability and magnitude of an adverse effect. It contains components relating to both the likelihood of a harm occurring and the extent of its consequences.[88] The extent of harm may be defined as an increased incidence of premature deaths or illnesses among populations, an increased likelihood of illness or death for an individual, an expected number of years of shortened lifespan, a lifetime loss of earnings potential, or other measures. The basic purpose of expressing risk is to quantify the potential environmental harm to be incurred or avoided by implementation of a specific policy or regulation.[89]

Hazard identification is the first phase in the process of assessing risk. This requires identifying the agent in the environment which may cause harm and assessing the evidence which associates exposure to the agent with the resulting harm.[90] Such evidence may come from epidemiological studies, animal studies, studies based upon

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85. *Id.* at 16.

86. Mark Eliot Shere, *The Myth of Meaningful Environmental Risk Assessment*, 19 HARV. ENVTL. L. REV. 409, 412 (1995) (citing EPA RISK ASSESSMENT COUNCIL, GUIDANCE FOR RISK ASSESSMENT 4 (Nov. 1991)).

87. This is the nomenclature I have adopted as representative of various descriptions in the literature. Regardless of the nomenclature used, functions of the four steps are very similar in the implementation of risk assessment in different applications. See, for example, the methodology outlined in Milton Russell & Michael Gruber, *Risk Assessment in Environmental Policy Making*, 236 SCI. 286, 286 (1987), concerning the regulation of toxic chemicals. Compare the model of risk assessment in CHARLES A. WENTZ, HAZARDOUS WASTE MANAGEMENT 21-22 (1989), involving designation of hazardous waste.

In assessing the hazard due to contaminated sites regulated under RCRA and CERCLA, the EPA includes a fifth step which involves analyzing the effects of variability and uncertainty in the other steps of the audit. In other approaches, this is done in the risk characterization step. *See* David E. Burmaster & Jeanne W. Appling, *Introduction to Human Health Risk Assessment, with an Emphasis on Contaminated Properties*, 25 Env't. Rep. (BNA) 2431, 2432 fig.2 (Apr. 7, 1995).

88. WILLIAM W. LOWRANCE, OF ACCEPTABLE RISK 70 (1976).

89. A more narrow definition of risk is the magnitude of the harm times its probability of occurrence. Technically, this is the expected value (or expected cost) of the adverse effect. This is a useful definition and often is what is effectively used in practice. However, it is too narrow as a generic definition, particularly in cases where actual probabilities are too uncertain to quantify. *See* EDMUND A. C. CROUCH & RICHARD WILSON, RISK/BENEFIT ANALYSIS 9-11 (1982).

90. Russell & Gruber, *supra* note 87, at 286.

the effects of a harmful agent on human or animal cells *in vitro*, or comparison with known effects of a related harmful agent with a similar chemical structure.[91] It may also require consideration of circumstances or conditions present which affect the potential for harm to people or the environment.[92] In general, this step outlines the nature and extent of the hazard to be addressed.[93]

The second step, exposure pathway assessment, analyzes the pathways by which a harmful agent may migrate from its source to a receptor, such as a person.[94] A source may be a hazardous waste landfill, a pesticide applied to a food crop, or a nuclear power plant. In cases of toxic chemicals, the pathway may include actual entry mechanisms such as inhalation, ingestion, or skin contact,[95] whereas in harmful agents such as radiation, it may involve simple exposure. If there is no barrier to prevent an exposure, by either the agent moving to the receptor or the receptor moving into contact with the agent, it is a complete pathway.[96] If no complete pathways exist, there can be no exposure and no risk related to the source.[97] Exposure pathway assessment may also require the estimation of the dose which may be delivered along the pathway.[98]

The third step, dose-response assessment, attempts to quantify the harmful effect which a delivered exposure to a certain quantity of a harmful agent may have on the receptor.[99] In addition to dosage, which measures the intensity of exposure, the dose-response assessment must account for frequency and duration of exposure. With many agents, large doses over a short period can be less harmful than low doses over a long

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91. OFFICE OF TECH. ASSESSMENT, CONGRESS OF THE UNITED STATES, ASSESSMENT OF TECHNOLOGIES FOR DETERMINING CANCER RISKS FROM THE ENVIRONMENT 113 (1981).

92. For example, in toxic site assessment, the determination of extent and depth of contamination is part of the hazard identification step. Burmaster & Appling, *supra* note 87, at 2432.

93. *Id.*

94. *Id.* at 2434.

95. *Id.* at 2435.

96. *Id.* at 2434.

97. *Id.*

98. *Id.*

99. The evaluation of the response to a given dose of a harmful agent will depend on how the dose is defined. There are three common ways to characterize dose: exposure dose, absorbed dose, and biologically effective dose (BED). In toxic chemical exposure, for example, exposure dose measures the total weight of chemical entering the body through an exposure pathway, without regard to how much may be eliminated from the body without being metabolized and absorbed. *Id.* at 2435. Absorbed dose is the amount of chemical which is absorbed and metabolized, and is always smaller than the exposure dose. *Id.* BED is the amount that may reach a sensitive organ and cause actual biological damage. *Id.* Exposure dose is most frequently encountered since it is usually easiest to measure.

The proper definition of dosage is important in characterizing risk to a population in a scientifically sound manner. A vague or incorrect definition of dosage may lead to improper assessment of risk and subsequent poor decision-making. This is evident in the measurement of dosage for radiation exposure, which mirrors the distinction in chemical exposure. Radiation exposure is measured in Roentgen units, which measure the total energy which an ionizing radiation can deliver to an object by passing through it, whether or not it is absorbed. Radiation absorbed by an object is expressed in rads (radiation absorbed dose), which measure the ionizing energy actually absorbed by the object. The dose equivalent is expressed in rems (Roentgen equivalent in man), to account for the fact that different types of radiation which deliver the same ionizing energy to an object may produce different biological effects. The dose equivalent for a certain type of radiation is found by multiplying the absorbed dose in rads by the Relative Biological Effectiveness (RBE) factor. The RBE for x-rays and electrons is 1, for slow neutrons is 5, and for alpha radiation is 20. Since the dose equivalent measures the actual biological effect on the human body, limits on occupational exposure to radiation are expressed in rems, and this is the exposure which must be measured and tracked for persons working in a radiation environment. *See* DAVID HALLIDAY & ROBERT RESNICK, FUNDAMENTALS OF PHYSICS 1089-90 (1988).

time period.[100] Risk assessment in environmental policy therefore tends to be less concerned with acute, short-term effects, and focuses more on chronic exposures over periods ranging from one year to a lifetime.[101] However, high, short-term exposures may still present serious health risks which can affect the response assessment.[102]

The dosage response itself is usually expressed in terms of risk similar to those previously discussed, e.g., shortened life expectancy, increased incidence of cancer above background levels, or similar harm, in response to a given exposure at a given frequency over a given duration. Uncertainties in the dose-response relationship arise from many sources: variations in response from person to person, differences in response between humans and experimental animal subjects, and uncertainties in knowing the maximum safe exposure level to an agent.[103]

The fourth step of the risk assessment process, risk characterization, combines the information in the previous steps to quantitatively define the overall health risk due to the source in terms of magnitude and likelihood.[104] Depending on the type of risk being analyzed, the "output" of this step may be expressible in numerical terms, such as a total hazard index or an incremental lifetime cancer risk due to use or presence of a certain chemical.[105] For less easily quantifiable risks, the characterization may present a description of possible effects or scenarios and their likelihoods. This step should also describe for the risk manager the major assumptions used in the assessment and the remaining uncertainties which cannot be easily quantified.[106]

B. Problems in Applying Risk Assessment

While these methods help to improve the understanding of the true nature of the harm presented by an environmental agent, and can help to shape regulatory responses and programs, their use as predominant decision-making tools raises some fundamental concerns. Many scientists question whether the state of scientific knowledge is sufficiently advanced to support the guidelines which have been developed even in areas where risk assessment methodology has been applied, such as carcinogen risk assessment.[107] Some see it by its very nature as a "limited methodology" that was developed in the context of hazardous chemical exposure, and not suitable in its present state of development to be pushed beyond this application.[108] In fact, the EPA has

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100. Burmaster & Appling, *supra* note 87, at 2435.

101. *Id.*

102. *Id.*

103. These uncertainties are often handled by setting a "reference dose" (RfD) level at a level somewhere below the lowest dosage known to produce the harmful effects. *Id.* at 2432. This lowest dosage, known as the Lowest Observed Adverse Affects Level or LOAEL, is often divided by 10 to arrive at the RfD. *Id.* at 2432-33.

A different approach is taken for carcinogens, which are assumed to have no safe exposure level. For these substances, the response is assumed to be a linear relationship between the lowest observed dosage which produces an effect, and zero dosage. This relationship is called the cancer slope factor (CSF) and is used to estimate human response to a carcinogen at low exposure levels. *Id.* at 2433.

104. Note that a statistical element is present in all three previous phases of the risk assessment methodology. Statistical treatment may be appropriate in the hazard identification step (probability of a release), the pathway assessment (probability of propagation along a pathway), and dose-response assessment (probability and magnitude of harm resulting from a given exposure).

105. Burmaster & Appling, *supra* note 87, at 2436.

106. Russell & Gruber, *supra* note 87, at 286.

107. *Id.* at 287.

108. Paul A. Locke, *Regulatory Reform and the Myth of "Realistic Risk,"* ENVTL. F., Jan./Feb.

found it difficult to perform rigorous quantitative risk assessments outside of cancer risks.[109] Even within this context, risk assessment in its present state is inadequate to analyze the interrelated effects of multiple chemical exposure, or the effects of other biological factors.[110]

Another concern is that, since the methods rely heavily on the use of statistical analysis and inference, they are subject to the assumptions and requirements of statistical methods in general. The application of statistical methods requires, either explicitly or implicitly, the construction of statistical models.[111] Different models may give widely varying statistical results from the same data, and the validity of the result depends on how well the assumed model reflects the real world.[112]

Reliable statistical analysis also requires a sufficient quantity of data to make meaningful tests within acceptable limits of error. When risk analysis attempts to evaluate a health effect which has a very low incidence of occurrence in the population, it is often very difficult to obtain an adequate sample size or other data sufficient to support an inference.[113]

When the low incidence of occurrence of a certain harm is coupled with the potential for catastrophic damage, it leads to the risk assessment problem known as the "zero-infinity" dilemma. This problem relates to certain environmental hazards which have common characteristics that magnify the dangers of a threat in the public perception. It complicates and often politicizes the task of the agency responsible for regulating them. The four characteristics are: a poorly understood mechanism by which the harm operates, a potentially catastrophic cost, a relatively modest benefit, and a very low subjective probability of occurrence of the harm.[114] Examples of such risks are nuclear power accidents, exposure to certain toxic chemicals, and atmospheric ozone depletion.[115] The extreme example is the "zero-infinity" case: a threat which has a negligible chance of occurrence, but overwhelmingly catastrophic consequences. The

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1995, at 35.

109. PERCIVAL, *supra* note 11, at 660.

110. *Id.*

111. CROUCH & WILSON, *supra* note 89, at 52.

112. THE CONSERVATION FOUNDATION, RISK ASSESSMENT AND RISK CONTROL 26 (1985).

113. There are two basic sources of error when evaluating a proposed hypothesis through statistical analysis. These are the erroneous rejection of a hypothesis when it is true and the erroneous retention of a hypothesis when it is false and should be rejected. The smaller the sample size in the analysis, the greater the probability for *each* type of error, all other factors being equal. *Cf.* JAY L. DEVORE, PROBABILITY AND STATISTICS FOR ENGINEERING AND THE SCIENCES 280-87 (1987).

In addition to the large amount of data required for valid hypothesis testing, there are other common problems in the application of statistical analysis to the environmental area. These include the possibilities of large measurement errors, missing or suspected values in the data set, data values close to or below the detectable limits of measurement, the need to measure more than one variable at a time, complicated cause-effect relationships, and complex trends in data over time or distance. RICHARD O. GILBERT, STATISTICAL METHODS FOR ENVIRONMENTAL POLLUTION MONITORING 3 (1987).

114. Talbot Page, *A Generic View of Toxic Chemicals and Similar Risks*, 7 ECOLOGY L.Q. 207, 208-09 (1978).

115. *Id.* at 208. Not all the characteristics are equally prominent in each type of risk. For example, the benefits of nuclear power may not be modest, but they may be perceived to be relatively modest in comparison to the potential harm. On the other hand, the benefit from the use of a food coloring agent may be very modest compared to the risk of carcinogenicity. Similarly, the causes of a nuclear accident may be better understood than the mechanism of action of a carcinogen, though as the Three-Mile Island disaster showed, the scenario leading up to a nuclear accident can be unpredictable. *See* PRESIDENT'S COMMISSION ON THE ACCIDENT AT THREE MILE ISLAND, THE NEED FOR CHANGE: THE LEGACY OF TMI 27-33 (1979).

uncertainties involved in dealing with such an issue are so great that the agency is unable to make any quantitative assessment of the harms and benefits. An agency is then forced to either ignore the possibility in its analysis or make an arbitrary judgment that even a negligible risk will not be tolerated.[116]

A reliance on risk assessment as a predominant decision tool also raises some of the concerns of "single purpose planning" raised in objection to the cost-benefit approach described *supra*. By focusing on human health and efficient allocation of resources, the methodology may ignore or derogate other important ecological principles. Finally, some critics maintain that scientific principles cannot take the place of values and equity in policy and decision-making.[117]

C. The Function of Risk Management

Ideally, risk assessment provides a scientific and quantitative measure of the potential for harm to human health or the environment from a particular problem. Risk management is the process of using this information to make decisions, set priorities, and communicate the results to affected stakeholders. Risk management must take into account the economic, political, social, cultural, and perceptual factors which surround the problem.[118] It must also take note of the limitations on action imposed by statutes, budgetary constraints, political realities, lack of complete information, and uncertainties in what is known.

Risk management may include the use of cost-benefit analysis in setting regulatory policy when costs and benefits can be adequately quantified. However, when the benefit is in terms of health or longevity, this leaves many people uncomfortable with what seems to be the placing of a dollar figure on the value of preventing a premature death, or some similar approach.[119] The more productive use of risk assessment by an agency may be in setting priorities for its internal actions, or in using the results to influence the setting of priorities which are externally imposed.[120] Comparisons of risks for various options and alternatives can lead to the greatest reduction in total risk for a certain expenditure level.[121]

The other common use of risk management has been to design regulations, in terms of deciding which harms to address and how stringent a level of control to apply.[122] When a particular harmful agent may be introduced into the environment by various pathways, and these different mechanisms may have widely different impacts in terms of magnitude and likelihood, comparative risk assessment can shape the regu-

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116. The first approach was taken by the Nuclear Regulatory Commission (NRC) in assessing the impact of a class nine (breach of reactor containment) nuclear disaster. Its exclusion of this impact from the EIS was upheld in *Carolina Environmental Study Group v. United States*, 510 F.2d 796 (D.C. Cir. 1975). The second approach is exemplified by the Delaney clause of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 348(c)(3) (1994), prohibiting the use of any food additive which shows evidence of carcinogenicity in animals.

117. For example, the equitable sharing of risks may be as important a principle as the minimization of risks. *See* David Clarke, *Looking at Risk*, ENVTL. F., Mar./Apr. 1991, at 12, 16.

118. WENTZ, *supra* note 87, at 22.

119. *See* David Corn, *Benefits Package*, 260 THE NATION 441, 442 (1995) ("'Do we really want to take as our model E.P.A.'s estimate, in doing its cost-benefit analysis of cutting lead levels in drinking water, that each lowered I.Q. point costs a child $4,588 in lost earnings?'") (quoting testimony of Carl Pope, executive director, Sierra Club, on H.R. 1022).

120. Russell & Gruber, *supra* note 87, at 287.

121. *Id.*

122. *Id.*

lations to place priority on the most severe risks. This can improve the efficiency of regulation and minimize economic and social costs to the regulated entities and the consuming public.[123]

Beyond decision-making and setting of priorities, an important function of risk management is to adequately communicate the knowledge about risks which risk assessment produces. This communication function has two dimensions. The first is to inform policy makers of the risk-related effects of their policy choices and selections among alternatives. This will aid them in determining what level of risk is acceptable and which alternatives will provide an adequate level of safety.[124]

The second dimension is to communicate realistic risk information to the public concerning the policy choices being made. It is important in this undertaking that the public should recognize that no choice can eliminate all risk.[125] Using the results of risk assessment, the presentation can include comparisons which indicate the true severity of risk associated with each policy alternative. However, mere comparisons, if not carefully presented, can manipulate the public perception and be misleading.[126] To avoid this result, the presentation should express risks in a familiar context and provide some indication of the uncertainties involved in the assessment process. It should also be sensitive to public concerns by including non-quantitative information on such factors as voluntariness, catastrophic potential, familiarity, and controllability. These factors can be realistically incorporated in a proper application of risk assessment.

D. Problems in Applying Risk Management

The challenge to successful risk management is to be able to express the risks associated with a given environmental problem in terms that are understandable and credible to both decision-makers and the public. When the public perception of a threat is distorted or inaccurate, due to insufficient information, inadequate understanding, or misguided attitudes, the quality of legislation designed to address the threat is likely to suffer.

The level of public concern over a specific problem, particularly one that involves a direct harm to health, often depends on both the perceived risk and the level of acceptable risk related to that harm. Both the degree of perceived risk and the degree of risk that an ordinary person is willing to find acceptable in a given situation may vary greatly from that of an expert risk assessor. Risk perceptions of the ordinary person are influenced by characteristics of the hazard, including familiarity, knowledge, catastrophic potential, and degree of control by the individual.[127] This perception is for most people an intuitive judgment based on their experience with the particular

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123. *Id.*

124. *Id.* at 288.

125. CONSERVATION FOUNDATION, *supra* note 112, at 5.

126. Paul Slovic et al., *Informing People About Risk,in* BANBURY REPORT 6: PRODUCT LABELLING AND HEALTH RISKS 165, 170-75 (L. Morris et al. eds., 1980), *reprinted in* JUDITH AREEN ET AL., LAW, SCIENCE, AND MEDICINE 711-13 (1984).

127. Research has shown that, for the ordinary person, risk perceptions and risk acceptance are influenced by family, friends, co-workers, and public figures. Risk attitudes may even be formed after an experience with a particular hazard as a rationalization for earlier behavior. Once formed, risk attitudes are difficult to change even in the face of evidence. Paul Slovic, *Perception of Risk*, 236 SCI. 280, 281 (1987).

hazard, which often is through news media coverage.[128] Risk acceptance is strongly related to the perceived benefit of the activity and to the degree of voluntariness of the exposure.[129]

As a result of the interactions among these factors, the public tends to be concerned with environmental threats that experts would rank relatively low as a health risk, and vice versa. For example, surveys indicate that public concern is highest with respect to active and abandoned hazardous waste sites, even though experts believe these to be small health risks.[130] The public attitude is not surprising given the involuntary nature of exposure due to a release from a hazardous waste site and its catastrophic potential. On the other hand, while experts rate both outdoor and indoor air pollution as high health risks, these threats, especially indoor air pollution, rank lower in public concern.[131] This is probably due to familiarity and perceived lack of catastrophic potential, since health effects from air pollution tend to arise only from long-term exposure.[132]

E. EDB: A Case Study in the Application of Risk Assessment and Risk Management

The history of the regulation of EDB in the 1980s is a good illustration of the application of risk assessment and risk management methodologies in environmental regulation, as well as some of the inherent problems. The initial data which indicated carcinogenic potential for EDB came from clinical laboratory studies on animals. The studies showed an increased cancer risk associated with the three entry pathways of "gavage [forced feeding], inhalation, and skin painting."[133] Human exposure pathways were identified by way of dietary exposure through fruit and uncooked grain products which had been treated with EDB,[134] and later through groundwater contamination which affected drinking water supplies.[135]

Initially the EPA modeled the dosage risk based on the "one-hit" model, which resulted in a high risk estimate from exposure, both for agricultural workers and the public.[136] Criticism of this model as unrealistic[137] led the EPA to modify its assessment by calculating differential risks for different age groups from adjusted exposure durations. The model was still considered conservative, having adopted a linear low-dose-response relationship, and its risk estimate was considered an upper-bound risk.[138] This risk still appeared to be high, however, and led the EPA in 1983 to cancel registration of EDB as a soil fumigant.[139] The EPA proposed cancellation as a

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128. *Id.* at 280.

129. Some research indicates that a person may be willing to accept a risk from a voluntary activity up to 1000 times greater than that from an involuntary exposure which provides the same benefit. *Id.* at 282.

130. PERCIVAL, *supra* note 11, at 662 fig.5.1.

131. *Id.*

132. *Id.* at 757.

133. Russell & Gruber, *supra* note 87, at 288.

134. Improvements in detection methods made possible the detection of EDB residues in food products which previously had shown no trace of EDB. *See* WENTZ, *supra* note 87, at 25.

135. Russell & Gruber, *supra* note 87, at 288.

136. *Id.*

137. For a description of the "one-hit" model and a challenge to the "no threshold" theory of carcinogens, see Thomas H. Jukes, *Chasing a Receding Zero: Impact of the Zero Threshold Concept on Actions of Regulatory Officials*, *in* RATIONAL READINGS, *supra* note 14, at 329, 329-33 (1992).

138. Russell & Gruber, *supra* note 87, at 288.

139. Intent to Cancel Registration of Pesticide Products Containing Ethylene Dibromide, 48 Fed.

fruit and grain fumigant by 1984.[140]

By this time, public interest in the hazard had become very strong,[141] and many states were adopting stringent safety standards for EDB residues in food which would have required destruction of a large amount of existing grain-based food inventories.[142] This destruction would have caused severe economic dislocation and provided a questionable public health benefit. To avoid this, the EPA used risk assessment to determine which existing food supplies represented an acceptable health risk and which should be destroyed. The assessment indicated that dietary exposure from soil fumigation and grain fumigation represented the highest public risks, in the range of 1 in 10,000 to 1 in 1,000,000 increased cancer risk resulting from lifetime exposure.[143] However, risk from consuming existing food supplies over a relatively short period of time was found to be low enough that destruction was not necessary.[144] As a result, the EPA suspended most uses of EDB, but did not order destruction of existing foodstocks. The risk assessment also prioritized the dangers by severity of the risk, with groundwater contamination presenting the greatest risk, followed by grain products, then fruit.[145]

The use of risk assessment allowed a more orderly removal of EDB from the environment than would have otherwise occurred, and prevented the severe waste which would have resulted from destruction of existing food stocks. However, while the methodology limited the influences of misguided risk perceptions and political decisions on the process, it did not eliminate them, and in many ways the process was still driven by the pressures of media attention and public apprehension. Nor did the EPA action satisfy critics on both sides of the issue.[146]

This history of EDB regulation is not necessarily a typical or exemplary application of risk assessment and risk management, but it does illustrate two things. First, it is a concrete example of the use of risk assessment principles in the type of application to which they are well suited. Second, it shows that, despite the application of these sound scientific principles in their present state of development, political and perceptual factors may still have a significant influence on the process.

IV. PROPOSED LEGISLATION: THE RISK ASSESSMENT AND COST BENEFIT ACT OF 1995

Despite the inherent problems, the movement continues toward increased reliance on risk assessment and risk management as a way to improve the uniformity, efficiency, and accountability of environmental regulation. The Risk Assessment and Cost

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Reg. 46,234 (1983).

140. *Id.*

141. Charlotte Low, *Pressure Mounts for New EDB Standards*, L.A. DAILY J., Feb. 14, 1984, at 5.

142. Bill Abrams, *Six States Plan to Exceed U.S. on EDB Curbs*, WALL ST. J., Feb. 24, 1984, at 8.

143. Russell & Gruber, *supra* note 87, at 288.

144. *Id.*

145. *Id.*

146. *See* Philip Shabecoff, *Administration's Action on EDB Does Not Satisfy Critics*, L.A. DAILY J., Feb. 7, 1984, at 4 (describing objections by consumer groups that the action left known carcinogens in the food supply); *The EDB Flakeout*, WALL ST. J., Feb. 14, 1984, at 32 (claiming the ban was premature). *See also* George Miller, *Federal Callousness and EDB*, L.A. DAILY J., March 12, 1984, at 4 (criticizing OSHA for failing to set occupational exposure limits to EDB following the EPA suspension).

Benefit Act of 1995[147] (hereinafter the Act) seeks to impose the methodologies of risk assessment and risk management onto the decision-making processes of regulatory agencies.

The purpose of the Act is "[t]o provide regulatory reform and to focus national economic resources on the greatest risks to human health, safety, and the environment . . . ."[148] It calls for setting regulatory priorities based on "scientifically sound, objective, and unbiased risk assessments, comparative risk analysis, and risk management choices that are grounded in cost-benefit principles."[149] The Act also states that "improvements are needed in both the quality of assessments and the characterization and communication of findings[,]"[150] and that "public stake holders must be fully involved in the risk-decision making process."[151] The Act thus seeks to improve both the scientific validity of governmental regulation and the involvement and understanding of the affected public.

A. Risk Assessment and Communication

Title I defines the scope of the Act and outlines the principles of risk assessment and risk management which it mandates for regulatory agencies. The Act applies to specifically listed federal agencies and to other agencies which may be designated by the President.[152] It requires risk assessment and risk management studies to be undertaken for any major rule[153] promulgated by a covered agency "to protect human health, safety or the environment,"[154] any environmental cleanup plan under the Solid Waste Disposal Act (SWDA) or CERCLA,[155] and any listing of a hazardous substance or carcinogen.[156]

The Act spells out principles to be applied in risk assessment and risk management proposals. These include, *inter alia*: a focus on a "biological basis to assume a resulting harm in humans[;]"[157] the presentation of "plausible and alternative assumptions, inferences, or models;"[158] providing the "best estimate or estimates" of risk for

147. H.R. 1022, 104th Cong. (1995).
148. *Id.* preamble.
149. *Id.* § 2(3).
150. *Id.* § 2(4).
151. *Id.* § 2(5).
152. Covered federal agencies are the EPA, the Occupational Safety and Health Administration (OSHA), the Department of Transportation (DOT), the Food and Drug Administration (FDA) the Department of Energy (DOE), The Department of the Interior (DOI), the Department of Agriculture (DOA), the Consumer Product Safety Commission (CPSC), the National Oceanographic and Atmospheric Administration (NOAA), the United States Army Corps of Engineers (the Corps), the Mine Safety and Health Administration (MSHA), the Nuclear Regulatory Commission (NRC), and other agencies which the President, acting through the Office of Management and Budget (OMB), determines should be covered. H.R. 1022, 104th Cong. § 110(5) (1995).
153. A "major rule" is defined as any regulation which is likely to result in an increase in cost, direct or indirect, to either the private or public sector, of $25,000,000 or more. However, it does not include any regulations or actions which authorize or approve an individual substance or product. *Id.* § 5(3).
154. *Id.* § 103(b)(2)(b)(i).
155. *Id.* § 103(b)(2)(b)(ii) (The Solid Waste Disposal Act (SWDA) is codified at 42 U.S.C.A. §§ 6901-6992 (West 1995 & Supp. July 1996)).
156. *Id.* § 103(b)(2)(v).
157. *Id.* § 104(b)(1).
158. *Id.* § 104(b)(2)(A).

specific populations or resources;[159] explanations of exposure scenarios;[160] and comparisons of estimated risks with other familiar risks "routinely encountered by the general public . . . ."[161]

The Act recognizes that any risk assessment exercise requires the selection of statistical models as well as reliance upon assumptions and inferences. It therefore requires each covered agency to report to Congress concerning the policy or value judgments upon which it bases its assumptions and model selection.[162] With this provision, Congress apparently intends to maintain close supervision over the policy decisions and value judgments of the agencies.

The Act also provides for training and research in risk assessment methodologies. It authorizes the head of each covered agency to evaluate and implement research and training needs for the agency.[163] It also authorizes the Office of Management and Budget (OMB), in conjunction with the National Research Council, to conduct a study and provide common risk assessment and risk management guidelines to Congress and the covered agencies.[164]

Despite its purpose in attempting to found all major decision-making in risk assessment and cost benefit principles, Title I contains a "saving clause" which preserves any existing statutory standard or requirement "designed to protect health, safety, or the environment."[165] How this saving provision will interact with the other provisions of the Act and with the purposes of other environmental statutes is one of the major uncertainties in the effect of this legislation.[166] Presumably, it will preserve the risk assessment guidelines presently in force in the Superfund Act. Whether it will preserve a more stringent criterion, such as the rigid feasibility standard for a health regulation under OSHA, is less clear.

B. Risk Reduction Benefits and Costs

Title II of the Act describes the mechanisms by which regulatory agencies are to implement the principles outlined in Title I. The bill generally requires that covered federal agencies should, to the extent feasible, base major decisions on scientifically based risk assessments. The heart of the bill is its provision for decision criteria. It requires that any final rule of an agency be based on "scientific and economic evaluations of all significant and relevant information and risk assessments provided to the agency[,]"[167] and that this decision criteria "shall supplement and, to the extent there is a conflict, supersede the decision criteria for rule making otherwise applicable under the statute pursuant to which the rule is promulgated."[168] Thus the bill provides a "supermandate" to override decision criteria of existing laws.

The Act directs the OMB to guide the agencies in the implementation of these

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159. H.R. 1022, 104th Cong. § 105(1)(A) (1995).
160. *Id.* § 105(2).
161. *Id.* § 105(3).
162. *Id.* § 107(b).
163. *Id.* § 108(b).
164. H.R. 1022, 104th Cong. § 109(a) (1995).
165. *Id.* § 103(c).
166. *See Risk Assessment and Cost/Benefit Analysis for New Regulations: Hearings on H.R. 9 Before the Subcomm. on Commerce, Trade, and Hazardous Materials and the Subcomm. on Health and Environment, House Comm. on Commerce*, 104th Cong. 4 (1995) (remarks of Rep. Dingell).
167. H.R. 1022, 104th Cong. § 202(a)(1) (1995).
168. *Id.* § 202(b)(1).

requirements, including "any new requirements or procedures needed to supplement prior agency practice[,]"[169] and generally places the development of risk and cost-benefit analysis methodology under the control of the OMB.[170] The Act provides special rules for environmental cleanup plans, defining any cleanup plan for which costs are likely to exceed $5,000,000 as a "major rule," and making it specifically subject to the decision criteria of the Act.[171] This provision will likely subject most cleanup proposals under the Superfund Act to the mandates of risk assessment and cost-benefit analysis.

C. Peer Review

Title III of the Act requires the head of each covered agency to develop a peer review program for the agency's regulatory activities. The program is to create peer review panels, made up of experts from industry, public interest and environmental groups, state and local governments, universities, and other interested parties.[172] These panels are to review the risk assessment and/or cost analysis which forms the basis for any proposed rule which is expected to have a cost impact of $100,000,000 or more per year, and to review any other significant risk assessment designated by the Director of the OMB.[173] The peer review panels are to report on the scientific and economic merit of the analysis method and the data used.[174]

The Act intends the inclusivity of the peer review panels to cover representatives of the regulated industries. It provides that the panels "shall not exclude peer reviewers with substantial and relevant expertise merely because they represent entities that may have a potential interest in the outcome, provided that interest is fully disclosed to the agency . . . ."[175] This provision meets some of the criticism that regulated entities have too little participation in the decision process. However, when the rule under consideration applies to a single entity, the Act forbids a representative of that entity from being on a peer review panel.[176]

D. Judicial Review

Title IV of the Act provides for judicial review of covered agency actions. It grants to any court that has jurisdiction to review an agency action under an enabling statute the concurrent jurisdiction to review the agency's compliance with this Act.[177] It directs the court to treat any agency action as unlawful if the risk assessment and characterization documents do not comply with the Act's requirements. One of the most far-reaching effects of the provision for judicial review is the standard of review it imposes, as it requires that the covered agencies must "substantially comply" with

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169. *Id.* § 203(1).
170. *Id.* § 203(2).
171. *Id.* § 204.
172. *Id.* § 301(a)(1).
173. H.R. 1022, 104th Cong. § 301(b) (1995).
174. *Id.* § 301(c).
175. *Id.* § 301(a)(3).
176. *Id.*
177. *Id.* § 401. The Act does not provide an independent basis for federal court jurisdiction to review an agency action. Instead it provides to any court which has jurisdiction to review an agency action, under either the statute which created the agency authority or the Administrative Procedures Act, jurisdiction to review that same action for compliance with this Act.

the risk assessment and risk guidelines spelled out in Title I.[178] This is in contrast to the discretion which enabling statutes generally confer on regulatory agencies.

E. Plan and Priorities

The remaining titles of the Act require agencies to establish plans for assessing new information and setting priorities. Title V requires each covered agency to "provide procedures for receiving and considering new information from the public[,]" and "set priorities and procedures for review, and, where appropriate, revision of . . . risk assessment and risk characterization documents and . . . health or environmental effects values."[179] The proponents thus intend to keep the review process ongoing for regulatory rules promulgated under the risk assessment guidelines and cost-benefit guidelines.

Title VI of the Act requires the government to set priorities for reviewing existing regulatory programs as to their cost-effectiveness and the risk benefits they provide.[180] The President is directed to report to Congress every two years to "recommend priorities for modifications to, elimination of, or strategies for existing Federal regulatory programs designed to protect public health."[181]

These are the remedial provisions of the Act, designed to implement ongoing review and correction of existing regulations and programs. The intent is to bring existing programs into line with risk assessment and cost-benefit principles, according to the priorities established by the President. Thus, by constant review and revision, proponents hope to bring a large segment of the regulatory bureaucracy into compliance with the principles embodied in the Act.

V. EFFECT ON REGULATORY AGENCIES

The impact of this reform on present regulatory practices will probably depend primarily on how completely the "supermandate" provision supplants the decision criteria in existing environmental statutes with one based on risk assessment and risk management principles. However, since the risk assessment methodologies which the Act implements have been developed mainly in the context of human health risks, it seems clear that the focus of regulatory decisions will shift toward human health issues and away from other ecological goals such as preservation of wilderness and biodiversity.

Probably the greatest impact will be on severe command-and-control regulations such as the ESA.[182] It seems particularly difficult to frame the threat to an endangered species in the terms of risk assessment methodologies, such as hazard identification, etc. However, a superseding decision criterion based on "best estimates of risk" to a resource would presumably force the EPA to consider the probability of success in actually preserving a species as well as the risk of extinction before the agency could list the species as endangered. Applying an objective cost-benefit analysis to the protection of an endangered species will also be difficult since the benefits realized by preserving a species are much more difficult to quantify than the costs incurred in

178. H.R. 1022, 104th Cong. § 401 (1995).
179. *Id.* § 501(a).
180. *Id.* § 601(a).
181. *Id.* § 601(c).
182. *See supra* note 28 and accompanying text.

forgoing development. Despite the fact that loss of biodiversity is seen by experts as a serious ecological risk,[183] the saving clause may do little to preserve the present character of the ESA. While this would depend on interpretation of the meaning of a standard promulgated to protect "the environment," the thrust of the reform is decidedly toward human health and economic efficiency, and away from the ESA's strict ecology principles.

The extent to which this will affect the technology-driven and deadline-based approaches of the FWPCA and CAA is less clear. The saving clause would presumably prevent an agency from using a risk assessment or cost-benefit analysis to roll back an existing health or safety standard. But in the promulgation of any new standards based on BAT, the new approach would require greater attention by the agency to cost and feasibility. Particularly with technology-forcing standards which are forward-looking, such as those relating to continued reduction in auto emissions, the agency will be forced to quantify the benefit in reduced health risks versus the economic cost to the industry.

In ensuring that the development of air and water standards is in substantial compliance with the Act, the agency will also be forced to deal with the other elements of risk assessment, such as exposure pathways and dosage-response characteristics. Since point source emissions would be subject to further exposure pathway assessment before dosage risks on human receptors can be assessed, the methodology appears better suited to the development of ambient standards than point source limitations. However, given the limited state of scientific knowledge about these elements outside the contexts of toxicology and carcinogenesis, progress in the development of new standards may become more difficult. It may be especially difficult to quantify risks in terms of human populations when the effect of the hazard on human health and safety is indirect, such as in eutrophication of lakes.[184]

While the focus will be increasingly on human health, the reform will also attempt to reduce the social and economic costs of regulation. It may therefore direct attention to the severe restriction of the Delaney clause on carcinogenic food additives.[185] Since the passage of this clause in 1958, scientists have greatly improved our ability to quantify the risks associated with exposure to low concentrations of carcinogens,[186] and thus have provided a basis for risk-benefit assessment. While the "supermandate" decision criterion of the reform may not be sufficient to override the explicit language of the Delaney clause, bills have already been introduced to relax its provisions and permit residues in food that present *de minimis* risks.[187] If less stringent standards for food residues do come about, it is probable that risk assessment methodology will be involved in the comparison of economic benefits to health risks. However, this may well occur independently of this specific reform.

The reform will probably have less impact on procedural, cost-benefit based statutes such as NEPA and on incentive-based approaches such as offsets under the

183. 1991 COUNCIL ON ENVTL. QUALITY, TWENTY-FIRST ANN. REP. 146-47.

184. Eutrophication is the process by which the oxygen content of a lake is artificially depleted by an overload of nutrients. *See* R.A. BAILEY ET AL., CHEMISTRY OF THE ENVIRONMENT 319-20 (1978). Pollutants which lead to eutrophication are nitrates and especially phosphates. *Id.* at 377.

185. *See supra* note 116.

186. Richard A. Merrill, *Congress as Scientists*, ENVTL. F., Jan./Feb. 1994, at 20, 23-24.

187. *Id.* at 20.

CAA. The proposed bills would mainly add a new dimension to the current environmental assessment procedures under NEPA by increasing the emphasis on quantification of risks and benefits and emphasizing scientific justifications to support final decision-making. Nor is there any inherent incompatibility between incentive-based regulation and risk assessment, since risks associated with an incentive approach can be analyzed as well as with any other approach.

It is unlikely, however, that these bills would provide any hoped-for reduction in administrative burden that the present statutes impose. If anything, the requirements to prepare risk assessment and risk characterization documents for environmental regulation programs and EIS's will add another layer of study and analysis, with opportunities for comment and controversy, to an already cumbersome process. With the additional opportunities for peer review and judicial challenge based on a substantial compliance standard, the regulatory process may well become much slower. While some may welcome the reduced volume of regulation, this may cut both ways by slowing down the prioritized review and revision of existing programs.[188]

VI. PROBLEMS IN APPLICATION

The purpose of applying the principles of the Act is to avoid the types of unscientific or irrational decisions which have given rise to the need for reform. For example, a scientifically sound risk assessment may have prevented the unwarranted response to the Alar scare.[189] A sound risk communication program, which gave the public a true picture of the relative threats to health and the costs and benefits of mitigation, may also have lead to different approaches in the EDB ban[190] or the asbestos removal program from public schools.[191] Beyond such obvious benefits, however, the effectiveness of the bill in providing a thorough reform and improvement of the regulatory process is more difficult to establish.

A. Scientific Drawbacks

A serious problem with the bill is that some of the principles which it requires to be implemented in the promulgation of regulations either cannot be supported on scientific grounds or lack scientific precision. Proponents of the reform charge that agencies are too conservative in estimates of risk and develop greatly exaggerated estimates from relatively insignificant threats to the public.[192] However, the requirement in section 105(1)(A) that the agency must determine the "best estimate of risk" is not scientifically supportable. Any estimate of risk will depend on the statistical model used to develop it, and there is no scientific definition of "best estimate" of risk.[193] The definition of "best estimate of risk" then becomes a policy issue. These definitions of risk will also depend on the relevant population which is selected for application of the statistical model. The fear is that, by dictating how the agency must define the relevant population, the bill will limit the discretion agencies now have to protect particularly

188. *Risk Assessment and Cost/Benefit Analysis for New Regulations: Hearings on H.R. 9 Before the Subcomm. on Commerce, Trade, and Hazardous Materials and the Subcomm. on Health and Environment, House Comm. on Commerce*, 104th Cong. 4 (1995) (remarks of Rep. Dingell).

189. *See supra* text accompanying note 77.

190. *See supra* text accompanying note 75.

191. *See supra* text accompanying note 82.

192. Beth Baker, *Risk Assessment Kills Bills*, 45 BIOSCIENCE 15 (1995).

193. Richard Stone, *Agencies Decry Fuzzy Science in Bill*, 267 SCI. 1089, 1090 (1995).

susceptible populations, such as children who are at risk for lead poisoning.[194]

The Act also fails to distinguish between "theoretical" risk and "actuarial" risk. While theoretical risks are estimated from statistical models, actuarial risks are determined from the actual frequency of occurrence of a harmful effect in the population. Agencies tend to use conservative estimates of theoretical risk to ensure protection of public health.[195] If the bill is interpreted to mandate the use of actuarial risk as the "best estimate" of risk, this margin of safety may be lost.

These problems in definition are one source of unreliability in the use of risk assessment to set policy and priorities in certain areas of human health and safety. Even if these difficulties could be resolved, much uncertainty would remain in the reliability of risk assessment methodologies as a unified approach to environmental regulation. The scientific methods themselves which are used to identify hazards involve much uncertainty,[196] and many practitioners question whether certainty in these methods is a realistic goal.[197] The attempt to quantify and compare risks objectively ignores the subjective differences which people attach to different classes of risk, such as voluntary versus involuntary risks.[198] Finally, the overriding focus on human health issues, while clearly an important goal of environmental policy, ignores ecological risks which may similarly affect the well-being of society.[199]

B. Policy Drawbacks

While this approach to regulatory reform has significant scientific drawbacks, the policy implications are even more severe. A fundamental shortcoming of the Act is that it does not cure the flaws in the underlying environmental statutes themselves which have caused the regulatory problems, especially the "lack of flexibility to meet regulations, and the adversarial, litigious nature of the process."[200] Nor does the Act remedy the problem of overlapping and conflicting requirements in some laws and regulations. The Act instead is a remedial measure which is to be superimposed onto the existing regulatory structure in an effort to bring the process in line with risk assessment and risk management principles. It generally adds one or more new layers of analysis, report, commentary, and challenge to each major agency decision, depending on the expected economic impact. Many people involved in environmental regulation are not convinced that this will achieve the intended purpose of the bill.[201]

Furthermore, the risk assessment methodology by which the bill attempts to accomplish this general remedial undertaking was largely developed in the limited

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194. *Id.* at 1089.

195. Tina E. Levine, *Assessment and Communication of Risk from Pesticide Residues in Food*, 47 FOOD & DRUG L.J. 207, 212 (1992).

196. John Carey, *So Many Chemicals, So Few Answers*, BUS. WK., Mar. 13, 1995, at 98.

197. "Defenses and reforms for risk assessment share a common flaw in failing to account for the profound uncertainty in the process. When the magnitude of this uncertainty is recognized, risk assessment is properly seen as incapable of generating meaningful information." Shere, *supra* note 86, at 479-80.

198. Kristin Shrader-Frechette, *Number Crunching and Comparative Assessment of Environmental Risks*, 45 BIOSCIENCE 66 (1995).

199. *Id.*

200. Emily T. Smith et al., *Voodoo Regulation?*, BUS. WK., Mar. 13, 1995, at 96, 96.

201. "Our concern is that this legislation, in its current form, will undermine these laudatory goals [of quality science and prioritizing of government resources] by elevating simplistic slogans to unworkable public policy . . . ." Letter from Carol M. Browner, Administrator, EPA, to Reps. Dingell & Brown, *in* 141 CONG. REC. H2334 (daily ed. Feb. 28, 1995).

context of toxic and carcinogen exposure. There is little reliable guidance on how to apply these methodologies to broader environmental problems such as air and water quality and protection of biodiversity. In the area of worker safety, the same problem exists for the development of workplace safety standards outside the areas of toxic or carcinogenic exposure, for example in the development of industry-wide standards for safety apparel and work practices. Risk assessment methodologies in their present state of development may be of such marginal applicability in these areas that they would provide little improvement in the regulatory scheme.

The Act accommodates this lack of development to a certain extent by setting forth its "supermandate" on decision criteria in Title II in very general terms, requiring that agencies base their decisions on "all significant and relevant information and risk assessments provided to the agency . . . ."[202] However, this generality is inconsistent with the "substantial compliance" standard of judicial review provided in Title IV. The vagueness of the supermandate criteria will make it very difficult for a court to determine what "substantial compliance" is, or what it was intended to be. This can open up practically any agency action covered under this Act to substantial litigation.

Typically, courts have given great deference to the discretionary authority of regulatory agencies in promulgating regulations pursuant to the enabling act. The usual standard has been that courts will uphold regulations that are not arbitrary and capricious.[203] However, the proponents of this regulatory reform specifically intend to "substitute[] a substantial evidence test for the arbitrary and capricious test so that the agencies must really demonstrate to a court that they are complying with the Act's cost-benefit requirements."[204] Congress clearly intends to limit the traditional discretion which agencies have exercised, and thus assert its own control to a greater extent in this area of policy. The proponents see judicial review as "one of the key features in protecting the regulated community, average Americans, from the threat of over regulations and regulations that do not meet the test of good science and cost-benefit analysis."[205] Not surprisingly, opponents of the judicial review provision foresee that it will impose a great burden on agency action with its procedural requirements[206] and will allow regulated entities to tie up proposed actions in litigation for years.[207]

Peer review panels provided in Title III are also controversial. While independent peer review has long been recognized as an essential element of scientifically sound risk assessment, its use in the regulatory area has not been widespread.[208] The proponents of peer review claim that its purpose is to "provide adequate guidance and over-

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202. H.R. 1022, 104th Cong. § 202(a)(1) (1995).

203. The Administrative Procedures Act requires a court in review of an agency action to set aside any action which is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law . . . ." 5 U.S.C. § 706(2)(a) (1994). Unless an enabling statute requires a higher standard, courts will not usually impose one judicially. *See* Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402 (1971).

204. 141 CONG. REC. H2327 (daily ed. Feb. 28, 1995) (remarks of Rep. Bilirakas).

205. 141 CONG. REC. H2327 (daily ed. Feb. 28, 1995) (remarks of Rep. McIntosh).

206. "The judicial review provision could be called 'The Full Employment Bill for Lawyers and Lobbyists.'" 141 CONG. REC. H.2323 (daily ed. Feb. 28, 1993) (remarks of Rep. Roemer).

207. "Any industry that does not like the regulation that comes out of that maze can go into court and challenge the regulation, tie it up for years. . . . This legislation adds so many procedural requirements, it would allow any industry that opposes a new regulation to delay and litigate the regulation to death . . . ." 141 CONG. REC. H2258-59 (daily ed. Feb. 27, 1995) (remarks of Rep. Waxman).

208. CONSERVATION FOUNDATION, *supra* note 112, at 37.

sight to ensure that these tools are being properly utilized."[209] However, the inclusivity of the peer review panels leads opponents to fear that representatives of regulated industries will have too much influence on the actions of regulatory agencies through this process.[210]

The other component of the "supermandate" criterion, cost-benefit analysis, also has its limitations in the environmental area. A true cost-benefit analysis requires the objective quantification of costs and benefits. However, the quantification of costs and benefits in government programs, even outside the environmental area, involves many problems that are not commonly encountered in the private sector.[211] These problems are magnified in the environmental area because the external costs of environmental harm are so difficult to assess and account for in the analysis. The Act defines "costs" to include "direct and indirect costs to the United States Government, to State, local, and tribal governments, and to the private sector, wage earners, consumers, and the economy" of a particular environmental strategy.[212] It defines benefits as the "reasonably identifiable significant health, safety, environmental, social and economic benefits" that will result from the implementation of the strategy.[213] However, the cost or benefit of an environmental impact depends both on the damage to the environment which is incurred or avoided and the value placed on the affected resources. Therefore the evaluation of environmental costs is subjective and even somewhat circular.[214] Not surprisingly, estimates of the costs and benefits realized in environmental assessments often differ widely and involve wide margins of error.[215] Since direct costs to the private sector can usually be estimated with more certainty,[216] they are likely to receive greater regard than the more speculative costs of environmental harm. In its definition of costs and benefits that can be included in the analysis, the Act itself imposes a higher standard on environmental and health benefits by requiring that they be "significant." These factors all affect the objectivity and soundness of the methodologies which the Act seeks to impose on covered agencies.

The greatest policy flaw in the Act's imposition of cost-benefit analysis on agency decision-making, however, is that it may frequently conflict with the basic mandates

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209. 141 CONG. REC. H2327 (daily ed. Feb. 28, 1995) (remarks of Rep. Doyle).

210. "[I]t allows for the corporate insiders, the lobbyists, the scientists, of companies that are, in fact, with financial interest in the regulation which is being considered, to be able to sit on the peer review group which is going to be evaluating the risk, that regulation which will be put on the books." 141 CONG. REC. H2338 (daily ed. Feb. 28, 1995) (remarks of Rep. Markey).

211. These include the problem of selecting the viewpoint from which the analysis should be made (e.g., from the viewpoint of the community as opposed to that of the regulated industry); the problem of selecting the proper discount rate for determining equivalent values of costs and benefits that occur at different times; the difficulty in distinguishing costs from disbenefits; and the need for incremental analysis when more than two alternatives are available. *See* DONALD G. NEWNAN, ENGINEERING ECONOMIC ANALYSIS 421-427 (1988).

212. H.R. 1022, 104th Cong. § 5(1) (1995).

213. *Id.* § 5(2).

214. TERRY L. ANDERSON & DONALD R. LEAL, FREE MARKET ENVIRONMENTALISM 81 (1991).

215. Joseph P. Biniek, *Benefit-Cost Analysis: An Evaluation, in* CONTROVERSIES IN ENVIRONMENTAL POLICY 136, 139-140 (Sheldon Kamieniecki et al. eds., 1986).

216. Even the accurate determination of private sector costs is not without difficulties. Some problems in obtaining accurate estimates of costs incurred by industry due to environmental regulation include the difficulty in determining the differential cost of the pollution control expenditures over baseline costs, the true cost impact of measures which increase production as well as abate pollution, the costs of pollution control which are not recognized as such, and the difficulty in separating pollution control costs from related costs such as industrial safety measures. *Id.* at 144-145.

of many regulatory schemes to protect human health and safety. When these mandates exist, they provide a "statutory 'floor'" for necessary regulation, and the agency can take the cost of compliance into account only if the statutory floor can be met.[217] The Act's general requirement for cost-benefit analysis will undermine the statutory mandate when all adequate regulatory alternatives are costly. In such a situation, the requirement of cost-benefit analysis clearly conflicts with the Act's purpose of focusing regulatory efforts on human health and safety. The Act provides no guidance on how to resolve this conflict.

In addition to these shortcomings in the scientific and policy areas, the other major goal of the bill, the effective communication of risk and cost-benefit comparisons to the public, will likewise prove elusive. In addition to the subjectivity of risk perceptions by the public and the media, complex comparisons of risk are difficult to present in a way that the public will understand or believe.[218] Particularly when the risk quantifications themselves are so highly dependent on the underlying assumptions, the presentation of risk comparisons, without an understandable explanation of the assumptions, models, and uncertainties involved, does not provide any sounder basis for decision-making than would a presentation based on pure policy arguments.[219]

These various criticisms of the bill show how difficult it may be to achieve many of the stated purposes of the Act. Most of these problems are inherent in the nature of risk assessment and risk management methodologies. The research and studies of risk assessment methods which the bill authorizes may lead to many improvements, but there is no guarantee that they can overcome these problems to a significant degree.

CONCLUSION

If current proposals to increase the use of risk assessment and risk management in environmental regulation pass the Congress and become law, the results for regulators, regulated entities, and the public are likely to be mixed. These methodologies can be very powerful and beneficial when they are applied in areas to which they are well-suited. They can be especially useful in quantifying risks scientifically when an adequate scientific basis is available, in comparing and communicating these identified risks in a realistic way, in setting priorities, and in directing resources into mitigating the most severe threats to human health.

When successfully implemented, these techniques should go far in reducing some of the costly and unprofitable environmental endeavors which were undertaken in the past without sufficient understanding or justification. Effective and comprehensible communication of the comparative risks and benefits of major regulatory programs will

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217. Letter from Ivan Selin, Chairman, NRC, to Rep. Dingell, *in Risk Assessment and Cost/Benefit Analysis for New Regulations: Hearings on H.R. 9 Before the Subcomm. on Commerce, Trade, and Hazardous Materials and the Subcomm. on Health and Environment, House Comm. on Commerce*, 104th Cong. 6 (1995).

218. "In the midst of controversy concerning EPA risk assessment processes and assumptions, the Agency must communicate with a public that tends to see things as either 'safe' or 'unsafe'." Levine, *supra* note 195, at 212. In addition, perceptions of unfairness and helplessness often drive the public perception of risk in issues that affect public health. *Id.* (*citing* Ned Groth, *Communicating with Consumers about Food Safety and Risk Issues*, 45 FOOD TECH. 248 (1991)).

219. *See* Shere, *supra* note 86, at 475 ("The problem with these and similar reform proposals is that they assume that the uncertainties are manageable, so that the risk assessment process can continue even if the uncertainties are made explicit. But a risk assessment that acknowledges an uncertainty of millions or billions of fold would properly be dismissed as useless.").

also improve the public perception of the process, especially among the members of the public who are directly regulated.

However, the dependence of these methods on adequate scientific knowledge can be their Achilles' heel. When an adequate basis does not exist to support their application, the voluminous studies and documents which will be engendered will run the risk of becoming exercises in futility. They will hamper the ability of agencies to respond quickly to serious threats unless the agencies can make a convincing case for an emergency.[220] The costs involved in the additional research, review, and study of risk assessment methods and investigations will not be insignificant. And in situations involving the "zero-infinity" dilemma, the lack of quantifiable risks and harms makes these methods practically useless.

For such reasons, the reforms which are attempting to institute risk assessment to provide a single unifying approach to environmental regulation are not likely to be successful. For many of the problems we face, we simply lack the sound theoretical understanding necessary to perform a meaningful assessment of risks and benefits. Yet some of these problems are too serious to admit of delay, and we will be unable to postpone our responses until more knowledge is obtained.

It is true that much of the justification for the early reliance on command-and-control regulation no longer exists. These regulations accomplished their goal of focusing the nation's efforts on environmental improvement, and have brought significant progress. It is therefore possible and desirable to provide more flexibility and economic sense into new regulations. Agencies have already been directed to begin this process by executive order.[221]

The Act, however, attempts to impose a "one size fits all" regulatory scheme on both present and future environmental statutes.[222] The present statutes have been enacted in response to widely differing problems, involving complex circumstances and facing varying political, social, and economic climates. There is no reason to believe that future statutes will face a less diverse set of situations. This attempt to force these broadly different problems into the same mold may easily result in much of the same inconsistency, conflict, and inefficiency that has plagued environmental policy since its inception.

Few would argue against the proposition that a better approach to regulation would be to cure the defects in the underlying legislation which have brought us to our present condition. This can be accomplished to some extent by executive order, and to

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220. The Act provides that it does not apply to "[a] situation that the head of an affected agency determines to be an emergency. In such circumstances, the head of the agency shall comply with the provisions of this Act within as reasonable a time as is practical." H.R. 1022, 104th Cong. § 3(1) (1995). While this provision appears to contradict itself, its probable intent is to allow an agency to promulgate a major rule in an emergency situation without performing a risk assessment, but require the agency to follow up with a risk assessment within a reasonable time.

221. Many of the principles embodied in H.R. 1022 are contained in the executive order. Agencies have been directed to "examine whether existing regulations (or other law) have created or contributed to the problem that a new regulation is intended to correct, and whether those regulations (or other law) should be modified[,]" to "consider, to the extent reasonable, the degree and nature of risks posed by various substances or activities within its jurisdiction[,]" and to "assess both the costs and the benefits of the intended regulation, and . . . propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs." Exec. Order No. 12866, 58 Fed. Reg. 51,735 (1993).

222. 141 CONG. REC. H2270 (daily ed. Feb. 27, 1995) (remarks of Rep. Manton).

a greater extent by careful and rational revision of existing statutes. The attempt to force the use of risk assessment and cost-benefit methodologies in situations to which they are not well suited, and to limit the traditional discretion of agencies to respond to complex or unforeseen problems, may in the long run have an adverse effect on the goal of protecting human health and safety. It will almost certainly do harm to our broader environmental and ecological values.

The proponents of risk assessment and risk management should recognize its limitations as well as its benefits. While we should implement these methods to their fullest potential where they are effective, we should keep other options available when different approaches are needed.

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