

Issue Brief for Congress

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The Role of Risk Analysis and Risk Management in Environmental Protection

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The Role of Risk Analysis and Risk Management in Environmental Protection

SUMMARY

The outlook is uncertain in the 108th Congress for legislation that would promote use of environmental risk analysis. In the 107th Congress there was little legislative activity involving environmental risk analysis or broader regulatory reform legislation, especially after September 11, 2001. On the other hand, there were administrative reforms promoting risk analysis in the Executive Branch, particularly in the form of directives from the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget.

Risk analysis is the systematic evaluation of hazards and their possible effects. Views on the potential uses of risk analysis differ. Although, most experts and policy-makers agree that risk analysis is a valuable tool to inform decisions, they disagree about the extent to which risk estimates may be biased and should be allowed to influence public policies to protect health and the environment.

Some Members, many academics, and regulated industries argue that risk analysis is objective and reflects sound science. They argue it should be used to target federal programs to address the worst risks to health and the environment first, to achieve risk reduction in more cost-effective and flexible ways that minimize overall economic impacts, and to ensure that risk reduction achieved by regulations is worth the cost.

Other Members, some academics, and many environmentalists argue that excessive reliance on risk analysis to evaluate problems and solutions related to human health and the environment, especially quantitative risk analysis, ignores other important facets of policy decisions, such as environmental impacts, timeliness, fairness, effects on democratic rights and liberties, practicality, morality, reversibility of effects, regulatory stability, flexibility, or aesthetic values. Critics charge that quantitative methods cannot assess very long-term or newly discovered threats. They also believe that quantitative cost-benefit analyses (which are derived in part from risk analyses) undervalue environmental and health benefits, exaggerate costs, and focus on relatively widespread but individually small costs and risks rather than on much larger costs and risks to smaller, and often more vulnerable, groups. In addition, they charge, risk analysis typically evaluates data for well-studied and relatively well-understood hazards, ignoring emerging concerns about hazards that are poorly understood.

The quality of any risk analysis depends on adequacy of data and validity of method. For environmental hazards and most health and ecological effects, data are limited, methods are controversial, and consequently, quantitative risk estimates are very imprecise and highly uncertain.

MOST RECENT DEVELOPMENTS

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BACKGROUND AND ANALYSIS

As a potentially valuable tool for addressing concerns about the growing cost to regulated industries and communities of compliance with environmental requirements, risk analysis may be useful to EPA and Congress to set priorities among programs and evaluate management options. However, considerable controversy revolves around the value of risk analysis and the role it should play in environmental decision making. (For more detailed information, see CRS Report 98-619, *Risk Analysis: Background on Environmental Protection Agency Mandates* and CRS Report 98-618, *Environmental Risk Analysis: A Review of Public Policy Issues*.)

What Is Risk Analysis?

Professional risk analysts do not agree on how key terms should be defined, but for the purpose of discussion, this report uses the following specific definitions. In the context of environmental issues, “risk” is defined as the probability of occurrence of a particular adverse effect on human health or the environment as a result of exposure to a “hazard,” which may be a hazardous chemical in the environment, a natural hazard, or a hazardous technology. “Risk assessment” refers to a formal or informal procedure producing a quantitative estimate of environmental risk. For example, risk assessment is often used to estimate the expected rate of illness or death in a population exposed to a hazardous chemical. “Risk analysis” is used more broadly to include quantitative and qualitative evaluation of all relevant attributes of environmental hazards, risks, adverse effects, events and conditions that lead to or modify adverse effects, and populations or environments that influence or experience adverse effects. “Risk management” is the process of deciding what should be done about a hazard, the population exposed, or adverse effects, implementing the decision, and evaluating the results. It also refers to decision making at the program or agency level, for example, deciding which hazards should be managed and in what order. Comparative (or relative) risk analysis and cost-benefit analysis are aids to risk management.

Views on Potential Uses of Risk Analysis

How Valuable a Tool?

Most people seem to agree that risk analysis is a potentially valuable tool for summarizing scientific information obtained from animal experiments and studies of accidental or occupational human exposures to hazards. But, people disagree about how risk analysis should be used and how much influence it should have on government decisions.

Regulated industries and many academics support legislation that would increase use by environmental policy makers of risk analysis, arguing that it is a scientific and objective basis for making rational risk management decisions. It allows comparisons of the importance of perceived problems and evaluation of the need for proposed solutions, they maintain. Thus, it permits efficient allocation of limited resources.

Other academics and most environmentalists stress the limitations of risk analysis. Activists for environmental justice (that is, avoidance of disproportionate risks to low-income and minority communities) oppose efforts to increase the influence of risk analysis, and especially quantitative risk estimates, on environmental decisions, because it tends to focus attention on relatively small risks to large populations (for example, the U.S. population as a whole) rather than on large risks to smaller groups, such as workers, the economically disadvantaged, or ethnic minorities.

Is It a Scientific Basis for Environmental Decisions?

Some policymakers promote risk analysis as an objective scientific basis for environmental planning and decisions by federal agencies, Congress, and the public. In their opinion, more risk analysis would lead to more rational decisions and replace what they regard as the piecemeal environmental policy that has grown in response to real and imagined crises. They favor legislation mandating use of risk analysis of environmental, health, and safety problems to inform Congress and the public, who may then evaluate and prioritize problems based on sound science.

Opponents of mandated risk analysis argue that the science used in risk analysis is immature and suitable only for assessing immediate threats or the risk of developing cancer. In addition, they warn that risk analysis oversimplifies the problems faced by policymakers and managers of environmental programs, for example, by generally focusing on one hazard and one effect at a time, or on problems or aspects of problems that already are well understood. Critics of risk analysis also assert risk assessment methods are complex and easily manipulated for political purposes. Thus, it is argued, the decision-making process may be less democratic to the extent it is ostensibly based on risk.

Many who promote the use of risk analysis acknowledge that it has limitations but believe these can be overcome through data collection, research, peer review, or the establishment of guidelines for the consistent conduct of analysis and presentation of results. The President's Office of Management and Budget (OMB) has established guidelines for cost-benefit analysis and risk assessments conducted by federal agencies. Agencies might be directed to adopt detailed guidelines for risk assessments, consistent with OMB

guidelines, to identify research and training needs in risk assessment, and to develop a strategy to meet those needs. Finally, legislation could require peer review of agencies' risk analyses of proposed and final significant rules and their alternatives, as well as other risk analyses with potentially significant effects on public policy, as determined by OMB.

Some legislative proposals have attempted to ensure scientific objectivity by mandating it. For example, S. 746, as reported in the 106th Congress, would have required scientists to consider "all relevant" and "all reliable" scientific data and to perform an "objective" assessment "based on the weight of the scientific evidence." However, the effect of these legislated mandates on agency behavior is unpredictable due to the variety of circumstances surrounding risk assessments and the legal consequences of EPA actions. For example, the validity of the "weight-of-the-[scientific]-evidence" approach in practice depends on the quality and comprehensiveness (or representativeness) of the data. Therefore, a legal requirement to rely on the approach may be interpreted by scientists as a directive either to base decisions on *available* data even if data are inadequate and misleading, or to collect additional data to meet minimum data requirements, even if the aspect of the risk assessment for which data are unavailable is unimportant to the risk analysis as a whole or to significant regulatory or policy decisions. Such uncertainty is likely to lead to legal challenges.

Should It Be Used to Compare Costs and Environmental or Health Benefits?

Many policymakers want to use the results of risk analysis and cost analysis to identify economically reasonable environmental management strategies. Various decision criteria have been proposed for identifying such strategies, all of which would require comparisons of the estimated costs and environmental or health benefits of existing or proposed regulations and reasonable alternatives. However, proposals have differed in whether they would have required 1) consideration of particular alternatives, 2) qualitative or quantitative analysis, and 3) comparisons of risks to costs for each alternative, costs of one to costs of another, or risks of one to risks of another. Different proposals also would provide EPA with different levels of discretion. S. 746, as reported in the 106th Congress, would have required consideration of "flexible" regulatory options, qualitative and quantitative costs and benefits, and comparisons of risks to costs, costs to costs, and risks to risks of the alternatives. Legislative proposals in earlier congresses (e.g., S. 2362, in the 106th Congress) would have required cost-benefit analysis of proposed air quality standards and would have authorized EPA to set a standard for which estimated benefits justified costs.

Some critics of EPA assert that environmental regulations adversely impact the national economy and international competitiveness of American businesses. They want EPA to use cost-benefit analysis to identify less expensive strategies to reduce only the greatest risks. Some would prohibit promulgation of regulations expected to cost more than they save in economic terms (that is, that were not expected to produce a net benefit) or that cost more than an alternative that would also achieve the statutory objective. In contrast, proposals that advanced in the House and Senate of the 104th Congress did not require regulators to base decisions on national net benefits. Rather, they promoted adoption of "flexible," cost-effective alternatives and authorized consideration of risks and costs borne by special segments of the general population.

The Unfunded Mandates Reform Act (P.L. 104-4) requires all agencies to select from a reasonable number of regulatory alternatives the least costly, most cost-effective, or least burdensome alternative that achieves the objectives of the rule and is consistent with law or to explain why such an alternative was not adopted. In the 106th Congress, S. 746, as reported, would have directed agencies for major environmental rules —

- to perform a cost-benefit analysis;
- to make “a reasonable determination, based on the rule-making record as a whole” as to whether the rule is likely to provide benefits that justify the costs and whether it “is likely to substantially achieve the rule making objective in a more cost-effective manner, or with greater net benefits, than the other reasonable alternatives considered by the agency;” to conduct a risk assessment; and
- to provide for peer review of risk assessments and, if the rule is likely to cost more than \$500 million, of the economic analysis.

However, existing laws would still determine the degree to which such cost-benefit comparisons could affect the choice of regulatory options.

Some people object to quantitative comparisons of costs with the monetary value of benefits of environmental or health laws and regulations. Whether they object on moral or ethical grounds or for scientific reasons, they want benefits described in qualitative as well as quantitative terms. Key proposals in the 104th, 105th, and 106th Congresses would have permitted or required qualitative descriptions of benefits as well as costs.

Critics of cost-benefit analysis argue that the process is easily manipulated for political purposes, and that evidence of manipulation is easy to conceal, especially from people who lack economic or scientific training. Moreover, the quality of economic analyses varies widely, they believe, and most quantitative cost-benefit analyses undervalue environmental and health benefits and exaggerate costs. A Resources for the Future study found that cost estimates for proposed environmental and occupational safety rules more often over-estimated than under-estimated costs. Economic analysts also tend to focus on relatively widespread but individually small costs and risks rather than on much larger costs and risks to smaller, and often more vulnerable, groups, critics charge.

Many of these concerns about the quality of cost-benefit analyses might be addressed through peer review, oversight by OMB or another agency, or other measures. OMB already is required by P.L. 104-208 to assess costs and benefits for major federal regulations.

Another criticism aimed at proposals to require cost-benefit analysis is that they would consume scarce EPA resources, sometimes to no purpose, because some authorizing statutes do not permit EPA to consider costs.

Finally, many argue that cost-benefit analysis could delay EPA’s issuance of many regulations, and delays would mean that lives or habitats might be irretrievably lost that could have been saved had the regulation been in effect. Thus, the net benefit of regulating would be reduced, they claim. In addition, some fear that delays will increase the cost of analysis if the Agency misses statutory or judicial deadlines and environmental groups respond, as they often do, by filing lawsuits. However, legislation could extend statutory

deadlines until its requirements for cost-benefit analysis were satisfied, or could authorize agencies to request extension of court-ordered deadlines.

Should Priorities Be Based on Relative Risks and Risk Reduction Opportunities?

The results of risk analysis also can be used to weigh the relative need for various federal environmental programs. Some policymakers argue that EPA, the states, and localities should prioritize expenditures based on relative opportunity for risk reduction. Opponents of risk management based on relative risks and risk reduction potential contend that comparative risk analysis is an unscientific, ad hoc procedure that lends a false air of objectivity to the subjective judgments of scientists. Opponents question whether an exercise that combines the diverse views of an unrepresentative sample of government scientists to produce a single prioritized list of hazards is more informative than a thorough recitation of the points on which scientists with diverse viewpoints agree and disagree, such as may occur in a hearing or an advisory committee. Critics argue that priority setting requires value judgments, and scientists are no more qualified than others to decide whether, for example, the risk of a small decrement in intelligence for 3 to 4 million children exposed to lead-based paint is more or less significant than the risk of approximately 13,600 deaths annually from lung cancer due to indoor levels of radon gas. It is even more difficult and less scientific to compare ecological risks with risks to human health, these critics contend.

Others protest that risk-based prioritization focuses on death or disease rates in the population as a whole, ignoring other equally important issues, such as the feasibility of controlling a risk or the fairness of the result. All means of risk reduction are not equally desirable, these critics contend, citing diverse examples such as the wearing of a gas mask and modification of a production process to reduce use of toxic chemicals. The nature of hazards also matters, according to some who point out that risk is sometimes desirable, and many risks, such as driving a car or skydiving, are taken voluntarily either for the benefits that may be obtained or for the thrill of the experience. Priorities should be based on all relevant information about hazards and available management options, not on risk alone, they argue. Since scientists are expert only at determining probabilities, the public or its representatives should be asked to contribute their expertise to the process of priority setting.

When EPA's Science Advisory Board was asked to update its 1990 relative risk report *Reducing Risk*,¹ it instead initiated a project to define "the next step" in environmental decision making. The Board failed to achieve the goal of this project, "to articulate a complete and rational method for including all aspects of integrated environmental decision-making in a single process," but in its final report, *Toward Integrated Environmental Decision-Making*, it provided a framework and challenged EPA to develop the necessary tools to move in that direction. The Board described integrated environmental decision making, in the cover letter to the final report to the EPA Administrator, as follows.

One of the principle features of "the next step" is the involvement of a wider range of people — and their perspectives/values — in the decision-making process. The

¹ For a summary of the 1990 report, see CRS Report 98-618, *Environmental Risk Analysis: A Review of Public Policy Issues*.

Framework also emphasizes use of the best science (both natural and social sciences) to assess cumulative, aggregate risks; to consider a broader range of options for managing or preventing risks; to make clear the role of societal (public) values in deciding what to protect; to clarify the trade-offs (including costs and benefits) associated with choosing some management scenarios and not others; and to evaluate progress toward desired environmental outcomes (page 6).

Thus, instead of producing a prioritized list of environmental risks, the SAB advocated development of a wider range of tools for examining environmental issues and a more consultative process for ranking.

The Information Value of Risk Analysis

There appears to be general agreement that more information is needed to inform decisions. Views diverge, however, regarding the type of information needed and whether it would be best provided by risk analysis.

Key Factors Determining the Quality of Information Provided

Under ideal conditions, a risk analysis gathers, organizes, and summarizes all of the important information relevant to hazard management. It includes qualitative as well as quantitative information about the characteristics of the hazard, exposed population, potential effects, and available management strategies; describes scientific uncertainties; and provides a range of forecasts based on alternative, scientifically plausible assumptions about the relationship between exposure to the hazard and potential health or environmental effects.

In practice, however, the type of information provided by risk analysis varies from comprehensive to superficial, accurate to biased, and quantitative to qualitative, because risk analysis is a field of inquiry rather than a single method. Risk analysts use a variety of procedures and models adapted from other fields of study such as sanitary and industrial engineering, psychology, economics, sociology, statistics, and operations research. Methods developed for other purposes (for example, to determine life insurance rates) sometimes are difficult to apply to, and may be scientifically invalid for, environmental hazards.

A second consideration is that risk analysis is a tool for evaluating what is known about things that cannot be known with certainty — that is, it is only used to describe the effects of hazards that are unpredictable due to their natural randomness or a lack of scientific understanding of the principles that govern their occurrence. Risk analysis always produces an estimate, never a prediction, and estimates vary in quality. (Weather forecasts, for example, are relatively well-informed risk estimates.) Thus, risk analysts can only discuss the likelihood of various outcomes and, at best, may present risks as statistical probabilities. If there is no past experience with a hazard, there is no basis for any forecast, much less a quantitative estimate. If there is experience but no record to ensure accurate recall, risk estimates are likely to be unreliable.

Finally, sometimes risk analysis can provide no information at all, even when data are abundant. Science cannot always explain complex or unusual relationships between the exposures to hazards and the potential health and ecological effects.

Quality of the Database

The quality of available data on exposure levels and potential effects determines the quality of information that can be provided by a risk analysis. The most effective way to improve risk assessment, the National Academy of Sciences (NAS) has concluded, is to improve the quality and comprehensiveness of knowledge. Data on human exposure to chemicals generally is acknowledged to be inadequate. See, for example, *Toxic Chemicals: Long-Term Coordinated Strategy Needed to Measure Exposures in Humans* by the U.S. General Accounting Office (May 2000, GAO/HEHS-00-80). H.R. 3448 in the 106th Congress aimed to improve collection and management of information about environmental quality, which may be used to approximate human exposure.

The situation for toxicity data, which is needed to assess potential human health effects of chemical exposures, was summarized in a report by the U.S. Office of Technology Assessment (OTA). It estimated that 62,512 chemicals are in commerce in the United States today, and another 1500 new chemicals enter the market annually. Environmental experts believe that “good” data on health effects exist for only 10% of commercial chemicals. In a 1995 report, OTA estimated that roughly 30,000 of the chemicals that have been in U.S. commerce since 1976 are polymers that present little health risk. Another 25,000 are produced in low volume (less than 10,000 pounds per year, including some chemicals which no longer are in production). There remain approximately 15,000 chemicals produced in significant volumes. About 3 or 4 thousand chemicals are produced in amounts greater than one million pounds per year. OTA reported, “For perhaps thousands of these chemicals of potential concern, toxicity and exposure data remain inadequate for risk assessment.” Of course, many of these may be harmless, but data are also inadequate for many chemicals Congress has deemed “hazardous,” according to NAS. NAS evaluated the availability of data for risk analyses of 189 hazardous air pollutants and concluded EPA did not have “sufficient data to assess fully the health risks ... within the time permitted by the Clean Air Act Amendments of 1990” (*Science and Judgment in Risk Assessment*, 1994, National Academy Press, Washington, p. 8-13). At least 12 federal agencies are currently conducting health risk assessment research to fill the gaps in scientific understanding, but according to OTA, their efforts are poorly coordinated and supported at a level that is less than 0.5% of the cost of complying with EPA regulations. The data situation is much worse for environmental effects.

The Environmental Defense (ED, formerly Environmental Defense Fund) reported in 1997 on research conducted to determine the adequacy of test data for chemicals produced in amounts greater than one million pounds per year that have been identified as subjects of regulatory attention. The adequacy of test data was determined based on the *public* availability of the minimum screening information data set that was created by the Organization for Economic Cooperation and Development (OECD) Chemicals Program in 1990. This data set is adequate to perform preliminary assessment of the potential human health hazard of a chemical, but does not provide sufficient data to conduct a comprehensive health risk assessment, according to ED. ED drew a random sample of 100 chemicals and found that 71% did not meet the OECD minimum data requirement. Most of the chemicals in the sample had been tested for their ability to cause mutations (genetic toxicity) and developmental toxicity, but there were no reproductive toxicity data for 53% of the chemicals. Most of the chemicals had not been tested for any form of toxicity due to chronic exposure. According to the authors of the study, the Chemical Manufacturers’ Association

(CMA) independently concluded that only 53% of the chemicals lacked adequate public data, but acknowledged that a key international chemical database had very recently become available for public scrutiny. Critics of the ED study, however, charged that up to three-fourths of chemicals have been adequately evaluated.

EPA evaluated the availability of toxicity data for industrial chemicals produced in high volumes and reported that there was a complete set of health and environmental effects data for only 7%. There were no publicly available data for 1,216 of the 2,863 chemicals evaluated by EPA. EPA and Vice President Gore called on the chemical industry to produce data to fill the gaps at an EPA-estimated total cost of \$427 million. That cost represents about 0.2% of total annual sales of the top 100 U.S. chemical companies, according to EPA. The chemical industry has supported the voluntary high-production-volume (HPV) chemical testing initiative, but estimates the cost could approach \$765 million and place U.S. companies at a competitive disadvantage internationally. More than 430 companies have publicly committed to make health and environmental hazard data available on approximately 2,080 HPV chemicals by 2005. Animal rights groups criticized early descriptions of the HPV testing initiative for garnering information of dubious value and requiring laboratory experiments for thousands of animals. EPA responded by examining alternative test methods that could reduce the number of animals needed and reduce the pain and suffering of any animals employed. The Agency produced guidance for companies responsible for chemical testing which should reduce animal usage by 68 to 80 percent, according to EPA. On December 26, 2000, EPA published a proposed rule that would require manufacturers and processors of 37 additional HPV chemicals to conduct toxicity testing (65 *Federal Register* 81,657). EPA estimated that the final rule would be issued in September 2002, but it has not yet been published in the *Federal Register* (67 *Federal Register* 33829, May 13, 2002).

Risk Assessment Methods

Environmental risk assessment is a relatively new and immature field; this is evident in the state of development of its analytic methods for assessing exposure levels and their potential adverse effects. Current methods of estimating human or ecological exposure levels generally focus on individual hazards (e.g., arsenic or repetitive motions) and isolated incidents or constant long-term exposures. Therefore, they inadequately account for common, real-life conditions, such as fluctuating exposures to multiple hazards. The most developed and well established methods of estimating potential adverse effects probably are those used to analyze acute human health effects of high short-term risks (e.g., many occupational injuries). Methods also are fairly well developed for assessing human cancer risks of chemicals, although gaps in scientific understanding of cancer make these risk estimates very uncertain. These methods evaluate and model the results of animal experiments and human studies to estimate cancer risk due to exposure to individual chemicals. Due to the variety of models that may be used, estimates of cancer risk usually vary widely. Methods to evaluate risks of other health effects (such as impaired immunity, reproductive problems, or birth defects) are less well established. Methods for ecological risk analysis are still primitive.

There are at least four ways to promote the development and use of the best available methods for risk analysis: peer review, research and training, oversight, and provision of guidelines. Such methods help to ensure that risk assessments are conducted consistently

and are, therefore, more easily evaluated by independent experts. However, they do not ensure that scientists will agree with the resulting risk estimates. The NAS has identified at least 50 decisions required in conducting a cancer risk assessment that cannot be made on a scientific basis. Thus, controversy grows from the subjective judgments, the science policies, that make risk assessment possible and from the high stakes that ride on risk estimates.

Legislative Activity

Legislation in the 107th Congress

In the 107th Congress there was little legislative activity involving environmental risk analysis or broader regulatory reform legislation, especially after September 11, 2001. On the other hand, there were administrative reforms promoting risk analysis in the Executive Branch, particularly in the form of directives from the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget. Far-reaching risk provisions were included in one introduced bill, H.R. 2694, which would have elevated the U.S. Environmental Protection Agency to cabinet status. Section 120 would have required quantitative risk assessment, cost assessment, and comparative risk assessment for each proposed or final regulation relating to public health and safety or the environment. It also would have mandated certification by the Secretary that the assessments have been evaluated by the Science Advisory Board and were supported by “the best available scientific data,” and that the rule would produce benefits justifying the cost and would substantially advance public health and safety or the environment. A less far-reaching proposal, S. 855, would have mandated evaluation of health effects for “vulnerable sub-populations” and established a U.S. policy of protecting them from pollution with “an adequate margin of safety.” There were similar proposals in the 106th Congress (i.e., H.R. 199 and S. 1112).

For information about proposals in the 103rd through the 105th Congresses, see CRS Report RL30031. *Environmental Risk and Cost-Benefit Analysis: A Review of Proposed Legislative Mandates, 1993-1998*.

CONGRESSIONAL HEARINGS, REPORTS, AND DOCUMENTS

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FOR ADDITIONAL READING

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CRS Report RL30116. *Congressional Review of Agency Rulemaking: A Brief Overview and Assessment After Three Years*.

CRS Report RL30043. *Environmental, Health, and Safety Tradeoffs: A Discussion of Policymaking Opportunities and Constraints*.

CRS Report 98-618. *Environmental Risk Analysis: A Review of Public Policy Issues*.

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