Commission on Risk Assessment and Risk Management

Risk Assessment and Risk Management in Regulatory Decision-Making

DISCUSSION DRAFT

J. 21/10/96

9 January 1996

COMMISSION ON RISK ASSESSMENT AND RISK MANAGEMENT

Gilbert S. Omenn (*Chairman*), Dean, School of Public Health and Community Medicine, University of Washington, Seattle, WA

Alan C. Kessler (*Vice-Chairman*), Partner, Buchanan Ingersoll, Philadelphia, PA

Norman T. Anderson, Director of Research, American Lung Association of Maine, Augusta, ME

Peter Y. Chiu, Kaiser Permanente, Department of Urgent Care, Milpitas, CA

John Doull, Professor, Department of Pharmacology, Toxicology and Therapeutics, Kansas University Medical Center, Kansas City, KS

Bernard Goldstein, Director, Environmental and Occupational Health Sciences Institute and Chairman, Department of Environmental and Community Medicine, Robert Wood Johnson School of Medicine, Piscataway, NJ

Joshua Lederberg, President Emeritus, Rockefeller University, New York, NY

Sheila McGuire, President, Iowa Health Research Institute, Boone, IA

David Rall, Former Director, National Institute of Environmental Health Sciences, Washington, DC

Virginia V. Weldon, Senior Vice President for Public Policy, Monsanto Company, St. Louis, MO

Staff

Gail Charnley, Executive Director

Sharon Newsome, Associate Director

Joanna Foellmer, Program Specialist and Designated Federal Official

Table of Contents

Executive Summary

[to be written after issues and recommendations are agreed upon]

1.0

Introduction

Since the 1983 National Research Council report, *Risk Assessment in the Federal Government: Managing the Process* ("the Red Book"), established risk assessment and risk management as separate activities ("two distinct elements"), scientists and policy-makers have debated the role of risk assessment in regulatory decision-making. While the authors of the Red Book did not intend risk assessment and risk management to be practiced in isolation from one another, the use of risk assessment as a tool in support of decision-making has had limited implementation. The report recognized the importance of communication between the risk assessor and the risk manager, but did not offer guidance to facilitate such interaction; as a result, the practice of risk assessment has evolved essentially in the absence of a risk management context. Reacting to this isolationist evolutionary tendency a decade later, the authors of the 1994 National Research Council report, *Science and Judgment in Risk Assessment*, concluded that science-policy judgments made in the course of risk assessment would be improved if they were more clearly informed by a regulatory agency's priorities and goals in risk management. Protecting the integrity of risk assessment, along with building more productive linkages to make risk assessment more accurate and relevant to risk management, were both considered essential. As P.F. Deisler (1988) put it, "The ideal separation should not be taken to mean that the two activities be isolated from each other until the grand cataclysmic communication of risk characterization."

The National Research Council has described risk assessment as "the use of the factual base to define the health effects of exposure of individuals or populations to hazardous materials and situations" (NRC 1983), and as a process that "entails the evaluation of information on the

hazardous properties of substances, on the extent of human exposure to them, and on the characterization of the resulting risk" (NRC 1994). Risk assessment is a systematic approach to organizing scientific information about potentially hazardous situations. Risk assessments are based on logically compelling scientific information when it is available and on scientifically informed policy judgments when it is not. A review of cancer risk assessments by the National Research Council identified a minimum of fifty places in a risk assessment that could not be based on data and that required science-based assumptions and judgments (NRC 1994). Because there are extensive uncertainties and assumptions inherent in any risk assessment (NRC 1994, OSTP 1995), estimates of health risk obtained by performing a risk assessment are not scientific (syllogistic) estimates of actual risk. They are conditional (contingent) estimates of the actual risk that could exist under certain sets of assumptions (can be derived from the stated); and are useful for guiding decisions about risk reduction (as such they can provided the most scientifically defensible basis for), and for pointing to the most critical lapses in the information base on which these inferences are based.

The National Research Council has defined risk management as "the process of weighing policy alternatives and selecting the most appropriate regulatory action, integrating the results of risk assessment with engineering data and with social, economic, and political concerns to reach a decision" (NRC 1983). To some extent, risk assessment has evolved in the absence of a risk management context, due to the distinction that ~~was~~ has been made between these activities ("two distinct elements") as ratified by the National Research Council in 1983. There was a fear that the many assumptions relied upon in risk assessment would be corrupted by the politics of risk management. The result has been a tendency to produce risk assessments that often have poorly served the goals of risk management. [The same dilemma pertains to the coupling of intelligence with national security policy.]

In practice, the results of a risk assessment are integrated with other information—such as political, social, economic, and engineering considerations—to arrive at decisions about the need and methods for risk reduction (NRC 1994). Performing sound risk assessments is important; however, the results of a risk assessment constitute only one of many considerations in a regulatory decision. Simply performing risk assessments and other

analyses such as cost/benefit analyses, and certifying that they were conducted, does not address critical challenges in assuring rational and cost-effective risk management under the complex statutes designed to protect human health and the environment that regulatory agencies must satisfy.

One problem with focussing on a risk assessment-based approach to risk management decisions about health protection in an environmental context is its lack of a public-health base. The public-health foundation of environmental health protection has been obscured by legalistic regulatory command-and-control approaches and by technically based, centralized decision-making processes that can be unrelated to the real causes of public health risk or to the problems faced by local communities. For example, the U.S. EPA now has far more lawyers than public-health professionals—at its inception in 1970, EPA had 650 U.S. Public Health Service commissioned officers; it now has fewer than 200. In contrast, EPA now employs about ??? attorneys. This focus on legal and regulatory expertise has obscured the public health principles and goals that are the foundation of our environmental health laws.

Another problem with risk assessment-based risk management is pervasive public distrust, which has led to increased politicization and conflict. Over the last 25 years, the United States has achieved a significantly cleaner environment and an increasingly healthy population. Life expectancy continues to increase and non-tobacco-related cancer incidence to decrease. Yet the American public becomes increasingly concerned about risk, believing our air, water, and food to be more contaminated with toxicants than ever. Public perceptions of health and environmental risk clearly differ from scientists' and regulators' perceptions, and can be attributed to a sensitivity to technical, social, and psychological qualities that are not well-modelled by technical risk assessments (Slovic 1993). The important role of public perception in risk assessment and risk management has become apparent, but is not yet well accounted for.

As a result of concern about meeting the critical challenges currently facing risk assessment-based risk management and regulatory decision-making, the Commission on Risk Assessment and Risk Management was convened in May 1994, in response to Section 112(o) of the 1990 Amendments to the Clean Air Act, to address the role that risk assessment and risk management play in regulatory decision-making. The ten members of the Commission were appointed by the president, by the majority and minority leaders of the House and Senate, and by the president of the National Academy of Sciences. The Commission has met 15 times since then, in Washington, DC and in several other cities across the United States, to hear testimony from a variety of individuals, organizations, and interests, on issues related to its mandate.[1]

Congress first decided to turn to a commission when, while drafting the 1990 Amendments, agreement could not be reached on the best way for the U.S. Environmental Protection Agency (EPA) to determine whether any risks to human health remained after Maximum Available Control Technology was implemented to reduce contaminant emissions to air from industrial facilities, and if so, what to do about them. There was a concern that after technological solutions to pollution control were in place, some risks to health might remain, but there was disagreement about the risk-assessment techniques and assumptions that should be used to estimate those risks, about the benchmarks that should be used to distinguish between negligible and unacceptable risks, and about the risk-management methods that should be used to mitigate them, should they exist.

The Commission's mandate was not restricted to air pollution, the EPA, or the particulars of the Clean Air Act, however. The mandate required the Commission to address the broader issues of exposure assessment, uses and limitations of risk assessment, the uncertainty and variability underlying risk estimation, risk management policies with regard to comparing and

[1]A copy of the Commission's mandate is included as Appendix A.1.

communicating risks and choice of risk-based standards, and the desirability of consistent standards of negligible risk across agencies and programs.[2] The Commission was also asked to comment on the conclusions of *Science and Judgment in Risk Assessment* (NRC 1994) (see Appendix A.3).

The Commission's mandate was particularly timely because of the regulatory reform debate that began in the 103rd Congress and that reached full swing in the 104th Congress. The regulatory reform legislation proposed in those Congresses called essentially for an overhaul of the methods used to perform and to communicate the results of health and ecologic risk assessments, and specified criteria for rulemaking that would require the benefits of an agency rule affecting health, safety, or the environment to be reasonably related to its costs, where the results of a risk assessment would provide direct input to estimating those costs and benefits.

Congress' concerns reflected the views of many that risk-management decisions by regulatory agencies were overly stringent, were based on risk assessments that overstated and exaggerated actual risks to health and the environment, and were made behind closed doors by agency bureaucrats with no accountability. Congress' response to those concerns was in turn viewed by many as an attempt to legislate science and to reverse twenty-five years of successful environmental protection. It has been the goal of the Commission to resolve some of those issues under dispute so that future risk assessments and risk-management decisions will be science-based where possible, and based on informed and reasonable policies and judgments when scientific support is scarce.

This report is the product of the Commission's deliberations and evaluations, and responds to

---

[2]A survey of federal risk assessment and risk management practices is included as Appendix A.2.

the concerns of those who provided testimony to the Commission to the extent possible.[3] This is a draft report intended for public review and comment. The Commission welcomes written comments on the report, and asks that they be sent to the Commission's office at 529 14th Street, NW, Suite 452, Washington, DC 20045. Comments should be received in that office by June 15, 1996, if they are to be considered in the preparation of the final report. The Commission's final report will be issued in August 1996.

[3]A list of the individuals who testified at Commission meetings is included as Appendix A.4.

2.0

Uses and Limitations of Risk Assessment in Regulatory Decision-Making

Health risk assessment has evolved from an aid to regulatory decision-making conducted informally by technical experts behind closed doors, into a somewhat standardized process that is the subject of research, symposia, graduate school courses, and Congressional debate. Parties affected by risk-based decisions demand an open and accessible regulatory process including risk assessments that reflect their views. Many academic scientists believe risk assessment can and should not be done because of their necessarily subjective basis. Many environmental activists think risk assessments are inappropriate because they cannot reflect the spectrum of individual sensitivities and multiple exposures that occur in a population. Critics of risk assessment are justified in their criticisms; however, decisions must be made about the best ways to protect and improve the quality of human health and the environment, and despite its many limitations, risk assessment has emerged as a useful adjunct to such decision-making.

This chapter makes recommendations about the conduct of health and ecologic risk assessments that are hoped will improve the tool of risk assessment and its utility and relevance in decision-making.

2.1

Cancer Risk Assessment

2.1.1 ❦ ***ISSUE:*** Tremendous efforts are devoted to the identification and application of mathematical dose-response models used for low-dose extrapolation of the effects of suspect human carcinogens. The accuracy of those models at low doses is not known.

RECOMMENDATION

The Commission recommends that a margin-of-safety approach, like that currently used for noncarcinogens, be explored for the purpose of setting standards for carcinogens.

RATIONALE

A large part of the debate about cancer risk assessment has focussed on identifying the correct mathematical models to apply to bioassay or epidemiologic data to extrapolate below the range of effects that can be observed at high doses. Because an effect below that which is observable is, by definition, unobservable, the accuracy or validity of those models at low doses cannot be known. Consequently, the accuracy or validity of the potency estimates obtained on the basis of those models is not known.

The purpose of identifying exposure concentrations associated with negligible risk is public-health protection. Public-health protection is not served by endless debates about mathematical dose-response models that delay regulatory agency's abilities to set standards. A simplified method of identifying appropriate standards for carcinogens is needed.

Many investigators have explored the potential relationship between toxicity and carcinogenicity, and found that there is a high correlation between the maximum tolerated dose (MTD) used in cancer bioassays and measures of carcinogenic potency (Bernstein et al. 1985, Crouch et al. 1987, Rieth and Starr 1989a,b, Zeise et al. 1984, 1985, 1986). Using the method of Gaylor (1989), Krewski et al. (1993) showed that an estimate of the upper-bound dose corresponding to the 95% upper confidence limit for an increased cancer risk of 10^{-6} based on the linearized multistage model can be made in the absence of a standard bioassay by dividing the MTD by 380,000. That is, the dose of a carcinogen that is associated with negligible risk in humans can be estimated by dividing the dose approximating a Lowest-Observable-Adverse-Effect Level (LOAEL) for toxicity by 380,000. Other authors have demonstrated similar associations (cite).

The distinction between "nonthreshold" carcinogens and "threshold" noncarcinogens is becoming progressively blurred, and the resources available to investigate the mechanistic activity of carcinogens or other toxicants are progressively eroded. A method for setting negligible-risk standards that is less sensitive to understanding exactly how a substance elicits toxicity, but that can be relied upon to protect public health, is needed. Methods for setting standards for carcinogens on the basis of LOAELs or benchmark doses, and a margin of safety, should be explored.

2.1.2 ❦ ***ISSUE:*** When tested using chronic rodent bioassays, a number of chemicals elicit only tumors that are unlikely to have human relevance due to mechanistic or physiologic considerations. Regulating all substances that are positive in rodent bioassays as human carcinogens, without considering mechanisms of tumor induction and their human relevance, will not result in significant health benefits.

❦ *RECOMMENDATION*

The Commission recommends that when chemicals tested in rodent bioassays induce only tumors that are not relevant to humans, they should not be regulated on the basis of carcinogenicity. Criteria are needed to facilitate decisions regarding human relevance, so that risk assessments of such substances are no longer needlessly delayed.

❦ *RATIONALE*

Approximately half of the over 600 chemicals tested for carcinogenicity in rodents by the National Cancer Institute or National Toxicology Program yielded results considered positive in at least one sex of one species tested. Many of those chemicals were common food components such as vitamins, essential elements, and sugars, that have no evidence of carcinogenicity in humans. Some of those chemicals induced tumors in rodent organs that have no human equivalent, such as the forestomach or Zymbal gland. Some induced tumors using biologic mechanisms that have no human equivalent, such as α-2-μglobulin-mediated male rat kidney tumors. And some, like saccharin, induced tumors only at doses that were so high that the tumors resulted from high-dose toxicity and not from any inherent carcinogenic properties of the chemical.

As currently practiced, cancer risk assessment produces statistical estimates of risk that are useful for regulatory purposes but that have little biologic basis. Mechanisms of carcinogenesis are considered in a weight-of-evidence context, but their relevance to human cancer risk is not explicitly evaluated. The revised cancer risk assessment guidelines currently under development specify that during the hazard identification phase, three categories of classification are possible: likely or possible human carcinogen, not relevant to human cancer risk, and unknown. The guidelines include no explicit criteria for classifying a substance as

irrelevant to human cancer risk, however.[1]

At least ten years have passed since the human relevance of α-2-μglobulin-associated kidney tumors was first questioned, yet it was only relatively recently that EPA made the decision to consider them irrelevant (EPA 1991). Over fifteen (twenty??) years have passed since the human relevance of saccharin carcinogenicity was doubted, yet packages of sugar substitutes including saccharin still must carry the legally required warning that its use may be hazardous to health because it has been determined to cause cancer in laboratory animals. [insert thyroid follicular cell reference when obtained] The relevance of a variety of other tumors has also been questioned for at least ten years—male $B6C3F_1$ mouse liver tumors, Swiss mouse lung tumors, rodent Zymbal gland tumors, rodent forestomach tumors—and decisions regarding their use in risk assessment have yet to be made. Delaying such decisions can only lead to wasted time and resources. Criteria must be developed for classifying substances and tumors as irrelevant to humans so that future decisions can be made as quickly and efficiently as possible.

[1]The guidelines do indicate that to depart from a standard default assumption, there must be an accepted theoretical basis for an alternative mechanism, and adequate evidence to demonstrate that a particular case fits that alternative.

2.2

Noncancer Risk Assessment

2.2.1 ❦ ***ISSUE:*** Current quantitative methods for evaluating the likelihood of adverse health effects other than cancer cannot be used to estimate the magnitude of those risks above the benchmark used to distinguish unacceptable from negligible risk. Communicating information about noncancer risks and identifying appropriate risk-management options would be more effective if quantitative information on the magnitude of noncancer risks were available.

❦ ***RECOMMENDATION***

The Commission recommends that methods be developed to estimate the magnitude of noncancer risks when toxicant doses exceed those associated with negligible risk, and that quantitative estimates of noncancer risk be accompanied by qualitative information on the nature and severity of the health effects that might be expected.

❦ ***RATIONALE***

Currently, regulatory agencies evaluate risks to human health other than cancer using benchmarks such as Reference Doses (RfDs) or Acceptable Daily Intakes (ADIs). If toxicant doses do not exceed their benchmarks, risks to health are considered unlikely; when doses exceed their benchmarks, risks to health are considered possible. Such comparisons do not generate quantitative estimates of risk, nor do they provide any information on the nature and severity of the health effects to be avoided. Decision makers, affected parties, and the public need more information than a simple benchmark comparison if useful, defensible, and cost-

effective decisions about methods for risk reduction are to be identified and implemented.

2.2.2 ❦ ***ISSUE:*** Current quantitative risk assessment methods for health effects other than cancer have a number of limitations, but appear to be adequately protective of human health.

❦ ***RECOMMENDATION***

To help overcome many of the limitations inherent in current noncancer risk assessment methods, the Commission endorses the benchmark dose approach[1] for assessing risks to human health when adequate data to support its use are available.

❦ ***RATIONALE***

Less effort has been directed towards developing methods to assess the risks of noncarcinogens than of carcinogens. One reason for the disparity is the heterogeneous nature of health effects other than cancer. Another is a lack of consensus about how to account for inconsistent experimental design. .. stochastic (uncertainty

The method currently in use to set standards for regulating noncarcinogenic toxicant exposures, the No-Observed-Adverse-Effect-Level (NOAEL)/uncertainty factor approach, does not make full use of available data, ignores dose-response information, is constrained by experimental design, and lacks a biologic basis. Identification of NOAELs is subject to a great deal of judgment and inconsistency—a recent review of an OECD pesticide project compared the NOAELs identified by regulatory agencies of five OECD countries, and found them to differ 20- to over 30-fold. Additional variation in the application of uncertainty factors to NOAELs to set standards for acceptable levels of exposure contributed to

[1]A benchmark dose is a statistical lower confidence limit for a dose that produces a predetermined change in response rate of an adverse effect compared to background.

differences that ranged up to three orders of magnitude.

In contrast to the NOAEL/uncertainty factor, the benchmark dose approach takes advantage of dose-response data, incorporates data variability, offers flexibility with regard to the response level of concern, and accounts more accurately for experimental design. The benchmark dose approach also lacks a biologic basis, but is at least consistent with relationships between dose and response. It also has the disadvantage of relying on the use of uncertainty factors to calculate RfDs or other standards from benchmark doses (although none would be necessary to account for use of a Lowest-Observed-Adverse-Effect Level in the absence of a NOAEL).

Further application and development of the benchmark dose approach is encouraged, to improve its scientific basis. It should continue to be applied to a variety of end points of toxicity, including ecologic end points. Its application to nongenotoxic carcinogenic responses should be pursued. Methods to incorporate mechanistic or biologic-based information should be developed.

Adopting a common response level approach to assessing the risks of diverse end points, such as that provided by benchmark doses, should contribute to a greatly improved ability for risk managers to compare potential actions and to a greater consistency among risk-management decisions. NOAEL/uncertainty factor-based standards currently in place are sufficiently protective of human health, however, and should be changed only if available data indicate that a benchmark dose-derived standard would more accurately reflect the likelihood of a substance's toxicity.

2.3

Ecologic Risk Assessment

2.3.1 ❦ ***ISSUE:*** Is the EPA framework for evaluating ecological risk appropriate?

❦ ***RECOMMENDATION***

The Commission supports the use of the EPA ecological risk assessment framework with the critical addition of stakeholder involvement in the initial problem formulation stage. Clear, explicit guidance is needed for several aspects of the framework.

❦ ***RATIONALE***

Ecological risk assessment has been used informally for many years to make decisions about resource management and pollution control. However, it is only within the last few years that a concerted effort has been made to define the characteristics of ecological risk assessment and to establish a common language for discussing approaches and results. At the same time, there are a greater number of ecological risk assessments being done by an increasing number of federal agencies. The growing consensus around the EPA ecological risk assessment framework makes it especially important that it fulfill this wide range of needs. In particular, the framework should include stakeholders in the initial planning stage of the process and there should be clear, specific guidance on the framework's implementation.

The EPA ecological risk assessment framework is an appropriate template for organizing and evaluating information on risks to non-human living systems (see figure A). In the problem

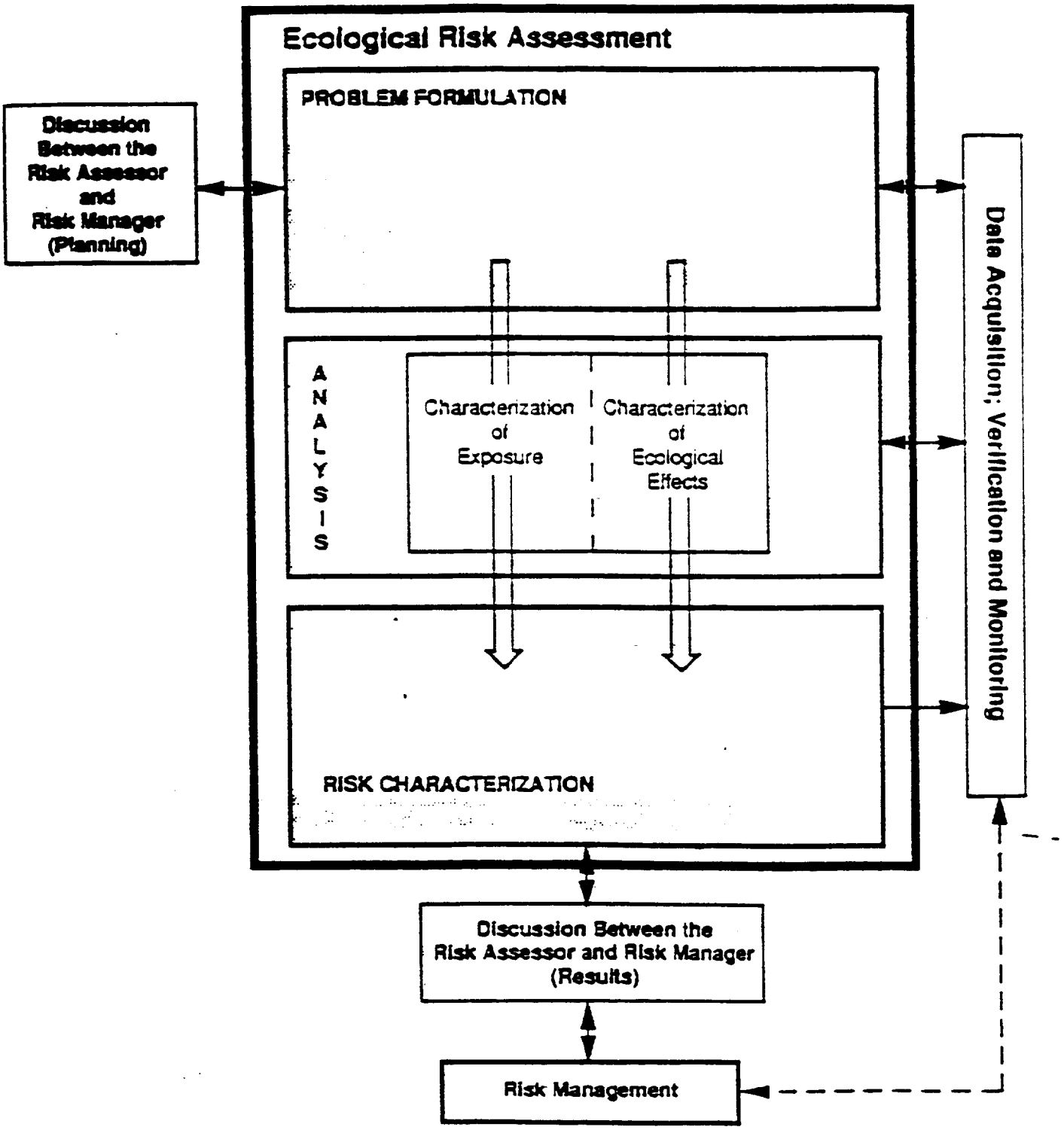


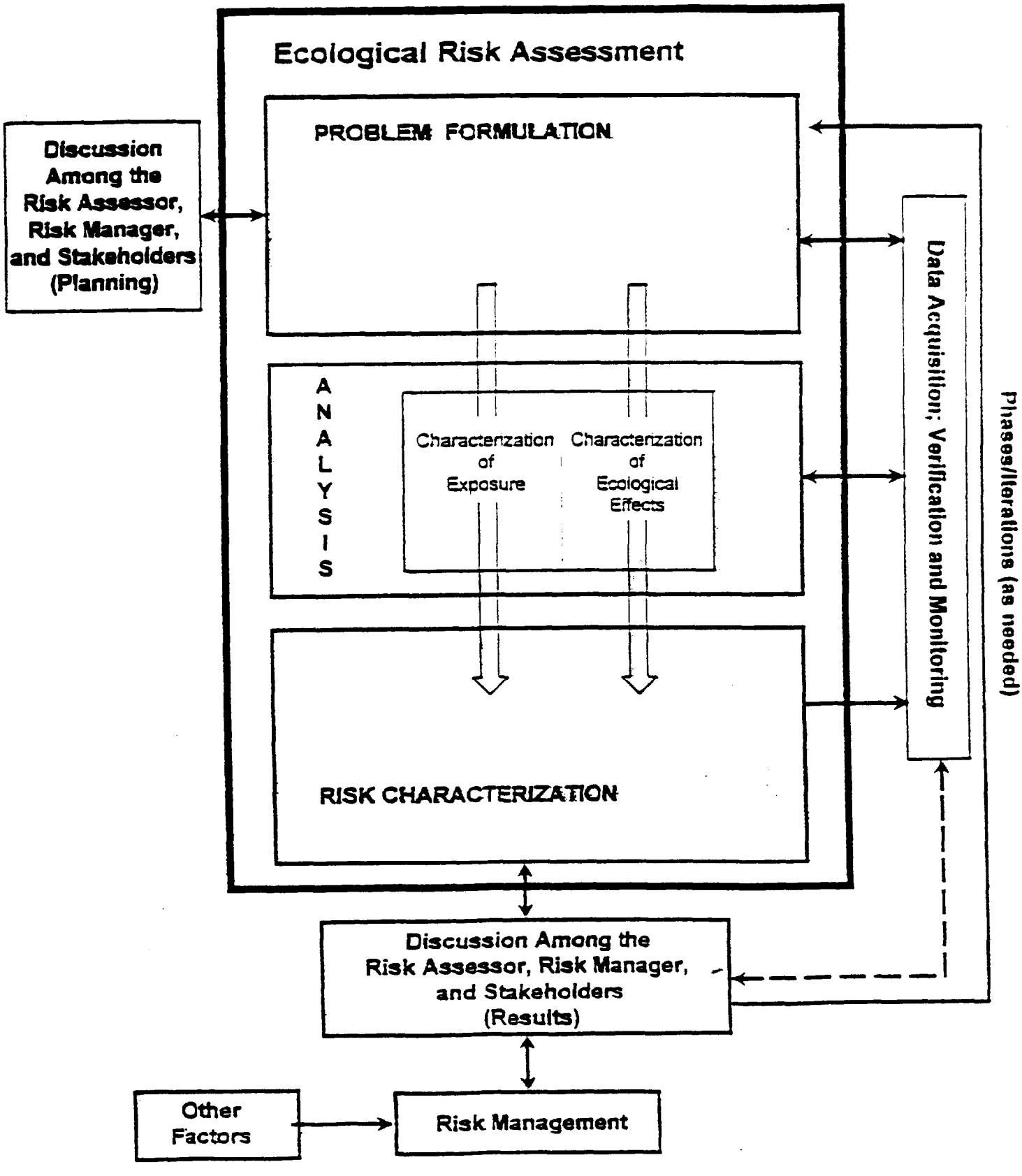
Figure A: USEPA Ecological Framework

formulation stage, the environmental values to be protected or the goals of the assessment are defined. In addition, the appropriate level of ecological organization (such as individual specie, population or community), the endpoints or potential receptors of stress, and ways to measure those endpoints are identified.

In contrast to human health risk assessment, in which stakeholders, risk assessors, and risk managers tend to share an essentially common view of the value of individual human beings and the health of the general population, ecological risk assessment has no commonly accepted starting point. For example, some may focus on the need to maintain biological diversity, others may be drawn to protecting particular plants or animals, while still others may relate to aesthetic quality. Balancing these disparate goals is the challenge of the problem formulation stage and the likelihood of success will be increased by including stakeholders in the process at this early stage. Figure B reflects the Commission's proposal to add stakeholders to the participants in the problem formulation stage. There may be many small or well-defined assessments that are part of established regulatory programs where it may not be practical to involve stakeholders in each and every case. In particular, stakeholder involvement should be considered for larger local or regional assessments where affected parties hold a range of interests and values.

The collaboration between risk assessors, risk managers, and stakeholders provides an opportunity to bridge the gaps in understanding, language systems, and values. If the affected parties do not participate in the early decisions about goals, endpoints, and measurements, then the analysis is likely to fail to provide useful information for decision-making. Consideration of economic and legal issues will also be facilitated by the early inclusion of stakeholders. Stakeholder involvement in the planning and problem formulation stage of the ecological risk assessment has been endorsed by a range of organizations, including the Risk Science Institute, the American Industrial Health Council, the Environmental Defense Fund, the State of California, and Environment Canada.

Figure B: **Modified Ecological Framework**



In a review of ecological risk assessment case studies, EPA said that the strengths and weaknesses of the studies seemed to originate, in large part, from decisions made during the problem formulation stage. However, there is very little guidance on how this process should occur and who should be involved. The addition of stakeholders in this stage requires guidance on who, when, and how to include affected parties.

The analysis stage of the EPA ecological risk assessment consists of two distinct but interrelated activities, exposure characterization and ecological effects characterization. During the exposure characterization, the spatial and temporal distribution of a stressor or stressors and their contact with ecological components are predicted or measured. During the characterization of ecological effects, the adverse effects elicited by a stressor or stressors and, potentially, the cause-and-effect relationships are evaluated. One method for analyzing cause-and-effect relationships is the index of biotic integrity developed by Karr (Karr 1991) that is now in use by more than 30 states in their water quality programs. The index of biotic integrity is a multi-metric index that documents the equivalent of ecological dose-response curves. Guidance is needed on when to use this tool and others of varying complexity, such as fate and transport models, toxicity tests, and field studies, and which tools are most appropriate for a given problem.

Finally, in the risk characterization stage, the exposure characterization and the ecological effects characterization are integrated to evaluate the likelihood that adverse ecological effects can be associated with exposure to a stressor or stressors. The assumptions and uncertainties of the assessment are explained and the strengths and weaknesses of the analyses are described. Risk characterization for ecological risk assessments is an area with little standardization. For example, there are many sources of uncertainty in ecological risk assessment and guidance is needed for the use of qualitative and quantitative descriptions of uncertainty. Guidance with explicit directions and examples would greatly improve the conduct of this important stage in the ecological risk assessment.

In some cases, risk characterization is interpreted simply as a restatement of test results. In other cases, risk characterization is viewed as the final stage of a weight-of-evidence evaluation that relates the analysis results to the assessment endpoints. However, there is no consensus on the definition of "weight-of-evidence" evaluation or how it should be applied. Often the approach reflects an individual's professional judgment and the conclusions may not be transparent to others. There are three ways in which this tool can be improved. A definition of a "weight-of-evidence" evaluation should be established for use in ecological risk assessment. An effort should be undertaken to examine the professional judgments that underpin weight-of-evidence evaluations and how they can be made more explicit. Finally, guidance for conducting quantitative and qualitative weight-of-evidence evaluations should be developed. As the final step in the framework, the risk characterization should synthesize and provide information that can be understood and applied to risk management decisions.

The EPA ecological risk assessment framework has been most successful in analyzing risks from chemical stressors because that scenario is the most similar to a human health risk assessment. However, the framework is being used with greater frequency for more complex problems with modifications well within the overall framework. This maturation of the framework tool is critical if it is to assist in solving the important problems of protecting biological diversity, maintaining ecosystem health, and guiding sustainable development.

2.4

Sensitive Subpopulations Requiring Special Consideration

2.4.1 ❦ ***ISSUE:*** Differences in individual susceptibility, concurrent exposures, and cultural practices make some populations more sensitive to the effects of toxicant exposures.

❦ ***RECOMMENDATION***

The Commission recommends that risk assessments be conducted so as to identify increased risk to potentially sensitive subpopulations by involving affected parties in the early stages of the assessment, evaluating all known sources of exposure to a particular toxicant and to toxicants with similar or synergistic modes of action, and characterizing exposure factors specific to particular subpopulations.

❦ ***RATIONALE***

There are a number of potentially susceptible and sensitive subpopulations that may be of special concern when conducting risk assessments and making risk-management decisions. Susceptibility may be determined by a number of factors, including age, gender, genetic predisposition, ethnic origin, socioeconomic status, geographic location, and lifestyle. Current regulatory approaches for controlling toxicant exposures generally do not reflect those differences in individual susceptibility, nor do they account for elevated levels of contaminant exposures that may occur in minority communities or areas of lower socioeconomic status.

Increased risks of adverse health effects from contaminant exposures can result from increased exposures or from an increased ability to react to a given exposure. Exposure is a function of the concentration of a substance in the environment and the degree of contact an individual has with that substance. Susceptibility to the effects of exposure depends on the sensitivity of an individual's response to changes in the dose. The following charts present examples of factors that can place particular populations at potentially higher risks.

High Risk Based on Exposure

Population	Factors Affecting Exposure Level
Industrial and agricultural workers	Elevated exposure to airborne and dermal toxicants; increased activity resulting in increased dose of inhaled toxicants relative to someone at rest
Sports and subsistence fishermen	Elevated consumption of contaminated fish
Low income and minority communities	Elevated exposure to lead

High Risk Based on Susceptibility

Population	Factor Affecting Response to Exposure
Asthmatics	Increased airway responsiveness to allergens and respiratory irritants and URI
Infants/young children	Increased sensitivity to the neurological effects of lead exposure
Alpha 1 antitrypsin-deficient individuals	Innate pathological changes within the lung aggravated by exposure to airborne irritants
Elderly	Diminished detoxification mechanisms

Fetus

The Clinton Administration, the 103rd and 104th Congresses, and several interest groups have made attempts to address the issue of sensitive or high-risk populations in several ways. The Clinton Executive Order 12898 on environmental justice is aimed at ensuring that federal programs protect minority and low-income populations from disproportionately high exposures and adverse human health and environmental effects. In Congress, amendments have been proposed to the Safe Drinking Water Act, regulatory reform legislation, the Federal Insecticide Fungicide and Rodenticide Act, and other bills that would require standards to be set so as to protect such subpopulations as the elderly, children, and women of childbearing age.

EPA has responded to the potentially greater susceptibility of one subpopulation, children, by issuing a new policy that will, "for the first time [require that] assessments of environmental risks will consistently take into account health risks to children and infants from environmental hazards in the air, land, food, and water" (EPA 1995). The new policy followed a National Research Council report that concluded "variations in dietary exposure to pesticides and health risks related to age and to such other factors as geographic region and ethnicity are not addressed

in current regulatory practice" (NRC 1993).

The use of safety factors in standard-setting is an attempt to account for and protect sensitive populations in the absence of specific knowledge about the nature or extent of that sensitivity. Generally, risk assessments use conservative exposure assumptions and either uncertainty factors or conservative dose-response modeling assumptions to account for variations in exposure and response among different individuals. Those methods of attempting to consider potentially high-risk populations are rarely sufficient to address site-specific concerns, and are increasingly criticized. As knowledge and information increase, there is an opportunity to move away from those default assumptions.

For example, characterizing exposure factors specific to a particular subpopulation can target a risk assessment and broaden risk-management options. In one particular case, the Commission learned at a hearing in Seattle from Asian and Pacific Islanders regarding the importance of considering their fish consumption patterns. The diets of this population consist of a much higher level of fish consumption and consumption of parts of the seafood that concentrate pollutants than the general population, placing them at higher risk from contaminants in fish. Incorporation of this exposure information into the risk assessment of Puget Sound enhanced its quality and provided valuable information for the risk-management decision.

Another situation in which using specific information gathered from the community and stakeholders could reduce the need for default assumptions and improve the quality of a risk assessment might be that of a community with a disproportionately high number of polluting operations such as a municipal incinerator, a chemical plant, and an abandoned hazardous waste site, placing it in a category of higher environmental risk relative to other communities. Involving that community and other stakeholders in the planning stages of a risk assessment in that community would help identify sources of toxicant exposure, age and occupation of citizens, and other factors that might influence risk.

Finally, there are opportunities to identify and evaluate risks to sensitive individuals. Asthmatics, for example, comprise 5-10% of the general population in the United States. Some types of air pollution can pose a greater risk to this subpopulation than to the general public. By identifying the size of the population at risk and characterizing the risk specific to that population, it is possible to make a more realistic characterization of the risk than if it were based on the general population.

Need for balance. Environment cannot be rendered totally pure with respect to allergens or infectious agents. But those impacts should be given due weight in overall risk assessment

~~It is important to acknowledge that tailoring risk assessments to identify sensitive subpopulations need not imply that management of the~~ Recognition of susceptible population's risk ~~will~~ necessarily result in more stringent regulatory restrictions. ~~Information about the risk to specific subpopulations can lead to a risk management decision that emphasizes~~ education plays a role, as it did in the case of the Asian and Pacific Islanders in Seattle, where risk management consisted of distributing educational brochures and sign postings around the affected water bodies. Contaminated urban industrial sites, sometimes referred to as brown fields, offer another opportunity for designing, with the involvement of minority and low-income stakeholder, risk-management strategies with less stringent clean-up standards but appropriate to local land use ~~to achieve~~ economic redevelopment. ~~Enforcement and evaluation of non-regulatory risk management strategies such as these is essential to ensure that the expected reduction in risk is occurring.~~

2.5

Uncertain Risk Estimates

2.5.1 ❦ ***ISSUE:*** While there is general agreement as to the value of qualitative statements describing critical uncertainties in health risk assessments, formal quantitative approaches to uncertainty analysis are difficult to perform, potentially inaccurate, and may be unnecessary.

❦ ***RECOMMENDATION***

The Commission recommends that qualitative descriptions of the primary sources of uncertainty associated with a risk assessment should be included in a risk characterization, but a formal quantitative approach ~~should be considered unnecessary for~~ may go beyond the needs of *routine* risk assessments.

❦ ***RATIONALE***

Most estimates of potential human health risks from chemical exposures in the environment are plagued by: incomplete sampling and analysis of contaminated media; mathematical models of those incomplete data instead of measurements of actual exposure levels; generalized demographic information from which assumptions about actual exposure conditions, frequencies, and durations must be made; default assumptions about population characteristics that presume all members of the population to be identical; and information on chemical toxicity that is derived from poorly characterized workplace exposures or high-dose experiments in rodents. Most of the assumptions used in risk assessments incorporate some conservatism to be health-protective (e.g., using an upper limit on contaminant levels instead of average levels; assuming that the most sensitive species represents human sensitivity), so

that many believe risk estimates are generally higher than actual risks. Because risk assessments concatenate multiple conservative assumptions, estimated risks might be several orders of magnitude greater than actual risks. Alternatively, lack of understanding of a substance's underlying toxicity or its low-dose mechanisms, for example, could lead to significant underestimation of actual risks. It is important that risk assessments incorporate some evaluation of the degree of uncertainty associated with risk estimates, so that the level of confidence that may be placed in those estimates is known.

Support for routine, formal quantitative analysis of uncertainty is based on the desire to move away from poorly supported default assumptions and point estimates of risk that convey a sense of false accuracy and that fail to convey any sense of the confidence that the risk assessor has in the estimates or their inherent complexity. Providing a numerical range of risk estimates reflecting uncertainty and variability is thought to allow more informed and transparent decisions than are possible when only a single point estimate is generated. However, communicating a range of risk estimates may be misconstrued by those unfamiliar with quantitative methods as implying that each of the numbers in the range is equally likely or plausible, and therefore valid for regulation. Many risk estimates are crude yardsticks for decision-making. In this context, the routine provision of a range of risk estimates may only confuse and delay the regulatory process.

Generating ranges or probabilistic distributions of risk estimates instead of point estimates is thought to portray more accurately the range of possible risks experienced by an exposed population. When data are scarce, however, assumptions about the underlying shape of the risk distribution will be needed—that is, when uncertainty is greatest, a range of probabilities based on assumptions would replace point estimates based on assumptions. Approximating uncertainty introduces yet another source of uncertainty.

Providing distributions of risk estimates is also thought to counteract the perceived pro-

regulatory bias inherent in compounding conservative default assumptions. Any range of risk estimates will inevitably include an upper-bound confidence interval at least as stringent as currently provided by point estimates, however. When confronted by an array of estimates, regulators and community groups are likely to choose from the more stringent portion of the range. Using formal uncertainty analysis to support less stringent regulation is unlikely to succeed. If the risk-management process is perceived to be overly stringent, then the risk-management process should be modified, not the risk assessment method.

Advancing risk assessment as a tool for public and environmental health decision-making should be seen primarily as a problem of biology and public health, not of applied mathematics. ~~Instead of devoting valuable resources to developing and defending guidelines for routine mathematical uncertainty analysis,~~ determining the toxicologic mechanisms underlying disease causation ~~should be pursued~~. often warrants higher priority than the pursuit of mathematical precision ~~is~~

2.5.2 ❦ ***ISSUE:*** Few risk-assessment issues easily lend themselves to validation, and many uncertainty issues in risk assessment are inherently unresolvable.

❦ ***RECOMMENDATION***

The effectiveness of risk-reduction strategies should be monitored wherever possible.[1] Health and environmental data should be linked more closely to create a more integrated public-health context for risk and to provide a more fruitful basis for addressing uncertainties in risk assessment than is possible using quantitative uncertainty analysis.

❦ ***RATIONALE***

---

[1]Useful models in this regard are the ACGIH's ongoing review of occupational health standards and the Harvard Six City Study.

Science-based policy decisions are generally made in the absence of requirements for testing or validation. The nineteenth-century epidemiologist John Snow developed a well-documented hypothesis concerning the genesis of several cholera outbreaks in London during the mid-1800s. Based on that hypothesis, he convinced city officials to remove the handle on the Broad Street pump, a major source of contaminated water. Following this action, he evaluated its effectiveness, and noted a dramatic decrease in the incidence of cholera.

Modern examples in which studies to measure effectiveness have proven useful are in the areas of occupational health and in evaluating the impact of criteria air pollutants. Generally, standards in those areas focus on acute health effects that can be measured by existing health data bases (e.g., vital statistics, hospital discharge data). Those standards are also supported by environmental surveillance information, thus enabling the study of the relationships between dose and effect. In these cases the margin of safety between actual exposure levels and the health effect of concern is usually quite narrow, if it exists at all, so the effectiveness of an intervention is potentially subject to measurement.

Few issues in risk assessment lend themselves easily to that sort of validation, however. Many current regulatory decisions focus on reducing public-health risks that are already relatively low. For example, risk assessments omit discussions of the health consequences of cigarette smoking, alcohol consumption, occupational injuries, or motor-vehicle accidents. Also, most health effects considered by risk assessments are chronic and multifactorial in nature (e.g., cancer, developmental effects, neurotoxicity). It is therefore very difficult to measure the extent of risk reduction achieved by an intervention, or to identify the impact of one specific intervention relative to others that are being implemented in the same time frame or relative to the background variability in disease incidence.

For example, suppose an intervention lowers the incremental risk of developing cancer from exposure to emissions from a local industrial facility from 1 in 10,000 to 1 in 1,000,000. No health

study could be designed to measure the effectiveness of that intervention, because an incremental change of that magnitude cannot be measured. Conclusions about effectiveness must rely exclusively on exposure information and the assumption that some proportional decrease in risk occurs when exposure is reduced. Considerable amounts of money are being spent to prevent or reduce risks whose existence can be neither confirmed nor denied, giving rise to arguments over cost and efficiency that cannot be resolved scientifically.

In contrast to risk assessment, which focusses on specific risk factors, studies of public health focus on the prevalence of a particular health effect and how it can be influenced by incremental changes in risk factors (e.g., lowering the speed limit from 65 to 55 miles per hour to reduce the number of motor vehicle accidents, increasing the excise tax on cigarettes to prevent smoking among youths). The success of public-health interventions, from John Snow to the present day, has been due to the ability to demonstrate their effectiveness in improving health status. As the ongoing challenges to those interventions demonstrate, however, there are implementation difficulties even when the underlying data base is supportive.

Developing good baseline and surveillance information about disease incidence, linking health and environmental data, and determining regional differences in disease prevalence, their trends over time, and their relationships to risk factors of concern, would improve our ability to implement effective interventions and be confident that they are, in fact, effective.

2.6

Peer Review

2.6.1 ❦ ***ISSUE:*** Peer review plays a critical role in risk assessment, economic analysis, and regulatory decision-making.

❦ ***RECOMMENDATION***

The Commission recommends that clear, written, and easily accessible guidelines for peer review should be established by regulatory agencies and programs. Those guidelines should distinguish among the three stages of peer review in the regulatory process: addressing the validity of technical data, addressing their interpretation, and addressing the use of those data or their interpretaton in decision-making.

❦ ***RATIONALE***

The development and evolution of scientific knowledge requires effective communication among scientists. Peer review is the most important and effective mechanism for facilitating this communication. It is also a mechanism for establishing priorities and for determining the accuracy or validity of data, observations, interpretations, conclusions, and policy recommendations. Peer review can vary from the simple act of seeking the advice of a colleague over the phone to a more formal procedure that incorporates many features of the judicial system. In the context of risk analysis, peer review can do more than increase the credibility of and confidence in an assessment—it can serve as a basis for building consensus among affected parties by including stakeholder representatives in a substantial and contributory role.

The first stage of peer review in the regulatory process evaluates the accuracy, representativeness, and quality of technical data such as health and ecologic effects data, exposure data, or economic data. Technical data used to support risk assessments or economic analyses should be drawn from peer-reviewed literature, be subjected to peer review by independent scientific experts, and have been generated by studies that followed a published and generally accepted protocol for quality assurance. Raw data from studies that play key roles in an analysis should also be reviewed and evaluated at this stage.

The second stage of peer review, interpretation of technical data, might involve issues such the choice of dose-response model used to extrapolate rodent tumor data for a particular substance to humans, the choice of endpoints used to evaluate the impact of contaminants on an ecosystem, or the choice of benefits used as part of an economic analysis and the basis of their cost estimates. This stage of peer review could also address broader policy data-interpretation issues, such as the choice of default assumptions generally used in risk assessments or decisions about departing from those default assumptions.

Establishing guidelines for the final stage of peer review is problematic. Most peer-review panels are useful for evaluating highly focussed topics, but tend to lack an understanding of the history and philosophy of an agency's decision-making process. Quality control of regulatory decision-making has traditionally been accomplished through the judicial system. Effective use of peer review as a collaborative decision-making process (which is really more quality control than peer review), that involves stakeholders or affected parties, can decrease the likelihood of controversy over the outcome and thus reduce the extent to which the courts must be relied upon. Implementing the framework for risk-management decision-making described in this report would be an effective way to address this category of peer review.

Administrative details such as whether to use internal or external peer reviewers, how peer reviewers are selected, how consistency among an agency's programs should or should not be

ensured, and how the outcome of the peer review will be implemented, should be addressed by an agency's peer-review policies.

Peer review should not be conducted simply to seek legitamacy for agency decisions and positions but should be used to improve the quality of decisions and positions. Bypassing the standard routes of validation via press releases, other media events, ~~or Congressional testimony~~ can short-circuit the self-correcting mechanisms of science and damage the process and image of peer review and quality control.

❦ ***RECOMMENDATION***

The Commission recommends that the level of peer review should be commensurate with the level of scientific importance and regulatory impact of the decision.

❦ ***RATIONALE***

Full peer review is unlikely to be needed for every regulatory decision. The most effective and efficient use of peer-review panels should be made on a case-by-case basis, taking into account issues such as the economic impact that a decision might have, the extent to which the information on which a decision is to be based might be considered controversial, and agency resource constraints. Peer review should *not* be used as a device to stall controversial policy decisions.

❦ ***RECOMMENDATION***

The Commission recommends that members of peer-review panels should be chosen on the basis of their expertise and with a goal of balancing, not eliminating, bias.

❦ *RATIONALE*

EPA's peer-review policy specifies the need for independent scientific experts and the importance of avoiding bias. When selecting members for its committees, the National Research Council policy is to focus on balancing bias rather than eliminating it, because the most knowledgeable committee members often have strong opinions and may have collateral interests in their areas of expertise. The Commission prefers the National Research Council's approach to that of EPA, and believes that expertise should be the primary criterion for selection. Diversity of scientific expertise plays a very valuable role in peer review. Efforts should be made also to achieve a culturally diverse membership, to draw upon younger scientists, and to provide training or guidance in good peer-review practices.

The individual or individuals responsible for selecting peer-review panel membership can have a great deal of influence on the nature of the bias of the membership, the areas of expertise represented, and by extension, on the outcome of the review. That "gatekeeper" role should be structured carefully to ensure that a small number of individuals does not have undue influence on panel characteristics or decisions. Needless to say, full disclosure of potential conflicts of interest is imperative; but properly disclosed such conflicts need not bar experts' participation in external review.

2.7

Complex Mixtures

2.7.1 ❦ ***ISSUE:*** Humans are exposed to many chemicals simultaneously from the environment, but regulations focus on single chemicals and seldom take other exposures into account. Risk assessments generally assume that the risks from multiple agents can be added together to obtain total risk, and do not take into account potential synergistic or antagonistic interactions that could lead to under- or over-estimation of human risk.

❦ ***RECOMMENDATION***

The Commission supports continued reliance on the assumption that either doses or effects, as appropriate, can be added together for the purpose of risk assessment when exposure to chemical mixtures occurs at low, environmental doses, and when those chemicals have similar toxic effects or affect the same organ. The components of mixtures with independent effects should be considered independently, not additively.

❦ ***RATIONALE***

Estimating the potential human toxicity of chemical mixtures is difficult because of inadequate chemical and toxicological characterization. For the purpose of human health risk assessment, the practice has been to assume either response additivity or dose additivity for similar components of a mixture. The additivity assumption has caused some concern because of the

possibility that synergistic interactions[1] among mixture components or their effects could occur, leading to a toxic response greater than that predicted on the basis of additivity and consequently to underestimation of the risk of human toxicity. Interactive effects (either synergistic or antagonistic) are usually highly dose-dependent, however (Filov et al. 1979); as a result, characterizing interactions that occur at one set of dose levels is likely to provide very little information about interactions at another set of dose levels. "High" dose levels for combined effects are defined as the exposure levels at which statistically significant increases in cancer risk, for example, are observed in either laboratory or epidemiologic studies, or as levels that are close to their NOAELs. For the most part, exposure to chemical mixtures in the environment occurs at "low" levels, however—at least three orders of magnitude below those at which a toxic response is observable in rodent bioassays. As a result, evaluating interactions that are observed in bioassays gives little insight into the effects of chemical mixtures at environmental levels of exposure.

The combined effect of exposure to a chemical mixture is determined by the way in which individual components of the mixture affect the biological processes involved in toxicity. The components of a mixture can affect those biological processes in a variety of ways—any event that affects the absorption, distribution, metabolism, or elimination of a compound will affect the level of that compound that is available to react with DNA, for example, or other cellular target. Because all chemical-biological interactions are the result of reactions at many cellular sites with multiple molecules of agents, any mathematical dose-response model of a response that depends on such mechanisms would have to be non-linear at low doses. For example, if

[1]"Interaction" is a general term that has been applied to toxicity-test results that deviate from dose- or response-additive behavior expected on the basis of dose-response curves obtained from individual agents. "Synergism" is any result that is greater than would be expected from simple addition of doses or responses. In epidemiology, synergism is a result that is greater than would be predicted on the basis of multiplication of the individual relative risks. "Antagonism" is a situation in which the response is less than would be predicted on the basis of simple addition of doses or responses, or on the basis of multiplication of relative risks. Such classifications are thus dose-response model-dependent.

two chemicals combined to form a carcinogenic agent, the rate of formation would be proportional to the product of the concentrations of the two chemicals. A linear reduction in the concentrations of the chemicals would thus result in a quadratic reduction in the formation of the carcinogenic agent and in its consequent risk. The nonlinearity of the typical chemical-biological interaction strongly suggests that mechanisms of any disease process that depends on such interactions are only marginally important at environmental levels of exposure. At high doses of one or more mixture components (such as cigarette smoke and some occupational exposures), the multiplicative effect term can dominate the toxic response, and the combined effect can be much greater than the sum of the individual effects. However, if exposures are reduced by several orders of magnitude, the combined effect would be, to a very close approximation, equal to the sum of the individual effects. Whether one or hundreds of mixture components are included, deviation from additivity would not be an appreciable relative amount. The NRC report *Complex Mixtures* (NRC 1988) supports that conclusion, stating, "On the basis of theoretical considerations and its examination of some epidemiologic studies, the committee noted that effects of exposures to agents with low response rates usually appear to be additive. The only examples of interaction that were considered greater than additive occurred in humans exposed to agents, such as cigarette smoke, that alone produced a high incidence of effects. Current quantitative models used to assess cancer risks support these results."

The additivity assumption should be confined to mixtures of agents that have similar toxicity or that affect the same organ, however. Exposure to agents with different targets and different effects will lead to risks of each effect that are independent of each other. The components of such mixtures should be considered independently.

Experimental evidence appears to support the low-dose additivity or independence assumptions. For example, when eight or nine arbitrarily chosen noncarcinogens with unrelated mechanisms of action and target organs were administered to rats for four weeks, no

adverse effects were seen when the concentrations of each agent were one-third to one-tenth of their respective NOAELs. When the concentrations approximated their NOAELs, some minor toxicologic effects were observed. When the agents were administered at their LOAELs, however, a range of interactive effects was observed, both synergistic and antagonistic, in addition to additive effects (Jonker et al. 1990, Groten et al. 1994). In experiments using agents with the same target organ but different mechanisms of action, administration of four nephrotoxicants to male rats resulted in no effects at doses one-fourth of their respective NOAELs, in minor effects when doses were equal to their NOAELs, and in greater toxicity than that induced by each compound alone at doses equal to their LOAELs (Jonker et al. 1993) [need to review study—is this antagonism?]. Administration of four nephrotoxicants with the same mechanism of action to rats at doses equal to one-half their respective LOAELs resulted in clear nephrotoxicity, while doses equal to their NOAELs produced only a slight increase in kidney weight (no lower doses were tested) (Jonker et al. 1994). Overall, fewer than 3% of the 331 studies in the EPA Database on Toxic Interactions show clear evidence of synergism at bioassay dose levels.

3.0

Risk Management and Regulatory Decision-Making

Risk assessment can provide a valuable framework for setting environmental, health, and safety regulatory priorities and for allocating resources within regulatory agencies. Technical risk assessments seldom set the regulatory agenda, however, because of the different ways in which the non-technical public perceives risks. Risk assessment provides only part of the information that risk managers use, along with information about public values, statutory requirements, and cost-effectiveness, to make decisions about the need for and methods of risk reduction. Different regulatory goals have engendered different risk-assessment methods, different definitions of negligible and unacceptable risk, and different roles for risk assessment to play in decision-making.

This chapter examines some of the issues that have arisen as the use of risk assessment in regulatory decision-making has evolved and matured. The use of bright lines, or benchmarks to distinguish negligible from unacceptable risk, has led to questions about what those lines should be, who decides what they should be, and to which situations they should be applied. Communicating decisions about whether a risk is or is not unacceptable to parties affected by those decisions has become a complex and confusing undertaking. Making decisions about how to allocate resources towards risk reduction can be made partly on the basis of risk, and methods to do so are developing. Making decisions that include information on the costs of implementing or failing to implement a risk-reducing activity, which can include consideration of the results of risk assessments, has become increasingly important in this era of resource constraints. Examining the legality of risk-related decisions and the process by which they were made can either assure reasonable, supportable decisions or hopelessly impede the

regulatory process. And finally, striving for consistency among decisions made by different agencies can improve regulatory predictability but hinder regulatory flexibility. Recommendations on each of those issues are made that are hoped might contribute to the further evolution and improvement of risk-based decision-making.

3.1

Bright Lines

3.1.1 ❦ ***ISSUE:*** Should risk managers have clearly demarcated bright lines[1] defining boundaries between unacceptable and negligible risks to guide their decisions?

❦ ***RECOMMENDATION***

The Commission supports the use of bright lines as guideposts or goals for decision-making. Using a range between bright lines as a goal (such as between incremental cancer risks of 10^{-6} to 10^{-4}), where decisions about protective action are negotiable, is consistent with the flexibility needed to account for uncertain and variable risks, differences in the size of populations potentially at risk, and differences in local factors such as community values.

❦ ***RATIONALE***

Bright lines are chosen to provide a pragmatic definition of "safe" and "unsafe". A bright line is a single numerical value between unacceptable and negligible levels of risk. Regulated parties are expected to demonstrate that risk estimates are below the bright line in order to operate a manufacturing facility, introduce a new product to the market, or sell foods with low levels of contaminants.

---

[1] An example of a bright line is 10^{-5} excess cancer risk, which means that if a risk assessment predicts that out of a population of 100,000 people exposed to a substance more than one case of cancer is likely to occur as a result of exposure, then that risk is unacceptable and protective action is required. Conversely, if the predicted risk is less than 10^{-5}, that risk is negligible and no protective action is required.

Risk managers are accustomed to the clear guidance provided by bright lines for implementing and determining compliance with risk-based standards or guidelines. Measurable contaminant concentrations—like permissible exposure limits (PELs) or threshold limit values (TLVs) in the workplace, action levels for food contaminants like aflatoxin on peanuts or mercury in swordfish, and National Ambient Air Quality Standards (NAAQS) for carbon monoxide or ozone levels in air—provide assurance that risks should be negligible so long as contaminant exposure concentrations are below the bright line of those values. If risks or contaminant concentrations are found to exceed their bright lines, action is expected to be taken to protect workers, consumers, or the community. Small quantitative differences in contaminant concentrations above or below those lines can make a big difference in whether protective actions are taken. Nonetheless, bright lines provide a basis for consistent decision-making.

Bright lines expressed as contaminant concentrations are easier to implement than bright lines expressed as risks. Although concentration-based bright lines are derived from some judgment about what exposure level constitutes negligible risk, risk managers or compliance officers can easily determine whether or not they are being met because they can actually be measured. When bright lines are expressed as risks, uncertain and variable risk estimates must be compared to determine compliance. Comparing risk levels will become even more difficult as distributional approaches to risk estimation are implemented.

Ranges of bright lines have often been adopted by regulatory policy. For example, under Superfund, a pair of bright lines has been used to define a potentially acceptable risk range for carcinogens. A contaminated site is considered to pose a negligible risk if a multi-pathway risk assessment of the site produces an upper-bound lifetime incremental cancer risk estimate not exceeding 10^{-6}. The site is considered an unacceptable risk, requiring remediation, if the risk estimate is 10^{-4} or higher. Between 10^{6} and 10^{4}, remedial actions, if any, are determined on a case-by-case basis.

There are several potential problems with using specified bright lines. Bright lines are burdened by all of the uncertainty, variability, and assumptions inherent in risk estimation; thus, the all-or-nothing nature of a bright line could be misunderstood and construed to imply that an exact boundary exists between safety and risk. Risk assessments themselves could be manipulated so that their results occur above or below the bright line according to a risk manager's particular policy preferences. Bright lines have the potential to be applied inflexibly, leading to decisions that do not reflect the unique characteristics of particular populations. Regulators and stakeholders have little or no experience using bright lines for decisions based on cost-effectiveness or cost-benefit analyses.

We need a catch phrase for the penumbral zone, the range where a local politically legitimized group can take responsibility for the tradeoffs of perceived risk and costs of regulatory compliance.

❦ ***RECOMMENDATION***

In addition to ranges between bright lines intended to protect the general population, additional bright lines should be established to protect especially susceptible subpopulations, such as young children, pregnant women, or adults with lung disease.

❦ ***RATIONALE***

Section 2.4 of this report discusses sensitive subpopulations and the need to consider such populations in risk assessments. The results of risk assessments that include consideration of sensitive subpopulations might be expressed in terms of an estimated risk for the general population, and a different estimated risk for a sensitive subpopulation. Those risk estimates could be used to establish a bright line for the general population and a different bright line for the sensitive subpopulation. Decisions about appropriate levels of risk reduction could then be made with the benefit of the knowledge of those differences.

how does that make sense. The bright line is aimed at the source not the receiver.

3.1.2 ❦ ***ISSUE:*** Should bright lines be specified by Congressional legislation, promulgated as a part of normal agency rulemaking, or established by individual precedents?

❦ ***RECOMMENDATION***

The Commission recommends that Congress leave the establishment of specific bright lines or ranges of bright lines to regulatory agencies. Congress should continue to provide broad guidance, using such qualitative language as "substantially reducing risk", "achieving exposure levels associated with negligible risks", or "assuring reasonable certainty of negligible risks" with regard to risks, and "benefits justify and are reasonably related to costs" with regard to economic analysis.

❦ ***RATIONALE***

Congress has included bright line risk provisions in several legislative bills proposed in recent years. Only in the 1990 Clean Air Act Amendments, however, did Congress pass legislation specifying a quantitative risk level for the first time, when it mandated the development of a strategy for controlling residual risks after Maximum Available Control Technology implementation based on an incremental lifetime cancer risk level of 10^{-6}.

Bright lines have been well established by regulatory policy despite their absence in legislation. For example, the Food and Drug Administration regulates intentional and unintentional additives in food by calculating an "estimated daily intake" and comparing that value to a previously established "acceptable daily intake". When the ratio exceeds 1.0, the agency considers the exposure unacceptable (Flamm & Lorentzen, 1988). Noncancer health effects are evaluated similarly under Superfund; contaminant doses are compared to values called Reference Doses. If the ratio is less than a bright line of 1.0, adverse effects are

considered unlikely and no action is required.

In practice, legislated bright lines may do little to constrain agency decisions, because the agencies (either centrally or regionally) will exercise considerable discretion in the conduct and evaluation of risk assessments (such as choosing and justifying assumptions and selecting the most relevant data sets), even if procedural guidance such as that proposed by the 104th Congress is enacted. For similar reasons, the absolute value of a risk judged to be negligible is of less importance than the size of that risk compared with similar risks, or with dissimilar but familiar risks. Even more important should be evidence that exposures and risks judged to be too high are, in fact, being reduced.

3.2

Communicating Risk

3.2.1 ❦ ***ISSUE:*** Risk communication is a critical component of the risk-management process, but it has received too little funding and too little attention by both risk assessors and risk managers. Effective risk communication greatly influences the acceptability of a risk assessment and risk-management decision to stakeholders.

❦ ***RECOMMENDATION***

The Commission urges the adoption of comprehensive risk communication programs within regulatory agencies that provide for research on risk communication messages, training of risk managers and others engaged in communicating risk to the public, and the inclusion of risk communication funding, objectives, and evaluation in risk management plans.

❦ ***RATIONALE***

Since the process of risk assessment has been used by the federal government to support decision-making, there has been a need for risk communication. The National Research Council has defined risk communication as "an interactive process of exchange of information and opinions among individuals, groups, and institutions. It involves multiple messages about the nature of risk and other messages not strictly about risk, that express concerns, opinions, or reaction to risk messages or to legal and institutional arrangements for risk management" (NRC 1989). In an effort to improve risk communication and thereby improve the understanding of risk, Congress has made various proposals to increase the transparency of risk assessments and

considered unlikely and no action is required.

In practice, legislated bright lines may do little to constrain agency decisions, because the agencies (either centrally or regionally) will exercise considerable discretion in the conduct and evaluation of risk assessments (such as choosing and justifying assumptions and selecting the most relevant data sets), even if procedural guidance such as that proposed by the 104th Congress is enacted. For similar reasons, the absolute value of a risk judged to be negligible is of less importance than the size of that risk compared with similar risks, or with dissimilar but familiar risks. Even more important should be evidence that exposures and risks judged to be too high are, in fact, being reduced.

to require the use of risk comparisons. Transparency is generally equated with revealing and characterizing the assumptions, uncertainties, default factors, and methods used to estimate risks. Legislation has also been proposed that would require agencies to compare the risk to be regulated to other risks regulated by the agency and to other risks experienced by the public. However, risk communication is not a straightforward process.

One of many examples where risk communication has gone awry is the case where a pesticide residue was compared to the risks associated with aflatoxin in peanut butter. Mothers responded angrily because the communicator was perceived as trying to trivialize their concerns and, moreover, was calling into question their abilities as mothers by pointing out another risk that was unknown to them. Both risks were not controllable at the individual level without giving up something of value, generating great frustration.

The level of fright that can be generated by media-amplified scare stories has to be counted among the hazards to be mitigated by competent and trustworthy regulatory action.

A growing body of research provides some guidance on communicating risk information effectively and on using risk comparisons to communicate risk. Some researchers have suggested that people's perception's of risk must be considered, because they will influence how a new activity, product, or situation is evaluated and accepted or rejected. Paul Slovic has identified seven psychological dimensions that influence people's perceptions of risk: voluntariness, exposed individual's knowledge of risk, dread, severity of consequences, control, equity, and novelty (Holtgrave 1993). Another model of risk perception considers probability of gain, probability of loss, probability of status quo, and expected benefit and harm (Holtgrave 1993).

Regulatory agencies are sometimes party to such communications as they lobby for their budgets in competition with other legislative priorities.

he mental models approach suggests that people process new information within the context of their existing beliefs. The three main tenets of the mental models approach are: the recipient of any communication needs a basic understanding of the exposure, effects, and mitigation processes relevant to making decisions about a hazardous process; recipients' existing beliefs affect how they interpret and use any new information; and risk information should be presented

with appropriate text structure and enforced with textual aids. Those researchers have said that "one should no more release an untested communication than an untested product" (Holtgtave 1993).

Experimental research shows that people avoid unfamiliar risks more than known risks, even when objective probabilities are similar. Attempts to fully disclose uncertainties in risk analysis may thus generate public concern, suggesting not that the public be protectedfrom knowledge of scientific facts but that such information should be communicated carefully and transparently.

With the growing use of risk assessments and risk estimates by regulatory agencies, there is a need to increase public understanding and credibility of that information. In general, agencies and Congress have emphasized the importance of improving the quality of risk assessments, while paying less attention to the need for training and educating risk assessors and risk managers on how best to communicate information about risk. Comprehensive risk communication programs need to be established within regulatory agencies. Funding for training risk assessors and risk managers in risk communication and for testing risk communication messages should be part of each risk management agency's budget. In addition, communication should be a specific component of risk management plans. Specific communication objectives, such as awareness and involvement of stakeholders, should be identified in the plans, along with appropriate methods for evaluating the effectiveness of a communication.

The state of the art of risk communication has moved from trying to explain risk information to a non-technical audience, to a highly evolved stage of building partnerships between plant managers and nearby residents, companies and consumers, and agency risk managers and the public. To make this transition successfully, an investment of time and resources is needed.

3.3

Comparative Risk Assessment

3.3.1 ❦ ***ISSUE:*** Government agencies responsible for protecting human health and the environment are confronted with many statutory mandates but have limited time and resources to implement them.

❦ ***RECOMMENDATION***

The Commission recommends that agencies use the comparative risk-ranking paradigm to make resource allocation decisions. That paradigm includes organizing teams of analysts or stakeholders, such as business and environmental representatives; making a comprehensive list of environmental problems; assembling the best information possible about the sources of the problems and the risks they pose to human health, ecosystems, and the quality of life; ranking the problems in order of the seriousness of the risks they pose; and using the rankings to guide strategic planning and budgeting.

❦ ***RATIONALE***

Priority setting by comparing risks is one way to confront and weigh choices when money, time, and staff are in limited supply. The call for greater use of this tool has come from many sources, including Supreme Court Justice Stephen Breyer, the Carnegie Commission on Science, Technology and Government, the National Academy of Public Administration, and many members of Congress.

Comparative risk assessment for priority setting is a process that brings together elements of risk assessment, cost-benefit analysis, strategic planning, and public involvement. Combining those analytic tools with questions of ethics, values, and principals of democratic governance leads to a very high level of complexity that requires commitment of technical and human resources.

Although the Environmental Protection Agency and the Department of Energy have had some experience with comparative risk ranking for priority setting, the paradigm has developed primarily from the 34 state, 10 local, and 2 tribal projects fostered by EPA. To begin the process, a planning team is assembled to define the problems to be addressed and initially set project goals. The planning team writes a work plan that includes the project's structure, budget, and methods. In addition, the team identifies the individuals needed to achieve the project goals, who then become the comparative risk team. Potential stakeholders include representatives from the highest political officeholder sponsoring the project, such as the governor or mayor; agencies, such as environmental protection, health department, natural resources, agricultural department, and land use commission; and legislators, academics, business interests, environmentalists, farmers, fishers, and ethnic and racial representatives. The organizational units include a project manager, who supervises all aspects of the project, and a steering committee that provides overall direction for the project. A public advisory committee ensures public participation in the process and that the project's work remains understandable, relevant, and credible to the public. Finally, technical work groups perform data collection, data analysis, and preliminary rankings. The technical work groups may be arranged by medium, by risk type, or by combining them into one large work group (EPA 1993).

While each federal agency will need to adapt the fundamental elements of the comparative risk-ranking paradigm to its mission, statutory mandates, and current and emerging responsibilities, it is easily translated to the federal level by substituting Congressional staff from authorizing

committees of the Congress for gubernatorial, mayoral, and state legislative representatives and identifying stakeholders based on the programs and projects of the specific agency. Depending on the agency, it will be important to include representatives from state, local, and other federal agencies with shared responsibility.

The participants in each comparative risk project must decide whether or how to address such issues as environmental equity, future risks, and effects across jurisdictional boundaries. Another area of early decision-making is agreeing on risk ranking methods and processes. Most comparative risk projects look at three criteria when ranking risks: effect on human health, effect on ecosystems, and effect on quality of life, including economic well-being. Ranking methods have ranged from voting by participants, formulae which rely more heavily on quantitative data, matrix-based discussions that employ graphics in a shared decision-making process, decision-seeking consensus, and bargaining or tradeoffs among stakeholders. Typically, a comparative risk ranking project may take two to three years to complete. Keeping participants, the press, and the political leadership enthusiastic and motivated throughout the process can be a challenge.

While priority setting may be the primary goal of comparative risk projects, there are often a number of other benefits that make the time and effort valuable (Minard 1993).

- Comprehensive catalog of problems. Most comparative risk projects produce a catalog of a state's environmental problems. The analysis is an important foundation for the project, yet can be a resource for the public and managers separate from the priority-setting goal.

- Increased knowledge among public and government decision-makers about a variety of issues. Participants in a comparative risk project learn about problems that are not part

of their daily interests or responsibilities. The interdisciplinary activity improves understanding and appreciation of competing priorities and provides potential new insight into solutions.

- Teamwork and trust. As a result of increased communication between different institutions and interest groups, new avenues of cooperation can be established across agencies and with new interest groups. While adversarial relationships among interest groups may not be eliminated or turf conflicts between agencies may not disappear, comparative risk projects can reveal unexpected agreement among parties and understanding of differences in perspectives.

- Consensus for change. The process itself helps build coalitions that favor shifting priorities to higher-risk endeavors. In turn, the broader public support for a common agenda allows agencies and legislatures to move money and staff into priority areas with less litigation, less controversy, and less second-guessing of each other. Increased public involvement has increased project success. Making significant changes in governmental activities takes public understanding and support. In a comparative risk-ranking process, where ranking includes value-laden choices, the group making the ranking should have a clear understanding of how the public's values relate to the choices.

The comparative risk ranking paradigm emerging from the state, local, and tribal projects supported by EPA provides a useful starting point for federal agencies to use in ranking priorities and making resource allocation decisions.

3.4

Economic Analysis

3.4.1 ❦ ***ISSUE:*** The results of risk assessments are frequently based on assumptions that are inconsistent with the needs of cost-benefit analysis.

❦ ***RECOMMENDATION***

The Commission recommends greater collaboration between risk assessors and economists who must rely on the results of risk assessments, to minimize the inconsistencies between scientific and economic approaches to characterizing risks. Where inconsistencies exist, they should be revealed explicitly as sources of analytic uncertainty.

❦ ***RATIONALE***

The results of a risk assessment are used in cost-benefit analysis to estimate benefits, but risk characterization end-points are often inconsistent with economic valuation start-points. The traditional methods of evaluating health effects for the purpose of health risk assessment can conflict with the needs of the economist who is asked, at least implicitly, to provide information on individual preferences for avoiding health risks. For example, a 10% improvement in lung function is not meaningful to most individuals. They do not demand greater lung function, they want fewer sick days. Health risk assessments seldom evaluate risks in terms of sick days, and there are no economic studies available that can be used to value a 10% improvement in lung function. Closer collaboration between economists who are familiar with the valuation literature and scientists who are estimating concentration-response

functions can help avoid such mismatches by seeking end points that can be meaningfully evaluated in terms of both their risk and their economic value.

Another conflict between the needs of the economist and the results of risk assessments is that health risk assessments generally focus on individual rather than population risk. There are two reasons why economic analysis focusses on estimating benefits for the population at large. First, if costs are to be compared with benefits, it would make no sense to compare total costs to the benefits experienced by only one (hypothetical "maximally reasonably exposed") individual. Second, even if one were performing a cost-effectiveness analysis in which abatement costs per risk to the maximally exposed individual were being estimated, the resulting estimates could be very misleading. Suppose that two abatement strategies were equally costly, but one had a very high individual risk and low population risk (because few people were exposed to the pollutant of concern), while another strategy exposed many more people but the individual risk was small. A cost-effectiveness analysis based on individual risk would lead to adoption of the first strategy instead of the one based on the population risk, which could be considered the more relevant measure.

Another inconsistency results from the traditional risk-assessment practice of building uncertainty about risk characterization into the assumptions used to estimate risks. This tradition purposely skews risk estimates upwards to build in a margin of error that is intended to protect a population from health risks (estimating average risk reductions instead might result in protection of only part of a population), and thus provides only one point at the upper end of a risk distribution. According to economic tradition, the analyst attempts to describe the distribution of risks (or the distribution of risk improvements) in the population and leaves it to the decision-maker to decide what is an acceptable level of protection and which strategies deliver that level of protection. Current trends towards moving away from expressing risk-assessment results in terms of upper-bound point estimates and using distributions of risks instead may overcome this inconsistency.

Finally, there is an inconsistency that can result from the tendency of risk assessment to rely more on expert opinion and the tendency of economic analysis to rely more on the perceptions of non-technical individuals. An economist's job is to reveal individual preferences for products or activities associated with risks, where those preferences are conditional on individual risk perceptions; economic estimates of damages are based on individuals' willingness to pay to avoid risks. Individual risk perceptions are frequently inconsistent with expert opinion (see section 3.2), so using one as the basis for evaluating the other is also inconsistent. Resolving these inconsistencies will require judgments regarding the appropriate weighting of the opinions of experts and that of informed individuals.

Above all there is no consensus on the economic valuation of a human life saved or prevented. In its place can be an assessment of the most efficient allocation of resources to conserve lives, but this merely shifts the value judgments to the zone of income distribution: How heavily should I be taxed to save another's life.

3.4.2 ❦ ***ISSUE:*** Like human health risk assessment, cost-benefit analysis is an uncertain procedure. Cost-benefit analysis produces estimates of the costs and benefits associated with alternative regulatory and non-regulatory options that rely on data to the extent they are available and relevant, but that also rely on judgments, assumptions, and extrapolations.

❦ ***RECOMMENDATION***

The Commission recommends that the primary sources of uncertainty associated with the results of a cost-benefit analysis be identified, characterized, stated explicitly, and quantified if possible. The results of a cost-benefit analysis should not be expressed as though they are accurate measures of actual economic costs and benefits.

❦ ***RATIONALE***

As inputs to economic analysis, the results of health risk assessments contribute a large degree of uncertainty. The uncertainty associated with an upper-bound point estimate of individual risk may range over several orders of magnitude. Economic analysis relies not on point estimates of individual risk, but on the entire probability distribution of potential costs or

benefits for an entire affected population, which cannot be meaningfully extrapolated from an upper-bound point estimate of individual risk. Economic analysis relies on information about the central tendencies (mean or median) of costs and benefits for a population as a whole, so that aggregate expected net benefits can be evaluated. Determining central tendencies requires as much information as possible on the probability distributions underlying the important components of costs and benefits. If a scientific assessment of risk provides information only on the upper bounds of hazards, then the economic analysis will either overstate the net benefits to the general population or have relevance only to the tail of the risk distribution.

Other sources of uncertainty in cost-benefit analyses used in an environmental context come from the difficulties inherent in valuing the benefits of environmental assets. Environmental assets include features of the natural environment whose degradation people would be willing to pay to avoid. Such assets include recreation areas, endangered species, visual range, open space, wetlands, etc. People may value improvement in those assets because they use the services such assets provide ("use value") and because "they are there" ("non-use value"); quantitative estimates of value in both cases are likely to be highly variable.

Because there are so many sources of uncertainty associated with the assumptions upon which economic analysis is based, it is misleading to express the results of economic analyses as single, quantitative estimates of costs or benefits. Cost-benefit analysis results should include more than single estimates of costs and benefits, expressed in a manner that reflects their inherent uncertainty. In some cases, Monte Carlo or other simulation methods can provide some sense of the distribution of possible outcomes. In other cases, it may be possible to assess only a few alternative scenarios, with some qualitative information about their relative plausibility. In all cases, however, it is essential to state explicitly what the level of confidence in the outcome may be and to identify the primary sources of uncertainty.

3.4.3 ❦ ***ISSUE:*** In most common applications of cost-benefit analysis, the aggregation of measures of individual welfare to measure social welfare treats all individuals anonymously—that is, no one's welfare is weighted more heavily than anyone else's—leading to potentially disproportionate or inequitable distributions of costs and benefits.

❦ ***RECOMMENDATION***

By analogy to including consideration of especially susceptible subpopulations in human health risk assessments, the Commission recommends that methods or criteria be developed, through an appropriate political process if necessary, to assign different weights in an aggregation of measures of individual welfare to segments of society or to individuals who might otherwise bear disproportionate changes in social welfare.

❦ ***RATIONALE***

Cost-benefit analysis does not judge the equity implications of the policies it seeks to evaluate. For example, if implementing a policy affecting health, safety, or the environment increases the welfare of rich people and decreases the welfare of poor people, but the rich peoples' gain outweighs the poor peoples' loss, then cost-benefit analysis would consider the policy to lead to an improvement in aggregate social welfare, while acknowledging the disproportionate or inequitable distributions of costs and benefits. Weighting of individual welfare need not always be conducted using the default assumption of anonymity, without explicitly incorporating equity considerations, however.

Departing from the anonymity default requires two things: identifying groups or individuals within the societal group potentially impacted by a policy that are likely to feel that impact differentially, and weighting those groups or individuals so that an equitable aggregation can

be achieved. As with human health risk assessment, the first objective is fairly readily achieved—we know that children or pregnant women, for example, might require special consideration because they can experience the adverse effects of toxicant exposure to a greater degree than the general population. By analogy, identifying particular population segments that will no longer be able to afford certain fruits or vegetables because of a change in the policy regulating permissible pesticide residues, for example, while identifying other population segments whose health risks from pesticides are reduced because they can afford to continue to buy those fruits and vegetables, is relatively straightforward. The second objective, deciding how the different groups should be weighted so that equity in cost-benefit analysis is achieved (or, in the human health risk assessment example, determining to what extent children or pregnant women are more sensitive to toxicants and how standard-setting should reflect those differences quantitatively), is highly problematic. ~~There are~~ no correct or accurate weightings ~~that~~ are possible—~~weights must be assigned subjectively. Any decisions based primarily on subjectivity is unlikely to lack controversy.~~

Decisions about how equity weights should be determined and when they should be used instead of the anonymity default might be made if methods or criteria to do so were established and agreed upon. Such methods or criteria could be developed using a process similar to that used recently by the EPA to develop cancer risk assessment guidelines, for example, in which the agency actively sought input from a wide range of interests, and through a collaborative process, was able to develop guidelines that represent a reasonable consensus.

3.4.4 ❦ ***ISSUE:*** Methods used to estimate the value of reducing risks to health are generally derived from a wage rate context, which can be inappropriate for an environmental policy context due to the differences in the extent to which attributes of risk perception such as dread, source of risk, voluntariness, and controllability can affect those estimates.

❦ ***RECOMMENDATION***

The Commission recommends that research be undertaken to investigate public perceptions of human health risks associated with environmental contamination, for the purpose of relating cost estimates for risk reduction to the less quantitative factors associated with those perceptions.

❦ ***RATIONALE***

There is a growing recognition that compensating wage studies have limitations for valuing mortality risk reductions in an environmental context. There are several limitations of such studies: they reflect risk preferences of perhaps a less risk-averse group than the average in society; they reflect voluntarily borne risks; more life-years are lost to accidental death than those associated with, for example, cancer, the effects of which may be discounted because they occur far into the future; and the source of the risk is an accident, not a business polluting as part of its normal operations, for example.

Social values play an important role in risk perception and risk acceptance. Research has shown that many of the public's reactions to risk can be attributed to a sensitivity to technical, social and psychological qualities of hazards that generally are not accounted for in technical risk assessments (such as uncertainty about risks, perceived inequities in the distribution of risks and benefits, aversion to being exposed to dreaded or involuntary risks). According to Paul Slovic, an individual's perception of a particular risk is influenced by seven psychological dimensions: voluntariness, knowledge of risk, dread, severity of consequences, control, equity, and novelty. A psychometric paradigm based on those seven dimensions uses psychometric scaling and multivariate analysis techniques to produce quantitative representations or "cognitive maps" of risk attitude and perceptions. This framework, in which risk is seen as multidimensional, representing the confluence of a variety of public

values and attitudes, has long served as a basis for making quantitative risk comparisons (see section 5.4). Another analytic framework, the conjoint expected risk model, uses four dimensions to rate or rank risks: probability of gain, probability of loss, probability of status quo, and expected benefit and harm.

Because each of those risk-perception frameworks uses elements of both risk assessment and cost-benefit analysis to generate quantitative rankings of risks, quantitative attributes of risk perception or risk comparison could be used to better inform quantitative estimation of environmental risk-related costs and benefits. Interaction between research programs that focus on risk perception and those that focus on cost-benefit analysis could provide a basis for doing so.

3.4.5 ❦ ***ISSUE:*** Benefits valuation for regulatory purposes is very inconsistent among regulatory agencies.

❦ ***RECOMMENDATION***

The Commission recommends that to achieve more consistent benefits valuation among regulatory agencies, mortality risks should be stated explicitly and valued using best estimates or ranges of estimates.

❦ ***RATIONALE***

Although a succession of administrations has issued executive orders requiring consideration of costs and benefits in rulemaking, those administrations have explicitly refused to establish a specific value (or range of values) for a mortality risk reduction (or life saved), or to establish a basis for evaluating a cost-per-life-saved estimate of a regulatory option. As a result, under

current guidance, agencies may choose not to value mortality risks (or "lives") explicitly or choose not to subject their regulations to a comparison with a benchmark for cost-effectiveness.

This valuation inconsistency takes several forms, including whether an analysis even includes explicit values for mortality risk reductions, how such values are incorporated, and what values are chosen. For those agencies explicitly valuing mortality risk reductions, the implied "value of a statistical life" ranges from $1 million to $10 million. For agencies that do not explicitly value mortality risk reductions, but instead make decisions based on an "acceptable" cost-per-life-saved, the implicit value of a statistical life can be far higher. One study of EPA regulatory decisions affecting cancer risks found regulations promulgated that cost over $50 million per life saved. OMB's study of such behavior involving a broader range of causes of death found even higher costs per life saved, as did a recent CBO study of drinking water standards. The issue is not whether a life is truly worth $50 MM. It's rather whether this is the most efficient use of societal resources, when investments might do as much in other areas by a factor of 50x as many lives.

Encouraging agencies and programs to value mortality risks using best estimates or ranges of estimates of such values could reduce inter- and intra-agency inconsistency. "Best" estimates can be devised within an interagency process that takes into account consensus and the range of uncertainty around such values in the literature, including the comparability of various types of risks. Government and private resources are less likely to be wasted when agency rulemaking more consistently reduces mortality risks at comparable costs. Explicit valuation of reductions in mortality risks also makes it easier to compare regulatory alternatives where there are non-quantifiable benefits.

3.5

Judicial Review

3.5.1 ❦ ***ISSUE:*** The regulatory reform legislation introduced in the 104th Congress includes detailed and prescriptive provisions for agency regulation. The combination of prescriptive and detailed substantive requirements, with provisions for broad judicial review, leads ~~inextricably~~ inexorably to litigation that is unlikely to improve the quality and effectiveness of our regulatory system.

❦ ***RECOMMENDATION***

The Commission recommends that courts should remain limited to review of procedural issues and defer to agency expertise. Decisional criteria should not be judicially reviewable; review is available upon agency issuance of a final rule. Judicial review of major rules should include, and be limited to, questions of whether risk assessments and cost-benefit analyses were performed, and if so, whether they were performed using accepted procedures and standards by individuals recognized by the regulatory community to be experienced and appropriately qualified.

❦ ***RATIONALE***

The "substantial evidence" test referred to in the Administrative Procedures Act (APA) as currently enacted is entirely different from the proposed amendments to the APA included in the regulatory reform legislation introduced in the 104th Congress. Those amendments included a new standard of "substantial support", which would require a reviewing court to

hold agency action unlawful if the agency findings and conclusions were found to be "without *substantial support* in the rulemaking file, viewed as a whole, *for the asserted or necessary factual basis...*". This would require courts to determine whether there was substantial support in the record to sustain the "asserted" or "factual basis" of the agency rulemaking.

Historically, the scope of judicial review has been under the narrow "arbitrary and capricious" standard, and courts have exercised judicial restraint. Courts consistently have held that, under the provision of the APA, agencies are entitled to deference with regard to factual questions involving scientific matters in their own areas of expertise. Moreover, mixed questions of law and fact, at least to the extent they are fact-dominated, also require deferential ~~action~~ review.

1. New "major" rules require that risk assessments and cost benefit analysis be performed.

2. Inclusion of "Decisional Criteria" (those criteria pursuant to which a rules *validity* is determined) in legislation supplements all enabling statutes such that considerations of cost and risk and cost-benefit analyses that support those considerations are included as part of the agency record.

B. Judicial Review of prescriptive requirements and Decisional Criteria

1. Decisional Criteria allows issues of cost, including the risk assessments and cost-benefit analysis, to become part of the agency record. If reform legislation grants judicial review of Decisional Criteria, then the risk assessments and cost-benefit analysis become the subject of judicial scrutiny.

a. Decisional Criteria increase the substantive content of the record a court

considers in its review. Under the reform legislation, statutes that have historically limited regulatory decisions to technically-based criteria can be reviewed on considerations of cost -- driven by the risk assessments and cost-benefit analyses.

2. Judicial review requires then that a court review the prescriptive measures required by the reform legislation.

   a. Consequently, the rulemaking record, including the risk assessments, cost-benefit analysis and peer review of risk assessments can be challenged after an agency proposes a rule. Once challenged, a court must then review the policy judgments made by an agency in developing the risk assessment and cost-benefit analysis findings (determinations that have historically been left to agency discretion). Reform legislation requires that the risk assessment and cost-benefit analysis and peer review report of the risk assessment be reviewed in determining the *legality* of the regulation.

3.5.2 ❦ ***ISSUE:*** The addition of a new standard to the Administrative Procedures Act expands the historical role of the courts in review of agency action.

❦ ***RECOMMENDATION***

The Commission recommends that The Administrative Procedures Act should not be amended to include a new standard of review that applies wholesale to every rulemaking. Courts have historically exercised deference to agency interpretation and action in areas where judges are not otherwise qualified to review the veracity of the information presented, and regulatory reform legislation should not broaden the required inquiry of a court to areas in which judges

ultimately lack the background, expertise, or resources to do so.

❦ ***RATIONALE***

1. By adding a new standard that applies to all rules adopted vis a vis the provisions which apply to *every rulemaking*, the reviewing court is invited to judicially review the risk assessments and cost-benefit analysis and peer review report to determine the *legality* of the regulation.

2. Courts that have historically deferred to agency interpretation and action will be required to review, and reject agency action, if the agency failed to consider permissible interpretations of statutes or failed to explain in "reasoned analysis" why interpretations were adopted or rejected. Again, these types of amendments require courts to review the underlying risk assessment and cost-benefit analysis required under reform legislation.

   a. In the 104th Congress, one proposed bill that offered amendments to the APA provided that its new provisions "apply and supplement" the requirements contained in *any* statute for review of final agency action. Essentially, this would have meant that a court -- in any review of any issue deemed "final" -- be required to consider the prescriptive assessments and analyses that were conducted during the rulemaking.

B. Consequences of Increased Judicial Review

1. In a period of "litigation reform," new avenues of tort possibilities are being created by the prescriptive reform legislation and amendments to historically developed provisions of the APA.

a. The critical question to be asked is not "Whether," but "To what degree does a court review science-based decision making?

b. Courts should not be set up through legislation to be another layer of "peer review" (albeit a review without the necessary background, experience, time and resources).

(1) Courts should not be engaged to review the veracity of the underlying science.

(2) Judicial review under the reform legislation nearly destroys judicial deference in favor of comprehensive judicial involvement. Legislation should not compel the abandonment of precedent in the review of agency rulemaking.

2. Adding layers of judicial involvement in the regulatory rulemaking process does not help an already overburdened system.

a. The reform legislation significantly expand the scope of judicial review by creating new opportunities to challenge agency action earlier than what historically has been deemed to be "final" agency action in a regulatory decision or rulemaking context.

Courts' limited resources are best conserved

b. ~~Courts function best when engaged to decide~~ societal issues. ~~Therefore,~~ when science-based regulatory decisions *affect societal issues*, courts may review such decisions to assure that the assessments and analyses are properly used in the agency's decision to regulate.

3.5.3 ❦ ***ISSUE:*** Regulatory reform legislation would permit interlocutory, or intermediate, appeal of final agency action.

❦ ***RECOMMENDATION***

The Commission recommends that each step of the rulemaking process should not be deemed "final agency action" under any reform legislation. Amendments to the Administrative Procedures Act should not contemplate the premature interruption of the agency decision-making or rulemaking process.

❦ ***RATIONALE***

A. Historical provisions for review under the APA

1. Judicial review is granted on "final agency action." Review is of the "rulemaking record."

   a. Petitioner for review must exhaust all other administrative remedies available prior to seeking a court's review of the agency's determination.

   b. This requirement is a procedural safeguard that not only ensures the establishment of a "rulemaking record," but also preserves it.

2. Outside of the judicial review context, an agency is allowed to apply its expertise, exercise its informed discretion, and create a more complete record, such that if judicial review becomes necessary there is a full record to

adjudicate.

a. Enforcement of procedural defaults within an administrative context allows an agency to monitor and correct mistakes and developing more fully a record of the rulemaking process.

b. A fully developed record promotes judicial economy.

B. Reform legislation permits interlocutory, or intermediate, appeal of final agency action.

1. Reform Legislation provides that a number of agency decisions and determinations be deemed "final agency action." Under the provisions of the APA, "final agency action" is immediately reviewable (i.e., prior to the final rulemaking).

a. The opportunity to develop the rulemaking record is hindered; consequently, judicial review is conducted on an incomplete record.

2. The excessive new occasions for judicial review are inconsistent with notions of judicial and litigation reform efforts and will result in costly and unacceptable delays in regulatory rulemaking.

3.5.4 ❦ ***ISSUE:*** Alternatives to increased judicial review exist that would achieve the goal of assuring rational, cost-effective regulatory action affecting health, safety, and the environment.

❦ ***RECOMMENDATION***

The Commission recommends the following possibilities to judicial review: mandatory negotiated rulemaking, compulsory arbitration, and expert peer review.

❦ ***RATIONALE***

3.6

Inter- and Intra-Agency Consistency

3.6.1 ❦ ***ISSUE:*** Risk assessment and risk management practices are poorly coordinated among regulatory agencies and programs, even among those with overlapping interests and jurisdictions, leading to inconsistency, idiosyncrasy, and impaired credibility.

❦ ***RECOMMENDATION***

The Commission recommends that an organization such as the Office of Science, Technology, and Policy be given responsibility for coordinating risk assessment and risk management practices among regulatory agencies and programs, so that inappropriate inconsistencies can be resolved.

❦ ***RATIONALE***

Current practices in the use of risk assessment and risk management in regulatory programs vary among Federal agencies and even among regulatory programs within the EPA. Some of this variation is attributable to different requirements among the Federal laws authorizing regulatory activity, either in the form of explicit methodologic requirements that assessments must follow or as differently mandated regulatory responsibilities that the assessments must support. Other differences reflect variations in policy among organizations, adopted as a matter of differing scientific and policy judgment or simply because of the independent establishment of varying precedents and preferences.

This array of methods reflects the fact that there is no single, agreed upon scientific procedure for the assessment of health risks from chemical exposures. The primary reason is that the needs of the risk assessment process, to make projections of possible human health risks for the variety of types and levels of exposures that may arise, far outstrip the ability of scientific investigation to give firm answers. The practical need remains, however, to make characterizations of the risk consequences (including the uncertainty about those consequences) of various potential actions and activities by industries, by government, by individuals, and by society as a whole.

Faced with this practical problem, regulatory agencies have arrived at practical methods. These methods include reliance on procedures that, while attempting to embody information from the available data, of necessity rely on uncertainty-bridging principles derived from a combination of general knowledge about chemicals, their behaviors in the environment and their toxic effects, a desire to maintain internal case-by-case consistency in how uncertainties are resolved, and a desire to ensure that regulatory decisions are likely to fulfill the legislative mandates about public health protection.

Time and experience have largely succeeded in defining a common framework and structure for risk assessment. Within this framework, however, there continues to be vigorous debate about the most appropriate risk assessment approaches, the bearing of various kinds of data on risk projections, and the degree and appropriateness of conservatism in risk assessment methods. Faced with this continuing disagreement about methods, various Federal regulatory agencies have adopted somewhat different procedures. In part, this diversity can be attributed to the different questions being asked of the risk assessment process in different regulatory contexts by different statutes. In part, it reflects different institutional judgments about the most appropriate methods and different scientific judgments about matters with high scientific uncertainty. And in part, it reflects simple policy choice made for the sake of consistency within each organization (which, owing to independent histories, becomes inconsistent among

organizations).

The effect of this diversity of methods among federal regulatory agencies is to make it difficult to compare risks, or the actions taken to mitigate those risks, from one regulatory program to another. One program's concern for a one-in-a-million cancer risk, say, may be based on an upper bound low-dose extrapolation to an average person in the exposed population extrapolated from mice based on a presumption of equal toxicity when daily doses are scaled by surface area, while another program's one-in-a-million is for a hypothetical person exposed to an agent at the regulatory limit for 45 years based on a maximum likelihood low-dose extrapolation and the presumption that equitoxic doses are proportional to body weight.

Although defaults and standard methods are necessary in the face of uncertainty and lack of case-specific knowledge, variation among agencies and programs in the choice of defaults enhances the sense of arbitrariness in risk analyses. In cases where regulatory responsibilities overlap or when different groups have cause to assess the same exposures, differences in assessment outcome can lead to conflict and confusion among the public and the regulated community. Designating an office or organization as a central coordinator for practices regarding the use of risk assessment and risk management in regulatory programs would reduce confusion and improve the credibility of regulatory decisions related to risk reduction.

4.0

Framework for Risk Management

4.1 ❦ ***ISSUE***: Current efforts to manage environmental, health, and safety risks are often fragmented and conflicting, and their effectiveness as means of protecting public health or the environment is often uncertain. There is no integrated process for effectively managing and reducing risks.

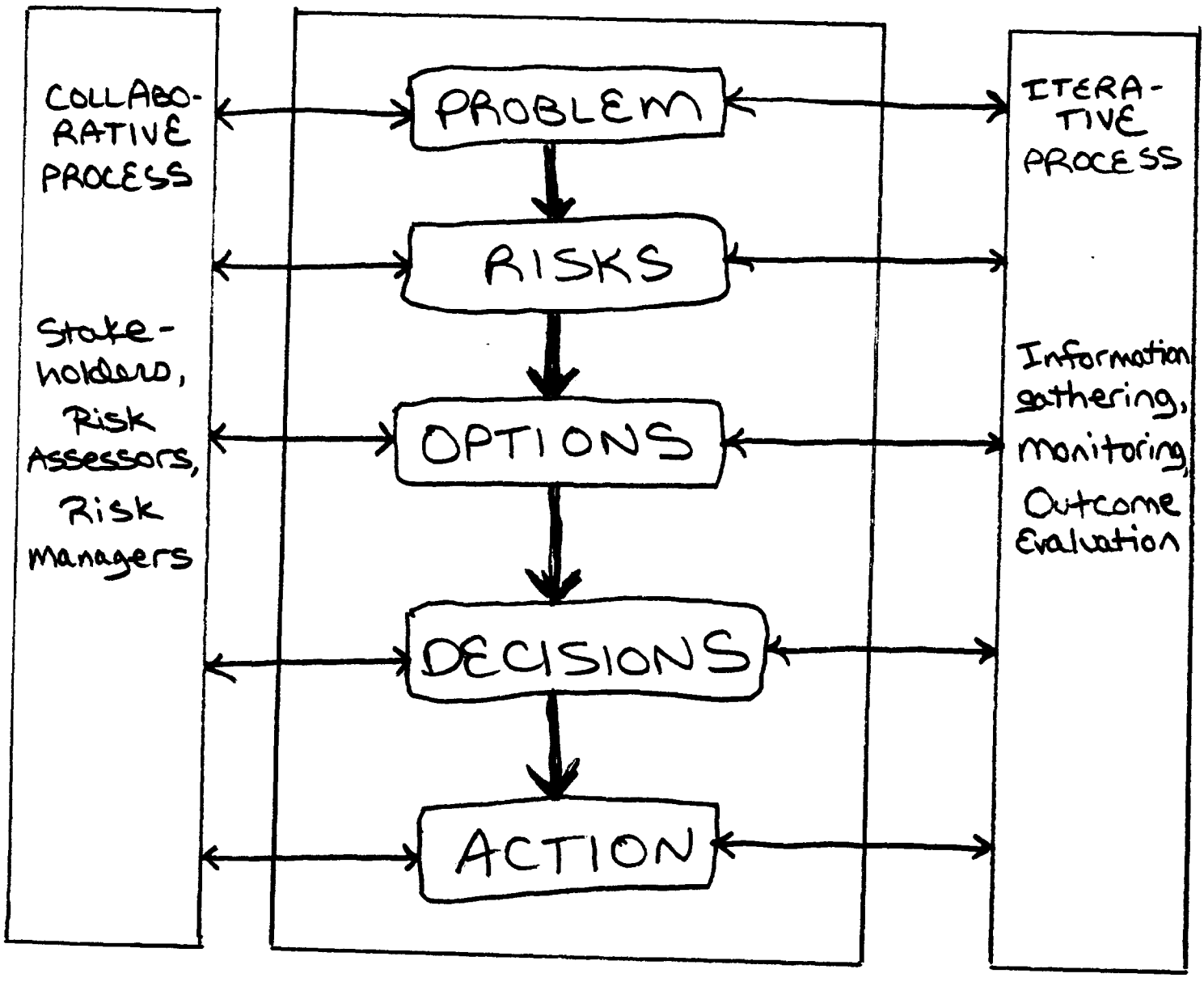
❦ ***RECOMMENDATION***

The Commission recommends that a systematic, comprehensive risk-management framework be used to manage and reduce environmental, health, and safety risks. That framework should move risk management beyond the current statutorily fragmented, chemical-by-chemical, medium-by-medium, risk-by-risk, command-and-control approaches. The framework should include a collaborative and iterative process so that risk assessment results can be integrated with public values and with social, political, economic, and other considerations, to make risk-management decisions.

❦ ***RATIONALE***

Risk assessment is a useful method for organizing experimental and observational information on which to base decisions about controlling or preventing risks to public health and the environment. Risk assessment does not provide accurate estimates of actual health effects in humans or environmental receptors; it does not provide a mechanism for considering social values, perceptions, and ethics; it does not provide a means to identify the hazards that pose the

Figure 4.1. Framework for Risk Management



greatest risks to public health or the environment; and, it does not provide a means to develop or identify the most cost-effective strategies to control hazards. Risk management is the process that should incorporate those considerations into decision-making, but currently there is no consistent, comprehensive strategy for managing, controlling, or reducing risks to public health or the environment.

In the absence of a consistent, comprehensive approach to risk management, the Commission proposes the risk-management framework shown in Figure 4.1. Our framework puts a decision-analysis framework in an environmental and public-health risk context. The framework has five steps: problem, risks, options, decision, and action. Each step involves different sets of questions. Answers to those questions form the basis of the systematic and comprehensive nature of the risk-management framework. Use of a collaborative process and an iterative process guides how the answers are obtained.

The following is a description of the five steps and the iterative and collaborative processes that occur throughout the five steps.

1. Problem: *What is the problem?* A problem might be identified on the basis of environmental monitoring, emissions inventories, disease surveillance, epidemiologic observation, or public concern. The problem should be examined in not just a medium- and pollutant-specific manner, but also in a comprehensive and multimedia context. Potential inter-relationships among different problems should also be considered. After the problem is characterized, goals and objectives of problem intervention are identified.

2. Risks: *What risks does this problem pose to public health or the environment?* Risk is considered to be the likelihood of an occurrence of an adverse effect on human health, the environment, or public welfare. The goal is to articulate the factual and scientific basis of the problem and to identify any subjective perceptions of the problem by characterizing its risks to

human and environmental health, cultural and societal values, quality of life, and environmental equity. Cumulative risks from related problems should also be identified, and where appropriate, comparative risk analysis should be performed.

3. Options: *What should be done about the problem and what are the potential consequences of intervention?* Solutions to the problem are identified by stakeholders, regulators, and scientists, as appropriate, and might include both regulatory alternatives such as permits, regulations, and enforcement actions, and non-regulatory solutions such as pollution prevention, recycling, market incentives, voluntary reductions, or education. Institutional, financial, and other arrangements for implementing the solutions are identified. The extent of risk reduction and the relationships between the costs and benefits of each solution are determined and compared. Potential impacts of the solution, including ethical considerations, are characterized.

4. Decision: *What is the best solution to the problem and how should that decision be made?* The goals and objectives of problem intervention are reviewed and the most feasible and acceptable solution to the problem is identified, with involvement of affected parties. The criteria for feasible and acceptable might be that which is the most reasonable and cost-effective, or that which minimizes risks in the most cost-effective manner. A mechanism for conflict resolution, or for reaching closure in the absence of consensus, is identified and implemented.

5. Action: *How effective is the decision?* The solution is implemented and the outcomes of the solution are evaluated. The impact that the solution has on the problem is characterized, for example, through environmental monitoring or through analysis of relationships between inverventions and trends in health and environmental indicators. The original problem is redefined and the five steps repeated, if appropriate.

The framework is implemented iteratively; that is, the process is refined based on continuing

information acquisition, verification, and monitoring. This process is similar to the one used in scientific investigations—conclusions can be changed based on new data. Iteration could apply to a rule that has already been promulgated and is found to be irrelevant or inappropriate in light of new information; or, iteration could occur as a new rule or approach to a problem is being developed, as public comment, negotiation, or analysis redefine that problem or other issues of concern. It is possible that exploring a problem more deeply in the analysis stages may lead to a better understanding of how a problem should have been defined and scoped at the outset. Using an iterative process to scope a problem may actually speed up the process, as goals and issues are clarified, possibly leading to a quicker resolution than expected initially if it becomes apparent that proceeding with the entire process is no longer necessary. Of course, iteration must not be allowed to become a device for indefinite delay.

The framework is also implemented collaboratively; that is, the process is conducted with full participation of stakeholders or affected parties.[1] Such partnerships facilitate the exchange of information and ideas that all parties need to make informed decisions about reducing risks. A number of studies have shown that the success of a regulatory action or decision depends on the involvement of affected parties in the scoping and decision-making process (Richards 1993). While risk assessors and risk managers may tend to base their responses primarily on technical and scientific information, non-technical stakeholders are likely to base their responses on very different, more value-laden perceptions and concerns. Both must play a role in decision-making if the outcome is to succeed—effective collaboration plays a central role in effective implementation, especially if the general public is expected to change its view of environmental protection as being solely a government-industry responsibility and to participate in both the choice and implementation of risk-management strategies (McCallum

[1]Stakeholders are people or organizations that are likely to be affected by the outcome, and might include the community, elected officials, industries or businesses, and regulatory agencies. The identity of the stakeholders will depend on the characteristics of the particular problem to be addressed.

and Santos 1995). Meaningful stakeholder involvement in regulatory decisions will require a shift in attitudes of agency decision-makers as well, however, so that the affected public is seen as part of the problem-solving process rather than as an obstacle to it (Van Horn 1988, Chess et al. 1995). It is clear that "public comment" and "public meetings" are not substitutes for collaborative approaches to problem-solving (although they may be appropriate in some cases).

A potential disadvantage of our framework may be the investments of both time and money required to implement a collaborative and systematic process. While the process may lead to considerable long-term savings, the up-front cost of implementation may be an obstacle.[2] In addition, while assessing impacts on human and environmental health involve fairly well-established, if controversial and evolving procedures, evaluating impacts on public welfare, which includes considerations of costs, benefits, values, ethics, and perceptions, is considerably less straightforward. Different mechanisms for integrating those considerations into risk management must be explored.

Thus there are three critical advantages of our risk-management framework, which represents a major shift in the role that risk assessment plays in risk management decision-making. First, an integrated, holistic, top-down approach to a public health or environmental problem is used instead of a chemical-by-chemical, medium-by-medium, bottom-up approach to characterizing individual risks. Second, communication, collaboration, and negotiation among stakeholders are emphasized in an open and inclusive process so that public values can be included in the shaping of risk-management strategies. The result is decisions that are more pragmatic and more easily implemented than those made in the absence of consensus, and solutions that no single

---

[2]It is unlikely that performing every step of a complete analysis will be required for every decision-making problem, however. Different levels of decisions require different levels of analysis. The framework described here is meant to provide a guideline for a thought process that might be pursued when decision-making issues arise.

participant could have devised because of the diversity of interests, knowledge, and technical expertise represented. And finally, like the scientific process, the risk-management process is iterative. At any stage of the process, conclusions and decisions can change on the basis of new information, and the problem can be reformulated and reevaluated as more information is acquired.

5.0

Recommendations for Specific Regulatory Agencies and Programs

[as yet to be provided]

References

[not yet revised to reflect new draft]

Agency for Toxic Substances Disease Registry (ATSDR). 1988. The Nature and Extent of lead Poisoning in Children in the United States: A Report to Congress. Centers for Disease Control. Atlanta, Georgia.

Agency for Toxic Substances Disease Registry (ATSDR). 1995. Testimony before the Senate Appropriations, Labor, Health and Human Services, Education Subcommittee. May 5.

Beranek, W., Jr., Davies, C.J., and Moses, S. 1985. Issues in Peer Review of the Scientific Basis for Regulatory Decisions. American Chemical Society.

Bernstein, L., Gold, L.S., Ames, B.N., Pike, M.C., and Hoel, D.G. 1985. Some tautologous aspects of the comparison of carcinogenic potency in rats and mice. Fund. Appl. Toxicol. 5:79-86

Berry, B.J.L. 1977. The Social Burdens of Environment Pollution: A Comparative Metropolitan Data Source. Ballinger Publishing Co. Cambridge, MA.

Breyer, S.G. 1993. Breaking the Vicious Circle: Toward Effective Risk Regulation. Harvard University Press. Cambridge, MA

Bullard, R.D. and Wright, B.H. 1992. The Quest for Environmental Equity: Mobilizing the African-American Community for Social Change. In: R.E. Dunlap and A.G. Mertig, eds. American Environmentalism. Taylor and Francis: Philadelphia, PA.

Burns, J.E. 1974. Organochlorine pesticide and polychlorinated biphenyl residues in biopsied human adipose tissue—Texas 1969-72. Pesticide Monitoring 7:122-124.

Byrd, D. and Lave, L.B. 1987. Narrowing the Range: A framework for risk regulators. Issues in Science and Technology. Summer. Pages 92-100.

California Comparative Risk Project. 1994. Towards the 21st Century: Planning for the Protection of California's Environment. Final Report. May.

Chess, C., Salomone, K.L., Hance. B.J., and Saville, A. 1995. Results of a national symposium on risk communication: next steps for gevernment agencies. Risk Analysis 15:115-125

Chess, C. and Hance, B.J. 1989. Opening Doors: Making Risk Communication Agency Reality. Environment: Vol. 31.

Congressional Research Service (CRS). 1994. Risk Analysis and Cost-Benefit Analysis of Environmental Regulations. The Library of Congress.

Costner, P. and Thornton, J. 1990. Playing with Fire: Hazardous Waste Incineration. Greenpeace USA. Washington, D.C.

Crouch, E.A.C., Wilson, R., and Zeise, L. 1987. Tautology or not tautology? J. Toxicol. Environ. Health 20:1-10

Davies, J.C., Covello, V.T., and Allen, F.W., eds. 1987. Proceedings of the National Conference on Risk Communication. The Conservation Foundation. Washington, D.C.

Davies, J.E. *et al.* 1972. The role of social class in human pesticide pollution. Am. J. Epidemiol. 96:334-338.

Deisler, P.F. 1988. [title] Environ. Sci. Tech. 22:15-19

Flamm, W.G. and Lorentzen, R.J. 1988. Quantitative Risk Assessment (QRA): A Special Problem in the Approval of New Products. In: C.R. Cothern, M.A. Mehlman, and W.L. Marcus, eds. Risk Assessment and Risk Management of Industrial and Environmental Chemicals. Princeton Scientific Publishing Co., Inc.: Princeton, NJ

Gaylor, D.W. 1989. Preliminary estimates of the virtually safe dose for tumors obtained from the maximum tolerated dose. Reg. Toxicol. Pharmacol. 9:101-108

Gelobter, M. 1987. The distribution of outdoor air pollution by income and races: 1970-1984. Master's thesis for the University of California Energy and Resources Group. Berkeley, CA.

Gelobter, M. 1992. Toward a model of environmental discrimination. In: B. Bryant and P. Mohai, eds. Race and the Incidence of Environmental Hazards. Westview Press. Boulder, CO.

Gold, L.S., Sawyer, C.B., Magaw, R., Backman, G.M., de Veciana, M., Levinson, R., Hooper, N.K., Havender, W.R., Bernstein, L., Peto, R., Pike, M.C., and Ames, B.N. 1984. A carcinogenic potency database of the standardized results of animal bioassays. Environ. Health Perspect. 58:9-21

Gold, L.S., de Veciana, M., Backman, G.M., Magaw, R., Lopipero, P., Smith, M., Blumenthal, M., Levinson, R., Bernstein, L., and Ames, B.N. 1986. Chronological

supplement to the carcinogenic potency database: Standardized results of animal bioassays published through December 1982. Environ. Health Perspect. 67:161-200

Gold, L.S., Slone, T.H., Backman, G.M., Magaw, R., Da Costa, M., Lopipero, P., Blumenthal, M., and Ames, B.N. 1987. Second chronological supplement to the carcinogenic potency database: Standardized results of animal bioassays published through December 1984 and by the National Toxicology Program through May 1986. Environ. Health Perspect. 74:237-329

Gold, L.S., Slone, T.H., Backman, G.M., Eisenberg, S., Da Costa, M., Wong, M., Manley, N.B., Rohrbach, L., and Ames, B.N. 1990. Third chronological supplement to the carcingoenic potency database: Standardized results of animal bioassays published through December 1986 and by the National Toxicology Program through June 1987. Environ. Health Perspect. 84:215-286

Goldman, B.A. 1993. Not Just Prosperity. National Wildlife Federation.

Goldman, B.A. 1995. An Environmental Justice Paradigm for Risk Assessment. Environmental Equity Seminar Series. (Sponsored by Duke University, North Carolina Central University, U.S. Environmental Protection Agency) Raleigh, North Carolina. April 17.

Goldstein, B. 1989. The maximally exposed individual: an inappropriate basis for public health decisionmaking. Environ. Forum. Nov.-Dec.

Gould, J.M. 1986. Quality of Life in American Neighborhoods: Levels of Affluence, Toxic Waste, and Cancer Mortality in Residential Zip Code Areas. Westview Press. Boulder, CO.

Harvard Group on Risk Management Reform. 1995. Reform of Risk Regulation: Achieving More Protection at Less Cost. Center for Risk Analysis. Harvard School of Public Health

Hoffman, W.S., Adler, H., Fishbein, W.I., and Bauer, F.C. 1967. Relation of pesticide concentration in fat to pathological changes in tissues. Arch. Environ. Health. 15:758-762.

Krewski, D., Gaylor, D.W., Soms, A.P., and Szyszkowicz, M. 1993. Correlation Between Carcinogenic Potency and the Maximum Tolerated Dose: Implications for Risk Assessment. Appendix F in NRC (1993)

Kutz, F.W., Yobs, A.R., and Strassman, S.C. 1977. Racial stratification of organochlorine insecticide residues in human adipose tissue. J. Occup. Med. 19:619-622.

McCallum, D.B. and Santos, S. 1995. Participation and Persuasion. A Communications

Perspective on Risk Management. In: (Need)

Minard, R., Jr. 1994. A Practitioner's Guide to Comparative Risk--and how we got here. Prepared for the Relative Risk Ranking Roundtable. Resources for the Future.

National Academy of Public Administration (NAPA). 1995. Setting Priorities, Getting Results: A New Direction for EPA. Washington, D.C.

National Research Council (NRC). 1983. Risk Assessment in the Federal Government: Managing the Process. National Academy Press. Washington, D.C.

National Research Council (NRC). 1989. Improving Risk Communication. National Academy Press. Washington, D.C.

National Research Council (NRC). 1993. Issues in Risk Assessment. National Academy Press. Washington, DC

National Research Council (NRC). 1994. Science and Judgment in Risk Assessment. National Academy Press. Washington, D.C.

Northeast Center for Comparative Risk. 1993. State Comparative Risk Projects: A Force for Change. Vermont Law School. South Royalton, VT.

Office of Science and Technology Policy (OSTP). 1995. [incomplete]

Peto, R., Pike, M.C., Bernstein, L., Gold, L.S., and Ames, B.N. 1984. The TD_{50}: A proposed general convention for the numerical description of the carcinogenic potency of chemicals in chronic-exposure animal experiments. Environ. Health Perspect. 58:1-8

President's Council on Sustainable Development (PCSD). 1995a. January

President's Council on Sustainable Development (PCSD). 1995b. Public comment survey

Richards, M. 1993. Siting Industrial Facilities. Lessons from the Social Science Literature. Presented at the Fifth Annual International Conference of the Society for the Advancement of Socio-Economics. Environmental Decision-Making. New York City. March 26-28.

Rieth, J.P. and Starr, T.B. 1989a. Chronic bioassays: Relevance to quantitative risk assessment of carcinogens. Reg. Toxicol. Pharmacol. 10:160-173

Rieth, J.P. and Starr, T.B. 1989b. Experimental design constraints on carcinogenic potency

estimates. J. Toxicol. Environ. Health 27:287-296

Rosenthal, A., Gray, G.M., and Graham, J.D. 1992. Legislating Acceptable Cancer Risk from Exposure to Toxic Chemicals. Ecology Law Quarterly 19:269-362

Slovic, P., Fishchoff, B., and Lichtenstein, S. 1980. Facts and fears: Understanding perceived risk. In: R.C. Schwing and W.A. Albers, Jr., eds. Societal Risk Assessment: How Safe Is Safe Enough? Plenum Press. New York.

Spitzer, H. 1995. Peer Review Practices in the Federal Government. Prepared for the American Industrial Health Council.

The National Law Journal. 1992. Unequal Protection: The Racial Divide in Environmental Law. Special Supplement. September 21.

United Church of Christ Commission for Racial Justice and Public Data Access, Inc. 1987. Toxic Wastes and Race in the United States: A National Report on the Racial and Socio-Economic Characteristics of Communities with Hazardous Waste Sites. New York, New York.

United Nations Commission on Environment and Development (UNCED). 1987. Our Common Future. Chaired by Dr. Gro Harlem Bruntdland.

U.S. Environmental Protection Agency (EPA). 1987. Unfinished Business: A Comparative Assessment of Environmental Problems. Office of Policy Analysis. Washington, D.C.

U.S. Environmental Protection Agency (EPA). 1990. Reducing Risk: Setting Priorities and Strategies For Environmental Protection. Science Advisory Board. SAB-EC-90-0021. Washington, D.C.

U.S. Environmental Protection Agency (EPA). 1991. Guidance for Risk Assessment. [incomplete]

U.S. Environmental Protection Agency (EPA). 1992. Environmental Equity: Reducing Risk For All Communities. EPA230-R-008. Office of Policy, Planning and Evaluation. Washington, D.C.

U.S. Environmental Protection Agency (EPA). 1992a. Framework for Ecological Risk Assessment. EPA/630/R-92/001. Risk Assessment Forum. Washington, DC

U.S. Environmental Protection Agency (EPA). 1993. A Review of Ecological Assessment Case Studies from a Risk Assessment Perspective. EPA/630/R-92/003. Risk Assessment

Forum. Washington, DC

U.S. General Accounting Office (GAO). 1983. Siting of Hazardous Waste Landfills and Their Correlation with Racial and Economic Status of Surrounding Communities. Washington, D.C. Government Printing Office.

Van Horn, C.E. 1988. Breaking the Environmental Gridlock. The Eagleton Institute of Politics. Rutgers University. New Brunswick, N.J.

Vermont Agency of Natural Resources. 1991. Environment 1991: Risks to Vermont and Vermonters.

West, P., Fly, J.M., Larkin, F., and Marans, R.W. 1992. Minority anglers and toxic fish consumption: evidence from a statewide survey of Michigan. In: B. Bryant and P. Mohai, eds. Race and the Incidence of Environmental Hazards. Westview Press. Boulder, CO.

Yankelovich, D. 1991. Coming to Public Judgment: Making Democracy Work in a Complex World. Syracuse University Press.

Zeise, L., Wilson, R., and Crouch, E. 1984. Use of acute toxicity to estimate carcinogenic risk. Risk Anal. 4:187-199

Zeise, L., Crouch, E.A.C., and Wilson, R. 1985. Reply to comments: On the relationship of toxicity and carcinogenicity. Risk Anal. 5:265-270

Zeise, L., Crouch, E.A.C., and Wilson, R. 1986. A possible relationship between toxicity and carcinogenicity. J. Am. Coll. Toxicol. 5:137-151

Zimmerman, R. 1993. Social equity and environmental risk. Risk Anal. 13:649-666.

Appendix A.1

Mandate of the Commission on Risk Assessment and Risk Management

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
ADVISORY COMMITTEE CHARTER

RISK ASSESSMENT AND MANAGEMENT COMMISSION

1. PURPOSE. This charter renews the Risk Assessment and Management Commission in accordance with requirements of the Federal Advisory Committee Act, 5 U.S.C. App. 2, §9(c).

2. AUTHORITY. The Commission was specifically directed under Section 303 of the Clean Air Act, as amended on November 15, 1990.

3. OBJECTIVE AND SCOPE OF ACTIVITY. As required by the Clean Air Act Amendments of 1990, the Risk Assessment and Management Commission shall make a full investigation of the policy implications and appropriate uses of risk assessment and risk management in regulatory programs under various Federal laws to prevent cancer and other chronic human health effects which may result from exposure to hazardous substances.

The Commission shall consider:

(a) The report of the National Academy of Sciences authorized by section 112(0) of the Clean air Act, the use and limitations of risk assessment in establishing emissions and effluent standards, ambient standards, exposure standards, acceptable concentration levels, tolerances or other environmental criteria for hazardous substances that present a risk of carcinogenic effects or other chronic health effects and reductions in the number of persons exposed at various levels of risk, the incidence of cancer, and other public health factors;

(b) The most appropriate methods for measuring and describing cancer risks or risks of other chronic health effects from exposure to hazardous substances considering such alternative approaches as the lifetime risk of cancer or other effects to the individual or individuals most exposed to emissions from a source or sources on both an actual and worst case basis, the range of such risks, the total number of health effects avoided by exposures standards, acceptable concentration levels, tolerances and other environmental criteria, reductions in the number of persons exposed at various levels of risk, the incidence of cancer, and other public health factors;

(c) Methods to reflect uncertainties in measurement and estimation techniques, the existence of synergistic or antagonistic effects among hazardous substances, the accuracy of extrapolating human health risks from animal exposure data, and the

existence of unquantified direct or indirect effects on human health in risk assessment studies;

(d) Risk management policy issues including the use of lifetime cancer risks to individuals most exposed, incidence of cancer, the cost and technical feasibility of exposure reduction measures and the use of site specific actual exposure information in setting emissions standards and other limitations applicable to sources of exposure to hazardous substances; and

(e) Comment on the degree to which it is possible or desirable to develop a consistent standard of acceptable risk, among various Federal programs.

4. FUNCTIONS. (a) In the conduct of the studies required by this section, the Commission is authorized to contract (in accordance with Federal contract law) with nongovernmental entities that are competent to perform research or investigations within the Commission's mandate, and to hold public hearings, forums, and workshops to enable full public participation.

(b) The Commission may appoint and fix the pay of such staff as it deems necessary in accordance with the provisions of title 5, United States code. The Commission may request the temporary assignment of personnel from the Environmental Protection Agency or other Federal agencies.

(c) The members of the Commission who are not officers or employees of the United States, while attending conferences or meetings of the Commission or while otherwise serving at the request of the Chair, shall be entitled to receive compensation at a rate not in excess of the maximum rate of pay for Grade GS 18, as provided in the General Schedule under section 5332 of title 5 of the United States Code, including travel time, and while away from their homes or regular places of business they may be allowed travel expenses, including per diem in lieu of subsistence as authorized by law for persons in the Government service employed intermittently.

(d) A report containing the results of all Commission studies and investigations under this section, together with any appropriate legislative recommendations or administrative recommendations, shall be made available to the public for comment not later than 42 months after the date of enactment of the Clean Air Act Amendments of 1990 and shall be submitted to the President and to the Congress not later than 48 months after such date of enactment. In the report, the Commission shall make recommendations with respect to the appropriate use of risk assessment and risk management in Federal regulatory programs to prevent cancer or other chronic health effects which may result from exposure to hazardous substances.

5. COMPOSITION AND MEETINGS. The Commission shall be composed of ten members who shall have knowledge or experience in fields of risk assessment or risk management, including three members to be appointed by the President, two members to be appointed by the Speaker of the House of Representatives, one member to be appointed by the minority Leader of the House of Representatives, two members to be appointed by the Majority Leader of the Senate, one member to be appointed by the Minority leader of the Senate, and one member to be appointed by the President of the National Academy of Sciences. Meetings will be held as necessary. A full-time employee of the Environmental Protection Agency has been assigned as the Designated Federal Officer, who will be present at all meetings and is authorized to adjourn any meeting whenever it is determined to be in the public interest. The estimated annual operating cost of the Commission for FY94 was approximately $48,976.38, which includes .35 FTE work year of staff support. This figure will increase in FY95 once the Commission hires it's staff, meets on a monthly basis for a year, obtains office space, etc. The Office of the Administrator oversees and executes the budget assigned to the Commission and the Office of Air provides administrative support as provided by the Clean Air Act Amendments of 1990.

6. DURATION. The Commission shall cease to exist upon the date determined by the Commission, but not later than 9 months after the submission of such report.

NOV 14 1994
Agency Approval Date

NOV 15 1994
Date Filed with Congress

Fred Hansen
Deputy Administrator