Order Code IB94036

CRS Issue Brief for Congress
Received through the CRS Web

The Role of Risk Analysis and Risk Management in Environmental Protection

Updated March 12, 2002

Linda-Jo Schierow
Resources, Science, and Industry Division

CONTENTS

The Role of Risk Analysis and Risk Management in Environmental Protection

SUMMARY

Compared to the 104th through 106th Congresses, during its first session the 107th Congress showed little interest in legislation that would promote use of environmental risk analysis. This relative inactivity may reflect the change in Administration and some Members' approval of proposed administrative reforms promoting risk analysis, particularly in the form of directives from the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget.

To date, several bills have been introduced, and one, H.R. 2694, includes far-reaching risk provisions in conjunction with elevating the U.S. Environmental Protection Agency to cabinet status. Section 120 would require 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 mandates certification by the Secretary that the assessments have been evaluated by the Science Advisory Board and are 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.

S. 855 would mandate evaluation of health effects for "vulnerable sub-populations" and establish 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).

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, especially quantitative analysis of risks to human health, to evaluate problems and solutions 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 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.

The quality of risk analysis depends on adequacy of data and validity of method. For environmental hazards and most health and ecological effects, data are limited, and methods are controversial.

MOST RECENT DEVELOPMENTS

Compared to the 104th through 106th Congresses, during its first session the 107th Congress showed little interest in legislation that would promote use of environmental risk analysis. This relative inactivity may reflect the change in Administration and some Members' approval of proposed administrative reforms promoting risk analysis, particularly in the form of directives from the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget.

To date, far-reaching risk provisions are included in one introduced bill, H.R. 2694, which would elevate the U.S. Environmental Protection Agency to cabinet status. Section 120 would require 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 mandate certification by the Secretary that the assessments have been evaluated by the Science Advisory Board and are 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 mandate evaluation of health effects for "vulnerable sub-populations" and establish 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).

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. S. 746, as reported in the 106th Congress, would require the President's Office of Management and Budget (OMB), in consultation with the Council of Economic Advisors, the Director of the Office of Science and Technology Policy, and relevant agency heads, to establish guidelines for cost-benefit analysis and risk assessments. The bill also would direct agencies to adopt detailed guidelines for risk assessments, consistent with guidelines issued by OMB, to identify research and training needs in risk assessment, and to develop a strategy to meet those needs. Finally, the proposed legislation would 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 proposals attempt to ensure scientific objectivity by mandating it. For example, S. 746, as reported in the 106th Congress, would require 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 require 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. S. 2362, as introduced in the 106th Congress, would require cost-benefit analysis of proposed air quality standards and would authorize EPA to set a standard for which estimated benefits justify 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 direct 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. All the key proposals in the 104th Congress, as well as S. 981, as reported in the 105th Congress, and S. 746, as reported in the 106th Congress, would permit or require qualitative descriptions of benefits as well as costs. Because S. 981, as reported in the 105th Congress, required a determination about "net benefits," some argued that it would have forced agencies to quantify benefits. In the 106th Congress, language was added to S. 746, as reported, to ensure analysis of qualitative benefits.

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 recent study at Resources for the Future 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. H.R. 1074, as passed by the House in the 106th Congress, would mandate OMB analysis of the costs, benefits, and net benefits of major rules and alternatives for which costs and benefits were considered in a regulatory impact analysis. S. 746, as reported in the 106th Congress, would require OMB oversight of rule making and peer review of risk assessments with potentially significant policy impacts, including for major rules, and of cost-benefit analyses for rules likely to have an annual effect on the economy of at least $500 million. It also would require periodic OMB evaluations of the quality of agencies' analyses and OMB development of guidelines for cost-benefit analysis, risk analysis, and peer review. S. 746, as reported in the 106th Congress, also would require agencies to develop their own detailed guidelines for risk and economic assessments. P.L. 106-312 establishes a pilot project authorizing an independent General Accounting Office evaluation of an agency's analysis of the potential benefits and costs of a proposed or final economically significant rule, alternative regulatory approaches, and other aspects of the rule analyzed as required by law, if an evaluation is requested by a chairman or ranking member of a congressional committee of jurisdiction.

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. During mark up of S. 981 on March 10, 1998 in the 105th Congress, an amendment was defeated which would have waived requirements if agencies did not have the resources required to perform analyses and peer reviews.

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. S. 746, as reported in the 106th Congress, would extend statutory deadlines occurring within 2 years of enactment for 6 months or until the requirements of the new law were satisfied. The bill also would 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. In the 104th Congress, the Senate Appropriations subcommittee with jurisdiction over EPA spending was particularly concerned about what it described as EPA's refusal to identify activities that address the greatest risks. Supported by the recommendations of a National Academy of Public Administration study, the subcommittee directed EPA to determine its highest priorities and the funding needed to address them. EPA maintained that it was working on setting priorities based on relative risks, statutory and judicial deadlines, legal mandates, program costs and benefits and other factors.

EPA's Science Advisory Board released a draft report suggesting a new risk-based approach to making environmental decisions in April 1998. This report on the SAB's Integrated Risk Project was prepared in response to a request from EPA administrators for an update to the SAB 1990 relative risk report *Reducing Risk*. For a summary of the draft report, see CRS Report 98-618, *Environmental Risk Analysis: A Review of Public Policy Issues.*

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.

H.R. 3311, as introduced, and S. 746, as reported, in the 106th Congress, would require a comparative risk analysis, a study of methodologies for comparing dissimilar risks, and recommendations on the use of comparative risk analysis in setting priorities from an accredited scientific institution under contract to OMB. This project would have to be conducted through an open process providing peer review and opportunities for public participation.

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. H.R. 3311, as introduced, and S. 746, as reported, in the 106th Congress, would require agencies to report on the uncertainties surrounding risk estimates.

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).

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. All four provisions were included in S. 746, as reported to the Senate in the 106th Congress. 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 106th Congress

The 106th Congress did not act on comprehensive regulatory reform legislation or major provisions related to risk analysis by EPA. H.R. 3311, as introduced, and S. 746, as reported, in the 106th Congress, would have codified requirements for cost-benefit analysis and risk assessment (currently required by executive order) and executive oversight of rulemaking. In contrast to S. 746, as reported, H.R. 3311 would have required no determination by an

agency that compared costs and benefits, would not have required evaluation of risks to subpopulations, would have more strongly encouraged quantitative analysis, and would have defined more rules as major and allowed no exceptions, and therefore would have required more analyses. The Thompson-Levin bill (i.e., S. 746) was similar to a bill that was reported in the 105th Congress, as it would have been amended by an amendment proposed by President Clinton. More limited proposals (i.e., H.R. 199, H.R. 525, and S. 1112) also were introduced, but few were acted upon. However, S. 1198 became P.L. 106-312 on October 17, 2000. It establishes a pilot project authorizing an independent General Accounting Office evaluation of an agency's analysis of the potential benefits and costs of a proposed or final economically significant rule, alternative regulatory approaches, and other aspects of the rule analyzed as required by law, if an evaluation is requested by a chairman or ranking member of a congressional committee of jurisdiction, and if funding for the project is appropriated. The consolidated FY2001 appropriations act (P.L. 106-554) did not provide funding for the project.

Legislation in the 107th Congress

Compared to the 104th through 106th Congresses, during its first session the 107th Congress showed little interest in legislation that would promote use of environmental risk analysis. This relative inactivity may reflect the change in Administration and some Members' approval of proposed administrative reforms promoting risk analysis, particularly in the form of directives from the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget. To date, far-reaching risk provisions are included in one introduced bill, H.R. 2694, which would elevate the U.S. Environmental Protection Agency to cabinet status. Section 120 would require 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 mandate certification by the Secretary that the assessments have been evaluated by the Science Advisory Board and are 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 mandate evaluation of health effects for "vulnerable sub-populations" and establish 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).

LEGISLATION

H.R. 324 (Boehlert)

Recycle America's Land Act of 2001. Would require risk assessments conducted under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (i.e., Superfund) to be objective, unbiased, based on all reasonably available, relevant, and reliable scientific and technical information and on an analysis of the weight of scientific evidence supporting conclusions about potential risk to health and the environment. Introduced January 31, 2001; referred to Committees on Energy and Commerce, Transportation and Infrastructure, and Ways and Means.

H.R. 2694 (Horn)

Department of Environmental Protection Act. Section 120 would require quantitative risk assessment, cost assessment, and comparative risk assessment for each proposed or final Department of Environmental Protection regulation relating to public health and safety or the environment. It would mandate certification by the Secretary that such assessments have been evaluated by the Science Advisory Board and are 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. Introduced August 1, 2001; referred to Committee on Government Reform.

S. 855 (Boxer)

Children's Environmental Protection Act. Amends the Toxic Substances Control Act to establish U.S. policy of protecting "vulnerable subpopulations" that are likely to experience special exposure to environmental pollutants or associated health effects. Requires EPA to evaluate environmental health risks to vulnerable subpopulations separately and to protect them by providing an adequate margin of safety and, if data are lacking, at least a 10-fold safety factor. Prohibits use of some pesticides in schools and daycare centers and requires parental notification of pesticide use. Also requires EPA to identify pollutants common in areas frequented by children, to develop guidelines to reduce exposure to such pollutants, and to list substances and products with suspected health risks to children as well as safer alternatives. Mandates amendments to the Emergency Planning and Community Right-to-Know Act Section 313 to require additional reporting of emissions for certain persistent, bioaccumulative, toxic substances. Introduced May 9, 2001; referred to Committee on Environment and Public Works.

S. 940 (Dodd)

Children's Environmental Protection and Right to Know Act. Amends the Emergency Planning and Community Right-To-Know Act of 1986, Section 313, to require additional reporting of environmental releases of certain persistent, bioaccumulative, toxic substances. Extends reporting requirements to amounts of covered chemicals used as well as released and to all industrial sectors that use or release toxic chemicals in volumes similar to the volumes used in covered industries. Requires consolidation of all federal reporting requirements for regulated industries. Amends the Federal Hazardous Substances Act to require EPA and the Consumer Product Safety Commission to list substances toxic to children and require new long and short-term strategies for chemical testing and risk assessment to ensure that risks to children are fully understood. Requires manufacturers to report on products containing substances toxic to children. Authorizes civil enforcement action. Establishes a fund to receive penalties assessed as a result of civil action that may be used to fund enforcement activities. Introduced May 23, 2001 as Title II, Subtitle E, of the Leave No Child Behind Act of 2001; referred to Committee on Finance.

CONGRESSIONAL HEARINGS, REPORTS, AND DOCUMENTS

United States Congress. House. Committee on Commerce. Subcommittees on Commerce, Trade, and Hazardous Materials and on Health and Environment. *Risk Assessment and Cost/Benefit Analysis for New Regulations*. Joint Hearings, 104th Congress, 1st sess., February 1 - 2, 1995. Washington, U.S. Govt. Print. Off., 1995. 380 p.

United States Congress. House. Committee on Science. Subcommittee on Energy and Environment. *The Science of Risk Assessment: Implications for Federal Regulation*, Hearing, 105th Congress, 2nd sess., July 15, 1998. Washington, U.S. Govt. Print. Off., 1998. 637 p.

United States Congress. Senate. Committee on Environment and Public Works. *Regulatory Reform and Environmental Laws*. Hearing, 104th Congress, 1st sess., March 22, 1995. Washington, U.S. Govt. Print. Off., 1995. 250 p.

United States Congress. Senate. Committee on Governmental Affairs. *S. 981—the Regulatory Improvement Act of 1998.* Hearing, 105th Congress, 2nd sess., February 24, 1998. Washington, U.S. Govt. Print. Off., 1998. 435 p.

FOR ADDITIONAL READING

CRS Products

CRS Issue Brief IB95035. *Federal Regulatory Reform: An Overview.* 13 p. Updated regularly.

CRS Report RL30116. *Congressional Review of Agency Rulemaking: A Brief Overview and Assessment After Three Years.* 18 p. March 31, 1999.

CRS Report RL30043. *Environmental, Health, and Safety Tradeoffs: A Discussion of Policymaking Opportunities and Constraints*. 19 p. February 1, 1999.

CRS Report 98-618, *Environmental Risk Analysis: A Review of Public Policy Issues*. 40 p., Appendix. July 15, 1998.

CRS Report RL30031. *Environmental Risk and Cost-Benefit Analysis: A Review of Proposed Legislative Mandates, 1993-1998.* 24 p. January 22, 1999.

CRS Report 98-619, *Risk Analysis: Background on Environmental Protection Agency Mandates*. 23 p. Appendix. June 12, 1998.