CRS Report for Congress

Risk Analysis and Cost-Benefit Analysis of Environmental Regulations

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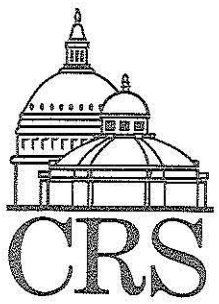

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SUMMARY

Concerns about the national economy, environment, public health, and the quality of EPA's regulatory process have led Congress to consider proposals to require EPA analyses of risks, costs, and benefits of proposed regulations. Proponents of analysis want the results used to design more efficient regulations and to prioritize environmental problems for Federal attention. Risk analysis summarizes available scientific information about hazardous activities, chemicals, or technologies and the effects they may have on exposed animals or people under various conditions, for example, with or without regulation. Risk and economic analyses can be qualitative or, if information is sufficient, quantitative, but economists can only quantify economic benefits of environmental regulations if scientists can quantitatively estimate risks to health and the environment.

Economic analysis and risk analysis of many management options already are required by executive order and statute; EPA has conducted such analyses for 20 years. The quality of its analyses and the influence of the results on management decisions have been both praised and criticized. Some environmental statutes prevent EPA from using analytic results in developing regulations.

Prospects are high that the 104th Congress will consider legislative proposals to promote EPA risk and economic analyses. Five general questions are at issue: 1) How valuable is the information provided by risk analysis for policymakers? 2) Is risk analysis a scientific basis for environmental decisions? 3) Should risk analysis be used to quantify environmental and health benefits? 4) Should priorities be based on relative risks? and 5) Given that EPA already analyzes risks, costs, and benefits, would additional requirements for analysis improve risk management? People generally agree that risk analysis is valuable for summarizing scientific information, but disagree about its scientific objectivity and information value for environmental policymakers, because risk is only one aspect of environmental problems. Also, the quality of information provided by risk analysis depends heavily on the quality of available data, which varies, so that the results of risk analysis almost always are debatable.

Some general legislative approaches include: 1) authorizing or requiring EPA to analyze regulations, 2) authorizing or requiring EPA to consider costs and/or risks in making regulatory decisions, 3) requiring reports to Congress on the results of regulatory analyses, 4) authorizing funding for analysis, 5) requiring research and development of analytic methods, the database, or guidelines for risk assessment, 6) establishing guidelines for risk assessment or presentation of results, and 7) requiring peer review. An appended comparison of analytic requirements in key legislative proposals and executive orders finds President Clinton's order to be most comprehensive.

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Risk Analysis and Cost-Benefit Analysis of Environmental Regulations

INTRODUCTION

Many Governors, Mayors, Members of Congress, and others are concerned about the high cost of compliance with environmental regulations. In particular, some believe EPA has promulgated requirements that achieve small increments in environmental quality or human health protection without adequately considering the economic costs of those decisions. They argue that the resources consumed in promulgating, enforcing, and complying with such regulations could better protect public health and the environment if they were more commensurate with the risks potentially avoided by regulation and were directed to controlling environmental hazards posing greater risks. Therefore, many support legislation requiring risk analysis of environmental problems and economic analysis of EPA regulations. EPA supporters argue that EPA has analyzed risks, costs, and benefits for major regulations and most other significant decisions for more than a decade. However, many of the Agency's decisions are driven by specific statutory mandates, discussed below, that may limit EPA's regulatory flexibility or its ability to consider cost when developing regulations. Other risk management decisions are driven by ambiguous legislative language which EPA cautiously interprets for various reasons, including uncertainty about health risks and lawsuits from environmental groups. Congress establishes priorities for EPA's regulatory activities when it mandates deadlines for issuance of regulations in environmental legislation and authorizes or appropriates funds for specific programs. According to some sources, EPA has little discretionary authority to choose targets for regulations based on risks.[1]

Various legislative proposals in the 103rd Congress addressed the issue of how EPA should manage risks. Some would have required EPA to conduct formal economic analyses of existing and proposed environmental regulations and forego regulation when costs exceed quantifiable benefits. Others would have had EPA evaluate regulations and their alternatives based on the magnitude of risk potentially controlled by each option. Still others would have required EPA analysis of the relative magnitude of risks addressed by its regulations. More modest proposals would have established an office of environmental risk within EPA or mandated research to improve the quality of risk analysis or communication of the results. Prospects are high that the 104th Congress will continue to debate these proposals.

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[1] For example, Dan Beardsley, former EPA official with the Office of International Activities, as quoted in: Roberts, L. "Counting on Science at EPA." *Science*, v. 249, August 10, 1990. p. 618.

This report describes and analyzes the issues and legislative options related to risk analysis and risk management at EPA and considers the potential impact of proposed legislation on EPA's rule-making process and final regulations. The report begins by defining some key terms used in the discussion and by providing: background information on EPA's historical use of risk and economic analyses; provisions of existing law that authorize, mandate, or constrain the use of the results of risk analysis and economic analysis by EPA; and various studies of EPA's risk analysis and economic analysis policies and practices. The second major section of the report summarizes and analyzes proposals, issues, and legislative options. The report concludes with a brief summary of the legislative activities in the 103rd Congress and a list of selected references. (For more information about specific proposed legislation, see CRS Issue Brief IB 94036, *The Role of Risk Analysis and Risk Management in Environmental Protection* and the CRS Report *Comparison of Environmental Risk Provisions in the 103rd Congress*, 94-716 ENR.)

The Environment and Natural Resources Policy Division of CRS conducted an advanced workshop on cost-benefit-risk analysis of proposed EPA regulations on July 19, 1993. Guest speakers who presented five perspectives were: John Graham, Professor and Director, Harvard Center for Risk Analysis, Harvard School of Public Health; James D. Wilson, Regulatory Issues Director, Monsanto Company, and President, Society for Risk Analysis; Erik Olson, Senior Attorney, Natural Resources Defense Council, and former EPA employee; Adam Finkel, Fellow, Center for Risk Management, Resources for the Future; and Richard D. Morgenstern, Director, Office of Policy Analysis, Office of Policy, Planning, and Evaluation, U.S. EPA. The purpose of the workshop was to examine areas of agreement and disagreement among panelists regarding the advantages and disadvantages of increased use of cost-benefit-risk analysis of EPA regulations. Drs. Graham and Wilson spoke in favor of, and Mr. Olson spoke against, an increased role for cost-benefit-risk analysis at EPA. Dr. Finkel provided arguments both for and against an increased role for cost-benefit-risk analysis at EPA. Dr. Morgenstern discussed the legal, fiscal, and practical considerations that affect EPA's use of cost-benefit-risk analysis. The speakers' presentations, answers to follow-up questions, and participation in an open discussion with the moderator and audience provided valuable information that is referenced throughout the analytic section of the report.

BACKGROUND

DEFINITIONS

Experts in risk analysis disagree about how "risk" and related terms should be defined. For the purpose of this discussion, however, the following definitions have been adopted. "**Environmental 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 an environmental hazard; an "**environmental hazard**" may be a hazardous chemical in the environment, a natural hazard, or a hazardous technology (for example, a dam).

"**Environmental risk assessment**" refers to any formal or informal scientific procedure used to produce a quantitative estimate of environmental risk. For example, risk assessment is often used to estimate the expected rate of illness or death in a human population exposed to a hazardous chemical based on the number of experimental animals affected by various doses of the chemical as measured in laboratory experiments.[2]

THE FOUR STEPS OF RISK ANALYSIS

hazard identification: determining whether a particular chemical causes a particular health effect

dose-response assessment: determining the relationship between magnitude of exposure and probability the health effect will occur

exposure assessment: determining the extent of exposure before or after application of regulatory controls

risk characterization: describing the nature and often the magnitude of risk, including attendant uncertainty

"**Environmental risk analysis**" is defined more broadly to include any quantitative or qualitative scientific description of an environmental hazard, the potential adverse effects of exposure, the risks of these effects, events and conditions that may lead to or modify adverse effects, populations or environments that influence or experience adverse effects, and uncertainties with regard to any of these factors.[3] Generally, risk analyses are based on scientists' evaluations of results of scientific research, extrapolations of these results to predict the type and to estimate the extent of effects in exposed populations, and judgments about the number and characteristics of persons exposed to hazards at various levels. The final step in risk analysis is "**risk characterization**," which summarizes scientific judgments about the existence and overall magnitude (that is, the incidence) of adverse effects given specified levels of exposure to a hazard.

"**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. Decision makers may consider social, political, economic, legal, ethical, and engineering information as well as scientific risk estimates in choosing among available risk management options. Comparative risk analysis and economic analyses use the results of environmental risk assessments but are risk management activities, conducted to inform decisions about management options. Risk management decisions often require value

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[2] Laboratory studies of toxicity are supervised and interpreted by toxicologists. Epidemiologists, who also contribute data for risk assessment, study the health of human populations who have been exposed, usually accidentally or occupationally, to a hazard.

[3] Others might use these terms differently. The important point is that it is necessary to distinguish between an analysis that focuses exclusively on the numbers associated with a hazard and a broader analysis that also considers such qualitative features as the dread a hazard inspires or the irreversibility of harm. A similar distinction is drawn between "economic analysis" and "cost-benefit-risk assessment" below.

judgments on such questions as "What level of risk is acceptable?" and "What level of expenditure is reasonable?" Another aspect of risk management is "**risk communication**" which includes any information exchange about a hazard or risk.

A "**comparative risk analysis**" evaluates a number of environmental hazards relative to one another and assigns to each a priority, based on one or more characteristics of the individual hazards. Often ranks are based on the relative magnitude of risk, which presupposes that a quantitative environmental risk assessment has been conducted for each hazard. A comparative risk analysis may group hazards, for example, as "high," "medium," or "low" risks, or arrange them in rank order. Alternatively, hazards may be evaluated based on the amount of risk that may be avoided using available technologies and resources. This is often referred to as ranking according to "**risk reduction opportunities**."

"**Economic analysis**" refers to any systematic procedure to evaluate real or anticipated resource expenditures and losses (costs) relative to real or anticipated gains (benefits). "**Cost-benefit-risk assessment**" is the quantification and monetary valuation of the expenditures, gains, and losses, and the calculation of net benefits to society associated with the adoption of a particular regulation (or alternative management strategy) to address an environmental hazard. *Quantitative environmental risk analysis (that is, risk assessment) is a necessary prerequisite to the conduct of cost-benefit-risk assessment of environmental regulations*, because the "**benefits**" are the risks avoided (that is, the adverse effects on human health or the environment, or risks of such effects, that the regulation is meant to address.) Risk assessment may be used to estimate the number of people or animals likely to be harmed by exposure to the hazard under each regulatory strategy, including a "do-nothing-different" strategy that reflects the current policy, or regulation, or laissez faire. Benefits may be expressed in such terms as numbers of lives saved or illnesses or species extinctions avoided. Risk that is expected to remain after a new regulation is implemented may be subtracted from the risk under current conditions to estimate risk reduction opportunities -- that is, the "**expected benefit**" -- of each regulatory alternative. If benefits are translated into monetary terms to allow cost-benefit-risk assessment, various techniques may be used to calculate the dollar values of health effects; these values may be derived from studies of how much people are willing to pay to avoid exposure to a hazard or particular adverse effect, or based on savings of direct costs, such as health care expenditures, salary loss for the duration of an illness, or the years of work lost to premature death. The intent is to estimate the gross monetary value of benefits to society, rather than to individuals. "**Net benefit**" is the expected monetary benefit less the cost of implementing the regulation.

RISK ANALYSIS AT EPA

Origin of Environmental Risk Analysis

Most of the major environmental protection statutes have provisions that require, or have been interpreted by EPA to require, decisions about the amount of pollution or potentially polluting activity that is considered to be "safe." To inform such decisions, EPA began soon after it was formed in 1970 to systematically collect and analyze data to describe and evaluate environmental conditions and trends. EPA's earliest efforts to evaluate environmental data, however, were frustrated by the difficulty of defining "good" environmental quality; scientists could not agree on a definition. They readily agreed, however, that the environment should not be hazardous to human health or ecosystems. Therefore, EPA began to focus efforts on defining risks.

Procedures for analyzing hazards and measuring risks existed prior to 1970, but had been developed for purposes other than environmental protection (for example, to determine life insurance rates or the likelihood of flooding) and had not been widely applied to more complex environmental hazards. Because EPA urgently needed suitable tools to carry out its mission, it supported the development of the newly consolidated field of risk analysis and helped to found the Society for Risk Analysis.[4] The Agency was among the first to apply the methods of risk analysis to problems in environmental protection. EPA developed new procedures and adapted methods from such disciplines as sanitary and industrial engineering, psychology, economics, sociology, statistics, and operations research. By the mid 1970s, EPA was conducting risk analyses to support some of its decisions.

Influence of Federal Guidelines on EPA Risk Analysis

Other Federal agencies with responsibilities for protecting human health and safety, such as the Food and Drug Administration (FDA) and the Occupational Safety and Health Administration (OSHA), also were conducting risk analyses by the mid 1970s. Each agency independently developed analytic procedures suitable for its mission, authority, and budget; published results of risk assessments; and, designed risk management activities with reference to scientists' risk estimates. However, because agencies often shared jurisdiction over an industry or chemical and sometimes came to different conclusions about the level of risk associated with chemicals or industries, as well as the level of risk that should be regulated (a risk management decision), some independent investigators and industry scientists were of the opinion that certain Federal scientific risk assessments were of poor scientific quality. They criticized the

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[4] The Society for Risk Analysis is an international organization of professionals with a strong interest in risk analysis. The membership is multidisciplinary including toxicologists, epidemiologists, statisticians, chemists, physicists, political scientists, economists, psychologists, journalists, sociologists, policy analysts, public affairs specialists, and educators. Researchers, practitioners, and users of risk analysis attend the annual meeting to present papers and learn about the latest risk research.

Federal Government for allowing inconsistent analyses of risks.[5] Often criticisms targeted EPA which tended to produce higher risk estimates and to regulate more stringently.

These criticisms of Federal risk analyses focussed on the diverse choices made by different agencies to cope with inherent uncertainties of risk analysis that arise from missing or ambiguous information on hazards and gaps in current scientific theory. Although generally characterized as a scientific activity, risk analysis is not, and probably can never be, entirely objective or fact-based. Risk analysis was developed to evaluate what is known about things that cannot be known with certainty. Thus, risk analysis produces an estimate, never an exact prediction, of the magnitude and severity of risk. (Weather forecasts, for example, are risk estimates.) Environmental risk analysis is especially beset by many uncertainties, because data usually are sparse, and scientific theories explaining hazards, exposures, and effects often have not been established. To conduct a risk analysis under these conditions, requires choices among plausible alternative assumptions and competing theories to bridge the gaps. Because these choices cannot be based on science alone, they are subject to challenge. For example, if data are available for two animal species, which data should an analyst use or how should data be combined to estimate risk to a third species? The National Academy of Sciences (NAS) identified 50 choices beyond the realm of science (so-called "inference choices") that affect risk analyses.[6] For an excellent, though somewhat dated, discussion of inference choices in the context of cancer risk analysis, see chapter two in *Making Cancer Policy* by Mark Rushefsky.[7]

In 1977, the EPA, OSHA, the Consumer Product Safety Commission (CPSC), and FDA responded to the criticisms of risk analyses by establishing an Interagency Regulatory Liaison Group (IRLG) to coordinate procedures for analyzing cancer risks.[8] The Food Safety and Quality Service of the U.S. Department of Agriculture (USDA) joined the IRLG soon thereafter. The IRLG proposed in 1979 a general "cancer policy" to coordinate risk analysis and risk management across agencies to the extent permitted by statute. According to the NAS, this was "the first evidence that all the [F]ederal regulatory agencies agreed on the inference options applicable to the identification of carcinogenic hazards and measurement of risks".[9]

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[5] Environmentalists also criticized EPA's risk assessments, but their complaint was that EPA used risk assessment to justify less rigorous enforcement of environmental statutes.

[6] National Academy of Sciences. *Risk Assessment in the Federal Government: Managing the Process*. Washington, D.C., National Academy Press. 1983. pp. 29-33.

[7] Rushefsky, Mark E. *Making Cancer Policy*. New York, State University of New York Press, 1986, p. 37-54.

[8] The IRLG was disbanded in 1981.

[9] NAS. Ibid. p. 61.

However, the IRLG policy was controversial. Some scientists and industrial and environmental groups accused the Carter Administration of allowing policy prescriptions to influence scientific judgments. In response, Congress authorized a study by the NAS on institutional arrangements that might improve the agencies' use of risk analysis.[10]

The NAS published the results of the study in a 1983 landmark report, *Risk Assessment in the Federal Government: Managing the Process*, also known as "The Red Book." It described the risk analysis policies and practices of all Federal agencies and concluded that no change in institutional structure was necessary or desirable to improve risk assessments. In addition, the Academy provided a general framework for cancer risk assessment that still is used today; recommended that agencies separate risk assessment from risk management; and suggested development of uniform general risk assessment guidelines for the Federal Government.

In 1985, the NAS framework was adopted by the White House Office of Science and Technology Policy (OSTP), which included scientists from the regulatory agencies, the National Institutes of Health, and other Federal agencies. Although the OSTP decision was not binding on the agencies' risk analysis practices, it provided a consistent basis for developing agency guidelines.

The Reagan and Bush Administrations convened numerous interagency meetings, conducted studies, and issued guidance in the hope that uniform policies and procedures might be established to guide risk analysis and management in the Federal Government. However, no formal guidelines materialized. In August 1994, an interagency work group for the Clinton Administration released *Draft Principles for Risk Assessment, Management, and Communication* to serve as a "general policy framework" for implementing regulatory policy.

Many argue that interagency guidelines cannot, or should not, be established, because the different missions and objectives of Federal agencies require them to adopt different approaches to analyzing and managing risks. Others claim that such guidelines are undesirable because they might freeze development of risk analysis at an immature stage, when its procedures are still rapidly evolving. Still others favor adoption of formal guidance because it would make the decision-making process more transparent to outside observers and, they argue, reduce the influence of politics on scientific judgments made during risk analyses.

In response to criticisms and calls for consistent risk analyses, EPA became in 1977 the first Federal agency to propose interim guidelines for its cancer risk

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[10] The study was authorized in the Act making appropriations for Agriculture, Rural Development, and Related Agencies programs for the fiscal year ending September 30, 1981 (P. L. 96-528). The study was carried out by the National Research Council with support from the Food and Drug Administration.

assessments. In 1986, it was the first agency to establish final guidelines for analyzing risks of cancer and other health effects, all of which were based on the 1983 NAS framework (51 *Federal Register* 33992-34054, Sept. 24, 1986). In addition to cancer risks, the 1986 guidelines for analysis addressed: the risk that a chemical will cause mutations affecting future generations or damage to human development (developmental risks); human exposure to individual chemicals; and human health risks of chemical mixtures. The Agency revised its guidelines for developmental risks in 1991 and for exposure in 1992 (56 *Federal Register* 63798-63826, Dec. 5, 1991; 57 *Federal Register* 22888-22938, May 29, 1992).

In recent years, EPA has continued to be "the main player in developing and revising risk assessment guidelines ... [O]nly EPA has completed scientific reviews of some of its guidelines and formally modified them in response to new scientific information," according to the Congressional Office of Technology Assessment.[11] EPA's cancer risk assessment guidelines currently are being revised. In addition, guidelines currently are being developed for analyzing neurotoxicity and reproductive risks and for exposure measurements. The Agency has proposed a rough framework for ecological risk analysis based on recommendations of the NAS.[12]

State of the Art of Risk Analysis: EPA

Concerns about the scientific quality of risk analyses by Federal agencies have generated numerous studies, often at the request of Congress. A 1987 Office of Technology Assessment comprehensive study of agency policies for animal carcinogenicity studies and for identifying, assessing, and regulating carcinogens concluded:

> Both risk assessment and risk management incorporate policy choices and reflect the values of the risk assessors and managers. Some agencies have attempted to establish separate staffs for the two tasks, but this separation does not eliminate the need to make policy choices about the assumptions used in risk assessments.
>
> The values and policy preferences of decision-makers, risk assessors, and representatives of industry, labor unions, environmental organizations, and public interest groups often differ. Scientists disagree about the nature of scientific evidence. These differences

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[11] U.S. Congress Office of Technology Assessment. *Researching Health Risks*. Washington, U.S. Govt. Print. Off. 1993. p. 120.

[12] U.S. EPA, Risk Assessment Forum. *Framework for Ecological Risk Assessment*.EPA/630/R-92/001. Washington, U.S. Environmental Protection Agency, February 1992. 41 p.

U.S. EPA, Risk Assessment Forum. *Report on the Ecological Risk Assessment Guidelines Strategic Planning Workshop*. EPA/630/R-92/002. Washington, U.S. Environmental Protection Agency, February 1992. 57 p.

U.S. EPA, Risk Assessment Forum. *Draft Ecological Risk Assessment: Issue Papers*. EPA/630/R-94/004A. September 1993. 544 p.

explain some of the past controversies over the regulation of specific carcinogenic chemicals and the development of agency policies.

... Adoption of general guidelines cannot resolve these specific disputes.[13]

Responding to a mandate in the Clean Air Act Amendments of 1990, the NAS National Research Council assessed the current state of EPA risk analyses. The 1994 NAS report *Science and Judgment in Risk Assessment* concluded:

- EPA should generally retain its conservative approach to risk assessment (in which the Agency makes judgments that err, if necessary, on the side of public safety) in the initial phase of setting standards, but EPA should more clearly state its principles.

- EPA should develop and use an iterative approach to risk assessment, beginning with relatively inexpensive screening techniques and moving on to more resource-intensive levels of data gathering, model construction, and model application as each situation warrants. At each level, risk should be reevaluated to produce a more precise estimate. Iteration should cease when no further refinement of the risk estimate is needed to inform risk managers.

- EPA should work to continually improve the models and data used in risk assessments and develop a standard procedure for deviating from its conservative approach to risk assessment when warranted by scientific considerations.

- In its reports to decisionmakers and the public, EPA should present information about the sources and magnitudes of uncertainty as well as point estimates of risk.

- "Risk assessment is a set of tools, not an end in itself. The limited resources available should be spent to generate information that helps risk managers to choose the best possible course of action among the available options" (p. E-14).

The Clean Air Act Amendments of 1990 also established a Risk Assessment and Management Commission to consider the NAS report, methods for measuring and describing risks of chronic human health effects from exposure to hazardous substances, methods to reflect uncertainties, and risk management policy issues. The Commission also was directed to comment on the possibility of developing a consistent risk assessment methodology, or standard of acceptable risk, among various Federal programs.

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[13] U.S. Congress. Office of Technology Assessment. *Identifying and Regulating Carcinogens: Background Paper.* OTA-BP-H-42. Washington, U.S. Govt. Print. Off., November 1987. p. 5.

Members of this Commission have been appointed and the first meeting was held May 16, 1994.[14] At this meeting it was agreed that the Commission would address the contentious issues surrounding proposed legislation requiring risk analysis and Executive Order 12866 on regulatory review (discussed below). The Commission is about two years behind the schedule set by Congress, and hopes to issue its final report in March 1996.

RISK MANAGEMENT AT EPA

The 103rd Congress debated whether EPA has adequately considered risks and costs when exercising its discretionary authority. Specifically, some questioned whether EPA has targeted its resources to address hazards posing the largest environmental risks and whether EPA regulations to reduce risks are worth the cost of compliance and implementation. The 104th Congress is expected to continue debating these issues. This section of the report summarizes EPA's use of risk comparisons and cost-benefit-risk analysis in regulatory decisions.

Comparative Risk Analysis at EPA

In the mid 1980s, the EPA Administrator commissioned a special task force to compare the risks associated with major environmental problems that remained to be controlled, given the level of Federal risk management that existed at the time. The purpose was to help the Administrator determine where available EPA resources could be applied to greatest effect.[15] Senior EPA career managers and technical experts assigned to the task force ranked 31 environmental problems in a 1987 report *Unfinished Business: A Comparative Assessment of Environmental Problems*.

EPA scientists based their ranking on available data, but reported that data gaps and uncertainty about risks plagued their efforts. Ranks did not take into account the feasibility of controlling risks, the economic benefits of activities posing risks, the limits of EPA's statutory authority, or the distribution of risks and benefits geographically, over time, or among people. Problems were ranked based on relative risks within four categories: human cancer risks, other risks to human health, ecological effects, and human welfare (including such effects as visibility impairment and damage to building materials). Scientists grouped environmental problems within categories as relatively high, moderate, or low risks.

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[14] The ten members of the Commission are: Barbara Bankoff (appointed by President Bush), Peter Y. Chiu and Alan Craig Kessler (appointed by President Clinton), David P. Rall and Norman Anderson (appointed by the Majority Leader of the Senate), Gilbert Omenn and Joshua Lederberg (appointed by the Speaker of the House), Virginia Weldon (appointed by the Minority Leader of the House), John Doull (appointed by the Minority Leader of the Senate), and Bernard Goldstein (appointed by the President of the National Academy of Sciences).

[15] U.S. EPA, Office of Policy Analysis. *Unfinished Business: A Comparative Assessment of Environmental Problems*. Washington, U.S. Environmental Protection Agency, February 1987. p. xiii.

The exercise revealed that no environmental problem ranked relatively high or relatively low in all four categories of risk. Problems ranked relatively high or moderate in three or more categories included: criteria air pollutants (that is, lead, sulfur dioxide, nitrogen oxides, particulates, carbon monoxide, and tropospheric ozone), stratospheric ozone depletion, pesticide residues on food, and other pesticide risks. Other relatively high risks to human health included: hazardous air pollutants, indoor air pollution, indoor radon, pesticide application, exposure to hazardous substances in consumer products, and worker exposures to chemicals. Additional problems posing high risks to ecology or human welfare included: global warming; surface water pollution; physical alteration of wetlands, estuaries, and other aquatic habitats; and mining wastes.

Interpretation of these results requires caution. For example, the low relative risk of hazardous waste sites (as indicated by data available in 1987) was due, in part, to the existence of regulations and availability of funds to treat the problem. Problems such as indoor air pollution were characterized as relatively risky, at least in part, because they were not regulated by any Federal agency.

EPA scientists next compared the relative risk of each problem with its budget allocation and the results of national polls of public concerns. The public reported: high concern about chemical waste disposal, water pollution, chemical plant accidents, and air pollution; moderate concern about oil spills, worker exposure, pesticides, and drinking water; and low concern about indoor air pollution, consumer products, radiation (other than nuclear power), and global warming.

EPA concluded that its budget correlated better with the priorities of the public than with the scientists' evaluations of residual risks. However, there are several reasons why this conclusion may be suspect. First, EPA did not ask the public to rank environmental hazards, and it did not use the results of scientific studies of how people rank hazards based on risk. (The results of one such study are shown in the figure titled "How People Evaluate Hazards.")[16] Rather, EPA staff compiled public responses to questions asked in national opinion polls in 1985 and 1986 about 19 environmental problems which roughly coincided with the 31 hazards ranked by EPA scientists. Thus, the scientists' rankings were assigned after hours of careful deliberation, while the public was simply responding to a few questions in an opinion poll. In addition, the scientists and public responded to different questions. Scientists addressed the question, "Of the environmental hazards that are recognized, which pose the highest risks and remain to be controlled?" The public was asked, "Which of

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[16] Scientists, engineers, and other experts in the evaluation of hazards tend to use and interpret the term "risk" in a narrow actuarial sense (e.g., as average, annual mortality rates for a population), whereas non-experts may employ or interpret any of several common meanings of the term, depending on the context. Often, the public interprets "risk" in a very personal way, depending on whether they or their families are exposed. In scientific studies that asked the public to estimate the annual mortality rate for hazards, public and scientific hazard rankings are more similar. For example, see Fischhoff, B., S. Watson, and C. Hope. "Defining Risk." *Policy Sciences*, v. 17, n. 2, (1984). p. 123-139.

these 9 problems are most serious?" or in some cases, "How serious is the problem of [chemical waste disposal, for example]?" Finally, the public responses were compiled and interpreted by EPA staff.

EPA's Science Advisory Board (SAB), an advisory group of independent scientists, reviewed EPA's efforts in its 1990 report *Reducing Risk: Setting Priorities and Strategies*. SAB praised EPA for considering "the long-term public policy importance of understanding relative risks," but criticized the accuracy and methods of ranking and the omission of important environmental problems. It devised its own method and ranked a different, though overlapping, set of environmental issues. The results were largely consistent with those of the EPA scientists, but the SAB expressed more concern about ecological risks because of "the vital links between human life and natural ecosystems." The SAB identified the following hazards that remained to be controlled as the highest human health risks: ambient air pollutants (both toxic and criteria), occupational chemical exposures, indoor air (including radon), and pollutants in drinking water. Relatively high-risk problems affecting ecology and human welfare included: habitat alteration, loss of biological diversity, stratospheric ozone depletion, and global climate change.

Congress appears to support EPA's efforts to rank and compare environmental risks, but to question whether the Agency uses relative risks in the preparation of its budget proposals. Recently, the National Academy of Public Administration (NAPA) initiated a study mandated by a provision in EPA's FY 1994 appropriations legislation (Public Law 103-124). NAPA is "to address whether the Agency's resources are being directed to the most pressing

HOW PEOPLE EVALUATE HAZARDS

Research has shown that risk experts and the public rank hazards in the same order when they are asked to judge the lethality of hazards (Fischhoff, B. and D. MacGregor. "Judged Lethality: How Much People Seem to Know Depends Upon How They Are Asked," *Risk Analysis*, v. 3, n. 4, 1983: 229-236.) However, when asked to judge relative "riskiness", people rank hazards differently, depending on their personal perspectives, training, knowledge, and values. Risk analysts have been trained to evaluate hazards based primarily on annual, average, national death rates. Other groups use broader (and potentially more comprehensive) criteria (as illustrated on page 40.)

Ordering of Perceived Risk for 30 Activities and Technologies

	League of Women Voters	College Students	"Active Club" Members	Risk Experts
Nuclear Power	1	1	8	20
Motor Vehicles	2	5	3	1
Handguns	3	2	1	4
Smoking	4	3	4	2
Motorcycles	5	6	2	6
Alcoholic beverages	6	7	5	3
General (private) aviation	7	15	11	12
Police Work	8	8	7	17
Pesticides	9	4	15	8
Surgery	10	11	9	5
Fire fighting	11	10	6	18
Large construction	12	14	13	13
Hunting	13	18	10	23
Spray Cans	14	13	23	26
Mountain Climbing	15	22	12	29
Bicycles	16	24	14	15
Commercial aviation	17	16	18	16
Electric power	18	19	19	9
Swimming	19	30	17	10
Contraceptives	20	9	22	11
Skiing	21	25	16	30
X rays	22	17	24	7
High school and college football	23	26	21	27
Railroads	24	23	20	19
Food preservatives	25	12	28	14
Food coloring	26	20	30	21
Power mowers	27	28	25	28
Prescription antibiotics	28	21	26	24
Home appliances	29	27	27	22
Vaccinations	30	29	29	25

Note: The ordering is based on the geometric mean risk ratings within each group. Rank 1 represents the most risky activity or technology.

Source: Adapted from Slovic, P., B. Fischhoff, and S. Lichtenstein. "Facts and fears: Understanding perceived risk." p. 191. In: Schwing, R.C. and W. A. Albers, Jr., (eds.). *Societal Risk Assessment: How Safe Is Safe Enough?* New York, Plenum Press, 1980.

environmental hazards, the Agency's statutory mandates in the context of relative risk to human health and the environment, and the effectiveness of the Agency's organizational structure," (S. Rept. 103-137, p. 110). Congress urged NAPA to work with the Risk Assessment and Management Commission (established under the Clean Air Act Amendments of 1990 and discussed above) and NAS. NAPA hopes to report study results prior to February 1995.

Economic Analysis

EPA began analyzing the costs of proposed regulations in the early 1970s. Benefit analysis began a bit later because it is more difficult to describe systematically the progress a proposed or existing regulation will achieve toward goals such as "fishable, swimmable waters" or safe drinking water. At first, the results of EPA's cost-benefit analyses often compared costs expressed in dollars with benefits described qualitatively. Gradually, however, quantitative measures of benefits replaced qualitative descriptions. Recently, the consistent measure of the benefits of an environmental regulation became the risks avoided, expressed as, for example, numbers of lives saved or critical ecosystems protected. To permit mathematical calculations of "net benefits" or a benefit-cost ratio, analysts use various methods to translate the measures of avoided risk into dollars.[17]

Statutory directives, executive orders, and judicial decisions encouraged this development of methods for expressing and comparing the costs and benefits of environmental regulations, but legal mandates also sometimes discourage EPA's use of economic analysis when developing regulations. The following sections describe some key provisions of Federal law and how they might influence EPA actions.

The Influence of Environmental Statutes

Many of EPA's regulatory decisions are driven by specific statutory mandates concerning the degree of protection to be achieved, the actions to be taken, and the criteria to be considered. These mandates vary in specificity, sometimes granting EPA broad discretionary power, and other times little or no power, to consider the economic impacts of its decisions. Some authorize or even require consideration of economic factors, but others do not. A few have provisions that arguably inhibit EPA's ability to consider costs. No statutory provision requires an analysis of net benefits as part of the rulemaking process (although requirements in some statutes to weigh costs and benefits may imply a net benefit analysis). Selected relevant provisions of some key environmental statutes are described below and are summarized in Table 1.

Section 109 of the Clean Air Act (CAA, 42 U.S.C. 7401-7626) mandates the establishment of national primary ambient air quality standards for

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[17] As defined above, "net benefit" is the value of the benefit less the cost, that is, the difference of costs subtracted from benefits. The benefit-cost ratio is the quotient of benefits divided by costs.

Table 1. Statutory Authority for Considering Risks, Technological Capacity, and Costs in Developing Regulations

Statute	Authorized Considerations*	Degree of Protection
Clean Air Act		
§ 109 (national primary ambient air quality standards)	Risk	Protect public health with an adequate margin of safety
§ 112(d) (emission standards for hazardous air pollutants from stationary sources)	Risk, technology, and cost	"The maximum degree of reduction in emissions ... achievable" taking into account costs and any non-air quality health and environmental impacts and energy requirements; may consider health threshold with respect to pollutants for which it has been established, "with an ample margin of safety"
§ 112(f) (emission standards for residual risks of hazardous air pollutants from stationary sources)	Risk (human health); risk and cost (environmental protection)	Provide an ample margin of safety to protect the public health or to prevent, taking into consideration costs, energy, safety and other relevant factors, an adverse environmental effect
§ 202 (emission standards for new motor vehicles)	Risk, technology, and cost	Standards which reflect the greatest degree of emission reduction achievable through technology available, taking into consideration cost, energy, and safety factors; technology must not present an unreasonable risk to health, welfare, or safety
Clean Water Act § 307 (effluent limitations for industrial discharges of toxic pollutants)	Risk, technology, and cost	Defined by applying best available technology, economically achievable, "which will result in reasonable further progress toward the national goal of eliminating the discharge of all pollutants," and to "provide an ample margin of safety" taking into consideration "the toxicity of the pollutant, its persistence, degradability, the usual or potential presence of the affected organisms in any waters, the importance of the affected organisms and the nature and extent of the effect of the toxic pollutant on such organisms, and the extent to which effective control is being or may be achieved under other regulatory authority."

Table 1. Statutory Authority for Considering Risks, Technological Capacity, and Costs in Developing Regulations

Statute	Authorized Considerations*	Degree of Protection
Safe Drinking Water Act § 1412(b)(4)	Risk, technology, and cost	Set water quality goal such that "no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety;" set the enforceable standard as close to health-based goal "as is feasible," given the best technology available (taking costs into consideration)
Resource Conservation and Recovery Act § 3004(a)	Risk[18]	"That necessary to protect human health and the environment"
Federal Food, Drug and Cosmetic Act		
§ 408 (pesticide residues in unprocessed food)	Risk and cost	To the extent necessary to protect the public health, giving appropriate consideration to the necessity for the production of an adequate, wholesome and economical food supply
§ 409 (non-carcinogenic pesticide residues that are concentrated in foods)	Risk	Assure that "the proposed use ... will be safe;" "reasonable certainty in the minds of competent scientists that the additive is not harmful to man or animal;" "the proposed usages of such additives are in amounts accepted ... as safe"
§ 409 (carcinogenic pesticide residues that are concentrated in processed food)	Risk	No residue permitted if the pesticide is found to induce cancer when ingested by man or animal
Federal Insecticide, Fungicide, and Rodenticide Act § 3(b)(5) and § 2(bb)	Risk and cost	"Without unreasonable adverse effects on the environment;" "unreasonable adverse effects on the environment" is defined as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide"

[18] The Act neither encourages nor excludes consideration of costs.

Table 1. Statutory Authority for Considering Risks, Technological Capacity, and Costs in Developing Regulations

Statute	Authorized Considerations*	Degree of Protection
Toxic Substances Control Act		
§ 4 (to require testing)	Risk and cost	"Prevent unreasonable risk of injury to health or the environment"
§ 6 (to regulate)	Risk and cost	"To protect adequately against such (unreasonable) risk using the least burdensome requirement;" "it is in the public interest;" "shall consider ... a comparison of the estimated costs of complying ... and the relative efficiency ... to protect against such risk of injury"
Comprehensive Environmental Response, Compensation, and Liability Act § 121	Risk, technology, and cost	"At a minimum which assures protection of human health and the environment;" at least attains any promulgated standard, requirement, criteria, or limitation under a Federal law or State environmental or facility siting law that is more stringent; "at least attains Maximum Contaminant Level Goals established under the Safe Drinking Water Act and water quality criteria established under section 304 or 303 of the Clean Water Act, where such goals or criteria are relevant and appropriate under the circumstances of the release or threatened release;" However, remedial action may achieve a lesser standard if compliance is technically impracticable from an engineering perspective, compliance would result in greater risk, the State has not consistently applied its standard, Federal funds are inadequate, or other conditions are met

* These are apparently authorized considerations, given the paraphrased or quoted statutory language under the heading "Degree of Protection". Other interpretations of the cited statutory provisions are possible and may have legal precedence.

pollutants from numerous or diffuse sources whose emissions may cause or contribute to air pollution that may "reasonably be anticipated to endanger public health or welfare" [§ 108(a)(1)]. Under this provision, EPA is required to set standards such that their attainment and maintenance "are requisite to protect the public health" in the judgment of the Administrator, based on air

quality criteria and allowing an adequate margin of safety. Air quality criteria are compilations of information reflecting the latest scientific knowledge relevant to the assessment of risks to public health or welfare posed by the presence of criteria pollutants in the ambient air [§ 108(a)(2)]. This statutory provision only authorizes consideration of environmental and human health risks.

In contrast, the CAA § 112(d) requires EPA to consider risks, available technologies, and costs in promulgating regulations to control emissions of 188 hazardous air pollutants from major industrial sources.[19] It directs EPA to require source facilities to apply the "maximum achievable control technology," taking into account costs and other factors. However, subsection (f) of this section also requires EPA to evaluate and report to Congress on the need for health-based standards for these hazardous air pollutants. If Congress fails to act on the basis of EPA's report, EPA is required, if necessary, to promulgate technological standards for industries that provide an ample margin of safety to protect public health and reduce the lifetime excess cancer risks for the most exposed individual to less than one in a million. (This provision will take effect after 2001.) This latter provision does not permit EPA to consider the cost of regulation because the statute defines the level of protection EPA standards must afford.[20] Subsection (f) also requires prevention of adverse environmental effects "with an ample margin of safety" but allows consideration of costs, energy, safety and other relevant factors.

The CAA § 202 requires EPA to establish emission standards for new motor vehicles which reflect the greatest degree of emission reduction achievable through available technology that does not itself pose an unreasonable risk to health, welfare, or safety. These emission standards are set after consideration of cost, energy, and safety factors.

Finally, section 312 of the Clean Air Act requires EPA to conduct comprehensive analyses of the impact of the Act on the public health, economy, and environment of the United States and to report to Congress every two years

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[19] Prior to enactment of the Clean Air Act Amendments of 1990, §112 was widely known as the "cost-blind" statutory provision that required EPA to base decisions on risk alone, that is, without regard to cost. However, the extremely slow pace at which EPA established risk-based regulations led Congress to amend the law.

[20] The statute requires provision of "an ample margin of safety to protect public health in accordance with this section (as in effect before the date of enactment of the Clean Air Act Amendments of 1990)." The reference to the Act prior to amendment indicates that Congress intended a strict interpretation of this language. The Court of Appeals for the District of Columbia Circuit decided in 1987 that section 112 of the Act required EPA to determine what is "safe" based "solely upon the risk to health," and that EPA "could not under any circumstances consider cost and technological feasibility at this stage of the analysis" under the Act (Natural Resources Defense Council v. EPA, 824F.2d at 1164-1165). However, the Court stated that costs and technological feasibility could be considered in promulgating an emissions standard below the "safe" level to provide an "ample margin" and to "take into account the inherent limitations of risk assessment and the limited scientific knowledge of the effects of exposure to carcinogens at various levels."

on the results. It requires consideration of the costs, benefits, and other effects associated with compliance. Specific instructions are given for assessment of costs and benefits of regulations.

Section 307 of the Clean Water Act (33 U.S.C. 1251 *et seq.*) requires EPA to set effluent limitations for discharges of toxic pollutants to surface waters achievable by applying the best available technology that is economically achievable and "will result in reasonable further progress toward the national goal of eliminating the discharge of all pollutants" [§ 301(b)(2)(A).] In addition, the Act requires effluent standards to provide an ample margin of safety, taking into account "the toxicity of the pollutant, its persistence, degradability, the usual or potential presence of the affected organisms in any waters, the importance of the affected organisms and the nature and extent of the effect of the toxic pollutant on such organisms, and the extent to which effective control is being or may be achieved under other regulatory authority." The Act does not instruct the Agency in how it should balance these considerations relative to one another.

The Safe Drinking Water Act does not directly delineate how EPA is to balance risks and costs in setting drinking water standards, but rather has several provisions that, when taken together, inform the Agency on this matter. The Act requires EPA to set drinking water quality goals at levels believed to be safe, and directs the Agency to issue regulations that will reduce levels of contaminants to as close to the goals as is "feasible". In 1986, Congress revised the definition of "feasible" to mean feasible with the use of the "best available technology" that the EPA Administrator determines is available (taking costs into consideration). The law previously used the term 'best *generally available* technology.' Since 1986, the Administrator has been authorized to adopt regulations that may be achieved by use of technologies that are available, although they may not be as widely available or appropriate for controlling water quality in small-scale systems as technologies that are generally available.

The legislative history states that the Administrator's determination of what technologies are available (taking costs into account) in setting drinking water standards should be based on what may reasonably be afforded by large metropolitan or regional public water systems.[21] EPA considers systems serving 50,000 persons or more to be large systems. Only five percent of all public water systems are this large; consequently some smaller public water systems may experience financial hardship meeting regulations. Although legislative history is not necessarily binding on the Agency, EPA has relied on it for guidance in determining congressional intent.

The Resource Conservation and Recovery Act (42 U.S.C. 6901-6991i) aims to assure that hazardous waste management practices "are conducted in a manner which protects human health and the environment" (§ 6902.) It further

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[21] U.S. Senate. Committee on Environment and Public Works. *A Legislative History of the Safe Drinking Water Act.* 97th Cong. 2d. Sess. Serial No. 97-9. Feb. 1982. p. 550.
See also 132 Cong. Rec. S6287 (daily ed. May 21, 1986).

states that it is the national policy of the United States "that, wherever feasible, the generation of hazardous waste is to be reduced or eliminated as expeditiously as possible. Waste that is nevertheless generated should be treated, stored, or disposed of so as to minimize the present and future threat to human health and the environment" (§ 6902.) The Act requires EPA to establish standards "as may be necessary to protect human health and the environment" (§ 6922 - 6924.) The Act does not specify that consideration of costs is permitted, required, or prohibited.

The Federal Food, Drug, and Cosmetic Act, as amended, (FFDCA, 21 U.S.C. 301-394) contains at least two different requirements for evaluating risks and benefits of standards for pesticide residues on food, depending on whether a food is a raw agricultural commodity (e.g., fresh fruit) or a processed food (e.g., jelly) and whether the pesticide has been shown to produce cancer in people or animals. For raw agricultural commodities, section 346a (better known as section 408 of the Act) allows EPA to consider the risks and benefits of pesticide use in setting standards for pesticide residues "to the extent necessary to protect the public health." This section applies equally to carcinogenic and non-carcinogenic pesticides.

In contrast, section 348 (section 409 of the Act), which regulates food additives, treats carcinogens and non-carcinogens differently. Pesticide residues on raw foods that concentrate during processing (for example, canning, drying, or freezing) are treated as food additives. The Act requires EPA to regulate all food additives to assure that "the proposed use ... will be safe." According to the legislative history, "the test which should determine whether or not a particular additive may be used ... should be that of reasonable certainty in the minds of competent scientists that the additive is not harmful to man or animal" (S. Rept. 2422, 85th Cong., 2nd Sess., Aug. 18, 1958, p. 2-3.) The Senate Committee report also stated that the use of food additives "may benefit our people and our economy when the proposed usages of such additives are in amounts accepted ... as safe." This seems to indicate that Congress expects EPA to weigh risks of additives against the benefits they provide when the Agency considers whether a particular pesticide use is "safe" or "not harmful". EPA has interpreted the legislative history to allow risk-benefit balancing (53 *Federal Register* 41106, October 19, 1988.

However, the "Delaney clause" in the same section of the Act prohibits any use of a food additive (including pesticides residues that concentrate during processing) that is shown to be carcinogenic, regardless of the level of risk posed. This interpretation of Delaney as a zero-risk provision for carcinogens that concentrate in processed food was recently supported by the U.S. Court of Appeals for the Ninth Circuit (Les *et al.* vs. Reilly, July 8, 1992.)

The Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 - 136y) directs EPA to limit the sale or use of pesticides "to the extent necessary to prevent unreasonable adverse effects on the environment." The statute further defines this to mean "any unreasonable risk to man or the environment,

taking into account the economic, social, and environmental costs and benefits of the use of any pesticide."

The Toxic Substances Control Act, as amended, (15 U.S.C. 2601-2671) mandates the screening of new and existing chemicals in commerce to determine whether their production, distribution, use, or disposal might pose an unreasonable risk of injury to health or the environment. To that end, EPA is authorized to require companies manufacturing such chemicals to provide data on the chemical's characteristics and use. If the Administrator determines that a chemical poses a "significant risk of serious or widespread harm to human beings from cancer, gene mutations, or birth defects," the Act requires EPA to promulgate regulations to prevent or reduce "to a sufficient extent such risks or publish in the Federal Register a finding that such risk is not unreasonable." The Act requires EPA in promulgating a regulation to consider and publish a statement concerning the potential health and environmental effects of the chemical, the magnitude of exposure to the chemical, the benefits of the chemical for various uses and the availability of substitutes, and "the reasonably ascertainable economic consequences of the regulation, after consideration of the effect on the national economy, small business, technological innovation, the environment, and public health. The Act directs the Administrator to regulate "to protect adequately against such risk using the least burdensome requirement," but to regulate only if it is in the public interest. In determining whether regulation is in the public interest, EPA is directed to consider all relevant aspects of the risk, a comparison of the estimated costs of compliance and the relative efficiency in protecting against risk.

The Comprehensive Emergency Response, Compensation, and Liability Act, as amended, (CERCLA, 42 U.S.C. 9601-9675 and 26 U.S.C. 4611, 4612, 4661, 4662, 4681, and 4682) requires choice of cost-effective remedial actions for contaminated sites, but also requires that the degree of cleanup "at a minimum assures protection of human health and the environment." In effect, CERCLA's standard of risk protection varies from site to site, because for cleanup purposes, the numerical standards, criteria, and goals of all other applicable Federal and State environmental statutes are applied to the conditions at the site. The statute specifically states that where remedial action is taken to protect groundwater, it must at least attain the water quality goals established under the Safe Drinking Water Act, a level of protection greater than is provided by the national primary drinking water standards. CERCLA also specifically requires attainment of the water quality criteria developed by EPA for surface water under the authority of the Clean Water Act; water quality criteria are set at a level that is expected to protect human health and aquatic plant and animal species.

In summary, each environmental statute approaches the problem of controlling risk from a different vantage point and authorizes consideration of different factors by EPA. Some statutes authorize several different approaches for controlling different kinds of risk. One statute, CERCLA, incorporates all of the other statutory approaches to risk, at least in effect. These diverse statutes, however, seem to conform to a few general rules: they generally allow

consideration of the costs of regulation at some stage of risk management, either explicitly or by reference to feasible, practical, or available technology (the Delaney clause is an exception to this rule); they tend to exclude costs from consideration in the development of scientific documents (e.g., water quality criteria,) safety goals (e.g., safe drinking water goals,) or health-based standards of ambient environmental quality (e.g., primary air quality standards,) all of which clearly are meant to be protective of health and the environment; and they require consideration of costs when EPA directly regulates commerce, that is, the production, distribution, and use of commercial products.

Statutes Requiring Analysis of Federal Regulations

Three Acts of Congress, the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Paperwork Reduction Act, as amended, (44 U.S.C. 3501 *et seq.*) and the National Environmental Policy Act (42 U.S.C. 4321-4347) impose additional requirements on Federal agencies for analysis of proposed and existing regulations. The Regulatory Flexibility Act requires agencies to review proposed regulations to describe the impact of proposed rules on, or certify that they will not have a significant economic impact on a substantial number of, small entities which include small businesses, small governmental jurisdictions, and small not-for-profit organizations. It also requires consideration of possible alternatives to the regulatory proposal that will accomplish the objectives while minimizing the impact on small entities. Agencies are required to project reporting, recordkeeping, and other compliance requirements of proposed regulations. EPA's Small Business Ombudsman provides guidelines for analysis of economic impacts on small businesses. The Paperwork Reduction Act, as amended, requires agencies to assess the paperwork and reporting burden placed on the Agency and industry by proposed regulations. In addition, the National Environmental Policy Act (NEPA) requires agencies (other than EPA) to prepare an environmental impact statement for each **major** regulation [15 U.S.C. 793(c)(1); 33 U.S.C. 1371(c)]. The Code of Federal Regulations defines a major regulation under NEPA as a regulation that individually or together with other regulations, may have a major impact on the human environment (40 CFR § 1505,18.) "Impact" is defined as synonymous with "effects" which may be ecological, aesthetic, historic, cultural, economic, social, or health, whether direct, indirect, long-term, short-term, or cumulative (40 CFR § 1508.8.) The regulations further state, "Major reinforces but does not have a meaning independent of significantly." "Significantly," in turn, is defined with reference to the geographic and social context (for example, an impact is significant to society as a whole if it affects all humans or the Nation, while a local impact may be significant for a smaller project), and the severity of impact ("intensity").

Because they are statutory, provisions of these Acts supersede the provisions of all executive orders, discussed below, but they generally complement, rather than contradict, the provisions of the executive orders issued by President Reagan and President Clinton. The statutes do not preempt provisions of other statutes authorizing regulatory activity, however.

President Reagan's Executive Orders (Now Revoked)

Federal agencies also have conducted economic analyses in response to directives from the Chief Executive. To the extent permitted by enabling statutes, the President's Office of Management and Budget (OMB) has required all regulatory agencies to conduct increasingly detailed and quantitative analyses of costs and benefits ever since "Quality of Life" reviews were required under President Nixon. Prior to 1981, EPA's quantitative analyses of regulations aimed at pollution control (as opposed to control of commerce in toxic chemicals) emphasized costs and "affordability".[22] After February 1981, however, when President Reagan issued Executive Order 12291 (revoked in 1993) requiring agencies to perform Regulatory Impact analysis (RIA), cost-benefit analysis was required for all proposed and final "major" rules (46 *Federal Register* 13193, Feb. 19, 1981.) The executive orders defined "major rules" to mean any regulation likely to have an effect on the national economy of $100 million or more. Rules with a smaller economic impact were also "major" if they were likely to result in: a major increase in costs or prices for consumers, individual industries, Federal, State, or local government, or geographic regions; or a significant adverse effect on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets. Proposed legislation in the 103rd Congress and the House Republican's 1994 Contract with America would codify this executive order.

The Reagan order reflected that Administration's commitment to provide "regulatory relief," by providing that "to the extent permitted by law," "regulatory action shall not be undertaken unless the potential benefits to society from the regulation outweigh the potential costs." The order required selection of regulatory **objectives** to maximize net benefits and of the least cost **option** for attaining objectives, unless existing laws prevented this approach. In general, under the Reagan and Bush Administrations, an RIA required an evaluation of all potential costs and benefits that would accompany implementation of a rule, including effects that could not be quantified in monetary terms. Agencies were required to compare the costs and benefits of the proposed rule to the alternative of no regulation as well as to other approaches that could achieve the same objective at lower costs. OMB guidelines for agencies explicitly required analysis of all major alternatives to the proposed rule.[23]

A requirement for risk analysis was not explicit in President Reagan's 1981 order but implied by the mandate to assess net benefits of environmental and health and safety regulations. Most benefits of such regulations are the risks avoided due to Federal action. In January 1985, a second executive order made

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[22] Fraas, Arthur. The Role of Economic Analysis in Shaping Environmental Policy. Law and Contemporary Problems, Assessing the Environmental Protection Agency After Twenty Years: Law, Politics, and Economics. Durham, N.C., Duke University Press, 1991. p. 118.

[23] U.S. Office of Management and Budget, Executive Office of the President. Interim Regulatory Impact Analysis Guidance. Washington, U.S. Govt. Print. Off., 1981.

the requirement for risk analysis (to the extent permitted by law) explicit. President Reagan's Executive Order 12498 (now revoked) on the Regulatory Planning Process (50 *Federal Register* 1036) required agencies to adopt principles contained in an August 11, 1983 report by the President's Task Force for Regulatory Relief. One principle states that "regulations that seek to reduce health or safety risks should be based upon scientific risk assessment procedures, and should address risks that are real and significant rather than hypothetical or remote."

EPA's Response to the Reagan Orders

EPA published its interpretation of the first Reagan Administration executive order in a 1983 report *Guidelines for Performing Regulatory Impact Analysis*.[24] These Guidelines describe how the Reagan Administration expected the directives applicable to all Federal regulatory agencies to be applied in analyses of environmental regulations controlling individual pollutants or particular waste streams.[25] The introduction to the Guidelines summarizes the requirements for Regulatory Impact Analysis (RIA) as follows:

> Benefits and costs should be quantified and monetized in the RIA to the extent possible. The RIA should discuss fully benefits and costs that cannot be quantified and should assess their importance relative to those that are quantified or monetized. When many benefits cannot easily be monetized, or when law requires a specific regulatory objective, cost-effectiveness analysis may be used to evaluate regulatory alternatives.[26]

It further states that "[t]he goal of regulatory impact analysis is to develop and organize information on benefits, costs, and economic impacts so as to clarify trade-offs among alternative regulatory options." The Guidelines clearly indicate

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[24] U.S. EPA, Office of Policy Analysis. Guidelines for Performing Regulatory Impact Analysis. EPA-230-01-84-003. (December 1983).

[25] The introduction to the Guidelines notes that "[t]hey are not readily applicable to regulations for generic information gathering, testing, and procedural rules. In these situations, program offices should contact EPA's Office of Policy, Planning, and Evaluation and OMB in the early stages about procedures, extent of detail, and degree of quantification appropriate for the RIA."

[26] The cost-effectiveness of a regulation is generally defined as the annual cost divided by a measure of progress toward the objective. There is no single definition of the "most cost-effective regulation", but an alternative usually is selected in one of three ways: 1) by choosing the most efficient (least cost) way of achieving the objective; 2) by choosing the alternative that maximizes benefits for a particular cost; or 3) by comparing the relationship between costs and benefits for increasingly stringent regulatory alternatives, and then choosing the regulation that, relative to more and less stringent regulations, provides a significant increase in benefits for a reasonable increase in costs. (This method does not point to a single best choice but can identify regulations that obtain relatively tiny increments of protection for human health or the environment at relatively high costs) (U.S. EPA. Guidelines, p. M14.)

that compliance with Executive Order 12291 required risk analysis to quantify health effects.

The Guidelines permitted RIAs to vary in level of detail provided, extent to which costs and benefits were quantified, and level of precision of the information assessed. Variation also was allowed to accommodate the nature and quantity of data, available analytic techniques, resource or time constraints, or the difficulty of analyzing some environmental problems or regulatory approaches.

In quantifying potential health effects, EPA's Guidelines specified that chemical substances should be evaluated individually based on a weight-of-evidence scientific evaluation. In addition, the guidelines required discussion of particularly sensitive populations, the duration, reversibility, and nature of adverse effects and whether effects resulted from single or repeated exposures to the substance. They required estimation of the risk reduction that would be achieved by a rule, expressed as, for example, numbers of lives saved or illnesses prevented. To permit mathematical calculations of "net benefits," the Guidelines directed analysts to estimate the monetary value of the quantified health benefits based on studies of willingness to pay to avoid illness or cost savings such as health care costs or lost earnings.[27] The monetary value of lives saved by a regulation was required to be estimated statistically for populations.[28]

The Reagan Administration also required some economic analysis for regulations that were not major rules, and all rules were sent to OMB for review. EPA Guidelines state, "sufficient analysis must be performed to demonstrate that the rule meets the objectives of the Executive Order. At a minimum, this should include costs and economic impact (distributional effects) analyses" (p. M3.) However, OMB routinely waived review of certain categories of rules, such as certain rules granting pesticide tolerance exemptions; OMB did not usually require cost-benefit analysis for regulations that revoked requirements (or otherwise "deregulated").[29]

Between 1981 and 1992, EPA issued 1,594 proposed rules and 1,686 final rules, including 92 major proposed rules (5.9 %) and 60 major final rules (3.6 %).[30] Formal cost-benefit analyses were prepared for approximately 80 percent

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[27] As defined above, "net benefit" is the value of the benefit less the cost, that is, the difference of costs subtracted from benefits. The benefit-cost ratio is the quotient of benefits divided by costs.

[28] A more detailed discussion of these guidelines may be found in CRS Report 89-161 ENR, *Health Benefits of Air Pollution Control*, in the chapter by Morris A. (Bud) Ward. p. 295-378.

[29] U.S. EPA. Guidelines. p. 3 (footnote).

[30] Luken, Ralph A., and Arthur G. Fraas. The U.S. Regulatory Analysis Framework: A Review. *Oxford Review of Economic Policy* v. 9, n. 4, 1993. p. 100.

U.S. Office of Management and Budget, Executive Office of the President. Regulatory Program of the U.S. Government. Washington, U.S. Govt. Print. Off., various years.

of the major final rules. The number of cost-benefit analyses prepared for final non-major and all proposed rules is unknown. Several final major rules without comprehensive cost-benefit analyses had court-imposed deadlines for publication (which may have allowed too little time for a comprehensive analysis), and some other rules without analyses were withdrawn or returned to EPA by OMB for further analysis.[31]

The quality of EPA's cost-benefit analyses for final, major rules was inconsistent according to reviews by EPA's Office of Policy, Planning and Evaluation, by Arthur Fraas, a career official in OMB, and by Morris A. (Bud) Ward, Executive Director of the Environmental Health Center, National Safety Council.[32] According to EPA, incomplete analyses in most cases were due to the inadequacy or unavailability of the necessary scientific and/or economic data. In other cases, reviewers have hypothesized that analysis may have suffered due to time constraints imposed by statutory and judicial deadlines, lack of resources to hire additional analysts, and the difficulty of quantifying such benefits as safe drinking water or clean air and of determining their worth in monetary terms.[33] Moreover, in February 1994 testimony before the Subcommittee on Environment, Energy, and Natural Resources of the House Committee on Government Operations, EPA's Assistant Administrator for Prevention, Pesticides and Toxic Substances testified that EPA has routinely adjusted the amount of analysis to the relative importance of the potential impact of a rule.[34]

Despite the uneven quality of EPA's cost-benefit analyses, the Agency's study concluded that "EPA's benefit-cost analyses have resulted in several cases of increased net benefits to society from environmental regulations" and "analyses yielded a return on investment of 1,000 to 1."[35] Between February 1981 and February 1986, EPA's investment (estimated cost of preparing a formal analysis) for a major rule ranged from $210,000 to $2,380,000 and

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[31] Fraas. The Role of Economic Analysis in Shaping Environmental Policy. p. 118.

[32] Ward, Morris A. "Evaluating Health Benefits in Clean Air Act Regulatory Impact Analyses." In: Blodgett, John (ed.) *Health Benefits of Air Pollution Control: A Discussion*, p. 295-378, Washington, U.S. Congressional Research Service, 89-161 ENR, February 27, 1989. 378 p.

Fraas. The Role of Economic Analysis in Shaping Environmental Policy. p. 118.

U.S. EPA, Economic Studies Branch, Office of Policy Analysis. EPA's Use of Benefit-Cost Analysis 1981-1986. August 1987.

[33] Fraas. The Role of Economic Analysis in Shaping Environmental Policy. p. 120.

U.S. Office of Management and Budget, Executive Office of the President. Report on Executive Order No. 12866. May 1, 1994. p. 34, 46.

[34] Goldman, Lynn. Statement before the Subcommittee on Environment, Energy and Natural Resources and the Subcommittee on Legislation and National Security Committee on Government Operations, House of Representatives. February 1, 1994.

[35] U.S. EPA. EPA's Use of Benefit-Cost Analysis 1981-1986. p. 1 and 2.

averaged $675,000.[36] There are no figures available for more recent years or for the preparation of less comprehensive analyses for rules that were not "major" rules.

In many cases, EPA performed cost-benefit analyses but statutory provisions limited their use. According to EPA, it "was able to consider the full implications of its benefit-cost analyses when setting only 6 of the 15 regulations studied" between 1981 and 1986.[37]

Regulatory Planning and Review in the Clinton Administration

Executive Order 12866. On September 30, 1993, President Clinton signed Executive Order 12866 on Regulatory Planning and Review (58 *Federal Register* 51735, Oct. 4, 1993) which revoked and replaced the two Reagan Administration executive orders, Executive Order 12291 requiring RIAs and Executive Order 12498 establishing the regulatory planning process. OMB issued guidance on implementing President Clinton's order October 12, 1993.

On October 26, 1993, President Clinton issued Executive Order 12875, Enhancing the Intergovernmental Partnership, which supplements but does not supersede the requirements contained in Executive Order 12866.

The Reagan and Clinton orders are similar in many ways, but several differences exist that are likely to affect regulatory decisions where the agencies have discretionary authority to consider cost-benefit and risk analyses. Table 2 compares some key provisions relating to cost-benefit and risk analyses in the executive orders issued by Presidents Reagan and Clinton.

The expressed purpose of President Clinton's executive order is to improve the development process for Federal regulations, making it more visible to the public and more efficient and ensuring the primacy of agencies in making decisions and the integrity and legitimacy of oversight. In remarks prior to the signing of Executive Order 12866 on September 30, 1993, the President highlighted unprecedented provisions that, he said, open the regulatory process to public scrutiny while limiting involvement by the President and Vice President in the regulatory process. He directed all Federal agencies to confer with OMB and the public during the early stages of deliberations about whether and how to regulate, to record the basis for regulatory decisions, and to make the records available to the public. Another stated goal of the Clinton Administration is to expedite regulatory action. The early involvement of OMB and others in regulatory planning is intended to serve this purpose. In contrast, President Reagan's orders were intended to improve the quality but also to reduce the number of regulations, and he sought to ensure Presidential oversight of the regulatory process.

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[36] Ibid. p. 6-5.

[37] Ibid. p. 2.

Table 2. Key provisions of President Reagan's Executive Orders 12291 and 12498, now revoked, and President Clinton's Executive Orders 12866 and 12875

Decision Point	Now Revoked Executive Orders 12291 and 12498	Executive Orders 12866 and 12875
Whether to regulate	Only when the potential benefits to society exceed the potential costs to society, to the extent permitted by law	Only when required by law, necessary to interpret the law, or necessary due to compelling public need; only upon a reasoned determination that the benefits justify costs; and only if it would not create a mandate upon a State, local, or tribal government, unless funds are provided by the Federal Government to pay direct costs incurred by that government or the agency provides to OMB a description of: 1) the extent of prior consultation with that government; 2) the nature of that government's concerns, 3) written communications submitted by such government, and 4) the agency's position supporting the need to issue the regulation
Which regulations to analyze	"Major" rules designated by the agency or OMB, both existing and proposed (See Table 3.)[38]	"Significant rules," existing and proposed (See Table 3.)
How priorities are to be established	Maximize aggregate net benefits to society, taking into account the condition of the particular industries affected, the condition of the national economy, and other regulatory actions contemplated; target risks that are real and significant rather than hypothetical or remote	After consideration of degree and nature of risk
How to choose a regulatory objective	To extent permitted by law, to maximize net benefits	To implement law; to address significant problems, including the failure of private markets or public institutions; or to address compelling public need such as material failures of private markets to protect or improve the health and safety of the public, the environment, or the well-being of Americans

[38] All rules were analyzed and sent to OMB, but only to determine whether they are likely to result in an annual effect on the economy of $100 million or more.

Decision Point	Now Revoked Executive Orders 12291 and 12498	Executive Orders 12866 and 12875
Which regulatory approach to choose	To the extent permitted by law, the alternative with the least net cost; address ends rather than means[39]	To extent permitted by law, maximize net benefits; minimize burden for society (including individuals, businesses of differing sizes, and other entities (including small communities and governmental entities), taking into account the costs of cumulative regulations; and designed in the most cost-effective manner. Requires consideration of incentives for innovation, consistency, predictability, enforcement and compliance costs, flexibility, distributive impacts, and equity. Requires specification of performance objectives.
What to analyze, generally	Potential benefits, costs, and net benefits, including effects that cannot be quantified in monetary terms, of the proposed regulation relative to the alternative of no regulation; alternative approaches that could substantially achieve the same objective at lower cost[40]	All costs and benefits (including quantitative and qualitative) of the proposed regulation and alternatives, including the alternative of no regulation and alternatives that do not regulate directly (e.g., by providing economic incentives or information); explore use of regulatory negotiation and other consensual processes
What to analyze, specifically	Costs to consumers, individual industries, Federal, State, or local government agencies, or geographic regions; effects on competition, employment, investment, productivity, innovation, or on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets; and who is likely to receive the benefits and bear the costs	Effects on the efficient functioning of the economy and private markets (productivity, employment, and competitiveness); health and safety; the natural environment; implementation and compliance costs; costs of cumulative regulations; effects on State, local, and tribal governments, including availability of resources to carry out mandates; and discrimination or bias

[39] Additional criteria are specified in guidelines provided by OMB (Circular Number A-94, October 29, 1992, and the Regulatory Program of the U.S. Government for April 1 1991 to March 31, 1992, Appendix V) and EPA (cited above), but these are not included in Table 1. OMB staff have indicated that their guidelines are not expected to change as a result of the Clinton order, and EPA has not issued guidance since it reprinted its 1983 Guidelines with revised appendices in 1991. With regard to choice of a regulatory approach, OMB guidelines state that: entry into private markets should be regulated only where necessary to protect health or safety or to manage public resources efficiently; uniform quality standards for private goods or services should not be prescribed except where products are needlessly unsafe or product variations are wasteful, and voluntary private standards have failed to correct the problem; qualifications for receiving government licenses should be the minimum necessary; encourage unrestricted exchange of rights or obligations created by regulation; and the terms or conditions of Federal grants, contracts, or financial assistance should be limited to the minimum necessary to achieve the purposes for which the funds were authorized and appropriated.

[40] According to page 5 of EPA's 1983 Guidelines, the benefits and costs of proposed regulations and important alternatives were to be compared to the benefits and costs in the absence of regulation, referred to as the "baseline". In addition, the Guidelines required consideration of alternatives to Federal regulation such as "negotiated voluntary actions, and market, judicial, or State or local regulatory mechanisms" and "market-oriented regulatory alternatives."

Decision Point	Now Revoked Executive Orders 12291 and 12498	Executive Orders 12866 and 12875
Comparative risk analysis	No provision	Requires agencies to include in their annual Regulatory Plan comparisons of the magnitude of the risk addressed by each regulatory activity to other risks within the agency's jurisdiction
Basis for analysis	Adequate information; scientific risk assessment procedures	Best reasonably obtainable scientific, technical, economic, and other information
How to treat State, local, and tribal governments	Should not preempt State laws or regulations except to guarantee rights of national citizenship or to avoid significant burdens on interstate commerce[41]	Develop a process to permit meaningful and timely input by State, local, and tribal governments in the development of regulatory proposals containing significant unfunded mandates; in all cases, seek views of State, local, and tribal officials; assess effects on State, local, and tribal governments; minimize burdens on State, local, and tribal governments; harmonize Federal regulations with State, local, and tribal functions; streamline process for waiver application by State, local, or tribal governments, attempt to increase opportunities for use of flexible policy approaches in jurisdictions of applicants where appropriate, render a decision to applicants within 120 days, and notify applicant and explain decisions to deny such applications in writing; OMB to consult with State, local, and tribal government representatives quarterly
How to treat the private sector	Regulations should be substantially supported by the full record, with full consideration to public comments	Seek stakeholder views before publishing a Notice of Proposed Rule Making; periodically consult with representatives of businesses, nongovernmental organizations, and the public

[41] President Reagan's Executive Order 12612 on Federalism Considerations in Policy Formulation and Implementation is still in effect. In general, it aims to "restore the division of governmental responsibilities between the national government and the States that was intended by the Framers of the Constitution and to ensure that the principles of federalism established by the Framers guide the Executive departments and agencies in the formulation and implementation of policies" (52 *Federal Register* 41685, Oct. 26, 1987). Section 6(c)(3) of the order required agencies preparing Federalism Assessments for policies "[i]dentify the extent to which the policy imposes additional costs or burdens on the States, including the likely source of funding for the States and the ability of the States to fulfill the purposes of the policy."

The order of the Clinton Administration directs Federal agencies to promulgate regulations only when necessary due to "compelling public need" and after a reasoned determination that the benefits justify costs, or when required by law. The Reagan order, as mentioned above, permitted regulation only when benefits exceeded costs, unless this approach was prevented by law.

The Clinton order directs agencies to conduct cost-benefit analysis for all "significant regulatory actions." The definition of "significant regulatory action" appears to be more inclusive than the "major rule" definition of Executive Order 12291, indicating that more regulations may be subject to cost-benefit and risk analysis under the Clinton order. (However, OMB will not review rules that are not found to be significant and may not require cost assessments for such rules, as discussed below.) The Clinton Administration also defines advanced notices of proposed rulemaking as regulatory actions; such notices were not defined as rules under the Reagan Administration. The two categories of regulations are compared in Table 3.

President Clinton directs each agency to determine the significance of proposed regulatory activities initially, but authorizes OMB to designate additional rules as significant (within ten days of receiving the agency's list of planned regulatory actions). OMB also is permitted to waive review of an agency's significant regulatory actions. Under the two previous Administrations OMB had similar authority, that is, to designate rules as major and to waive review of particular major rules.

President Clinton requires each agency to "consider the degree and nature of the risks posed by various substances or activities within its jurisdiction" in setting priorities. In contrast, President Reagan required agencies to maximize net economic benefits in setting priorities.

The executive orders of Presidents Reagan and Clinton direct agencies to use different criteria in choosing regulatory objectives. Under the Reagan orders, agencies were required to pursue regulatory objectives that would "maximize net benefits", that is, achieve the greatest possible economic gain for society, to the extent permitted by law. Under the Clinton order, agencies will select regulatory objectives that address significant problems or compelling public need. Economic impacts are not considered in the choice of objectives (although prior to promulgating a regulation, agencies must determine that benefits justify costs, unless the regulation is required by law).

Having determined the targets of regulations, the Reagan Administration directed agencies to choose the regulatory alternative with the "least net cost". The Clinton Administration established three criteria for choosing a regulatory approach: maximize net benefits, minimize the overall regulatory burden for various segments of society, and design the most cost-effective regulation or alternative to achieve the objective. The philosophy of the Clinton order emphasizes the importance of net benefits. It states:

> Further, in choosing among alternative regulatory approaches, agencies should select those approaches that maximize net

Table 3. Characteristics of "Major Rules" and "Significant Regulatory Actions"

Decision Factor	Major Rules	Significant Regulatory Actions
Overall economy	Likely to result in an annual effect on the economy of $100 million or more	May have an annual effect on the economy of $100 million or more
Sectors of the economy	Likely to result in: a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets	May adversely affect in a material way the economy, any sector of the economy, productivity, competition, jobs, or State, local, or tribal governments or communities[42]
Environment and public health	Not included[43]	May adversely affect the environment or public health or safety
Action of other agencies	Not included[43]	May create a serious inconsistency with an action taken or planned by another agency
Budget	Not included[43]	May alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients
Novel legal or policy issues	Not included[43]	May raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles for regulatory planning and review specified in the order

benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity), unless a statute requires another regulatory approach [section 1(a)].

[42] OMB has notified agencies that regulatory actions containing an unfunded mandate should be submitted for review under Executive Order 12866. Since OMB only reviews significant regulatory actions, presumably the presence of an unfunded mandate qualifies a rule as significant.

[43] Effects on the environment, public health or safety, actions of other agencies, budget, or novel legal or policy issues may be considered in a cost-benefit-risk analysis conducted in accord with E.O. 12291, but these effects alone are not sufficient to trigger the requirement to conduct an analysis.

Both the Clinton order and Guidelines for the Reagan orders require consideration of alternatives to Federal regulation such as those that rely on negotiation or economic incentives.

The Reagan orders required analysis of potential benefits, costs, and net benefits of the proposed regulation and alternatives that cost less. Costs, benefits, and net benefits for each alternative were compared to those for the alternative of no regulation. The Clinton order similarly requires analysis of all costs and benefits of the proposed regulation and alternatives, including the alternative of no regulation. It also requires analysis of net benefits (in order to choose an approach that maximizes net benefits) and cost-effectiveness of regulatory alternatives. Thus, the Clinton order appears to have a more comprehensive set of analytic requirements.

More specifically, the Reagan orders required analysts to focus on economic, adverse impacts of regulations (that is, costs) for consumers, individual industries, Federal, State, and local governments, and geographic regions. The orders required measurement of effects on competition, employment, investment, productivity, innovation, and international competitiveness. They also required consideration of the distribution of costs and benefits, that is, who pays and who gains. The Clinton order also requires analysis of the costs of enforcement and compliance to governments, regulated entities, and the public; impacts on innovation; and consideration of who pays and who gains. In addition, the Clinton Administration specifically requires analysis of benefits to the environment and public health and safety. The consistency, predictability, and flexibility of regulations must also be considered. Finally, the Clinton order explicitly requires consideration of whether the impacts are fair.

The Clinton order directs agencies to prepare and submit to OMB an annual Regulatory Plan, in which they identify their planned significant regulatory activities, including a description of how each action will reduce risks. Agencies must compare the magnitude of the risk addressed by each activity to the magnitudes of other risks within the jurisdiction of the agency. The Reagan Administration also required agencies to submit information about regulatory actions underway or planned, but no requirement existed to compare risks addressed by regulations. Instead, the Reagan order focused agency attention on regulatory action to revise or rescind existing rules.

President Clinton's Executive Order 12866 established a Regulatory Working Group to serve as a forum for interagency discussions. Topics to be addressed include comparative risk assessment, innovative regulatory techniques, and streamlined approaches for small businesses and other entities to facilitate their compliance with regulations. Interagency groups also were established under previous Administrations, often to promote coordination of regulatory activity and harmonization of risk assessment practices.

The executive orders of Presidents Reagan and Clinton require analysis to be based on scientific information. In addition, the Clinton Administration

requires agencies to use the "best reasonably obtainable scientific information." President Reagan required analysis "based on adequate information" and risk assessment.

The Reagan orders prohibited Federal agencies from preempting State laws or regulations except to protect civil rights or interstate commerce. Under the Clinton order, OMB is required to meet four times per year with representatives of State, local, and tribal governments to identify planned and existing regulatory activities with potentially significant impacts. Several meetings already have taken place. Representatives of businesses, nongovernmental organizations, and the public also must be consulted about the significance of planned regulatory actions. OMB and the Small Business Administration sponsored two meetings in 1994. The Clinton order requires Federal agencies to develop a process to permit meaningful and timely input by State, local, and tribal governments in the development of regulatory proposals containing significant unfunded mandates. It prohibits the promulgation of regulations that would create a mandate upon a State, local, or tribal government, unless funds are provided by the Federal Government to pay direct costs incurred by that government or the agency provides to OMB a description of: 1) the extent of prior consultation with that government; 2) the nature of that government's concerns, 3) written communications submitted by such government, and 4) the agency's position supporting the need to issue the regulation. The order also directs Federal agencies: to review and streamline processes for waiver applications by State, local, or tribal governments, to attempt to increase opportunities for use of flexible policy approaches in jurisdictions of applicants where appropriate; and to render decisions to applicants within 120 days, notifying and explaining decisions to deny such applications in writing.

EPA's Implementation of Executive Order 12866. An interagency analytical work group is developing principles of analysis for use by all agencies and OMB under Executive Order 12866. This group will decide such technical issues as the rate that future costs and benefits will be discounted to estimate their present value.[44] Technical principles also were developed under the Reagan executive orders. Agencies also are developing implementation guidelines. The final draft of EPA's guidelines is expected to be completed by late 1994, according to EPA's Regulatory Management Division. These internal EPA guidelines will be reviewed by EPA's Science Advisory Board (SAB) and revised, if necessary. The final report may be released in mid-1995.

Since guidelines are still being developed, it is probably premature to draw conclusions about the effect of President Clinton's order. However, an OMB report on agencies' implementation of the order in the first 6 months after publication of the executive order indicates that OMB completed reviews for 42 significant EPA rules, including 21 proposed and 21 final significant rules. For comparison, between 1981 and 1992, EPA issued 60 major final rules and 92

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[44] The discount rate was 10% under President Reagan and 7% under President Bush. A 10% discount rate means that the present value of an asset or loss to be realized one year in the future is 90% of its future value.

major proposed rules. However, because these figures are not truly comparable they should be interpreted with caution. More comparable figures were not available from OMB or EPA.

OMB issued guidance for agencies April 5, 1994, on how to develop the regulatory plan. Draft regulatory plans are due at OMB June 1 each year and a unified plan for the Federal Government will be issued each fall with the semi-annual regulatory agenda (the list of regulations agencies expect to issue in the next 6 months.) The Clinton Administration issued its first regulatory agenda on November 14, 1994 (59 *Federal Register* 57003).[45]

EPA submitted its first plan for review of existing significant regulations on December 29, 1993. The plan describes a broad, bottom-up process by which Agency managers and the Administrator will receive nominations for regulations that should be reviewed and outlines the procedure the Agency will follow to designate significant regulations for the final list to be included in the annual Regulatory Plan. According to EPA's plan, EPA program offices will be more directly involved in planning with less intercession by the EPA Office of Policy, Planning and Evaluation than occurred during previous Administrations.

In a separate September 30, 1993 memorandum to heads of departments and agencies on agency rulemaking procedures, President Clinton directed agencies to examine their internal review procedures for regulations to determine whether and how they might be improved and streamlined. All agencies were required to report the review results to the President. EPA announced June 15, 1994 that it had developed a rule-making process which places regulations in one of three tiers based on the political sensitivity of the rule and the number of media-specific program offices and statutes that would be affected by the rule.[46] The Tier 1 rules are most politically sensitive or controversial and affect major stakeholders and several different programs in the Agency. Tier 1 rules require the most complex and detailed analysis and review processes. According to Assistant Administrator for Policy, Planning, and Evaluation David Gardiner, Tier 3 rules are not necessarily unimportant or inexpensive, but they are less complicated to address and need less review by senior Agency officials. The new process is meant to focus EPA resources where they are most needed, to produce better Tier 1 and Tier 2 rules with a stronger basis in science, and to expedite the development of rules in Tier 3. Of the 352 regulations EPA will be working on through 1995, the Agency designated 27 Tier 1 rules, 158 Tier 2 rules, and 167 Tier 3 rules.

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[45] The Government did not publish a unified plan in 1993.

[46] Bureau of National Affairs. Daily Environment Reporter, no. 118, June 22, 1994, p. AA-1. For the complete text of *EPA's Action Development Process: Regulatory and Policy Development.* Guidelines for Implementation, see Section E.

ANALYSIS

ISSUES IN ENVIRONMENTAL RISK MANAGEMENT

According to panelists in the 1993 CRS workshop on cost-benefit-risk analysis, several developments have spurred congressional interest in the potential utility of environmental risk analysis for informing risk management decisions, including: complaints about inflexible, unprioritized, and "unfunded Federal mandates" imposed on State and local governments, the growing cost of compliance with environmental requirements to regulated industries, the need to reduce the budget deficit while reauthorizing several of the major environmental statutes, and consideration of proposals to elevate EPA to departmental (that is, cabinet) status amidst allegations of inefficient and ineffective EPA programs. Such developments led many to conclude that Federal managers responsible for environmental protection were not doing enough to control costs and should be held accountable; they should be required to use risk analysis and economic analysis to demonstrate that proposed regulations will efficiently reduce serious risks to human health or the environment.

These proponents of risk analysis suggested that it could serve risk management in two general ways: 1) as a basis for comparing and ranking environmental hazards, permitting assignment of priorities for regulatory action, and 2) as a basis for evaluating the effectiveness of specific regulations in reducing risks relative to the costs of compliance and implementation. Debates about these general approaches and more specific legislative proposals promoting risk analysis revolved around five general issues: 1) How valuable is the information provided by risk analysis for policymakers? 2) Is risk analysis a scientific basis for environmental decisions? 3) Should risk analysis be used to quantify environmental and health benefits? 4) Should EPA priorities be based on relative risks and risk reduction opportunities? and 5) Given that EPA already does risk analysis and economic analysis, would additional requirements for analysis improve risk management?

How Valuable Is the Information Provided?

Most people seem to agree that risk analysis is a potentially valuable tool for summarizing scientific information about the potential human health effects of exposure to an environmental hazard.[47] EPA Administrator Browner and Dr. Lynn Goldman, Assistant Administrator for Pollution Prevention, Pesticides and Toxic Substances, have testified repeatedly that they believe risk analysis is a useful tool. Former Administrator Reilly and EPA's Science Advisory Board (SAB), a group of independent scientists appointed by the Administrator who review the scientific bases for EPA's decisions, also have praised risk analysis.

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[47] The information summarized in risk analysis generally is obtained from animal experiments, studies of the effects on humans who have been exposed to hazards, short-term tests on bacteria or living tissues of people or animals, and knowledge and theories about the structure and behavior of chemicals.

The National Academy of Sciences, U.S. General Accounting Office, several State and local government associations, regulated industries, and many academics support the use of risk analysis by Federal agencies.

The apparently widespread agreement regarding the value of risk analysis breaks down, however, when questions arise about how risk analysis should be used and how much influence it should have on Federal regulatory decisions. Opinions range along a continuum. At one end is the belief that risk analysis and economic analysis should be conducted to inform every regulatory decision; EPA should first regulate hazards found to pose the greatest risks, and the reduction in risk due to the regulation should be large enough to justify the cost of implementation and compliance. At the other end of the continuum is the view that EPA should regulate all environmental hazards posing risks unacceptable to the public, unless those responsible for creating the risk (or those profiting from it) demonstrate that it is insignificant or justified, for example, by the benefits provided and a lack of safer alternatives. In this view, chemical releases to the environment are presumed to be unacceptable and should be eliminated and the "polluter should pay" for compliance as well as for toxicity testing and risk analyses, regardless of cost.

Other opinions about the value of risk analysis fall between these two extremes. For example, Presidents Reagan and Bush required, and President Clinton requires analysis of risks and costs for Federal regulations likely to have a "major" or "significant" effect, respectively, on the Nation. The Clinton Administration's requirements govern the current level of risk analysis at EPA. State and local governments and regulated industries generally support a greater role for risk and economic analyses in EPA's risk management decisions to control compliance costs. In contrast, environmentalists and environmental justice activists generally oppose legislation promoting EPA analysis of risks, costs, and benefits, because they fear increased attention to risks will reduce consideration of other important information, for example, about pollution prevention opportunities or potential ecological or aesthetic impacts of management options. These groups prefer the current level of attention to risk, or less.

The CRS workshop panelists generally agreed that decisionmakers need better information about risks, costs, and other aspects of regulatory decisions, including consequences of regulatory options that are not quantifiable, and thought that risk analysis might provide some of that needed information, if it is appropriately adapted to decisionmakers' needs. For example, they noted that risk analysis is useful for such analytic purposes as clarifying trade-offs (that is, choices among mutually exclusive options each of which has both good and bad potential consequences.)

The CRS workshop panelists disagreed about whether risk analysis as currently practiced should be promoted through legislation. Disagreements stem in part from the fact that the information value of risk analysis is highly variable, depending on factors discussed in detail in a later major section of this report.

Is It a Scientific Basis for Environmental Decisions?

Some promote risk analysis because they believe it is an objective scientific basis for environmental policies and management. In their opinion, risk analysis should be used to inform Federal agencies, Congress, and the public, in the hope that it will lead to rational decisions and environmental protection strategies, and replace what these observers regard as a piecemeal environmental policy that developed in response to real and imagined crises. They favor legislation mandating risk analysis by EPA and reports to Congress.

Opponents of such legislation argue that a mandate for risk analysis will not improve environmental decisions, because it is neither pure science nor entirely objective and, they assert, it is easily manipulated for political or venal purposes. The CRS workshop panelists agreed that the results of risk analyses are always debateable, and therefore, reliance on the results of risk analyses in regulating perpetuates debates over how to regulate. In addition, they noted that when risk is managed by comparing risk estimates for different problems or for regulatory options, value judgments are necessary. This issue is discussed under the heading "*Should Priorities Be Based on Relative Risks and Risk Reduction Opportunities?*"

Opponents of legislation mandating risk analysis by EPA also claim that the science used in risk analysis is immature and only is validated for assessing the risk of developing cancer. In addition, they maintain that, for most chemicals, health effects, and ecological effects, data do not exist because scientists have not done the necessary studies, and without data, risk analysis is meaningless. Even when data are available, they argue that human data are usually only from studies of adult white males with occupational exposures, and animal studies are insensitive to risks affecting fewer than 1 % of test animals. CRS workshop panelists agreed that risk analysis focusses attention on the few chemicals that have been tested for toxicity and currently ignores chemical mixtures, possible synergistic effects, and the effects of exposure to multiple emissions sources. The validity of this claim is further discussed in the section of this report titled "The Information Value of Risk Analysis."

CRS workshop panelists agreed that there is cause for concern about the quality of quantitative estimates of risk, costs, and benefits. They said this is because the quality of underlying data is questionable, analyses are difficult to do well and vulnerable to human error, and results are presented without accompanying information about the range of possible estimates that might be produced by different scientists. For example, one panelist claimed that although it is generally thought that risk analyses are deliberately conservative and therefore protective of human health, this is not always true; some risk estimates probably underestimate risk.

Many who promote risk analysis acknowledge that it has limitations but believe they can be overcome through research and development of improved analytic methods or through the establishment of guidelines for the conduct of analysis and presentation of results. Even the imperfect information produced

by risk analysis today is valuable, some argue, and should be considered by decision makers. Clear explanations of the assumptions and uncertainties associated with the risk estimates and standardized methods would reduce the chance of misuse or misunderstanding, proponents of the legislation believe. The consensus among CRS workshop panelists was that risk analysis is quite sophisticated and constantly improving. Several proposals in the 103rd Congress would have required development and use of guidelines for risk analysis, comparative risk analysis, and risk communication, as well as research to improve risk analysis methods.

Should It Be Used to Quantify Environmental and Health Benefits?

Many policymakers would like risk analysis to be used to quantify risk reduction potential of environmental management strategies. Some also want to quantify benefits to permit comparison with the costs of management options. Such information, they argue, would help identify economically efficient choices, that is, how to get the "biggest bang for the buck." Some of these policymakers believe that spending for environmental protection should be managed more efficiently because it is a considerable amount of money, too much to spend wastefully. Others believe spending for environmental protection is excessive, squandering too many public and private resources to produce small or uncertain gains in environmental protection and public health. Legislation addressing these concerns would require EPA to conduct risk assessment and economic assessment (either net benefit or cost-effectiveness assessments) of regulations.[48] Two exemplary proposals were offered by Senator Johnston in the 103rd Congress as amendments to S. 171, a bill to elevate EPA to departmental status, and S. 2019, a bill to amend and reauthorize the Safe Drinking Water Act. Both amendments were accepted and the bills passed the Senate. The requirements of these amendments are summarized and compared to those of the Reagan and Clinton Administrations' executive orders in the appendix to this report.

EPA's most severe critics assert that environmental regulations adversely impact the national economy and international competitiveness of American businesses. (For an analysis of the economic consequences of environmental regulations, see CRS Report 94-175, *Economic and Environmental Policymaking: Two-Stepping to a Waltz.*)

Many environmentalists and others object to quantitative cost-benefit-risk assessment of environmental or health and safety laws and regulations on moral or ethical grounds, claiming that benefits such as life, health, and an aesthetically pleasing environment should not be equated with commodities bought and sold in the market and valued in monetary terms. They want benefits described fully, in qualitative as well as quantitative terms.

Others criticize proposals to rely more heavily on quantitative risk assessment for political reasons. They charge that the complexity of the analytic

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[48] Various forms of economic analysis are discussed on page 4 and in footnotes 16 and 25.

process allows analysts and interest groups to conceal important value judgments and questionable assumptions. Thus, critics of risk analysis legislation argue, the results of risk analysis may be misleading to policymakers, who are the ones charged with the responsibility for making the decisions. Moreover, complexity allows an intellectual elite and those wealthy enough to hire their expertise to dominate discussions and decisions, according to these opponents of legislation.

Scientific objections also have been raised to quantitative assessment of the benefits of risk reduction by those who believe that the economic theories and methods employed to express the value of benefits in dollars are inadequate and unreliable. For example, they contend that surveys asking how much one is willing to pay to obtain a hypothetical reduction in risk are irrelevant to important decisions about real choices in daily life. They argue that for real decisions many factors are considered in addition to the magnitude of risk reduction. For example, people may consider the quality of the benefits and costs, characteristics of those who bear the costs and receive the benefits, the degree of choice available to those exposed, timing of the decision and health or environmental consequences, economic and social status of individuals who benefit or potentially suffer prior to and following the decision, certainty of the risk and cost estimates, and the perceived necessity of choosing among the proffered options. Some believe the only valid approach to quantifying society's values is case-by-case.

DIMENSIONS OF RISK

People untrained in risk analysis evaluate the overall "riskiness" of hazards based on many criteria, such as --

- the necessity of exposure (voluntariness)
- competence and trustworthiness of the hazard managers
- potential for large-scale disaster (at one time and place)
- novelty or complexity of the hazard (making it difficult to manage)
- personal or familial exposure to risk
- exposure of children
- expectation of personal or familial benefits
- quality of harm (severity, duration, reversibility, dreadfulness)

EPA's Science Advisory Board agrees with these critics, in part. It has criticized EPA's methods for assuming that the future value of an ecological resource must be less than its present value. It concluded in a 1990 report that this policy inevitably leads to depletion of irreplaceable natural resources.[49] Moreover, reliance on measures such as the public's "willingness to pay" exacerbates this problem, according to

[49] U.S. EPA, Science Advisory Board. Reducing Risk: Setting Priorities and Strategies for Environmental Protection. Washington, U.S. Environmental Protection Agency, September 1990. p. 8.

the Board. For example, although many members of the public may not care about wetlands, these nonetheless contribute to the larger ecosystem and are valuable now and in the future, for such purposes as waterfowl and fish habitat and to filter pollutants from water. Therefore, the Board concluded, techniques need to be developed to assess the real long-term value of ecosystems.

Critics of quantitative economic analysis also claim that the costs of environmental and health and safety regulations may be exaggerated, because data often are provided by regulated industries, and EPA ignores the "learning curve"; the critics believe real costs tend to go down with time as companies gain experience in complying. In contrast to monetary values, unquantifiable benefits are excluded from analysis, according to critics who are particularly concerned about the discounting of benefits to future generations. CRS workshop panelists noted that EPA has been unable to quantify benefits such as clean ground water and that the Agency claims it does not know how to evaluate costs and benefits of some of its programs.

The insensitivity of quantitative analysis to the value of environmental and health benefits to future generations is an example of the general inability of economic methods to account for uneven distributions of environmental risks and regulatory costs and benefits among people, according to this view. Advocates for environmental justice who seek to eliminate alleged disproportionate risks borne by low-income and minority communities argue that those subgroups may be burdened and other groups may reap a disproportionate share of the risk reduction, while taxpayers and consumers bear the cost of implementation and compliance. Instead of, or in addition to, weighing total costs against total benefits, they want EPA to describe distributions of risks and benefits and to consider inequities in developing environmental regulations. Existing statutes may limit EPA's authority to address this concern in regulations, however. For example, statutes sometimes direct States to design remedies for risks.

Many promoters and critics of environmental risk analysis agree that the results of quantitative risk assessments should not be reported as a single number known as a "point estimate." Point estimates of risk often are used, they believe, (as did CRS workshop panelists) 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. EPA often assesses and reports risk estimates for vulnerable individuals, so this concern may be overstated. Nevertheless, CRS workshop panelists agreed that the results of risk analyses too often are reported as single numbers (point estimates). They would prefer analysts present a range of risk estimates that might be obtained by different scientists with different values and deliberately discuss scientific uncertainty so that decisionmakers are not misled. The quality of the data underlying the risk assessments also should be revealed, they agreed. According to some panelists, cost data and estimates often are uncertain and should be presented as a range of plausible values.

Still others charge that if the goal is to reduce costs of regulations, then Congress should revise the statutes, not just add requirements for quantitative analysis of risks and economic impacts, because EPA cannot consider costs of regulations under some major environmental statutes that dictate the degree of protection to be achieved. In this view, a mandate to analyze in itself is inefficient, because analysis will consume scarce EPA resources, sometimes without purpose. Statutes that impose the greatest regulatory compliance costs (and therefore would be the preferred targets for analytic requirements meant to increase efficiency) prohibit consideration of compliance costs or health, human welfare, and environmental benefits, according to OMB analyst Arthur Fraas.[50]

Finally, many argue that formal quantitative cost-benefit-risk analysis would delay EPA's issuance of some regulations, and delays will mean that lives or habitats might be lost that could have been saved had the regulation been in effect. Delays may even increase the cost of analysis, for example, if the Agency misses statutory or judicial deadlines and environmental groups respond by filing lawsuits, critics argue. Thus, they claim the net benefit of environmental regulation might be reduced. On the other hand, if analysis is cut short to meet deadlines, industries may charge that EPA regulations are arbitrary and capricious. Depending on the statutory requirements, this may also lead to legal challenges. Some critics believe that regulating based on risk is too time consuming, resulting in delayed implementation of statutes enacted to protect human health and the environment. They cite rationale for the Clean Air Act Amendments of 1990 (CAAA) as an example. Before enactment of the CAAA, section 112 of the Clean Air Act required EPA to regulate emissions of hazardous air pollutants based on risk. Only 6 pollutants were regulated in 13 years under that Act. Dissatisfied with the pace of regulation, Congress amended the Act in 1990 to require EPA regulation of emissions of 189 hazardous pollutants based on available pollution control technology.[51]

CRS panelists agreed that data collection and risk analysis can delay regulatory action and consume resources that might otherwise be used to prevent, reduce, or redress environmental pollution. They noted a tendency for agencies to analyze more than is necessary to inform risk managers, and advised that risk analysis should cease when the cost of conducting the analysis and of delayed decisions outweighs the potential value of additional information to decisionmakers.

Those who practice cost-benefit-risk analysis have responded to some of these criticisms by developing new methods. Policymakers also have responded by modifying proposals. For example, the original Johnston amendment that was incorporated into S. 171, a bill to elevate EPA to cabinet status, applied to

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[50] Luken and Fraas. The U.S. Regulatory Analysis Framework: A Review. p. 100.

[51] U.S. Library of Congress. Congressional Research Service. *A Legislative History of the Clean Air Act Amendments of 1990.* Volume 1. Washington, U.S. Govt. Print. Off., Nov. 1993. p. 860-863.

all final rules. The revised version of the Johnston amendment which was accepted as a floor amendment to Senate-passed S. 2019, a bill to reauthorize the Safe Drinking Water Act, required risk and economic analyses only for rules with an annual impact of $100 million or more. In recent years, approximately 3.5 percent of EPA's published rules were expected to have an economic impact greater than $100 million. Thus, the revised provision would have consumed fewer resources.

Critics of cost-benefit-risk assessment are not necessarily opposed to designing efficient environmental protection strategies; many argue that cost-effectiveness is an acceptable form of analysis of alternative management strategies. Cost-effectiveness analysis begins after the health and safety or environmental goal (that is, the level of risk reduction desired) has been established; the analysis then identifies the least cost means of obtaining the benefits. The revised Johnston amendment (section 18 in S. 2019) appeared to require cost-effectiveness analysis.

Should Priorities Be Based on Relative Risks?

EPA's experiments with comparative risk analysis, and similar State experiments that were encouraged and funded by EPA, have generated considerable interest among legislators. Many would like scientists to provide information on how environmental hazards rank based on risk estimates, believing that this information would facilitate decisions about legislative and regulatory priorities. Some have suggested that Federal, State, and local governments should enact budgets and allocate resources that tie the greatest expenditures to environmental hazards posing the greatest risks. Others have proposed that EPA provide perspective for viewing environmental hazards within the context of other Federal programs; they would require EPA to compare the risks of regulated environmental hazards with risks of other regulated and unregulated hazards.

Those who object to comparative risk proposals contend that comparative risk analysis is an unscientific, *ad hoc* procedure that lends a false air of objectivity to the subjective judgments of scientists. They 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. Priority setting requires value judgments, they argue, and should be made politically; 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. Which is worse, one person dying or 10,000 people feeling sick most of the time? Does it matter if the one dying is a child, or a smoker? It is even more difficult and less scientific to compare ecological risks with risks to human health, these critics contend. According to this view, scientists are expert only at determining probabilities, and the public or its representatives

should be asked to contribute their expertise to the process of priority setting. EPA's Science Advisory Board agrees with this view. In *Reducing Risk* it stated:

> ... because they experience those risks first-hand, the public should have a substantial voice in establishing risk-reduction priorities. Thus EPA should include broad public participation in its efforts to rank environmental risks. Such participation will help educate the public about the technical aspects of environmental risks, and it will help educate the government about the subjective values that the public attaches to such risks. The result should be broader national support for risk-reduction policies that necessarily must be predicated on imperfect and evolving scientific understanding and subjective public opinion.[52]

Critics of risk management based on risk comparisons alone (that is, relative risks) also argue that risk is only one aspect of the environmental problems. Some argue that risk comparisons often focus on average national rates of death or disease and ignore equally important factors, such as the acceptability of available risk reduction strategies or the fairness of the result. Priorities should be based on all relevant information about hazards and available management options, not on risk alone, and should be made democratically, they assert. They reason that all means of risk reduction are not equally desirable, citing diverse examples such as the wearing of a gas mask or modification of a production process to reduce use of toxic chemicals.[53] Benefits provided by hazards also vary and should be considered, according to this view, because risk is not always undesirable, 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. Panelists at the CRS workshop agreed that risk analysis, especially quantitative assessment, tends to emphasize the magnitude and severity of consequences over other aspects of the situation, such as whether exposure to the hazard is necessary or voluntary or whether the people who profit from a hazard are the same as the people who are at risk or the people who pay to reduce risk.

In 1989, the NAS published a report that summarized the state of knowledge about how best to communicate about risks.[54] This report is noteworthy primarily because it was a consensus document prepared by the

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[52] U.S. EPA, Science Advisory Board. *Reducing Risk: Setting Priorities and Strategies for Environmental Protection*. Washington, U.S. Environmental Protection Agency. (1990) p. 24.

[53] In general, risk may be eliminated, avoided, or reduced by eliminating, controlling, or isolating the hazard. Alternatively, risk may be reduced without affecting the hazard by preventing or reducing exposure of people or other living things to the hazard. A population also might be compensated for any adverse effects experienced in the event of exposure. The risks of specific hazards may or may not be easily controlled in any of these ways.

[54] National Research Council. *Improving Risk Communication*. Washington, D.C., National Academy Press, 1989. p. 97.

Committee on Risk Perception and Communication of the National Research Council (NRC), a large group of scholars and practitioners with widely differing political perspectives. One topic addressed by the report was how to employ risk comparisons. According to the Committee, risks should only be compared when risks are comparable; risks are comparable when they "exhibit qualitative characteristics that are reasonably similar."[55] This means that the most comparable risks generally are experienced in the same way by the same population for the same reason. For example, the risks of riding a bicycle, walking, or being driven to school may be easily compared. In contrast, the risk of being struck by lightening is not comparable to the risk of traveling, because although both are familiar, the former derives from a natural phenomenon beyond human control; in addition, an individual's risk of being killed by lightening is greatly reduced with little effort, for example by remaining indoors during storms or employing devices to deflect electrical charges. Several qualitative characteristics of hazards (risks) are particularly important to comparability, according to experts including: the magnitude and severity of the potential harm, likelihood of harm, voluntariness of exposure, immediacy of effect, trustworthiness of people managing the hazard (risk), population likely to be exposed, concentration of effects in time and space, population likely to benefit from the activity that creates the risk, and the degree of familiarity of (or adaptation to) the hazard. In addition, the NRC committee cautioned against appearing to select risks for comparison that "minimize or otherwise trivialize the risk in question," for example, by comparing a hazard (risk) like lightening that seems highly unlikely to inflict personal harm to one that is less well understood by scientists and causes deep distress to some individuals, like hazardous waste sites.[56]

Many proponents as well as opponents of risk comparisons agree that if hazards are compared based on risk estimates, risks to subpopulations should be considered as well as risks to the population as a whole. In addition, some propose that distinguishing characteristics of hazards that may affect the acceptability of risks should be highlighted. Committees of jurisdiction reported several bills in the 103rd Congress that required risk comparisons as well as identification of distinguishing characteristics of hazards and consideration of risks to vulnerable subpopulations.

Would Additional Analysis Improve Risk Management?

Proponents of risk analysis, comparative risk analysis, or economic analysis of the potential effects of environmental regulations have various options for promoting the activity. This section examines selected potential impacts of seven general approaches: 1) authorizing or requiring EPA to analyze regulations, 2) authorizing or requiring EPA to consider costs, relative risks, or the relationship between costs and benefits in making regulatory decisions, 3) requiring EPA to report to Congress on the results of regulatory analysis, 4)

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[55] Ibid.

[56] Ibid.

authorizing additional funding for analysis, 5) mandating research and development of analytic methods, the database, or guidelines for risk assessment, 6) establishing guidelines for risk assessment or the presentation of analytic results, or 7) requiring peer review.

In general, provision of statutory authority to conduct or to consider the results of analyses probably would generate less controversy than a mandate, which the Executive might oppose. Some argue that constraints on the prerogatives of managers may violate tenets of good management by reducing the flexibility needed to allocate resources efficiently and to adapt quickly to changing circumstances.

The potential effect on EPA of legislation authorizing or requiring economic or risk analysis or consideration of risks, relative risks, costs, and/or benefits in developing regulations would depend largely on which regulations were to be analyzed. Legislation affecting only "major" or "significant" regulations might have relatively less impact, because EPA already is required, to the extent permitted by law, to conduct and consider the results of cost-benefit-risk analysis for all regulatory actions that are "significant." Statutory requirements would apply even in the absence of an executive order.

Legislation requiring analysis of additional regulations could provide information that now is not readily available. Information about alternative regulatory strategies and their potential consequences (that is, implementation and compliance costs, the risks avoided, and other benefits) could help policymakers and the general public set priorities, allocate resources, and evaluate existing Federal laws and programs.

On the other hand, additional requirements for analysis would require additional resources. The Congressional Budget Office has estimated that it would cost $20 million to analyze all "non-routine" EPA regulatory actions (approximately 50 percent of all regulatory actions.) In the absence of additional resources, the increased number of required analyses might force EPA to reduce the quality of analysis for "significant" regulations. If EPA were to sacrifice analytic quality underpinning its regulations, it might be more vulnerable to legal challenges from regulated entities.

Additional private expenditures also might result from new statutory requirements, because EPA's analyses often use data provided by regulated industries. To supply data for additional analyses, EPA might require additional data collection and reporting by such industries.

Additional requirements for analysis might delay EPA implementing provisions of major environmental statutes. Any such delays would likely anger environmental groups, who might seek to judicially compel EPA action. Delays could also affect regulated industries, for example, if the regulations delayed were meant to clarify or reduce existing regulatory requirements.

Such delays or increases in the cost of regulating might be reduced, however, if legislation authorized analyses that varied in detail in proportion to the significance of regulations. CRS workshop panelists believed that Federal agencies sometimes analyze more than is necessary to inform risk managers. To the extent that this is true, EPA might be able to reduce the overall cost of promulgating regulations, if Congress gave it the authority to vary the depth of analyses.

A Federal mandate to conduct risk analysis to support regulations also might affect data collection, according to CRS workshop panelists. They cautioned that a mandate might discourage industries from doing research and collecting data, because once data are produced, for example, on chemical toxicity, EPA is perceived as being more likely to conduct risk analysis and to regulate.

Requiring analysis or consideration of risks and costs would not necessarily prevent regulation of very small risks. Nor would such a requirement prevent promulgation of regulations that are costly for regulated industries or State or local governments. Since 1981, EPA has almost invariably conducted risk and economic analyses in developing its more costly regulations. Critics have claimed that in come cases the costs appear high relative to the risks they address. Many of EPA's critics believe the Agency is simply too protective of health and the environment. However, an equally plausible explanation for such regulations may be that authorizing statutes constrain EPA (or are interpreted by EPA to constrain it) from considering costs or the magnitude of risk when setting the standards or safety criteria.

If it is determined that some statutes require EPA to regulate insignificant risks regardless of cost, Congress could choose to override existing statutory authority by omitting the standard "saving" clause from legislation that requires consideration of risks, costs, or cost-effectiveness of regulations. However, this would likely require review of each potentially affected environmental statute: an overriding statute might have unintended consequences that would be difficult to predict. In addition, significant opposition might be expected to such legislation because it might appear to reduce the overall level of protection of the environment and public health. Alternatively, Congress might consider amending the requirements for analysis in each environmental statute.

Instead of authorizing or requiring EPA analysis or consideration of risks, costs, or relative risks, legislation could require periodic EPA reports on the results of such analyses of environmental regulations; such reports might assist Members with oversight responsibilities or alert Members on authorizing committees to provisions in authorizing statutes in need of reexamination. Such reports arguably would consume relatively less of EPA's resources and might serve additional purposes, for example, to inform the general public about Federal programs.

Given the historically high level of EPA involvement in risk and economic analyses and the fact that EPA has conducted analyses of proposed regulations

for two decades, often on its own initiative, Congress might conclude that inadequate funds help explain perceived regulatory failures. In this case, Congress might choose to provide additional funding targeted to EPA's analytic activities; more and better analyses and better regulatory decisions might be obtained. A similar argument might be made for eliminating statutory deadlines contained in authorizing statutes: by providing additional time for analysis prior to promulgation of regulations, Congress might enable more comprehensive analyses and more rational decision processes.

Because the NAS has concluded that the greatest improvement in risk analysis might be obtained by improving the quality and comprehensiveness of knowledge, Congress might choose to authorize or mandate EPA attention to research and development.[57] Analytic methods, data collection, or guidelines might be targeted for development. Such legislation would likely generate less controversy.

Finally, those who believe that EPA is dominated by political rather than scientific considerations might prefer to impose scientific guidelines or standards for risk assessment or the presentation of analytic results. Such guidelines or standards could be mandated by Congress, to be developed by EPA, another agency, an interagency workgroup, or an outside body with the relevant expertise. It is questionable, however, whether any group could develop detailed guidance that would be applicable to the array of environmental problems and accepted as "scientific" and unbiased. Many groups have tried to accomplish this task and failed over the last 25 years. In addition, detailed guidance may be difficult to update quickly enough to keep up with rapid changes in science.

Alternatively, Congress could encourage or require development of a system for independent peer review of risk analyses and economic analyses that underpin proposed regulations. Peer review is a familiar and well-established practice among scientists and it generates little controversy. Scientists have found no other means to be as effective for enforcing high standards of quality for scientific publications. Only peer review has been found to be flexible enough to respond quickly to changes in scientific knowledge and methods.

THE INFORMATION VALUE OF RISK ANALYSIS

There appears to be general agreement that policymakers need more information to inform risk management decisions. Views diverge, however, regarding the type of information needed and whether it is best provided by risk analysis. The debate might benefit, therefore, from explicit consideration of what information risk analysis provides.

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[57] NAS, National Research Council. *Risk Assessment in the Federal Government: Managing the Process.* Washington, DC, National Academy Press, 1983. p.5-6.

Key Factors Determining the Quality of Information Provided

Under ideal conditions, a risk analysis might gather, organize, and summarize all of the important information relevant to hazard management. It would include qualitative as well as quantitative information about the characteristics of the hazard, exposed population, potential effects, and potential effects of available management strategies; describe scientific uncertainties; and provide 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 environmental risk analysis varies from abundant (but often with critical gaps) to superficial, from accurate to biased, because risk analysis is a field of inquiry rather than a single method. Risk analysts study hazards using a variety of procedures adapted from other fields of study. Sanitary and industrial engineering, psychology, economics, sociology, statistics, and operations research, for example, have provided models and procedures used by risk analysts. Because some of these methods were developed for different purposes (for example, to determine actuarially sound life insurance rates), they often have not been scientifically validated for, and are difficult to apply to, environmental hazards. The defining characteristic of methods used in risk analysis is a reliance on past experience to predict future events. If there is no past experience, there are no data and there can be no meaningful analysis.

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 either to their randomness or to lack of data or scientific understanding of the principles that govern their occurrence. Its methods were developed to allow agencies to implement legislation despite incomplete data and scientific understanding.

Risk analysis always produces an estimate, never an exact 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 (although risk estimates may be made based on conceptual models or experiences with similar hazards.) If there is experience but no record to ensure accurate recall, risk estimates are likely to be unreliable.

Finally, there are times when risk analysis can provide no information at all, because some environmental hazards and effects defy risk analysis, 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. For example, chemicals in the environment that suppress immune systems may not be recognized as hazards, because their effects will be seen as a variety of health problems, each of which may be attributed to a

different cause. In other cases, only people with certain innate characteristics may be affected by exposure to a toxic substance.

Quality of the Database

The quality of available data largely determines the quality of information that can be provided by a risk analysis. Thus, the NAS concluded in 1983 that the most effective way to improve risk assessment in the Federal Government is to improve the quality and comprehensiveness of knowledge.[58] The current data situation was summarized in a recent report by the Congressional Office of Technology Assessment (OTA).[59] 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, according to OTA. Of course, many of these new chemicals that have not been tested adequately may be harmless, but according to NAS, data are also inadequate for many chemicals that Congress has deemed "hazardous." NAS recently evaluated the availability of data for risk analyses for 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."[60] OTA reported that at least 12 Federal agencies are currently conducting health risk assessment research to fill the gaps in scientific understanding, but their efforts are poorly coordinated and supported at a level that is less than 0.5 percent of the cost of complying with EPA regulations. (This figure does not include research relevant to the analysis of ecological risks.)

Risk Assessment Methods

Environmental risk analysis is a relatively new and immature field, and this is evident in the state of development of its methods. The most developed and well established analytic methods probably are those concerning acute effects; for chronic effects, the most developed are those used to assess human cancer risks of chemicals. These methods evaluate and model the results of animal experiments and human studies to estimate the risk that people will develop cancer following various levels of exposure to individual chemicals. Many of EPA's environmental standards, emission limits, and quality criteria are based on the results of cancer risk assessment. Other categories of risks, such as mutagenicity and immunotoxicity are rarely assessed, representing a substantial hole in risk assessment methodology.

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[58] NAS, National Research Council. *Risk Assessment in the Federal Government: Managing the Process*. Washington, DC, National Academy Press, 1983. p.5-6.

[59] U.S. Congress, Office of Technology Assessment. *Researching Health Risks*, OTA-BBS-570. Washington, U.S. Govt. Print. Off., Nov. 1993. 228 p.

[60] NAS, National Research Council. *Science and Judgment in Risk Assessment*. Washington, National Academy Press. (1994) p. 8-13.

Even cancer risk assessment is beset by the absence of scientific data and theories. The scientific judgments and inference choices that are used to fill these gaps are controversial, because they are shaped by a scientist's values, different scientists have different values, and different choices lead to different risk estimates. Many social scientists who study technical controversies believe that "ostensible disputes over the science are, in reality, over the values inherent in the assumptions."[61] The NAS has identified at least 50 inference choices required in conducting a cancer risk assessment that cannot be made on a scientific basis, and many of these decisions have strong implications for public policy. For example, analysts must determine how much evidence is enough to conclude that a chemical is a possible human carcinogen. Some want strong evidence prior to classification; they prefer to err, if necessary, by withholding judgment until they are sure a problem exists. Others would act on the first available evidence; they prefer to err on the side of alerting public officials to a possible risk.

To reduce the influence of values on individual risk estimates and to ensure that the assumptions and inferences choices made by agencies are clearly expressed, NAS has suggested that Federal agencies should develop and adopt guidelines for risk assessment. EPA adopted the first guidelines for cancer risk assessment in 1977. A revision was promulgated in 1986, and a second revision is in progress.

EPA also established guidelines in 1986 for analyzing: the risk that a chemical will cause mutations affecting future generations or damage to human development; human exposure to a chemical; and human health risks of chemical mixtures. The Agency revised its guidelines for developmental toxicants in 1991 and for exposure in 1992. EPA's cancer risk assessment guidelines currently are being revised. In addition, guidelines are being developed for analyzing neurotoxicity and reproductive and for exposure measurements. The Agency has proposed a rough framework for ecological risk analysis based on recommendations of the NAS.[62] No guidelines are established for assessing the risk of a chemical's adverse effects on the nervous, respiratory, or immune systems, or for other lethal and sublethal effects. *There is no established scientific procedure for assessing ecological risks or for conducting comparative risk analysis.*

Guidelines are necessary to ensure that risk assessments are conducted consistently and, therefore, are more easily evaluated by independent experts.

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[61] Rushefsky, Mark E. "Assuming the Conclusions: Risk Assessment in the Development of Cancer Policy." *Politics and the Life Sciences*, v. 4, (August), 1986. p. 31.

[62] U.S. EPA, Risk Assessment Forum. *Framework for Ecological Risk Assessment.*EPA/630/R-92/001. Washington, U.S. Environmental Protection Agency, February 1992. 41 p.

U.S. EPA, Risk Assessment Forum. *Report on the Ecological Risk Assessment Guidelines Strategic Planning Workshop.* EPA/630/R-92/002. Washington, U.S. Environmental Protection Agency, February 1992. 57 p.

U.S. EPA, Risk Assessment Forum. *Draft Ecological Risk Assessment: Issue Papers.* EPA/630/R-94/004A. September 1993. 544 p.

SOME SUBJECTIVE JUDGMENTS IN RISK ASSESSMENT

What kinds of evidence are needed to demonstrate carcinogenicity?

How important are toxicity studies that show an effect relative to studies that show no effect?

How are benign and malignant tumors in animals counted?

What are the appropriate dose levels for experiments?

How should animal doses be compared to human doses?

How should animal effects be compared to human effects?

Are the effects observed at high doses expected to occur at low doses?

Should different chemical carcinogens be treated differently?

How should carcinogenicity be compared to mutagenicity? To birth defects?

Source: Adapted from Rushefsky, M. *Making Cancer Policy*. Albany, NY, State University of New York Press, 1986. p. 40.

(Independent evaluations of risk assessment by qualified experts, or peer review, is the traditional means by which scientists ensure adherence to professional standards of quality in practice.) However, guidelines do not ensure that equally competent scientists will agree with the risk estimates produced by the process. In fact, some scientists criticize EPA's risk estimates for carcinogens because they do not agree with the guidelines or think different rules should apply to certain chemicals. Controversy surrounds risk assessment only partly because the field is so young that its methods have not been studied thoroughly and adequately validated. NAS concluded in its 1983 report:

> Dissatisfaction with the actions of [F]ederal regulatory agencies is often expressed as criticism of the conduct and administration of the risk assessment process. The Committee believes that the basic problem in risk assessment is the sparseness and uncertainty of the scientific knowledge of the health hazards addressed, and this problem has no ready solution. The field has been developing rapidly, and the greatest improvements in risk assessment result from the acquisition of more and better data, which decreases the need to rely on inference and informed judgment to bridge gaps in knowledge" (p. 5-6).[63]

Thus, controversy will not disappear when risk analysis matures, because it grows inevitably from value judgments based on different ethical systems and

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[63] Ibid.

inference choices embodied in agencies' science policies which make risk assessment possible as well as from the special interests that stakeholders have in EPA's risk estimates.

LEGISLATIVE ACTIVITIES

LEGISLATION IN THE 103RD CONGRESS

More than a dozen bills and amendments on environmental risk analysis were introduced in the 103rd Congress. One was enacted, but it applied to the Department of Agriculture, not EPA. Nine other bills were passed by one chamber or reported by the committees of jurisdiction.

Arguably, the most influential risk proposals in the 103rd Congress were offered by Senator Johnston. The two "Johnston amendments" would have required EPA to analyze risks, costs, and benefits for proposed and final regulations. The original "Johnston amendment" was the first risk legislation debated on the Senate floor, and it was adopted on April 29, 1993, by a vote of 95 to 3. The amendment was incorporated as section 123 in S. 171, a bill to raise the U.S. Environmental Protection Agency (EPA) to department (cabinet) status. A similar proposal that would have amended a House bill to elevate EPA to the cabinet (H.R. 3425) was unsuccessful, however. The rule for consideration of the reported bill was defeated on the House floor, reportedly in part because the rule would have prevented introduction of non-germane amendments, such as that on risk and cost-benefit analysis.

During the second session of the 103rd Congress, Senator Johnston addressed some of the key concerns of House Members when he introduced a revised version of his amendment. It was adopted by the Senate during the May 18, 1994 floor debate on Senate-passed S. 2019, a bill to amend and reauthorize the Safe Drinking Water Act. Both amendments are summarized in the Appendix. The Appendix also compares the amendments' provisions with requirements in President Clinton's executive orders, which some argue, eliminate the need for legislation.

The Senate also passed S. 2019, amending and reauthorizing the Safe Drinking Water Act, which included in §15 a revised version of a bill originally introduced by Senator Moynihan (S. 110) that would have required EPA to rank pollution sources based on risk. The Senate also adopted House-passed H.R. 820, the National Competitiveness Act of 1993, after amending it to require all Federal agencies to prepare and publish an economic and employment impact statement for each rule and notice published in the *Federal Register*. The House passed H.R. 1994 reauthorizing EPA's environmental research program and establishing a core research program on risk reduction, and H.R. 3870 promoting research, development and deployment of environmental technologies and requiring OSTP to establish a protocol for conducting and reporting the results of risk assessments which are conducted to inform efforts to prioritize research projects. The House Committee on Science, Space and Technology

reported H.R. 4306, amended, Oct. 7, 1994 (H.Rept. 103-857). It would have established a program in EPA to develop risk assessment guidelines, oversee their implementation, provide for scientific peer review, identify and conduct research on risk assessment methods, and develop risk characterization guidance and oversee its implementation. A pilot program on comparative risk analysis and an interagency coordinating process in OSTP also would have been established by H.R. 4306.

For more detailed information on these and other proposals in the 103rd Congress, see CRS Report 94-716, *Comparison of Environmental Risk Provisions in the 103rd Congress.*

OUTLOOK FOR THE 104TH CONGRESS

The House Republican Contract with America promises that within the first 100 days of the 104th Congress risk legislation will be introduced, debated, and voted upon in the House. Title III of the "Job Creation and Wage Enhancement Act of 1995" (JCWEA), one of the draft bills distributed with the House Republican contract, appears to integrate several of the proposals that saw action in the 103rd Congress. For example, the JCWEA title III contains a slightly modified version of the original Johnston amendment, with coverage expanded beyond EPA to include all Federal agencies that promulgate regulations concerning human health and safety or the environment.

In addition, some proposals that did not advance in the 103rd Congress may have more vigor in the 104th; for example, almost all the provisions of H.R. 2910, the Risk Communication Act of 1993, are found in the JCWEA title III. It would require Federal agencies to distinguish explicitly between scientific findings and other considerations in risk assessments, to consider negative as well as positive experimental data, and to explain underlying assumptions and models. It also specifies the contents of all public risk characterizations and requires each agency to establish guidance for risk assessment and risk characterization. A modified version of H.R. 3695, which also was contained in the Republican Budget Initiative for Fiscal Year 1995, appears in title VII of the draft JCWEA. It would codify most of President Reagan's Executive Order 12291, but would significantly expand the requirements for Regulatory Impact Analysis and would define a "major rule" as any proposed regulatory action that would affect more than 100 persons or for which any one person would be required to expend more than $1 million to comply.

For more information on these or other proposals in the 104th Congress, see the CRS Issue Brief *The Role of Risk Analysis and Risk Management in Environmental Protection* (IB 94036).

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APPENDIX

REQUIREMENTS FOR ANALYSIS OF RISKS, COSTS, AND BENEFITS IN SENATE-PASSED BILLS OF THE 103RD CONGRESS: A COMPARISON WITH REQUIREMENTS IN EXECUTIVE ORDERS OF PRESIDENTS REAGAN AND CLINTON

Introduction

The Senate of the 103rd Congress passed two versions of a proposal known as the Johnston amendment (S. 171, § 123 and S. 2019, § 18) that would have required economic and risk analyses for EPA regulations. The original Johnston amendment was incorporated into S. 171, a bill to elevate EPA to cabinet status. It would have required analyses for all EPA final rules and EPA certification that the benefits justified the costs. The revised version of the Johnston amendment, which was attached to Senate-passed S. 2019, a bill to reauthorize the Safe Drinking Water Act, would have required risk and economic analyses only for rules with an annual impact of $100 million or more, and certification that the proposed rule was cost-effective. It also would have required risk analysis for subpopulations at potentially greater risk than the population as a whole. A slightly modified version of the original Johnston amendment to S. 171 appears in the publicly distributed draft of the "Job Creation and Wage Enhancement Act of 1995" (title III, subtitle B), which the House Republican Contract with America states will be brought to the House floor within the first 100 days of the 104th Congress.

Many have argued that the provisions in the Johnston amendments are unnecessary, because EPA already is required by order of the President to analyze risks, costs, and benefits of its most costly regulations. According to the Clinton Administration, the President's Executive Orders 12866 on Regulatory Planning and Review and 12875 on Enhancing the Intergovernmental Partnership, extended and built upon the earlier orders of President Reagan on Federal Regulation (Executive Order 12291) and the Regulatory Planning Process (Executive Order 12498) (which were revoked and replaced by Executive Order 12866). Proponents of statutory requirements for risk and economic analyses counter that a legislative mandate to EPA is needed despite any overlap with Presidential orders, because the latter may be revoked by future Administrations. For example, they point out, President Clinton revoked President Reagan's Executive Orders 12291 on Federal Regulation and 12498 on the Regulatory Planning Process when he issued Executive Order 12866 on Regulatory Planning and Review. Title VII of the draft "Job Creation and Wage Enhancement Act of 1995" would codify most of Executive Order 12291, but would significantly expand the contents of an RIA and define a "major rule" as any proposed regulatory action that would affect more than 100 persons or for which any one person would be required to expend more than $1 million to comply.

This Appendix summarizes and compares the proposed requirements of the Johnston amendments and the executive orders for regulatory review issued by Presidents Reagan and Clinton. The discussion is summarized in Table 1.

Provisions of the Johnston Amendment to S. 171[64]

To the extent permitted by law, the Senate-approved Johnston amendment to S. 171 would require the Department of the Environment, when promulgating any final regulation relating to human health and safety or the environment, to publish in the *Federal Register*:

(1) an estimate of the risk to public health and safety addressed by the regulation and its effect on human health or the environment and the costs associated with implementation of, and compliance with, the regulation;

(2) a comparative analysis of the risk addressed by the regulation relative to other risks to which the public is exposed;

(3) the Secretary's certification that:

(A) the estimate and analysis are based upon a scientific evaluation of the risk and are supported by the best available scientific data;
(B) the regulation will substantially advance the purpose of protecting the human health and safety or the environment against the specified identified risk; and
(C) the regulation will produce benefits to the human health and safety or the environment that will justify the implementation and compliance costs to the Government and the public.

If the Secretary cannot make the certification, the Secretary must report to Congress that the certification cannot be made and must include a statement of the reasons in the final regulation. Finally, the amendment states that the certification does not modify any statutes and is not subject to judicial review, and that "nothing in this section shall be construed to grant a cause of action to any person."

Several undefined terms and phrases in the Johnston amendment to S. 171 complicate evaluation and comparison to the executive orders. For example, is "an estimate, performed with as much specificity as practicable" (S. 171, as passed, §123) a single number, a range of numbers, a detailed quantitative description of the relationship between risks and costs, or simply a judgment about the value of a regulation? Because the debate surrounding the amendment seemed to assume that it is meant to require quantitative cost-benefit and risk analysis, a similar assumption is adopted in this report for purposes of discussion. *Based on this interpretation,* the S. 171 Johnston amendment's requirement to estimate risks and costs of environmental regulations seems similar to the requirements for analyses under executive

[64] Section 123 in Senate-passed S. 171.

orders, now revoked, that were issued by previous Administrations.[65] An important difference between the Johnston amendment to S. 171 and the other documents discussed below, however, is that this original Johnston amendment would apply to every final regulation issued by EPA, regardless of its significance, whereas the revised Johnston amendment and the two executive orders apply only to major or significant regulations.

Provisions of the Johnston Amendment to S. 2019

To the extent permitted by law, the Senate-approved Johnston amendment to S. 2019 (section 18) would require EPA, when promulgating any proposed or final major regulation relating to human health or the environment, to publish in the *Federal Register* a clear and concise statement that:

> (1) describes and, to the extent practicable, quantifies the risks to be addressed by the regulation, including risks to significant subpopulations who are disproportionately exposed or particularly sensitive;
>
> (2) compares the risks to be addressed to at least three other risks regulated by EPA or another Federal agency and at least three other risks not directly regulated by the Federal Government;
>
> (3) estimates the costs to the U.S. Government, State and local governments and the private sector of implementing and complying with the regulation and the benefits of the regulation, including quantifiable measures and qualitative measures that are difficult to quantify; and
>
> (4) contains a certification by the Administrator that:
>
> > (A) the analyses are based on the best reasonably obtainable scientific information;
> > (B) the regulation is likely to significantly reduce the risks to be addressed;
> > (C) there is no regulatory alternative that is allowed by the statute that would achieve an equivalent reduction in risk in a more cost-effective manner; and
> > (D) the regulation is likely to produce benefits that will justify the costs.

The amendment defines a major regulation as "a regulation that the Administrator determines may have an effect on the economy of $100 million or more in any one year." As in the original Johnston amendment to S. 171, EPA must report to Congress identifying major regulations for which complete certification could not be made and summarize the reasons. The amendment to

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[65] For example, Executive Order 12044, issued by President Carter in 1978 and revoked by President Reagan in 1981, required Federal agencies to perform Regulatory Impact Assessments (RIAs) to consider the economic consequences of proposed regulations. The RIAs were to include a statement of the problem, a description of alternative ways of alleviating the problem, the economic costs of each alternative proposed, and the reason for selecting one of the options.

S. 2019 also contains a clause clarifying the effect of its amendment on other statutes. This savings clause, however, is broader than the one contained in S. 171. S. 2019 states that nothing in the section affects any other provision of Federal law, shall delay action required to meet a deadline imposed by statute or a court, or creates any right to judicial or administrative review. Further, it states that in the event that a regulation is subject to judicial or administrative review under another provision of law, any alleged failure to comply with this section may not be used as grounds for affecting or invalidating such regulation.

Compared to the Johnston amendment to S. 171, the Johnston amendment to S. 2019 more clearly indicates the extent to which risks and benefits of regulations should be quantified. Risks would be quantified "to the extent practicable" while costs and benefits would be estimated "including both quantifiable measures ... to the fullest extent that they can be estimated, and qualitative measures that are difficult to quantify."

By requiring analyses of proposed as well as final rules, S. 2019's Johnston amendment provides an opportunity for public comments before final regulations are promulgated, an opportunity not afforded by S. 171. Analysis of proposed rules in addition to final rules probably would not increase the burden on EPA (compared to the requirements of S. 171), however, because the Johnston provisions in S. 2019 apply only to major regulations, and only about 3.6 percent of the 168 final rules promulgated and 5.9 percent of the 1,594 rules proposed by EPA between 1981 and 1992 were "major."[66] In addition, S. 2019 allows EPA to publish a reference to the published statement for a proposed major rule in lieu of repeating the statement for a final major rule if it is substantially similar to the proposed rule.

Senate-passed S. 2019 would require risks to be compared to at least six other risks, whereas the amendment to S. 171 does not specify how many comparisons would be appropriate.

The Johnston amendment to S. 2019 requires EPA to analyze risks to significant subpopulations in addition to risks to the population as a whole; this provision reflects concerns about relatively large risks to small groups with higher exposures or unusual sensitivity to environmental hazards.

Under S. 2019, the Administrator must certify that regulations proposed or promulgated are the most cost-effective of the regulatory alternatives permitted by the authorizing statutes. This provision allows EPA to consider unquantifiable benefits of regulation, such as ethical and environmental benefits, in addition to economic benefits in establishing goals and standards for environmental quality and human health. In contrast, S. 171 might be interpreted to require certification that costs are justified quantitatively by the benefits, for example, by demonstrating that the regulation will produce a net benefit.

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[66] Luken, Ralph A., and Arthur G. Fraas. The U.S. Regulatory Analysis Framework: A Review. *Oxford Review of Economic Policy* v. 9, n. 4, 1993. p. 100.

Comparison of Provisions

Table A-1 summarizes the following discussion.

First, it should be noted that none of the provisions compared below supersedes specific mandates in authorizing statutes, such as the Clean Air Act or the Safe Drinking Water Act, with regard to how EPA should weigh costs and risks in developing regulations; executive orders never supersede statutory mandates, and the Johnston amendments explicitly state that the requirement for certification (described below) does not modify any statutes.

The expressed purpose of President Clinton's executive order is to improve the development process for Federal regulations, making it more visible to the public and more efficient and ensuring the primacy of agencies in making decisions and the integrity and legitimacy of oversight. Another stated goal of the Clinton Administration is to expedite regulatory action. In contrast, President Reagan's orders were intended to improve the quality but also to reduce the number of regulations, and he sought to ensure more Presidential oversight of the regulatory process. The Johnston amendments would ensure that the public and Congress are informed about the Agency's estimates of risks, costs, and benefits associated with EPA regulations and that EPA officials have thought about the consequences of regulating. A key difference between the Johnston amendments and the executive orders is that the Johnston amendments would apply only to EPA, whereas the orders applied/apply to most Federal agencies.

The new order of the Clinton Administration directs agencies to promulgate regulations only when necessary due to "compelling public need" and after a reasoned determination that the benefits justify costs, or when required by law. The Reagan order, as mentioned above, permitted regulation only when benefits exceeded costs, unless this approach was prevented by law. The Johnston amendments are silent on this question.

The Clinton order directs agencies to conduct cost-benefit analysis for all "significant regulatory actions." The definition of "significant regulatory action" is more inclusive than the "major rule" definition of Executive Order 12291, indicating that more regulations may be subject to cost-benefit and risk analysis under the Clinton order. (However, OMB will not review rules that are not found to be significant and may not require cost assessments for such rules, as discussed below.) Whether the Johnston amendment to S. 171 would be still more inclusive with respect to rules issued by EPA is unclear, because although it requires cost-benefit and risk analysis of all final regulations, regardless of their significance, it does not address proposed rules, notices of proposed rulemaking, or advanced notices of proposed rulemaking, all of which are defined as regulatory actions under the Clinton order and as rules under the Reagan order (with the exception of advanced notices of proposed rulemaking which were not included under the Reagan order). The revised Johnston amendment (S. 2019, §18) applies to proposed and final major rules.

President Clinton directs each agency to determine the significance of proposed regulatory activities initially, but authorizes OMB to designate additional rules as significant (within ten days of receiving the agency's list of planned regulatory actions). OMB also is permitted to waive review of an agency's significant regulatory actions. Under the two previous Administrations, OMB had similar authority, that is, to designate rules as major and to waive review of particular major rules. The Johnston amendments do not provide OMB or EPA discretionary power but recognize that circumstances may prevent EPA compliance. In such cases, S. 171 and S. 2019 would require EPA to report the reasons for noncompliance in the *Federal Register* and to Congress.

President Clinton requires agencies to "consider the degree and nature of the risks posed by various substances or activities within its jurisdiction" in setting priorities for regulation. President Reagan required agencies instead to maximize net benefits. The Johnston amendments do not mention the setting of priorities, but EPA would be required to publish a comparative analysis of the risk addressed by the regulation relative to other risks to which the public is exposed.

The executive orders of Presidents Reagan and Clinton direct agencies to use different criteria in choosing particular regulatory objectives. Under the Reagan orders, agencies were required to pursue regulatory objectives that would "maximize net benefits", that is, achieve the greatest possible gain for society. Under the Clinton order, agencies will select regulatory objectives that address significant problems or compelling public need. The Johnston amendments are silent on this issue.

Having determined the targets of regulation, the Reagan Administration directed agencies to choose the regulatory alternative with the "least net cost." The Clinton Administration established three criteria for choosing a regulatory approach: maximize net benefits, minimize the overall regulatory burden for various segments of society, and design the most cost-effective regulation or alternative to achieve the objective. Again, the Johnston amendments do not address this issue.

The Reagan orders required analysis of potential benefits, costs, and net benefits of the proposed regulation and alternatives that cost less. Costs, benefits, and net benefits for each alternative were compared to those for the alternative of no regulation. The Clinton order similarly requires analysis of all costs and benefits of the proposed regulation and alternatives, including the alternative of no regulation. It also requires analysis of net benefits and cost-effectiveness of regulatory alternatives. The Johnston amendments would require analysis of risks and relative risks addressed by EPA regulations and the costs and benefits of regulating. The Johnston amendment to S. 171 could be interpreted to require calculation of net benefits, whereas the Johnston amendment to S. 2019 would require cost-effectiveness analysis of regulatory alternatives. The Clinton order appears to have the most comprehensive set of analytic requirements.

The Reagan orders and the Clinton order require analysis of the costs of enforcement and compliance to governments, regulated entities, and the public; impacts on innovation; and consideration of who pays and who gains. In addition, the Clinton Administration specifically requires analysis of benefits to the environment and public health and safety. The consistency, predictability, and flexibility of regulations must be considered as well. Finally, the Clinton order requires consideration of whether the impacts are fair. The Johnston amendment to S. 171 would require analysis of risk to individuals addressed by the regulation, the health and environmental effects of the regulation, and implementation and compliance costs. The Johnston amendment to S. 2019 would require analysis of risks to human health or the environment addressed by the regulation, including risks to significant subpopulations that are disproportionately exposed or particularly sensitive, the quantitative and qualitative benefits of the regulation, and the costs to the U.S. Government, State and local governments, and the private sector of implementing and complying with the regulation.

The Clinton order directs agencies to prepare and submit to OMB an annual Regulatory Plan, in which they identify their planned significant regulatory activities, including a description of how each action will reduce risks. Agencies must compare the magnitude of the risk addressed by each activity to the magnitudes of other risks within the jurisdiction of the agency. President Clinton's requirement for comparative risk analysis is similar to a provision in the Johnston amendments. The Reagan Administration did not require agencies to compare risks addressed by regulations, but they were required to submit information about regulatory actions underway or planned.

President Clinton's Executive Order 12866 also established a Regulatory Working Group to serve as a forum for interagency discussions. Topics to be addressed include comparative risk assessment, innovative regulatory techniques, and streamlined approaches for small businesses and other entities to facilitate their compliance with regulations. Interagency groups also were established under previous Administrations, often to promote coordination of regulatory activity and harmonization of risk assessment practices. The Johnston amendments do not address this issue.

The executive orders of Presidents Reagan and Clinton and the Johnston amendments all require analysis to be based on scientific information. In addition, the Clinton Administration and Johnston amendment to S. 2019 require agencies to use the "best reasonably obtainable scientific information." President Reagan required analysis "based on adequate information" and risk assessment. The Johnston amendment to S. 171 requires evaluation of risks and use of "the best available scientific data."

The Reagan orders prohibited Federal agencies, to the extent permitted by Federal law, from preempting State laws or regulations, except to protect civil rights or interstate commerce. Under the Clinton order, OMB is required to meet four times per year with representatives of State, local, and tribal governments to identify planned and existing regulatory activities with potentially significant impacts. Representatives of businesses, nongovernmental

organizations, and the public also must be consulted about the significance of planned regulatory actions. The Johnston amendments do not address the role of State, local, or tribal governments or the private sector in the development of regulations.

Table A-1. Key provisions of the Johnston Amendments to S. 171 and S. 2019, President Reagan's Revoked Executive Orders 12291 and 12498, and President Clinton's Executive Orders 12866 and 12875

Decision Point	Johnston Amendments to S. 171 and S. 2019	Reagan Administration Executive Orders 12291/12498	Clinton Administration Executive Orders 12866/12875
Purpose of analysis	To publish estimates of health risks and costs and benefits of regulating; to certify the value of the regulation (see "Certification" below); and, to inform Congress if such certification cannot be made	To reduce the burdens of existing and future regulations, increase agency accountability, provide for Presidential oversight of the regulatory process, minimize duplication and conflict of regulations, and insure well-reasoned regulations	To enhance planning and coordination with respect to both new and existing regulations; to reaffirm the primacy of Federal agencies in the regulatory decision-making process; to restore the integrity and legitimacy of regulatory review and oversight; and to make the process more accessible and open to the public

Decision Point	Johnston Amendments to S. 171 and S. 2019	Reagan Administration Executive Orders 12291/12498	Clinton Administration Executive Orders 12866/12875
Certification	S. 171 - Requires EPA to certify that: 1) the estimate and analysis are based on scientific evaluation of risk and supported by the best available scientific data; 2) the rule will substantially advance the purpose of protecting human health and safety or the environment; and 3) the rule will produce benefits that justify the cost of implementation and compliance. Requires report to Congress if certification cannot be made. S. 2019 - Requires EPA to certify that: 1) analyses are based on the best reasonably obtainable scientific information; 2) the regulation is likely to significantly reduce the risks; 3) there is no more cost-effective regulatory alternative allowed by statute; and 4) the regulation is likely to produce benefits that will justify the costs. Requires report to Congress if rules cannot be certified.	No provision	No provision

Decision Point	Johnston Amendments to S. 171 and S. 2019	Reagan Administration Executive Orders 12291/12498	Clinton Administration Executive Orders 12866/12875
Whether to regulate	Not applicable	Only when the potential benefits to society exceed the potential costs to society, to the extent permitted by law	Only when required by law, necessary to interpret the law or due to compelling public need; upon a reasoned determination that benefits justify costs; and if it would not create a mandate upon a State, local, or tribal government, unless the Federal Government provides funds to pay direct costs incurred by that government or the agency provides OMB a description of: 1) the extent of prior consultation with that government; 2) the nature of that government's concerns, 3) written communications submitted by such government, and 4) support for the need to regulate
Which regulations to analyze	S. 171 - Final regulations relating to human health and safety or the environment promulgated after the date of enactment S. 2019 - Proposed and final major regulations defined as any rule that may have an effect on the economy of $100 million or more in any one year	All existing[67] and proposed "major" rules of Federal agencies defined as any rule likely to result in: an annual effect on the economy of $100 million or more; a major increase in costs or prices for consumers, individual industries; Federal, State, or local government, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets	All existing[68] and proposed "significant regulatory actions" of Federal agencies defined as any rule that is likely to: have an annual effect on the economy of $100 million or more; adversely affect in a material way the economy, any sector of the economy, productivity, competition, jobs, or State, local, or tribal governments or communities; the environment or public health or safety; create a serious inconsistency with action taken or planned by another agency; alter the budgetary impact of entitlements, grants, user fees, or loan programs or rights and obligations of recipients; or raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles for regulatory planning and review in the order

67 Executive Order 12291, section 3(i), directs agencies to initiate reviews of rules in effect at the time of the order in accord with the purposes of the order and to perform RIAs of major rules. The order authorizes the Director of OMB to designate rules for review and to establish schedules for review and analyses under the order.

68 Section 5 of the order directs Federal agencies to submit to OMB a program under which the agency will periodically review its existing significant regulations to determine whether any should be modified or eliminated to make the agency's regulatory program "more effective in achieving the regulatory objectives, less burdensome, or in greater alignment with the President's priorities and the principles set forth in this Executive order."

Decision Point	Johnston Amendments to S. 171 and S. 2019	Reagan Administration Executive Orders 12291/12498	Clinton Administration Executive Orders 12866/12875
How priorities are to be established	Not applicable	Maximize total net benefits to society, taking into account condition of the particular industries affected, the national economy, and other regulatory actions contemplated; target risks that are real and significant rather than hypothetical or remote	After consideration of degree and nature of risk
How to choose a regulatory objective	Not applicable	To the extent permitted by law, to maximize net benefits	To implement law; to address significant problems; or to address compelling public need such as material failures of private markets to protect or improve the health and safety of the public, the environment, or the well-being of the American people
Which regulatory option to choose	Not applicable	To the extent permitted by law, the alternative with the least net cost; address ends rather than means. See below for additional guidelines.[69]	To the extent permitted by law: maximize net benefits; minimize the burden to society; and designed in the most cost-effective manner. Requires consideration of incentives for innovation, consistency, predictability, costs of enforcement and compliance, flexibility, distributive impacts, and equity. Requires specification of performance objectives.

[69] Additional criteria are specified in guidelines provided by OMB (Circular Number A-94, October 29, 1992, and the Regulatory Program of the U.S. Government for April 1 1991 to March 31, 1992, Appendix V) and EPA (cited above), but these are not included in Table 1. OMB staff have indicated that their guidelines are not expected to change as a result of the Clinton order, and EPA has not issued guidance since it reprinted its 1983 Guidelines with revised appendices in 1991 (EPA-230-01-84-003). Respecting choice of regulatory approach, OMB guidelines state: entry into private markets should be regulated only where necessary to protect health or safety or to manage public resources efficiently; uniform quality standards for private goods or services should not be prescribed except where products are needlessly unsafe or product variations are wasteful, and voluntary private standards have failed to correct the problem; qualifications for receiving government licenses should be the minimum necessary; encourage unrestricted exchange of rights or obligations created by regulation; and the terms or conditions of Federal grants, contracts, or financial assistance should be limited to the minimum necessary to achieve the purposes for which the funds were authorized and appropriated.

Decision Point	Johnston Amendments to S. 171 and S. 2019	Reagan Administration Executive Orders 12291/12498	Clinton Administration Executive Orders 12866/12875
What to analyze, generally	S. 171 - Risk to health addressed by regulation, effects of regulation, costs, and relative risks to health and safety S. 2019 - Risk to human health or the environment addressed by the regulation, costs, benefits, and relative risk to human health or the environment	Potential benefits, costs, and net benefits, including effects that cannot be quantified in monetary terms, of the proposed regulation relative to the alternative of no regulation; alternative approaches that could substantially achieve the same objective at lower cost[70]	All costs and benefits (including quantitative and qualitative) of the proposed regulation and alternatives, including the alternative of no regulation and alternatives that do not regulate directly (such as, those that provide economic incentives or information to the public); explore use of regulatory negotiation and other consensual processes
What to analyze, specifically	S. 171 - Risk to health and safety of individuals; effects on health or the environment; implementation and compliance costs; and comparative health risks S. 2019 - Human health risks to significant subpopulations disproportionately exposed or particularly sensitive; relative risks for at least 6 other hazards; implementation and compliance costs; and qualitative and quantitative benefits	Costs to consumers, individual industries, Federal, State, or local government agencies, or geographic regions; effects on competition, employment, investment, productivity, innovation, or on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets; and who is likely to receive the benefits and bear the costs	Effects on the efficient functioning of the economy and private markets (including productivity, employment, and competitiveness); health and safety; the natural environment; direct cost to government in administering the regulation and to businesses and others in complying; costs of cumulative regulations; effects on State, local, and tribal governments, including availability of resources to carry out mandates; and discrimination or bias

70 According to page 5 of EPA's 1983 Guidelines, the benefits and costs of proposed regulations and important alternatives were to be compared to the benefits and costs in the absence of regulation, referred to as the "baseline". In addition, the Guidelines required consideration of alternatives to Federal regulation such as "negotiated voluntary actions, and market, judicial, or State or local regulatory mechanisms" and "market-oriented regulatory alternatives."

Decision Point	Johnston Amendments to S. 171 and S. 2019	Reagan Administration Executive Orders 12291/12498	Clinton Administration Executive Orders 12866/12875
Comparative risk analysis	S. 171 - Requires comparative analysis of risk addressed by the regulation and other risks to which the public is exposed S. 2019 - Requires comparative analysis of the risk relative to at least 6 other risks, 3 regulated and 3 not regulated by the Federal Government	No provision	Requires agencies to include in their annual Regulatory Plan comparisons of the magnitude of the risk addressed by each regulatory activity to other risks within the agency's jurisdiction
Basis for analysis	S. 171 - Scientific evaluation of the risks and the best available scientific data S. 2019 - Best reasonably obtainable scientific information	Adequate information; scientific risk-assessment procedures	Best reasonably obtainable scientific, technical, economic, and other information
How to treat State, local, and tribal governments	Not applicable	Should not preempt State laws or regulations except to guarantee rights of national citizenship or to avoid significant burdens on interstate commerce[71]	Develop process for input by State, local, and tribal governments in developing regulatory proposals with significant unfunded mandates; in all cases, seek views of such government officials; assess effects and minimize burdens on such governments; harmonize Federal regulations with State, local, and tribal functions; avoid undue interference with such governments; and streamline waiver application process for such governments, increasing opportunities for flexible policy approaches; OMB to consult with State, local, and tribal government representatives quarterly

[71] President Reagan's Executive Order 12612 on Federalism Considerations in Policy Formulation and Implementation is still in effect. In general, it aims to "restore the division of governmental responsibilities between the national government and the States that was intended by the Framers of the Constitution and to ensure that the principles of federalism established by the Framers guide the Executive departments and agencies in the formulation and implementation of policies" (52 *Federal Register* 41685, Oct. 26, 1987). Section 6(c)(3) of the order required agencies preparing Federalism Assessments for policies "[i]dentify the extent to which the policy imposes additional costs or burdens on the States, including the likely source of funding for the States and the ability of the States to fulfill the purposes of the policy."

Decision Point	Johnston Amendments to S. 171 and S. 2019	Reagan Administration Executive Orders 12291/12498	Clinton Administration Executive Orders 12866/12875
How to treat the private sector	Not applicable	Regulations should be substantially supported by the full record, with full consideration to public comments	Seek stakeholder views before publishing a Notice of Proposed Rule Making; consult with representatives of businesses, nongovernmental organizations, and the public periodically

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