Understanding RISK Analysis

A Short Guide for Health, Safety, and Environmental Policy Making

INTERNET EDITION

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Preface

The purpose of this document is to provide a brief, readable guide to risk analysis, especially to those interested in health, safety, and environmental policy making. The original text was written by Mark Boroush, formerly of the Congressional Office of Technology Assessment. Many persons reviewed the document, and we are grateful for their help. The effort was supervised by Ray Garant of the American Chemical Society and Terry Davies of Resources for the Future.

American Chemical Society
RISK Education Project

The American Chemical Society (ACS), founded in 1876, is a nonprofit professional organization and the world's largest scientific society. ACS was chartered by Congress in 1937, and its membership includes over 150,000 chemical scientists and chemical engineers.

The mission of the Risk Education Project is to increase the level of awareness and knowledge in Congress about issues involving risk, including assessment, management, characterization, policy, and communication. The project is funded by a generous grant from the Eastman Kodak Company.

Resources for the Future
Center for RISK Management

Resources for the Future (RFF) is an independent nonprofit organization engaged in research and public education on natural resources and environmental issues. The Center for Risk Management at RFF conducts interdisciplinary research, training, and outreach on environmental policy. Its cosponsorship of activities with the Risk Education Project is funded in part by a grant from the Carnegie Corporation of New York, a private foundation.

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1 Why the Attention to RISK Analysis?

Risk is widely recognized as precisely what it implies—a possibility. Within the context of risk analysis, it refers to the possibility of injury, harm, or other adverse and unwanted effects. Risks are commonplace in all of our lives.

Risk analysis, risk assessment, and *risk management* are relatively new terms in public debate; however, they are practices with lengthy histories. According to historians, the first professional risk assessors were from ancient Babylon (3200 B.C.); they were a special sect of people who served as consultants offering advice on risky, uncertain, or difficult decisions in life—such as marriage proposals or selecting building sites.

For more than a century now, risk assessment and risk management have been everyday activities of banking, insurance, and business operations in the world's industrialized economies. Serious applications in human health and safety emerged in the early decades of this century; research on natural hazard risks and disaster management followed.

Presently, risk analysis is being used to evaluate and manage the potential of unwanted circumstances in a large array of areas: industrial explosions; machine part and other mechanical and process failures; workplace injuries; injury or death from diseases, natural causes, lifestyles, and voluntarily pursued activities; the impacts of economic development on ecosystems; and financial market transactions—among others.

The Emergence of RISK Analysis in Health, Safety, and Environmental Policy

Industrial hygiene, epidemiology, and toxicology grew as fields of practice and research late in the 19th century. Serious scientific study of the risk factors and adverse effects associated with technology began early in this century. By the 1930s, a substantial body of scientific evidence had been collected regarding the quantitative relationships between occupational exposures to hazardous substances and their effects on human health. Over the several subsequent decades, scientific research aimed at identifying appropriate safety margins for exposures had become well established.

An initial application of this growing base of technical knowledge was to establish no-observed-effect levels (NOELs)—an early use of what later became one of the foundational elements of contemporary quantitative risk

assessment. From the 1930s onward, professional organizations such as the American Society of Mechanical Engineers (ASME) and the American Conference of Governmental Industrial Hygienists (ACGIH) used this knowledge base to establish various health and safety codes and standards pertaining to industrial equipment, activities, and exposures to noxious agents.

When concerns turned to low-dose exposures to ionizing radiation and to potentially carcinogenic chemicals in the 1960s, the NOEL approach to hazard management proved problematic, because no-effect threshold levels could not be established. This shortcoming prompted considerable basic scientific research to understand the effects of low-dose exposures on humans. In the 1960s, the Nuclear Regulatory Commission (NRC) began to use computer models to estimate the human risks of exposures to ionizing radiation. And in the early 1970s, the Food and Drug Administration (FDA) began to employ similar methods in its evaluation and regulation of potential carcinogens in foods.

Congress's historic legislation of the early 1970s, establishing a statutory framework for regulating health, safety, and environmental hazards, and the creation of the Environmental Protection Agency (EPA) and the Occupational Safety and Health Administration (OSHA) considerably raised the role of risk analysis in the regulatory process and stimulated professionalization of the field. In the intervening decades, risk analysis has become an increasingly central component of the nation's policy making concerning health, safety, and environmental quality. Modern, quantitative methods of contemporary risk assessment emerged in the mid-1970s, and they have been applied to a wide variety of regulatory issues, including pesticide residues; food additives; pharmaceutical agents; pollutants in drinking water, soil, ambient air, indoor air, and other environmental media; the safety-related features of industrial processes and transportation equipment; and other hazardous aspects of consumer products.

Most observers would agree that over the past several decades the advancement of risk analysis in regulatory decision making has promoted rational policy deliberation. Yet, as real-world practice indicates, risk analyses have often been as much the source of controversy in regulatory considerations as the facilitator of consensus. The current state of scientific understanding has often been found to be incomplete, indecisive, and controversial in attempting to resolve the important questions about the type and size of specific hazards. Additionally, considerations in risk management—issues of risk acceptability and how to balance trade-offs among competing interests—are beyond the technical / scientific debate. Thus, in deciding what we might expect from a policy-making process in which risk analysis is prominent, it is essential to recognize the character, strengths, and limitations of the analytical methods involved.

2 Analyzing, Managing, and Communicating RISK *An Overview*

The analysis, management, and communication of risks to human health and safety and environmental quality is an evolving field. Various aspects of the theory and practice continue to be debated among risk professionals, policy makers, and the risk-interested public. Nonetheless, there is agreement that *risk assessment, comparative risk analysis* (CRA), *risk communication,* and *risk management* are the essential pillars of the field. An overview of the basic content of these activities follows.

RISK Assessment

Risk assessments are conducted to estimate how much damage or injury can be expected from exposures to a given risk agent and to assist in judging whether these consequences are great enough to require increased management or regulation. Depending on the kind of hazard, the effects of primary concern might be workplace injuries; reproductive and genetic abnormalities; diseases such as cancer or other debilitating illnesses; or ecological effects such as species extinction, loss of habitat, and other kinds of ecosystem damage.

In the health, safety, and environmental fields, risk is usually identified as the likelihood that individuals (or a population) will incur an increased incidence of adverse effects such as disabling injury, disease, or death. Risk frequently is expressed in quantitative probability terms—such as some number of additional cancer deaths over a lifetime in a population of 1 million exposed people. (A risk of 1 in 10,000 is often described as a "10^{-4} risk", 1 in 1 million as a "10^{-6} risk", and so on.) Historically, risks of less than 10^{-6} in magnitude have not been the object of concern. More qualitative characterizations are also used—such as low, medium, high—where quantification is either infeasible or unnecessary.

Risk assessments range widely in scope and complexity, depending on the application: from simple screening analyses to major analytical efforts that require years of effort and a substantial budget. Contemporary risk assessments ordinarily rely on many branches of science—on the methods and knowledge of disciplines such as toxicology, epidemiology, other health and environmental sciences, systems engineering, and related technical areas.

The methods and sequence of steps involved in conducting a risk assessment vary with the kind of risk and its possible consequences. A more specific discussion of these elements for several key risk assessment areas follows in a later section. In its most general form, however, the process consists of a *source assessment*, an *exposure assessment*, an *effects assessment*, and is normally concluded by an integrative *risk characterization*.

Source assessment seeks to identify and evaluate the sequences of events through which an exposure to a risk agent could arise. In risk assessments of engineering systems, for example, this can be a particularly extensive and detailed exercise—such as evaluating the possibility that a pump in a manufacturing operation might fail, leading through a series of steps to increased levels of toxic substances on the shop floor. Alternatively, this kind of analysis might be aimed at finished products, whose physical features along with typical use patterns could result in safety hazards.

Exposure assessment seeks to determine the number and kinds of people exposed to a risk agent, along with the magnitude, duration, and timing of their exposures. An example is estimating the fate and distribution of a toxic chemical released from a manufacturing facility and providing a description of the characteristics of the exposure of human populations along the path of the chemical. Depending on the needs of the analysis, the evaluation might focus on current, past, or future exposures.

Effects assessment determines the extent of adverse effects likely to result from given levels of exposure to a risk agent. For resource and efficiency reasons, this kind of analysis is usually conducted in stages. The initial analytical step is to determine if exposures to a risk agent at any level could cause adverse effects—for example, whether exposures to a particular industrial chemical could cause cancer or seriously impair nervous system function. Then, if such a conclusion is drawn, a more detailed study is conducted to determine what quantitative relationship (dose–response) exists between the level of exposure and the incidence of adverse effects.

Risk characterization is the concluding step of a risk assessment. This is an important integrative task, which involves assembling the prior analysis components into a bottom-line picture of the nature and extent of the risk. The principal topics include the kinds of health effects likely to arise, the risk's potency (i.e., the severity of the adverse effects), the populations affected, the likelihood of exposure, and the risk's ultimate magnitude (i.e., potency adjusted for the likelihood of exposure). Risk characterizations are usually the principal means through which a risk assessment's findings are communicated to risk managers, policy makers, journalists, and the public.

In the past, risk characterizations have frequently consisted of brief descriptions of potential adverse effects and affected populations, along

with a single numerical estimate of the level of risk that would summarize whether humans would experience any of the various forms of toxicity or other effects associated with the risk agent. (Often this figure has been in the form of a *plausible upper bound* on risk, deliberately prepared to provide a conservative estimate that minimizes the chance of underreporting the actual level of risk.) More recently, however, this "short form" approach to risk characterization has been criticized. It is now generally acknowledged that characterizations need to provide deeper insight into how risk estimates and findings are generated (including a discussion of the assumptions that underlie the calculations). In addition, characterizations should consider a range of plausible risk estimates (which could result from the use of plausible alternative assumptions or differing models of exposure and dose–response relationships) and should more clearly discuss the uncertainties and limitations in the empirical data on which the risk assessment is based.

Comparative RISK Assessment

Comparative risk assessment has been an aspect of risk analysis since the late 1980s (although its roots lie at least a decade earlier). In essence, comparative risk assessment is directed at developing risk rankings and priorities that would put various kinds of hazards on an ordered scale from small to large.

There are two principal forms of comparative risk assessment. *Specific risk comparison* refers to side-by-side evaluation of the risk (on an absolute or relative basis) associated with exposures to a few substances, products, or activities. Such comparisons may involve similar risk agents (e.g., the comparative cancer risks of two chemically similar pesticides) or widely different agents (the cancer risk from a particular pesticide compared with the risk of death or injury from automobile travel).

The second form is *programmatic comparative risk assessment*, which seeks to make macro-level comparisons among many widely differing types of risks, usually to provide information for setting regulatory and budgetary priorities for hazard reduction. In this kind of comparison, risk rankings are based on the relative magnitude of risk (which hazards pose the greatest threat) or on relative risk reduction opportunities (i.e., the amount of risk that can be avoided with available technologies and resources).

The methods for conducting comparative risk assessment are still developing. Methods to appropriately conduct these kinds of analyses remain controversial, as is the concept of using relative risk comparisons to establish priorities for hazard reduction. The challenges are particularly difficult when comparisons across widely different risks are involved.

RISK Management

The essential tasks of risk management are to (1) determine what hazards present more danger than society (as represented by its government) is willing to accept; (2) consider what control options are available; and (3) decide on appropriate actions to reduce (or eliminate) unacceptable risks. At the broadest level, risk management includes a range of management and policy-making activities: agenda setting, risk reduction decision making, program implementation, and outcome evaluation. As discussed in a later section, the nation's laws and policy programs directed at risk are made up of a complex framework through which decisions about risk management are made.

Risk assessments provide a basic input to risk management. However, such assessments do not of themselves provide answers to many questions that risk managers must answer. What level of exposure to a risk agent is an unacceptable risk—and, conversely, what level is acceptably safe? How should uncertainties about the extent of risks be hedged? What trade-offs should be made among risk reduction, benefits derived, and new costs incurred in achieving improved risk control? Will new risks arise as a consequence of reducing existing risks—and how should such trade-offs be considered should they arise? Which of the existing hazards deserve the greatest attention and resources? Such issues are clearly influenced by society's values and priorities, and dealing with them requires the political considerations associated with establishing policy in a democratic manner.

There are several policy approaches to hazard reduction. Command and control measures, which include regulations, permits, and enforcement actions, represent one avenue that has a long-standing history in U.S. risk management. Other options include market-based economic incentives that prompt desired changes in industrial production decisions and consumer behaviors; voluntary reductions of risk-producing activities; promotion of pollution prevention; and information and education programs to modify behaviors by alerting consumers and technology users of the risk involved in their choices.

Ultimately, those with the responsibility to manage risks in society's interest must make responsible decisions about risk control and hazard reduction—and work through issues that are not always easy to resolve, including legal obligations, uncertainties in the risk assessment evidence, and trade-offs among competing interests to protect the public's health and welfare. Risk assessment, cost analyses, and other analytical tools can assist the good judgment of the policy maker in making such decisions.

RISK Communication

Risk communication covers a range of activities directed at increasing the public's knowledge of risk issues and participation in risk management. This includes, for example, warning labels that provide consumer education about existing hazards, development of publicly accessible databases characterizing hazardous circumstances, and public hearings on risk management issues.

Risk communication emerged as a recognized element of risk management early in the 1980s. At this time, it was realized that a large fraction of the public was not familiar with the nature of risk and that risk management decisions could not simply be made by technical experts and public officials and then imposed and justified to the public after the fact. Risk communication is now viewed as being a dialogue among interested parties—risk experts, policy makers, and affected segments of the public

3 RISK Analysis in Regulatory Decision Making

Agency Conduct of RISK Analysis

In the United States, over the last several decades, risk assessments have become increasingly prominent inputs to the standard-setting and program implementation efforts of such federal agencies as the Consumer Product Safety Commission (CPSC), the EPA, the FDA, the NRC, OSHA, the Department of Agriculture, and the Department of Transportation, as well as state-level agencies and offices with similar responsibilities.

Decision makers responsible for managing risks now rely on risk assessments to estimate which of the existing hazards are significant enough to warrant policy attention. The scope of the risk assessments employed varies from case to case—ranging from relatively simple screening assessments using standard assumptions about exposures, to much more expansive studies involving data collection and modeling, to highly detailed analyses of situation- or site-specific circumstances.

The Statutory Context for RISK Analysis

Over the past 25 years, Congress has enacted numerous laws that address health, safety, and environmental quality (see Table 1). These statutes were established independently, and the extent of authority for setting standards and establishing priorities varies widely across agencies and among statutes. Some of these laws give considerable discretion to the responsible agency, whereas others tightly specify regulatory approaches and the mix of considerations that agencies must follow in making policy decisions. Judicial review and other court actions have refined decision-making criteria and have often sharpened the procedural differences between the statutes.

Although all of these statutes invoke risk in a direct way, the mandate for risk management and the criteria specified for policy making vary in significant respects among different statutory provisions. *Table 1* lists some of the risk-related provisions in a selected group of current federal

laws that illustrate these differences. Most fall under one of the following three categories:

• *Health-based standards.* For health-based standards, the mandate requires hazards to be regulated without regard to cost factors or the current availability of suitable control technology. For example, Section 109 of the 1970 Clean Air Act directed EPA to establish standards for certain air pollutants that provided an "ample margin of safety" for the "most sensitive" groups. The standards were to be set based only on whether health risks existed and regardless of new costs imposed or technological limitations.

• *Technology-based standards.* In this case, the mandate requires the adoption of "best practicable control technology," "best available technology," or other similar kinds of pollution controls or treatments. Here, the overriding considerations are not risk reduction but the cost and efficacy of a control measure in reducing pollutant or contaminant concerns. An example is the Safe Drinking Water Act, where maximum contaminant level goals are specified based solely on health considerations, but the actual standards are developed on technological feasibility and cost grounds.

• *Risk-balancing standards.* Here, the balance of the benefits of risk reduction against the costs incurred is considered in setting risk management goals. Under the Federal Insecticide, Fungicide, and Rodenticide Act, EPA's regulation of pesticides must seek to balance the health and environmental impact of a chemical, the costs of regulation, benefits, and other societal concerns.

TABLE 1

Representative Risk-Related Provisions in Selected Federal Statutes

Occupational Safety and Health Act Sections 3(8) and 6(b)(5)	Safety and health risks in the workplace	Material impairment of health or functional capacity What is reasonably necessary or appropriate to provide safe and healthful employment	Attain highest degree of health and safety protection Best available evidence Technical and economic feasibility
Clean Air Act Section 109	National Ambient Air Quality Standards	Protect public health	Set standards to provide ample margin of safety
Section 112	Emissions standards for hazardous air pollutants	Adverse effects to health and the environment	Reduce emissions using maximum achievable control technology, and later address residual risk
Section 202	Emissions standards for new motor vehicles	Unreasonable risk to health, welfare, or safety	Greatest degree of emission reduction achievable through technology available, taking into consideration cost, energy, and safety factors
Toxic Substances Control Act Section 6	Existing chemicals in commerce	Unreasonable risks to health and the environment	Balance risks against economic benefits, considering alternative technologies
Federal Insecticide, Fungicide, and Rodenticide Act Section 3	Pesticides	Unreasonable risks to health and the environment	Balance risks against economic benefits to pesticide users and society
Comprehensive Environmnetal Response, Compensation , and Liability Act Section 303 Section 9621	Toxic Release Inventory Hazardous waste site remediation	Hazards to human health or the environment Persistence, toxicity, mobility, and propensity to bioaccumulate, short- and long-term health effects	Reporting is based largely on hazard and quantity used Protect human health and the environment in cost-effective manner
Safe Drinking Water Act Section 300g-1(b)	Drinking water quality	Known or anticipated adverse effects on human health	Set a goal (maximum contaminant level goal, MCLG) with an adequate margin of safety and define a maximum contaminant level (MCL) as close as feasible to the goal

Source: Office of Science and Technology Policy, Executive Office of the President, *Science, Risk, and Public Policy*, March 1995.

Many statutes mix the elements of the above categories. For example, OSHA's setting of health standards under the Occupational Safety and Health Act requires that where the risk of health impairment is "significant" (such as workplace exposures to carcinogenic or other toxic substances) the responsible substances are to be fully removed (via performance-based standards) from the workplace—constrained only by "technological and economic feasibility".

RISK Analysis and Executive Oversight

Risk assessments have been notably influenced by the continuing flow of executive orders, issued by every president since Richard Nixon. These orders require federal rule-making agencies proposing significant regulatory actions to conduct regulatory planning and prepare regulatory impact assessments.

The current requirements, those of President Clinton's 1993 executive order (E.O. 12866), introduced a number of significant changes in the procedures for regulatory planning and executive oversight of rule makings. The order, however, retains the requirement for preparation of a formal assessment for all "significant regulatory actions" (defining significant as an annual effect of $100 million or more on the economy or a major increase in cost or prices for individual industries, levels of government, or geographic areas). The assessments are required to consider the potential benefits and costs of the intended action and other policy alternatives available (including nonregulatory means).

Under this administrative guidance, risk assessments are required to fill out the benefits side of the impact equation, that is, to provide an analytical basis for estimating the decrease in adverse health effects or other impacts expected from adoption of the new risk management measures proposed. In this capacity, risk assessments (their findings, methods, and underlying assumptions) have often been a source of controversy among policy makers, stakeholders, and other interested parties in the give-and-take of the regulatory rule-making process.

RISK Assessment Contrasted with Other Inputs for RISK Decision Making

Risk assessment is regarded by experts and policy makers as a valuable tool for decision making. Even so, there is disagreement about the extent to which its findings should influence decisions about risk.

Proponents view risk assessment as a tool for ensuring that agency risk management decisions are rational and based on the best available science, and for helping to target resources on the worst hazards and on risk reduc-

tions that are worth their cost. Critics of this approach find that the very process of risk assessment allows some level of risk to be considered acceptable (i.e., that a risk–benefit balance can be found); this may be unlawful under some statutes and may be perceived as unethical in some circumstances. Others conclude that risk assessments are a tenuous basis for policy making because of the data and knowledge limitations and other uncertainties frequently encountered in conducting them.

Other risk management approaches that have been used in the United States and other nations include mandating reductions of risks to levels that are *as low as reasonably achievable* (ALARA), requiring adoption of *best available technologies* (BAT), or imposing outright bans on the use / consumption of hazardous agents. These alternative approaches, however, have their shortcomings as well. ALARA or BAT can be costly to implement and may not result in a worthwhile benefit to society—if, for example, the magnitude of the uncontrolled risk is not high. Likewise, banning a risk agent may not guarantee a significant risk reduction or justify the associated financial sacrifice, because, for example, a ban could result in the use of a hazardous substitute.

4) RISK Assessment Methods

Hazardous agents and sources can differ considerably with respect to the phenomena governing their occurrence and the kinds of effects produced in exposed populations. As a general rule, the approaches and methods for conducting risk assessments must be tailored to match these features—which makes risk assessment far from a "turn the crank" analytical process. In health, safety, and environmental policy issues, the tools of health risk assessment, engineering systems risk assessment, and ecological risk assessment provide the essential foundation for risk analysis. The basic features of each of these fields are discussed below.

Health RISK Assessment

A health risk assessment seeks to identify the kinds of adverse health outcomes that may be associated with exposure to a potentially harmful substance (or some other health-threatening risk agent) and to predict the likelihood that specific human populations will experience such effects at given exposure levels.

Most of the health risk assessments conducted over the past several decades have been directed at estimating the health consequences of exposures to toxic chemicals, with particular attention to the potential for cancer. Accordingly, this emphasis is evident in the concepts, methods, and language used to depict the health risk assessment process. Nonetheless, the importance of examining noncancer health effects (such as nervous or immune system impairments, organ damage, and reproductive and developmental effects) or risk agents other than chemicals (such as industrial processes whose features or failure modes may pose risks of injury or disease to workers and surrounding communities) is well recognized. Methods for these other kinds of health risk assessments have also developed. Much of the cutting-edge work in risk assessment is now focused on noncancer health effects.

Basic Steps in Conducting a Health RISK Assessment

A 1983 National Academy of Sciences panel (*Risk Assessment in the Federal Government: Managing the Process*), seeking to standardize and

coordinate the various risk analysis practices that had come to be employed, recommended a four-step process for conducting health risk assessments. This process, outlined below, has become the standard model for the field.

Hazard identification. This initial risk assessment activity is directed at determining if a substance (or other health-threatening risk agent) could cause particular adverse health effects in human populations. For example, will exposure to a particular substance cause cancer? Will it harm the nervous system or immune system? Will it give rise to reproductive defects or other serious health conditions or disabilities?

Dose–response assessment. This step seeks to identify the quantitative relationship between a dose level and the resulting incidence of injury or disease. Most substances—even many of those used for beneficial purposes—cause harm when consumed in large enough quantity. For example, an anesthetic may cause headaches at low doses, a medically advantageous sleep at higher doses, but is lethal at very high doses. Thus, the riskiness of a substance cannot be determined with confidence unless the dose–response relationship is quantified.

With noncarcinogens (or the noncarcinogenic effects of carcinogens), the normal working assumption (backed up by theory and empirical evidence) is that biological effects occur only after a threshold level of exposure has been exceeded. Various thresholds have come to be established; they include a *lowest observable effect level* (LOEL), the smallest dose that causes any detectable effect; a *no-observed-effect level* (NOEL), the dose at or below which no biological effects of any type are detected; and a *no-observed-adverse-effect level* (NOAEL), the dose at or below which no harmful effects are detected. Toxicologists generally seek to identify (via animal testing, with progressively higher and lower exposure levels to a suspected toxic substance) several of these dose–response markers to help map thresholds.

With suspected carcinogens, however, the working assumption is usually that no threshold exists, (i.e., that exposures to carcinogenic substances pose some risk even at the smallest level of exposure). This concept has long been a mainstay of cancer risk assessment; the concept is based primarily on what is known about the health effects mechanisms associated with exposures to ionizing radiation and toxic substances. More recent findings about the induction of cancer suggest that a wider range of mechanisms may be at play, depending on the substance involved, and that for some carcinogens there may be a threshold below which cancer does not occur.

Exposure assessment. This step attempts to identify the nature and size of the population(s) exposed to the risk agent, along with the magnitude,

duration, and spatial extent of exposure. Depending on the purpose, the exposure assessment could concern past or current exposures or those anticipated in the future.

Case by case, the steps involved in an exposure assessment vary widely, because circumstances differ with respect to how much is known about existing exposures and what information is available. The most reliable picture comes from direct monitoring (personal, biological, and / or ambient) of the amounts of the substance to which people are actually exposed over time. This sort of information is, however, often not available. In fact, lack of knowledge about actual exposures is one of the weaker links in the knowledge chain supporting risk assessments. As a consequence, a good deal of what is done is derived from models and from generalized assumptions about relevant physical parameters and human behaviors.

Numerous pathways exist through which exposures can occur (direct and indirect), and a large number of variables and moderating factors can be involved. For example, estimating the movement of a chemical in the environment depends on considerations such as how easily it evaporates, how easily it dissolves in different media (such as water or animal fat), how strongly it attaches to the soil, and how long it persists in the environment. On the human behavior side of the exposure equation, the issues include how much water or specific types of food people consume each day; whether or not people filter their water; how they prepare their food; what balance of time during the day is spent indoors versus outdoors, and so on.

Risk characterization. This concluding task in a risk assessment combines the principal findings of the hazard characterization, dose–response, and exposure phases of the risk assessment into an integrated picture of the nature and expected frequency of adverse health effects in exposed populations. Ordinarily, the "bottom line" forthcoming from a risk characterization is a primary determinant of the risk management phase that follows risk assessment.

Sources of Evidence for Health RISK Assessments

Health risk assessment draws on the knowledge and methods of various scientific fields. The kinds of data and findings that ordinarily are used include the following:

• *Epidemiologic studies.* Epidemiology examines the occurrence of disease in human populations and tries to determine the causes. These studies are an important source of information because they are based on the experience of human subjects. When the levels of exposure to a risk agent

and other relevant substances can be well documented, the exposed population well defined, and the kinds of adverse effect(s) known in advance, epidemiology provides the most direct way of determining the effects of a risk agent on human biology.

Epidemiology's weakness is that these essential conditions are often not met. The presence of confounding factors, such as simultaneous exposures to other toxic substances, can make the health effects of a given risk agent difficult to determine.

Additionally, it is difficult to accurately account for population mobility and the genetic variability of humans (which can, among other things, significantly affect an individual's susceptibility to many diseases). Moreover, epidemiologic studies are usually not sufficiently sensitive (in a statistical sense) to allow the detection of small changes in risk levels (such as might be associated with low-dose exposures to chemicals in the environment).

• *Toxicological studies*. Most of the information used to predict the adverse health effects of exposures to substances comes from animal testing or test tube procedures using cells or tissues isolated from animals or humans. These kinds of studies allow the examination of potentially toxic substances while accounting for different exposure levels and genetic variability. Animals, including the rodents frequently used in toxicological testing, biologically resemble humans in many ways. A good body of evidence indicates that animal studies can be used in many (but not all) instances to deduce hazards to human health—although, not always to indicate the precise level of risk that humans would face.

Considerable research has been conducted over the years in toxicology and has been directed at developing and employing various animal models to predict adverse health effects in humans; understanding the mechanisms of toxicity; and assessing the extent to which biological processes and toxic effects are similar in test animals and humans. One of the particularly significant advances over the last decade is the development of physiologically based pharmacokinetic (PB-PK) models as a basis for predicting human health effects from rodent data. These models seek to account for the various differences between test species and humans by considering body weight, metabolic capacity and products, respiration rate, blood flow, fat content, and other biological parameters.

Despite their merits, toxicological studies suffer from some serious limitations. Cost considerations typically limit the number of test animals to a few hundred. To make up for such limited sample sizes, research designs must use high exposure levels—perhaps 1000 times or more greater than typical human environmental exposures—to maximize the likelihood that health effects can be detected with acceptable statistical

precision. (Without such high exposures, study designs might require millions of experimental animals.) As a consequence, estimating a substance's ability to cause adverse health effects at the (low) levels typical of environmental exposures depends on extrapolating the dose–response relationships from the (high exposure) experimental data down to levels well below the range verifiable by experimental data.

A number of mathematical models, based on various scientific theories of how toxic substances cause biological effects, have been developed to perform such extrapolations. The scientific community, however, often disagrees on what is the most appropriate theory. In addition, the models associated with differing health effects theories can give vastly different estimates of the level of risk associated with human exposures (see discussion later in this section).

• *Structure–activity studies*. This kind of analysis seeks to evaluate toxicity based on the substance's chemical structure. The large and still growing base of empirical knowledge about molecular structure and toxicity has made this approach more feasible.

Nevertheless, such relationships are not simple. Experience has shown that, although this method can be informative, its predictive capacity is far from perfect.

• *Exposure data and exposure modeling*. Information about the exposures of human populations to risk agents is a crucial input to the risk assessment process. Risk assessors need this information to estimate the amount of the substance that reaches the cells, tissues, or organs of exposed individuals. In general, exposure assessment involves identifying the pathways (e.g., air, food, and water) by which a substance travels through the environment; the changes the substance undergoes en route; its environmental concentrations relative to time, distance, and direction from its source; the routes through which human exposures could occur (e.g., oral, dermal, and inhalation); and the distribution of sensitive population subgroups (such as children or pregnant women).

When reliable data on actual human exposures are not available—a not infrequent circumstance—the gaps in information must be filled in by simulation models, generalized assumptions, or some combination of the two. To provide estimates of the exposure levels experienced, information on the movement and activity patterns of at-risk human populations is coupled with modeled estimates of the transport and distribution of substances from their sources to various environmental media (the atmosphere, ground or surface water, soil, the food chain).

Various computerized simulation models have been developed to estimate the transport and distribution of substances in the environment.

Some are specific for classes of substances whereas others are based on the various media in which transport occurs. Still others are multimedia in nature and address the combined impact of numerous routes of exposure.

Many risk assessments draw on several or all of these types of evidence. Additionally, other kinds of studies can play important roles. For example, basic research on metabolism, pharmacokinetics, and the mechanisms of toxicity is often used to evaluate the relevance of the above approaches in predicting adverse health effects in humans.

Sources of Controversy in Health RISK Assessments

The risk assessment process as outlined above has a number of strengths: a structure for collecting, organizing, and evaluating data; a capacity to base policy decisions on the estimated level of human risks; a basis for focusing research efforts on important risk assessment topics; and, in principle, a basis for ranking risks and focusing hazard management resources.

Nonetheless, the process has a number of limitations: It can involve exceedingly complex analyses, with much judgmental weighing of diverse data; it is vulnerable to limitations in data and to uncertainties in scientific reasoning; and it requires a good many assumptions, at least some of which will be debatable. Risk assessment findings are frequently controversial, for one or more of the following reasons:

• *Risk inferences dependent on animal testing.* Human data provide the most straightforward basis for gauging the level of human health risk. For various (and usually compelling) reasons, animal bioassays remain a central risk assessment tool, particularly in assessing possible carcinogens. Animal testing is widely regarded as the next best approach, if adequate human data are not available. Supporters of animal testing conclude that it provides a reasonable basis for assessment.

There are problems, however: (1) The high (in terms of level or duration) exposures used in the standard animal test designs usually have no parallel in humans, thus creating the need for extrapolations to levels outside that verifiable by experimental data (a situation science shies from). (2) The high exposures may provide a misleading picture of the potential for health effects, because it is possible that the high doses induce effects that do not arise at lower doses. (3) Finally, some toxic mechanisms and pathways that occur in animals may not occur in humans.

Although animal models may be useful in many cases, there is always a chance of false negatives or false positives. One particularly graphic example of this circumstance is the drug thalidomide (prescribed during pregnancy for therapeutic reasons), which caused severe birth defects in the

children of women taking the substance. However, no adverse health effects were found in animal testing.

When a dose–response relationship derives from data on test animals, the need for an additional extrapolation arises: namely, translating the observed effects in animals to predicted risk in human populations. The usual approach is to introduce one or more inter-species extrapolation adjustments (usually termed *scaling factors*) to account for biological differences between the test animal and humans (such factors as lifespan, body size, genetic variability, and metabolic rate, among others) that may influence the response to exposures of a given substance. Working conventions about these adjustments have emerged over the years, but their exact nature remains controversial among scientists.

In principle, the human response to the substance in question may be more or less sensitive than what is observed in the animal tested. Nonetheless, the working convention has been to assume greater sensitivity on the part of humans. Numerically speaking, the risk estimates from test animal dose–response data are substantially adjusted upward by 1 or more powers of 10. In a few cases, epidemiologic data are available to gauge the dose–response relationship. However, for most cases, the low level of most environmental exposures to suspected carcinogens combined with the lack of a threshold means that estimates of human cancer risk rely on the low-dose predictions from mathematical extrapolation models. The extrapolations are based on comparatively high dose levels given to laboratory animals.

Presently, about half a dozen extrapolation models are used routinely (including the one-hit, multistage, multihit, Weibull, and probit models). Many federal regulatory agencies have traditionally employed the *linearized, multistage model*, which does not exhibit a threshold and is based on the concepts that cancer develops in stages and that a carcinogen can have an effect at each stage. The analytical difficulty is that different models may all fit the (high-dose) experimental data extremely well but yield starkly different predictions of risk at the low exposure levels that are of primary concern for real-world risk management decisions (see *Chart 1*). Recent research has tended to indicate that some carcinogenic threshholds exist, and therefore other models may prove more appropriate.

• *Weight of evidence*. Ordinarily, risk assessors will review and consider the findings of numerous published studies in the process of conducting a risk assessment. Such material often varies considerably in quality. In the past, regulatory agencies often placed heavy emphasis on any study (regardless of quality) that showed a substance to be a potential health hazard. This strategy, which minimizes the potential of underestimating the actual

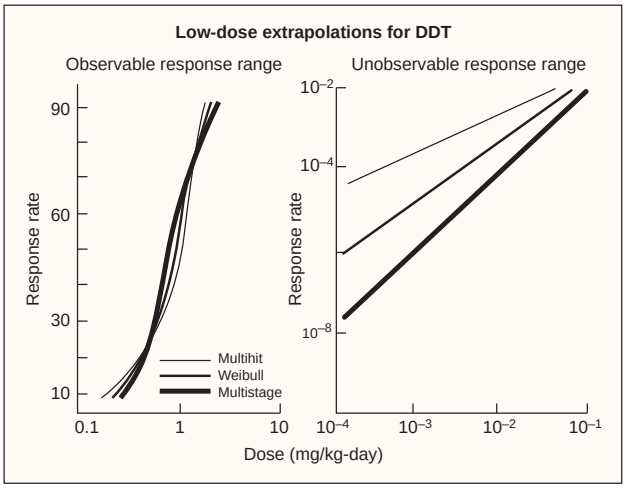
CHART 1

Low-Dose Extrapolations in Cancer Risk Assessments—the Challenge of Predicting the Level of Human Risk

Estimating the level of human cancer risk depends on extrapolating the health effects observed in the high-dose experimental data with laboratory animals down to the much lower levels typical of environmental exposures. Various models have been developed for this purpose, reflecting differing concepts of the biological mechanisms of cancer induction at work.

The difficulty of this approach, however, as well illustrated below by a risk analysis for DDT, is that differing extrapolation models that fit experimental data well can yield vastly different estimates of the level of risk at low exposure levels. On the basis of current scientific knowledge, it is often not easy (or possible), to conclude which of the models provides the most reliable estimate.

In this evaluation of the cancer risk of DDT exposure, the output of each of the three extrapolation models considered (all widely used in risk assessment work) fits the experimental data well and provides similar estimates of the level of risk across much of the observed exposure range. However, the models' predictions of risk levels become increasingly disparate at the lower dose levels more characteristic of human environmental exposures. At the smallest level shown here, the predicted levels of risk span a difference of nearly 4 orders of magnitude—and range from a level that would be of clear public health concern (10^{-4}) to one that probably would not (10^{-8}).



Source: Based on Paustenbach, D. J. Retrospective on U.S. Health Risk Assessment: How Others Can Benefit, *Risk* 1995, 6, 283–332.

level of human risk in the face of uncertainty, has provoked much controversy.

This problem began to recede in the 1990s, when the scientific community and most regulators accepted that not all data should be given equal status, and that only data of similar quality should receive equal weight. This *weight of evidence* approach takes into consideration the quality and adequacy of the available studies (in hazard identification, dose–response, or exposure assessment).

• *Conservative bias in assumptions.* Assumptions invariably play a significant role in the quantitative stages of risk assessments—filling in where hard data may not be readily available and providing a way forward where scientific understanding may be incomplete or nonexistent. Regulatory agencies have developed a host of standard assumptions (often termed *defaults*) for use in these circumstances (and when evidence to the contrary is absent).

The 1983 National Academy of Sciences report (*Risk Assessment in the Federal Government: Managing the Process*) referred to 50 previously identified points in the risk assessment process where scientific uncertainty is encountered and assumed links are needed to make predictions. These circumstances span most of the critical analytical areas in a risk assessment: translating animal risk estimates to human risk predictions, dose–response extrapolations, and various aspects of exposure assessment.

Critics have argued that these defaults tend to be very conservative—erring excessively on the side of caution and resulting in predictions that are likely to overstate the actual level of human risk. Examples include the use of test data from the most sensitive species, the choice of a dose–response extrapolation model that yields the highest estimation of risk (usually, the linearized, multistage model), and exposure scenarios that focus on maximally exposed individuals rather than that typical for the majority of individuals in the exposed population.

Regulatory agencies defend their choices as prudent, given the substantial scientific uncertainties and their statutory responsibility to protect the nation's health (which may specify protection of the most susceptible individuals in exposed populations). Furthermore, some analysts believe that even with these conservative assumptions, risks may still be underestimated. For example, test animals are not exposed at the beginning of their lives when they are more susceptible to some substances, and the cumulative effect of exposure to a substance from many possible routes or multiple substances is usually not considered in risk assessments.

The debate on this topic goes on—and will not soon end. There is now greater recognition that risk characterizations should provide a better

account of the full range of credible risk estimates supported by the evidence (i.e., not just the upper-bound estimate forthcoming from the model that yields the highest risk prediction) and the significance of other alternative assumptions in the risk calculations (such as with regard to exposures).

• *Human variability.* In most cases, substantial variation will exist among individuals in their susceptibility to a given substance. Small children, for example, may be more vulnerable than adults. Additionally, genetic variability in humans can give rise to substantial differences across a population. Although both of these considerations are important to the estimation of risk, they add considerable difficulty to the assessment process.

• *Mixtures and interactions.* Day-to-day life involves exposures to a large number of substances, either concurrently or sequentially, by various routes, from a variety of sources over varying periods of time. Nonetheless, with very few exceptions, risk assessments and the regulations that result have dealt with a single type of exposure to a single chemical. Little is known about the effects of most chemicals when encountered in mixtures.

The simplest and most common assumption employed is that the risk characteristics of the components of a mixture are straightforwardly *additive*. However, the combined effect may be either *synergistic* (in which the overall risk of the mixture is greater than predicted by the additive model) or *antagonistic* (in which the overall risk is less than predicted by the additive model). For example, studies have shown that simultaneous exposures to tobacco smoke and radon result in a health risk that is greater than posed by exposure to either alone. Alternatively, some evidence shows that dioxin, when present before exposure to another carcinogen, works to reduce the rate of cancer from exposure to the second carcinogen.

• *Treatment of uncertainties.* A good many risk assessments—particularly those where carcinogenicity is suspected—do not reduce to a single risk figure or characterization that can be cited with confidence. The exact relationship of animal tests to human risk and the predictive value of high-exposure occupational epidemiology to environmental exposures are unclear. It is difficult, in many cases, to determine the most appropriate mathematical model for extrapolating from high to low doses in dose–response evaluation. Additionally, exposure assessments (particularly where many pathways are involved) are often substantially simplified relative to the real-world circumstances.

Advances in science will help to diminish these limitations. However,

debatable assumptions, plausible risk estimates that contrast sharply, and various other uncertainties are likely to remain the name of the game in health risk assessment for some time to come—making risk management an exercise conducted under uncertainty. The risk assessment community now recognizes that risk managers need better understanding of the uncertainties in risk analyses, along with insight about the sensitivity of the findings to possible alternative assumptions (regarding dose–response assumptions, scaling factors, exposure scenarios, etc.). Risk characterizations, in addition to providing a quantitative estimate of risk or a range of possible values, should also discuss the assumptions involved in determining the magnitude of risk, the strengths and weaknesses of the evidence used, the significance of any uncertainties that remain, and the implications of any probable alternative assumptions that might have been made in risk calculations.

A second (and reinforcing) development is the use of modern mathematical / probabilistic techniques in risk assessment, which facilitates the treatment of uncertainties in risk calculations.

Engineering Systems RISK Assessment

Efforts to systematically evaluate the probabilities and consequences of acute, catastrophic failures of engineered systems are well established in numerous industrial sectors. Applications of risk assessment methods to this kind of problem emerged in the aircraft industry in the 1960s, in the nuclear power industry in the 1970s, and in various chemical process industries in the 1980s.

Risk assessments in these areas are often undertaken to stimulate refinements in engineering design that lower the level of risk. Such analyses are also used to measure a company's exposure to financial liability or to assist in disaster management planning.

Failures of engineered systems can impose acute and / or chronic effects on human health and sizable impacts on the environment. Accordingly, risk analyses of engineered systems often play a significant role in the risk assessments conducted by regulatory agencies with health and safety protection responsibilities.

Risk analyses of engineered systems usually involve detailed engineering evaluations of system design and operations. The prospect of failures is often analyzed with the help of probabilistic / scenario tools such as *fault tree analysis* and *event tree analysis*. The considerations involved include historical operating and accident experience; vulnerabilities to human errors; and the failure rates of key components such as valves, pipes, and dials. As with health risk assessment, these inputs are based on a mix of hard data, modeled simulations, and expert judgment.

Ecological RISK Assessment

Even though there is a long history of evaluating environmental and ecosystem impacts, the concept of ecological risk has only recently emerged as a distinct field of risk assessment. Ecological risk is based on the understanding that healthy ecosystems can provide renewable resources and food, water storage and flood control, biodegradation and removal of contaminants from air and water, pest and disease control, moderation of climatic extremes, recreational opportunities, and scenic beauty. The objective of an ecological risk assessment is to estimate the possibility of adverse impacts on one or more of these ecosystem dimensions from exposures to ecosystem / environmental stressors such as technology (roads, buildings, and other types of development) and pollutants. The scope of an ecological risk assessment may be fairly narrowly defined, such as the adverse effects of development in a local wetlands area, or widely encompassing, such as the worldwide issues of global climate change.

Ecological risk assessment is increasingly viewed as relevant to complex ecological problems and policy questions, such as the decline of Pacific salmon in the U.S. Pacific Northwest or the current decrease in biological diversity in many parts of the globe. To date, however, applications of ecological risk assessment have focused chiefly on the risks of chemicals in the environment, with the impacts on animal species as surrogates for measuring ecological health.

Methodologically, ecological risk assessment draws widely on the standard procedures of environmental impact analysis and monitoring. Tests of animal species (such as fish or insects) are commonly used tools as are computer-assisted geographic analysis and computerized ecosystem simulations. Additionally, expert judgments and opinions also play a substantial role because ecosystems are complex and do not lend themselves entirely to experiments or modeling.

Ecological risk assessment's greatest challenge is to work out practical concepts and measures of what comprises ecological health at a whole system level. At the root, this involves deciding what ecological changes are adverse (and, thereby, undesirable) and which are beneficial (and desired). Scientific theory goes only so far on these questions, and social and political values weigh in heavily. In a recent long-range strategic planning document, EPA identified the "…need to develop the scientific understanding and tools to better measure, model, and maintain or restore the integrity and sustainability of ecosystems at local, regional, and national scales now and in the future…" as a primary target for its near-term research programs.

5 Engaging the Public in RISK Decisions

The experience of the last several decades suggests that identifying sound, credible, and effective hazard reduction priorities and solutions depends in large measure on an informed public—with the public having a working knowledge of risk issues and opportunities to express opinions and become involved in risk assessment and risk management activities. Often the public receives its information from the media, and thus it is important for the media to present balanced and reliable risk reporting. If the media do not report accurately, constructive public involvement becomes more difficult.

Communicating RISK Assessments to the Public: An Important Challenge

Much work has been done by researchers and practitioners in the field of environmental communications since the early 1980s—when risk communication emerged as a distinct element of risk analysis—to better explain how the public perceives and processes risks and to identify ways to improve the transfer of information between risk experts and the public.

The public's response to risk issues is complex, multidimensional, and diverse—because "the public" is actually many publics with differing values and stakes in risk issues. The underlying problems of communication and education are challenging. Even so, the field has had some success in increasing the knowledge base for designing communication efforts.

Much remains to be accomplished in the arena of risk education and risk communication. The risk assessment process needs to be opened to greater participation and scrutiny by affected publics. This will increase the need to facilitate the public's ability to understand risk information and policy makers' ability to understand how the public thinks about risk.

A Gap in Expert and Public Perceptions of RISK

One of the ongoing problems of risk assessment and risk management is that the public and experts can differ considerably on the comparative significance of various risks. The differing bases of technical understanding account for some of this—a problem which risk communication has been

working to address. Even accounting for this factor, it is clear from survey data that a sizable gap exists between risk experts and nontechnical citizens over how to appropriately define and measure risk.

Risk experts and officials with technical training tend to focus on—and are comfortable with—the standard concept of risk as the possibility of damage or unwanted effects. By contrast, the nontechnical public often expands the concept of risk to include various nondamage attributes (see *Table 2*). These added considerations are diverse, but in a general way reflect both societal values and the play of the anger and fear that hazards can readily evoke.

Such considerations can be extremely influential in shaping the public's reaction to a hazard—even to the point of overpowering scientific findings about the magnitude of the risk. For example, pesticide residues in food and the operation of nuclear power plants continue to be very prominent public concerns—both of which scientific risk calculations indicate to be relatively small hazards. Although scientific findings consider high-fat diets or exposure to radon to be more serious public health concerns, they draw far less public attention.

TABLE 2

Some Key Nondamage Attributes of Risk

Involuntary	Risks voluntarily assumed are ranked differently from those imposed by others.
Uncontrollable	The inability to personally make a difference decreases a risk's acceptability.
Immoral	Pollution is often viewed as a consummate evil. And statements that hazards are "too low to worry about" can engender suspicion.
Unfamiliar	Generally speaking, more familiar risks are regarded as more acceptable.
Dreadful	Risks that cause highly feared or dreaded consequences are viewed as more dangerous.
Uncertain	Scientific uncertainty about the effect, severity, or prevalence of a hazard tends to escalate unease.
Catastrophic	Large-scale disasters such as a plane crash weigh more seriously in the public's mind than individual events such as exposures to radon gas in a neighbor's basement.
Memorable	Risks embedded in remarkable events have greater impact than risks that arise in less prominent circumstances.
Unfair	Substantial outrage is a more likely result if people feel they are being wrongfully exposed.
Untrustworthy	The level of outrage is higher if the source of the risk is not trusted.

Source: Foundation for American Communications and National Sea Grant College Program. *Reporting on Risk: A Handbook for Journalists and Citizens;* The Annapolis Center, 1995, pp 84–86.

This gap between the public's understanding of risk and that of risk assessors is an obstacle both in making policy decisions about acceptable risk and in effectively communicating the extent of risk that exists to the public and decision makers.

Broadening Participation in the Process of RISK Characterization

These previous considerations are consistent with the realization that the conventional process of risk characterization would benefit from some reworking, particularly to increase the opportunities for the participation of those outside the scientific and risk analysis communities. This perspective is articulated at length in a recent (1996) National Research Council (NRC) report, *Understanding Risk: Informing Decisions in a Democratic Society.*

The NRC committee responsible for this report supports the importance of bringing the best science to bear in analyzing risks, while emphasizing that the science currently available for conducting risk assessments is often incomplete, imprecise, and laden with debatable assumptions and that conflicts among the values and interests of the affected publics are common in risk assessment and risk management. The history of many recent controversial risk management decisions shows that, too often, issues and questions regarded as important by public officials and concerned citizens had not been included in framing the decision or in the analysis and characterization prepared.

Broadly, the committee advocates replacing the "risk characterization as translation" approach of the National Academy of Sciences' 1983 *Risk Assessment in the Federal Government* report (which conceived of risk characterization as principally translating the results of technical risk analyses into lay terms) with a process that is more widely inclusive and "deliberative" in nature. Different kinds of risk decisions will require different kinds of assessments. However, decisions on complex or extremely controversial hazards may well require broad representation of affected parties from the earliest stages of data gathering and analysis.

6 Evolving Efforts To Compare and Rank RISKS

Analysts of the nation's health, safety, and environmental policies have undertaken risk comparisons in various ways for a good many years. However, in the 1990s the comparative risk analysis (CRA) approach has commanded much more attention. This approach has provided useful perspective and information to the decision-making process, but care should be taken to recognize that other types of information are needed for almost all major decisions.

There is common-sense appeal in linking CRA more closely to priority setting and program planning. This provides a means to address important questions about the public interest and policy goals that have not arisen in the current risk policy-making system. Nonetheless, the methodological challenges in conducting CRA are considerable, and opinions vary widely on the value that CRA can add to policy making.

Origins of the Comparative RISK Paradigm

The development that sparked the current interest in CRA was an EPA project analyzing the relative risks of 31 pollution sources—the first programmatic comparative risk study undertaken. The project's widely noted 1987 report (*Unfinished Business: A Comparative Assessment of Environmental Problems*) concluded that the environmental problems posing the greatest risk to the nation (such as exposures to radon, indoor air pollution generally, global warming, and ozone depletion) did not have high priority in EPA's budget—and in some cases were not even a part of the agency's existing statutory mandates.

Congress's interest in comparative risk and risk-based priority setting has existed at a modest level for a number of years. Rep. Don Ritter (R-Pennsylvania) introduced risk-based legislation in 1979. Since 1991 Sen. Daniel Patrick Moynihan (D-New York) has introduced bills seeking to require EPA to periodically conduct a CRA of its programs. Congressional attention to CRA increased considerably in the 103rd Congress during consideration of the provisions of the "Contract with America", and CRA continues to be an active area of discussion.

The success of the several relative risk-ranking projects undertaken by

the EPA has led to a good many subsequent efforts. Several dozen comparative risk projects have been initiated by state governments and some localities. Additionally, EPA has established information clearinghouses and other programs to support this kind of effort.

Challenges in Conducting Comparative RISK Analysis (CRA)

Currently, CRA consists of a pair of distinct analytical activities: (1) *specific risk comparisons*, which involve side-by-side evaluations of distinct risks, on the basis of likelihood and severity of effects; and (2) *programmatic comparative risk assessment*, which seeks to make "big picture" comparisons among many and widely differing hazards.

Specific risk comparisons can be particularly useful when one is considering the relative importance of risks within the context of similar products, activities, or risk management actions. One application has been in the area of risk communication, where such comparisons have been helpful in facilitating nontechnical audiences' understanding of the significance of varying risk levels (for example, weighing the expected risks of new products or technologies against those that are already accepted or tolerated).

Paired comparisons of reasonably similar risks represent the most straightforward application of CRA. Such evaluations might be conducted simply, based on estimated risk levels and the extent of anticipated harm. For example, a pair of chemical pesticides might be compared with respect to their expected chronic health effects, adjusted for likelihood. Alternatively, one might compare the likelihood of serious injury posed by driving to a desired destination against that of taking the train.

Even so, complexity can ratchet up quickly even with these simple kinds of comparisons. The health effects relevant for consideration may be multiple (e.g., cancer, reproductive effects, and organ dysfunction) and may differ significantly by chemical (e.g., cancer predominates as the most serious effect in one, but another health problem is primary in the other). Additionally, it may also be appropriate to include adjustments for compensating benefits (e.g., one of the chemicals may enhance the productivity of agricultural operations, whereas the other does not).

In general, the comparison process becomes more difficult as the *dissimilarity* of the compared risks increases—indeed, to such a point that the meaningfulness of the comparative exercise may be problematic. As *Table 3* outlines, differing risks can, and often do, take on disparate characteristics—with respect to the source, kinds of effects, distribution over space and time, and the nondamage attributes that may be relevant. Furthermore, significant differences may exist with respect to the state of

knowledge about cause and effect (e.g., the risk of cancer from exposure to a particular chemical may be poorly understood and take considerable scientific research to resolve, whereas the risk factors in automobile accidents are known with greater certainty).

TABLE 3
Dimensions in Which Risks Can Significantly Differ

Source of the hazard	Including toxic chemicals; technological failures; hazards of natural origins, such as earthquakes or violent weather episodes
Kinds of effects	Such as cancer, other kinds of health effects and disabilities, ecological impacts, economic consequences
Distribution of effects over space and time	Various combinations of chronic exposures, acute exposures, exposures to limited populations, and exposures over wide areas
Nondamage characteristics	Including whether the risk is voluntarily taken or involuntarily borne, the extent to which the risk is controllable, the degree of dread associated with the risk

Source: Based on Office of Science and Technology Policy, Executive Office of the President. *Science, Risk, and Public Policy*, March 1995.

Useful risk comparisons depend on "boiling down" these various characteristics into a common measure. And this often involves measuring things that can be difficult to scale and / or developing judgments about how dissimilar attributes trade off against each other. For example, how much more seriously should a risk be judged if it is imposed involuntarily? How should substantially different health effects, such as cancer deaths in adults versus the effects of lead poisoning in children, be valued? Or how should one or more uncertain human health effects be integrated with ecosystem impacts of uncertain permanency?

Additionally, all risk comparisons become considerably more complex when the views of differing individuals are brought into focus—many of whom may disagree on matters such as the relevant attributes for comparisons, the trade-off relationships to be assumed, and the way uncertainty should be included in the analysis. Furthermore, sizable uncertainties—over the nature of health effects, the level of exposures, or various other factors—can make it difficult to combine the various attributes of a hazard into a single risk measure and, thereby, blunt the precision of the comparison process.

Programmatic CRA is viewed as relevant chiefly for various kinds of macro comparisons such as priorities within and across the various statutes

in an agency's portfolio. With *programmatic* CRA, much remains to be done to develop well-defined guidance on how these studies should be undertaken. All such projects face numerous questions at the outset that go to the heart of what the project will be (see *Table 4*). Many of these issues come with various options and involve nontrivial considerations about analytical methods and limitations, study process, and the scope and depth of the desired findings.

TABLE 4
Major Issues in Designing a CRA Project

Scope and direction	• What purpose is the CRA to serve? • Who will participate and what will be the mode of interaction? • What specifically is to be compared? • What kind of final output is intended? • How should the effects of noncontrol (e.g., pollution prevention) programs be reflected?
Approach to risk estimation	• What types and groupings of risks should be considered? • What time horizon is to be considered? • How should the existing levels of risk control be factored in? • Should the risk analysis focus on total or marginal (i.e., program by program) risks? • How should uncertainties be factored into the analysis? • What factors other than health and environmental damage should be included? • How should any geographic differences in the sources and sinks of risk be handled?
Approach to risk comparison	• What method for risk ranking (scientific/technical only or wider to include societal values)? • What method for comparison (common quantitative metric or multiple perspectives)?
Follow-up applications of study findings	What steps will be taken with the study's findings to raise the level of understanding about significant hazards, improve communications among those involved in the policy process, and build consensus toward appropriate action?

Source: Davies, J. Clarence, Ed., *Comparing Environmental Risks: Tools for Setting Government Priorities*, Resources for the Future: Washington, DC, 1996.

All of the methodological complexities of specific risk comparisons carry forward into programmatic CRA. In fact, they arise at a much grander scale—because, by its nature, programmatic CRA spans many, dissimilar risks and provides a ready forum for value debates over what is important

in gauging the seriousness of a hazard and in establishing priorities.

Arguably, the strength of programmatic CRA is the opportunity it provides for discussion and debate among various important points of view: technical experts, policy makers, and the public. Additionally, the process facilitates addressing important public policy questions, which, although difficult, are essential to address and which will be resolved through other, less systematic approaches if not answered through CRA.

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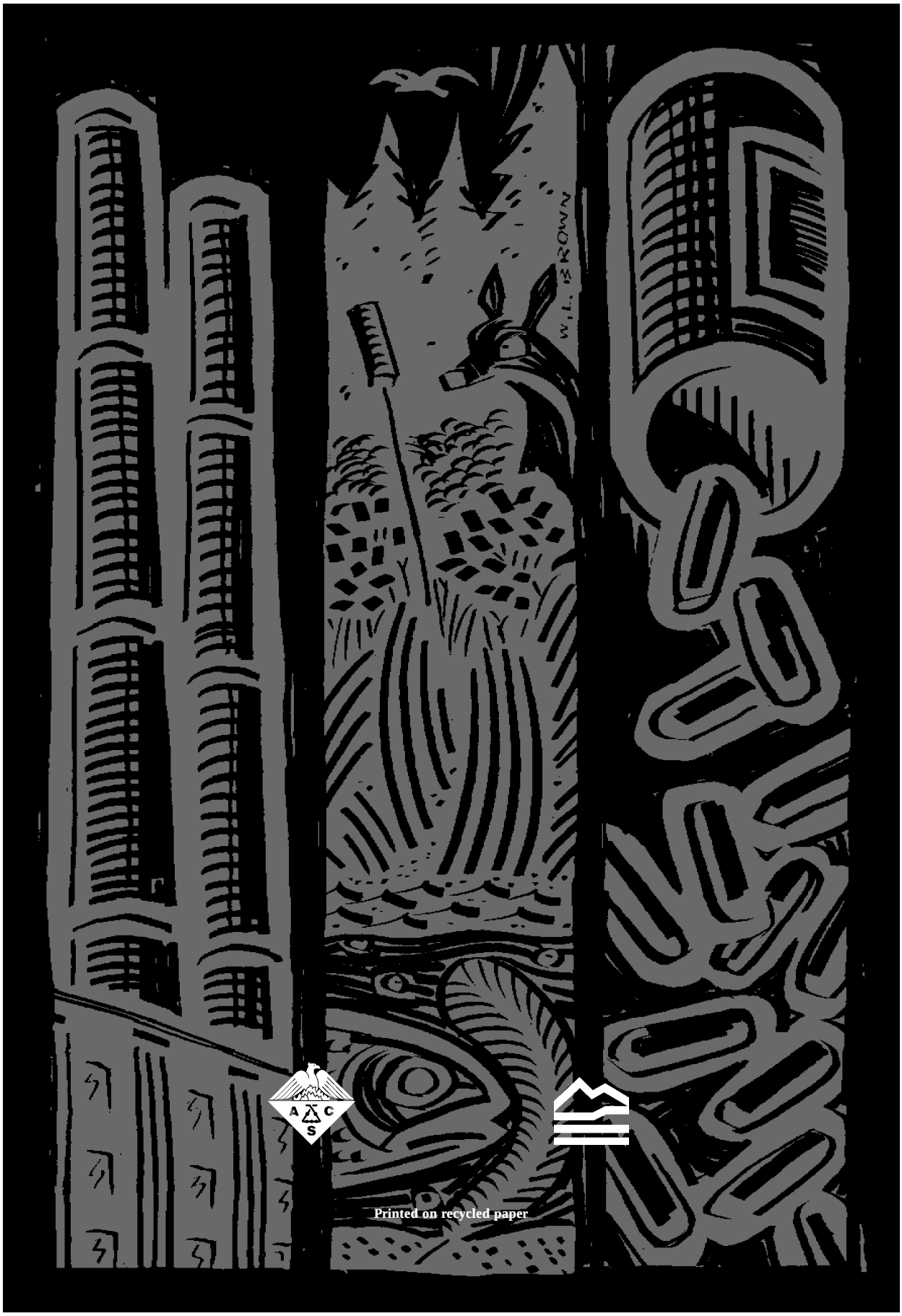

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