Final Report
Volume 2
1997

Risk Assessment and Risk Management In Regulatory Decision-Making

The Presidential/Congressional Commission on Risk Assessment and Risk Management

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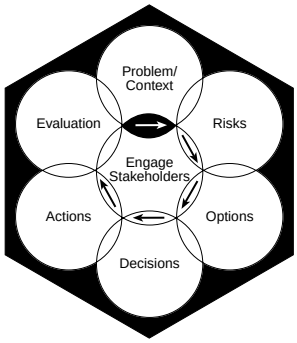

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The Presidential/Congressional Commission on Risk Assessment and Risk Management

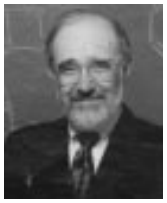
Dr. Gilbert S. Omenn, Chairman, is Professor of Environmental Health and of Medicine and Dean of the School of Public Health and Community Medicine at the University of Washington, Seattle. From 1977 to 1981, Dr. Omenn was a Deputy Science and Technology Adviser in the White House Office of Science and Technology Policy and then an Associate Director of the Office of Management and Budget. The author of 380 research papers and scientific reviews, as well as author/editor of 14 books, Dr. Omenn received his A.B. from Princeton University, his M.D. from Harvard, and a Ph.D. in genetics from the University of Washington.

Alan C. Kessler, Vice-Chairman, is a partner in the Philadelphia office of the law firm of Buchanan Ingersoll Professional Corporation. Mr. Kessler has extensive experience in the defense and litigation of major class action toxic tort suits in federal and state courts, as well as experience in the successful defense and prosecution of major federal antitrust and securities class action suits. He has been elected three times as a Township Commissioner for the Lower Merion Township in Montgomery County, Pennsylvania (population 58,000). Mr. Kessler received his B.A. from the University of Delaware and his law degree from the University of Maryland.

Norman T. Anderson is Director of Research for the American Lung Association of Maine. He was a regional air toxicologist for the U.S. Environmental Protection Agency in Boston; a regulatory toxicologist for the Maine Bureau of Health, and an environmental health scientist for the Maine Department of Environmental Protection. Mr. Anderson received his B.A. from Brown University and his Masters of Science in Public Health from the University of North Carolina in Chapel Hill.

Dr. Peter Y. Chiu is Senior Physician and Service Committee Chair for The Kaiser Permanente Medical Group in Milpitas, CA, and an Assistant Clinical Professor at the Stanford University Medical School. Dr. Chiu has been a Fellow of the American Academy of Family Physicians since 1989, and also has been a registered civil engineer in California since 1972. He also served on the California Regional Water Quality Control Board from 1979 to 1984. Dr. Chiu received his B.S. in Civil Engineering, his Masters of Public Health degree, and his Doctor of Public Health degree from the University of California, Berkeley; and his M.D. degree from Stanford University.

Dr. John Doull is a Professor of Pharmacology and Toxicology and Therapeutics at the University of Kansas Medical Center. A former president of the American Board of Toxicology and the Society of Toxicology, Dr. Doull served on the boards of the American Academy of Clinical Toxicology and The Toxicology Forum. He is the recipient of many professional honors, including one named for him, the John Doull Award presented by the Mid-America Chapter of the Society of Toxicology. Dr. Doull received his B.S. in Chemistry from Montana State College, and his Ph.D. in Pharmacology and M.D. degrees from the University of Chicago.



Dr. Bernard Goldstein is Director of the Environmental and Occupational Health Sciences Institute, a joint program of the University of Medicine and Dentistry of New Jersey-Robert Wood Johnson Medical School and Rutgers University, and Chairman of the Department of Environmental and Community Medicine at the medical school. From 1983 to 1985 he was Assistant Administrator for Research and Development at the U.S. Environmental Protection Agency. Dr. Goldstein received his B.S. degree from the University of Wisconsin and his M.D. from New York University School of Medicine.

Dr. Joshua Lederberg, a Noble Prize winning research geneticist, is President Emeritus of The Rockefeller University and remains a professor and Sackler Foundation Scholar there. He received the 1958 Nobel Prize in Medicine for studies on the exchange of genetic material in bacteria and the U.S. National Medal of Science in 1989. He has been a member of the National Academy of Sciences since 1957 and is a charter member of its Institute of Medicine. He served as Chairman of the President's Cancer Panel from 1979 to 1981. Dr. Lederberg received his B.A. from Columbia College, was a medical student at Columbia University College of Physicians and Surgeons, and obtained his Ph.D. from Yale.

Dr. Sheila M. McGuire is president of the Iowa Health Research Institute and an expert in the epidemiology of oral diseases, geriatrics research, and fluoride research. She is a former Assistant Professor in the Harvard Medical School's Department of Dental Care Administration and adjunct faculty member at the University of Iowa College of Dentistry. Dr. McGuire received her Doctor of Dental Surgery degree from the University of Iowa; her Master's in Epidemiology from the Harvard School of Public Health; and her Doctorate of Medical Sciences in Epidemiology from Harvard.

Staff

Sharon Newsome, Associate Director

Joanna Foellmer, Program Specialist and Designated Federal Official

Office: 529 14th Street, N.W., Suite 420
Washington, DC 20045
Tel. 202-233-9537
Fax: 202-233-9540
WWW: http://www.riskworld.com

Dr. David Rall is the former Director of the National Institute of Environmental Health Sciences (NIEHS) and is one of the world's leading authorities on toxicology and environmental health. He was the founding Director of the National Toxicology Program, the largest toxicity testing program in the world, and has authored and co-authored approximately 170 papers relating to comparative pharmacology, cancer chemotherapy, pesticide toxicology, drug research and regulation, among other topics. Dr. Rall received his B.S. degree from North Central College and his M.S. and Ph.D. degrees in Pharmacology, as well as his M.D. degree, from Northwestern University.

Dr. Virginia V. Weldon is Senior Vice President, Public Policy, for Monsanto Company. Prior to joining Monsanto, Dr. Weldon was a professor of pediatrics, deputy chancellor for medical affairs, and vice president of the Medical Center at Washington University School of Medicine and Medical Center. She is a member of the President's Committee of Advisors on Science and Technology, and a distinguished service member of the Association of American Medical Colleges, whose assembly she chaired in 1985-86. Dr. Weldon received her A.B. degree from Smith College and her M.D. degree from the State University of New York at Buffalo.

Dr. Gail Charnley, Executive Director, is an expert in environmental toxicology and risk assessment. Prior to becoming the Commission's executive director, she was acting director of the Toxicology and Risk Assessment Program at the National Academy of Sciences. She has chaired several U.S. Army Science Board committees and is currently serving as a councilor of the Society for Risk Analysis. Dr. Charnley received her A.B. in Biochemistry from Wellesley College and her Ph.D. in Toxicology from the Massachusetts Institute of Technology.

Preface

The Commission is grateful to the many people who provided information, advice, and critical comment on our June 1996 Draft Report. As a result of that valuable counsel, our Final Report is much improved.

Volume 1 of our Final Report, released on January 29, 1997, is a reader-friendly 64-page report that focuses exclusively on the Commission's comprehensive new Risk Management Framework, which was supported by an overwhelming majority of comments. We set forth principles for making good risk management decisions and for actively engaging stakeholders in the process. The aim is to move beyond one-chemical, one-risk regulatory actions for protection of air, water, foods, or the workplace and put problems into their public health, ecological, cultural, and community contexts to facilitate better accepted, more effective, and more cost-effective decisions.

With this volume, Volume 2 of our Final Report, the Commission completely updates the 1996 Draft Report. We address many technical and policy issues related to health and environmental risk-based decisions. We make recommendations for specific federal regulatory programs and agencies. In response to comments, we have clarified our recommendations for management of residual risks from section 112 Clean Air Act hazardous air pollutants; for a common metric to assist comparative risk assessment and risk communication for both carcinogens and noncarcinogens; and for use of bright lines as guideposts for implementing decisions. We modified our tabulation of rodent tumor bioassay mechanisms that may not be relevant to human cancer risk if they are the only responses observed and are due to the mechanisms we list, and explained better the difference between probabilistic analyses of variation in exposure versus probabilistic analyses of uncertainty in estimates of risk levels. The recommendations on Superfund have been altered to take into account the administrative changes made over the past year. A recommendation to establish a process for updating permissible exposure limits for the air contaminants in the workplace has been added to those directed at the Occupational Safety and Health Administration. An analogous stakeholder process is recommended to update the 1976 Toxic Substances Control Act.

We were pleased that actions by Congress addressed our 1996 recommendations to modify the Delaney clause for pesticide residues, to evaluate context under the Safe Drinking Water Act, and to remove the Resource Conservation and Recovery Act land-ban that complicated Superfund cleanup.

My fellow Commissioners and I thank the many people who have contributed to our deliberations: 109 people who testified at hearings in Washington, DC and at six regional hearings; staff at the regulatory agencies who provided information and resources; 130 people and organizations who provided written comments; and members and staff of the Congress and leaders and staff of the Clinton Administration for their advice and for the interest they have taken in our findings and recommendations. We particularly thank our splendid staff: Gail Charnley, Executive Director, Sharon Newsome, Associate Director, and Joanna Foellmer, Program Specialist and Designated Federal Official. We look forward to working with Congress, the Administration, state and local governments, and interested citizens to develop strategies for implementing our recommendations and improving risk assessment and risk management practices for the 21st century

Gilbert S. Omenn
Chair

NOTE: The Commission's June 1996 Draft Report, both volumes of our Final Report, and all supplementary reports (listed in Appendix A7 of Volume 2) can be found on the Commission's homepage at the Riskworld website: http://www.riskworld.com.

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Executive Summary

Public opinion polls have consistently shown strong support throughout the United States for effective environmental stewardship and for identifying and addressing risks to the environment, public health, and worker health. At the same time, many citizens and local officials are demanding greater attention to priorities and costs. There is an emerging national vision of sustainable development for our environment, our economy, and our society, which this Commission shares. Regulatory agencies, businesses, environmental and public health advocates, and communities deserve credit for well documented gains in air quality, water quality, habitat protection, worker health and safety, product safety, waste disposal, recycling, and pollution prevention achieved over the last 25 years. The Commission values and seeks to sustain such gains. Our findings and recommendations reflect an increasing need to recognize and capitalize on lessons learned and our intent to stimulate even more effective, more efficient, risk-based means of protecting public health and the environment.

The Commission on Risk Assessment and Risk Management was mandated by Congress in the Clean Air Act Amendments of 1990 "to 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 began meeting in May 1994 and held hearings across the country, obtaining information and insights that made important contributions to our deliberations and to our findings and recommendations. We issued a Draft Report for public review and comment in June 1996, and introduced a framework for making risk management decisions. Based on the 130 formal comments that we received, on comments made at public meetings and scientific meetings, and on numerous informal discussions with stakeholders, we refined our recommendations to produce this Final Report to Congress and the President of the United States. Part 1 of our two-volume Final Report focuses solely on our Risk Management Framework and its implementation. It is a reader-friendly document explaining the Framework, the process of putting problems in public health context, and the strategies that can be used to stimulate effective stakeholder involvement. It has many real-world examples.

Now in Volume 2, we have revised the entire Draft Report to update our findings. We make recommendations about the uses and limitations of risk assessment, economic analysis, risk management, and regulatory decision-making; and we address selected activities of specific regulatory agencies and programs.

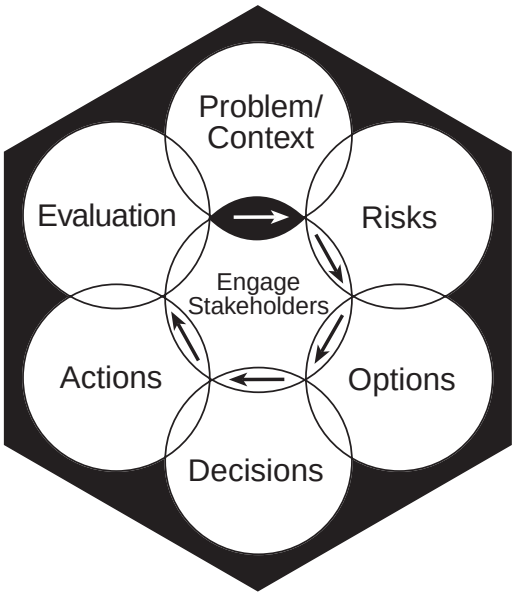
A New Risk Management Framework

The Commission has adopted a unique risk management perspective to guide investments of precious public sector and private sector resources in risk-related research, risk assessment, risk characterization, and risk reduction. We recognize that it is time to modify the traditional approaches to assessing and reducing risks that have relied on a chemical-by-chemical, medium-by-medium, risk-by-risk strategy. While risk assessment has been growing more complex and sophisticated, the output of risk assessment for the regulatory process often seems too focused on refining assumption-laden mathematical estimates of small risks associated with exposure to individual chemicals rather

than on the overall goal—risk reduction and improved health status. Scientists, federal agencies, the National Academy of Sciences/National Research Council, and many other organizations have issued many reports with recommendations for improving health risk assessment. Despite many years of managing risks, however, there have been few systematic attempts to examine the role of risk assessment itself in risk management and health and environmental protection. No generally accepted framework or principles for making risk management decisions has emerged.

We propose a systematic, comprehensive framework that can address various contaminants, media, and sources of exposure, as well as public values, perceptions, and ethics, and that keeps the focus on the risk management goal. The new Risk Management Framework comprises six stages (see figure):

The Commission's Risk Management Framework



- Formulate the problem in broad context.
- Analyze the risks.
- Define the options.
- Make sound decisions.
- Take actions to implement the decisions.
- Perform an evaluation of the effectiveness of the actions taken.

The Framework explicitly embraces collaborative and early involvement of stakeholders; the process can be refined and its conclusions can be changed as important new information is acquired. The Framework requires that a potential or current problem be put into a broader context of public health or environmental health and that the interdependence of related multimedia problems be identified. The Framework focuses on cumulative risks to human and environmental health and on addressing the benefits, costs, and social, cultural, ethical, political, and legal dimensions of risk reduction options. Our Framework is described in great detail in Volume 1 and is summarized in Section 2 of this volume.

The Commission's Framework can help to improve the cumbersome, fragmented risk management approach often used by the federal regulatory agencies—an approach that resulted from the patchwork of Congressional statutes that have been enacted over the last 25 years to address individual risks. Coordination within and among agencies and among Congressional committees and subcommittees can advance the more comprehensive proposed Framework without a new, overarching environmental statute. When individual environmental statutes are reauthorized, they can be modified to reflect the comprehensive nature of the Framework. The Framework is also applicable to risk management activities carried out by public and private entities at the state, regional, and local levels and through federal/state performance partnerships. Despite potential obstacles, we believe that implementation of this Framework will enable the country to manage risks more effectively and more

efficiently and to make progress toward the goal of sustainable development.

Risk Management and Regulatory Decision-Making

Risk managers use information from risk assessment and economic analysis, together with information about public values and statutory requirements, to make decisions about the need for and methods of risk reduction. The wide array of statutes and their implementing regulations have resulted in different definitions of negligible and unacceptable risk.

Improvement of Risk Communication: In communicating with various audiences about risks, risk assessors and risk managers must seek a two-way interaction, learning about patterns of exposure, gaining an understanding of the different perceptions people have of what is a negligible risk and what is an unacceptable risk, and describing risks and uncertainties openly and understandably. Relying on overly precise single estimates of risk is unjustified.

We support the use of comparisons of specific risks related to a proposed action. Such comparisons are most understandable and helpful when they involve chemically related agents, different sources of exposure to the same agents, different agents to which humans might be exposed in similar ways, and different agents that produce similar effects. Such context can help all stakeholders, including risk assessors, to understand the potential benefit of reducing exposures to an agent. We recommend that such risks be expressed in terms of potential adverse effects per year in a given community or exposed population, as well as per hypothetical lifetime.

We also recommend the identification and evaluation of a common metric to assist comparative risk assessment and risk communication related to both carcinogens and noncarcinogens. We have moved this recommendation from the toxicity assessment section to the risk communication section.

Bright Lines: Bright lines are specific exposure concentrations that are meant to provide a clear distinction between what is considered safe and what is not. Bright lines can be useful as guideposts or goals for decision-making but should not be applied inflexibly, because of uncertainty about risks and variation in susceptibility. We support the use of sets of bright lines to protect both the general population and specific populations potentially at higher risk, such as children and pregnant women. We recommend that Congress not legislate particular bright lines. In response to comments, we have clarified the differences between bright lines for measurable emissions, exposures, and contaminant concentrations and attempts to use bright bright lines for estimated low levels of probabilistic risks, which cannot be measured.

Standards for Judicial Review: We recommend that judicial review be limited, as now, to final agency action, and that the existing arbitrary-and-capricious standard be retained.

Uses and Limitations of Risk Assessment

The Commission considers risk assessment a useful analytic process that provides valuable contributions to risk management, public health, and environmental policy decisions. Risk assessment was developed because Congress, regulators, and the public require scientists to go beyond scientific observations of the relationships between exposures to chemicals and pollutants and their effects on people, the environment, or test systems, and to rely on many scientific inferences and assumptions to answer social questions about what is unsafe. When basic judgments regarding a chemical's toxicity to humans are unresolved, however, sophisticated and complex risk assessments cannot substitute for basic ignorance about the chemical's toxicity to humans. We recommend that the performance of risk assessments be guided by an understanding of the issues that will be important to managers' decisions and to the public's understand-

ing of what is needed to protect public health and the environment.

Use of Scientific Advances in Toxicity Assessments: The Commission recognizes that important advances are being made in the scientific basis for risk assessment. Further developments will improve the recognition and estimation of risks to humans associated with chemical and other exposures in the environment and provide biologic markers for measuring exposure, early effects, and variation in susceptibility. We recommend the use of all relevant peer-reviewed information about a chemical's mode of action in evaluating the weight of the scientific evidence supporting its toxicity in humans. We support current agency efforts to distinguish more clearly between experimental findings in rodent or other bioassays that are predictive for humans and findings that are not. We recognize that risks from microbial and radiation exposures, not just chemical exposures, need to be addressed.

Use of Realistic Scenarios in Exposure Assessments: The Commission supports basing risk management decisions on exposure assessments derived from realistic scenarios. Agencies should continue to move away from using the hypothetical "maximally exposed individual" to evaluate whether a risk exists, toward more realistic assumptions based on available scientific data, as they have done in recent analyses. We recommend use of analytic methods that, when data permit, combine the many characteristics of probable exposure into an assessment of the overall population's exposures. Where possible, exposure assessments should include information about specific groups, such as infants, children, pregnant women, low-income groups, and minority group communities with exposures influenced by particular cultural or social practices. Stakeholders can provide information about patterns and sources of exposure that otherwise might be neglected.

Recognition of Risk Associated with Chemical Mixtures: We agree with testimony that we need data and risk estimates about chemical mixtures and combined chemical-microbial-radiation exposures, because people are exposed to multiple hazards. We recommend direct toxicity assays of environmental mixtures.

Uses and Limitations of Economic Analysis

The Commission supports the use of economic analysis as a consideration, but not as the overriding determinant of risk management decisions. Both human health and ecological benefits should be accounted for when the consequences of actions to reduce emissions, exposures, and risks are being evaluated. We call for explicit descriptions of the assumptions, data sources, sources of uncertainty, and distributions of benefits and costs across society associated with economic analyses, in parallel with the descriptions associated with risk assessments.

The Role of Peer Review

We support efficient use of peer review, with care to exclude financial conflicts, for both risk assessment and economic analysis. Overall quality and effectiveness of peer review practices should be evaluated periodically by the agencies. We urge Congress to match resources to its demands on agencies for research, risk assessment, and economic analysis and to allow the agencies considerable discretion in allocating resources for peer review.

Recommendations for Agencies

The Commission developed findings and recommendations about several federal agencies and programs in order to illustrate our general recommendations, address inconsistencies, and assist Congress and the agencies on particular

matters. As agencies begin to comply with the Government Performance and Results Act of 1993, these recommendations may be helpful in identifying performance indicators.

Environmental Protection Agency: In the 1990 amendments to the Clean Air Act, Congress mandated that this Commission review and make recommendations on the analysis and management of residual risks associated with section 112 hazardous air pollutants after the completion of the current technology-based risk reduction program. We present a tiered approach to set priorities for this huge effort and emphasize the critical need for more and better emissions and exposure data before meaningful analyses are possible. We recommend that residual risks associated with hazardous air pollutants be considered in the context of risks associated with the same pollutants from other sources, in the context of other air pollutants, and in the context of other risks to health. We have clarified the tiered scheme presented in the Draft Report.

We recommend more frequent determinations of future land use at the start of Superfund site risk assessments and we endorse a comprehensive watershed management approach to managing risks under the Clean Water Act. We are pleased that our recommendations were accommodated in the 1996 Safe Drinking Water Act.

Occupational Safety and Health Administration: We recommend establishing guidelines for agency risk assessments and a streamlined process for developing permissible exposure limits for air contaminants in the workplace. We also endorse greater cooperation between OSHA and the National Institute for Occupational Safety and Health.

Food and Drug Administration: We recommend a substantial modification of the "Delaney clause" to a standard of reasonable certainty of no harm for all population groups, as was enacted in the Food Quality Protection Act of 1996. We endorse international harmonization of risk assessment and clinical trial protocols for pharmaceuticals, and restoration of FDA's authority to require scientific evidence supporting health claims for dietary supplements.

Department of Agriculture: We recommend that risk assessment and benefit-cost analysis be performed early in the rule-making process instead of at the decision stage for both microbial and chemical hazards.

Department of Energy and Department of Defense: We support further development and evaluation of risk-based approaches to priority-setting and budget-making for cleanup of contaminated sites at federal facilities.

The Commission will remain active until June 1997 to assist the Congress, the Administration, and various other interested parties in considering these recommendations and finding common ground with relevant proposals from others. The Commission believes that our Risk Management Framework will prove to be far more useful and effective than traditional regulatory approaches to solving common multimedia risk problems and, along with the other recommendations in our Final Report, will help improve risk management decision-making as we tackle the problems of the 21st Century.

1 Introduction

This report authored by the Commission on Risk Assessment and Risk Management, proposes a major new era in environmental and health protection. Our Framework for Risk Management puts particular risks in both a public health and ecological context, involves stakeholders from the earliest stages, and moves beyond the one-chemical, one-risk, medium-by-medium approach of most current regulation.

The Commission on Risk Assessment and Risk Management was mandated by Congress in the 1990 amendments to the Clean Air Act to address the assessment and management of risks that are regulated under the many laws aimed at protecting both the environment and the health and safety of the American people from potentially dangerous exposures to chemicals and other hazardous substances in air, water, food, the workplace, and consumer products. Of the ten members of the Commission, three were appointed by the president, six by the majority and minority leaders of the House and Senate, and one by the president of the National Academy of Sciences. Biographies of the Commissioners appear in Appendix A1.

The Commission's mandate (see Appendix A2) is summarized in the following phrases:

- Assess the uses and limitations of risk assessment.
- Evaluate exposure scenarios used to characterize current or potential risks.
- Determine how to describe and explain uncertainties.
- Enhance strategies for risk-based management decisions.
- Review desirability of consistency across federal programs.

The Clinton Administration subsequently asked the Commission to comment on the conclusions of *Science and Judgment in Risk Assessment* (NRC 1994a) (see Appendix A3) and to make recommendations about peer review.

Congress decided to create the Commission when agreement could not be reached, during drafting of the 1990 Clean Air Act Amendments, on the best way for the U.S. Environmental Protection Agency (EPA) to determine whether any significant risks to human health will remain after the implementation of technology-based controls to reduce hazardous pollutant emissions from stationary sources and, if so, what to do about those residual risks. Disagreement persisted about the risk assessment techniques and assumptions that should be used to estimate such residual risks, about the benchmarks to distinguish between negligible and unacceptable risks, and about the risk management methods to mitigate unacceptable risks. The Commission's mandate is not restricted to evaluating air pollution, the particulars of the Clean Air Act, or even the EPA. It is, however, limited to assessing "cancer and other chronic human health effects," so we have not addressed physical safety or acute-exposure health hazards nor such environmental problems as global climate change, ozone depletion in the stratosphere, and protection of wetlands and other habitats. In this report we do discuss the dependence of human health on a healthy environment, the applicability of the general approaches of health risk assessment to ecological risk assessment, and the need for benefit-cost analyses of proposed actions to assess benefits beyond those to human health.

Vision

Through our deliberations, the Commission developed a shared vision of a sustainable environment, economy, and society. Like the National Commission on the Environment (1992) and the President's Council on Sustainable Development (1996), we seek a convergence of economic and environmental goals and actions. We also recognize the need to encompass the diverse socioeconomic conditions and cultural practices of the people of this nation. Finally, we propose a comprehensive, risk-based approach that puts specific actions in a public health and ecological context.

Background

The public recognition of environmental problems has produced tremendous improvement during the last 25 years in air quality, water quality, safety at work, safety of consumer products (including drugs and foods), testing of new chemicals before they are introduced into commerce, cleanup and disposal of hazardous wastes, and scientific study of the health and ecological effects of chemicals, radiation, and microorganisms. Historically, improvements in the health of the public have come primarily from environmental interventions, such as proper waste disposal, in-

What Is Risk?

Risk is defined as the probability that a substance or situation will produce harm under specified conditions. Risk is a combination of two factors:

- The probability that an adverse event will occur (such as a specific disease or type of injury).
- The consequences of the adverse event.

Risk encompasses impacts on public health and on the environment, and arises from exposure and hazard. Risk does not exist if exposure to a harmful substance or situation does not or will not occur. Hazard is determined by whether a particular substance or situation has the potential to cause harmful effects.

What Is Risk Assessment?

Risk assessment is the systematic, scientific characterization of potential adverse effects of human or ecological exposures to hazardous agents or activities. Risk assessment is performed by considering the types of hazards, the extent of exposure to the hazards, and information about the relationship between exposures and responses, including variation in susceptibility. Adverse effects or responses could result from exposures to chemicals, microorganisms, radiation, or natural events.

What Is Risk Management?

Risk management is the process of identifying, evaluating, selecting, and implementing actions to reduce risk to human health and to ecosystems. The goal of risk management is scientifically sound, cost-effective, integrated actions that reduce or prevent risks while taking into account social, cultural, ethical, political, and legal considerations.

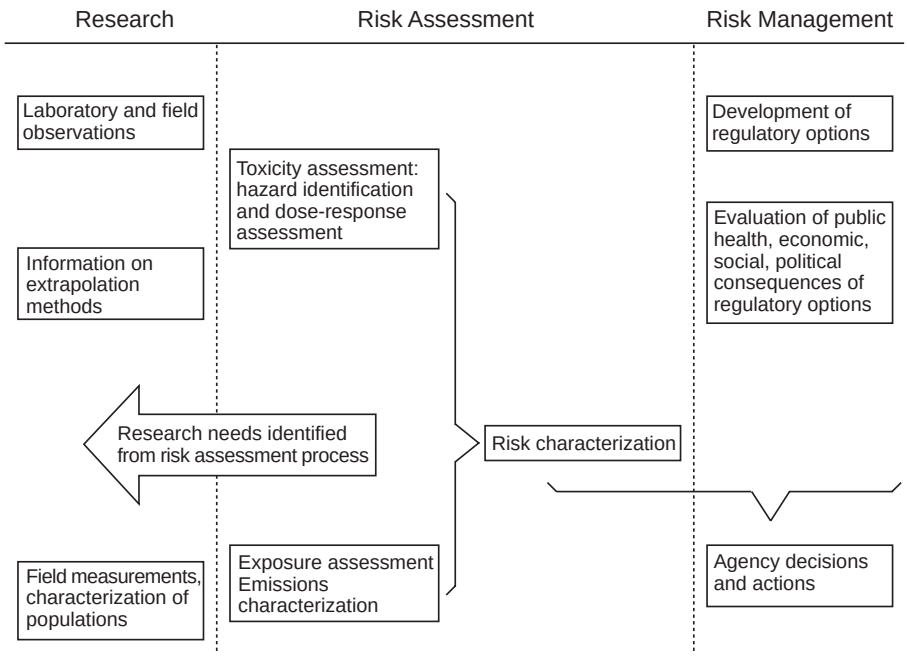
dustrial hygiene, quarantines, clean water, and vaccines. Although many federal environmental laws have an overarching goal of protecting the public's health and the environment, most environmental statutes have been media-specific and have relied on regulatory rather than public health approaches.

Only continued action can sustain the progress of the last 25 years, especially as the economy and the population grow and new technologies emerge. We believe that the effort will be most effective if regulatory and public health agencies work together.

Risk Assessment

Risk is a combination of the probability of an adverse event and the nature and severity of the event. We deal with risks all the time in everyday life—risks to our health, our environment, our pocketbooks, our social relationships. Risk is time-related, ranging from immediate consequences of various actions or lack of action to consequences over a lifetime for an individual and much longer periods for the whole society or the planet. We make decisions to avoid risks, to reduce risks, to reduce the consequences of events, and to insure against the financial consequences of risks. We tend to downplay some risks; we find others frightening. Of course, people vary in their assessments of risk, and their actions or concerns tend to vary accordingly. Often, the people who face specific risks are different from the people who benefit from the products or activities that generate the risks, leading to conflict and litigation over proposed risk-reduction actions. Risk assessment itself has become controversial because of its important role in the protection of human health and the environment.

Figure 1.1. Elements of risk assessment and risk management.



Source: *Science and Judgment in Risk Assessment* (NRC 1994a). Reprinted with permission.

A generally accepted framework and nomenclature for health risk assessment was established in 1983 by a National Academy of Sciences committee report, *Risk Assessment in the Federal Government: Managing the Process* (NRC 1983). The now universally recognized four-step framework for characterizing the likelihood of adverse health effects from particular chemical exposures is described briefly below and shown in the context of scientific issues and regulatory impact in Figure 1.1.

1 *Hazard identification*: Determine the identities and quantities of chemicals present as contaminants in the environment or manufactured for various uses and the types of hazards they may pose to human health.

2 *Dose-response assessment*: Evaluate the relationship between chemical exposure concentrations (dose) and the incidence of adverse effects in humans or other species (response).

3 *Exposure assessment*: Determine the conditions under which people could be exposed to contaminants and the doses that could occur as a result of such exposure scenarios.

4 *Risk characterization*: Describe the nature of adverse effects that can be attributed to chemical contaminants, estimate their likelihood in various exposed populations, and evaluate the strength of the evidence and the uncertainty associated with the risk estimates.

Congress directed the Commission to focus on what it called "chronic health effects," meaning effects that do not occur immediately—unlike injuries from falling off a construction platform—but are the result of exposures that might take months, years, or decades to manifest as health problems. Risks from chronic exposures arise from activities associated with the use and production of food, energy, industrial and consumer goods, and from the wastes produced through daily living. We recognize that voluntary uses of specific consumer products are also major contributors to death and poor health. Cigarette smoking leads the list by a wide margin, accounting for an estimated 400,000 deaths every year; use of alcoholic beverages, for about 100,000 deaths; and motor vehicle collisions for about 25,000 deaths.

While individual sources of contaminants may contribute little to overall public health risks, the risk may be substantial when viewed collectively. As an example, 60,000 deaths per year have been attributed to occupational and environmental chemical exposures of all types (McGinnis and Foege 1993). A more recent estimate attributes up to 60,000 deaths per year to particulate air pollution (Shprentz et al. 1996). Aggregating and setting priorities among environmental problems would allow them to compete for attention and resources with other public health problems.

Although people most fear cancer as a cause of death, cancer is not the only health concern associated with environmental pollutants. Reproductive impairments, birth abnormalities, asthma and other respiratory diseases, and effects on all the organ systems of the body warrant serious attention from a risk management and disease prevention perspective. Even when those health effects have modest impacts on mortality, they may be important burdens on the quality of life.

Risk assessment goes beyond scientific observations of exposures and effects in people, animals, or test systems to investigating social questions about what is unsafe. There is a difference between what can be studied experimentally or be observed directly and what represents policy-driven extrapolation based on scientific inferences and many assumptions. The 1994 National Research Council report *Science and Judgment in Risk Assessment* captured this combination of science and values in its title. The usefulness, credibility, and validity of risk assessments would be greatly enhanced by generating more data and relying on fewer assumptions.

Risk Management

We face a huge challenge to manage comprehensively the health risks associated with the vast array of pollution-generating activities in this country. Actions that reduce hazardous substance emissions or exposures can reduce risks to health. Our regulatory agencies are expected to control potential cancer risks, for example, down to an extremely low level. A limit of less than one extra cancer death from a particular chemical per one million persons exposed over a 70-year lifetime is commonly used for screening purposes; when exceeded, such risk levels serve as a justification for seeking monitoring data to more accurately characterize exposures and risks or for taking actions to reduce exposures. In contrast, risk criteria used in regulating occupational exposure to specific chemicals often correspond to about one extra cancer death among a hypothetical 1,000 workers exposed over a working lifetime. For noncancer risks, regulatory agencies aim to reduce exposures below presumed threshold levels for adverse effects.

As directed by Congress and reinforced by the Clinton Administration, we have framed our analyses and recommendations from the perspective of risk management. What are the community, public health, and environmental contexts for formulating a particular problem, characterizing its risks, choosing a course of action, and evaluating the impact of such actions? How do we use the tools of risk assessment and of economic analysis and consider social and cultural information to make more efficient, more understandable, and less costly decisions about reducing risks that are judged to be too high? How do we make decisions when information about risks, benefits, and costs is incomplete or uncertain? How do we compare risks and risk-reduction actions of various kinds to determine which deserve higher priority? It is crucial to reach out to affected parties and communities to obtain knowledge about the nature of past and present exposures and to understand their concerns and perceptions about the risks under discussion and related risks. Communication about risks is a two-way process.

To address those questions, in June 1996 the Commission proposed a comprehensive Risk Management Framework for making decisions about reducing risks to public health and the environment. The process includes detailed consideration of risk and cost and provides a context for social and cultural considerations. One important feature of the Framework is its explicit involvement of stakeholders in decisions about how to reduce the risks that affect them, through consensus or despite disagreement, depending on the circumstances. Another feature is the integrated, multimedia approach the Framework takes to address multiple risks instead of individual risks. Public comments on the Draft Report showed strong support for the Framework and its key elements of context and stakeholder involvement, but emphasized the clear need for more and better data to support evaluations of risk.

Our Report

This report is Volume 2 of the Commission's Final Report. Volume 1 focuses exclusively on the characteristics and implementation of the Commission's Framework for Risk Management, in response to public comments advising that the Framework be clarified and illustrated in a format broadly accessible to diverse stakeholders.

Both volumes are the product of the Commission's hearings and deliberations since May 1994 and address concerns of those who provided testimony before the Commission (Appendix A4), concerns of those who provided comments on our June 1996 Draft Report (Appendices A5 and A6), and points raised in issue papers prepared for the Commission by several experts (Appendix A7).

Section 2 following this introduction describes the Framework and its application. Section 3 addresses ways to improve risk communication and risk management. Section 4 provides guidance on how to approach risk assessment. Section 5 provides guidance for analysis of the options and costs of potential risk reduction actions. Section 6 focuses

on the role of peer review in risk assessment and risk management. Finally, Section 7 offers recommendations for specific federal regulatory agencies and programs. The Final Report, the reports abstracted in Appendix A7, and the June 1996 Draft Report are available from the Commission's home page on the internet at http://www.riskworld.com.

2

The Framework for Environmental Health Risk Management

Much of the progress our nation has made in improving the quality of our environment and our workplaces, as well as the safety of pharmaceutical drugs, food, and other consumer products has relied on effective risk management. In the environmental arena, however, statutes and legal precedents tend to dictate risk management approaches that focus on one type of risk (e.g., cancers or birth defects in humans) posed by a single chemical in a single medium (air, water, or land). Conclusions about risk are based almost exclusively on observations of toxicity from high doses of the chemical in laboratory animals or in the workplace. While these approaches have reduced health, safety, and environmental risks in recent decades, they are not adequate for solving the more complex risk problems we now face.

Creative, integrated strategies that consider multiple environmental media and multiple sources of risk are needed if we are to sustain and strengthen the improvements attained in recent decades. Developing these strategies requires a risk management approach that addresses the interdependence and cumulative effects of various problems, engages a wide range of stakeholders, and enables the setting of priorities. To help meet these needs, the Commission has developed the systematic, comprehensive Risk Management Framework, illustrated in Figure 2.1. The Framework has six stages:

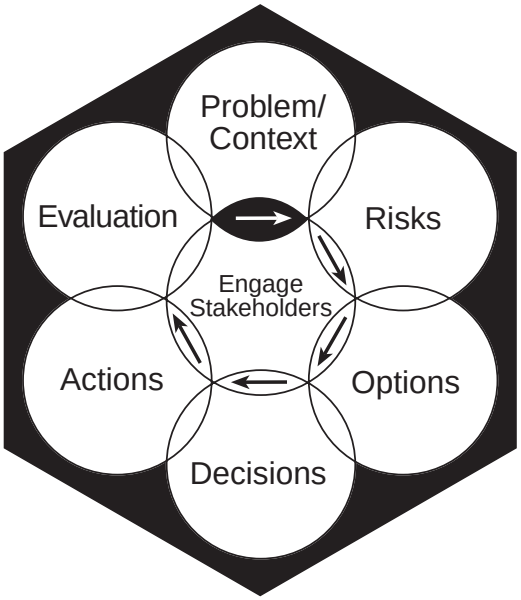
1. Define the ***problem*** and put it in ***context***.
2. ***Analyze*** the risks associated with the problem in context.
3. ***Examine*** options for addressing the risks.
4. Make ***decisions*** about which options to implement.
5. Take ***actions*** to implement the decisions.
6. Conduct an ***evaluation*** of the results of the action.

The Framework is conducted:

- In ***collaboration*** with stakeholders.
- Using ***iterations*** if new information emerges that changes the need for or nature of risk management.

This Framework is designed to help all types of risk managers—government officials, private sector businesses, individual members of the public—achieve good risk management decisions, as defined on page 9 (Principles for Risk Management Decision-Making).

Figure 2.1. The Commission's Framework for Environmental Health Risk Management.



The Framework is general enough to work in a wide variety of situations. The level of effort and resources invested in using the Framework can be scaled to the importance of the problem, potential severity and economic impact of the risk, level of controversy surrounding it, and resource constraints. The Framework is primarily intended for risk decisions related to setting standards, controlling pollution, protecting health, and cleaning up the environment. It is useful for addressing these types of decisions at a local community level (e.g., siting an incinerator or cleaning up a hazardous waste site) or a national level (e.g., developing a national program for controlling motor vehicle emissions). The Framework need not be invoked for risk situations that are routinely and expeditiously managed—for example, by hazardous materials response teams, emergency room physicians, firefighter rescue teams, and voluntary product recalls.

Every stage of the Framework relies on three key principles:

- ***Broader contexts.*** Instead of evaluating single risks associated with single chemicals in single environmental media, the Framework puts health and environmental problems in their larger, real-world contexts. Assessing problems in context involves evaluating different sources of a particular chemical or chemical exposure, considering other chemicals that could affect a particular risk or pose additional risks, considering similar risks, and determining the extent to which different exposures contribute to a particular health effect of concern. The goal of contextual assessment is to clarify the impact that individual risk management actions are likely to have on public health or the environment and to help direct actions and resources to where they will be most effective.
- ***Stakeholder participation***. Involvement of stakeholders—parties who are affected by the risk management problem—is critical to making and successfully implementing sound, cost-effective, informed risk management decisions. For this reason, the Framework encourages stakeholder involvement to the extent appropriate and feasible during all stages of the risk management process. The means and value of involving stakeholders are discussed on page 15.
- ***Iteration***. Valuable information or perspectives may emerge during any stage of the risk management process. This Framework therefore, gives risk managers and stakeholders the flexibility to revisit early stages of the process and to revise earlier deliberations and decisions in light of new findings. The Importance of Iteration on page 32 provides more information.

Each stage of the Framework is described below, followed by recommendations to Congress and the Administration for facilitating its implementation.

Defining Problems and Putting Them in Context

The problem/context stage is the most important step in the Risk Management Framework. This stage involves five components, described in detail below:

- Identify and characterize an environmental health problem, or a potential problem, caused by chemicals or other hazardous agents or situations.
- Put the problem into its public health and ecological context.
- Determine risk management goals.
- Identify risk managers with the authority or responsibility to take the necessary actions.
- Implement a process for engaging stakeholders.

1. Identify and Characterize the Problem

An environmental or human health problem may already be well recognized or may be a latent problem. Ideally, problems will be anticipated and addressed at a very early stage, through such methods and indicators as:

- Emissions inventories; (e.g. the Toxic Release Inventory).
- Environmental monitoring, such as measuring concentrations of solvents that pollute ground water.
- Biological monitoring, such as measuring children's blood lead levels or anemia.
- Toxicity testing in laboratory animals to help identify chemicals that might pose risks to humans or ecosystems.
- Toxicity testing using sentinel species in the environment to help identify the impacts of pollution on ecosystems.
- Disease surveillance, such as observing increases in the occurrence and severity of asthma or noting regional differences in the rates of a particular cancer or birth defect.
- Epidemiologic studies,such as observations of workplace exposures and particular disease rates.

Principles for Risk Management Decision-Making

A good risk management decision . . .

- Addresses a clearly articulated problem in its public health and ecological context.
- Emerges from a decision-making process that elicits the views of those affected by the decision, so that differing technical assessments, public values, knowledge, and perceptions are considered.
- Is based on a careful analysis of the weight of scientific evidence that supports conclusions about a problem's potential risks to human health and the environment.
- Is made after examining a range of regulatory and nonregulatory risk management options.
- Reduces or eliminates risks in ways that:
  - Are based on the best available scientific, economic, and other technical information.
  - Account for their multisource, multimedia, multichemical, and multirisk contexts.
  - Are feasible, with benefits reasonably related to their costs.
  - Give priority to preventing risks, not just controlling them.
  - Use alternatives to command-and-control regulation, where applicable.
  - Are sensitive to political, social, legal, and cultural considerations.
  - Include incentives for innovation, evaluation, and research.
- Can be implemented effectively, expeditiously, flexibly, and with stakeholder support.
- Can be shown to have a significant impact on the risks of concern.
- Can be revised and changed when significant new information becomes available, while avoiding "paralysis by analysis."

- Lack of compliance with local or national standards to control contaminant concentrations in air, water, soil, or food.
- A permit application or a violation of a standard or permit (e.g., facility siting, wastewater discharge).
- A bad odor, as in communities where gasoline additives (oxygenated fuels) were used to reduce carbon monoxide emissions from automobiles.
- Community reaction, as may result when an agency decides to build a municipal solid waste incinerator in a neighborhood that was not consulted about the decision.
- Media or environmental activist reports about a risk based on preliminary or incomplete information that arouse public concern.

Characterizing a problem involves investigating both cause and effect. For example, it could involve identifying which pollutants or other stressors (such as sediment in a stream) are causing the problem, determining the sources of the pollutants or other stressors, and then determining which human and/or ecological populations are affected. While problem identification may be performed by an individual stakeholder (including the risk management authority), problem characterization should be performed in collaboration with other stakeholders.

The Important and Synergistic Roles of Regulatory and Public Health Agencies in Identifying and Reducing Environmental Health Risks

The effort to sustain our gains in public health and environmental health protection will be most effective if regulatory and public health agencies work together. Regulatory and public health agencies have important and complementary roles to play in setting policies for environmental health protection and risk management. Yet, in general, these two communities do not interact sufficiently, and the connections between environmental exposures and public health are not well established.

The likely synergy between environmental and public health agencies is a reservoir of untapped potential for environmental risk management. Many environmental pollution problems can be identified by their public health contexts. For example, construction of an asphalt batch plant was proposed in Boston. Public health officials found that the residents of the urban community in which it was to be constructed had a relatively high incidence of asthma and cardiovascular disease. Those findings signaled a potential environmental health problem that could have been exacerbated by emissions from the asphalt plant. On that basis, construction of the plant was opposed by citizens and by the public health agency, and a decision was made to try to locate the plant elsewhere.

Environmental, public health, and social agencies can work together with community activists to define problems and to develop and implement strategies to manage environmental risks in the full context of poverty, poor schools, and inadequate housing. As our society works to reduce risks in an era of diminishing resources, it is vital that environmental and public health agencies collaborate in deploying the tools of public health—epidemiology, exposure assessment, surveillance, nutrition, genetics, and behavior change—to identify and evaluate the most cost-effective ways to reduce risks and improve public health in all segments of the population. The public health community should accept an influential role in setting national, state, and local priorities and in developing strategies to understand, manage, and prevent environmental risk.

Here are some questions to ask when characterizing a problem:

Hazard

- What is the problem? Why is it a problem? How was it first recognized?
- What types of adverse effects might the problem cause? Are they reversible?
- How imminently might the effects be experienced? In other words, are the effects likely to appear in the near future, later on in life, or in future generations? How urgent is the need for action? For example, a tank car carrying flammable solvents that overturns in a suburban neighborhood requires immediate attention (and therefore does not require implementation of this Framework); a municipal solid waste incinerator operating normally in the same neighborhood can be assessed more deliberately.
- How do stakeholders perceive the hazard? Do different groups of stakeholders have different perceptions and concerns? For example, parents of children at risk from exposure to an industrial pollutant may feel quite differently about a hazard than workers whose income depends on the facility causing the problem. When these are the same people—that is, the parents are also the workers—perceptions of the hazard can be quite complex.

Exposure

- Who may be exposed? Does the exposure pose different risks to different groups? For example, are the elderly, children, immunosuppressed individuals, or certain ethnic groups at greater risk than others due to age; medical, genetic or socioeconomic factors; diet; or activity patterns?
- What are all the relevant sources of exposure? How much does each source contribute to the problem?
- Are the exposures likely to be short- or long-term? What is their frequency?

How the problem is characterized will have a tremendous impact on the focus and likely outcome of the risk management process. For example, a problem related to waste disposal capacity could be characterized:

- By waste haulers as the result of inadequate landfill space.
- By local government officials as inadequate recycling of residential or industrial waste.
- By environmental advocates as too much waste generation.

If a problem is characterized too narrowly or incorrectly, risk managers and other stakeholders will invest their resources in exploring and implementing solutions that will be inadequate, less effective, or more costly than they might have been. Also, inappropriate solutions can produce unintended consequences; for example, tightening solid waste disposal regulations can lead to an increase in illegal dumping. Until recently, Resource Conservation and Recovery Act land-disposal regulations restricting intrasite movement of wastes may have increased risks and costs for Superfund site cleanups by requiring the trucking of wastes to off-site incineration facilities. Therefore, it is very important to consider the full context of the problem, as described below, before proceeding with other stages of the risk management process.

2. Carefully Consider the Context

A full understanding of the context of a risk problem is essential for effectively managing the risk. Yet historically most risk management has occurred in an artificially narrow context that considers just one chemical, one environmental medium, and one risk at a time. Since this narrow context does not reflect the true complexities of risk situations, it results in risk management decisions and actions that are less effective than they could be. The Commission's Framework expands the context of risk management by including a step in the opening stage, described here, to explicitly consider and define a comprehensive context for a specific

risk that is broadly reflective of real-life risk situations. To do this, risk managers and stakeholders must systematically consider several key dimensions of the risk's context:

- Multisource context. *Is the population exposed to the same pollutant from other sources?* For example, a local community might be concerned about breathing pollutants such as hydrocarbons released to the air from a nearby power plant, but might also be breathing hydrocarbons residents from motor vehicle exhaust, wood stoves, secondhand tobacco smoke, or other sources. See The Multisource Context: Air Toxics and The Multisource Context: Residual Risks From Petroleum Sources on page 13 for elaboration.

- Multimedia context. *Is exposure to the pollutant also occurring from other environmental media?* In the power plant example, the community members who are concerned about breathing pollutants could also be exposed to them from food, water, or soil. Other sources of hydrocarbons could be food (such as broiled meats) and soil (resulting from cumulative contamination from decades of emissions from the power plant, vehicles, and other sources). See The Multimedia Context: Residual Risks From Secondary Lead Smelters on page 14 for elaboration.

- Multichemical context. *Do other pollutants from the same sources pose additional risks to the population of concern?* Do the pollutants interact? Are their effects cumulative? In the power plant example, other air pollutants may pose risks for similar adverse effects or may produce different effects when in combination than either produce alone. For example, hydrocarbons are usually attached to very small particles, which can increase cancer risk and which can also interact with ozone and other air pollutants to form smog.

- Multirisk context. *How great a risk does the problem pose compared to other similar risks that the community faces from environmental chemicals?* For example, the risks of respiratory disease associated with exposure to power plant emissions might be compared with the risks of diseases associated with exposure to heavy metals from local municipal solid waste incinerator emissions and the risk of neurological disorders resulting from exposure to a local drinking water source that is contaminated with industrial solvents. The Multirisk Context: Ecological Degradation on page 14 provides an ecological example.

There may be even broader public health or ecological contexts that local governments and public health agencies have to confront and weigh against chemical exposures—for example, a high incidence of HIV or other infections, a low rate of childhood vaccination, a high drug use and crime rate, or a high rate of alcoholism and its contribution to liver disease, birth defects, and injuries from automobile accidents.

In the power plant example, the initial problem is defined as the health risks posed by air pollutants emitted by a particular type of industrial facility in a particular geographic area. The multisource context would involve identifying other sources (e.g., other types of industrial facilities, motor vehicles) that emit those same pollutants to the air in the same geographic area. The multimedia context would involve identifying other environmental media that serve as local pathways of exposure to the same pollutants. The multichemical context would involve comparing the risks from those particular pollutants with the risks associated with other important air pollutants from the same source, such as sulfur oxides and nitrogen oxides. Finally, the multirisk context could consider risks posed by water contamination and solid wastes in the area and other risks to public health.

An initial problem might also be identified and evaluated on the basis of a particular health effect instead of on the basis of contaminant emissions. For example, the increasing incidence and mortality rates of asthma could be addressed. The rea-

sons for the increases are not known, but likely candidates include sulfur oxides, smog, particles, and second-hand tobacco smoke.

The relevant contexts that are identified and characterized, and the rationale for their identification, should be incorporated into the risk analysis (see How Should Risks Be Analyzed? on page 21).

The Multisource Context: Air Toxics

Under the 1990 Clean Air Act, EPA is required to promulgate maximum available control technology (MACT) standards for major sources of hazardous air pollution. MACT standards reduce, but do not necessarily eliminate, air pollutants from these sources. For this reason, the Clean Air Act requires EPA to assess the residual risk caused by the air emissions that will remain after MACT standards are implemented.

Several types of industrial facilities that emit the hazardous air pollutants benzene, 1,3-butadiene, formaldehyde, and acetaldehyde will require MACT standards. A 1993 EPA study of the risks associated with motor vehicle emissions of these same pollutants provides an important context for evaluating the residual risk from those facilities (EPA 1993a).

Motor vehicles contribute 60, 94, 33, and 39 percent of the nationwide total of benzene, 1,3-butadiene, formaldehyde, and acetaldehyde air pollution, respectively. EPA estimated the cancer risk of these pollutants for the years 1990, 2000, and 2010. For the 1990 estimate, EPA assumed that 1990 automotive technology was in place. For the 2000 and 2010 estimates, EPA assumed that a number of controls would be in place, including those required by California's stringent emissions standards and the use of reformulated gasoline by vehicles in all areas of the country that do not attain the current national ambient air quality standard for ozone.

Benzene, formaldehyde, and acetaldehyde from motor vehicles were each estimated to cause no more than 30 additional cases of cancer nationwide per year in any of the years evaluated, while 1,3-butadiene was estimated to cause no more than 300. (At present there are more than 500,000 new cases of cancer each year in the United States.)

The fact that air toxics from industries properly controlled under MACT standards are not likely to be the major sources of cancer risk will be an important context for EPA to consider when it assesses the residual risks from industries and compares them to risks from other sources of cancer and respiratory disease. This situation reinforces the need to view all air pollution risk management activities in one context. Both EPA and California have started to do just that by developing integrated air toxics strategies.

The Multisource Context: Residual Risks From Petroleum Sources

In July 1994 EPA promulgated a MACT standard for petroleum refinery emissions. That standard was based partly on EPA's finding that benzene in refinery emissions poses a potential leukemia risk to exposed populations. The standard will reduce, but not eliminate, the benzene and other hazardous air pollutants emitted by petroleum refineries.

Once the standard is implemented, a series of local and regional risk assessments will be conducted to determine whether the remaining benzene in emissions from individual petroleum refineries may pose a leukemia risk in their local area. At this stage it will be important to consider other sources of benzene in the air. In fact, motor vehicle emissions are the largest single source of airborne benzene in the United States, and the risk from mobile sources and other important benzene emission sources such as cigarette smoke and consumer products used at home could be compared to the residual risk from refineries. It would be appropriate for stakeholders to identify who has responsibility for controlling the other sources.

If the residual leukemia risk from refinery emissions is significant compared to the leukemia risk from other sources, risk-reduction efforts should focus on refinery emissions. If the refinery risk proves insignificant, however, risk reduction might better be directed at other sources. The overall goal

should be to direct risk management resources where they will do the most good to protect or improve the community's health.

A situation in which the multisource context was ignored, with unfortunate results, arose in New Jersey. Benzene is a contaminant found in the air and sometimes the ground water near marine oil terminals. Benzene levels were measured inside homes near such a terminal and, because the levels were believed to be unsafe, residents were evacuated. In fact, the benzene levels were well within the range found in homes nowhere near any external source; but residents have refused to return to their homes, property values have decreased substantially, and a great deal of community discord persists.

The Multimedia Context: Residual Risks From Secondary Lead Smelters

EPA promulgated MACT standards for secondary lead smelters to reduce human exposure to arsenic, lead, and other pollutants in their emissions. Assessing residual risk was difficult because few site-specific data were available on exposure to smelter emissions. To compensate for this data gap, EPA performed a screening risk assessment that relied on many assumptions.

Arsenic. Arsenic causes skin disorders and can increase lung cancer risk. EPA's screening assessment indicated that residual arsenic emissions 100 meters from a smelter would be about one hundred times the average air concentration of arsenic in the United States and about one thousand times the maximum exposure level that EPA considers to pose negligible risk. An examination of other major sources of arsenic exposure (principally seafood consumption and smoking), however, indicates that smelter emissions actually account for only one-tenth of exposure to arsenic for people living 100 meters from the smelter. Thus, the total exposure context raises a broader risk management issue about what actions should be taken to reduce exposure from all sources. The first step should be to measure actual arsenic concentrations in air around the smelter to compare more accurately the contributions of all sources of arsenic.

Lead. Exposure to lead can cause brain damage, and children are particularly vulnerable. EPA's screening risk assessment found that exposure to lead emissions 100 meters from a secondary lead smelter would be about ten times greater than both the national ambient air quality standard for lead and the average concentration of lead in the United States. Although there are many other sources of human exposure to lead, an analysis of total exposure around the smelter shows that the smelter itself is by far the primary contributor; thus, the total exposure context confirms that smelters should be the leading target for risk reduction in those communities. Monitoring children's blood lead levels would be a good first step to help guide risk management actions and to evaluate their results.

The Multirisk Context: Ecological Degradation

Many problems not only have multiple sources (the multisource and multimedia contexts), but also are interdependent with other problems (the multirisk context). For example, degradation of watersheds typically is caused by a variety of sources that may include specific industrial discharges, urban and agricultural runoff, land-disturbance activities such as logging and grazing, diversion of water for domestic and agricultural use, overfishing, the introduction of exotic species, and deposition of air pollutants into water. To develop effective solutions, risk managers must consider these problems in multisource and multirisk contexts.

One example of a problem requiring multirisk analyses and multisource solutions is the decline of salmon populations in the Columbia River Basin. According to *Pacific Fisherman Yearbooks*, the annual salmon and steelhead catch ranged between 25 and 44 million pounds of fish in the early 1900s. By the 1940s, the range had declined to between 13 and 30 million pounds due to overfishing, irrigation, and power dams. Since that time, many believe that the salmon fisheries have been further stressed by nuclear reactors that have contributed radiation, heat, and chemicals to the Hanford Reach of the Columbia River and by population increases

that have resulted in pollution from sewage treatment plants, industrial discharges, and runoff. In the tributaries, timber harvesting has increased sedimentation, water temperature, and blockages of important spawning habitats. Salmon populations have continued to decline.

The ecological consequences of this degradation are accompanied by other impacts. For example, the decline in the salmon fisheries has affected the diet, culture, and religious practices of the Yakama Indian Nation. To successfully address the Columbia River's degradation, risk managers will need to consider multiple sources of stress and complex risk management strategies.

3. Identify Risk Management Goals

The goals of risk management are varied. They may be risk related, aiming to:

- Reduce or eliminate risks from exposure to hazardous substances.
- Reduce the incidence of an adverse effect.
- Reduce the rate of habitat loss.

They may be economic, aiming to:

- Reduce the risk without causing job loss.
- Reduce the risk without reducing property values.

They may involve public values, aiming to:

- Protect the most sensitive population.
- Protect children.
- Preserve a species from extinction.

They may also be dictated by statute, policy, or existing regulations.

Risk management goals should be used to guide the next stage of the Framework—Analyzing Risks—but the results of risk analysis may lead stakeholders and decision-makers to redefine those goals. It is important to identify the goals early, so they may guide the rest of the decision-making process.

4. Identify Risk Managers

The risk manager is the person responsible for managing the problem. Who is the most appropriate risk manager in a particular situation will depend on the problem's context. In some situations, such as a regulatory context, it will be obvious to all stakeholders that the responsible regulatory agency should or must manage the problem. In other cases, it may not be obvious, or different stakeholders may have different opinions. Although it is preferable to resolve the issue of who should be the risk manager or managers at this stage, who the risk manager should be may not become evident until the risk management options are identified. Often, risk management responsibilities can be shared or may evolve with changing circumstances.

Many different types of people may be risk managers, including:

Federal regulators	Plant managers
State regulators	Public health officials
Local regulators	Clinicians
Local businesses	Citizens
Industries	

5. Establish a Process for Engaging Stakeholders

A stakeholder is anyone who has a "stake" in a risk management situation. Stakeholders typically include groups that are affected or potentially affected by the risk, the risk managers, and groups that will be affected by any efforts to manage the source of the risk. The overlap between "Engage Stakeholders" and "Problem/Context" in the Framework hexagon on page 7 is larger and darker than the other overlaps because active stakeholder involvement at this particular stage is the most critical element of the decision-making process.

Who the stakeholders are depends entirely on the situation.

- In the case of a contaminated site, stakeholders include those whose health, economic well-being, and quality of life are currently affected or would be affected by the cleanup and the site's subsequent use. Also included are those who are legally responsible for the site's contamination and cleanup, those with regulatory responsibility, and those who may speak on behalf of ecological considerations or future generations.
- In the case of an application for a pesticide reregistration, stakeholders include the pesticide manufacturer, owners of the farms where the pesticide is used, laborers who apply the pesticide, consumers who may be exposed to pesticide residues in foods, scientists who seek further pesticide research funding, trade associations like the Grocery Manufacturers' Association, those who speak on behalf of ecological considerations, and those with regulatory responsibility.
- In the case of a substantial decline in the oyster population in a bay because chemicals have been carried into the bay from farms and roads, stakeholders include the people who harvest the oysters, retailers, consumers, dairy farmers, pesticide manufacturers, manufacturers of automobile emissions control devices, local communities, those who speak on behalf of ecological considerations, and, of course, those with regulatory responsibility.

Questions that can help identify potential stakeholders include:

- Who might be affected by the risk management decision? (This includes not only groups that already know or believe they are affected, but also groups that may be affected but as yet do not know it.)
- Who has information and expertise that might be helpful?
- Who has been involved in similar risk situations before?
- Who has expressed interest in being involved in similar decisions before?
- Who might be reasonably angered if not included?

Thus, stakeholders may include:

- Community groups.
- Representatives of different geographic regions.
- Representatives of different cultural, economic, or ethnic groups.
- Local governments.
- Public health agencies.
- Businesses.
- Labor unions.
- Environmental advocacy organizations.
- Consumer rights organizations.
- Religious groups.
- Educational and research institutions.
- State and federal regulatory agencies.
- Trade associations.

Why Is Stakeholder Involvement Important?

Experience increasingly shows that risk management decisions made in collaboration with stakeholders are more effective and more durable. Stakeholders bring to the table important information, knowledge, expertise, and insights for crafting workable solutions. Stakeholders are more likely to accept and implement a risk management decision they have participated in shaping. According to a 1996 public opinion poll, 80 percent of U.S. citizens think that the responsibility for controlling risks should be shared by government, businesses,

communities, and individuals and that government at all levels should involve citizens in health and environmental protection.

Stakeholder collaboration is particularly important for risk management because there are many conflicting interpretations about the nature and significance of risks. Collaboration provides opportunities to bridge gaps in understanding, language, values, and perceptions. It facilitates an exchange of information and ideas that enables all parties to make informed decisions about reducing risks. Collaboration does not require consensus, but it does require that all parties listen to, consider, and respect each other's opinions, ideas, and contributions.

The Commission acknowledges concerns about the considerable costs and additional time needed to involve stakeholders in risk management. However, risk management by government agencies has generally been costly anyway, and investment in stakeholder involvement can bring long-term savings, especially when it catalyzes win-win solutions or when litigation becomes less likely or less protracted. The U.S. Department of Energy, the U.S. Department of Defense, and several states have reported that including community stakeholders in their decision-making process for cleaning up con-

Guidelines for Stakeholder Involvement

- Regulatory agencies or other organizations considering stakeholder involvement should be clear about the extent to which they are willing or able to respond to stakeholder involvement before they undertake such efforts. If a decision is not negotiable, don't waste stakeholders' time.
- The goals of stakeholder involvement should be clarified at the outset and stakeholders should be involved early in the decision-making process. Don't make saving money the sole criterion for success or expect stakeholder involvement to end controversy.
- Stakeholder involvement efforts should attempt to engage all potentially affected parties and solicit a diversity of perspectives. It may be necessary to provide appropriate incentives to encourage stakeholder participation.
- Stakeholders must be willing to negotiate and should be flexible. They must be prepared to listen to and learn from diverse viewpoints. Where possible, empower stakeholders to make decisions, including providing them with the opportunity to obtain technical assistance.
- Stakeholders should be given credit for their roles in a decision, and how stakeholder input was used should be explained. If stakeholder suggestions were not used, explain why.
- Stakeholder involvement should be made part of a regulatory agency's mission by:
  - Creating an office that supports stakeholder processes.
  - Seeking guidance from experts in stakeholder processes.
  - Training risk managers to take part in stakeholder involvement efforts.
  - Building on experiences of other agencies and on community partnerships.
  - Emphasizing that stakeholder involvement is a learning process.
- The nature, extent, and complexity of stakeholder involvement should be appropriate to the scope and impact of a decision and the potential of the decision to generate controversy.

taminated sites substantially reduced the overall time and expense required.

How Can Stakeholders Be Engaged?

The Risk Management Framework promotes at least some stakeholder participation at each stage of the process. Every risk management situation has a spectrum of interested and affected parties who have different perspectives, concerns, knowledge, and interests. Some parties are proactive in seeking involvement, while others are not. In all cases, however, risk managers should work to:

- Identify all stakeholder groups as early as possible in the process, beginning with the problem/context stage.
- Determine the optimal process for stakeholder involvement.

Offering incentives for stakeholders to become involved might be helpful in some cases. For example, some community stakeholders have received child care and transportation expenses or funding for technical reviews. Some industry stakeholders could be attracted by the potential for reduced reporting requirements or more efficient permitting. At times, industry stakeholders cover the expenses of community stakeholders through mechanisms such as community advisory groups.

Not all risk management decisions will benefit from extensive stakeholder collaboration. The nature and complexity of stakeholder involvement should be consistent with the:

- Complexity, uncertainty, impact, and level of controversy associated with the decision to be made.
- Urgency with which the problem must be addressed.
- Extent to which participants can have a genuine influence on the decision. If the decision is really not negotiable, stakeholders' time should not be wasted.

There are no hard-and-fast rules for stakeholder involvement. Research on stakeholder involvement is in its early stages, so we are still learning what works, what doesn't, and why. Nonetheless, we developed a number of guidelines for effective stakeholder involvement based on the experiences practitioners shared with the Commission. Those guidelines are described in the box on page 17 (Guidelines for Stakeholder Involvement).

Successfully Engaging Stakeholders: San Francisco Bay/Delta Accord

Declaring "a major victory of consensus over confrontation" on December 14, 1994, California Governor Pete Wilson and cabinet-level federal officials announced the signing of an historic agreement to protect the San Francisco Bay/Delta estuary, the largest and most productive estuary on the West Coast. Known as the Bay/Delta Accord, the agreement was negotiated by the leadership of the state's environmental, urban, and agricultural interests. The accord broke decades of gridlock on California water policy issues by establishing an integrated, ecosystem-based approach to protecting the estuary while providing more reliable supplies to the state's urban and agricultural water users.

The collaborative process that led to the accord marked a sharp departure from the decision-making approach traditionally used under the Clean Water Act and Endangered Species Act. Rather than issuing proposals developed by individual agency experts for formal public comment and review, the agencies worked together with environmental, urban, and agricultural interests over two years to identify common goals and mutually acceptable solutions. The final standards were developed through an extensive peer-review process that involved both local and national experts in estuarine systems. This approach drew far fewer legal and scientific challenges than accompany most major agency decisions and has been hailed as a national model for solving environmental problems.

Building on the success of this collaborative process, the state and federal agencies and interest groups have continued to work together as part of the new CALFED Bay/Delta Program to develop long-term ecosystem restoration goals. In 1996, the

agencies and interest groups reached consensus on a $995 million bond measure that will help finance the ecosystem restoration process and other projects vital to the program's success. The bond was passed by voters in November 1996.

Insufficient Stakeholder Collaboration: Granite City, Illinois

When stakeholders are not included early in the decision-making process, they are more likely to oppose the risk management decision and block its implementation. This has been happening in Granite City, Illinois, since 1993, according to testimony from Mayor Ronald Selph and Alderman Craig Tarpoff. Heavily contaminated with lead by a former smelter, much of the city was designated by EPA as a Superfund site. Based on soil sample analyses and a screening risk assessment model, EPA decided to remove the contaminated soil around 1,200 homes and businesses and haul it away.

Some believe that EPA made this decision without adequately consulting the community. City officials believe that this remedy ignored a number of problems:

- The potential health risks associated with recontamination by fugitive dust from the waste pile remaining at the smelter, which EPA was not going to remove.
- The health risks posed by fugitive dust from the trucking lot adjacent to the waste pile, which EPA was also not going to remove. This soil was contaminated with 50,000 parts per billion of lead.
- The common presence of lead-based paint in the area, which a local study suggested was the most important source of exposure to lead for children.
- The fact that 95 percent of the children had blood lead levels below 15 µg/dL.

The industrial facility held responsible for the contamination did not respond to EPA's decision, so the agency sued the facility. The city then filed a petition in the suit because officials felt that neither EPA nor the responsible party represented the best interests of the community. EPA began the cleanup anyway, but was restrained by court order. EPA retained an expert whose analysis supported the agency's choice of remedy, and the city retained an expert whose analysis concluded that removing contaminated soil would be fruitless unless the remaining sources of contamination—house paint, the smelter waste pile, and the trucking lot soil—were removed as well. Granite City residents are left confused and caught in the middle; some support the city and some support EPA. Property values have fallen. As of late 1996, the case remains unresolved and is back in federal courts.

Analyzing Risks

To make an effective risk management decision, risk managers and other stakeholders need to know what potential harm a situation poses and how likely it is that people or the environment will be harmed. Gathering and analyzing this information is referred to as risk assessment. The nature, extent, and focus of a risk assessment should be guided by the risk management goals. The results of a risk assessment—along with information about public values, statutory requirements, court decisions, equity considerations, benefits, and costs—are used to decide whether and how to manage the risks. Risk assessment can be controversial, reflecting the important role that both science and judgment play in drawing conclusions about the likelihood of effects on human health and the environment. Often, the controversy arises from what we don't know and from what risk assessments can't tell us, because our knowledge of human vulnerability and of environmental impacts is incomplete, especially at the relatively low levels of chemical exposure commonly encountered in the general community. Sometimes action is necessary even when information is lacking.

How Should Risk Be Characterized?

Risk results from a combination of hazard and exposure. Hazard is an intrinsic property of a substance or situation: for example, benzene can cause leukemia but not lung cancer; DDT can prevent eagles from reproducing in the wild, but does not affect prairie dogs; a rattlesnake bite can kill, but a garter snake bite does not. Exposure means contact between the hazardous substance and a person, population, or ecosystem. The more exposure, the greater the risk. When there is no current or potential exposure, there is no risk.

Risk assessment is performed by considering intrinsic hazards, the extent of exposure to the hazards, and information about the relationship between exposures and responses. Unfortunately, we seldom have enough information to accurately determine those factors, so risk assessors must use a combination of scientific information and their best judgment to characterize risks. Making judgments about risk on the basis of scientific information is called "evaluating the weight of the evidence." For example, considerations involved in analyzing the weight of the evidence associated with identifying a hazard using toxicity studies in rodents include the:

- Quality of the toxicity study.
- Appropriateness of the toxicity study methods.
- Consistency of results across studies.
- Biological plausibility of statistical associations.
- Similarity of results to responses and effects in humans.

It is important that risk assessors respect the objective, scientific basis of risks and procedures for making inferences in the absence of adequate data. Risk assessors should provide risk managers and other stakeholders with plausible conclusions about risk made on the basis of the available information, along with evaluations of the scientific weight of evidence supporting those conclusions and descriptions of major sources of uncertainty and alternative views.

The outcome of a risk assessment is called a risk characterization. Typically a risk characterization addresses the following:

- Considering the hazard and the exposure, what is the nature and likelihood of the health risk?
- Which individuals or groups are at risk? Are some people more likely to be at risk than others?
- How severe are the anticipated adverse impacts or effects?
- Are the effects reversible?
- What scientific evidence supports the conclusions about risk? How strong is the evidence?
- What is uncertain about the nature or magnitude of the risk?
- What is the range of informed views about the nature and probability of the risk?
- How confident are the risk analysts about their predictions of risk?
- What other sources cause the same type of effects or risks?
- What contribution does the particular source make to the overall risk of this kind of effect in the affected community? To the overall health of the community?
- How is the risk distributed in relation to other risks to the community?
- Does the risk have impacts besides those on health or the environment, such as social or cultural consequences?

The level of detail considered in a risk assessment and included in a risk chacterization should be commensurate with the problem's importance,

expected health or environmental impact, expected economic or social impact, urgency, and level of controversy, as well as with the expected impact and cost of protective measures.

Stakeholders' perception of a risk can vary substantially depending on such factors as the extent to which they are directly affected, whether they have voluntarily assumed the risk (as in choosing not to wear a seatbelt) or had the risk imposed on them (as in exposure to air pollutants), and whether they are connected with the cause of the risk. For this reason, the Commission recommends that a risk assessment characterize the scientific aspects of a risk and note its subjective, cultural, and comparative dimensions (see How Should Risks Be Analyzed? below). While they expand risk assessment beyond its traditional, more narrowly scientific scope, these additional dimensions will help educate all stakeholders about key factors affecting the perception of risk. Such education is likely to reduce controversy and litigation and to improve communication during the risk management process.

Risk characterization should form a common basis for the understanding of a problem among stakeholders. Stakeholder involvement within the Risk Management Framework should enhance the integrity of the risk assessment. Stakeholders play an important role in providing information that should be used in risk assessments and in identifying specific health and ecological concerns they would like to see addressed. For example, community stakeholders consulted at this stage can help identify groups with high exposures so that appropriate exposure assessments can be designed. Industry stakeholders can provide important information about a substance's toxicity and lifecycle.

The integrity of a risk assessment is best assured if it is undertaken or peer-reviewed independently (e.g. by unaffected scientists at regulatory agencies, universities, or research institutions). To relieve some of the burden on regulatory agencies and other public institutions, however, certification, auditing, and oversight programs should be considered, so that companies, industry organizations, and other

How Should Risks Be Analyzed?

- Clarify the factual and scientific basis of the risks posed by the problem, treating health and ecological risks both qualitatively and quantitatively. Describe the nature of the adverse effects, their severity, and their reversibility or preventability. Identify who is at risk and when they are at risk, and explain the possibility of multiple effects. Evaluate the weight of the scientific evidence and identify the primary sources of uncertainty. For ecological risks, consider indirect effects on human health through disruption of the environment and possible effects on future generations.
- With input from the problem/context stage, put the specific risks posed by the problem into their multisource, multimedia, multichemical, and multirisk contexts.
- Identify stakeholder perceptions of the risks posed by the problem.
- Combine information on the scientific and contextual aspects of the risks posed by the problem into a characterization of the problem's risks to human health or the environment. Include descriptions of stakeholder perceptions and any other social or cultural impacts of the problem.

organizations or individuals can provide risk assessments that are considered credible by all stakeholders. For example, to place greater responsibility on the private sector for cleaning up contaminated sites, the state of Massachusetts has instituted a successful program for certifying Licensed Site Professionals to oversee or perform site assessments or cleanups.

The Need for More Data

Lack of data is a major barrier to reliable risk assessments. For example, we lack data on the hazards that chemicals and other stressors pose, largely because of the ethical barriers to deliberately exposing humans, the limitations of tests in laboratory animals and cell systems, the technical uncertainties involved in extrapolating data from laboratory animals or cell systems to humans, the difficulties associated with determining differences in susceptibility among people, and the expense involved in studying hazards. As a result, many chemicals are never properly tested. We also lack data on actual human and ecological exposures to agents of concern, largely due to the privacy issues involved in studying humans directly and the substantial cost of the environmental monitoring needed to gather the data. The difficulties involved in studying chemical hazards and exposures mean that risk assessors cannot always accurately determine the health risks of an exposed population or the ecologic risks of an exposed ecosystem, the contribution of each individual source of exposure to the overall risk, or the success of risk management actions in reducing the risk from existing sources of exposure.

Some programs have been designed successfully to stimulate the production of data. For example, industry can avoid the labeling requirements of California's Proposition 65 by demonstrating that their product has a cancer risk of less than 1 in 100,000.

Risk assessment will be greatly improved if risk assessors and other members of the scientific and risk management communities can work to develop and validate new toxicity tests in laboratory animals, investigate similarities and differences between laboratory animals and humans, obtain data on exposures, and develop and validate models to help fill toxicity and exposure data gaps. When data are scarce and uncertainties are large, however, the precautionary principle should guide decision-making.

The Importance of Comprehensive, Multimedia Risk Analysis

Risk assessment provides the scientific foundation for risk management decision-making. Traditionally, risk assessments, like risk management, have largely focused on assessing the risks of a single chemical in a single medium. To achieve comprehensive, multimedia risk management, however, the risk assessment paradigm must be expanded.

A number of EPA offices are conducting more comprehensive risk assessments. When establishing a standard for exposure to a chemical in drinking water, EPA accounts for nondrinking water sources of exposure to that chemical. When considering whether to reregister a pesticide, EPA now considers other sources of exposure to that pesticide and to similar pesticides. In addition, EPA has perfomed some total exposure and cumulative exposure studies. Few other regulatory agencies consider exposures or risks this comprehensively, however, and EPA often does not do so because of resource or statutory limitations. Failure to account for multiple and cumulative exposures is one of the primary flaws of current risk assessment and risk management.

To the greatest extent possible, EPA and other regulatory agencies must work to develop and refine techniques for comprehensive risk assessment. One technique for assessing aggregate or cumulative risks from multiple pollutants and multiple sources is the method for regional risk assessment of air pollution developed by the Air and Waste Management Association. It was used in San Diego as part of California's "hot spots" program, which examines the potential for cumulative pollution from multiple facilities to affect neighborhoods in a county. The method generates a contour map of estimates of the maximum cancer risks associated with industrial facilities throughout the county, using meteorological data and information on con-

taminants, emission rates, and risks from individual facilities. The results can be used to estimate the relative contribution of individual industrial facilities to the overall regional risk associated with industrial facilities, to estimate the relative contribution industrial facilities make to background risks, and to compare risks from industrial facilities to risks associated with other sources of air pollution, such as motor vehicles.

Examining Options

This stage of the risk management process involves identifying potential risk management options and evaluating their effectiveness, feasibility, costs, benefits, unintended consequences, and cultural or social impacts. This process can begin whenever appropriate after defining the problem and considering the context. It does not have to wait until the risk analysis is completed, although a risk analysis often will provide important information for identifying and evaluating risk management options. In some cases, examining the options may help refine a risk analysis. Risk management goals may be redefined after risk managers and stakeholders gain some appreciation for the options and what they entail.

Stakeholders can play an important role in all facets of identifying and analyzing options. They can help risk managers:

- Develop methods for identifying risk-reduction options.
- Develop and analyze options.
- Evaluate the ability of each option to reduce or eliminate risk, along with its feasibility, costs, benefits, and legal, social, and cultural impacts.

The two components of this stage of the Risk Management Framework—identifying options and analyzing options—are described below. Creativity, imagination, and openness are key to success during this stage.

Identify Options

There are many different regulatory and nonregulatory approaches to reducing risk. These include:

- Encouraging pollution prevention either by reducing or eliminating the use of hazardous agents or by improving technology to reduce the likelihood that they will be released to the environment.
- Limiting pollutant emissions by requiring operating permits for industrial facilities, incinerators, and wastewater treatment plants.
- Taxing industries on the basis of the pollutants they release.
- Enforcing compliance by the Department of Agriculture when foods are found to be contaminated with microorganisms and by the Occupational Safety and Health Administration (OSHA) when workplace exposure limits are exceeded.
- Recycling and encouraging the use of recycled materials.
- Educating/informing affected communities about steps they can take to reduce their risks, such as posting signs warning about contaminated fish, showing workers which workplace practices lead to fewer chemical exposures, and encouraging people to reduce the fat and increase the fruits and vegetables in their diets.
- Establishing market or other incentives for voluntary behavior changes that will reduce risk, such as allowing companies to trade among themselves the amount of pollutants they are permitted to release and requiring facilities that emit pollutants to publicly report the amounts they release.
- Removing the source of risk, such as cleaning up a hazardous waste site, banning a pesticide that prevents birds from reproducing, or

removing contaminated food from the marketplace.

During this stage of the Framework, risk managers and stakeholders consider which of these and other types of options may be appropriate. Sometimes only one of these options will seem appropriate; however, a combination of options often will be most effective in reducing risk. The section Risk Management Options: Alternatives to Command and Control on page 49 provides more information on options.

Analyze Options

Once risk managers and stakeholders have identified potential options, they must assess the effectiveness, feasibility, benefits, and costs of each option, along with their potential legal, social, cultural, and political implications, to select an option. Key questions to ask include:

- What are the option's expected benefits?
- What are the option's expected costs?
- Who gains the benefits and who bears the costs?
- What are the equity or environmental justice implications?
- How feasible is the option, given the available time and resources as well as legal, political, statutory, and technology limitations?
- Does the option increase any risks?

Expected Benefits/Effectiveness

It is important to determine what the specific intended benefits will be because they will be evaluated at a later stage in the Framework. The most obvious benefit from risk management is risk reduction or elimination. This may take a number of forms, including improved health, habitat protection, or increased biodiversity. Other important potential benefits include savings in health care costs, technology development, the economic benefits of exporting new technologies, and the employment opportunities that new technology development and its application can bring. (Technology development can also be considered a cost; see Expected Costs on page 25.)

Because it is often difficult to detect risk reduction in the rates of disease, death, or habitat destruction, indirect methods of evaluating effectiveness and identifying reductions in risk may be necessary. Indirect indicators of risk reduction include reductions in:

- Pollution-generating activities, such as fewer vehicle miles traveled.
- Contaminant emissions from their sources, such as a facility's wastewater discharge point or stack emissions.
- Contaminant concentrations in environmental media, such as lower ozone, radon, or particulate levels in air; lower concentrations of industrial solvents in ground water; or lower concentrations of heavy metals in soil.
- Contaminant concentrations in other sources of exposure, such as less mercury in swordfish, fewer microorganisms in meat, or pesticide residues on fruit that are below detectable levels.
- The occurrence of particular biological markers of exposure or disease, such as chromium levels in hair, lead levels in blood, or changes in the components of the immune system.

All potential forms of risk reduction should be examined. The generation of other benefits, such as the identification or development of new technologies or approaches for controlling or reducing risks should be considered as well. Indirect measures of risk reduction or elimination are not the real objectives, however; they are only surrogates and are not always reliable. Direct measures of risk reduction or elimination should be used whenever possible and when indirect measures are used, the uncertainties surrounding their use should be discussed. When the stakes are high, investment in

developing and validating direct measures should be considered. The box Measuring the Effectiveness of a Risk Management Action on page 33 provides more detail on the challenges of measuring the effectiveness of actions to reduce risk.

Expected Costs

The costs of implementing an option may be monetary and nonmonetary. Monetary costs include the costs of:

- Technology development—researching and developing new engineering processes or equipment.
- Technology application—purchasing, installing, operating, and maintaining equipment needed to improve an industrial process or reduce emissions.
- Training needed to use new technology, carry out new procedures, or monitor effectiveness.
- Cleanup—hiring contractors and engineers to implement a remedy at a contaminated site.
- Transportation and infrastructure—removing hazardous materials and trucking them to a disposal site and, sometimes, improving roadways to accommodate the increase in heavy vehicle traffic.
- Health care, such as that needed for workers responsible for implementing an option that puts them at risk.
- Diversion of investments, or opportunity costs—such as having to spend money on environmental controls instead of using those resources to build a school or reduce taxes.

Nonmonetary costs include the costs of:

- Valued environmental assets lost, such as recreation areas, endangered species, visual range, open space, and wetlands.
- Flexibility and choice for consumers and businesses lost because certain products, practices, or processes are no longer available or permitted.
- Decreased sense of well-being or security.

Both types of costs should be considered when evaluating options. As with estimates of risks and benefits, however, cost estimates are uncertain. It is important to obtain independent and defensible cost estimates to the extent possible. See the section Uses and Limitations of Economic Analysis in Regulatory Decision-Making on page 93 for more about evaluating costs.

Distribution of Benefits and Costs

Critics contend that evaluations of costs and benefits are often blind to issues of environmental equity and fail to make explicit who bears the costs of a risk management decision and who gains the benefits. For example:

- If a new policy limits the application of a widely used pesticide, the cost of certain fruits and vegetables could increase significantly. Should this occur, those who still can afford to buy those fruits and vegetables may benefit by enjoying reduced health risks from pesticides. However, economists argue, others who can no longer afford those fruits and vegetables may suffer poorer nutrition and increased cancer risk associated with eating too few fruits and vegetables.
- A proposed freeway exit ramp in Boston would make commuting more convenient for office workers. Its location, however, would have exposed residents of Chinatown, a densely populated neighborhood, to substantially increased air pollutants.

As these examples illustrate, understanding and evaluating potentially inequitable costs and benefits are important for making risk management decisions.

Feasibility

A variety of technological, legal, political, economic, and other issues can constrain the feasibility of an option. The feasibility of actually implementing an option should be an important evalua-

tion criterion. For example, the feasibility of implementing a technological option may be limited by the availability of the technology or by its cost; implementing administrative options such as setting up a recycling program or providing incentives may be constrained by political or legal barriers. Options that are infeasible today, however, frequently can, through technology development or policy change, become feasible in the future.

Potential Adverse Consequences

Analysis must consider whether an option may cause any adverse consequences and determine what the tradeoffs among the different risks may be. One of the most important effects to consider is the potential for an option to increase one type of risk while reducing the risk of concern:

- Reducing pollutant concentrations in one environmental medium may increase pollutants in another medium. For example, using aeration reduces pollutants in drinking water by releasing them to the air. (Of course, if exposure to air is considerably less than exposure to drinking water, this tradeoff may be worthwhile.)
- Reducing long-term health risks for community members may produce short-term health risks and injury for workers, as can happen during cleanup of sites contaminated with hazardous chemical and radioactive wastes.
- Banning one substance because it might cause one health risk may increase the use of another substance that is known to cause another health risk or whose health effects are not known.

Other adverse consequences may be cultural, ethical, political, social, or economic, such as:

- Economic impacts on a community, including reduced property values or loss of jobs.
- Environmental justice issues, such as inequitable distribution of costs and benefits as mentioned above; disregard for a particular population group's dietary needs, preferences, or nutritional status; or giving priority to site cleanup efforts in more affluent areas.
- Harm to the social fabric of a town or tribe when relocating the people away from a highly contaminated area.

Linking Risk and Economics

In addition to considerations of risk, public values, and legal requirements, economic analysis can play an important role in the Risk Management Framework. For example, cost-effectiveness analysis can help identify the least costly risk management option for reaching a particular goal. And by clarifying who bears the costs and who gains the benefits, economic analysis can help identify inequities.

Economic analysis has strengths and limitations, and its role in regulatory decision-making is controversial. The section on Uses and Limitations of Economic Analysis for Regulatory Decision-Making on page 93 provides a detailed discussion of those issues.

Stakeholders and EPA Identify Risk Management Options for the Pulp and Paper Industry

In 1990, EPA assembled a team of experts in air and water pollution to formulate integrated rules to control water discharges and air emissions from the pulp, paper, and paperboard industry. A screening assessment of 104 mills that use chlorine as the bleaching agent for paper had found dioxins and furans in the mills' water discharge, sludge, and pulp at levels that have the potential to harm fish and wildlife and to cause cancer and other health effects in humans.

Before deciding how best to reduce these discharges, EPA held meetings, conference calls, and a symposium to seek views and information from many stakeholders—including individual companies, an industry association, consultants, vendors, labor unions, and environmental organizations. EPA shared its data and thinking about various approaches with stakeholders before publishing proposed rules in the

Federal Register. Even the preamble to the proposed limitations and standards was reviewed by stakeholders before being published. In all, five public meetings were held before the proposed rule was published in 1993.

During the many discussions of control options, environmentalists pressed for a "totally chlorine-free" option to eliminate the discharge of chlorinated pollutants. EPA proposed a technology option. Industry asked EPA to review a second option they considered more feasible. EPA assessed potential compliance costs, effluent reduction benefits, economic and environmental impacts, management practices, recovery systems, and equipment availability. The agency then proposed both technology options as well as a voluntary incentives program to encourage and reward individual mills that implement "totally chlorine-free" technologies. While the proposals did not satisfy everyone, stakeholder involvement improved the development of options.

Making Decisions

During this stage of the Framework, decision-makers review the information gathered during the analyses of risks and options to select the most appropriate solution. When the risk problem falls under the purview of a federal, state, or local regulatory authority, the regulatory agency makes the risk management decision. Consumers, manufacturers, and others responsible for wastes and pollution also can make socially important decisions to reduce or eliminate risks. A productive stakeholder involvement process can generate important guidance for decision-makers. Thus, decisions may reflect negotiation and compromise, as long as statutory requirements and intent are met. In some cases, win-win solutions are available that allow stakeholders with divergent views to achieve their primary goals.

Involving stakeholders and incorporating their recommendations where possible reorients the decision-making process from one dominated by regulators to one that includes those who must live with the consequences of the decision. This not only fosters successful implementation, but also can promote greater trust in government institutions.

What Is the Best Decision?

In most risk management situations, decision-makers will have a number of options from which to choose. Which option is optimal depends on the particular situation. Seven criteria, discussed below, are fundamental characteristics of any sound risk management decision. These criteria echo the key themes of the early stages of the Framework because their goal is to produce the most relevant and useful information for sound risk management decision-making.

Base the decision on the best available scientific, economic, and other technical information.

Usually, the technical information that is available is incomplete. Decision-makers often must rely on:

- Predictions about human hazards based on experiments in laboratory animals.
- Predictions about how much exposure occurs in a lifetime based on few or no measurements of the actual levels of exposure.
- Predictions about the risks to entire ecosystems that are based on observations in only one or two species.
- Assumptions and models of exposure, exposure-response relationships, and estimates of the costs and benefits of different options.

Because so many judgments must be made based on limited information, it is critical to consider all reliable information. Risk assessors and economists are responsible for providing decision-makers with the best technical information available or reasonably attainable, including evaluations of the weight of the evidence that supports different assumptions and conclusions.

Be sure the decision accounts for the problem's multisource, multimedia, multichemical, and multirisk contexts.

Considering a risk in isolation cannot provide decision-makers or the public with any sense of how important the risk is, compared with other risks, or of the impact that reducing or eliminating it might have on overall human and ecosystem health. Considering risks in context can help direct resources toward the risk management actions that will do the most good. As described in the Problem/Context section earlier in this report, decision-makers must develop a more comprehensive and holistic appreciation of problems and their contexts so that meaningful, practicable goals can be defined and attained.

Choose risk management options that are feasible, with benefits reasonably related to their costs.

Many risk management options may be infeasible for social, political, cultural, legal, or economic reasons (see the Examining Options section of this report) or because they do not reduce risks to the extent needed. For example, ground water remediation using pump-and-treat technology may be infeasible because, for a variety of technical and hydrogeologic reasons, it will not sufficiently reduce contaminant concentrations in the ground water. Removing all the soil from an entire valley that is heavily contaminated with mining waste is infeasible. Expecting everyone to stop driving automobiles is infeasible. On the other hand, the costs of reducing acid rain by controlling power plant emissions are considered justified by their benefits—protecting streams and lakes and reducing damage to automobile finishes and construction materials. Of course, the feasibility and cost-effectiveness of an option may change in the future as technology is improved or as society's values change.

Give priority to preventing risks, not just controlling them.

If pollutants are not released into the environment, exposure cannot occur. If exposure does not and will not occur, risks will not result. Where feasible, preventing contaminant releases is preferable to removing them or cleaning them up later, since preventing releases can avoid the costs of remediation and health care. Many industries have found that eliminating pollutants can substantially reduce the cost of producing a product.

Use alternatives to command-and-control regulation, where applicable.

Command-and-control risk management strategies have significantly improved human health and environmental protection. Alternative strategies will enable even greater levels of protection by encouraging industries, municipalities, and other stakeholders to tailor remedies to reflect the circumstances of individual sources and locations. Encouraging flexibility can result in risk management options that meet or exceed expectations and that are cost-effective. Various alternatives to command-and-control strategies are described in the Examining Options section of this report.

Be sensitive to political, social, legal, and cultural considerations.

The least costly risk management option is not always the most desirable. An option is more likely to be implemented successfully if it takes into account important cultural needs or social impacts (see the discussion of stakeholder involvement in the Problem/Context section of this report).

Include incentives for innovation, evaluation, and research.

Command-and-control risk management strategies that specify technology that must be used or actions that must be taken can fail to stimulate better, cleaner, and more cost-effective approaches. Without evaluation, the success (or failure) of a risk management action and its unintended consequences may not be determined (see the Evaluating Results section of this report). Incentives for research are needed to generate knowledge about hazards, exposures, options, and actions.

What Happens If There Isn't Enough Information To Make a Decision?

Decision-makers must balance the value of obtaining additional information against the need for a decision, however uncertain. Sometimes a decision must be made under the precautionary principle. Every effort should be made to avoid "paralysis by analysis" where the need for additional information is used as an excuse to avoid or postpone decision-making. When sufficient information is available to make a risk management decision or when additional information or analysis would not contribute significantly to the quality of the decision, the decision should not be postponed. "Value-of-information" techniques can be used to provide perspective on the next steps to be taken. (See Value of Obtaining Additional Information on page 91 for elaboration.)

Making Decisions: Steel Industry

The Clean Air Act Amendments of 1990 required EPA to cut toxic air pollution from iron and steel plant coke ovens, which produce the material used in blast furnaces to convert iron ore to iron. Coke oven air emissions were already regulated by OSHA, by the states, and by EPA under the hazardous substance notification requirements of Superfund. The issue of how best to reduce coke oven emissions was contentious and had been deadlocked for 20 years.

To break this logjam, EPA initiated a negotiated rulemaking process with extensive stakeholder involvement. Over two years, the Agency met with representatives of industry and industry associations, labor unions, states, and environmental groups in workshops and informal and formal meetings. Negotiators worked with stakeholders to develop a regulation that all parties could support. By exchanging concessions in areas of differing importance to various stakeholders, the parties resolved such major issues as what emissions data would be used, monitoring methods, numerical emission limits, costs and economics, and work practices. They also identified and discussed emission sources, enforcement and implementation needs, future research, and integrating the proposed regulation with EPA's new permitting system. The resulting regulation reduces hazardous air pollution by 1,500 tons per year.

Taking Action

Traditionally, implementation has been driven by regulatory agencies' requirements. Businesses and municipalities are generally the implementers. The chances of success are significantly improved, however, when other stakeholders also play key roles. Depending on the situation, protagonists may include:

- Public health agencies.
- Other public agencies.
- Community groups.
- Citizens.
- Businesses.
- Industries.
- Unions/workers.
- Technical experts.

These groups can help develop and implement a plan for taking action; explain to affected communities what decision was made, and why, and what actions will be taken; and monitor progress. The box Examples of Risk Management Actions on page 30 provides specific examples of risk management activities that stakeholders can perform or support.

Involving stakeholders in the decision-making process, not only produces a better risk management decision but also lays a foundation for stakeholder involvement in implementation. Involved stakeholders are more likely to understand and support the decision and to have developed the relationships, knowledge, communication channels, and administrative mechanisms to work together on implementing the decision.

Taking Action: San Francisco Bay

The San Francisco Bay is vulnerable to many sources of pollution. In 1978, the Association of Bay Area Governments developed a regional environmental management plan to control pollution in the bay. The plan was prepared through an extensive collaborative process that involved a broad spectrum of stakeholders—federal, state, and local regulatory agencies; business, labor, and environmental groups; ethnic minorities; and city and county governments. During the decision-making process, stakeholders raised important issues about federal-state-local relationships, the social and economic impact of land-use controls, and the extent of air-quality improvement likely to be obtained.

Stakeholders who were involved in analyzing problems and solutions and in making decisions supported the final plan and its implementation. While some aspects of the plan might have been developed and implemented without the help of stakeholders, most of the actions were implemented more expeditiously as a direct result of stakeholder involvement.

Many actions recommended by the plan were

Examples of Risk Management Actions

- Public health agencies educating different cultural, ethnic, and socioeconomic groups about practices to modify or avoid, such as smoking, alcohol consumption, high-fat diets, eating parts of contaminated fish that concentrate pollutants, and chemical or radiation hazards in the home.
- Municipalities working to reduce nonpoint sources of pollution, such as runoff from highways, by preventing erosion; upgrading drinking water, sewage, and municipal solid waste treatment facilities; or instituting recycling programs.
- Community groups working with local businesses and industries to monitor the success of their risk-reduction activities.
- Citizens recycling, purchasing products that use recycled materials, or complying with automobile emissions testing.
- Businesses no longer selling products that can harm the environment; disposing of wastes safely; or working with employees to anticipate and reduce worksite safety and health risks.
- Industries reducing or eliminating emissions or discharges to ambient air, workplace air, and bodies of water by upgrading air pollution control technology, upgrading wastewater treatment, and improving manufacturing processes (such as developing a closed-loop system , recycling wastes, or substituting less hazardous materials).
- Unions working with industries to identify less hazardous workplace practices and processes; educating workers about practices that reduce hazardous exposures in the workplace and hazardous emissions to the environment, such as proper waste disposal; or helping employers monitor the success of risk-reduction activities.
- Technical experts providing technical assistance to local agencies, community groups, businesses, and unions to help implement risk-reducing actions.

implemented by public agencies, businesses, industries, and private citizens. For example:

- A state implementation plan for regional air quality resulted in designation under the federal Clean Air Act as an attainment area for ozone in 1995.
- Almost all the industrial and municipal wastewater treatment facilities have been upgraded.
- Erosion-control measures to reduce nonpoint-source pollution have been in place for many years.
- A council of water-supply agencies was formed and has engaged in cooperative efforts, such as developing a regional drought-response strategy.
- Hazardous-material spill response teams have become available at the city and county levels.
- Technical assistance was provided to local agencies to initiate recycling programs.

The plan has served as a blueprint for environmental management activities in the Bay Area.

Evaluating Results

At this stage of risk management, decision-makers and other stakeholders review what risk management actions have been implemented and how effective they have been. Evaluating effectiveness involves monitoring and measuring, as well as comparing the actual benefits and costs to estimates made in the decision-making stage. The effectiveness of the process leading to implementation should also be evaluated at this stage.

Evaluation provides important information about:

- Whether the actions accomplished what was intended and whether the predicted benefits and costs were accurate.
- Whether any modifications are needed to the risk management plan to improve success.
- Whether any critical information gaps hindered success.
- Whether any new information has emerged that indicates a decision or a stage of the Framework should be revisited.
- Whether the Framework process was effective and how stakeholder involvement contributed to the outcome.
- What lessons can be learned to guide future risk management decisions or to improve the decision-making process.

Tools for evaluation include environmental and health monitoring, research, disease surveillance, analyses of costs and benefits, and discussions with stakeholders.

Evaluation is critical to accountability and to ensure wise use of scarce resources. As part of its effort to impose accountability on agencies, Congress adopted the Government Performance and Results Act of 1993, which requires federal agencies to establish performance goals and measurements of achievement. Too often, past risk management actions have had little or no evaluation or follow-up after implementation, even when evaluation was mandated.

Planning for Evaluation

The overall implementation plan should specify when evaluation will be conducted, who will conduct it, and what will be evaluated. In most situations, periodic evaluation will be important. The focus of evaluation may shift with the stage of implementation, because it often may take time before the full impact of risk reduction can be measured. Evaluation might first focus more on progress and success in implementing the risk management plan. Later evaluations may focus on the success of the risk management actions in reducing risk. In comments to the Commission, Dave Sigman, representing the Chemical Manufacturers Association, strongly supported the need to document whether

risks are reduced and costs reasonably estimated with feedback to appropriate risk managers and decision-makers.

In the past, evaluation, when conducted, has been performed by the regulatory authority itself. As with other stages of the risk management process, evaluation will benefit if stakeholders are involved, helping to:

- Establish criteria for evaluation, including the definition of "success."
- Assure the credibility of the evaluation and the evaluators.
- Determine whether an action was successful.
- Identify what lessons can be learned.
- Identify information gaps.
- Determine whether cost and benefit estimates made when evaluating the risk management options were reasonable.

The Importance of Iteration

New information may emerge during evaluation that is of sufficient importance to warrant repeating parts of the Framework. For example, it might be necessary to revisit a decision if a more effective risk management option or a less costly option of equal effectiveness is developed. Public comment, negotiation, information-gathering, research, or analysis of risks and options could clarify or redefine the problem, change the focus to a different problem, or identify other risks in a broader context. In such cases, the risk management process will not be sequential, but rather flexible and iterative as important new information, ideas, and perspectives come to light.

While an iterative process is important for incorporating new information, it should not become an excuse for taking no action. Decisions must be made, even when information is imperfect.

Evaluating Results: Integrating Regulatory Activities at the State Level

Environmental agencies in Massachusetts, New York, and New Jersey have made significant efforts to integrate their regulatory activities and to incorporate pollution prevention into these activities. Massachusetts has adopted a single, integrated inspection to assess a facility's compliance with environmental statutes, instead of conducting separate medium-specific inspections. New York is using a facility-management strategy in which a team directed by a state-employed facility manager is assigned to targeted plants to coordinate medium-specific environmental programs. New Jersey is testing the use of a single, integrated permit for industrial facilities instead of separate permits for releases of pollution to each environmental medium.

On behalf of Congress, the General Accounting Office (GAO) evaluated the states' experiences with integrated programs, primarily through interviews. The evaluation is preliminary because the data needed to fully evaluate the states' experiences are not yet available.

GAO reported that Massachusetts and New York believe that their integrated approaches have been sufficiently successful to implement them statewide. Permits have only recently been issued as part of New Jersey's program. Industry officials in those states believe that the integrated approaches are beneficial to the environment, achieve regulatory efficiencies, and reduce costs. The states noted, however, that obtaining funding from EPA and meeting EPA's medium-specific reporting requirements were difficult and burdensome. In response, and to encourage other states to integrate environmental management, EPA proposed a new grant program designed to provide states with easier access to funding for multimedia programs and to facilitate easier reporting of multimedia activities.

Evaluating Results: Reducing the Use of Leaded Gasoline

One of the best documented evaluations of the impact of a risk management action on pollutant emission levels concerns leaded gasoline. The burning of gasoline was the single largest source (90 percent) of lead in the atmosphere beginning in the 1920s. Significantly less of the lead monitored in the air today comes from gasoline because EPA phased out the use of lead in gasoline. In 1984, the average lead content of gasoline was 0.44 grams per gallon; in 1991-1992, it was less than 0.0003 grams per gallon. EPA estimated that before the regulations to control lead in gasoline, the total amount of lead released to the air from motor vehicles was about 95 metric tons in 1979. In 1989, after the controls were fully implemented, only 2 metric tons were emitted from motor vehicles, with less than 35 percent of the lead in air attributable to gasoline. Today, the emission of lead from motor vehicles should be nearly zero, as required by the 1990 Clean Air Act.

Measuring the Effectiveness of a Risk Management Action

Few actions to reduce health or ecosystem risks lend themselves easily to measurement and validation. For example, it is difficult to observe changes in cancer risk because it can take many years for a tumor to develop after exposure occurs. Some other effects are easier to observe because they can appear soon after exposure—such as birth defects, anemia from lead, and asthma from sulfur oxides in the air. Relationships between action and effect often are detectable only when the action causes a sizable change in the amount of a pollutant (or other stressor) populations are exposed to, or when the health effect of interest is easy to recognize because it is rare and distinctive (such as the unusual type of liver tumor caused by breathing vinyl chloride in the workplace).

One difficulty in measuring effectiveness is that most environmental health risks are low compared with the risks of such directly countable effects as occupational injuries, motor-vehicle collisions, infant mortality, total cancer rates, and total birth defect rates. For example, suppose that a particular exposure is expected to cause no more than one additional case of cancer per year in a population of 10,000 and action is taken to reduce exposure to a level anticipated to cause, at most, one additional case of cancer per year in one million people (corresponding to one extra case per 100 years in that population of 10,000). With or without this action, cancer still will be the cause of death in 24 percent of the population. No health study or surveillance activity can measure the very small decrease in cancer incidence that would occur at the lower exposure level. Instead, risk managers must rely on indirect measures that indicate cancer incidence may decrease—such as decreased emissions, decreased exposure, and possibly decreases in biological markers of exposure or effects.

Progress is needed in several areas if we are to improve our ability to implement and measure the effectiveness of public health interventions. Specifically, we need to:

- Link studies of exposure and studies of adverse health or ecological outcomes.
- Determine regional differences in disease prevalence and disease incidence trends and risk factors.
- Develop good baseline and surveillance information about incidence rates of diseases specifically linked to environmental causes.
- Identify the most important environmental causes of diseases.

Implementing the Framework

The Commission's Risk Management Framework is designed to address complex, real-world issues. Yet environmental agencies may encounter legal and administrative hurdles when implementing the Framework because most programs, regulations, and procedures developed under current statutes often preclude an integrated approach. The Commission makes six recommendations, described below, to overcome these impediments.

Recommendation 1: Congress should coordinate the activities of committees and subcommittees with overlapping or related jurisdictional responsibilities for environmental issues, starting with joint oversight hearings.

Many different Congressional committees and subcommittees have overlapping and conflicting responsibilities for sources of and solutions to pollution. For example, the Transportation and Infrastructure Committee and the Commerce Committee in the House of Representatives both oversee EPA's implementation of Superfund and the Safe Drinking Water Act. In the Senate, the Agriculture Committee has jurisdiction over pesticides, while the Environment and Public Works Committee oversees other toxic substances. These competing responsibilities make it difficult to implement integrated strategies. We recognize the practical and political constraints that make coordination difficult.

Joint Congressional hearings could:

- Help put problems into public health or ecological context.
- Encourage EPA and other agencies to use their discretionary authority to implement the Commission's Risk Management Framework and comprehensive risk assessment reforms.
- Reinforce integrated approaches to reducing risks in industrial sectors and geographic areas.
- Evaluate experimental alternatives to command-and-control regulations.

For example, the Agriculture Committee and the Resources Committee in the House could stimulate coordinated approaches to integrating chemical and microbial risk assessment and benefit-cost practices throughout the U.S. Department of Agriculture. They could also promote the use of the Commission's Risk Management Framework by the Natural Resources Conservation Service in addressing erosion and water pollution from agricultural lands. Other committees should look at industrial sectors, such as iron and steel mills or oil refineries, to address sector-specific pollution and manufacturing processes on a multimedia basis.

Some committees address the environmental status of geographic areas, such as the House Resources Committee's jurisdiction over parks, wild and scenic rivers, and national forests, but no committee is charged with responsibility for the status of urban pollution or of watersheds. In the House, joint hearings involving the Resources Committee, the Agriculture Committee, and the Transportation and Infrastructure Committee, which has jurisdiction over the Clean Water Act, could better address the myriad stresses on a watershed. Similarly, the House Commerce Committee and the Transportation and Infrastructure Committee could hold joint hearings to encourage the use of the Commission's Risk Management Framework to comprehensively deal with Superfund sites.

Recommendation 2: The regulatory agencies should fully use their existing discretionary authority to propose and implement actions that address the most significant sources of the community's total exposure to hazards under review.

Many agencies have improved their risk assessment practices, used risk assessment in more programs, and begun to engage stakeholders in decision-making processes. In many cases, adoption of the Commission's Risk Management Framework by federal, state, and local agencies will not require changes in statutes so much as changes in the decision-making process to identify all the sources that account for total exposure and estimate the risks attributable to each source.

California's air toxics program provides a good model of an integrated regulatory strategy that is being achieved administratively. Rather than first assessing risks from individual sources, the program estimates the overall risk attributable to a particular chemical. Upon deciding that the risk is sufficiently high to warrant action, the program examines all identified stationary, mobile, and area sources of the chemicals to determine the most cost-effective reductions in emissions and exposure. The EPA has launched a similar cumulative exposure approach for hazardous air pollutants (see below).

Recommendation 3: The regulatory agencies should fully use their existing discretionary authority to expand stakeholder involvement in the development and implementation of solutions to environmental problems.

Successful integrated approaches depend on trust among agencies and stakeholders. Public notice and comment procedures are inadequate for building the level of trust and cooperation necessary for integrated approaches. Stakeholder involvement processes such as those used in the Common Sense Initiative and Project XL are a good beginning. As the participants have learned, however, unexpected challenges—such as disagreements about the composition of stakeholder groups and difficulties arriving at consensus—have slowed the completion of projects. We believe that implementation of our Guidelines for Stakeholder Involvement (see page 17) can increase prospects for productive stakeholder involvement.

Recommendation 4: Congress should reinforce implementation of the Commission's Risk Management Framework legislatively, statute-by-statute.

For several years, Congress has considered bills that would prescribe government-wide risk assessment and economic analysis practices and make them judicially enforceable. Also, an "organic act" has been proposed that would integrate the operations of EPA's program offices. The 104th Congress, however, found common ground for bipartisan action by reauthorizing specific statutes instead. For example, the Safe Drinking Water Act and the Food Quality Protection Act were modified in ways that provide flexible direction to consider risks, costs, benefits, population subgroups, and public values in decision-making. The 1996 Safe Drinking Water Act includes important provisions on the roles of risk assessment and economic analysis in setting standards and priorities for regulation without dictating the specific steps in the analysis or requiring one to outweigh another. It is a good example of how statutes can be modified to promote more flexible risk management strategies. Congress should consider legislative changes that:

- *Address geographic areas such as urban areas and watersheds.* Under the Clean Air Act Amendments of 1990, EPA is developing an integrated urban air toxics strategy that considers different types of pollutants and multiple sources of pollutants together, so that risk management actions in urban areas can address air pollution in context. In the case of watersheds, EPA already is working with states and localities to develop ecological risk assessments and integrated approaches to pollution problems. The Clean Water Act should be amended to establish a comprehensive, integrated watershed management approach.
- *Mandate authority for EPA to consider sources of significant indoor air pollution when evaluating the risks attributable to multiple sources of air pollution. EPA should collaborate with other agencies to reduce significant risk from indoor air exposures.* Numerous studies have shown that the concentrations of many contaminants in air are higher in homes than outdoors. While outdoor air pollution is extensively regulated, problems in offices, public buildings, and homes remain relatively unrecognized and unaddressed. Efforts by EPA, the Consumer Product Safety Commission (CPSC), and OSHA to regulate indoor air have been thwarted by lack of statutory authority and by

lack of agreement on the nature of the problems and the solutions. EPA's regulatory authority appears to be limited to outdoor air. OSHA is responsible for industrial environments. CPSC has authority over products, such as carpets and insulating materials. A coordinated approach by EPA, OSHA, and CPSC will not emerge without a mandate from Congress and cooperation from stakeholders.

- *Increase flexibility for meeting environmental protection goals.* Integrated approaches to compliance can provide greater cost-effectiveness and increased flexibility for facilities that go beyond current levels of environmental protection. EPA is currently experimenting with such approaches in its Common Sense Initiative and Project XL programs. However, EPA and participants must still meet the original regulatory requirements, even when more effective solutions are being implemented. For these projects to succeed, EPA needs the legal authority to provide flexibility in deciding how the regulated community can improve its environmental performance. Congress should explicitly authorize EPA and state agencies to enter into compliance agreements that waive certain current regulatory requirements if alternative controls can credibly achieve equal or, whenever feasible, greater environmental protection.

Recommendation 5: The Council on Environmental Quality (CEQ) should consider issuing guidance or regulations for implementing additional provisions of the existing National Environmental Policy Act (NEPA).

The National Environmental Policy Act offers some opportunities for implementing the Framework. Instead of aiming to protect specific places, activities, or environmental media, as do most environmental statutes, NEPA seeks to balance a broad range of environmental factors with "other essential considerations of national policy." The act states that its policies and goals are supplementary to those in agencies' existing statutory authorizations. NEPA regulations, which were issued in 1978, focus on procedural provisions to ensure that decisions about federal actions are made only after the environmental consequences of the actions are fully considered and that the public benefits of the actions outweigh their environmental costs. These regulations are generally consistent with the focus of the Framework.

In addition to procedural requirements, NEPA established six objectives for all federal programs: responsibility for the future; environmental equity; beneficial use; historical, cultural, and biological diversity and individual liberty; widespread prosperity; and management for quality and conservation. The act requires all federal agencies to use a "systematic, interdisciplinary approach" to planning and decision-making that incorporates the "natural and social sciences and the environmental design arts." An analysis by the Environmental Law Institute concluded that these provisions have not been implemented. Agencies could use these objectives to approach problems in the integrated, contextual manner envisioned in the Commission's Risk Management Framework. CEQ should work with other executive offices and the relevant federal agencies to craft guidance for implementing these NEPA provisions.

Recommendation 6: State and local regulatory and public health agencies should use the Risk Management Framework to address watershed, airshed, community, worksite, and indoor and outdoor environmental problems using an integrated, multimedia process with stakeholders.

We have given several examples of state and local actions that have been taken to address problems in a broad context with stakeholder involvement, such as California's toxics air program and efforts in Massachusetts, New York, and New Jersey to integrate regulatory actions. As in other areas of government endeavor, states and

localites engaged in successful integrated risk management projects can serve as catalysts for federal initiatives. State and local agencies often rely on federal models of regulation; however, as a result, they too focus primarily on single pollutants in single environmental media and on command-and-control approaches to regulation. State and local agencies should increase their ability both administratively and legislatively to implement the Commission's Risk Management Framework.

Looking Ahead

The Commission's Risk Management Framework is not a panacea. It can require substantial time to implement and, in some cases, it might lengthen the risk management process. The ability to implement the Framework will undoubtedly improve over time as parties gain more experience with its various aspects and as more relevant information becomes available. For example, more experience with and guidance for including stakeholders is needed. Both agencies and stakeholders need training to better understand and discuss health and environmental risk issues. Agencies and academic institutions must cooperate to generate more and better exposure and toxicity data and methods for assessing multiple and cumulative risks.

As illustrated in this report, some aspects of the Framework—such as stakeholder involvement and multimedia analysis—already are in use to some extent, although no risk management effort to date has employed all aspects of the Framework. Many of the questions and concerns associated with implementing the Framework will be clarified as it is applied and evaluated; however, gaining experience with the Framework can best be achieved if Congress and the Administration work together to overcome the statutory and administrative barriers described above.

In using this Framework, risk scientists and decision-makers will be embarking on an important new era in risk management designed to make wise use of limited risk management resources. As described throughout this report, the Framework's advantages include:

- Use of an integrated, holistic approach to make risk management more efficient and effective compared with the traditional chemical-by-chemical, medium-by-medium approach to characterizing individual risks.
- Identification and targeting of the most important sources of risk by putting individual problems into larger public health and environmental contexts and addressing multiple and cumulative risks.
- Emphasis on collaboration, communication, and negotiation in an open and inclusive process among stakeholders so that public values can inform and influence the shaping of risk management strategies. Stakeholder involvement can help generate decisions that are more pragmatic and more readily implemented than decisions that are made without considering the diversity of interests, knowledge, and technical expertise represented among stakeholders.
- Capacity for iteration. As with the scientific process itself, at any stage of the Framework, the discovery of critical new information can change conclusions and decisions and lead to reformulation and reevaluation of the problem at hand.

The Commission envisions the Framework to be far more useful and effective than traditional regulatory approaches to solving common multimedia risk problems.

3 Risk Management and Regulatory Decision-Making

This report brings a risk management perspective to issues surrounding risk assessment, risk communication, and risk reduction. Risk assessment can provide valuable information to those who set environmental, health, and safety regulatory priorities, allocate resources within regulatory agencies, and make regulatory decisions. Technical risk assessments seldom set the regulatory agenda, however, because of the different regulatory goals specified in the various environmental statutes and the different ways in which the public perceives risks.

This section presents five conclusions that have emerged from our examination of risk management and regulatory decision-making:

- The complex and often confusing process of communicating information about risks to diverse affected parties must be improved.
- Decisions about how to allocate resources to reduce risks can be made and explained partly on the basis of risk comparisons.
- The use of "bright lines" which distinguish between contaminant emissions and exposures associated with negligible risk levels and those associated with unacceptable risk levels, needs to be clarified.
- Moving from command-and-control regulation to nonregulatory approaches to risk reduction can increase both efficiency and effectiveness.
- Criteria for judicial review, a common element in major regulatory actions, should be reaffirmed.

This section offers recommendations on each of those topics in the hope of contributing to the evolution and improvement of risk-based decision-making.

Communicating and Comparing Risks

Effective risk communication is critical to successful implementation of the Risk Management Framework. Risk communication engages both the communicator and the audience in listening and in explaining information and opinions about the nature of risk and other topics that express concerns, opinions, or reactions to risk messages (NRC 1989). Various proposals to increase the transparency of risk assessments, which entails revealing and characterizing the assumptions, uncertainties, default factors, and methods used to estimate risks and to require the use of risk comparisons have been considered by Congress. As Congressman Thomas Bliley (R-VA) noted in his comments to the Commission, risk managers and the public need to understand, and have the right to know, what the weight of scientific evidence says about a health or environmental risk. Some risk comparison proposals would compel agencies to compare a risk to be regulated with other risks also regulated by the agency and other health risks experienced by the public.

This section discusses the need for better risk communication with the public, including the use of risk comparisons and the use of a common metric for describing exposures associated with different types of adverse health effects. A separate section, Comparative Risk Analysis for Risk Management Priority Setting, follows on page 46 and discusses the process of comparing and ranking risks to identify priorities and make resource allocations.

Identifying Risk Communication Needs

Finding

Stories abound of misunderstandings caused by poor communication about risks and risk reduction proposals. After a decade of research at leading universities and experience at all levels of government, much has been learned about how to enhance effective risk communication to gain the confidence of stakeholders, incorporate their views and knowledge, and influence favorably the acceptability of risk assessments and risk management decisions. That knowledge is not

reflected commonly in practice, however.

Recommendation

Regulatory agencies should adopt comprehensive risk communication programs that emphasize both the learning and explaining activities of communication. These programs should provide research on risk communication messages, train risk managers and others engaged in communicating risk, and include risk communication funding, objectives, and evaluation in risk management plans.

The Commission's Risk Management Frame work (Section 2) is built on continuous involvement of stakeholders and respectful learning from them. Effective risk communication is an essential ingredient in the success of the Framework, especially in the problem identification and options stages in the process.

Risk assessors now recognize that a community's response to learning that a local industry has put them at risk through release of pollutants tends to include a sense of outrage that inevitably magnifies their perception of risk. Studies of the differences between expert and public perceptions of risk have identified many of the factors that contribute to outrage (Sandman 1992). Those factors include involuntary exposures, lack of previous knowledge of the risk, and dread of effects and severe consequences (Slovic 1987). People factor in their perceived personal potential benefit and harm. For example, in comments to the Commission, the Argonne National Laboratory's Environmental Assessment Division pointed out that the dreaded and unfamiliar nature of environmental (non-medical) exposure to ionizing radiation has evoked even greater fear of radiation than of chemicals. A growing body of research provides some guidance on communicating risk information effectively, as detailed in a report prepared for the Commission by David McCallum (see Appendix A7). Our discussion here is not comprehensive; rather, it is intended to indicate the importance of effective risk communication to overcome the potential for mistakes and misunderstandings.

People interpret and use new information in the context of their existing beliefs. We need a basic understanding of the exposure, effects, and mitigation processes relevant to making decisions about a hazardous process, product, or site. Meeting those needs through risk communication should involve well-tested methods; an untested communication should no more be released than an untested product (Morgan et al. 1992). Risk communication means both listening and speaking, and risk communicators should learn about the concerns and values of their audience, their relevant knowledge, and their experience with risk issues. Stakeholders often have important knowledge of sources and patterns of exposure that analysts will need to integrate into a risk assessment. The degree to which information provided by stakeholders is incorporated into risk assessment and risk management decisions may enhance the prospects for trust, a key to effective communication and cooperative action. By listening, risk communicators can craft risk messages that better reflect the perspectives, technical knowledge, and concerns of the audience. Risk communicators must be prepared to explain and answer questions about any specific, relevant tests or surveys done in the community regarding incidences of illness or uptake of pollutants; they cannot rely on general models.

Effective communication must begin *before* important decisions have been made, as emphasized in the Commission's Framework for Risk Management. It can be facilitated in communities by citizen advisory panels, such as those supported by the EPA Superfund program and by the Department of Energy. Many corporations work continuously with citizen advisory panels in their communities. For example, Phillip Lewis, Vice President for Health and Safety at Rohm & Haas Company, noted in testimony to the Commission that the citizen advisory panels associated with each of his company's plants generate a better understanding of the questions and concerns of the community and an opportunity for the company to test risk communication messages before using them with the general public. Of course, not all citizen advi-

sory panels develop a trusting relationship with a company they are advising or are trusted by their communities.

With the growing use of risk assessments and risk estimates by regulatory agencies, there is a need to increase the public understanding and credibility of such information. The media play an important role because they can heavily influence public perceptions about risks and they can instigate concern or draw attention to neglected or underappreciated risks. Of course, broadcast media and print media have different agendas, and must be used in different ways to most effectively transmit information. Material with visual impact will appeal to television reporters. Print journalists are most concerned with who and how many people are affected, the severity of the potential impacts, any possible non-compliance with regulations, and the cost of damage, repairs, or remedies. They are particularly interested in conflicting views, especially among qualified scientists, about the nature and severity of the risks and about the costs and benefits of the remedies. Communicating with the media should be a part of a good risk communication plan. As with the public, honesty and accuracy are essential.

Agencies and Congress have emphasized the importance of improving the quality of risk assessments but have given less attention to the need for training and educating risk assessors and risk managers in communicating information about risk. Comprehensive risk communication programs that stress listening as well as explaining need to be established in regulatory agencies. Training risk assessors and risk managers in risk communication and testing risk communication messages should have as high priority as every other part of the risk management process. Specific communication objectives related to awareness and involvement of stakeholders should be identified in risk management plans, with appropriate methods for evaluating the effectiveness of communication. The National Research Council made the case in *Improving Risk Communication* that "risk managers need to consider communication as an important and integral aspect of risk management" (NRC 1989). The recent National Research Council report *Understanding Risk* strengthens and supports our recommendation to place public stakeholders in prominent roles (NRC 1996a).

The practice of risk communication is moving from trying to explain risk information to citizens toward building partnerships between plant managers and nearby residents, between companies and consumers, and between agency risk managers and the public. Although our air, water, and food are measurably cleaner and therefore less risky than they were 30 years ago, the fact that many citizens believe that they are at greater risk indicates that risk communication has a long way to go. Investments of time and resources are clearly needed.

Communicating About Risk by Comparing Different Kinds of Risk

Finding

People make informal judgments about risks every day. Some risks are familiar, even comfortable; others are unfamiliar and can be sources of considerable fear. Different people have different perceptions of the same risks. It is logical and reasonable for people to request comparisons or for Congress to incorporate mandates for risk comparisons in legislation. But some comparisons trigger resentment, as though a substantial risk were being dismissed or belittled.

Recommendation

Risk comparisons should help to convey the nature and magnitude of a particular risk estimate. Such comparisons should systematically address risks associated with different decision options, with chemically related agents, with the same agent from different exposure sources, with different kinds of agents with the same exposure pathway, or with different agents that produce similar effects.

Many kinds of risk comparisons exist. At the simple end of the spectrum are arithmetical comparisons of magnitude, such as a one-in-a-million cancer risk compared with a length

of one inch in 16 miles; comparisons of chemically related agents, such as one organophosphate pesticide with another; comparisons of the same agent with different exposure sources, such as polycyclic aromatic hydrocarbons from motor vehicle exhaust and broiled meat; comparisons of different agents with the same exposure pathway, such as foods containing naturally occuring carcinogenic components as well as synthetic additives; and comparisons of different agents that produce similar effects, such as the risk of lung cancer from inhaling radioactive radon particles versus smoking a particular number of cigarettes. Toward the complex end, multiple risks are compared across a variety of dimensions, such as the hazards to the public, workers, and ecosystems of different energy-producing or Superfund cleanup technologies.

In general, risk comparisons can help people to comprehend probabilities or magnitudes. Most people, including physicians, do not easily relate low-risk probabilities or ratios, such as "one-in-a-million," to their everyday experience. One solution is to make quantitative comparisons between familiar and less familiar risks. A better solution might be to use analogies—one-in-a-million is equivalent to 30 seconds in a year, 1 inch in 16 miles, or 1 drop in 16 gallons. Another solution might be to express risk in terms of the number of persons who might be affected per year or per hypothetical 70-year lifetime. Even more difficult to communicate is the fact that a one-in-a-million risk estimate currently is not an estimate of actual risk, but a statistical upper bound on the likelihood that a risk could exist; that is, the actual risk is likely to be much lower, and it could be zero, but it is quite unlikely to be higher.

Many people perceive the reduction of risk by two or more orders of magnitude as though each "power of ten" reduction were an equivalent reduction in risk. A better way to illustrate orders of magnitude of risk reduction for linear dose-response effect is shown in Figure 3.1: the bar graph depicts better than words that a reduction in risk from one in 1,000 (10^{-3}) to one in 10,000 (10^{-4}) is a reduction of 90% and that a further reduction to one in 100,000 (10^{-5}) is a reduction 10-fold less than the first reduction of 90%, i.e., a 9% reduction in the original risk. The amount of the risk reduction associated with lowered emissions and exposures is a much more meaningful concept to communicate verbally and graphically than estimates of absolute risk levels, such as 10^{-5}.

A different proposal for communicating risk magnitude is to use time intervals, which might be better understood than numerical probability estimates. Commissioner Goldstein indicates that converting probabilities per unit of population to periods per event, such as one death expected in 3,500 years, substantially altered the perception of threat (Weinstein et al. 1996). The city of Columbus, Ohio, did an analysis estimating that one death would occur in Columbus in 204 years from an additional cancer risk at the theoretical one-in-a-million level, compared with frequencies of several deaths per day or every few days for measurable risks, such as ordinary rates of heart disease, cancer, homicide, and automobile collisions. The mayor of Columbus, Gregory Lashutka, in testimony before the Commission, stated that that analogy helps citizens to understand the magnitude of the effects that any federal or state regulation concerning the environment, transportation, labor, or education might have on the community. We recommend expressing risks both as numbers of events in an actual exposed community or on an annual basis and per million hypothetical people over a lifetime.

Using comparisons to explain the magnitude of risks will be increasingly important as advances in analytic chemistry improve our ability to detect smaller and smaller amounts of chemicals in air, water, and other media. This phenomenon of a plummeting "nondetectable" level or a "vanishing zero" poses a problem, particularly in the assessment of risks associated with human carcinogens, when no level of exposure is assumed to be without risk.

Risk comparisons can be helpful, but they should be used cautiously and tested if possible. There are proven dangers in comparing familiar and unfamiliar risks, natural and manufactured risks, and vol-

untary and involuntary risks, such comparisons can be perceived as minimizing a risk (NRC 1989). It is sometimes difficult to find risks that are sufficiently similar to make a comparison meaningful. In general, comparisons of unlike risks should be avoided; they are often perceived as manipulative and confusing. Comparisons of risks associated with chemically related agents, risks associated with the same agent with different exposure sources, risks related to different kinds of agents with the same exposure pathway, or comparisons of different agents that produce similar effects can improve communication. Those comparisons are better because the qualitative characteristics are similar.

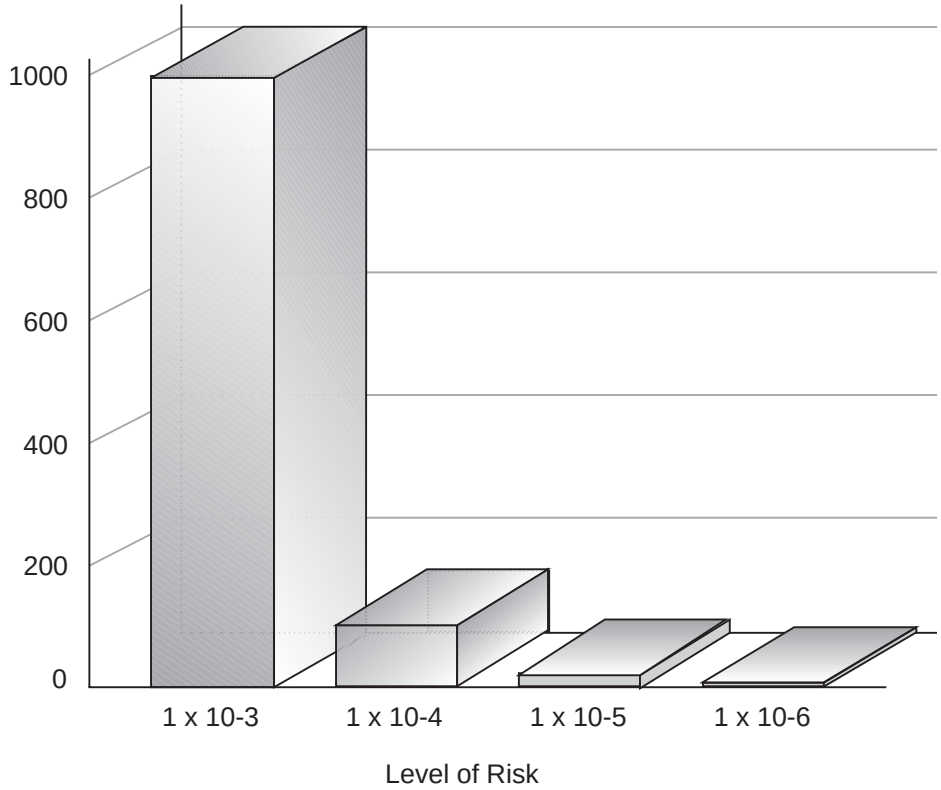
Risk comparisons can either improve or hinder risk communication. Testing messages that use risk comparisons, even informally, can help to avoid miscommunication and misunderstanding.

Need for a Common Metric

Finding

Chemicals suspected of causing cancer are regulated by assuming that every exposure has some risk. In contrast, chemicals suspected of causing other effects, such as developmental or reproductive toxicity, are regulated by assuming that there is a safe level of exposure. That simple dichotomy is not fully supportable by current scientific evidence. Furthermore, it results in expressions of risk for cancer and for other kinds of toxicity that cannot be compared and in striking discrepancies among maximal exposures considered to have negligible risk. These discrepancies are particularly salient when the same chemical has both carcinogenic and noncarcinogenic effects.

Figure 3.1 Reducing risk by orders of magnitude is *not* equivalent to linear reductions.



Recommendation

To assist in comparative risk assessment and risk communication, a common metric for comparing health risks should be sought by environmental protection and public health agencies. The Commission recommends that two complementary approaches be evaluated: (1) EPA's margin-of-exposure approach, which compares exposure levels of a chemical associated with specific carcinogenic or noncarcinogenic health effects to actual exposure levels; and (2) the margin-of-protection or safety factor approach, which is currently used everywhere to set "safe"

exposure levels for chemicals causing noncarcinogenic effects, and could be applied as well to carcinogens here in the U.S. as it is in many other countries.

Having a common metric with which to compare the health risk implications of actual exposure concentrations with exposure concentrations thought to be associated with negligible risk, and exposure concentrations shown to be associated with toxicity of various kinds would have important advantages over the present situation:

- *Harmonizing risk assessment methods for carcinogens and noncarcinogens might permit noncarcinogens greater emphasis than they now receive.*

- *Using a common metric for both carcinogens and noncarcinogens could improve risk communication.* The differences between toxic exposure levels, actual exposure levels, and exposure levels considered to pose negligible risk could be compared more easily for all types of exposures and health effects. Discrepancies in the size of acceptable margins of exposure or margins of protection for different chemicals and different effects would be highlighted. There is often no margin between the clinically manifest effect levels of section 109 criteria air pollutants and actual exposures, especially in areas where levels exceed the national ambient air quality standards. In contrast, there is a 1,000- to 100,000-fold difference between the concentration that would affect 10 percent of people (ED_{10}) and the virtually safe doses of hazardous air pollutants calculated to pose an incremental lifetime cancer risk of no more than one in 10,000 to one in one million. That discrepancy is illustrated by a comment from the Health Effects Institute: the number of excess annual deaths in Philadelphia attributed to airborne particulate matter at an exposure level equal to its national ambient air quality standard is greater than the cancer incidence attributable to any individual section 112 hazardous air pollutant ("air toxic") for the entire nation, based on an EPA study (EPA 1996a).

- *The distinct but complementary roles of risk assessment and risk management would be transparent.* Identifying a chemical's relevant effects and the doses at which they occur would be a science-based activity (as it is now), and drawing conclusions about levels of exposure that might be associated with negligible risk would clearly be a risk management responsibility, requiring consensus as to the level of protection that is desired and feasible for different effects and for different situations and population groups. For example, FDA uses a larger margin of protection for a substance in food that is consumed by most of the U.S. population than OSHA does for protection of workers exposed to a solvent used in industrial processes. OSHA has to consider feasibility when it sets workplace standards; FDA considers only health impacts and deals with much larger populations with greater variation in susceptibility. It is reasonable for an agency to choose different allowable exposures for different effects, such as, specifying a more stringent standard to protect against lung cancer than reversible breathing problems.

- *It would be easier to compare cancer risks to noncancer risks for making risk-management decisions.* For example, it might be easier to decide whether a hazardous-waste site classified as posing an upper-bound incremental lifetime cancer risk of 1 in 10,000 should receive a higher or lower priority for cleanup than a site classified as having a noncancer hazard index of 10. The same problem arises when residual risks from hazardous air pollutant emissions at various facilities are characterized and compared (see the section on EPA and residual risks on page 109).

- *It is misleading to express cancer risk in a manner that implies great precision, when cancer risk often is based on little or no more information than is available on noncancer effects.* Risks from carcinogens are generally expressed in terms of upper-bound or worst-case predictions of incidence or numbers of deaths per unit of the population over 70 years. Although those predictions are not intended to be interpreted as actual or measurable cancer risks, they often are, even when the information base is restricted to observable dose-response data from rodent bioassays. In only a limited number of cases have additional mechanistic data aided in extrapolating between species and from high to low exposures.

Two potentially useful common metrics exist that we believe should be evaluated: the margin of exposure and the margin of protection.

Margin of exposure (MOE). A margin of exposure is a ratio defined in EPA's *Proposed Guidelines for Carcinogen Risk Assessment* as a dose derived from a tumor bioassay, epidemiologic study, or biologic marker study, such as the exposure associated with a 10% response rate, divided by an actual or projected human exposure (EPA 1996b). Lower margins of exposure pose greater concern. For example, EPA determined that a margin of exposure of only 10 exists for neurotoxicity in workers exposed to acrylamide while engaged in sewer grouting applications. Thus, the typical sewer grouting worker may be exposed to levels of acrylamide close to the level estimated to produce neurotoxicity in humans (October 2, 1991 at 56FR49865).

Margins of exposure are specific to individual situations and do not by themselves communicate the likelihood of risk in an exposed population. Margins of exposure simply reflect the ratio between a level associated with observed toxicity in humans or animals and the actual level of exposure in a particular situation. Risk managers and stakeholders can evaluate a particular margin of exposure and decide whether it reflects an appropriate level of protection given the relevant risk management criteria. Those interpreting a margin of exposure in risk characterization and risk management can consider factors such as the slope of the dose-response relationship in the observable range, mode of action, nature and extent of the uncertainties, human variation in susceptibility to the response of concern, human sensitivity as compared with laboratory animals, and comparisons with margins of exposure of alternatives or other relevant hazards.

A margin of exposure cannot be equated with safety. Further discussion with stakeholders is necessary, as part of the risk communication and risk management processes, to consider likely levels of risk or safety and influence priorities for action. Typically, margins of exposure are much smaller in the workplace than in community settings.

Margin of protection (MOP). The margin of protection or safety factor method is used to derive estimates of acceptable daily intakes (ADI), reference doses (RfD), or reference concentrations (RfC) for noncancer effects. Those values represent chemical exposure concentrations that would be associated with negligible risk. A no-observed-adverse-effect level (NOAEL),[1] a lowest-observed-adverse-effect level (LOAEL), a benchmark dose, or some other level derived experimentally is divided by factors thought to account for variability and uncertainty to obtain the ADI, RfD, or RfC. Typically, a margin of protection is 1,000 when three safety factors of 10 each are used and multiplied together. If the resulting ADI, RfD, or RfC in food, water, soil, or air is not exceeded, adverse health effects are so unlikely that exposures are considered "safe." These negligible risk levels are inversely related to a chemical's toxic potency. This method is used in Canada, Europe, and many other countries for carcinogens as well as for chemicals causing other types of adverse effects. It is used in the U.S. primarily for noncarcinogens.

Several factors affect the interpretation of margins of exposure and margins of protection:

- *Severity of the health effects being compared.* Margins based on nasal irritation, for example, are not easily compared to those based on lung cancer or reproductive toxicity.

- *The exposure concentration associated with observable health effects that is chosen as the basis for deriving the margins (the "point of departure").* It may be difficult to compare a margin of protection derived from a NOAEL to a margin of protection based on a benchmark dose. Not only are NOAELs and benchmark doeses derived differently, NOAELs are associated with some level of safety because no effects are being observed, while benchmark doeses and ED_{10}s relate to observed effects. An additional safety factor of 10 is routinely used if the LOAEL is used instead of the NOAEL.
- *Dose-response relationships.* Dose-response relationships influence the interpretation of margins of exposure and margins of protection; as mechanistic knowledge increases, more sophisticated interpretation is facilitated. Margins of exposure and margins of protection are the same only when dose-response relationships are linear. If a contaminant has a nonlinear dose-response relationship, a margin of exposure of 10 might confer a margin of protection of, perhaps, 100 or more. It is important to try to evaluate the nature of the dose-response relationship when discussing the acceptability of a particular margin of exposure; doing so is difficult when extrapolating way below the range of exposures that produce observable effects in rodent bioassays or epidemiology studies.
- *Exposure duration and latency.* Differences in duration of exposure and in latency until effects become manifest complicate comparisons of dose-response relationships.

In the end, both margins of protection and margins of exposure can provide useful starting points for a broad range of stakeholders to query experts and regulators about risks of various adverse effects from individual agents or multiple agents and help build a consensus about risk management options and priorities.

Comparative Risk Analysis for Risk Management Priority Setting

Priority setting is necessary when money, time, and staff are limited. The Carnegie Commission on Science, Technology, and Government, the National Academy of Public Administration, many members of Congress, and Supreme Court Justice Stephen Breyer's book, *Breaking the Vicious Circle*, have recommended comparative risk assessment approaches for priority setting.[2] The process of comparing various types of risks includes problem identification, data collection and analysis, and risk ranking of environmental problems to developing an action plan and implementing new strategies for risk management and reducing risk. This process is a generic version of our Risk Management Framework for specific problems (Section 2).

Most comparative risk projects for priority setting have been conducted by state, local and tribal governments, typically led by one or more environmental protection, natural resource, or health agency. EPA's Regional and State Planning Division has provided grants, training, and problem-solving assistance. Our recommendation here is directed primarily at federal agencies.

Risk-Based Priorities and Resource Allocation

Finding

Federal regulatory agencies are confronted with many problems and issues related to health and environmental protection, but have limited time and resources for action. The risks associated with the problems and the resources available to act on them are often misaligned. EPA, state, local, and tribal comparative risk projects have been useful in identifying such mismatches and in refining the comparative risk process to better manage risks.

Recommendation

Federal regulatory agencies should try a comparative risk analysis approach on an experimental or demonstration basis to seek consensus on set-

ting priorities for risk management of environment, health, and safety hazards. The priorities, reflecting diverse stakeholder values and opinions, should influence agency resource allocation decisions and be fully discussed in Congressional oversight hearings. The Commission's Risk Management Framework—with its emphasis on context, total exposure, and early stakeholder engagement—should be useful.

EPA undertook some of the earliest efforts to use comparative risk assessment to rank environmental risks and set priorities for agency efforts. In 1987, EPA staff prepared a report, *Unfinished Business: A Comparative Assessment of Environmental Problems* (U.S. EPA 1987b), that identified risks receiving in their view inadequate attention from the agency. An important conclusion of the report was that the EPA's program priorities tended to reflect the public's perception of risks, rather than the most serious risks as judged by EPA scientists and staff. The Science Advisory Board reviewed that report and issued *Reducing Risk: Setting Priorities and Strategies for Environmental Protection* (EPA 1990). The Science Advisory Board emphasized the subjective nature of rankings and called for broad public participation in ranking environmental risks so that risk reduction policies based on imperfect and evolving scientific understanding and subjective public opinion might be more widely supported.

In 1995, EPA and Congress asked the Science Advisory Board to undertake an integrated ranking project as a follow-up to the risk rankings in *Reducing Risk*. The difference in those efforts and the EPA-funded state, local, and tribal comparative risk projects is the explicit incorporation of public values and perceptions of risk, a process of diverse stakeholder involvement, and inclusion of elected officials' representatives in the state, local, and tribal activities. As a result, it appears that the state, local, and tribal comparative risk assessment projects may have been more successful in influencing agency priorities and resource allocations. Unfortunately, legislative proposals requiring federal agencies to perform comparative risk analysis for priority setting and make appropriate adjustments in budget requests have had the same weakness. These proposals have not included stakeholders in the priority setting process and thus miss the opportunity to build public support for changes in funding allocations.

There is wide disagreement about the efficacy of using comparative risk analysis for setting priorities. In comments to the Commission, the Consumer Product Safety Commission and the Natural Resources Defense Council emphasized the limitation of comparative risk analysis and the need to provide agencies with some discretion in setting priorities. In contrast, the Chemical Manufacturers Association concluded that there has been sufficient experience with the comparative risk process to start using it to guide agency priorities. Of course, EPA priorities are often dominated by statutory and court-ordered deadlines, and Department of Energy priorities are influenced by Congressional appropriations and triparty agreements with state and federal regulators.

Comparative risk analysis for priority setting brings together science and public values by making clear what is known and what is not known about the environmental challenges we face. The comparative risk process includes organizing teams of agency and nonagency stakeholders, such as representatives of business and environmental groups; making a comprehensive list of environmental problems; assembling the available good information about the sources of the problems and the risks that they pose to human health, ecosystems, and quality of life; ranking the problems in order of the group's view of the risks posed; and using the rankings to guide strategic planning and budgeting. Methods for ranking the risks of identified problems have included voting by participants; formulas that rely more heavily on quantitative data; matrix-based discussions categorizing risks as high, medium, or low; decision-seeking consensus; and bargaining or tradeoffs among stakeholders. Comparative risk analysis for risk management tracks the six steps of the Commission's Risk Management Framework (see Section 2) and can mobilize and energize stakeholder participation.

Each federal agency will need to adapt the fundamental elements of the comparative risk ranking

approach to its mission, statutory mandates, and current and emerging responsibilities. At the federal level, agencies can substitute staff of authorizing committees of Congress for state and local representatives and can identify agency staff and affected stakeholders, including representatives of national and local environmental organizations, as participants on the basis of programs and projects of specific agencies. Depending on the agency, it will be important to include representatives from state, local, and other federal agencies with relevant programmatic responsibilities or interests. State and local participation will be especially important as roles and obligations change under the Unfunded Mandates Act of 1995, which places limits on the capacity of the federal government to implement new programs that will cost state and local governments over $50 million in any year, beginning with 1996.

Benefits other than priority setting often justify putting time and effort into the comparative risk analysis process (Minard and Jones 1993). Most comparative risk projects produce a catalog of the major environmental problems facing a state or locality, which can be a valuable resource for the public and for risk managers. Participants in a comparative risk project learn about a range of problems that might not be part of their daily interests or responsibilities. The comparative risk process improves understanding of competing priorities, provides an appreciation of the complexity of decision-making, and can stimulate new insights into solutions. As a result of increased communication among institutions and interest groups, new avenues of cooperation might be established. Adversarial relationships among interest groups and jurisdictional conflicts among agencies might not disappear, and could even be intensified, but comparative risk projects have revealed unexpected agreement among parties and enhanced understanding of differences in perspectives and values in some cases. Most important, experience has shown that the process itself can help to build coalitions that favor priority setting and shifting resources to the identified priorities. Broader public support for a common agenda might allow agencies, state legislatures, and Congress to move money and staff into priority problems with less litigation and less controversy. For example, Charles Kleeburg, director of the Seattle Drainage and Wastewater Utility, explained to the Commission that the city's success in forging consensus on ten priority problems that were acted on by the city government was a direct result of the influence and effectiveness of the comparative risk analysis process in the Mayor's Environmental Priorities Project. In contrast, testimony from EPA indicated that a great deal of controversy is generated when it tries to address problems that it knows are real but has not been directed by Congress to address.

Numerous challenges and limitations impede the usefulness of the process, as pointed out by Patricia Buffler and Carl Craner in testimony before the Commission about the California Comparative Risk Project. There is no guarantee that the process will produce consensus among stakeholders, agencies, and funding authorities. Resolving inconsistent data across problems, forcing all risks to conform to a common measurement, and integrating problems into a single list are important methodologic and political challenges. The degree of uncertainty varies across problems, making comparisons even more difficult. The process might not adequately account for environmental equity, emerging issues, and effects across jurisdictional boundaries. Those problems can result in some groups' objecting strongly to the rankings, in loss of opportunities for preventing future risks, and in the neglect of risks imported from or exported to other geographic areas. Lack of sufficient resources and time constraints can limit data collection, diminish the quality of data analysis, and hinder development of risk management strategies and recommendations. For example, changing the scope and criteria after a comparative risk project was well underway created conflict in California. For federal agencies, there may be additional problems of proposing changes to statutory mandates when priorities for resources change and in taking action in the absence of clear or explicit statutory direction.

The comparative risk process emerging from the

state, local, and tribal projects supported by EPA's Regional and State Planning Division constitutes a worthy starting point for federal agencies to use in ranking priorities and making resource allocation decisions. For example, the risk-based process being introduced by the Department of Energy's Environmental Management Program at the nation's nuclear waste sites is intended to test how well identification, analysis, and comparison of risks and remedies can be translated into budget decisions for those extremely complex sites. The Commission encourages federal regulatory agencies to continue to develop comparative risk approaches for priority setting.

Strategies for Managing Risk

Strategies for managing risk have centered traditionally on command-and-control regulatory programs and specific bright lines delineating between acceptable and unacceptable levels of cancer risk. Command-and-control regulatory programs have led to improved air quality, water quality, and better handling of solid and hazardous waste; however, additional ways of improving human health and environmental protection are becoming available and credible. Futhermore, use of risk estimates with bright lines, such as one-in-a-million, and single point estimates in general, provide a misleading implication of knowledge and certainty. As a result, reliance on command-and-control regulatory programs and use of strict bright lines in risk estimates to distingush between safe and unsafe are inconsistent with the Commission's Risk Management Framework and with the inclusion of cost, stakeholder values, and other considerations in decision-making.

Risk Management Options: Alternatives to Command and Control

Finding

Many risks to human health and the environment have been reduced over the last 25 years, primarily through command-and-control regulations of existing and new sources of emissions and through testing requirements for newly developed chemical products. In some cases, those practices have led to very high compliance costs and increased litigation, causing delays in human health and environmental protection. Performance goals for environmental protection can increase the flexibility risk managers and stakeholders have to pursue the most effective and efficient solutions. Having a range of solutions can facilitate decision-making when options to reduce or eliminate risk are identified. Implementation of the Government Performance and Review Act may provide a means of judging whether alternatives achieve environmental goals.

Recommendation

Risk managers and stakeholders should aggressively seek alternatives to command-and-control regulation to improve the efficiency and effectiveness of health and environmental protection and to reduce compliance and litigation costs. A sense of experimentation and a commitment to evaluation should be key elements of identifying and implementing alternatives. A safety net of command-and-control regulations should be maintained, however, to avoid reducing current levels of protection.

In the last quarter century, the United States has made extraordinary progress in human health and environmental protection as a result of substantial investments by governments and by industry and through effective public and political advocacy. We now have a system of regulatory controls, enforcement, and sanctions that has established a floor for environmental protection.

Command-and-control regulations set environmental standards that are enforced through penalties for violating permits. While this system has resulted in significant reductions in pollution, we appear to have reached a point of diminishing returns in many situations, in that each incremental improvement in community health and environmental risk reduction comes only with a large increase in control costs. In those cases, the benefits of additional regulation may be slight because so much risk reduction has already

been achieved. In other cases, the cost of risk reduction is aggravated by the rigidity of the underlying command-and-control regulatory system. Rule-makings and permitting processes become de facto design standards requiring the use of specific technologies for pollution control. There may not be adequate flexibility for tailoring remedies to reflect the circumstances of individual sources and locations, including the relative advantages that different companies might have in choosing risk reduction options. Ironically, some companies, especially small businesses, may prefer design or technology standards because resources for research and innovation are limited.

While government must set environmental and worker protection standards, there are important economic and environmental benefits in allowing risk managers and stakeholders greater flexibility in determining how to meet those standards. Greater flexibility must be coupled with agency monitoring and enforcement, however, to ensure that the expected level of environmental protection is being achieved. In addition, the fairness of who benefits and who pays the cost under alternative environmental protection approaches should be compared with the equity of who benefits and who pays the cost under the status quo. Environmental accounting, industrial ecology and life-cycle analysis, and environmental audits are emerging analytic tools that can assist in understanding the interaction between economic activity and environmental protection efforts.

For progress to continue in protecting human health and the environment, we must look beyond command-and-control regulatory programs for managing risk. The call for new tools to manage risk was particularly strong in presentations to the Commission outside Washington, DC. Walter Buckholz from Exxon Chemical Company in Houston, Texas, testified that command-and-control regulations were not controlling some contaminants well and called for the use of performance standards as more cost-effective. Jonathan Howes, Secretary of the North Carolina Department of Environment, Health, and Natural Resources, reported that a National Academy of Public Administration committee concluded that many businesses have chosen to exceed environmental standards if they can use their own strategies to achieve established pollution reduction targets. In other testimony, representatives of federal agencies emphasized their commitment and cited their projects aimed at finding additional options for achieving environmental and worker protection.

Education and information, incentives, monitoring, research, and surveillance are methods that may be helpful elements in risk management options. Right-to-know requirements are measures that rely on information and education for achieving risk reduction and environmental protection. Market-based incentives, subsidies, alternative compliance, and consensus, mediation, and dialogue projects are incentives that can be used when and where they make sense in responding to additional risk reduction opportunities. Research, monitoring, and surveillance are important ways of increasing knowledge about the problem, tracking the change that may be occurring, and observing health effects. When alternative tools for risk management are used, it is important to evaluate them for reliability in meeting or exceeding environmental goals, feasibility of implementation, and general effectiveness and efficiency.

The National Environmental Partnership Program System, started by EPA and the states in 1995, may provide a way to measure the success of the increasing use of alternatives to command-and-control regulations. The system is designed to give states greater flexibility to focus resources on the most serious environmental problems while enhancing accountability to the public and taxpayers for the improvement of environmental conditions and trends. Six states signed pilot Environmental Performance Agreements in 1996 and approximately 30 states are negotiating agreements in 1997. The development of core program performance measures will be an important tool for judging the functioning of state programs. Similarly, the Government Performance and Results Act of 1993 requires EPA to establish performance goals and accountability in carrying out the environmental statutes adopted by Congress.

Tools for Understanding Consequences of Economic Activity and Environmental Protection

Environmental Accounting. There is a movement from traditional accounting systems toward "environmental accounting" for both national and business accounts. In June 1995, EPA published *An Introduction to Environmental Accounting as a Business Management Tool: Key Concepts and Terms* (EPA 1995c). Many private-sector and private-public partnership forums are addressing this topic.

In traditional accounting of revenue, expenses, and net income of businesses, energy costs are lumped into overhead. Effects on and uses of natural resources—such as air, rivers, soils, and other environmental components—are neglected altogether. The challenge is to incorporate *all* costs involved in design, production, use, disposal, and reuse so as to arrive at a life-cycle analysis of a product or process. Assigning values to various environmental assets used and to real or potential environmental effects that have varied probabilities is problematic, however. Those assigned values may well drive the results of the analysis. Nevertheless, the process of environmental accounting can link environmental costs with activities and products and provide information that results in win-win opportunities to increase operational efficiency, improve worker safety, enhance product quality, and meet environmental protection goals. Unfortunately, bankers and investment advisers have been slow to encourage investments in these cost-saving initiatives. The President's Council on Sustainable Development (1996) recommended that national business associations provide technical assistance to companies interested in identifying environmental management costs and innovative ways to increase profits by reducing energy and materials use while better protecting public health and the environment. We agree.

Industrial Ecology and Life-Cycle Analysis. Proponents of industrial ecology envision a closed-loop system in which no resources are depleted; that is, all materials are perpetually reused, and no waste is produced or discarded. The loops might be closed within a factory, among industries in a region, or within national or global economies. Industrial ecology would integrate the producing and consuming segments of an economy to optimize the use and recycling of industrial materials and products. "Benign by design" chemistry, in which synthetic chemistry is designed to use and generate fewer hazardous substances, is a step toward achieving a closed-loop system. Quad Graphics, a Wisconsin based printing business, and Stonyfield Farm, a yogurt producer located in New Hampshire, are trying to establish eco-industrial parks where companies with compatible production processes can use resources more efficiently and reduce waste. Life-cycle analysis is important to the implementation of industrial ecology, because it provides information that can be used to understand the consequences of choices among materials, product designs, and process designs and to understand the fate of products when they are finally discarded by consumers. Life-cycle analyses have been mandated in the European Community. Nevertheless, industry representatives emphasize that life-cycle analysis relies on many assumptions and needs further research and development before it can be a reliable and cost-effecive tool.

Environmental Audits. Audits by industry and by third parties are another tool for influencing corporate compliance with command-and-control regulations, especially when penalties are eased for self-disclosed violations. Audits also allow emitters to highlight voluntary reduction of pollutant emissions to the air, water, and land. Environmental audits have become controversial with the passage of recent state legislation providing blanket protection from penalties for self-disclosed violations.

Using Education To Manage Risk

Right-To-Know Requirements. EPA's Toxic Release Inventory (TRI), mandated by the Superfund Amendments of 1986, and California Proposition 65 require the disclosure of information about chemical releases to the environment and labeling of chemicals in products, respectively. Those right-to-know laws educate the public and rely on attitudes toward toxicants

to encourage industry to reduce or eliminate their use or release.

The TRI is an annual measure of chemicals used, manufactured, transported, or released into the environment by facilities in communities throughout the United States. The 1995 TRI included approximately 600 chemicals. The TRI allows EPA, the states, industry, and the public to gauge industry's progress in reducing chemical use and waste generation. Reported toxic releases have declined by nearly 44 percent between 1988, the baseline year, and 1994, the last year for which data are available. Several companies have reported success in achieving a voluntary 75% reduction in toxic air emissions since 1988.

In the case of Proposition 65, the requirement to warn people about exposures to chemicals known to cause cancer, birth defects, or other reproductive harm has been an incentive to businesses to eliminate such chemicals or reduce exposures and associated risks below the bright lines for cancer and reproductive risks. Rather than relying on command and control, Proposition 65 uses disclosure of information and labeling requirements as risk management tools. Proposition 65 places the burden of proof of safety on manufacturers rather than on government agencies, requiring businesses to present a risk-based analysis to avoid having to label their products and substances as cancer-causing or reproductive toxicants. David Roe of the Environmental Defense Fund told the Commission that a key decision by the state environmental protection agency was to put the bright line for cancer risk at 10^{-5}, rather than 10^{-6} as proposed by environmentalists or 10^{-4} as proposed by business. Proposition 65 has been criticized by some in industry as using questionable science to produce faulty warnings. Others have reported that the responsible agency welcomes good risk-based analyses. The California Environmental Protection Agency's Risk Assessment Advisory Committee has called for the use of much more scientific information in evaluating cancer and reproductive hazards under Proposition 65 (RAAC 1996).

Using Incentives To Manage Risk

Market-Based Incentives. Market-based incentives rely on economic motivators to encourage environmental protection and cost-effectiveness. A prominent example of market-based incentives to achieve environmental protection is the use of tradable sulfur dioxide emission allowances to reduce acid rain. This program, mandated under the 1990 amendments to the Clean Air Act, permits electric utilities to reduce their emissions of sulfur dioxide, the precursor to acid precipitation, below allowable levels and sell the unused emission allowances to companies whose cost of compliance is substantially greater. The program caps aggregate sulfur dioxide emissions well below historical levels, while allowing emission reductions to be achieved more cost-effectively than by requiring every company to install the most expensive sulfur dioxide control technology. The cost of a ton of sulfur dioxide emission allowances has fallen well below projected costs, presumably reflecting technological advances. Similar programs are being developed to reduce regional nitrogen oxide emissions. The use of caps and tradable pollution allowances may not work well in some cases, such as toxic air pollutants, where sources create highly localized risks.

Other Incentives. In addition to the use of direct economic incentive policies, other positive incentives are available to encourage pollution prevention, some of which EPA has implemented. For example, some pesticides that require approval by EPA before they can be distributed, used, or sold can be given priority for approval if they are deemed safer for human health and the environment and thereby reach the marketplace faster than other pesticides. Safer products could receive more favorable treatment if labelling regulations are implemented, such as authority to use a special label, to give them greater prominence in the market. To encourage pollution prevention by manufacturing facilities, businesses could be given tax incentives to replace old facilities with new, cleaner processes that do not generate waste and pollution.

Another example pertaining to Title V permits under the Clean Air Act is EPA's Pollution Prevention in Permitting Pilot Project (P4 Project) with Intel Corporation, the Oregon Department of Environmental Quality, and the Northwest Pollution Prevention Resource Center as private, public, and nonprofit sector partners. The pilot is now being extended to five other companies in EPA regions 1, 4, 6, 9, and 10. The aim is to reduce production of air emissions, rather than control their release in ways that generate solid waste or waste water.

Subsidies. Subsidy programs can be powerful tools for reducing pollution while selectively encouraging economic activity. For example, agricultural land retirement programs have prevented excessive soil erosion and damage to water bodies and wildlife habitat. Government purchasing practices can also encourage the development of markets for products that are environmentally more sound. Care is needed to avoid excessive acquisition costs for products with small markets and to avoid buying products with one attractive attribute but other unfavorable characteristics, however. Some subsidy programs have had detrimental effects on the environment.

Alternative Compliance. Alternative compliance provides greater flexibility to industry by allowing choices in achieving emission or risk reduction specifications. Designed to achieve higher levels of environmental protection at lower cost and to foster integration of local concerns in environmental risk management decisions, this option can result in substantial savings for industry, communities, or any regulated entity that participates. For example, EPA's Project XL allows six companies (Intel Corporation, Anheuser Busch Companies, HADCO Corporation, Merck & Co., Inc, AT&T Microelectronics, and 3M Corporation) and two government agencies (California's South Coast Air Quality Management District and the Minnesota Pollution Control Agency) to experiment with different strategies for improving environmental protection. As of 1996, some projects were making faster progress than others. Intel negotiated the first agreement, but it was criticized by a number of organizations not included in the process as not achieving greater environmental protection. We recommend use of the Commission's Framework to address multimedia problems and to incorporate stakeholders. As noted in Volume 1, some of the difficulties with Project XL have arisen from the stakeholder involvement process used by EPA. Government also can provide greater compliance flexibility for those attempting to use innovative pollution reduction and control technologies. Use of the concept of a bubble to encompass a facility or geographic area and seek the best way to reduce a pollutant or pollutants within the bubble has also provided flexibility in compliance.

Consensus, Mediation, and Dialogue Projects. Negotiated rule-making and dialogue projects, such as EPA's Common Sense Initiative, offer opportunities for stakeholders to design new standards and solutions that protect human health and the environment more reliably and with greater cost-effectiveness and public acceptance. The Office of Management and Budget (OMB) ruled in 1996 that the cap on numbers of chartered advisory committees no longer applied to negotiated rule-making processes. With the Common Sense Initiative, begun in 1994, EPA has convened consensus-oriented teams of stakeholders to look for opportunities to turn complicated and inconsistent environmental regulations for six major industries—automobile manufacturing, computers and electronics, iron and steel, metal finishing, petroleum refining, and printing—into comprehensive sector-specific strategies for environmental protection. In 1996, the state of Michigan withdrew from the automobile manufacturing initiative, saying EPA was not providing sufficient flexibility. Several industrial sectors have launched their own initiatives, such as Responsible Care by the Chemical Manufacturers Association.

Using Monitoring, Research, and Surveillance To Manage Risks

Monitoring. Monitoring emissions and ambient conditions has been a long-term component of command-and-control regulatory programs and other efforts to characterize the status of the environment.

Monitoring can also be a useful risk management tool when a community is skeptical or suspicious of the effectiveness of risk management actions, making alternatives to traditional command-and-control programs more acceptable.

Research. Research can be an important management option when lack of knowledge about the source of a problem or its impacts make a course of action unclear (see Value of Obtaining Additional Information on page 91). EPA's cooperative effort with scientists to identify and design appropriate research projects on hormonally active agents, as directed by Congress, is an example of research to inform future risk management decision-making.

Surveillance. Health surveillance is an under used technique for observing effects of pollution on human health. While the incidence of cancer from environmental toxicants may be so small as to be unobservable, surveillance of other health effects such as asthma or heart attack death rates may lead to identification of problems needing additional risk reduction.

Bright Lines for Risk Management

Finding

There is much controversey about bright lines, "cut points," or decision criteria used in setting and evaluating compliance with standards, tolerances, cleanup levels, or other regulatory actions. Risk managers sometimes rely on clearly demarcated bright lines, defining boundaries between unacceptable and negligible upper limits on cancer risk, to guide their decisions. Congress has occasionally sought to include specified bright lines in legislation. A strict bright-line approach to decision-making cannot explicitly reflect uncertainty about risks, population variation in susceptibility, community preferences and values, or economic considerations, however, all of which are required by the Commission's Risk Management Framework.

Recommendation

Bright lines can be helpful as guideposts in screening risk assessments (see Tiered Scheme for Determining and Managing Residual Risks on page 109). Bright lines or ranges of bright lines tied to specific exposure or contaminant concentrations can be used for compliance. In addition to bright lines intended to protect the general population, bright lines can be used by regulators to protect especially susceptible subpopulations, such as young children, pregnant women, or adults with lung disease. Because of the need for flexibility, Congress should leave the establishment of specific bright lines or ranges of bright lines to the regulatory agencies.

A "bright line" is a single numerical value between unacceptable and negligible magnitudes of exposure or of risk. Bright lines are chosen to provide pragmatic definitions of "safe" and "unsafe" for those making risk management decisions and especially for those implementing, monitoring, and enforcing those decisions. An example of a measurable bright line is a tolerance level of 20 parts per billion for the carcinogen aflatoxin, which is produced by a fungus that grows on peanuts and corn. Peanut and corn crops are tested for aflatoxin contamination and if the level is greater than 20 parts per billion, they cannot be sold or consumed. If the level is less than 20 parts per billion, the crops are considered fit for human consumption.

Bright lines tied to upper-bound estimates of excess lifetime cancer risk which cannot be measured, are limited in their usefulness. Consider, for example, an excess lifetime cancer risk of 10^{-5}: if a risk assessment predicts that more than one case of cancer is likely to occur as a result of exposure to a substance in a population of 100,000 people exposed to it, that risk may be judged unacceptable and protective action be required; a predicted risk of less than 10^{-5} may be considered negligible and require no protective action. Risk-based bright lines must be converted to regulatory standards expressed as measurable exposure, emission, or contaminant concentrations for implementation and compliance. Regulated parties are expected to demonstrate compliance that estimated risks are below the bright line by showing that measured or estimated exposure concentrations are below the regu-

latory standard to operate a manufacturing facility, introduce a new product to the market, or sell foods with low concentrations of contaminants.

Risk-based bright lines are generally compared to single point estimates of risk to judge safety; *Science and Judgment in Risk Assessment* characterizes such bright lines and point estimates of risk as "magic numbers" whose use is inconsistent with knowledge about the variability and uncertainty inherent in estimates of risk (NRC 1994a). Strict use of bright lines is also inconsistent with the Risk Management Framework and with the inclusion of cost and other considerations in decision-making.

Several major problems arise in using of bright lines tied to risk levels. The all-or-nothing nature of use of a bright line could be misunderstood and construed to imply that there is an exact boundary between safety and risk, even though risk-based bright lines are burdened by all the uncertainty, variability, and assumptions inherent in cancer risk estimation. Risk assessments themselves can be manipulated so that their results emerge 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. As Roger Pryor, executive director of the Missouri Coalition for the Environment, testified before the Commission, health considerations, cost, and cultural differences all play a role in risk management decisions.

Ranges of bright lines have sometimes 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 risk assessment of the site produces an upper-bound lifetime incremental cancer risk estimate not exceeding 10^{-6}. The site is considered to pose 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 case by case.

Congress has included bright-line risk provisions in several legislative bills in recent years. In the 1990 Clean Air Act amendments, Congress specified a quantified risk level, when it mandated the development of a strategy for evaluating residual risks after maximum available control technology (MACT) implementation based on an incremental lifetime cancer risk of 10^{-6} (see Tiered Scheme for Determining and Managing Residual Risks on page 109).

In addition to ranges of bright lines, multiple bright lines should be considered. For example, Accounting for Differences in Susceptibility on page 71 discusses the need to consider sensitive subpopulations in risk assessments. The results of such risk assessments 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. EPA's deputy administrator, Fred Hansen, noted in his testimony before the Commission that getting away from single bright lines would be consistent with incorporating environmental justice considerations into risk management.

As noted above, regulatory standards expressed as contaminant concentrations are much easier to implement than risk levels. Risk managers are accustomed to the clear guidance provided by regulatory standards, expressed as emissions or exposure concentrations, for implementing and determining compliance. Measurable contaminant concentrations—such as permissible exposure limits or threshold limit values in the workplace, action levels for food contaminants like aflatoxin on peanuts or mercury in swordfish, and national ambient air quality standards for carbon monoxide or ozone in air—are intended to provide assurance that risks will be negligible so long as contaminant exposure concentrations are below the standards. Small quantitative differences from those standards, whether

above or below, can make a big difference in whether protective actions are taken, although some discretion may exist, analagous to failing to arrest a driver traveling at 57 miles per hour in a 55 mile-per-hour zone. Such regulatory standards reflect some judgment about what exposure constitutes negligible risk (or, in other cases, technologic feasibility).

Judicial Review of Regulatory Decisions to Manage Risk

Issues of judicial review that were raised by the 104th Congress—in the context of "regulatory reform" legislation and amendments to the Administrative Procedure Act (APA)—were carefully analyzed, vigorously debated, and are likely to be revisited by Congress. Those issues focused debate on the proper role of judicial review of agency action in the regulatory process.

Conceptually, judicial review is the check by the judicial branch on agency activity at an appropriate stage of the administrative process, and in an appropriate manner and degree. Agencies are authorized to act and promulgate regulations under enabling statutes passed by Congress. The various enabling statutes also grant the right and limit the extent of review of agency action by courts. Both agency action and judicial review of regulatory rulemaking are governed by the provisions of the APA. A party that is affected by agency action can seek judicial review of that action in court when all other administrative remedies and appeals have been exhausted. A preliminary, procedural, or intermediate action by an agency that is not directly reviewable by a court is subject to review under the APA only upon final agency action, however, so that it will not interrupt the regulatory process prematurely.

A reviewing court adjudicates procedural issues, interpretations of constitutional and statutory provisions, and determinations of the meaning or applicability of the terms of agency action. It can compel agency action unlawfully witheld and hold agency action to be unlawful if the court finds it to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law or in observance of procedure required by law. Moreover, when a reviewing court considers the record developed through formal agency hearings (formal hearings are required under certain enabling statutes), or when "substantial evidence" is otherwise required by statute, the court can hold agency action unlawful if that action is not supported by substantial evidence.

The Commission carefully considered these issues and the effect of each on the regulatory rule making process. In short, as discussed below, we submit that legislative initiatives should not provide for premature interruption of the administrative process nor expand the nature and extent of judicial review in ways that will require courts to devote substantial time and resources to the oversight of agency compliance with detailed procedural requirements or the resolution of complex scientific issues, but should consider the use of alternatives that assure rational and cost-effective regulatory action.

Premature Interruption of the Administrative Process

Finding

Interlocutory, or intermediate, appeals of discrete issues prematurely interrupt the administrative process.

Recommendation

Judicial review should be available only after agency action is complete and all administrative remedies have been exhausted.

Historically, provisions for judicial review under the APA grant review of the rulemaking record for "final agency action." This practice limits parties from interrupting the administrative process by seeking judicial review of discrete issues until all other administrative remedies have been pursued and exhausted. The APA provides a procedural safeguard that not only ensures the es-

tablishment of a rulemaking record but preserves that record. Thus, in the administrative context, an agency has the opportunity to apply its expertise, exercise its informed discretion, and create a more complete record, so that there is a full record upon which a court can adjudicate if judicial review is invoked.

Administrative procedure and practice require a party to challenge issues within the internal agency's deliberative process. Issues raised in an administrative proceeding allow an agency to monitor and correct its mistakes, omissions, or oversights. Without resorting to costly lawsuits and court-imposed remedies, the administrative review process provides agencies with an opportunity to research and develop more fully a record that identifies issues considered as part of the rulemaking process.

Proponents of some legislative initiatives maintained that they preserved the APA's premise that only final agency action is reviewable, but there were suggestions and debate as to what was considered to be final agency action. In various drafts of proposed legislation in the 104th Congress, a number of initial and intermediate agency determinations in the rule-making process were deemed final agency action. That would have created an opportunity to leap immediately out of the administrative context, where issues could be developed fully, and into the judicial arena, under the guise of final agency action. Interested parties could prematurely, and in piece-meal fashion, seek judicial review of discrete issues during the drafting and implementing of agency regulations, thereby delaying and hamstringing the regulatory process. Allowing premature interruption of the administrative process would impede development of the rulemaking record. As a consequence, judicial review would proceed on an incomplete record and issues would be adjudicated without a full and fair development of the underlying data and benefit of scientific analysis.

The Nature and Extent of Judicial Review

Finding

Legislation was proposed in the 104th Congress that specifies detailed requirements for making risk management decisions and for regulatory rule making. Those provisions would have governed the content of risk assessments and benefit-cost analyses, the procedures for preparing the analyses, and the regulatory decisions based on the analyses. Under accepted administrative law principles, all such requirements would be judicially reviewable, potentially leading to increased and more complex litigation over agency decision-making.

Recommendation

To be consistent with the Commission's Risk Management Framework, provisions that would make substantive risk assessments and benefit-cost analyses and their underlying factual support subject to expanded judicial review, as well as prescriptive and detailed procedures for conducting those assessments and analyses, should not be legislatively grafted across the board onto existing enabling statutes.

Although issues of scientific method and factual support for agency Finding s are currently subject to judicial review, courts typically have confined themselves to broad oversight in deference to agency scientific decision-making. Such deference allows agencies substantial flexibility in drawing upon their specialized expertise while ensuring that they follow accepted procedures and standards. Indeed, one of the primary reasons administrative agencies were created was to bring specialized expertise to bear on complex issues.

Some proposed legislative initiatives would have changed the nature and extent of judicial review of agency decisions. A legislative mandate to agencies to follow intricate, detailed procedures in developing benefit-cost analyses and risk assessments, combined with a change in the standard of judicial review of agency decision-making from the "arbitrary and capricious" standard to the less deferential "substantial evidence" standard (see below), inevitably would in-

volve courts in an investigation of much more than whether a rational basis exists to support an agency rule. In examining agency compliance with detailed substantive and procedural requirements under a broadened standard of review, courts would be likely to delve far more deeply into the many complex scientific issues affecting a rule. That change could create not only increased opportunities for litigation, but more complicated, more expensive litigation.

Some proposals also would have legislatively established criteria ("decisional criteria") that would be used to evaluate the validity of a rule and would supplement all existing enabling statutes.

Consequently, the Findings of cost and risk evaluations, conflicts with regard to scientific data, postulates representing the most reasonable inferences from supporting toxicologic and epidemiologic data, and determinations of whether an agency sufficiently used the appropriate information in its analysis would become part of the agency record subject to judicial scrutiny.

The Commission's Risk Management Framework (see Section 2) emphasizes the importance of evaluating information about risks, costs, benefits, and stakeholder values in regulatory decision-making. Legislatively specifying additional decisional criteria, however, such as requiring that incremental benefits exceed incremental costs, would limit agency flexibility in the rulemaking process and could expand the scope of judicial review. For example, section 109 of the Clean Air Act has been interpreted by the courts to preclude reliance on benefit-cost analyses. When EPA sets national ambient air quality standards under section 109, those standards must be based on evidence of adverse health effects and must be protective of even the most susceptible population subgroups. In contrast, the recently reauthorized Safe Drinking Water Act is an example of a statute that emphasizes the importance of considering costs and benefits in addition to feasibility and human health risks when setting drinking water standards.

We acknowledge that a compromise position was advanced that called for a program-by-program legislative approach tailoring decisional criteria to fit individual statutory schemes instead of insisting on an overarching mandate. We support a program-by-program legislative approach; however, to be consistent with the Commission's primary recommendation—the Risk Management Framework—we must emphasize the importance of providing flexible direction to agencies that enables them to consider risks, costs, benefits, and public values in decision-making without rigid decisional criteria.

Standard for Judicial Review

Finding

Proposed changes in standards for judicial review would reverse years of precedent and expand the historical role of the courts in reviewing agency action.

Recommendation

The standards by which courts review agency regulatory action, exercising great deference to agency interpretations of highly technical and scientific areas, should not be revised to broaden the scope of judicial inquiry.

Historically, the standard by which courts have reviewed most agency regulatory action has been the narrow "arbitrary and capricious" standard. Under the arbitrary and capricious standard, courts consistently have held that agencies are entitled to great deference with regard to factual questions involving scientific matters in their own fields of expertise. Such deference has extended to mixed questions of law and fact, at least to the extent they have been fact-dominated. For example, in *Northwest Motorcycle Association v. United States Department of Agriculture*,[3] an off-road vehicle (ORV) association petitioned for review of the United States Forest Service's decision to close forest trails to ORVs in designated areas of the Wenatchee National Forest. After exhausting all administrative remedies, the ORV association argued before the United States Court of Appeals for the Ninth Circuit that the Forest Service's conclusion was arbitrary and capricious.

In holding that the decision to close the trails was not arbitrary and capricious, the circuit court

limited its review to the administrative record as required under the provisions of the APA.[4] The court recited "evidence in the administrative record" that supported the Forest Service's Findings, and cautioned that "the court here is reviewing the evidence only to determine whether such evidence existed that justified the [Forest Service's] decision."[5]

The ORV association pointed to a number of alleged deficiencies in the administrative record. The court, however, replied that these deficiencies did not "mandate a Finding that the [Forest Service's] decision was arbitrary and capricious."[6] Rather, the court opined that the Forest Service, as fact-finder, was in the best position to determine the credibility of the evidence.[7] Acknowledging the long-standing precedents of judicial review under the APA, the court noted that it "is not empowered by [the APA] to substitute its judgment for [the] agency."[8] Thus, the basic standard for review of informal regulatory rulemaking is whether the agency action is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." The scope of review under this standard is a narrow one. In *Citizens to Preserve Overton Park v. Volpe*,[9] the United States Supreme Court held that agency action is entitled to a "presumption of regularity" and while that does not "shield [it] from a thorough, probing, in-depth review," the "ultimate standard of review is a narrow one." The reviewing court is to search for a "clear error of judgment," and cannot "substitute judgment for that of the agency."[10]

A starting point for analysis of the proper standard of review is an explanation of the type of Findings and type of file that are typical to informal rulemaking. The Findings and file reviewed under the arbitrary and capricious standard differ substantially from those required in formal adjudications under the APA.[11] The agency is not required to supply specific and detailed Findings and conclusions, but need only "incorporate in the rules a concise general statement of their basis and purpose." The agency need not discuss every item of fact or opinion included in the written comments submitted to it, although it must respond to significant comments and not be arbitrary and capricious. The "basis and purpose" statement must identify "what major issues of policy were ventilated by the informal proceedings and why the agency reacted to them as it did." In addition, the record "ordinarily will contain more generalized than specific information, may not contain information tested by cross-examination and will frequently contain much more conclusory information based on data gathered by interested parties."[12]

The court's paramount inquiry is whether a reasoned conclusion from the record as a whole could support and explain the agency's course of action.[13]

There have been proposals that would appear to greatly expand use of the broad "substantial evidence" standard now reserved for formal agency adjudications at the expense of the more narrow arbitrary and capricious standard. Proposed amendments to the APA would compel courts to hold agency action unlawful if the agency findings and conclusions are found to be "without substantial *support* in the rulemaking *file*, viewed as a whole, *for the asserted or necessary factual basis* …" [emphasis added]. Thus, the use of a substantial evidence standard apparently would be expanded beyond formal hearings to all rulemakings.[14]

While the substantial evidence standard is not a new standard of review, it typically (although not exclusively; see, for example, Toxic Substances Control Act) has been reserved for formal rulemaking and hearings. Courts have expressed some question about the application of the substantial evidence standard to informal rulemakings where the evidentiary standards and record development are different than in formal hearings (see *Aqua Slide 'n' Dive v. CPSC*[15] for an example). Courts that have historically deferred to agency interpre-

tation and action under an arbitrary and capricious standard[16] would, instead, have to find substantial support for that action in the agency file. Requiring a court to find substantial evidence lessens its ability to defer to agency decisions.

We believe that years of judicial and administrative precedent are well founded. Agencies, not courts, are better equipped to analyze highly scientific and technical findings. That precedent should not be legislatively overruled by expanding the standard of review.

Consensual Approaches as Alternatives to Increased Judicial Review

Finding

Consensual approaches to decision-making that could help assure rational and cost-effective regulatory actions affecting health, safety, and the environment are not commonly used as alternatives to increased judicial review.

Recommendation

Regulatory agencies should maximize consensual approaches to decision-making—such as negotiated rulemaking, alternative dispute resolution techniques, expert peer review, and informal practices such as meetings with groups of stakeholders (such as regulated parties and community representatives) and workshops—to explore alternative regulatory approaches.

Alternatives to judicial review that promote dialogue, interplay, and negotiation among regulators, the regulated community, and other stakeholders are used infrequently, other than in the context of agency policy initiatives. While variations of alternative dispute resolution procedures are sometimes used in the rulemaking and enforcement arenas, those uses clearly are the exception and not the rule.

For example, members of the regulated community, public-interest groups, and other interested parties engaged in a negotiated rulemaking process work together to analyze and discuss certain proposed regulatory initiatives. Those negotiated rulemaking sessions help the promulgating agency to better understand and develop possible alternatives to usual regulatory actions. EPA has embraced alternatives to regulatory controls with its Common Sense Initiatives, for example; for those stakeholders involved, the process has opened up communications with the regulatory agency, and it is hoped that fewer legal challenges will be filed in the course of the rulemaking process.

Chapter 3 Notes

1. See glossary.
2. Communicating About Risk by Comparing Different Kinds of Risk on page 41 of this report considers comparisons of specific risks for the purpose of risk communication.
3. 18 F.3d 1468 (9thCir. 1994).
4. Pursuant to 5 U.S.C. §706 of the APA, final agency action is reviewable; however, review is limited to the administrative record.
5. See 18 F.3d at 1473, fn 2.
6. *Id*. at 1476.
7. *Id*. at 1476.
8. *Id*. at 1476.
9. 401 U.S. 402, 91 S.Ct. 814, 28 L.Ed.2d 136 (1971).
10. See *Citizens to Preserve Overton Park*, 401 U.S. at 415-16, 91 S.Ct. at 823-824.
11. Formal agency adjudications, on appeal, are reviewed under the substantial evidence standard.
12. *Id*., at 1204.
13. See *Citizens to Preserve Overton Park*, 401 U.S. 402, 91 S.Ct. 814; *American Medical Association v. Matthews*, 429 F.Supp. 1179 (N.D. Ill 1977).
14. Although certain proposed legislation referenced "substantial support" rather than "substantial evidence," that legislation certainly appeared to call for a more intensive judicial scrutiny than is found in applications of the arbitrary and capricious standard.
15. 569 F.2d 831 (5th Cir. 1978).
16. Obviously, we are not addressing those specific statutes that individually require a substantial evidence standard. Nor are we suggesting that in future legislative initiatives Congress does not have the prerogative to require the substantial evidence standard. Rather, we are addressing a wholesale approach supplementing all existing legislation.

4 Uses and Limitations of Risk Assessment for Risk Management Decision-Making

Risk assessment is the systematic, scientific characterization of potential adverse effects of human exposures to hazardous agents or activities. Risk assessment as an organized activity of the federal agencies began in the 1970s. Earlier, the American Conference of Governmental Industrial Hygienists had set threshold limit values for exposures of workers, and the Food and Drug Administration (FDA) had set acceptable daily intakes of pesticide residues and food additives in the diet. In the mid-1970s, the Environmental Protection Agency (EPA) and FDA issued guidance for estimating risks associated with low-level exposures to potentially carcinogenic chemicals. Their guidance made upper-bound estimated risks of one extra cancer over the lifetime of 100,000 people (EPA) or 1 million people (FDA) action levels for regulatory attention. Estimated risks below those levels are considered negligible because they individually add so little to the background rate of about 240,000 cancer deaths per 1 million total deaths in the United States. The ultimate goal is, of course, to lower the background rate itself, a part of which can be attributed to an array of pollution-generating activities.

During 1977-1980, an interagency regulatory liaison group was actively engaged in bridging scientific, statutory, and policy responsibilities and activities of EPA, FDA, the Occupational Safety and Health Administration, the Consumer Product Safety Commission, and the Food Safety and Quality Service of the Department of Agriculture. The White House Office of Science and Technology Policy participated in the scientific discussions supporting risk assessment and risk management and published a scheme for identifying potential hazards, characterizing risks, and managing the risks, usually by reduction of use, emissions, or exposures (Calkins et al. 1980) (see Table 4.1).

That scheme makes clear that information about potential hazards can come from epidemiologic studies of workers and other people who are exposed to hazards, from direct experimental tests in animals and in cells in the laboratory, and from comparisons of chemical structures. The next stage involves the potency of the chemical (dose-response relationship), detailed understanding of exposure pathways, and the reasons for variation in responses among exposed people. Risk, then, is characterized both qualitatively (the nature of effects, the strength of evidence, and the reversibility or preventability of effects) and quantitatively (the probability of effects of various kinds and severities).

Performing full-scale risk assessments is a formidable task, requiring data, technical expertise, and peer review. Deciding to go forward with a risk assessment is a risk-management decision, and scaling the effort to the importance of the problem, with respect to scientific issues and regulatory impact, is crucial.

This section examines some of the risk assessment issues that are under debate, such as assessing toxicity and relevance to humans, accounting for variations in population exposures and susceptibility, describing uncertainties, evaluating risks of chemical mixtures, conducting ecologic risk assessments, and assessing risks associated with microorganisms and radiation.

Toxicity Assessment

Basing risk management decisions on observations and assumptions about the potential human toxicity of chemical exposures presents many challenges. The nature and magnitude of a population's exposures to chemical contaminants generally must be extrapolated from a few data on samples obtained from the contaminated sources (see Exposure Assessment on page 72). The nature of chemical hazards and the relation-

ships between exposures and effects often must be extrapolated to humans from toxicity tests in laboratory animals. In many cases, observations made using high doses in the laboratory or from high exposure levels in the workplace must be extrapolated to much lower environmental levels of human exposure. Extrapolating among species requires scientific information that can be used to make predictions about the relevance of a substance's toxicity in laboratory animals to human risk. Because the results of standard toxicity tests alone often do not provide enough information to make well-informed qualitative judgments about human relevance, testing strategies that rely on mechanism-based tests to evaluate substances' toxicity and carcinogenicity have been developed. Information about chemicals' modes of action can make important contributions to scientifically based human health risk assessment.

This section evaluates three issues: the use of detailed toxicity information to assess the relevance of rodent bioassay results to human cancer risk, the need for more toxicity testing of chemical mixtures and ways to evaluate their risks, and the need for risk assessments to consider information about variation in susceptibility to toxic effects.

Using Rodent Tests To Predict Human Cancer Risk

Finding

Chemicals that cause cancer in rodents are appropriately considered potentially carcinogenic in humans. Investigations of chemicals' mechanisms of action can greatly strengthen the link between findings in rodents and likely effects in humans. They can also provide biological plausibility for statistical associations in epidemiologic studies. However, some chemicals elicit tumors in rodents only through mechanisms or at doses that have been clearly demonstrated to be very different from mechanisms and exposures in humans. Regulatory agencies have been cautious in recognizing the distinctions and in issuing guidance on when such rodent responses should be discounted or disregarded.

Table 4.1. Framework for Regulatory Decision-Making.

Hazard Identification	Epidemiology Lifetime rodent bioassays Short-term, in vitro tests Structure/activity
Risk Characterization	Potency (dose/response) Exposure analysis Variations in susceptibility
Risk Reduction	Information Substitution Regulation/Prohibition

Recommendation

In general, tumors and other adverse effects observed in properly conducted animal bioassays should be considered predictive of similar effects or risks in humans. Chemicals found to elicit such effects should be regulated accordingly. If after adequate testing a chemical is found to produce only tumors that occur as a result of mechanisms or doses that have been clearly demonstrated to be not relevant to humans, that chemical should not be regulated as a carcinogen and should not require extensive risk assessment. Regulatory agencies should distinguish between tumor responses that are predictive and those that are not (see Table 4.2), and these judgments should be updated with advances in scientific knowledge about the underlying mechanisms.

The policy of presuming that a chemical that causes cancer when tested in laboratory rodents is potentially carcinogenic in humans is justified by considerable evidence and by the precautionary principle of being protective when uncertain. Rodent bioassays have played an important role in identifying human carcinogens numerous times. All 23 recognized human carcinogens are also carcinogenic in laboratory animals; for 18 of those, cancers occured in one or more organ sites in humans that are the same as those identified in the animal studies (see Table 4.3) (Rall 1988). There are other cases, however, where rodent tumor responses have been shown to be irrelevant to humans or may occur at doses far exceeding any recognized human exposures including workplace exposure. The Delaney clause prohibits chemicals that have been identified as carcinogens in rodents from being used as food additives, reguardless of whether the effects they produce are relevant to human carcinogenicity;other statutes permit scientific judgment.

From a risk management perspective, it is wasteful to expend limited risk assessment resources, risk management time, and public and legal involvement revisiting the issue of human relevance of the specific rodent response chemical by chemical. Of

Table 4.2. Rodent tumor mechanisms that may not be relevant to human cancer risk if they are the only responses observed and those responses are due to the mechanisms listed.

Tumor Mechanism	Tumor Site	Rodent Carcinogens
α-2u globulin-induced	Male rat kidney nephropathy	D-limonene, isophorones
Local hyperplasia	Forestomach	BHA, propionic acid, ethyl acrylate (administered by gavage)
Reactive hyperplasia from cytotoxic precipitated chemicals	Male rat bladder	Saccharin, melamine, nitrilotriacetic acid, fosetyl-Al
Overwhelming of clearance mechanism	Rat lung	Various particles, including titanium dioxide and carbon black (except ultrafine particles)
Sustained excessive hormonal stimulation	Thyroid	Amitrole, goitrogens, sulfamethazine

Table 4.3. Recognized human carcinogens (Rall 1988).

Chemical Carcinogens	Same Organ Sites Observed in Humans As in Laboratory Animals
4-Aminobiphenyl	✓
Analgesic mixtures with phenacetin	✓
Arsenic and arsenic compounds[1]	✓
Asbestos	✓
Azathioprine[2]	
Benzene[1]	✓
Benzidine	
Chlornaphazine	
Bis(chloromethyl)ether	✓
Myleran	✓
Certain combined chemotherapy for lymphoma	✓
Chlorambucil	✓
Chromium and certain chromium compounds	✓
Conjugated estrogens	✓
Cyclophosphamide	✓
Diethylstilbestrol	✓
Melphalan	✓
Methoxsalen with ultraviolet A	✓
Mustard gas	✓
2-Naphthylamine	✓
Soots, tars, and oils	✓
Treosulphan[2]	
Vinyl chloride	✓

[1]Not carcinogenic in standard rodent bioassays; shown to be carcinogenic in non-standard rodent bioassays only after clear evidence in humans was obtained.

[2]Not yet adequately studied in laboratory animals.

course, the evidence for hazard identifecation, exposure levels, and other effects must be evaluated for each chemical. Table 4.2 lists examples of rodent mechanisms and tumor responses that are candidates for classification as "not likely" to be predictive of carcinogenicity in humans according to EPA's *Proposed Guidelines for Carcinogen Risk Assessment* (EPA 1996b). That classification includes a subcategory of agents that elicit only rodent tumors that are irrelevant to human risk and another of agents that produce tumors at doses and via routes of exposure that need to be compared with known human occupational and general population exposures to determine relevance to human risk. Chemicals that produce tumors only in rodents because of striking pharmacokinetic differences can also be addressed. In general, the chemicals listed in Table 4.2 are not genotoxic; that is, they do not react directly with DNA. Instead, they cause local injury or otherwise stimulate local hyperplasia and cell division, which is associated with a low incidence of tumor formation.

For example, some chemicals are recognized to induce the accumulation of large amounts of α-2u globulin protein in the male rat kidney. Most scientists agree that this accumulation leads to damage to the kidney tubules, cell death, sustained cell proliferation, and tumor formation. Some scientists do not agree (Melnick et al. 1996). This response is not believed to occur in female rats or in other species, including humans. After 4 years of extensive study and review by EPA's Risk Assessment Forum and Science Advisory Board, the agency decided to disregard that particular rodent response for certain chemicals (EPA 1991). If that response is disregarded, risk assessment and regulation can be directed, as appropriate, at any other adverse effects, including kidney tumors not due to this protein-mediated mechanism.

Another tumor response that is believed to be irrelevant to humans is that which occurs only in the rodent forestomach after administration of a chemical by gavage (that is, via a tube placed in the stomach). Gavage is convenient for determining whether a chemical can cause tumors in organs distant from the stomach after absorption into the bloodstream, but can result in local cytotoxicity and hyperplasia. At least three commercially important chemicals (Table 4.2) have been found to produce tumors only in the forestomach and only following gavage. For example, butylated hydroxyanisole (BHA) was reviewed for FDA by a Federation of American Societies for Experimental Biology panel, which concluded in 1994 that there is a threshold for its tumor-producing cell proliferation. There is no evidence of a similar effect in humans (who lack forestomachs) and no scenario in which similar high dose local exposure would occur.

The saccharin debate of 1978-1979 highlighted rodent bladder tumors. An International Life Sciences Institute panel on rodent bladder carcinogenesis ultimately concluded that chemicals that precipitate in urine, or that elicit effects leading to precipitation of other chemicals, should be considered carcinogens only at high doses (Neumann and Olin 1995). If human exposures to such chemicals are much lower than the doses tested, the rodent response can be disregarded. Of course, bladder tumors can arise by other mechanisms that are relevant to human cancer.

Grossly overloading the rat lung's clearance mechanisms by administering particles directly to the lung has also been considered irrelevant to humans (Oberdörster 1995). EPA delisted titanium dioxide from the Toxic Release Inventory in 1988 for this reason (Fed Reg 53:23107-23202, 1988). The phenomenon may be applicable to particles in general, not only to titanium dioxide, but it has been declared irrelevant to humans only in the case of titanium dioxide. Declaring responses to other particles as not likely to predict human cancer risk would require criteria to determine what are "gross" particle overloads. Ultrafine particles (<0.1 microns) may well present a risk at much lower concentrations. Particles may also be carriers of hazardous chemicals that have adsorbed to them.

High doses of several pesticides and fungicides induce liver enzymes or thyroid enzymes that affect thyroid hormone levels, leading to hyperplasia and ultimately to thyroid tumor formation in ro-

dents. Because the feedback and transport systems for rodent thyroid hormones are very different from those in humans (McClain 1994), many believe that humans are far less sensitive to this response. EPA still assesses rat thyroid data on a case by case basis.

Finally, there have been many challenges to the interpretation of mouse liver tumor formation (not listed in Table 4.2). At least six potential mechanisms have been described, some of which occur in humans. Mouse liver tumors are among the most common seen in bioassays and pose particularly vexing problems for interpreting effects of chlorinated organic solvents.

Judgments about the likelihood of a chemical's or a tumor's human relevance should include careful evaluations of the weight of the scientific evidence. Some considerations include:

- Adequacy of experimental design and conduct.
- Occurrence of common versus rare tumors.
- Progression, or lack thereof, from a benign to a malignant tumor.
- Latency until tumor induction.
- Dose-response relationships.
- Genetic toxicity.

Toxicity testing protocols used to evaluate a chemical's carcinogenicity are a subject of intense debate. Leading toxicologists are eager to substitute newer tests for at least one of the two rodent species generally used in standard lifetime cancer bioassays. These newer tests employ newborn mice, which are quite sensitive and yield results in a few months, and specially developed transgenic mice with mutant p53 genes or other cancer-predisposing genes to make the mice more sensitive and provide mechanistic information. The goals are to apply scientific advances, get more information, and hopefully do so at lower cost and in less time.

Bringing a risk management perspective to the scientific review process might galvanize action. EPA reviews of the male rat kidney and rat thyroid tumor responses have required many years. The Commission recognizes that time is required to investigate chemicals' modes of action and endorses EPA's current plans to identify tumor responses in rodents that are not likely to be relevant to humans. We encourage EPA to apply those distinctions as early as possible in the risk assessment process, before time and resources are wasted. Other agencies should follow similar practices.

Evaluating Chemical Mixtures

Finding

Humans are exposed to many chemicals and other potentially toxic agents in the environment, but toxicity testing and regulations generally focus on one chemical at a time, often just in air, water, or food. Most risk assessments evaluate individual chemicals and then combine them by simple addition to estimate risk related to chemical mixtures. This method ignores potential synergistic or antagonistic interactions that could lead to under or overestimation of total risk, respectively. Knowledge of mechanisms of action can guide judgments of whether risks related to combinations of particular chemicals will be additive or independent.

Recommendation

Toxicity testing of complex environmental mixtures of regulatory importance should be performed for hazard identification and to generate comparative potency estimates of human risk. For risk assessments involving multiple chemical exposures at low concentrations, without information on mechanisms, risks should be added. If the chemicals act through separate mechanisms, their dose-response relationships should be considered separately.

As commonly practiced today, risk assessment and risk management consider exposures and risks in isolation from one another, typically chemical-by-chemical. For example, risks associated with air pollution are not put into the context of concurrent risks associated with contaminated drinking water or foodborne pesticide contamination. That fragmented approach to risk characterization is mostly a result of the fragmentation of responsibilities of different regulatory agencies and programs, but it can also be attributed to the limitations in our knowledge of the interdependence of different risks.

Failure to account for multiple and cumulative exposures is one of the primary flaws of current risk assessment and risk management, according to testimony received from Michael McCloskey, chairman of the Sierra Club, and others. Many people are surprised to learn that scientists usually do not test mixtures and that risk assessors and managers do not even try to account for the full array of exposures and health (or ecologic) risks. If the Framework is implemented and experience with testing and evaluating multiple chemical risks increases, it should be feasible to move beyond fragmentation. A promising new statute, the Food Quality Protection Act of 1996, requires estimates of aggregate, cumulative, and combined exposures to pesticides; some 9,000 tolerances for registered pesticides will need to be reassessed under this new mandate during the next 10 years.

Toxicity testing

Many complex mixtures—such as automobile exhaust, cigarette smoke, and other combustion products—have hundreds or thousands of chemical components. Attempting to identify and characterize each component and then adding their risks is clearly impractical. In those cases, the mixtures themselves can be tested for toxicity and their risks can be characterized on the same basis. For example, toxicity studies of diesel exhaust and other emissions have been conducted by the Health Effects Institute, jointly supported by EPA and motor vehicle manufacturers. The valuable results of those studies and others, such as tests of smoggy air from the Los Angeles basin, encourage us to recommend the testing of other important chemical mixtures.

Predicting a complex mixture's toxicity or risk can be assisted by testing it in bioassay systems and comparing the results with those from similar mixtures of known toxicity or risk. Bioassays that might be useful for testing mixtures could range from mutation tests in microorganisms to evaluation of effects on organs in culture or short-term tests of rodent respiratory function. A validated database of methods, bioassays, and biologic markers of effect and knowledge of the behavior of known mixtures in those bioassays will be needed to facilitate risk predictions for environmental mixtures. Such whole mixture testing could be considerably less expensive to perform than routine monitoring by chemical analysis for over 100 drinking water contaminants, for example, and might provide results that can be more easily extrapolated to human toxicity and discussed with stakeholders. The index of biotic integrity (see Ecological Risk Assessment on page 77) is another example of the use of a bioassay to integrate effects of numerous chemical exposures.

The experimental and epidemiologic database available for generating estimates of comparative potency of mixtures is not large. Most work has been applied to predicting lung cancer risks; for example, epidemiologic data are available on the carcinogenic potencies of coke oven emissions, coal roofing tar, coal smoke, aluminum smelters, and cigarette smoke. The human cancer risks of those emissions have been characterized and compared with their potencies in experimental systems to estimate the risks associated with mixtures that lack epidemiologic data, including automotive emissions (diesel and gasoline), woodstove emissions, residential oil furnace emissions, and ambient air particles; it is assumed that the relative carcinogenic potencies

observed in experiments would be similar for humans (Harris 1983, Lewtas 1993).

Enlarging the toxicity database for complex mixtures would be facilitated by coordinated research programs among epidemiologists, toxicologists, and clinical investigators (Mauderly 1993). For example, epidemiologists could provide information on the types of mixtures to which humans are exposed, patterns of exposure, populations of concern, health effects of concern, and the level of effects observed (or observable). Clinical studies could provide information on short-term responses and dose-response relationships, biological markers revealing short-term exposures and effects, and the likelihood of sensitive subpopulations. And toxicologists could provide judgments about the biological plausibility of the suspected exposure-response relationsip, the potential for chronic disease resulting from repeated exposures, causal and predictive relationships betweeen acute and chronic effects, identity of active constituents of mixtures, and effects of the exposure patterns.

Complex mixtures seemingly from the same source can vary considerably. For example, neither automobile engines nor gasolines are identical, so automobile exhaust is likely to vary substantially among sources and over time. The composition of air pollution varies with time of day and time of year, not to mention geographic location and source, so the toxicity of such mixtures is likely to vary considerably. Probabilistic approaches to describing the variability of composition within a class of mixtures and the relationship between that variability and toxicity should be explored. Coupling mathematical/statistical modeling (e.g., Monte Carlo techniques and physiologically based pharmacokinetic/pharmacodynamic dosimetry) with mechanistically based short-term toxicology studies may prove useful (Yang et al. 1995).

Assessing risks from multiple chemicals

Most of the information that is available on interactions among chemicals comes from human occupational studies and from rodent bioassays. Those studies generally evaluate doses that are much higher than the low, environmental doses commonly encountered. Interactive effects (either synergistic or antagonistic) depend heavily on dose; therefore, characterizing interactions that occur at one set of doses (such as those used in a rodent bioassay) is likely to provide very little information about interactions at very different doses (such as those generally encountered in the environment). “High” doses for combined effects are defined as those at which statistically significant increases in detrimental outcomes are observed in either laboratory or occupational studies. For the most part, exposure to chemical mixtures in the environment occurs at “low” doses—typically, one thousandth (or less) of the doses at which toxicity is observable in rodent bioassays or in epidemiologic studies of highly exposed workers. The ratio of exposures observed to cause adverse effects and actual human exposures is called the margin of exposure (EPA 1996b) (see Need for a Common Metric on page43).

The combined effects of exposure to chemicals in a mixture are determined by how individual components of the mixture affect the biological processes involved in toxicity. Components of a mixture can affect biological processes in many ways. For example, anything that affects the absorption, distribution, metabolism, or elimination of a chemical will affect the amount of that chemical that is available to react with DNA or other cellular targets. Because interactions leading to synergism or antagonism are the result of reactions of many molecules at many cellular sites, a mathematical dose-response model of a synergistic or antagonistic response that depends on such mechanisms is most likely nonlinear at low doses. Such logic strongly suggests that any disease process that depends on such interactions is only marginally important at low exposure levels. Only at high doses of one or more mixture components—such as cigarette smoke, alcohol, and some substances

in occupational exposures—is the combined effect likely to be detectably greater than the sum of the individual effects. For example, occupational exposure to asbestos is associated with a mortality ratio for lung cancer of up to 5 (that is, in comparison to persons not occupationally exposed to asbestos) and smoking with a mortality ratio for lung cancer of about 10; but asbestos workers who smoke have a mortality ratio for lung cancer of 50, not 15. Similarly, the risk of liver cancer associated with aflatoxin is increased markedly by hepatitis B virus infection.

The National Academy of Sciences report *Complex Mixtures* (NRC 1988) also concluded that effects of exposures to agents with low response rates usually appear to be additive. The experimental evidence that can be used to infer effects at low doses appears to support the assumption that low dose additivity does not underestimate, and in most cases probably overestimates, risk (see, for example, Ikeda 1988).

When the individual components of a chemical mixture exhibit different kinds of toxicity or have different biological mechanisms of toxicity, they do not interact—they act independently at low doses. In that case, the dose-response relationships for each chemical should be considered independently. For example, if the chemicals of concern at a Superfund site are copper, a gastrointestinal toxicant; lead, a developmental toxicant; and heptachlor, a neurologic toxicant, their toxicity should be evaluated independently and not combined into a single "noncancer" risk estimate. Experiments have shown that when groups of unrelated chemicals with unrelated targets of toxicity were administered to rodents simultaneously at doses equal to their separate NOAELs, no cumulative effects were observed; each chemical acted independently (Jonker et al. 1990, Groten et al. 1994). The same is true of groups of chemicals with the same target but different mechanisms of action (Jonker et al. 1993); studies in which similar chemicals with similar mechanisms and targets were administered simultaneously indicate that antagonism, is the usual outcome (Falk and Kotin 1964, Schmähl et al. 1977).

Accounting for Differences in Susceptibility

Finding

Genetic, nutritional, metabolic, and other differences make some segments of a population more susceptible than others to the effects of a given exposure to a given chemical; however, current regulatory approaches for reducing risks associated with chemical exposures generally do not include information on differences in individual susceptibility or encourage gathering evidence to identify them. In the absence of specific information about differences in susceptibility, risk assessments rely on assumptions and safety factors that are presumed to be protective of sensitive individuals.

Recommendation

Risk assessments should include consideration of genetic and other host differences in susceptibility, recognize the spectrum of interindividual variations within normal populations, and identify subpopulations especially susceptible to specific chemical exposures. Available information on the range of a population's susceptibility should be considered and used in place of assumptions. Where appropriate, knowledge of differences in susceptibility should be used to support additional bright lines for risk to protect especially susceptible subpopulations (see Bright Lines for Risk Management on page 54) and to tailor specific risk management actions to protect those subpopulations.

Susceptibility to the effects of chemical exposures depends on the sensitivity of a person's response to different doses. Susceptibility is influenced by many factors, including age, sex, genetic variation in metabolism of chemicals, genetic variation in response to agents or stressors at their sites of action, ethnic origin and ethnic practices, socioeconomic status, geographic location, and lifestyle factors, such as smoking, alcoholic beverage consumption, diet, physical activity, and recreational habits. Dose-response relationships are chemical-specific and

depend on a chemical's mode of action; people are not hypersusceptible to all kinds of exposures (Omenn 1982). The influence of concurrent exposures on risk is discussed in "Identifying Highly Exposed Populations" on page 75. The following are examples of subpopulations potentially at higher risk.

Population	Factor Affecting Response to Exposure
Asthmatics	Increased airway responsiveness to allergens, respiratory irritants, and infectious agents
Fetuses	Sensitivity of developing organs to toxicants that cause birth defects
Infants and young children	Sensitivity of developing brain to neurotoxic agents such as lead
α_1-Antitrypsin-deficient persons	Inherited deficiency of a protein that protects against chemical damage
Glutathione-*S*-transferase deficient	Diminished detoxification of some carcinogens and medicines
Socio-economic groups	Underlying nutritional deficits and poor access to health care
Elderly	Diminished detoxification and elimination mechanisms in kidney and liver

There are opportunities to identify, evaluate, and reduce risks to sensitive people. Asthmatics, for example, make up 5 to 10 percent of the general population in the United States. Some air pollutants, especially sulfur oxides, particles, and ozone, are respiratory irritants that pose a greater risk to this subpopulation than to the general public. Both the number of cases of asthma and the number of deaths from asthma are increasing in the United States. Blacks have a 15% higher prevalence of asthma than whites. Likewise, susceptibility to lung cancer appears to vary among ethnic groups; in the United States, the incidence of lung cancer in black men is 1.5 times that in white men, 2.5 times that in Hispanic men, 2 to 4 times that in Asian men, and 8 times that in American Indian men (NCI 1984). One source of individual and ethnic differences in susceptibility is differences in the activity of enzymes that affect chemical toxicity. Increased risks of cancers of the bladder, skin, colon, lung, and stomach have been associated with differences in the activity of specific enzymes that can activate or deactivate carcinogens. Susceptibility to organophosphate pesticide toxicity is also markedly influenced by the activity of a specific enzyme in the blood. Metabolism however is only one of many contributors to an individual's susceptibility .

Amendments to the Safe Drinking Water Act and to the Federal Insecticide, Fungicide and Rodenticide Act require such recognizable subpopulations as the elderly, children, and women of child-bearing age to be identified and considered more explicitly than they are currently in risk characterization and in standard-setting. The Food Quality Protection Act of 1996 requires an additional safety factor of 10 be used when pesticide risks are assessed, to allow for children's greater intake on the basis of body weight and potentially greater susceptibility, unless data are sufficient to justify a different safety factor. Recognition of subgroup susceptibility does not necessarily result in more stringent regulation, however. For example, people allergic to particular chemicals or pet animal proteins might modify their exposures or modify their responses (with medication). Identifying the size of the population at higher risk and describing the risk peculiar to that population during risk characterization, perhaps using biologic markers of susceptibility, will make it possible to characterize risks more realistically than is possible using only estimates for the general population. Risk communication messages can then be targeted more effectively.

Exposure Assessment

Exposure assessments can be simple or complex, depending on the needs of a particular risk management question. They are based on measurements, models, and assumptions, and generally focus on individual chemicals, media, and sources. Often, unvalidated mathematical models are used to make predictions about a population's exposure on the basis of limited information on chemical con-

tamination and assumptions about the population. The results oversimplify actual exposure magnitudes and conditions, in part to allow for population variability. And the methods generally do not consider other sources of exposure to the same or similar chemicals and their interdependence.

This section recommends ways to generate credible and understandable exposure information for informed decisions by risk managers and the public about the need for risk reduction. The Commission recommends that agencies show a preference for actual exposure data on communities and populations at risk.

Design of Exposure Assessments To Meet Risk Management Goals

Finding

Exposure assessments vary greatly in design and content. Complex risk management decisions often are based on simplistic, deterministic estimates of exposure derived from few data, many assumptions, and inadequately validated models. In contrast, some exposure assessments are more complex than is needed for straightforward risk management decisions.

Recommendation

Exposure assessments should be designed to be commensurate with the needs of the risk management decisions at issue. The design of an appropriate exposure assessment should take place at the problem/context stage of the risk management process.

Several measurement tools, statistical methods, and other procedures and considerations can be used to design and conduct an exposure assessment. No method or group of methods should be used in all cases. Selection of appropriate methods should be discussed and evaluated during the planning stages of a risk management process (the problem in context stage of the Commission's Risk Management Framework) to ensure that they meet the needs and expectations of risk managers and other stakeholders. The following general principles are suggested as the planning basis for an exposure assessment:

- Simple methods should be considered before more complex methods. Such a tiered assessment strategy is increasingly used in risk assessment and can be cost-effective.
- Chemicals are more biologically available in some media than in others; that is, the matrix within which chemicals occur (such as air, water, food, or soil) can greatly affect the extent of human exposure. The effect of the matrix should be considered in assessing exposure before assuming that contaminants are 100% bioavailable.
- Whenever possible, measurements should be obtained to support or validate any generic values used in exposure assessments, to check modeling results, or to provide more realistic estimates of exposure than can be obtained with models. Such measurements might include collecting data at locations where exposures are anticipated, monitoring the exposures experienced by individuals, collecting data on the physical and chemical conditions that affect the movement and bioavailability of chemicals, and providing information that relates exposure to effects, possibly using biologic markers. Measurements of exposure can be very different from estimated exposures based on source characteristics.

Using Realistic Exposure Scenarios

Finding

Because of statutory requirements and the desire not to underestimate chemical exposures, many risk assessments have estimated risks for a hypothetical, nonexistent "maximally exposed individual" (MEI) and have neglected information about the frequency, duration, and magnitude of actual population exposures. More recent assessments have used less extreme exposure scenarios. Con-

gress specified in the 1990 amendments to the Clean Air Act that, after maximum available control technology is implemented for stationary sources, further controls must be considered if the lifetime excess cancer risk to the "individual most exposed to emissions from a source" in a category exceeds 10^{-6}. The criteria for the "individual most exposed" were not stated; in fact, Congress mandated this Commission to advise what exposure scenarios should be used.

Recommendation

Exposure assessments should not be based on a hypothetical MEI. Screening risk assessments should rely on more representative estimates, such as EPA's high-end exposure estimate (HEEE) or a maximally exposed actual person and estimates of the total number of potentially exposed people in the geographical areas of interest. Risk management decisions should be based on refined exposure assessments that evaluate the distribution of a population's varied exposures and should address explicitly any segments of the population that have unusually high exposures. Exposure assessments should rely on population exposure data where possible instead of assumptions about exposure derived from source characteristics and models. The characteristics of actual or potential future populations in relation to specific sources of exposure should be emphasized and multiple sources of exposure should be reflected as appropriate in each case.

With the intention of protecting public health, past exposure assessment and health risk assessment practices have relied on exposure estimates derived from a hypothetical MEI who might spend a 70-year lifetime living at the point of greatest deposition from a plume of industrial contaminant emissions or who might spend a 70-year lifetime drinking only ground water with the highest concentrations of contaminants detected. The MEI was often so unrealistic that its use impaired the scientific credibility of health risk assessment.

Federal agencies have generally moved away from exposure assessments relying on such MEIs. For example, EPA's exposure assessment guidelines have adopted the use of distributions of individual exposures and HEEEs chosen from values in the upper tail of those distributions (EPA 1992a). EPA's risk characterization guidelines provide guidance on the use of exposure descriptors to characterize risk (EPA 1995a). At this time, implementation of those guidelines among EPA regional offices is uneven; some continue to use point estimates, while others use probability distributions of exposure estimates.

The Commission supports distributional approaches to exposure characterization that are based on knowledge of the characteristics of a population's variability. Where possible, the entire distribution of the variability associated with exposure should be used in a risk characterization (see Effective Risk Characterization To Support Decision-Making on page 85). That distribution should be based on the characteristics of the entire exposed population and not solely on a highly exposed subpopulation; any highly exposed subpopulations known to exist should be considered separately. If a single value representing a population's or subpopulation's exposure is required, such as for priority setting, a point in the upper end of the distribution should be used, such as the 95th percentile.

Agencies should develop standard distributions to use in exposure assessments as defaults when population-specific information is unavailable. If data limitations do not permit the development of a defensible exposure distribution, a value representing a hypothetical highly exposed individual should be used. Such point exposure estimates are appropriate for screening level risk assessments. Probabilistic exposure estimates should be considered when standard default methods are expected to yield unrealistically conservative exposure estimates, when population estimates of exposure are desired, or when the exposure assessment is complex. Mark Van Putten, of the National Wildlife Federation, testified before the Commission that the environmental justice movement has provided some

impetus for considering distributions instead of point estimates, on the grounds that populations with disproportionate exposures can be more explicitly identified and considered in risk assessments. We agree.

One advantage of using distributions to describe a population's exposure is that it focuses attention on population risk, not just individual risk. Considering the size of a population in addition to the distribution of its exposures is important; for example, although emissions in a rural area might pose the same individual risk as those in an urban area, the total population risk for the latter is much greater. Another advantage is that it focuses attention on the characteristics of the population ("receptor-based" analysis) instead of basing exposure estimates primarily on the emission or other characteristics of a particular source of contamination ("source-based" analysis). A population-based approach can be source-specific but should include information on the variables that influence the mode, frequency, and duration of exposures. A complementary community-based approach would begin by determining a population's exposures and moving from that information to identify sources of exposure. The total exposure assessment methodology (TEAM) study conducted by EPA and the Harvard Six Cities Survey, in which representative members of several urban populations wore small personal samplers to measure individual exposure to airborne chemicals (EPA 1987a, Dockery et al. 1993), are examples of a community-based approach to exposure assessment. The TEAM study also illustrates how dissimilar source-based predictions of exposures and actual exposures can be. Monitoring blood lead in a community's children and tracing the sources of lead is another example of receptor-based analysis.

Many exposure assessments are based on source characteristics, not population characteristics. For example, air pollution sources typically have been licensed on the basis of modeled projections of their stack emissions. Few data on actual population exposures exist. (The Six Cities and TEAM studies are notable exceptions.) Such data deficiencies create problems, as emphasized by Ellen Silbergeld, representing the Environmental Defense Fund, in testimony before the Commission: there is no direct way to estimate the actual health risks experienced by an exposed population; there is no way to assess the relative contribution of multiple sources to risk; and there are no baseline data with which to evaluate the effects of new sources or of pollution reduction activities on existing sources.

Resistance to collecting data on populations' actual exposures arises from the substantial time and expense associated with monitoring efforts, especially given the large variations in local climate and the problems associated with accurate detection of small pollutant exposures. Environmental monitoring is needed, however, to generate actual data that are consistent with a public health approach to risk assessment and with the Commission's Risk Management Framework. In some circumstances, the costs of monitoring, such as for blood lead, are small compared to the overall costs of remediating a Superfund site, for example, and can save funds amounting to several times the cost of the study. Although multipathway modeling is not scientifically well developed, at present, exposure assessment must begin to address aggregate exposures (see also Section 2 and Evaluating Chemical Mixtures on page 68). Stimulated in part by Toxic Release Inventory reports, communities are interested not just in what they are exposed to because of a particular industrial facility, but in how that facility adds to the burden of exposures that they are already experiencing. Focusing on real populations is essential to identifying multiple exposure situations. We expect biomarkers of exposure to become useful in validating exposure estimates and in relating exposures to specific subgroups and even to individuals.

Identifying Highly Exposed Populations

Finding

Some population groups are at increased risk for toxic effects of chemical exposures because their exposures are greater than those of other population groups. Cultural practices, occupa-

tional exposures, behavior patterns, eating habits, and effects of related chemicals can be responsible. The high-risk subpopulations might be of special concern when risk assessments are conducted and risk management decisions are made. Risk assessors often have not sought information from knowledgeable citizens and consequently have not explicitly considered specific exposure conditions that might be present in minority group communities, certain occupational settings, or areas of particular socioeconomic status.

Recommendation

Risk assessments should be conducted so as to identify groups of people who are likely to have higher exposures to the chemicals of interest. Affected parties should be consulted in the early stages of an assessment to obtain information about all known sources of exposure to a particular chemical and related chemicals and to characterize exposure factors peculiar to particular subpopulations and link them with host susceptibility factors (see Accounting for Differences in Susceptibility on page 71).

Increased risks of adverse health effects from contaminant exposures can result from increased doses, as well as from increased susceptibility, which was discussed in the section Accounting for Differences in Susceptibility on page 71. Dose is a function of the concentration of a substance in the environment and the extent of exposure that a person has to the substance. Advances in the use of biologic markers will help to define relationships between exposure and dose. Below is a list of some factors that can increase risk as a result of increased exposure.

The Clinton Administration, the 103rd and 104th Congresses, interest groups, and the scientific community have attempted to address the issue of high-risk populations in several ways. For example, Executive Order 12898 on Environmental Justice requires that federal programs protect minority-group and low-income populations from disproportionately high exposures and adverse human health and environmental effects. EPA addressed the potentially greater susceptibility of children to pesticides and pesticide residues by requiring that assessments of environmental risks explicitly take health risks to children and infants into account (EPA 1995b). Congress reinforced that practice when it passed the Food Quality and Protection Act of 1996, which responded to a National Research Council report that variations in dietary exposure to pesticides related to nutritional intake, age, geographic region, and ethnicity were not addressed adequately by current regulatory practice (NRC 1993). Infants and children might be more heavily exposed to pesticides than adults because of their relatively high intake of fruit juices, for example, and they are more susceptible to the toxic effects of pesticides because of the sensitivity of their still-developing nervous systems and probably because of their greater concomitant exposures to lead and other environmental hazards.

Population	Examples of factors that affect exposure
Industrial and agricultural workers	Greater exposure to job-related hazardous chemicals through breathing and skin contact; more lung exposure associated with physically demanding work
Subsistence and sport fishers	Higher fish consumption; consumption of unusual parts of fish
Infants and children	Higher consumption of fruit, vegetables, and fruit juices; higher inhalation rates
Low-income and minority-group communities	Greater exposure to lead from lead paint in houses and soils; greater exposure to second hand cigarette smoke; inequitable distribution of risk-generating activities

Community assistance in characterizing exposure factors peculiar to particular segments of the population can focus a risk assessment and broaden risk management options. The Commission heard testimony from Asians and Pacific Islanders about their fish consumption patterns and about the role that education can play in risk management. Not only do they consume more fish, but they consume fish parts that are usually discarded by others and in which pollutants are often concentrated, placing themselves at higher risk than the general population for the effects of contaminants in fish. They reported that educational brochures, signs around contaminated bodies of water, and community involvement led to voluntary reduction in exposure through modest changes in fish eating in the Seattle area. Of course, education is only one risk management alternative, and other stakeholders might not consider it to be appropriate or acceptable. In contrast to the Asians and Pacific Islanders, Mark Van Putten, of the National Wildlife Federation, testified that in the Great Lakes region it was difficult to convince risk managers that subsistence fishers, such as Native Americans, should be considered in risk assessments.

Specific information gathered from the community and stakeholders could reduce the need for default assumptions and improve the quality of risk assessments in communities with multiple polluting operations, such as a municipal incinerator, a chemical plant, a dry cleaning establishment, and an abandoned hazardous waste site. Involving the community and other stakeholders in the planning stages of a risk assessment can help to engage individuals, families, schools, businesses, and municipalities in targeted pollution prevention and pollution reduction actions that reduce exposures. The Commission's Risk Management Framework calls for stakeholders to be involved in every step of the process, including evaluation of the actions taken.

Ecological Risk Assessment

Ecological risk assessment was not included in the Commission's legislative mandate, but we would be remiss if, in a report on the use of risk assessment in regulatory programs, we considered only human health. Indeed, protection of human health and protection of the environment are often dual goals of the laws and regulations that use risk assessment to inform decision-making. The ability to sustain our ecosystems is crucial to our well-being, as they are used for producing food, building materials, and fiber, as well as recreation and spiritual sustenance. Of course, sustainability of ecosystems is a benefit regardless of human benefits. In addition, many environmental problems, such as global climate change and hormonally active contaminants, pose an inseparable combination of health and ecological risks. Nonetheless, this is not intended to be a comprehensive discussion of ecological risk assessments.

Framework for Evaluating Ecological Risk

Finding

Continuing efforts to develop a uniform ecological risk assessment approach persist. EPA's framework for evaluating ecological risk (Figure 4.1) has emerged as a useful way to organize many kinds of information about risks to the environment, although it does not yet include an explicit role for stakeholders. General guidelines for implementation of the EPA framework have been issued and meet immediate needs. As ChemRisk said in comments to the Commission, guidelines must be flexible to account for the many variables in any individual ecological risk assessment. As the effort to add complexity to the analyses continues, additional guidance on the developing technique will be needed while maintaining flexibility.

Recommendation

EPA and other agencies should continue together to implement the EPA ecological risk assessment framework. EPA's guidelines should be improved by an explicit discussion of how and when stakeholder involvement should be sought so that it is consistent with the Commission's Risk Management Framework and by a description of how measures and models should be selected. Other

agencies should develop clear guidance for putting various problems into context, choosing methods and tools for characterizing exposure and effects, characterizing uncertainty, and applying weight-of-evidence evaluations.

Ecological risk assessment has been used informally for many years to make decisions about resource management and pollution control. Within the last few years, a concerted effort has been made to define ecological risk assessment and to establish a common language for discussing approaches and results. At the same time, ecological risk assessments have been conducted by an increasing number of agencies, such as the Department of the Interior, the Department of Agriculture, and the National Marine Fisheries Service. As detailed in the Menzie-Cura report prepared for the Commission (see Appendix A7 for abstract), there is a growing consensus that the EPA ecological risk assessment framework (EPA 1992b), as it has evolved since 1992, can fulfill a wide range of needs, from providing information on environmental pollution to informing resource management and regulatory decision-making.

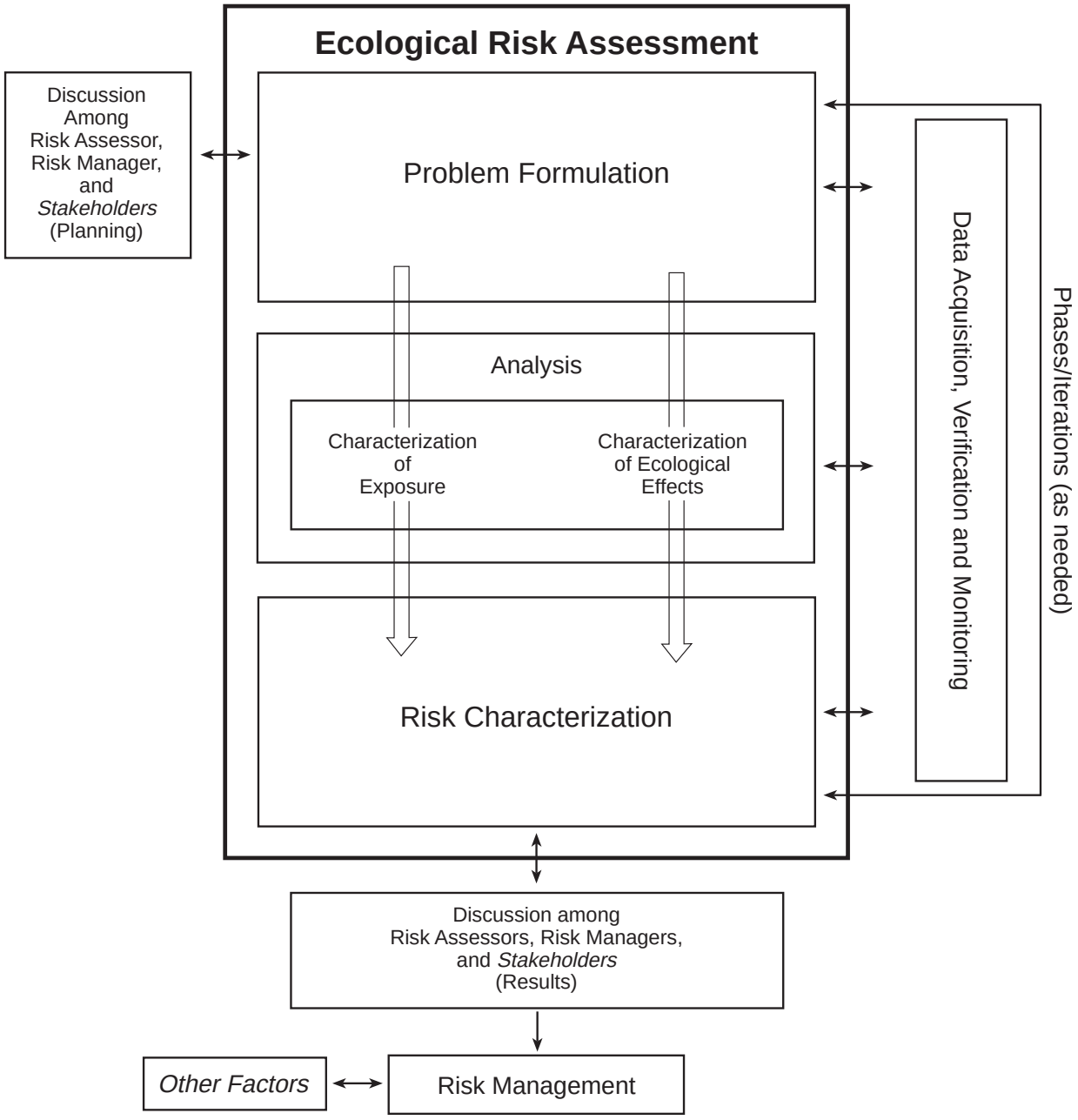
Each agency should develop guidance on the use of the framework appropriate to its needs. Considerable effort has been directed toward this end over the past few years. California, Massachusetts, Texas, and Washington have developed state-specific guidance. Within the EPA, guidance has or is being developed by Regions 1, 9, and 10. Other agencies and departments have produced guidelines tailored to their specific needs. The Tri-Service Procedural Guidelines for Ecological Risk Assessments prepared by the Department of Defense is a recent example. These efforts share conceptual elements reflected in the EPA Framework for Ecological Risk Assessment and the EPA Guidelines for Ecological Risk Assessment. Communication among these groups will foster sharing of developing concepts and tools.

Compared with the framework for human health risk assessment (NRC 1983), the EPA framework for ecological risk assessment changes the first step from hazard identification to problem identification in a holistic context. Thus, this approach is consistent with the Commission's Framework for Risk Management. In the problem formulation stage, the environmental values to be protected and the goals of the assessment should be defined. In addition, the appropriate level of ecological organization (such as individual species, population, or community), the end points, potential receptors, and ways to measure the end points must be identified.

Ecological risk assessment has no commonly accepted starting point. For example, some might focus on the need to maintain biological diversity, others might be drawn to protecting particular plants or animals, and still others might relate to aesthetic quality. Balancing those disparate goals is the challenge of the problem formulation stage. The likelihood of success will be increased by including stakeholders in the process at this early stage. Figure 4.1 reflects the Commission's proposal to add stakeholders, explicitly, to the participants in the problem formulation stage of EPA's framework. The brief discussion of stakeholders in the EPA guidelines puts too little emphasis on the important role stakeholders should play in ecological risk assessment. Many small or well defined assessments may be parts of established regulatory programs in which it would be impractical to involve stakeholders in every case; however, stakeholder involvement certainly should be considered for larger local or regional assessments in which affected parties hold a range of interests and values. In particular, stakeholder involvement seems especially important for place-based assessments, such as watershed and estuary assessments, for assessments of complex hazardous waste sites, and for the development of assessment methods that will be used in major regulatory programs.

In a review of ecological risk assessment case studies, EPA (1993b) concluded that the strengths and weaknesses of the studies frequently seemed to originate, from decisions made during the problem formulation stage. EPA's guidelines provide a good description of the problem formulation stage of the ecological risk assessment, but neglect to

Figure 4.1. EPA's framework for ecological risk assessment, modified to include stakeholders and factors in addition to risk. (Additions in italics.)



provide sufficient guidance on who should be involved and when and how to include stakeholders. It is especially important at this stage to identify federal, state, and local agency stakeholders with responsibilities for the resources being analyzed.

The collaboration that we recommend among risk assessors, risk managers, and stakeholders provides opportunities to bridge gaps in understanding, language systems, and values. If the affected parties do not participate in the early decisions about goals, end points, and measurements, the analysis is likely to fail to provide information useful for decision-making. Stakeholder involvement in the problem formulation stage of an ecological risk assessment has been endorsed by a range of organizations, including the Environmental Defense Fund, the American Industrial Health Council, the Risk Science Institute, the State of California, and Environment Canada.

The analysis stage of ecological risk assessment consists of two distinct, interrelated activities: characterization of exposure and characterization of ecological effects. During exposure characterization, the spatial and temporal distribution of a stressor or stressors and contact with ecological components are predicted or measured. During effects characterization, the adverse effects elicited by stressors and the cause-effect relationships are evaluated. Additional research is needed into the effects of multiple chemical, physical, and biological stressors and the appropriate metrics to assess effects.

One diagnostic tool for identifying effects is the index of biotic integrity developed by Karr (1991), who testified before the Commission in Seattle. Although not a perfect tool, this index is now used by more than 30 states in their water quality programs. The guidelines issued by EPA contain a good discussion of the strengths and limitations of various tools, but do not describe adequately how to select measures or methods, such as fate and transport models, toxicity tests, and field studies, that best evaluate different assessment endpoints or how to match tools to the scale of the problem or the level of the assessment. The most appropriate mix of tools must be decided on a case-by-case basis.

In its 1996 report *Ecological Risk Assessment: Sound Science Makes Good Business Sense*, the American Industrial Health Council suggested that addressing multiple species and multiple exposure pathways at different levels of ecosystem organization is best done with an iterative, tiered approach to data acquisition (AIHC 1993). The Commission agrees. Because ecological risk assessments can be data intensive, guidance on when and how to conduct a tiered, iterative approach is needed. Early tiers tend to be less expensive and more conservative; the more expensive, more sophisticated later tiers provide more accurate estimates of risk with less uncertainty. The intensity of data collection should be commensurate with the environmental benefits of greater certainty, the needs of stakeholders involved in the decision-making process, and the resources available.

Finally, in the risk characterization stage, characterizations of exposure and of ecological effects are integrated to evaluate the likelihood that exposures and adverse ecological effects will be associated with specific stressors. Risk characterization for ecological risk assessment has been subject to little standardization. If followed, EPA's proposed risk characterization guidelines should improve understanding and consistency. For example, there are many sources of uncertainty in ecological risk assessment; EPA's proposed guidelines indicate how to address them in the risk characterization.

The EPA guidelines use the term "lines of evidence" rather than "weight of evidence" to describe the evaluation of the underlying data and studies for accuracy, reliability, and relevance. It appears that there is no consensus on how to evaluate or apply the lines of evidence or weight-of-evidence in the context of ecological risk assessment. Because the approach reflects professional judgment, the conclusions might not be transparent to others. The professional judgments that underpin these weight-of-evidence evaluations should be examined and be made more explicit. The Massachusetts Department of Environmental Protection, for example, has been working with ecological risk assessors to develop quantitative and qualitative methods of evalu-

ating weight-of-evidence. The risk characterization must synthesize and provide information that can be applied to risk management decisions, again with extensive consultation with stakeholders (see Figure 4.1).

As in the Commission's Risk Management Framework, the risk assessor, risk manager, and stakeholders should consider other factors in making the risk management decision. Costs, legal constraints, feasibility of options, and enforcement mechanisms are among the issues that are not part of the risk assessment but are sometimes critical to the acceptability of the risk management actions. For that reason, we have added "other factors" as an explicit input to the risk management decision (see Figure 4.1).

The EPA ecological risk assessment framework has been most successful in analyzing risks associated with chemical stressors—the scenario most similar to typical human health risk assessments. However, the framework is being used with greater frequency for more complex problems. For example, EPA's Office of Water has experimented with changing the sequence of some of the components of the framework and has developed conceptual models at multiple organizational levels of the ecosystem; this version of ecological risk assessment is being used to assist in understanding stressors and their effects on watershed ecosystems (see Office of Water on page 128). In addition, the recently formed Office of Sustainable Ecosystems and Communities is leading an effort to focus on ecological risk assessment beyond toxic effects on individual organisms to a system approach that examines the food web or the broader landscape. Another appropriate use of EPA's ecological risk assessment framework would be in analyzing the impact on wildlife of chemicals that may disrupt endocrine functions.

The application of the ecological risk assessment framework must be refined as agencies gain experience so that complex biological, physical, and social stressors can be addressed in such important problems as protecting biological diversity, maintaining ecosystem health, and guiding sustainable development. It is timely to work with the international community to harmonize methods in the United States and abroad while the development of the paradigm is still evolving. As the Organization for Economic Cooperation and Development noted in its report *Environmental Performance Reviews: United States*, "knowledge about the conditions and trends of biodiversity in the U.S. is limited" (OECD 1996). Measurement tools, models, field studies, and surveillance of the consequences of risk management decisions are critically needed.

Environmental Hazards Other Than Chemicals

Public concern about risks associated with radioactive waste disposal, recent large-scale outbreaks of serious infectious disease from microorganisms such as *Cryptosporidium* in drinking water and *E. coli* in foods, and disasters from natural hazards such as floods, earthquakes, and hurricanes, remind us that chemicals do not constitute the only environmental threats to the public's health. In many situations, people (and ecosystems) are exposed to combinations of radiation, chemicals, and infectious agents—a broader version of the chemical mixtures problem (see Evaluating Chemical Mixtures on page 68). In many others, comparisons and tradeoffs among types of risk are necessary, such as potential risks associated with chemical byproducts of drinking water disinfection versus infectious risks associated with microbial contamination of drinking water). In such situations, chemical, radiation, and microbial exposures have to be evaluated concurrently.

To the public, environmental protection seems to be focused predominantly on chemicals, rather than radiation and microorganisms, although there is no doubt about the many serious health effects of exposure to ionizing radiation and microorganisms. Nell Ahl, director of the risk analysis program at the Department of Agriculture, expressed concern to the Commission about the disproportionate official emphasis placed on chemical hazards,

especially in view of the public outrage that was rightly engendered recently by the deaths and illnesses caused by toxin-producing *E. coli* contamination of under cooked hamburger or *Salmonella* contamination of eggs or ice cream. The public health consequences of exposing patients and workers to ionizing radiation and of exposing the general population to infectious agents are so well recognized that they are in the category of "familiar" risks, which psychologists have shown are far less frightening to the general public than "unfamiliar" or "dreaded" risks, even when the estimated magnitudes of the former are much higher. Nevertheless, small estimated risks from radiation, especially from potential radiation releases from nuclear power plant operations or wastes, continue to attract considerable public concern. For example, in testimony before the Commission in St. Louis, Kay Drey, of the Missouri Coalition for the Environment, expressed concern about our country's ability to manage its current radiation hazards and especially the anticipated decommissioning of commercial nuclear power plants at the end of their useful lives. The Department of Energy has recognized that a major challenge exists in decommissioning and disposing of nuclear reactors at federal facilities.

Risks From Radiation Hazards

Finding

Risk assessment methods for radiation hazards are well established, and regulatory strategies for occupational and environmental radiation exposures have been in place for many years. An elaborate standards process uses extragovernmental organizations, such as the National Council on Radiation Protection and Measurements and the International Commission for Radiological Protection; lead agencies are the Nuclear Regulatory Commission, Department of Energy, EPA Office of Air and Radiation, and FDA Division of Radiological Health. Unfortunately, scientists and regulators dealing with chemical hazards or with radiation hazards have been so independent of each other that there has been little combined analysis or combined risk management for medical, industrial, nuclear power, nuclear weapons production, and waste disposal settings where radiation and chemical contamination coexist.

Recommendation

A concerted effort should be made to evaluate and relate the methods, assumptions, mechanisms, and standards for radiation risks to those for chemicals to clarify and enhance the comparability of risk management decisions and investments, especially when both types of hazards are present.

The radiation protection literature began with devastating accounts of the health hazards of Roentgen rays (x rays), discovered in 1895 and introduced immediately into medical practice; pioneering scientists and workers developed radiation burns of the skin and internal cancers. We now know that radiation can affect genes, chromosomes, cell survival, and regeneration of rapid turnover tissues. The skin, bone marrow, intestine, oocytes, spermatogonia, lens of the eye, and respiratory tract are most vulnerable.

Natural sources of ionizing radiation include cosmic rays; radium and other radioactive elements in the earth's crust; potassium-40, carbon-14, and other radionuclides normally present in living cells; and inhaled radon and its progeny. The doses received from cosmic rays vary appreciably with altitude, so exposure is twice as high in Denver as at sea level and 100 times higher at jet aircraft altitudes. The largest exposures come from airborne radon-222, a colorless, odorless, alpha particle-emitting gas formed by the radioactive decay of radium-226 in the earth. Human exposure to radon varies—according to its concentration in indoor air—by more than a factor of 10. Smokers expose themselves to another decay product of radium—polonium-210 in tobacco—at up to 0.2 Sv/year, or 20 rems/year.

A discrepancy exists between the levels of risk that are considered negligible for radiation exposures and for chemical exposures. In the case of individual chemicals, exposure limits are generally set to keep incremental upper-bound cancer risks

for workers below one per thousand over a 45-year period of workplace exposure and, for the general population, below a range of one per 10,000 to one per million over a 70-year lifetime of exposure to the limits. In the case of radiation, the current occupational exposure limit is a whole body equivalent dose of 50 mSv/year or 5 rems/year (10CFR20, 1990 revisions), which would be equivalent to a lifetime excess total cancer risk of more than one in ten if experienced annually over a working lifetime, assuming a linear dose-response relationship (Upton 1996). (The rem is a composite of absorbed dose [rads] and energy transfer factors.) According to comments received from Tara O'Toole, Assistant Secretary for Environment, Safety and Health at the Department of Energy, occupational exposure limits recommended by the International Commission on Radiological Protection and the National Council on Radiation Protection and Measurements are equivalent to a lifetime cancer risk of one in one hundred (assuming about a 50-year exposure duration at the exposure limit in the absence of [as low as reasonably achievable] standards. Those risk estimates are well above those associated with similarly extreme scenarios of lifetime exposure to chemical carcinogens at the level of their occupational standards. However, risks from radiation and from chemicals are estimated differently; most importantly, radiation exposure limits integrate all ionizing radiation exposures, while chemical-specific exposure limits consider each chemical individually. O'Toole stated in her comments to the Commission that harmonizing radiation and chemical risk assessment methods will remain an elusive goal without these basic differences being articulated and discussed. We agree.

In other comments, O'Toole stated that she believes protective actions and the application of ALARA workplace practices lead to actual radiation exposures for workers that are much smaller than the limits. That view is echoed by comments received from several health physicists. Furthermore, radiation-exposed workers are continuously monitored so that high exposures can be detected promptly and corrected. For example, during the period from 1980 to 1994, the highest annual average dose equivalent per monitored Department of Energy worker receiving measurable exposure was 182 mrem/year, significantly less than the EPA's recommended annual exposure limit of 5 rem. Assuming an annual average occupational dose limit of 1,000 mrem, approximately five times greater than the Department of Energy's highest annual dose, the National Council on Radiation Protection and Measurements estimated a lifetime cancer risk from each year's exposure of between 10^{-5} and 10^{-4} (NCRP 1993). Multiplying these estimates by an assumed exposure of 35 years would make the risk level similar to the level used to limit workplace exposures to individual chemicals, roughly 10^{-3} lifetime excess cancer risk. Monitoring and job change lead to similarly lower actual exposures for workers exposed either to chemicals or to radiation. Chemical exposure limits are not annual averages or annual cumulative doses, however; rather, 24-hour average concentrations or even peak concentrations are the basis for limits. Staying below the limits thus requires mean exposures to be considerably lower than the regulatory limit.

The limit for unrestricted radiation exposure of a member of the public has been set at 1 mSv/year effective dose equivalent (100 mrems) by the Nuclear Regulatory Commission, one-fiftieth of the occupational exposure limit. This difference deserves some attention; pregnant women can be exposed to radiation both in the workplace and outside it, and the developing fetus presumably deserves the same level of protection in both places. As with workplace exposures, however, actual public (non-workplace) exposures are generally far lower than the limits, which represent only a small fraction of the amount of background radiation received annually from natural sources. Diagnostic and therapeutic uses of ionizing radiation in medicine constitute by far the greatest exposures.

The Conference of Radiation Control Program Directors issues a draft regulation in early 1997 that also adopted the 100 mrem exposure limit, aimed at protecting the general public from naturslly occuring radioactive materials that have accumulated from

industrial processes. Their appoach would leave to local analysis and negotiation how much less than 100 mrem per year should be the cleanup goal, allowing for consideration of specific site characteristica, identity of the radionuclides of concern, and other factors.

In contrast to radiation, the difference between occupational and general population exposure limits for chemicals is usually much greater than a factor of 50. For example, OSHA's limit on workplace exposure to nuisance dust is 15 milligrams per cubic meter of air, while EPA's national ambient air quality standard for particulates is 50 micrograms per cubic meter of air, 300 times less.

Low-level exposures to electric and magnetic fields, after extensive investigation and public debate, appear to have very low or negligible risk to the general population (NRC 1997).

Risks from Microorganisms

Finding

Methods for anticipating and assessing microbial hazards on a population basis, rather than on a clinical basis for individual patients, are less developed than those for chemicals or for radiation; they are hindered by limited data, especially epidemiologic and quantitative exposure data, and by the need for predictive models that can account for variation in infectivity, virulence, and uncertainties.

Recommendation

Efforts to improve risk assessment methods for microbiologic hazards and to collect data to validate and support those methods should be encouraged.

Interest in the public health aspects of infectious diseases and the need to improve their predictivity has been revived by several factors:

- The emergence and resurgence of infectious agents ranging from HIV and the Ebola virus to tuberculosis mycobacteria.
- The importance of antibiotic resistance mechanisms as a result of medical and veterinary overuse of antibiotics.
- The need for international sanitary and phytosanitary standards since the General Agreement on Tariffs and Trade was signed.

Inability to assess health risks associated with microorganisms and inattention to risk reduction can lead to disaster, as evidenced by the recent deaths and outbreaks of diarrhea caused by *Cryptosporidium* in Milwaukee's drinking water and by kidney failure in children who consumed *E. coli* toxin-contaminated hamburger meat in Seattle. Those deaths, unlike many cancer risks associated with low, environmental levels of exposure to chemicals, are observable and countable. FDA and USDA have primary responsibilities for foodborne, FDA for device-borne, and EPA for waterborne microbiological risks; the Centers for Disease Control and state and local health departments are active in public health monitoring. Internationally, Health Canada, Agriculture Canada, TNO in the Netherlands, and the Codex Alimentarius, jointly managed by the World Health Organization and the Food and Agriculture Organization, are engaged in microbiological risk management.

Empirical studies currently do not produce sufficient information to assess dose-response relationships in people, for several reasons:

- As with chemicals, most exposures to pathogens are below those associated with death or disease. However, microorganisms can multiply and greatly increase in numbers inside the human host.
- The body has effective defense mechanisms so long as white blood cell and immune systems are intact. Infectious agents can reduce the immune response or, in some cases, change their physical structure to avoid immune defenses.
- As with chemicals, susceptibility varies from person to person. Concurrent exposures to chemicals may affect susceptibility to infectious agents.

As a result, microbial risk assessment methods have increasingly relied on indirect measures of risk based on analytic models that estimate the extent of human exposure and the probability of human responses to exposure (Eisenberg et al. 1996a). Static models based on individual risks and population-based models that account for changes over time are being used conjunctively. (Haas 1983, Haas et al. 1993, Eisenberg et al. 1996a,b). It is difficult to quantify dose-response relationships for microorganisms using those models for several reasons:

- Epidemiologic factors, including secondary infection whereby someone who was infected by contaminated food or water infects other people.
- Host factors, such as the variable development of immunity to the organism.
- Complex contamination factors, such as meat being contaminated at the slaughterhouse, by infected food handlers, or during inappropriate storage by the retailer or the consumer.

Several ongoing efforts are intended to strengthen microbiological risk assessment. For example, the Committee on Food Hygiene of the Codex Alimentarius, a United Nations organization with responsibility for promoting international standards for food safety, has recently issued *Principles and Guidelines for the Application of Microbiological Risk Assessment* (FAO/WHO 1996). The report identifies the basic elements of a microbiological risk assessment, including the information needed and the decisions that must be made. It also identifies key information gaps, including the need for improved dietary intake information. An EPA-funded International Life Sciences Institute working group has recently produced a conceptual framework tailored to assessing risks from waterborne pathogens (ILSI 1996). Continuing efforts to systematically assess the applicability of existing and emerging models should be encouraged, along with monitoring and efforts to collect data comparable with data on chemical hazards, on characteristics of microorganism behavior, toxicity, dose-response relationships, and risks. In addition, potential effects of chemical and radiation exposures on susceptibility to microorganisms should be investigated.

These models and scientific studies would enhance the preventive strategy embodied in the Hazard Analysis Critical Control Point concept that has gradually been developed over the last 25 years to control foodborne pathogens (Van Schothorst 1990).

Risk Characterization

Effective risk communication requires sound risk characterization. Risks have generally been communicated to the public as single numerical estimates, which are easily misinterpreted and misused in the absence of qualitative information about the nature of the risk and about the weight of evidence that supports it. Effective risk characterizations should include clear messages about the nature, severity, and likelihood of risk rather than just numerical estimates. In some cases, mathematical descriptions of uncertainty can be useful for communicating about risks with decision-makers; in most cases, however, mathematical descriptions of uncertainty provide little useful information to support decision-making because most risk-related decisions are routine, made at the local level, and do not involve large stakes. Practical processes such as value-of-information techniques are needed for determining when risks have been sufficiently well characterized to reach a decision, when decisions should be made on the basis of the precautionary principle even if risks are not well characterized, or when data-gathering efforts are worth pursuing.

Effective Risk Characterization to Support Decision-Making

Finding

Risk characterization is the primary vehicle for communicating health risk assessment findings. Many risk characterizations have relied primarily on mathematical estimates of risk to communicate risk assessment findings, often conveying an unwarranted sense of precision while failing to con-

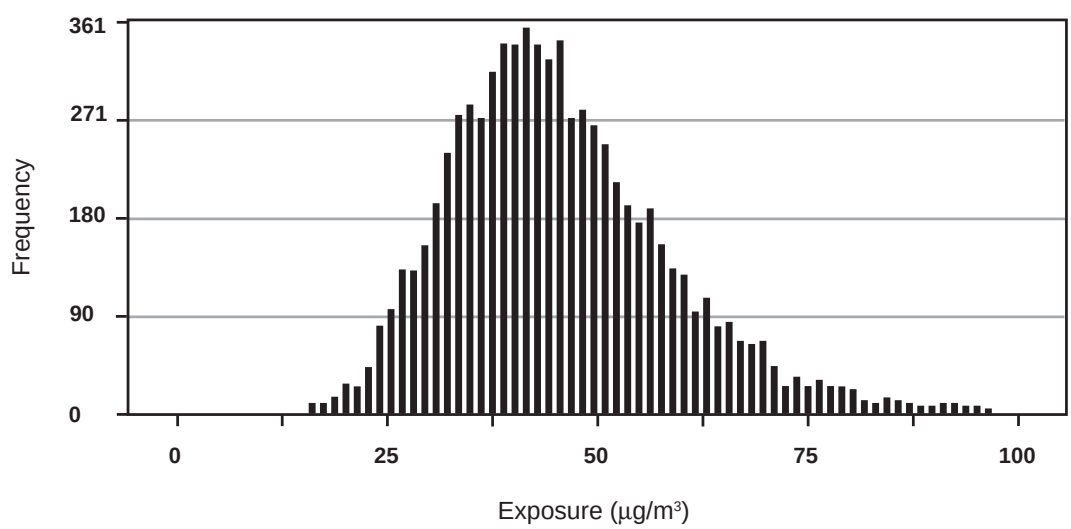
vey the range of scientific opinion. They are particularly difficult for audiences unfamiliar with risk assessment to comprehend. Effective risk management is impeded without effectively communicating information about who is at risk, how they might be affected, what the severity and reversibility of an adverse effect might be, how confident the risk assessors are about their predictions, and other qualitative information that is critical to decision-making.

Recommendation

Risk characterizations must include information that is useful for all parties participating in a risk management decision-making process. Mathematical estimates of risk are important and should be included, but qualitative information on the nature of adverse effects, the weight of the scientific evidence, and the risk assessment itself is likely to be most useful. Information on the range of informed views and the evidence that supports them also should be shared.

Risk assessment is an uncertain process that re-quires both scientific data and science-based judgment. Risk assessments are conducted to estimate risks below the range of observable events in people or in studies of laboratory animals. For example, 10-100 percent of laboratory animals exposed to a relatively high dose of a carcinogen throughout their lives might develop cancers, but regulatory agencies are expected to protect populations from exposure to doses of chemicals that might pose a risk of up to one in a million, not one in 10. The impact of a one-in-a-million cancer risk on a population cannot be detected or

Figure 4.2. Frequency distribution of a population's exposures to a contaminant released to air from a hazardous waste site, estimated using measurements of the contaminant concentration in the air at the site and Monte Carlo techniques.



The distribution reflects the number of people expected to experience each exposure concentration out of 10,000 people exposed. For example, about 270 people out of the 10,000 (y axis) are predicted to be exposed to 50 µg/m³ (x axis).

Source: David Burmaster

measured, because one-fourth of that population is already expected to die of cancer, even in the absence of a particular chemical exposure (see page 33). As a result, estimates of small risks are speculative; they cannot be verified. Expressing a small risk solely in numerical terms, especially in single numbers, is misleading and falsely conveys accuracy.

Communicating quantitative information about noncancer risks poses a different challenge because these risks are not expressed as numerical risk estimates, but as hazard indices. Noncancer risk is typically determined by comparing an estimated human dose to a dose that is considered to be "safe" or allowable (e.g., a reference dose or reference concentration); doses below the standard are considered unlikely to present any risk, while those just above that standard might be less safe, posing some uncharacterized risk of adverse health effects. Although is is possible to consider dose-response relationships for noncancer health effects above the standard, this has not been the general practice. Using a margin-of-exposure approach to cancer risk assessment instead of current methods would result in similar nonprobabilistic expressions of risk (see Need for a Common Metric on page 43).

Often, qualitative information is more useful and understandable than quantitative estimates of risk. Qualitative assessments include a careful description of the nature of the potential health effects of concern, who might experience the effects under different exposure conditions, the strength and consistency of the evidence that supports an agency's classification of a chemical or other exposure as a health hazard, and any means to prevent or reverse the effects of exposure. Qualitative information should also include the range of informed views about a risk and its nature, likelihood, and strength of the supporting evidence. For example, if an agency considers a substance likely to be a human carcinogen on the basis of studies of laboratory animals, but there is some evidence that the classification is flawed, both views should be presented. A discussion of that uncertainty would note the several types of evidence that support the substance's classification as a likely human carcinogen and also the contradictory evidence. Based on this type of discussion, the risk manager might conclude that because the weight of the scientific evidence supports the substance's classification, the best option is to regulate it as a carcinogen in the interest of protecting public health (i.e., invoking the precautionary principle). Alternatively, the risk manager might conclude that the evidence is so uncertain that it is best to focus on conducting additional research or to maintain the status quo. Useful guidance for including qualitative information in risk characterizations is found in EPA's Guidance for Risk Characterization (EPA 1995a). Effective ways to communicate quantitative and qualitative information about risks are discussed in more detail below and in Communicating and Comparing Risks on page 39.

While quantitative uncertainty characterizations are not always effective risk communication tools (see next section), we believe that using distributions to reflect the variability in a population's exposure characteristics can be useful. Considering exposure variabilities will also help clarify whose risks are being considered and the relationship between individual and population risk estimates. All stakeholders can easily comprehend that not all members of a population are exposed to identical doses of contaminants, and that different activities are associated with different exposures. For example, information on reference standards could be compared to a distribution of a population's exposures like that in Figure 4.2, derived using Monte Carlo techniques and exposure data from a hazardous waste site.

In this example, if the concentration of a chemical associated with a 10^{-5} cancer risk were 80 milligrams percubic meter of air, the risk manager and other decision-makers would recognize that most of the population is exposed to less than that concentration. The participants might decide that there is little cause for concern or might attempt to identify the characteristics of the segment of the population in the upper end of the distribution and consider risk reduction options directed at that seg-

ment. If the concentration of concern were 20 milligrams per cubic meter of air, participants would see that most of the population is exposed to higher concentrations, and would want to implement more extensive risk management measures directed at the entire population. The participants might also be interested in comparisons of exposures to contaminant concentrations associated with 10^{-4} or 10^{-6} cancer risks.

Comparing the distribution of a population's exposures to reference standards conveys information that can be more useful for decision-making than a single point estimate of risk or a hazard index, although care should be taken not to treat standards as inflexible bright lines. Priority-setting might not require exposure distributions, but more refined risk assessments that support decisions with greater regulatory impact would. Comparing the distribution of a population's exposures to a standard or family of standards (see Bright Lines for Risk Management on page 54) also conveys information to a risk manager that is less complex than a distribution of risks. In contrast with estimated risk levels, bright lines expressed as exposure concentrations can be measured; measurements facilitate implementation, evaluation, and compliance. The risk manager and the public can see clearly what the relationship between a reference standard and a particular population's or subpopulation's exposure is likely to be. That information can be used to evaluate the need for exposure reduction, and risk reduction can be directed at those who are likely to need it most.

Characterizing the Uncertainty Associated with Risk Estimates

Finding

Confusion persists regarding the differences between variability and uncertainty and their ramifications for decision-making. Variability comprises a population's natural heterogeneity or diversity. Using mathematical distributions to reflect the variability in a population's exposures can be a useful way to show that different members of a population receive different exposures, to help clarify whose risks are being considered, and to highlight the relationship between individual and population risk estimates. Uncertainty, in contrast, results from information that is only partly known or unknowable. Methods to mathematically describe uncertainty are still developing. The best way to present the results of a risk assessment so as to acknowledge uncertainty depends on the importance of the decision under consideration and the magnitude of the uncertainties. Sensitivity analyses of critical parameters for deciding among options are often desirable.

Recommendation

Risk characterizations intended for risk managers and the public should include narrative descriptions of the primary reasons for uncertainty and variability. They should summarize explicitly the weight of the evidence for conclusions about exposures, toxicity, and susceptibility. Probability distributions of the variability in a population's exposures should be used as appropriate to enhance characterization of exposures and communication of risks. The Commission recommends against routine use of formal quantitative analysis of uncertainties in risk estimation, particularly that related to evaluating toxicity. Continued development of quantitative methods should be encouraged by research and regulatory agencies.

Variability arises from differences in the nature and magnitude of a population's exposure to hazards and from variation in people's susceptibility to hazardous exposures. For example, people consume different amounts of fruits and vegetables, inhale different volumes of air according to their level of exercise, come into contact with different amounts of soil depending on occupational and recreational activities, and drink different amounts of water depending on physiological need, weather conditions, and activity level. Estimating a population's exposures to hazards depends on knowing how much contact people have with a contaminated medium. People vary in susceptibil-

ity due to nutritional, metabolic, genetic, and behavioral factors, as well as coexisting or previous exposures (see Identifying Highly Exposed Populations on page 75).

Uncertainty arises from information that is only partly known or unknowable, especially information about toxicity at low levels of exposure to a hazard. We often do not know all the reasons for variation in susceptibility, whether a chemical that produces tumors in rats will do so in humans, whether a site used for industrial purposes today will be needed for residential use in the future, and whether people who eat contaminated fish are likely to eat just the filet or also the internal organs where the contaminants are concentrated. A report prepared for the Commission by Cambridge Environmental, Inc., on health risk estimation (see Appendix A7 for abstract) suggests that most of the uncertainty in risk estimates can result from uncertainty about a substance's toxicity.

Risk assessors and regulators typically rely on assumptions and single numerical values to describe important quantities. For example, instead of describing variability in exposures, they may assume that everyone is exposed to the same amount by drinking 2 liters of contaminated water daily or breathing 20 cubic meters of contaminated air every day for 70 years. Instead of describing uncertainty about toxicity, they assume that, if a chemical causes cancer in laboratory rats, it will do so at equivalent doses in humans. They account for uncertainty in standard-setting for chemicals that cause reproductive effects, for example, by dividing NOAELs by uncertainty and safety factors (see page 110) based on judgments and assumptions. For example, they assume that interindividual variation in humans makes some people at least ten times more likely than laboratory animals to suffer noncancer health effects on lungs, the nervous system, or reproduction. Variability and uncertainty associated with risk estimates can and must be described qualitatively. There is a great deal of debate about the added value of describing them mathematically.

The Commission strongly supports using mathematical descriptions of variability, particularly distributions of a population's possible contaminant exposure concentrations (see previous section and Using Realistic Exposure Scenarios on page 73). In contrast, we are doubtful that much value is added, at least at present, by formal mathematical analyses of uncertainty. The National Research Council report *Science and Judgment in Risk Assessment* (NRC 1994a) addressed the extensive variability and uncertainty associated with estimating risks and concluded that, to the extent feasible, risk characterizations should not be reduced to a single number or even to a range of numbers intended to portray uncertainty. Instead, the report recommended, risk managers should be given risk characterizations that are both qualitative and quantitative and both verbal and mathematical, including mathematical descriptions of uncertainty to the greatest extent feasible.

The Commission concurs with *Science and Judgment in Risk Assessment* that *qualitative* descriptions of risk-related uncertainty are needed for most risk assessments. These narrratives should help to:

- Avoid the false sense that we know precisely the extent of the risk.
- Identify uncertainties with the largest impacts.
- Explain differences in risk estimates generated by different stakeholders.
- Suggest opportunities for valuable research.

EPA's proposed revisions to their guidelines for cancer risk assessment also endorse using narratives to identify reasons for uncertainty (EPA 1996b). As Granger Morgan of Carnegie Mellon University noted in his comments to the Commission, however, descriptors such as probable, likely, possible, improbable, and impossible mean very different things to different people and in different contexts, and may be more useful when they are calibrated with at least some quantification.

The Commission has concluded that *quantitative* uncertainty analyses of risk estimates are sel-

dom necessary and are not useful on a routine basis to support decision-making. Federal and state contractors have told the Commission that, when they perform comprehensive quantitative analyses of risk-related uncertainty and variability, they are ignored or misunderstood. For both uncertainty and variability, there is little consistency between practices at agency headquarters and what is considered acceptable by regional offices or states. Many risk estimates are crude yardsticks for decision-making; as Thomas Gentile, of New York State's Division of Air Resources, noted in his testimony before the Commission, many state-level risk managers want to know, "Is it safe or not?" They want their policy and technical staff to help them reach decisions based on the nature and severity of the problem, generally with single numbers that represent estimates of risk, generated in a consistent manner. Many risk managers told the Commission that they base their decisions on qualitative information and on the weight of the scientific evidence. In this context, the routine provision of a mathematical distribution representing the uncertainty of risk estimates was not encouraged. As noted by Commissioner Goldstein, many crucial economic policy decisions are made on the basis of point estimates of the gross domestic product, the unemployment rate, or the costs of major welfare or health care reform legislation, for example, without mathematical or even narrative descriptions of the considerable uncertainties.

Risk assessments are decision-making tools, not precise analyses of actual or measurable risk, so their focus should remain on how best to inform the ultimate goal—risk reduction—rather than on generating complex distributions of possible risk estimates. Probabilistic methods for quantitatively describing the uncertainties associated with toxicity and risk estimates are still under development and may be needed for using decision analysis and value of information techniques. Nevertheless, in many cases, resources are best spent on conducting research to reduce important sources of uncertainty. As Michael Jayjock of Rohm and Haas Company testified before the Commission, "Describing uncertainty is good. Reducing it is better." Uncertainties about risks and the absence of adequate data to adequately assess risk too often prolong the regulatory process.

Mathematical analyses may be useful among technical staff in generating their input to risk managers. However, it is inappropriate to delay the risk management decision-making process because of a requirement that each risk assessment at national, state, or local levels be accompanied by a formal uncertainty analysis. Many decisions are relatively straightforward, especially issuance of permits at the local or state level and judgments about compliance with specific measurable emission and ambient exposure concentration standards.

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 an unwarranted sense of accuracy. Providing a numerical range of possible risks is thought to allow more informed and more transparent decisions than are possible when only a single point estimate of risk is generated. However, in the absence of adequate explanation of the weight of scientific evidence, communication of a range or distribution of population risks has been misconstrued by those unfamiliar with quantitative methods as implying that all the numbers in the range may be equally plausible and therefore equally valid for regulation (Goldstein 1995, Goldstein 1996).

Providing distributions of risk is also thought to counteract the perceived bias toward overestimating risk that is due to a compounding of conservative default assumptions. However, when data are scarce and uncertainty is great, a range of probabilities based on assumptions would replace point estimates based on assumptions. Often disagreements arise about the underlying shapes of the distributions; folding assumptions about those shapes into a risk assessment incorporates the assessor's bias into the risk estimate. Furthermore, 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 could lead to either stricter or less stringent regulation.

Value of Obtaining Additional Information

Finding

Risk management is complicated by uncertainty and by the issue of how much information is enough to justify regulatory action. Risk managers face a dilemma: is it better to make a regulatory decision now based on an inherently uncertain risk assessment, or is it preferable to collect additional information first and then decide? Value-of-information techniques provide an analytic framework for resolving this dilemma and for preventing the regulatory paralysis associated with unbounded data gathering and analysis.

Recommendation

Risk characterizations should provide insight into the potential costs and value of acquiring additional information as an alternative to acting immediately on the basis of available data and the precautionary principle. In those cases where the quality of the information is poor and the stakes in decision-making are large, agencies should experiment with formal value-of-information methods to determine whether it is most appropriate to act or wait for improved information). Continued research in the methodologic development and application of value-of-information techniques to environmental policy issues should be encouraged.

A potential barrier to the successful implementation of the Commission's Risk Management Framework or to the effective use of tiered approaches to risk assessment and priority setting is conflict over the need for more information. If a simple screening risk assessment performed for the purpose of priority-setting yields results indicating that a particular industrial facility might pose an unacceptable risk, a more refined risk assessment might be desired. A more refined risk assessment would require more data than the screening risk assessment, so there would be an incentive for the owner of the facility to generate those data in the hopes that the more refined assessment would show that it does not pose an unacceptable risk. However, if the more refined risk assessment still indicated that the estimated risk is too high, the owner of the facility might decide that collecting even more data would be worth the investment if regulatory action would be deferred. Meanwhile, the community might be outraged by apparent collusion to delay action. Ellen Silbergeld, representing the Environmental Defense Fund, emphasized in her testimony before the Commission that the greatest barriers to credible risk assessments are the absence of data and the need for guidelines to determine how much information is enough to conclude an iterative process and support a decision. Comments from David Roe of the Environmental Defense Fund and from John Adams of the Natural Resources Defense Council reinforced the need for more and better data on exposure and toxicity to improve the usefulness and credibility of risk assessments. Likewise, Warner North, of Decision Focus, Inc., recommended incentives for both data collection and for speedy risk management decisions.

The challenge for risk managers is to bring analysis to bear on the question of whether collecting additional data is likely to lead to a better, more confident, or more widely accepted regulatory decision. For example, if a statutory mandate compels a particular pollution control technology regardless of the level of risk, then collecting additional data about risk will not influence the regulator's decision (unless the statute itself is changed). When low-cost control options are readily available that will reduce or prevent a plausible yet unproven risk, it might be preferable to proceed on the basis of the precautionary principle, rather than await more knowledge about the precise level of risk. Alternatively, high-cost control options may be good candidates for deferral if there is reason to believe that better information about the level of risk might change the ultimate regulatory choice (e.g., under a discretionary "unreasonable risk" statute).

When the effects of pollution may be persistent, irreversible, or catastrophic, risk managers should be reluctant about committing to strategies that require long-term data collection prior to undertaking protective actions. On the other hand, the costs of action could be reduced considerably if the risk manager can phase in new regulatory requirements gradually rather than imposing them immediately. Even if information about risk is fairly precise, there may be considerable uncertainty about the cost and effectiveness of various control strategies. Under these conditions, additional data collection about cost or effectiveness would make more sense than development of more precise risk estimates. As soon as a risk-related problem is identified, however, social impacts can begin, especially at the community level. For example, decreased property values and fear of disease may occur regardless of the availability of information or uncertainty about the magnitude of the risk. Efforts to obtain additional information must be balanced against a community's desire to address the risk promptly.

Whenever additional research is proposed prior to taking regulatory action, risk managers should insist on a careful understanding of the purpose of the research, its probable cost, and the time horizon for completion. The results of risk-related research may not be predictable, but the risk manager can insist on a planned and orderly approach to acquiring the new information. Even if a risk manager decides to act rather than to acquire better information about risk or cost, it may nonetheless be wise to launch research activities that can inform future regulatory choices and evaluations of the original decision.

The peer-reviewed literature contains a number of examples of applications of value-of-information methods to environmental policy questions (e.g., Morgan et al. 1978, Campbell et al. 1982, Evans et al. 1988, Lave et al. 1988, Reichard and Evans 1989, Morgan and Henrion 1990, Siegel et al. 1990, Hammitt and Cave 1991, North et al. 1992, Taylor et al. 1993, Dakins et al. 1994, Dakins et al. 1996, Thompson and Evans 1996). Value-of-information methods provide estimates of the value (typically in monetary terms) that the decision-maker would place on having improved information and consequently provide a sense of the amount of resources that could reasonably be spent to obtain better information.

In many cases, considerations of the value of information can be thought through qualitatively, without any formal quantitative analysis. However, when the stakes in a decision are large and the uncertainties complex, risk managers or their technical staffs may find it useful to experiment with formal value-of-information tools. Value-of-information analysis, formal and informal, can be a useful component of the Commission's dynamic Framework for improving the process of risk management.

5

Uses and Limitations of Economic Analysis in Regulatory Decision-Making

The regulatory reform debate in the 104th Congress highlighted the role of benefit-cost analysis and cost-effectiveness analysis in regulatory decision-making. Each of the last five presidents has issued an executive order requiring estimation and consideration of the benefits and costs of major regulatory actions, but the questions of whether and to what extent various regulatory decisions should be determined by economic considerations remains controversial.

Risk assessment results can be used as the basis for estimating costs and benefits the results of both risk assessment and economic analysis can contribute to or determine a regulatory decision. Risk assessment and economic analysis can involve large investments of resources and multiple assumptions however, and they produce uncertain results. Their results contribute only part of the information that must be considered in making decisions about the best ways to protect human health and the environment.

In view of the important and complementary roles of risk assessment and economic analysis, the Commission decided to consider the strengths and limitations of economic analysis, although we were not explicitly mandated to do so. We relied on an invited issue paper by Alan Krupnick, Michael Toman, and Ray Kopp of Resources for the Future (see Appendix A7 for abstract) and on invited testimony and comments received from Lester Lave of Carnegie Mellon University, Richard Morgenstern of Resources for the Future (on leave from EPA), Nicholas Ashford of MIT, Douglas MacLean of the University of Maryland, and John Graham of the Harvard School of Public Health.

Benefit-Cost Analysis and Cost-Effectiveness Analysis

This section briefly addresses the role of benefit-cost analysis (BCA) and cost-effectiveness analysis (CEA) (together referred to as "economic analysis") in regulatory decision-making. Some health and environmental statutes require the consideration of costs and benefits in risk-related decision-making; others explicitly exclude their consideration, while still others are silent. Like risk assessment results, the results of economic analyses have often been communicated solely in numeric terms accompanied by little information on assumptions, nonquantified benefits and costs, and the analyst's confidence in the results. The 1996 *Economic Report of the President* recognizes the important role of cost and benefit considerations in risk management decision-making, while highlighting the need to take uncertainty into account and to include factors that cannot be monetized or quantified.

Useful Roles in Regulatory Decision-Making

Finding

The role of economic analysis in regulatory decision-making is controversial. There is concern that economic analysis places too much emphasis on assigning dollar values to aspects of health and the environment, that are difficult—if not impossible—to quantify. There is also concern that regulatory decisions about health and environmental protection might be made strictly on the basis of whether their quantifiable benefits outweigh their monetized, quantifiable costs.

Recommendation

The tools of economic analysis should be recognized as legitimate and useful ways to obtain information for the Risk Management Framework

and for regulatory decisions that will affect health, safety, and the environment, but not as the sole or overriding determinant of those regulatory decisions. Information about costs and benefits that are intangible and that cannot be assigned monetary values should be addressed and considered explicitly. Assumptions and uncertainties should be specified.

Economic analysis plays an important role in the options stage of our Framework for Risk Man-agement (see Section 2). Like risk assessment, the tools of economic analysis have strengths and limitations. And like social and political considerations and information on risks to health and the environment, economic analysis can provide important input to risk management and regulatory policy decisions. Considering incremental costs and benefits in regulatory decision-making can help to clarify the tradeoffs and implications associated with alternative regulatory policies and help regulatory agencies to set priorities. Economic analysis can contribute to making better use of society's limited resources.

The objectives of CEA and BCA differ. CEA can help identify the risk management option that achieves a specified regulatory goal with the smallest cost or least reduction in overall social well-being. That is, CEA begins with an assumed health or environmental protection goal and then explores and compares the methods that could achieve that goal to identify the least costly one (while acknowledging that costs and benefits might be inequitably distributed; see page 96). For example, if the health-based goal is to lower the current ambient ozone standard to 0.1 ppm, CEA could be used to help to choose among options that are expected to attain the 0.1 ppm standard but use different approaches, generate different costs, and may have different probabilities of success. Tengs et al. (1995) used CEA to compare different life-saving medical interventions against a common measure, years of life saved.

CEA also can be used to assess different means of achieving intermediate regulatory goals. Suppose, for example, that several alternatives can be pursued to reduce automobile exhaust emissions as part of a larger ozone control strategy. CEA can be used to rank the cost per unit of emissions reduction of those alternatives. Policy makers could then compare the vehicle policies with other options to determine the least cost way to achieve the larger goal of ozone reduction. Disadvantages of CEA are that the most cost-effective option might not be the one that provides the most efficient allocation of resources and that only costs, not benefits, are considered.

BCA has a different role: it can be used to help formulate risk management policies and priorities and identify risk management goals that maximize net benefits across various levels of protection. For example, BCA can assess the benefits and costs of alternative health-based standards with different levels of health protection. Consider the following hypothetical example:

Possible Standard	No. Annual Health Effects Averted		Annual Cost of Controls ($ million)		Incremental Cost ($ million/ effect averted)
		Incremental Benefit		Incremental Cost	
status quo (100 ppm)	—		—		—
50 ppm	500	500	50	50	0.1
20 ppm	950	450	150	100	0.2
5 ppm	990	40	500	350	9
1 ppm	999	9	2,000	1,500	170

Note: Figures are chosen strictly to illustrate the method.

In this is example, BCA could assist EPA in selecting the standard that it should adopt by translating health effects into dollar-equivalent units with such methods as "willingness-to-pay." The willingness-to-pay concept reflects the economic principle that environmental quality and risk reductions ultimately are things people value, just as they value conventional consumer goods. Althouh it is subjective and can be unreliable, economists use this method to estimate how much people will give up to gain environmental improvements. It is only one approach that can be used to value costs and benefits, however. In this hypothetical example, if eco-

nomic analysis indicated that the public is willing to pay up to $5 million per averted health effect, the economically "efficient" standard would be between 5 and 20 ppm. BCA applied in a strict quantitative sense can be used only to the extent that costs and benefits can be monetized. This approach might be rejected if willingness-to-pay is unknown, benefits are nonquantifiable, or BCA is considered inapplicable. CEA, in contrast, could compare the costs of implementing different methods of control with the number of deaths or health effects that would be prevented by those controls. The policy maker would have to decide which cost is acceptable and select a standard that is consistent with that cost and in keeping with other desired goals of the decision-making process.

The advantage of BCA, in principle, is that it can be used to help make choices among policies and actions with quite different benefits and costs, guided by what members of society are thought to be willing to pay to reduce risks. It is no small challenge to compare, for example, costs and benefits of reducing lead derived from paint contamination in houses with those of ambient ozone reduction. In some cases, benefits and costs might be nonquantifiable because of the absence of reliable data, not because they are intrinsically nonquantifiable. In such cases, it is better to rely on qualitative analysis than to produce an indefensible quantitative analysis. When there are believed to be substantial benefits (or costs) that cannot be monetized, a BCA should be supplemented by discussion of the nonquantifiable elements, as emphasized in the 1996 *Economic Report of the President*. Effective methods of including nonquantifiable benefits in economic analysis are needed and should be pursued. At a minimum, good practice would include listing what the analyst believes are potentially important nonquantifiable benefits (and costs).

An example of a method for evaluating both quantifiable and nonquantifiable benefits is a study of environmental damages caused by the generation of electricity (Rowe et al. 1995). Benefits were divided into four categories: benefits quantifiable; damages probably *de minimis*, so quantification not justified; quantification possible but more resources required for analysis; and quantification not possible. The first category included the health benefits of reducing air pollution because the epidemiologic, cancer risk, and valuation literature regarding air pollution is relatively rich. The benefits of reducing acid deposition on crops, vegetation, and forests were placed in the second category. The third category included impacts of surface water chemical discharges on fisheries; monetization of the effects was thought to be possible for some chemicals, but many assumptions would be needed and the effects were unlikely to be large. The effect of greenhouse gases on climate was a prominent example in the fourth category; instead of monetization, a sensitivity analysis was provided, which indicated that every dollar of damage per ton of CO_2 emitted was equivalent to 0.1 cent per kilowatt-hour when electricity is generated by coal. Other category four examples are the effects of air pollution on wildlife and the effects of acid deposition on cultural and historic materials.

A BCA of a proposed policy should also be supplemented with information on its distributional consequences. In an assessment of aggregate benefits and costs there is no accounting for who bears the risks and could benefit from risk reduction and who bears the costs of implementing the policy. BCAs based on aggregate benefits and costs do not explicitly weigh consequences by income category or ethnic group (see next section). Equity considerations *can* be considered in BCA, but doing so requires agreement on how to weight different social groups. No objectively correct weights can be substantiated.

CEA, in contrast, does not require that benefits be monetized, although they can be monetized when appropriate. (Nonmonetized benefits cannot be aggregated.) CEA requires only that the "effectiveness" of a policy be defined by some physical measure (such as tons by which pollutants are reduced, or number of cancer deaths avoided). The

cost of different policies per unit of effect can be compared. CEA cannot inform the debate over the goals of a policy, but it can provide information about the cost per death or effect averted; it is up to the policy maker to decide how to use that information to make a decision. CEA, however, should be used cautiously in the analysis of a program with more than one favorable effect—for example, it saves lives, reduces illness, and provides ecological or aesthetic benefits—as it is difficult to compare these on the basis of cost per single beneficial effect. Only if the other favorable effects can be monetized and subtracted from the costs, can a net cost-per-life-saved calculation be made; similarly, an estimate of the net costs of ecological or aesthetic benefits can be made by deducting estimates of reduced morbidity and mortality risk.

A recent review of the conduct and use of economic analysis in support of EPA regulations indicates that economic analysis has so far played only a minor role in actual decision-making (Morgenstern 1997), primarily because:

- The economic analyses were not designed to address a sufficiently rich array of policy options and were thus rendered irrelevant to the actual decision.
- The scientific information about risk on which the benefits analyses were based was so weak that their credibility and influence were undermined.

Despite its limitations, BCA can provide useful information to help evaluate the favorable and unfavorable effects of proposed regulatory policies and should continue to be used as appropriate to inform but not as the sole criterion for decision-making. *Benefit-Cost Analysis in Environmental, Health, and Safety Regulation* stated that, "benefit-cost analysis is neither necessary nor sufficient for designing sensible public policy. If properly done, it can be very helpful to agencies in the decision-making process" (Arrow et al. 1996). Because estimates of costs and benefits are highly uncertain, BCA cannot be used to "prove" that the benefits of a policy outweigh its costs, or vice versa, Nonetheless, information about the incremental costs and benefits associated with options for a regulatory decision can serve the public interest and, in fact, is mandated in the Unfunded Mandates Reform Act of 1995 and in Executive Order 12866. Moreover, BCA can be an important element of a more inclusive set of decisional criteria for assessing the potential value of regulation. In particular, to ascertain that the benefits of regulations *justify* their costs, as stipulated in Executive Order 12866, it is important not only to identify and measure the incremental costs and benefits that can be quantified but also identify those which are less quantifiable.

Distributions of Costs and Benefits

Finding

Economic analyses have been criticized because they are often blind to issues of environmental equity and fail to make explicit who bears the costs of a regulatory decision and who reaps the benefits.

Recommendation

Economic analyses should present information, where practicable, that can be used to provide a firmer basis for evaluating any inequitable distributions of costs and benefits.

BCA generally does not address the equity implications of the policies that they seek to evaluate. For example, if implementing a policy that affects health, safety, or the environment decreases the welfare of the poor and increases the welfare of the wealthy, but the benefit to the wealthy outweighs the loss to the poor (in dollars, not percent income), BCA might show the policy to lead to an improvement in aggregate social welfare.

BCAs need not incorporate equity considerations quantitatively. Deciding how different groups should be weighted for equity in economic analysis is highly value-laden. However, if groups or individuals within a societal group potentially affected by a policy are likely to experience the impact differently then that should be identified and communicated to risk managers, regulatory decision-makers, and stakeholders, and considered as policies are formulated. For example, the implementation of a policy that reduces

permissible pesticides will result in some segments of the population enjoying reduced health risks when consuming the affected fruits and vegetables; it will also result in some who will no longer to be able to afford those fruits and vegetables. Evaluating such differences quantitatively would be problematic, but revealing them qualitatively would provide important information that could be considered in the regulatory decision.

Uncertainty and Inconsistency in Economic Analysis

The results of economic analyses, like the results of risk assessments, are often expressed as single numbers unaccompanied by any information on the precision or uncertainty that might be associated with them. The inconsistency among agencies and programs in estimating, for example, the cost per life saved in association with a regulatory decision in part reflects the uncertainty associated with valuing such a quantity.

Characterizing the Uncertainty Associated with Cost and Benefit Estimates

Finding

Like health risk assessment, economic analysis involves multiple assumptions and produces uncertain results. Estimates of the costs and benefits associated with alternative regulatory and nonregulatory options rely on data to the extent that they are available, relevant, and reasonably precise, but also rely on judgments, values, assumptions, and extrapolations.

Recommendation

The primary sources of uncertainty associated with the results of economic analyses should be identified, characterized, stated explicitly, and communicated clearly. The results of economic analyses should not be expressed as though they are precise measures of actual economic costs and benefits.

Many sources of uncertainty associated with the results of economic analyses. For example, the results of health risk assessments contribute substantial uncertainty and the uncertainty associated with an upper-bound point estimate of individual risk can 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 accurately 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 as well as measures of dispersion, so that aggregate expected net benefits can be evaluated. Determining central tendencies and measures of dispersion requires information 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 the economic analysis will either overstate the net benefits to the general population or be relevant only to the tail of the risk distribution. However, relying only on central tendencies might misrepresent net costs or benefits to particular subpopulations. Avoiding these inconsistencies requires changes in approaches to both health risk assessment and economic analysis, as discussed later on page 99.

Other sources of uncertainty in economic analyses used in an environmental context are associated with valuing the benefits of environmental assets. Environmental assets are features of the natural environment that people are willing to support financially to avoid their degradation. They include recreation areas, endangered species, visual range, open space, and wetlands. People might value preventing degradation of those assets because they use the services that the assets provide ("use value") or simply because of their existance ("non use value"). Quantitative estimates of value in both cases can be highly variable and often controversial, which may partly explain why natural

resource damage provisions in existing laws have been little used.

Cost estimates are also highly variable and imprecise, and they can vary according to the bias of the organizations affected. Regulatory agencies often must base their cost estimates on incomplete information from parties with economic interests at stake. The Office of Technology Assessment (1995) evaluated how agency estimates of the costs of new regulations before enactment differed from the actual costs incurred. For example, industry comments suggested that implementing the workplace standard for vinyl chloride would cost industries $1 billion; actual costs were about $250 million. OSHA predicted that implementing the workplace standard for cotton dust would cost industries about $280 million a year; actual annual costs were about $80 million. Neither of those estimates anticipated process and technology changes that substantially decreased costs, increased efficiency, and reduced exposures.

In general, according to MIT Professor Nicholas Ashford's testimony to the Commission, costs are initially overestimated for several reasons: costs are often provided by the regulated industries, the ability of regulated industries to learn more cost-effective means of compliance is neglected, economies of scale are ignored, and preregulatory cost estimates neglect the impressive effect that regulations can have on stimulating new technologies. Of course, estimating the economic impact of a new regulation before it occurs is inherently very difficult, relying of necessity on assumptions, judgments, and speculation.

Examples of documented cost underestimation are more difficult to identify, because of a dearth of retrospective analysis. Nevertheless, a number of analysts believe that it occurs with some frequency. For example, recent Clean Air Act rulemakings associated with operating permits did not adequately allow for affected emitters' opportunity cost that resulted from delays in receiving new permits. The Resource Conservation and Recovery Act's rule making on assessing the toxicity of waste materials inadvertantly included large volumes of lower-risk materials, increasing the actual costs of the rule compared with EPA's estimate.

Given the assumptions and uncertainties, it is misleading to express the results of economic analyses as single numerical estimates of costs or benefits. In some cases, probabilistic techniques could provide some sense of the distribution of possible outcomes. More generally, qualitative information included as narratives that assess a few alternative scenarios and their relative plausibility would be helpful. In all cases, however, it is essential to identify the primary sources of uncertainty.

Inconsistencies in Monetary Valuation of Benefits

Finding

Monetized valuation of benefits for regulatory purposes is inconsistent across regulatory agencies and programs.

Recommendation

To achieve more nearly consistent benefit valuation among regulatory agencies, the value of mortality risks should be stated explicitly and valued with best estimates or ranges of estimates and with consistent use of procedures and basic assumptions. Development of federal guidelines for benefit valuation involving stakeholder input should be considered.

Although several successive administrations have issued executive orders that require consideration of costs and benefits in rulemaking, those administrations have explicitly refused to establish a consistent basis for valuing reduction in death risk (or "statistical life" saved) associated with various policy options. As a result, under current guidance agencies may choose not to value death risks (or "lives") explicitly and avoid subjecting their regulations to comparison with a benchmark for cost effectiveness.

Inconsistency in valuation takes several forms, including whether an analysis includes explicit values for death risk reductions, how such values are incorporated, and what values are chosen. For agencies that do explicitly value death risk reductions,

the implied value of a statistical life ranges from $1 million to $10 million. For agencies that do not explicitly value death risk reductions, but instead base decisions on an "acceptable" cost per life saved, the implicit value of a statistical life can be far higher. One study of EPA regulatory decisions that affected cancer risks found regulations promulgated that cost more than $50 million per life saved. An Office of Management and Budget study of such behavior, involving a broader range of causes of death, found even higher costs per life saved, as did a recent Congressional Budget Office study of drinking water standards. In such cases, the decisions were probably driven by statutory or technological requirements. Another way of valuing lives or social costs is by the ratio of false negatives (failing to identify a chemical as a carcinogen) to false positives (inappropriately identifying a chemical as a carcinogen, thereby leading to regulation and loss of its beneficial uses), as illustrated by the Lave-Omenn value-of-information model for carcinogenicity test strategies (Lave et al. 1988, Omenn and Lave 1988, Omenn et al. 1995; see "Value of Obtaining Additional Information" on page 91).

Encouraging agencies and programs to value death risks with consistent procedures that lead to the best estimates or ranges of estimates of such values under specified conditions could reduce interagency and intra-agency inconsistency and possibly facilitate more cost-effective decisions across the agencies. "Best estimates"* could be devised within an interagency process that takes into account consensus and the range of uncertainty around published values, including the extent of comparability of various types of risks. Too-rigid protocols that reduce economists' flexibility to choose the data and analytical approach that best fit the problem should be avoided, however.

Linking Risk Assessment and Economic Analysis

Finding

Risk assessors are unfamiliar with the information about risks that is needed for economic analysis. As a result, the questions asked and the results of risk assessments often do not match the needs of economic analysis.

Recommendation

Risk assessors and economists who must rely on the results of risk assessments to estimate benefits should collaborate more to reduce the inconsistencies between scientific and economic approaches to characterizing risks and risk reduction alternatives. Risk assessors and economists should expand their methods to reduce mismatches.

Implementing the Commission's Risk Management Framework and using information on both risks and economics to make decisions require some consistency between risk and economics-related assumptions and conclusions. At present, risk assessors operate in a world essentially isolated from that of economists, and economists often have little knowledge of risk assessment. Furthermore, risk assessors and economists are generally attempting to answer different questions. Incompatible and contradictory practices will have to be reconciled if risk assessment and economic analysis are to be used together to support effective risk management decision-making.

For example, the results of risk assessments are used in economic analysis to estimate benefits, but risk characterization end points are often inconsistent with economic valuation starting points. The traditional methods of evaluating health effects for use in health risk assessment can conflict with the

*The term "best estimate" is ill-defined and controversial when used to describe the results of risk assessments (see abstract of paper prepared for the Commission by Cambridge Environmental, Inc., in Appendix A7). To economists, however, best estimate is a well defined and accepted concept, referring to central tendency or expected value. Such discrepancies must be acknowledged in order to be reconciled.

needs of economists who are asked, at least implicitly, to provide information on individual preferences for avoiding health risks. For example, a 10 percent improvement in lung function is not meaningful to most people. They do not demand greater lung function; they want fewer sick days. Health risk assessments seldom evaluate risks in terms of sick days, and no available economic studies can be used to value a 10 percent improvement in lung function. In addition, adverse effects other than cancer are generally regulated by comparing a chemical's exposure concentration to its reference standard, or "safe," concentration. Without a linear dose-response relationship, there is no basis for estimating a probability of risk (such as one extra cancer death out of a million people exposed over a lifetime). Economists' methods for evaluating risks require that risks be expressed as probabilities. Closer collaboration between economists who are familiar with the valuation literature and scientists who are estimating concentration-response functions might help to overcome such mismatches in estimating risk and economic value.

Another conflict between the needs of economists and the results of risk assessments arises because health risk assessments generally focus on individual risk estimates rather than population risk estimates. Economists estimate benefits for the population at large, for two reasons. First, if costs are to be compared with benefits, it would make no sense to compare total costs with benefits experienced by only one person, especially the hypothetical "maximally reasonably exposed" individual. Second, even if one were performing a CEA in which abatement costs per risk to the maximally exposed person were being estimated, the resulting estimates could be very misleading for the decision-maker. Suppose that two abatement strategies had equal cost, but one was related to a very high individual risk and low population risk (because few people were exposed to the pollutant of concern), and the other associated with exposing many more people but with low individual risk. A CEA based on individual risk would lead to adoption of the first strategy instead of the strategy based on the population risk, which could be considered the more relevant measure.

Inconsistency also results from the traditional risk assessment practice of relying on conservative assumptions to account for uncertainty about exposure or toxicity. That tradition purposely skews risk estimates upward to build in a margin of safety 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 provides only one point in the upper end of a risk distribution. According to standard practice, a BCA is an attempt to describe the distribution of risks (or the distribution of risk reductions) in the population and defer to a decision-maker to determine what is an adequate level of protection and which strategies deliver that level of protection. Computing cost-effectiveness measures on the basis of an upper-bound estimate of risk will result in a *lower-bound* estimate of the actual cost. Using distributions of risk estimates instead of upper-bound point estimates might overcome this inconsistency.

Finally, mismatch can result because risk assessment relies more on expert opinion and economic analysis relies more on the expressed preferences of nonexperts 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. Nonexperts' individual risk perceptions often disagree with expert opinion (see Identifying Risk Communication Needs on page 39). Resolving these inconsistencies will require judgments regarding the appropriate weighting of the opinions of experts and of informed, nonexpert people. Interaction and collaboration between nonexpert stakeholders and technical people may lead to convergence of views.

The use of margins of exposure by EPA to compare cancer and noncancer risks (see Need for a Common Metric on page 43) has been criticized as being unsuited to economists' needs for specified,

extrapolatable (not necessarily linear) dose-response curves down to very small exposures. That problem has always existed for noncancer effects, because they are thought to exhibit a threshold (no effect below a particular dose). Without a dose-response relationship, there is no basis to calculate incremental benefit and incremental cost as exposure concentrations are reduced. Putting aside the issue of defining that threshold, economists could combine "willingness-to-pay" methods and biological insights to put values on margins of exposure for various types of adverse effects. Having the margins decline due to increases in emissions and exposures would be a negative effect. Taking action to increase margins of exposure between exposures known to have adverse effects and exposures actually experienced in various occupational and environmental settings would be a benefit. Presumably, relative values or monetized estimates could be generated. It would be important to use the risk reduction presentation captured in Figure 3.1 to guide assessment of the amount of risk reduction gained as exposure levels were reduced progressively.

6 The Role of Peer Review in Regulatory Decision-Making

Peer review is an important and effective mechanism for evaluating the accuracy or appropriateness of technical data, observations, interpretations, and the scientific and economic aspects of regulatory decisions. Peer review should provide balanced, independent views. When used well, peer review can serve as a system of checks and balances for the technical aspects of the regulatory process.

Improving the Quality of Regulatory Decisions

Finding

Peer reviews should be conducted both to enhance the credibility of agency decisions and positions and to improve their technical quality. Peer review activities in federal regulatory agencies are generally devoted to evaluating the quality of the toxicologic, epidemiologic, ecological, and engineering data and the credibility of the scientific interpretations that may be used in making a regulatory decision. The quality and interpretation of other technical information, especially related to economic analyses and the social sciences, are generally ignored.

Recommendation

Peer review should play a critical role in evaluation of the quality of technical information used in regulatory decision-making. Peer review of economic and social science information should have as high a priority as peer review of health, ecologic, and engineering information. The primary criterion for membership on peer review panels should be expertise in the area of concern; however, financial conflicts must be avoided.

Peer review of the scientific and economic data presented in the risks and options stages of the Framework (Section 2) is essential for all major rules under development. An open process of sharing the findings and conclusions from peer review can increase the credibility of a risk assessment and stakeholders' confidence in the conclusions. Peer review might even be useful in the first stage of putting a problem in context, drawing in experienced ecologists, public health officials, and researchers.

The Commission believes that expertise in the technical area under evaluation should be the primary criterion for members of peer review panels. However, potential peer reviewers with financial conflicts should be disqualified from service on peer review panels that could specifically influence regulatory decisions related to the products or interests of their organizations. For example, if Monsanto manufactures a pesticide that is under review by EPA for potential classification as a likely human carcinogen, Monsanto employees or stockholders should not serve as peer reviewers, although they should certainly provide input to the technical analysis that is peer reviewed. If Ciba-Geigy manufactures a similar pesticide, Ciba-Geigy employees or stockholders should not serve as peer reviewers either, because they are competitors with Monsanto. These individuals often have a great deal of knowledge about the subject under discussion; however, and should be invited to share that knowledge in open sessions with the agencies and then, upon invitation, with peer review panels. Other industry scientists without scientists witout such clear financial conflicts would qualify.

Individuals with other kinds of financial interests may serve on peer review panels but must disclose those interests. Academic scientists working in the area of pesticide carcinogenesis may serve as peer reviewers but should recognize and disclose that their inputs to EPA's decision might have an indirect impact on the nature or direction of their research. Similarly, qualified staff or representatives of environmental organizations that work to reduce the use of carcino-

genic pesticides may qualify as peer reviewers, even if they may be perceived as enhancing their employment and their organization's visibility.

In contrast with financial conflicts, bias reflects views or positions taken that are largely intellectually or socially motivated. It is difficult, if not impossible and unwise, to eliminate bias. The Commission believes that criteria for constitution of peer review panels should include a balance of disclosed biases and inclusion of active, younger, and culturally diverse scientists and economists. Explicit criteria for revealing and evaluating conflicts and biases are needed (see The Conduct and Effectiveness of Peer Review below).

Although economists have very different expertise from toxicologists and epidemiologists (but not biostatisticians), we recommend a unifed peer reveiw panel, consistent with our recommendation to link assessment outputs and inputs for economic analysis (see page 99).

The person(s) responsible for selecting peer reviewers can have a great deal of influence on the nature and biases of the membership and the expertise represented; consequently, they can indirectly affect the outcome of the review. Those persons can also have a lot of influence on what is peer reviewed. That gatekeeper role should be structured carefully to ensure that biases affect the process as minimally as possible.

The Conduct and Effectiveness of Peer Review

Finding

EPA has a written policy for program-specific peer reviews (EPA 1994). FDA has an established policy for constitution of advisory panels, which function as technical review panels. Some agencies do not have official guidelines or policies for peer review, and essentially none has procedures for evaluating the effectiveness of peer reviews.

Recommendation

Clear, written guidelines for peer review should be established by regulatory agencies, and the effectiveness of agency peer review programs should be evaluated periodically. The extent of peer review should be commensurate with the importance of scientific or economic issues and the regulatory impact of the decision to be made. When peer review is judged to be unnecessary, an agency should provide an explanation and justification.

Official, written guidelines for the conduct of peer reviews help ensure the transparency of agency decision-making and enhance the credibility of agency decisions. Guidelines for consistent peer review procedures can enable agencies to address explicitly the questions and issues that are commonly raised during development of regulations. Administrative features—such as how peer reviewers are selected; which agency problems, risk assessments, regulatory options, or decisions will be subject to peer review; whether and how consistency among an agency's programs should be improved; and how the outcomes of peer review will be used—should be addressed by an agency's peer review policies. EPA's program-specific standard operating procedures for peer review required by its peer review policy (EPA 1994) are good examples of such guidelines.

Peer review policies should also provide guidance to agency staff for effectively framing the responsibilites of peer review panels, which should at a minimum include determining whether all the relevant data were evaluated, whether the conclusions based on those data are justified by the evidence, and whether the conclusions are communicated in a manner that reflects the weight of the scientific evidence.

In some cases, alternatives to traditional peer review panels may be appropriate. For example, while OSHA uses peer review panels for some complex issues, it relies to a greater extent on trial-type rulemaking hearings, that can be quite rigorous. The two approaches should be compared and evaluated against criteria based on agency or cross-agency policies. At CPSC, a formal peer review process is required before issuance of certain rules related to cancer, birth defects, or gene mutations. CPSC employs peer review voluntarily in certain cases with scientific con-

troversy; otherwise, this agency relies on the public comment pracess, usually two comment periods plus a hearing.

Agency peer review policies should also include a regular evaluation process to examine specific examples of an agency's use of peer review in its regulatory decision-making and ask how the peer review was conducted, whether and how the outcome of the peer review was used in a regulatory decision, whether the peer review was considered useful, and finally, how the process could be improved. The General Accounting Office (GAO) of the Congress recently published a report, *Peer Review: EPA's Implementation Remains Uneven*, which evaluated nine major agency work products that had been peer-reviewed under EPA's 1994 peer review policy (GAO 1996). The uneven implementation of its policy was attributed to confusion among agency staff about what peer review means, what its benefits are, and how and when it should be conducted. In addition, accountability and oversight mechanisms were found to be inadequate. Another agencywide evaluation of the role of peer review is described in the EPA publication *Safeguarding the Future: Credible Science, Credible Decisions* (EPA 1992b). Evaluations can be organized by the agency, (as EPA does through its Science Advisory Board), across agencies, such as by the Office of Science and Technology Policy or the GAO, by the risk assessment subcommittee of the administration's Committee on Environment and Natural Resources, or possibly by a rejuvenated Council for Environmental Quality.

Full peer review is unlikely to be needed for every regulatory decision. Implementing a peer review process for every regulatory decision or every step in a regulatory decision would lead to substantial delay and require excessive resources. The most effective and most efficient use of peer review should be decided case by case, taking into account such issues as the extent to which the scientific basis for a risk assessment or economic analysis might be considered controversial, the economic impact that a decision might have, and agency resource constraints. Peer review should *not* be used as a device to delay controversial policy decisions.

Evaluating the Use of Peer Review and of Scientific and Economic Analyses in Regulatory Decision-Making

Finding

There appear to be no mechanisms for evaluating the use of scientific and economic information in regulatory decisions.

Recommendation

Advisory groups should be used periodically to evaluate the use of technical information and the results of peer reviews in regulatory decision-making. Advisory groups for this purpose should be composed of stakeholders, including those with financial stakes. Such advisory groups would review the process, not override pending decisions.

Good science can be used to justify bad regulations. Asking whether relevant scientific or economic information was cited appropriately in a particular regulatory process is critical. There appear to be no mechanisms in place that support review of the use of technical information at the policy stage, although scientific advisers to the EPA administrator, the FDA commissioner, or the OSHA administrator may fill that role informally. Most peer reviews evaluate highly focused, technical topics because of the assumption that scientists and economists tend to lack an understanding of the history and philosophy of an agency's decision-making process. An advisory mechanism for evaluating the descriptions and uses of scientific and economic analysis in the decision-making stage should be developed.

In contrast to members of peer review panels reviewing pending matters, members of advisory groups would be permitted and expected to have conflicts of interest, financial or otherwise. Advisory groups of stakeholders would evaluate the use of the results of peer review in completed cases in the decision-making process as a lessons-learned exercise to support continuous improvement.

7 Recommendations for Specific Regulatory Agencies and Programs

Current practices in the use of risk assessment in regulatory programs vary among federal agencies and even among regulatory programs within EPA. Some of the variation is attributable to different requirements among 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. Some of the variation reflects differences in policy among organizations, adopted as a matter of differing scientific and policy judgment or simply because of the independent establishment of varied precedents, preferences, and objectives. Better coordination among agencies is needed, and there have been several calls for a central organization to coordinate all risk assessment activities.

Previous sections of this report have addressed the larger risk-assessment and risk-management issues that affect environmental health regulatory programs across the federal government. This section narrows those general issues and recommendations to individual agencies and programs and uses them as a basis for specific recommendations. This section is not meant to exhaustively evaluate all the federal agencies that assess and manage risks, but to highlight those that provided testimony to the Commission.

Consistency Among Agencies

Finding

Risk assessment practices are poorly coordinated among and often within regulatory agencies and programs, even among those with overlapping interests and jurisdictions. Inconsistencies and idiosyncratic practices impair the credibility of risk assessment. Nonetheless, the differences among agencies are relatively small considering the complexity and uncertainty of risk assessment.

Recommendation

When two or more agencies or program offices regulate similar health or ecological hazards associated with chronic exposures, they should coordinate their risk assessment methods and assumptions, unless there is a specific statutory requirement for different choices. Scientific disagreements should be explicated.

The primary reason for differening results among agencies is that the function of the risk assessment process—to project possible human health risks associated with the various types and magnitudes of exposures that might arise—outstrips the ability of scientific investigation to give firm answers. The practical need to characterize the risk consequences (including the uncertainty about them) of various potential actions and activities by industries, by government, by individuals, and by society as a whole remains.

There is general agreement on a common framework and structure for risk assessment, but debate continues vigorously about the most appropriate risk assessment approaches, the bearing of various kinds of data on risk projections, the level of risk that is considered negligible, and the degree and appropriateness of conservatism in risk assessment methods. The diversity of methods among federal regulatory agencies makes it difficult to compare risks and any mitigating actions from one regulatory program to another. For example, EPA and CPSC differ on several critical aspects in the performance of a quantitative risk assessment: EPA relies on the "maximally exposed individual" or, now, other upper-end exposure estimates while CPSC uses the average population exposure; EPA uses upper-bound risk estimates while CPSC uses maximum-likelihood estimates; EPA uses pharmacoki-

netic information for cross-species extrapolation, but CPSC declines doing so.

Defaults and standard methods are necessary in the face of uncertainty and lack of case-specific knowledge, but variation among agencies and programs increases the sense of arbitrariness in risk analyses. In cases where regulatory responsibilities overlap or different groups have occasion to assess the same exposures, differences in assessment outcome can lead to conflict and confusion among the public and the regulated community. When inconsistencies exist among agencies with overlapping regulatory responsibilities, a continuing effort is needed to harmonize methods and assumptions used in risk assessment. In cases where consistency is inappropriate, written justification should be provided. Lorenz Rhomberg's report to the Commission details the use of risk assessment by federal agencies and indicates where some of the inconsistencies exist (see Appendix A7).

In this global economy, there is and should be increasing efforts to harmonize toxicologic testing, clinical trials, and now risk assessment on an international basis.

Environmental Protection Agency

EPA has played a critical role in facilitating the substantial improvements in our environment that we have enjoyed over the last 27 years. The major sources of pollution contaminating our air, water, and soil have been greatly mitigated, largely as a result of its programs and private sector and state compliance. The complex problems that remain will require continued creativity and improved efficiency. This section addresses several of EPA's programs and offers recommendations that are aimed at improving the identification and management of risks.

Office of Air and Radiation

The 1990 amendments to section 112 of the Clean Air Act established an entirely new program to control hazardous air pollutants from point sources through the promulgation and implementation of technology-based standards. These standards are arrived at by identifying the maximum available control technology (MACT) currently in place. This strategy was mandated because the regulation of hazardous air pollution from point sources using a chemical-by-chemical, risk-based approach was judged ineffective and inefficient. Difficulty in setting new standards was characterized as "paralysis by analysis" by the Natural Resources Defense Council's David Hawkins, who was assistant administrator for the Office of Air and Radiation in the Carter Administration. The statutory language was interpreted for carcinogens to require an ample margin of safety below the no-effect level, which was assumed to be zero. The agency issued standards for only seven prominent agents, all in the 1970s (see Table 7.1).

As of January 1997, EPA had promulgated 20 MACT standards for 47 source categories and had proposed three more standards. In all, 174 source categories need MACT standards (see Table 7.2). When the MACT process is complete and the control technologies are in place, EPA must start again with each source category within 8 years to assess residual emissions and residual risks.

Table 7.1. Air pollutant standards promulgated.

Section 109 National Ambient Air Quality Standards	Section 112 Hazardous Air Pollutant Standards[2]
Sulfur dioxide	Vinyl chloride
Particulate matter	Asbestos
Ozone	Benzene
Nitrogen dioxide	Radionuclides
Hydrocarbons[1]	Mercury
Carbon monoxide	Arsenic
Lead	Beryllium

[1]Deleted in 1983.
[2]Regulated between 1970 and 1990.

This section presents recommendations regarding the assessment and management of residual risks, as the Commission was mandated by Congress, and addresses several related issues. We also address the topic of indoor air pollution.

Tiered Scheme for Determining and Managing Residual Risks

Finding

In the Clean Air Act Amendments of 1990, Congress directed EPA to require industry to improve the technologies they use to reduce emissions from point sources of hazardous air pollutants. Furthermore, Congress mandated that EPA determine whether any unacceptable residual risks to health from hazardous air pollutants remain after MACT has been implemented. EPA needs and wants guidance on how to implement these residual risk provisions.

Section 112 of the Clean Air Act Amendments of 1990 has been so stringently interpreted that if even a single facility within a source category is found to pose a residual cancer risk of 10^{-6} or more after MACT has been implemented, EPA must consider more stringent new standards for that source category. In the assessment and control of criteria air pollutants (section 109, Table 7.1) and hazardous air pollutants (section 112, Table 7.3), it is noted that the same industrial and utility point sources often contribute pollutants of both types. In addition, motor vehicles are major contributors to ambient levels of the criteria air pollutants ozone, carbon monoxide, and particles, and many hazardous air pollutants, including benzene, 1,3-butadiene, and formaldehyde.

Recommendation

To determine and manage residual risk after implementation of MACT, the Commission proposes that EPA carry out a specific tiered scheme (see Figure 7.1), to be conducted with stakeholder involvement:

1. Characterize and articulate the scope of the national, regional, and local air toxics problems and their public health and environmental contexts.
2. Use available data and default assumptions to perform screening level risk assessments to identify sources with the highest apparent risks.
3. Conduct more detailed assessments of sources and facilities with the highest risks, providing guidance and incentives to regulated parties to either conduct these risk assessments or reduce emissions to below screening thresholds.
4. At facilities that have incremental lifetime upper-bound cancer risks greater than one in 100,000 persons exposed or that have exposure concentrations greater than reference standards, examine and choose risk reduction options in light of total facility risks and public health context.
5. Consider reduction of residual risks from source categories of lesser priority.

Descriptions of Each Step and Rationale for the Scheme

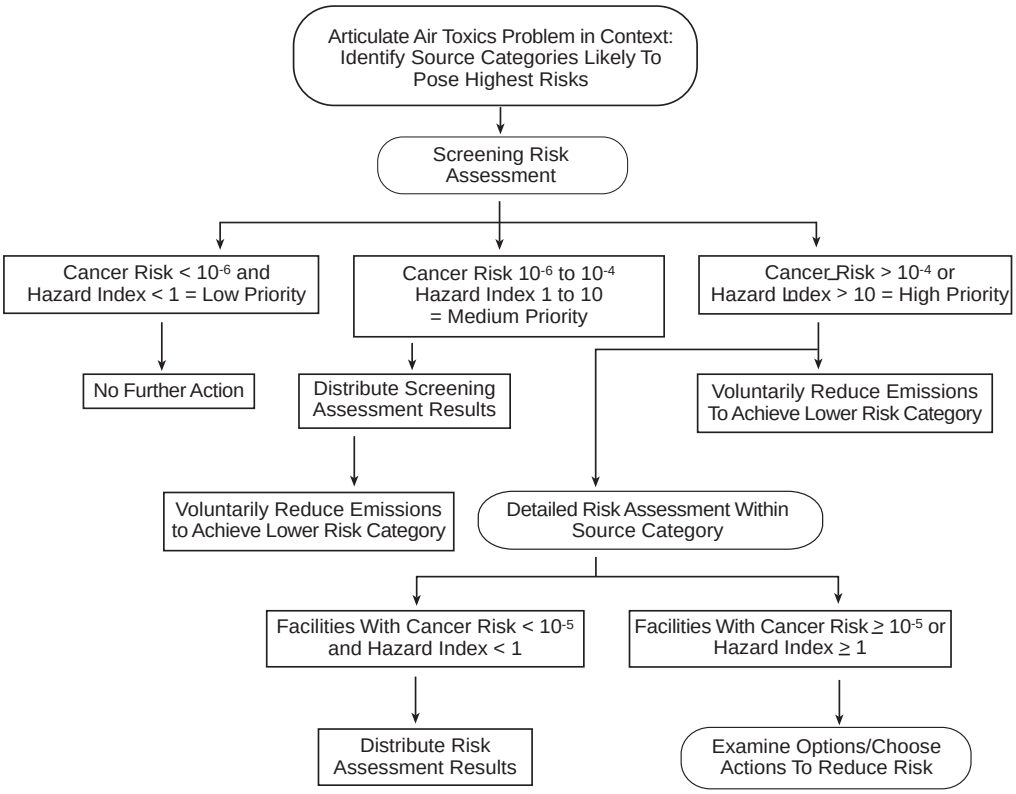
1. Problem/Context Characterization. Local, regional, and national levels of air toxics, by pollutant and by source category, must be put in the context of exposures from other air pollutant sources and from environmental pathways other than air. The goal is to build an understanding among stakeholders about the health context of residual emissions from the regulated point sources. Problem characterization, putting a problem in context, and engaging stakeholders are described in detail as part of the Commission's Risk Management Framework in Section 2.

In this initial step, EPA identifies the priority source categories likely to pose the highest residual risks. The Commission believes that EPA—through the experience gained developing MACT standards—has acquired enough information to iden-

tify the source categories most likely to pose significant residual risks, based on whether high priority hazardous air pollutants are present and whether there are highly exposed populations, or "hot spots."

2. Screening Risk Assessments. For these source categories or subcategories, EPA performs screening risk assessments using the Agency's tier 1 or tier 2 procedures for hazardous air pollutants (EPA 1992d, NRC 1994a), relying on many default assumptions regarding stack heights, distances to fence lines, emission rates, and "lookup tables" to estimate maximum off-site concentrations. The size of the exposed populations should also be considered. Each source category has numerous point sources across the country with different features, operating characteristics, and nearby populations; thus, a screening model must be developed that can be used to generalize risks and likely ranges of risks for each source category. The specific methods, criteria, and assumptions for performing screening risk assessments should be developed by EPA in partnership with state environmental regulatory

Figure 7.1. Scheme for determining and managing residual risk after MACT.



[1]A hazard index is the sum of the ratios of actual (or estimated) exposure concentrations to Reference Concentrations (RfCs). RfCs are considered to be exposure concentrations that are unlikely to be associated with adverse health effects. An RfC is derived by dividing a NOAEL, LOAEL, or BMD by "safety," "modifying," or "uncertainty" factors. In general, a factor of 10 is used to account for uncertainty related to interspecies variability, intraspecies variability, and subchronic to chronic bioassay variability, respectively, unless data (or expert judgment) exist to show that different factors should be used. If uncertainties have been resolved, such as for fluoride, a factor of 1 is used. Another factor of 10 is used if a NOAEL is unavailable. Every chemical has an RfC that is inversely related to its toxic potency. To obtain a hazard index, the ratios of exposure to RfC for each individual pollutant are combined.

agencies, with appropriate peer review and stakeholder input in an open and transparent process.

If source categories considered in the screening risk assessment model are found to pose a potential incremental lifetime cancer risk that exceeds one in a million (10^{-6}) or if a hazard index[1] exceeds one for a hypothetical person exposed to a reasonably representative estimated exposure level, the categories are classified further. If the screening value for cancer risk is $\geq 10^{-4}$ or a hazard index is $\geq$ 10 (far right in Figure 7.1), the source category is given high priority. More detailed risk assessments are performed first within that category, and regulated parties may voluntarily take steps at this stage to reduce emissions and achieve a lower risk category. If a cancer risk is between 10^{-6} and 10^{-4} and a hazard index is between 1 and 10, a source category is considered to have "medium" priority (middle of Figure 7.1). Risk assessment results are distributed to the affected industries and other interested parties, accompanied by appropriate caveats regarding the assumption-based, preliminary nature of the results, so that voluntary process changes or other actions may be evaluated to reduce emissions or risks associated with those sources. Some experience with source categories will be needed to see how well these values serve in forming appropriate categories.

Although the 1990 amendments to the Clean Air Act set 10^{-6} as the threshold for considering source categories for reduction of residual risk, those categories with screening risk estimates that fall within the 10^{-6} to 10^{-4} range might not actually require high priority categorization because of the conservative nature of the assumptions used in screening risk assessments. According to testimony received by the Commission from Joann Held and Tad Aburn, who manage air toxics programs in New Jersey and Maryland, respectively, using a flexible 10^{-6} to 10^{-4} approach is consistent with the permitting strategy already in place in a number of states, where facilities within that range can negotiate their options.

The 1990 amendments do not set a threshold for considering health risks other than cancer, which the Commission believes to be a serious omission. We chose a threshold hazard index of 10 because there are few hazardous air pollutants with RfCs that are within a factor of 10 of their no-observed-adverse-effect levels (NOAELs). Typically, RfCs are one-thousandth of a NOAEL, so a hazard index of 10 in these cases would still leave a margin of exposure of 100. Analogous screening risk assessments that have been performed at Superfund sites might provide useful information about the extent to which screening risk assessments generally identify hazards above and below 10.

3. Detailed Risk Assessments. In cooperation with all stakeholders, EPA and regulated parties perform detailed risk assessments using actual data in place of at least some default assumptions. Actual facilities are evaluated instead of generalized source categories. Options for additional controls or process changes are examined if more detailed risk assessments yield incremental lifetime cancer risks of $\geq 10^{-5}$ or hazard indices of ≥ 1 (bottom right of Figure 7.1). If the more detailed risk assessments yield incremental lifetime cancer risks of $< 10^{-5}$ and hazard indices of < 1, no further action is required. To the extent practical, when more than one source category of high priority is found at the same facility, their risks are evaluated together.

The Commission believes that EPA should be able to place the burden of preparing these risk assessments on the regulated parties by issuing appropriate guidance. Current EPA policy prohibits the Agency from requiring regulated parties to participate in the development of regulations that will affect them, although EPA may encourage them to do so. EPA may wish to reexamine this policy. The regulated parties will be the source of essential emissions data and operating parameters in any case. They may welcome the opportunity to find ways to reduce emissions in order to achieve screening model risk estimates that could avoid the need for detailed risk assessment and further controls.

The Commission prefers a 10^{-5} flexible bright line for actions to reduce residual cancer risk based on detailed risk assessments. We believe

this action level is consistent with Congressional guidance to use 10^{-6} for screening purposes and with the 1987 NRDC v. EPA *Vinyl Chloride* decision about what constitutes an "acceptable" risk "in the world in which we live" (824F.2d at 1165). The choice of this bright line or decision threshold will be better informed after some experience is gained across source categories replacing default assumptions with actual exposure data. Use of a threshold for action more stringent than a 10^{-5} lifetime upper-bound incremental cancer risk would continue an outdated practice of giving much greater attention to cancer risks than to all other health and ecological risks. Note that the 10^{-5} decision threshold reflects aggregate risks from hazardous air pollutants emitted from a particular source, not just risks from each chemical.

4. Risk Reduction. Identification and implementation of options to reduce risk, where required, are performed as part of a local or regional risk management process conducted within the Commission's Framework. Risk characterizations serve as starting points for discussions at the state and local levels during the permitting process. Risk estimates stimulate voluntary actions to reduce emissions and risks.

Context must be investigated further at this stage, estimating the contribution of the facility to overall air pollution and specific disease risks. Risk management with full stakeholder participation should address not only the individual facility context, but also the costs, benefits, equity, and values reflected in various risk reduction options (Section 2). In large facilities, there will be multiple sources, often in different MACT source categories. Use of bubble concepts and other techniques should be considered in the facility-wide permitting process.

5. Iteration. After determining the source categories considered to pose the greatest risks, the agency determines the need for proceeding with assessments of medium-priority and low-priority source categories and assesses the decision thresholds proposed here (see Figure 7.1) in light of comparative risks from other air pollutants.

A Specific Word of Caution

Implementing a tiered or phased approach to assessing risk, such as that recommended here and in *Science and Judgment in Risk Assessment* (NRC 1994a), could lead to awkward public relations circumstances. Situations might arise in which a community is told that a nearby facility might present a potential health risk, on the basis of a screening risk assessment, and is then assured, after a more detailed risk assessment, that the facility does not pose a threat. Members of the community are likely to remain suspicious and believe that the facility is hazardous despite messages to the contrary. This skepticism will be fueled by knowledge that both the critical data and the detailed risk assessment came from the regulated party. Communicating iterative estimates of risk to the public and the media without loss of credibility is extremely difficult and will require serious consideration in each case.

EPA has a special responsibility to communicate that:

- The purpose of a screening assessment is to separate sources that clearly pose negligible risks from sources that might pose higher risks.
- Screening assessments do not characterize the magnitudes of likely risks by generating upper-bound risk estimates.

Early and regular stakeholder participation might reduce the likelihood of conflict; outrage often arises when affected parties are brought into the process late (although there can be additional interested parties at later stages). Open review of the data used in risk assessments and stakeholder guidance for the performance of risk assessments should help.

Data Needed To Implement Section 112 of the Clean Air Act Amendments of 1990

Finding

Critical information gaps exist that hinder EPA from reliably determining to what extent MACT standards are reducing health risks and whether significant re-

Table 7.2. 174 Categories of Sources of Air Pollutants Needing Maximum Available Control Technology Standards Under the Clean Air Act and Regulation Promulgation Schedule by Industry Group

INDUSTRY GROUP	SOURCE CATEGORY[1]	SCHEDULED PROMULGATION DATE	FEDERAL REGISTER CITATION[2]
Fuel Combustion	Engine Test Facilities	11/15/00	
	Industrial Boilers[3]	11/15/00	
	Institutional/Commercial Boilers[3]	11/15/00	
	Process Heaters	11/15/00	
	Stationary Internal Combustion Engines[3]	11/15/00	
	Stationary Turbines[3]	11/15/00	
Non-Ferrous Metals Processing	Primary Aluminum Production	11/15/97	
	Primary Copper Smelting	11/15/97	
	Primary Lead Smelting	11/15/97	
	Primary Magnesium Refining	11/15/00	
	Secondary Aluminum Production	11/15/97	
	Secondary Lead Smelting	11/15/94	60FR32587(F)
Ferrous Metals Processing	Coke By-Products Plants	11/15/00	
	Coke Ovens: Charging, Top Side and Door Leaks	12/31/92	58FR57898(F) 59FR01922(C)
	Coke Ovens: Pushing, Quenching and Battery Stacks	11/15/00	
	Ferroalloys Production	11/15/97	
	Integrated Iron and Steel Manufacturing	11/15/00	
	Iron Foundries	11/15/00	
	Steel Foundries	11/15/00	
	Steel Pickling-HCl Process	11/15/97	
Mineral Products Processing	Alumina Processing	11/15/00	
	Asphalt Concrete Manufacturing	11/15/00	
	Asphalt Processing	11/15/00	
	Asphalt Roofing Manufacturing	11/15/00	
	Asphalt/Coal Tar Application - Metal Pipes	11/15/00	
	Chromium Refractories Production	11/15/00	
	Clay Products Manufacturing	11/15/00	
	Lime Manufacturing	11/15/00	
	Mineral Wool Production	11/15/97	
	Portland Cement Manufacturing	11/15/97	
	Taconite Iron Ore Processing	11/15/00	
	Wool Fiberglass Manufacturing	11/15/97	
Petroleum & Natural Gas Production & Refining	Oil and Natural Gas Production	11/15/97	
	Petroleum Refineries - Catalytic Cracking (Fluid and other) Units, Catalytic Reforming Units, and Sulfur Plant Units	11/15/97	
	Petroleum Refineries - Other Sources Not Distinctly Listed	11/15/94	60FR43244(F) 60FR49976(C)
Liquids Distribution	Gasoline Distribution (Stage 1)	11/15/94	59FR64303(F) 60FR07627(C) 60FR32912(C) 60FR43244(A) 60FR56133(a) 60FR62991(S)
	Marine Vessel Loading Operations	11/15/00	60FR48399(F)
	Organic Liquids Distribution (Non-Gasoline)	11/15/00	
Surface Coating Process	Aerospace Industries	11/15/94	60FR45948(F)
	Auto and Light Duty Truck (Surface Coating)	11/15/00	
	Flat Wood Paneling (Surface Coating)	11/15/00	
	Large Appliance (Surface Coating)	11/15/00	
	Magnetic Tapes (Surface Coating)	11/15/94	59FR64580(F)
	Manufacture of Paints, Coatings and Adhesives	11/15/00	
	Metal Can (Surface Coating)	11/15/00	
	Metal Coil (Surface Coating)	11/15/00	
	Metal Furniture (Surface Coating)	11/15/00	
	Miscellaneous Metal Parts and Products (Surface Coating)	11/15/00	
	Paper and Other Webs (Surface Coating)	11/15/00	
	Plastic Parts and Products (Surface Coating)	11/15/00	
	Printing, Coating and Dyeing of Fabrics	11/15/00	
	Printing/Publishing (Surface Coating)	11/15/94	61FR27132(F)
	Shipbuilding and Ship Repair (Surface Coating)	11/15/94	60FR64330(F)
	Wood Furniture (Surface Coating)	11/15/94	60FR62930(F)
Waste Treatment & Disposal	Hazardous Waste Incineration	11/15/00	
	Off-Site Waste and Recovery Operations	11/15/94	61FR34141(F)
	Publicly Owned Treatment Works (POTW) Emission	11/15/95	
	Sewage Sludge Incineration	11/15/00	
	Site Remediation	11/15/00	

INDUSTRY GROUP	SOURCE CATEGORY[1]	SCHEDULED PROMULGATION DATE	FEDERAL REGISTER CITATION[2]
Agricultural Chemicals Production	4-Chloro-2-Methylphenoxyacetic Acid Production	11/15/97	
	2,4-D Salts and Esters Production	~ sn	
	4,6-Dinitro-o-Cresol Production	11/15/97	
	Butadiene-Furfural Cotrimer (R-11) Production[4]	11/15/00	
	Captafol Production[4]	11/15/97	
	Captan Production[4]	11/15/97	
	Chloroned Production	11/15/97	
	Chlorothalonil Production[4]	11/15/97	
	Dacthal (tm) Production[4]	11/15/97	
	Sodium Pentachlorophenate Production	11/15/97	
	Tordon (tm) Acid Production[4]	11/15/97	
Fibers Production Processes	Acrylic Fibers/Modacrylic Fibers Production	11/15/97	
	Rayon Production	11/15/00	
	Spandex Production	11/15/00	
Food and Agriculture Processes	Baker's Yeast Manufacturing	11/15/00	
	Cellulose Food Manufacturing	11/15/00	
	Vegetable Oil Production	11/15/00	
Pharmaceutical Production Processes	Pharmaceutical Production[4]	11/15/97	
Polymers & Resins Production	Acetal Resins Production	11/15/97	
	Acrylonitrile-Butadiene-Styrene Production	11/15/94	61FR48208(F)
	Alkyd Resins Production	11/15/00	
	Amino Resins Production	11/15/97	
	Boat Manufacturing	11/15/00	
	Butyl Rubber Production	11/15/94	61FR46906(F)
	Carboxymethylcellulose Production	11/15/94	
	Cellulose Ethers Production	11/15/00	
	Ephichlorohydrin Elastomers Production	11/15/00	61FR46906(F)
	Epoxy Resins Production	11/15/94	60FR12670(F)
	Flexible Polyurethane Foam Production	l1/15/97	
	Hypalon (tm) Production[4]	11/15/94	61FR46906(F)
	Maleic Anhydride Copolymers Production	11/15/00	
	Methylcellulose Production	11/15/00	
	Methyl Methacrylate-Acrylonitrile-Butadiene-Styrene Production[4]	11/15/94	61FR48208(F)
	Methyl Metacrylate-Butadiene-Styrene Terpolymers Production[4]	11/15/94	61FR48208(F)
	Neoprene Production	11/15/94	61FR46906(F)
	Nitrile Butadiene Rubber Production	11/15/94	61FR46906(F)
	Nitrile Resins Production	11/15/00	61FR48208(F)
	Non-Nylon Polyamides Production	11/15/94	60FR12670(F)
	Nylon 6 Production	11/15/97	
	Phenolic Resins Production	11/15/97	
	Polybutadiene Rubber Production[4]	11/15/94	61FR46906(F)
	Polycarbonates Production[4]	11/15/97	
	Polyester Resins Production	11/15/00	
	Polyether Polyols Production	11/15/97	
	Polyethylene Terephthalate Production	11/15/94	61FR48208(F)
	Polymerized Vinylidene Chloride Production	11/15/00	
	Polymethyl Methacrylate Resins Production	11/15/00	
	Polystyrene Production	11/15/94	61FR48208(F)
	Polysulfide Rubber Production[4]	11/15/94	61FR46906(F)
	Polyvinyl Acetate Emulsions Production	11/15/00	
	Polyvinyl Alcohol Production	11/15/00	
	Polyvinyl Butyral Production	11/15/00	
	Polyvinyl Chloride and Copolymers Production	11/15/00	
	Reinforced Plastic Composites Production	11/15/97	
	Styrene-Acrylonitrile Production	11/15/94	61FR48208(F)
	Styrene Butadiene Rubber and Latex Production[4]	11/15/94	61FR46906(F)
Production of Inorganic Chemicals	Ammonium Sulfate Production-Caprolactam By-Product Plants	11/15/00	
	Antimony Oxides Manufacturing	11/15/00	
	Carbon Black Production	11/15/00	
	Chlorine Production[4]	11/15/97	
	Cyanuric Chloride Production	11/15/97	
	Fume Silica Production	11/15/00	
	Hydrochloric Acid Production	11/15/00	
	Hydrogen Cyanide Production	11/15/97	
	Hydrogen Fluoride Production	11/15/00	
	Phosphate Fertilizers Production	11/15/00	
	Phosphoric Acid Manufacturing	11/15/00	
	Sodium Cyanide Production	11/15/97	
	Uranium Hexafluoride Production	11/15/00	
Production of Organic Chemicals	Ethylene Processes	11/15/00	
	Ouaternary Ammonium Compounds Production	11/15/00	
	Synthetic Organic Chemicals Manufacturing	11/15/92	59FR19402(F), 59FR29196(A) 59FR48175(C), 59FR53359(S) 59FR53392(a), 59FR54131(S) 59FR54154(a), 60FR05320(S) 60FR18020(A), 60FR18071(a)

INDUSTRY GROUP	SOURCE CATEGORY[1]	SCHEDULED PROMULGATION DATE	FEDERAL REGISTER CITATION[2]
Miscellaneous Processes	Aerosol Can-Filling Facilities	11/15/00	
	Benzyltrimethylammonium Chloride Production	11/15/00	
	Carbonyl Sulfide Production	11/15/00	
	Chelating Agents Production	11/15/00	
	Chlorinated Paraffins Production[4]	11/15/00	
	Chromic Acid Anodizing	11/15/94	60FR04948(F) 60FR27598(C) 60FR33122(C)
	Commercial Dry Cleaning (Perchloroethylene) Transfer Machines	11/15/92	58FR49354(F) 58FR66287(A)
	Commercial Sterilization Facilities	11/15/94	59FR62585(F)
	Decorative Chromium Electroplating	11/15/94	60FR04948(F) 60FR27598(C) 60FR33122(C)
	Dry Cleaning (Petroleum Solvent)	11/15/00	
	Ethylidene Norborene Production[4]	11/15/00	
	Explosives Production	11/15/00	
	Flexible Polyurethane Foam Fabrication Operations	11/15/00	
	Friction Products Manufacturing	11/15/00	
	Halogenated Solvent Cleaners	11/18/94	59FR61801(F) 59FR67750(C) 60FR29484(C)
	Hard Chromium Electroplating	11/15/94	60FR04948(F) 60FR27598(C) 60FR33122(C)
	Hydrazine Production	11/15/00	
	Industrial Cleaning (Perchloroethylene) Dry-to-Dry Machines	11/15/92	58FR49354(F) 58FR66287(A)
	Industrial Dry Cleaning (Perchloroethylene) - Transfer Machines	11/15/92	58FR49354(F) 58FR66287(A)
	Industrial Process Cooling Towers	11/15/94	59FR46339(F)
	Leather Tanning and Finishing Operations	11/15/00	
	OBPA/1,3-Diisocyanate Production[4]	11/15/00	
	Paint Strippers Users	11/15/00	
	Photographic Chemicals Production	11/15/00	
	Phthalate Plasticizers Production	11/15/00	
	Plywood/Particle Board Manufacturing	11/15/00	
	Pulp and Paper Production	11/15/97	58FR66078(P) 59FR12567(C) 61FR09383(P)
	Rocket Engine Test Firing	11/15/00	
	Rubber Chemicals Manufacturing	11/15/00	
	Semiconductor Manufacturing	11/15/00	
	Symmetrical Terachloropyridine Production[4]	11/15/00	
	Tetrahydrobenzaldehyde Production	11/15/97	
	Tire Production	11/15/00	
Categories of Area Sources[5]	Chromic Acid Anodizing	11/15/94	60FR04948(F) 60FR27598(C) 60FR33122(C)
	Commercial Dry Cleaning (Perchloroethylene)-Dry-to-Dry Machines	11/15/92	58FR49354(F) 58FR66287(A)
	Commercial Dry Cleaning (Perchloroethylene)-Transfer Machines	11/15/92	58FR49354(F) 58FR66287(A)
	Commercial Sterilization Facilities	11/15/94	59FR62585(F)
	Decorative Chromium Electroplating	11/15/94	60FR04948(F) 60FR27598(C) 60FR33122(C)
	Halogenated Solvent Cleaners	11/15/94	59FR61801(F) 59FR67750(C) 60FR29484(C)
	Hard Chromium Electroplating	11/15/94	60FR04948(F) 60FR27598(C) 60FR33122(C)
	Secondary Lead Smelting	11/15/00	60FR32587(F)

[1]Only sources within any category located at a major source shall be subject to emission standards under Section 112 unless a finding is made of a threat of adverse effects to human health or the environment for the area sources in a category. All listed categories are exclusive of any specific operations or processes included under other categories that are listed separately.

[2]The markings in the "Scheduled Promulgation Date/FEDERAL REGISTER Citation" columns of Table 1 denote the following:

(A): amendment to a final rulemaking action
(a): proposed amendment to a final rulemaking action
(C): correction (or clarification) published subsequent to a proposed or final rulemaking action
(F): final rulemaking action
(P): proposed rulemaking action
(R): reopening of a proposed action for public comment
(S): announcement of a stay, or partial stay, of the rule requirement

[3]Sources defined as electric utility generating units under Section 112(a)(8) shall not be subject to emission standards pending the findings of the study required under Section 112(n)(1).

[4]Equipment handling specific chemicals for these categories or subsets of these categories are subject to negotiated standards for equipment leaks contained in the Hazardous Organic NESHAP (HON), which was promulgated on April 22, 1994. The HON includes a negotiated standards for equipment leaks from the SOCMI category and 20 non-SOCMI categories (or subsets of these categories). The specific processes affected within the categories are listed in Section XX.X0~) on page 9318 of the March 6, 1991 *Federal Register* notice (56FR9315).

[5]A finding of threat or adverse effects to human health or the environment was made for each category of area sources listed.

Table 7.3. 189 Hazardous Air Pollutants as listed in section 112 of the Clean Air Act.

Acetaldehyde
Acetamide
Acetonitrile
Acetophenone
2-Acetylaminofluorene
Acrolein
Acrylamide
Acrylic acid
Acrylonitrile
Allyl chloride
4-Aminobiphenyl
Aniline
Asbestos
Benzene (including benzene from gasoline)
Benzidine
Benzotrichloride
Benzyl chloride
Biphenyl
Bis (2-ethylhexyl) phthalate (DEHP)
Bis (chloromethyl) ether
Bromoform
1,3-Butadiene
Calcium cyanamide
Caprolactam[1]
Captan
Carbaryl
Carbon disulfide
Carbon tetrachloride
Carbonyl sulfide
Catechol
Chloramben
Chlorine
Chloroacetic acid
2-Chloroacetophenone
Chlorobenzene
Chlorobenzilate
Chloroform
Chloromethyl methyl ether
Chloroprene
Cresols/Cresylic acid (isomers & mixture)
o-Cresol
m-Cresol
p-Cresol
Cumene
2,4-D, salts and esters
DDE
Diazomethane
Dibenzofurans
1,2-Dibromo-3-chloropropane
Dibutylphthalate
1,4-Dichlorobenzene (p)
3,3-Dichlorobenzidene
Dichloroethyl ether (Bis(2o-Anisidine chloroethyl)ether)
1,3 Dichloropropene
Dichlorvos
Diethanolamine
N,N-Diethyl aniline (N,N-Dimethylaniline)
Diethyl sulfate
3,3-Dimethoxybenzidine
Dimethyl aminoazobenzene
3,3'-Dimethyl benzidine
Dimethyl carbamoyl chloride
Dimethyl formamide
1,1-Dimethyl hydrazine
Dimethyl phthalate
Dimethyl sulfate
4,6-Dinitro-o-cresol, and salts
2,4-Dinitrophenol
2,4-Dinitrotoluene
1,4-Dioxane (1,4-Diethyleneoxide)
1,2-Diphenylhydrazine
Epichlorohydrin (1-Chloro-2,3Chlordane epoxypropane)
1 ,2-Epoxybutane
Ethyl acrylate
Ethyl benzene
Ethyl carbamate (Urethane)
Ethyl chloride (Chloroethane)
Ethylene dibromide (Dibromoethane)
Ethylene dichloride (1,2-Dichloroethane)
Ethylene glycol
Ethylene imine (Aziridine)
Ethylene oxide
Ethylene thiourea
Ethylidene dichloride (1,1-Dichloroethane)
Formaldehyde
Heptachlor
Hexachlorobenzene
Hexachlorobutadiene
Hexachlorocyclopentadiene
Hexachloroethane
Hexamethylene-1, 6-diisocyanate
Hexamethylphosphoramide
Hexane
Hydrazine
Hydrochloric acid
Hydrogen fluoride (Hydrofluoric acid)
Hydroquinone
Isophorone
Lindane (all isomers)
Maleic anhydride
Methanol
Methoxychlor
Methyl bromide (Bromomethane)
Methyl chloride (Chloromethane)
Methyl chloroform (1,1,1-Trichloroethane)
Methyl ethyl ketone (2-Butanone)
Methyl hydrazine
Methyl iodide (Iodomethane)
Methyl isobutyl ketone (Hexone)
Methyl isocyanate
Methyl methacrylate
Methyl tert butyl ether
4,4'-Methylene bis (2-chloroaniline)
Methylene chloride (Dichloromethane)
Methylene diphenyl diisocyanate (MDI)
4,4-Methylenedianiline
Naphthalene
Nitrobenzene
4-Nitrobiphenyl
4-Nitrophenol
2-Nitropropane
N-Nitroso-N-methylurea
N-Nitrosodimethylamine
N-Nitrosomorpholine
Parathion
Pentachloronitrobenzene (Quintobenzene)
Pentachlorophenol
Phenol
p-Phenylenediamine
Phosgene
Phosphine
Phosphorus
Phthalic anhydride
Polychlorinated biphenyls (Aroclors)
1,3-Propane sultone
beta-Propiolactone
Propionaldehyde
Propoxur (Baygon)
Propylene dichloride (1,2-Dichloropropane)
Propylene oxide
1,2-Propylenimine (2-Methyl aziridine)
Quinoline
Quinone
Styrene
Styrene oxide
2,3,7,8-Tetrachlorodibenzo-p-dioxin
1,1,2,2-Tetrachloroethane
Tetrachloroethylene (Perchloroethylene)
Titanium tetrachloride
Toluene
2,4-Toluene diamine
2,4-Toluene diisocyanate
o-Toluidine
Toxaphene (chlorinated camphene)
1,2,4-Trichlorobenzene
1,1,2-Trichloroethane
Trichloroethylene
2,4,5-Trichlorophenol
2,4,6-Trichlorophenol
Triethylamine
Trifluralin
2,2,4-Trimethylpentane
Vinyl acetate
Vinyl bromide
Vinyl chloride
Vinylidene chloride (1,1-Dichloroethylene)
Xylenes (isomers and mixture)
o-Xylenes
m-Xylenes
p-Xylenes
Antimony Compounds
Arsenic Compounds (inorganic including arsine)
Beryllium Compounds
Cadmium Compounds
Chromium Compounds
Cobalt Compounds
Coke Oven Emissions
Cyanide Compounds
Glycol ethers
Lead Compounds
Manganese Compounds
Mercury Compounds
Fine mineral fibers
Nickel Compounds
Polycyclic Organic Matter[2]
Radionuclides (including radon)
Selenium Compounds

[1]Delisted
[2]Includes organic compounds with more than one benzene ring and that have a boiling point >100°C

sidual risks remain. There are means to collect needed data and stimulate needed studies in current statutes.

Recommendation

Sufficient toxicity and exposure data should be generated to provide a scientific basis for evaluating residual risks associated with hazardous air pollutants emitted from point sources. Both research programs and data collection efforts are needed. EPA should proceed with TSCA section 4 test rule proposals and with Clean Air Act section 114 emissions surveys.

Congress required that EPA determine through risk-based approaches the need for further control of hazardous air pollutants after implementation of MACT. EPA is poised to start evaluating the residual risks from hazardous air pollutants associated with source categories that have implemented MACT standards, however, data to assess the health risks of most hazardous air pollutants for regulatory purposes are lacking. According to EPA, approximately 40% of the 189 hazardous air pollutants listed in the amendments (one now deleted) cannot be classified as to their cancer hazard, and a noncancer assessment cannot be performed for about 60%. Furthermore, most of the toxicity data that do exist were obtained from experiments that used the oral route of administration, not the inhalation route more appropriate for air pollutants. Despite the fact that these most recent Clean Air Act amendments were passed six years ago, additional toxicity data apparently have not been generated. The existing toxicity data were not compiled until 1996.

The status of exposure data collection is no better. In 1996, EPA tried to perform case studies of potential residual risks after MACT implementation. The agency found that of the 20 source categories for which standards had been promulgated (Table 7.2), adequate data existed to perform even the most preliminary exposure assessments for only seven of them. Those preliminary assessments relied solely on stack heights, distances to fence lines, emission rates, and "lookup tables" to estimate maximum off-site concentrations. This enormous exposure data gap must be filled to perform screening analyses, and estimate residual risks reliably. Perhaps the regulated parties can generate emission estimates from their existing facility-specific (although not necessarily source-specific) TRI reports.

With regard to the Commission's Risk Management Framework, Congress dictated the Problem/Context stage of the MACT process, so EPA focused entirely on the options stage (i.e., MACT), without stepping back to characterize the problem and its context more fully or to evaluate risks. Congress established rigorous deadlines for EPA to promulgate MACT standards, yet provided limited funding for this major new responsibility, constraining the agency's ability to collect or generate data. As emphasized in testimony received by the Commission, EPA would be better positioned now had it clarified data gaps and initiated data development efforts.

EPA should explore partnerships with regulated industries to perform the batteries of toxicity tests and collect the emissions and exposure data needed to assess residual risk. EPA's testing authority under TSCA section 4 is one means for obtaining needed toxicity data for listed chemicals. In fact, EPA has very recently proposed a test rule under TSCA section 4 specifying a battery of toxicity tests for 20 chemicals chosen from the list of 188. Clean Air Act amendments section 114 questionnaires are a means for obtaining needed emissions data. EPA is using this authority to do so. Actual emissions data are often well below the MACT standard-based limits.

By looking at hazardous air pollutants in the larger context of air pollution in particular geographic areas, EPA will be able to make more informed decisions about reducing residual emissions. EPA will give priority to those sources that contribute most to overall risk.

MACT Partnership Program

Finding

In carrying out its hazardous air pollutant program, EPA has used a decision-making mechanism that involves the regulated parties at the very early stages of the process. This mechanism, referred to as the MACT partnership program, is intended to increase the amount of knowledge, skills, and resources devoted to the development of a MACT standard.

Recommendation

The partnership program should continue and be expanded as a stakeholder-based approach to setting MACT standards, including health and environmental organizations and community representatives. EPA should establish an evaluation process for the partnership program. The Commission recommends a similar approach to facilitate decision-making related to residual risk determinations.

The hazardous air pollutant provisions of the Clean Air Act require EPA to promulgate standards for 174 source categories over a clearly defined timetable (Table 7.2). The goal of EPA's partnership program is to reach decisions about MACT standards through a consensus-based decision-making process. Participants in this process hope that decisions can be made in a more timely and effective manner, and that points of disagreement can be identified and reduced. The Commission was told that use of the partnership program to facilitate decision-making shows promise in this regard, although a formal evaluation of the program is lacking.

Conceptually, the partnership approach appears to be preferable to other decision-making models that fail to include stakeholders. It is important to determine whether the decision-making mechanism actually is improved, however, both by expediting the promulgation of MACT standards and by yielding starting points for residual risk determinations.

Integrated Permitting

Finding

Many emissions sources can be subject to multiple MACT standards, as well as to additional Clean Air Act provisions (such as those addressing control of ozone and particles in ambient air), so the impact of multiple regulatory requirements must be considered.

Recommendation

EPA should continue its efforts to integrate multiple permitting requirements into a workable licensing system. It should consider adopting some regulatory flexibility for sources with multiple compliance schedules. This flexibility should focus on maximizing the cost effectiveness of pollution control measures within a reasonable time frame. It should also focus on the pollution reduction benefit that a more comprehensive regulatory program could achieve.

Control of individual pollutants should not be considered in the absence of an overall regulatory context. Because MACT addresses existing sources, consideration should be given to the effects of multiple control requirements on the sources operating within a facility. Generic pollution standards for individual processes might neglect how the processes interact with other sources within a facility. They might also neglect the logistical problems that can arise when particular processes are modified. More sophisticated policies for determining regulatory compliance are needed to address pollution control issues associated with complex sources. Emphasis should be given to applying MACT throughout a facility, with control technology requirements and time lines set to optimize both the effectiveness and the efficiency of pollution reduction measures. The partnership program should help facilitate an integrated approach.

Controlling Indoor Air Pollution

Finding

Compared with extensively regulated outdoor air pollution, indoor air pollution can pose a substantial risk to human health, yet, it receives little attention and remains largely unregulated. Efforts by EPA, Occupational Safety and Health Administration, Consumer Product Safety Commission, and other agencies to develop coordinated strategies for addressing indoor air pollution reportedly have been thwarted by the lack of agreement on the nature of the problems and their solutions, by their lack of statutory authority, and by the fact that jurisdiction over elements of indoor air pollution is shared by several regulatory agencies.

Recommendation

Congress and the administration should develop legislation mandating a coordinated strategy by EPA, OSHA, CPSC, and other federal agencies to address the growing problem of indoor air pollution.

Over the last two decades, public health attention has been drawn increasingly to the problem of indoor air pollution. The energy crises in the 1970s led to a lowering of fresh air ventilation rates recommended by the American Society of Heating, Refrigeration and Air Conditioning Engineers. Many building owners responded by lowering the amount of fresh air circulation through buildings and adding insulation to the walls. Meanwhile, increasing quantities of products containing volatile chemicals were introduced into buildings, such as plywood products and carpeting. A number of studies have shown that the concentrations of many contaminants in air are higher in homes and other buildings than outdoors. NIOSH has reported many complaints, mainly of nonspecific symptoms such as headache, nausea, and eye irritation. The lack of a clearly distinguishable constellation of symptoms and the many causes within indoor environments led to use of the term "sick building syndrome."

In addition, specific indoor air pollution problems have been identified or better appreciated over the last two decades. They include the effects of tobacco smoke, radon, asbestos, lead, and indoor allergens (e.g., mold and dust mites). Exposure to those pollutants is associated with clearly defined health effects, such as lung cancer and asthma; indeed, the incidence and severity of asthma has increased markedly in recent years. Unregulated uses of pesticides, cleaning chemicals, deodorants, and emissions from gas and wood stoves generate high concentrations of potentially toxic air pollutants. Legionellae and other infectious agents can live in air conditioning ducts and other indoor, moist niches and cause outbreaks of infections, possibly in combination with chemical exposures.

CPSC has taken an active role in conducting research on indoor air quality in order to protect consumers. CPSC's accomplishments include: a ban on asbestos in consumer products; a voluntary standard to limit formaldehyde emissions from particleboard and wall paneling; studies of exposures and health effects of biological pollutants in residences, conducted as part of the Harvard Six Cities Study; labeling of methylene chloride-containing products; and many others.

No regulatory framework exists for addressing indoor air pollution concerns, and there are essentially no enforceable standards. Due to their complexity, indoor air pollution problems may not be amenable to tradional command-and-control regulation. EPA's regulatory attention is focused mainly on outdoor air despite research findings on total exposures. The attention of OSHA is focused mainly on industrial environments, and CPSC addresses materials as consumer products. Meanwhile, many problems in offices, public buildings, and homes remain relatively unrecognized and unaddressed. All of these agencies recognize the growing importance of the problem, but none has the regulatory mandate to address it fully. There is an interagency task force, but it, too, lacks a statutory mandate.

Approaches to indoor air pollution assessment and education are fragmented at both the federal

and state levels. EPA's Office on Radon and Indoor Air Quality provides educational materials, and EPA coordinates indoor air research efforts on an intra-agency and interagency basis. NIOSH continues to be active in surveillance. Much political opposition to the development of a regulatory program remains, however. The Commission was told that recent OSHA public hearings on restricting smoking in the workplace and developing basic ventilation requirements was dominated by the tobacco industry and various building-owner organizations.

Indoor air quality problems are often complex and vary widely from one building to the next. Despite the differences, however, some guidance exists that can help to address these problems. EPA has produced excellent documents that can provide useful information, including a kit called "tools for schools" that provides schools with much needed assistance in addressing indoor air quality problems. The agency could gain valuable risk management expertise in this area as it provides technical assistance to building committees organized to address indoor air quality concerns, especially if the agency conducts evaluations of the effectiveness of these activities.

Superfund

When Congress enacted the original Superfund statute (Comprehensive Environmental Response, Compensation, and Liability Act, or CERCLA) in 1980, few were aware of the extent of the problem created by years of inappropriate or inadequate hazardous waste disposal practices. Many thought that the program would need to clean up just a few hundred sites, and expected the initial authorization of $1.6 billion plus reasonable expenditures by private companies to be sufficient and the cleanup to be quick. Today, we recognize that we must still address several hundred thousand contaminated sites, a legacy of an earlier industrial era. We also recognize that most of those sites are not so highly contaminated or complex as to require the attention and active management of the federal Superfund program. EPA, states, and others are working together on a range of approaches to address this wide array of contaminated sites. Many states now administer voluntary cleanup programs that can efficiently return contaminated lands to productive reuse. In particular, there is a focus on "brownfields" that can be restored and employed in the local economy.

Over the years, EPA has identified more than 40,000 potentially contaminated sites in its Comprehensive Environmental Response, Compensation, and Liability (CERCLIS) database. The shadow of liability under the Superfund statute hangs over all those sites. In 1996, EPA announced that more than 28,000 of those need no further federal attention—a step that should assist in removing them from the liability shadow. The federal government and the states continue to study, design, and carry out cleanups at the remaining 13,000 sites on the CERCLIS data base. To date, about 1,300 of the 13,000 have been placed on the National Priorities List (NPL) for federal attention, and more than 30% of the 1,300 have completed cleanup. Although each of the last two years has produced more completed cleanups than the entire first decade of the program, progress is slow. With an average cleanup cost of more than $20 million per site, it is also very expensive. As Clean Sites, Inc., president Toby Clark has testified before Congress, usually someone is happy when Congress causes billions of dollars to be spent; almost everyone, however, seems disappointed with Superfund, for diverse reasons.

The 1990 amendments to the Superfund National Contingency Plan (NCP) addressed the competing goals of the 1986 Superfund Amendments and Reauthorization Act (SARA) by establishing a site-specific decision process. Under this process, cleanup options must satisfy the threshold criteria of protecting human health and the environment and comply with the applicable or relevant and appropriate requirements ("ARARs") of other federal and more stringent state environmental laws. Tradeoffs among options that meet the threshold criteria are then balanced with respect to seven additional criteria that reflect the SARA's mandates to utilize permanent solutions and treatment technologies to the maximum extent practicable and to

be cost-effective. Neither SARA nor the NCP prescribes in detail how to ensure "protection" or how to compare or match options for the protection of health and the environment. Indeed, cleanup decisions often have to satisfy competing criteria in the statute and the NCP, such as long-term effectiveness and permanence of remedy; reduction of toxicity, mobility, or volume; short-term risks (especially to workers); and costs. Acceptability to states and communities are two relevant criteria.

In the years since promulgation of the NCP, EPA has put into place several rounds of administrative reforms to achieve a "faster, fairer, more efficient" program and address "worst sites first" under the constraints of the current law. In the last few years, EPA has emphasized the importance of using reasonably anticipated future land use in site-specific risk assessments and cleanup decisions; issued several important ground water guidance statements to implement recommendations of the National Research Council; acted to protect small parties, prospective purchasers, and innocent landowners from liability; instituted a risk-based priority-setting scheme for funding cleanup actions; and accelerated cleanups through, for example, presumptive remedies and the Superfund Accelerated Cleanup Model. It has also initiated the Brownfields Action Agenda and its pilot program, which seeks to empower states, communities, and other stakeholders through economic redevelopment, safe cleanup, and sustainable reuse of contaminated properties. EPA faces the challenge of implementing these improvements and goals consistently in its 10 regions and in states, territories, and tribal jurisdictions and of meeting reasonable expectations for cost effectiveness.

There is also a critical link between Superfund, the cleanup program for hazardous waste sites no longer in use, and the Resource Conservation and Recovery Act (RCRA), for management of wastes currently being generated. Designing Superfund cleanups and corrective actions to comply with applicable requirements for the treatment, storage, and disposal of RCRA hazardous waste has been difficult. Guidance on using treatability variances to comply with land disposal restrictions and more recent regulations governing Corrective Action Management Units (CAMUs) help, but compliance is still too complex.

Future Land Use

Finding

The Superfund program has struggled with many difficulties. One has been the inconsistent consideration of future land uses and of realistic exposure scenarios. Recently a number of administrative changes have significantly improved the operation of the program. In addition, the highly successful emergency removal actions of Superfund are not well appreciated, despite their timely and major contribution to reduction of public health and ecologic risks.

Recommmendation

Risk assessments and remedy selection should be based on reasonably anticipated current and future uses of a site. As EPA's Land Use Directive of 1995 states, reasonable assumptions about future land uses should be developed early in a process of seeking consensus with local officials and community representatives. Congress should encourage reuse of brownfields by providing liability protection to prospective purchasers who agree to provide access to the property by government authorities and do not exacerbate or add to the contamination. In addition, prospective purchasers who remediate a site should pay a premium to a fund that would cover the costs of future changes in cleanup standards.

Land use and other resource use assumptions play a critical role in determining how clean a site must be for adequate protection of health and the environment, which is a primary criterion under the Superfund NCP. A playground and an industrial warehouse are associated with very different potential exposure scenarios and therefore need different remedial approaches with potentially differing costs to achieve the same estimated level of health protection. EPA's administrative actions

and pilot projects to promote the reuse of brownfields include guidance documents about early consideration of future use, extensive coordination with communities and other stakeholders, deferral of NPL listing determinations while states oversee response actions, voluntary cleanup programs, and model agreements for purchasers.

Inclusion of affected communities from the start as partners in the investigation and remedy selection processes can improve the likelihood that the choice of remedy will reflect reasonably anticipated uses of the site and the wishes of the community. Involving community members should also reduce the dissonance and long delays that often occur when EPA proposes solutions before discussing goals and costs with stakeholders. Such a process is consistent with the Commission's Risk Management Framework.

Use of enforceable institutional controls can make it feasible to protect health and the environment reliably into the future at cleanup levels that are less stringent than those mandated for residential levels. For example, thoroughly cleaning up of a former industrial site in an urban area to a standard safe for young children would be unnecessary and might be so expensive as to preclude the redevelopment that might provide economic development opportunities in depressed areas and save pristine areas elsewhere. To overcome impediments to waste site cleanup, innovative approaches being developed at the state level should be carefully evaluated. Liability protection for prospective purchasers, with appropriate safeguards for access and exacerbation of contamination, is one approach worth considering. A premium could be levied for a fund that would cover the costs of future changes in cleanup standards. Assurances for non-NPL sites that brownfield development under qualified state programs will protect cooperating prospective purchasers from Superfund liability must be accompanied by a continuing monitoring program so that potentially hazardous migration of contaminants from the sites can be predicted, detected, and remedied. Hazardous on-site exposures due to changes in land use or failure to control access must also be prevented.

Risk-Based Cleanup Standards

Finding

EPA needs additional guidance about choosing risk-based cleanup standards. Remedy selection and cleanup standards are sometimes complicated by conflicting relevant and appropriate state or federal requirements.

Recommendation

EPA should continue to use its 10^{-6} to 10^{-4} risk range as a guide for site-specific risk-based cleanup goals, related to future land use. Site-specific data from the Remedial Investigation/ Feasibility Study process should be used to refine default assumptions when available. Because a risk estimate is a result of many assumptions and judgments, it is wise for Congress to eschew setting specific risk levels, leaving that decision to EPA and the states. The Commission prefers qualitative language in legislation, such as "reasonable certainty of no significant harm." The Applicable or Relevant and Appropriate state or other federal Requirements (ARAR) provision of the Superfund law should be amended to delete the "relevant and appropriate" language, because of the wide differences in interpretation that arise.

The risk range is being used productively by EPA. We recommend realistic high-end exposure scenarios for screening assessments and descriptive or probabilistic distributions or ranges of exposure for refined risk assessments (see Exposure Assessment on page 72).

Too much confusion and conflict over the ARAR provision has persisted and consequently the ARAR waiver clause has not been used efficiently. The state and federal regulations that can serve as ARARs were often not written for conditions at Superfund sites and greatly complicate remedy selection and implementation. We support retaining applicable state and federal requirements so long as they do not conflict with the risk-based goals tied to future land

use, as recommended in the preceding section.

Choice of Remedy

Finding

Many difficulties in implementing the balancing criteria of the National Contingency Plan for Superfund have arisen. For example, the requirements introduced in SARA in 1986 to "utilize permanent solutions and . . . treatment technologies to the maximum extent practicable" have been applied inflexibly at some sites. Interruption of exposure pathways and other controls might be more appropriate than treatment at some sites, particularly non-residential ones.

Recommendation

The mandate to use permanent solutions "to the maximum extent practicable" should be changed to the assurance of long-term reliability of protection of health and the environment. Treatment options to reduce toxicity, mobility, or volume of highly hazardous material should be used to ensure long-term reliability and should be overridden when no effective treatment remedy is available. EPA should continue to develop better coordinated mechanisms for proper compliance with RCRA hazardous waste standards at Superfund and RCRA corrective action sites, such as the Hazardous Waste Identification Rule for contaminated media. A design team approach, including states and responsible parties, should be encouraged to accelerate the remedial design phase of the cleanup. Remedies should be chosen to be most cost-effective in meeting necessary protective cleanup levels.

EPA, the states, potentially responsible parties, and citizens often are timid about applying on-site remedies that reduce toxicity, mobility, or volume of contaminants—incineration, solidification, vapor extraction, and bioremediation—and about restrictions on site use. Remedies involving removal to "elsewhere," usually landfills or off-site incinerators, generally are high cost remedies and often are resisted by local communities anxious about the numerous truck trips needed to haul away contaminated material or fearful of incineration and incineration malfunction. Parties must be encouraged to negotiate phases of cleanup, especially when even expensive remedial actions are inadequate for some aspects of the site. On-site technologies that reduce toxicity, mobility, or volume should be used when appropriate. They should be identified as EPA has begun to do, as "presumptive remedies" for appropriate sites and cleanups. Responsible parties should be given opportunities to propose and select alternative remedies if those remedies can meet overall cleanup objectives—including risk-based or residual contaminant or exposure levels—agreed on through a process open to public scrutiny. Cost effectiveness should be a factor; multiple health and ecologic effects might also need to be balanced, as might community cultural, social, and political factors.

One aspect of the law that makes implementation of Superfund cleanups especially difficult is RCRA land disposal restrictions, which have discouraged intrasite movement of wastes for less intensive—yet efficient—on-site treatment. EPA has taken steps to reduce the problem via its CAMU Rule and will do more through its Hazardous Waste Identification Rule for contaminated environmental media. Enactment in April 1996 of H.R. 2036, the Land Disposal Program Flexibility Act, provides a platform for complementing RCRA remediation reforms.

Revising Remedy Selection

Finding

Better and less expensive remedies are being identified as the Superfund cleanup program progresses. In addition, changing policies on consideration of future land use could make it possible to alter the remedy in favor of less reduction of contamination to reach the same cleanup standard, due to different exposure scenarios.

Recommendation

EPA should expand and implement its new policy directives to allow revisions of selected remedies.

EPA should establish procedures to provide appropriate and efficient redress of remedial actions in existing RODs in certain limited cases, such as land use restrictions, development of important new scientific information, or technologic advances. Companies and communities that invested in cleanup of NPL sites during the first 15 years of a steep learning curve for EPA and the nation should receive the benefits new information and new technology can bring. For example, reassessment of 30 to 50 years of pumping and treating of groundwater after initial reduction in contamination levels seems appropriate for reopening RODs. The Commission is encouraged by EPA's "remedy update" reform currently being implemented administratively. This effort is targeted primarily at bringing older groundwater RODs up to date with current science and technology regarding appropriate cleanup objectives for different types of contamination problems. Revising a ROD should not become an excuse for stopping or slowing down cleanup action.

Research and Training

Finding

There is a continuing need for information and education on the toxicity of various chemicals, physicochemical characteristics of contaminants, sources of exposure, and effectiveness of remedies.

Recommendation

Congress should continue to support essential support programs for Superfund—the Agency for Toxic Substances and Disease Registry (ATSDR), the National Institute of Environmental Health Sciences (NIEHS) Superfund Basic Research Program at universities, NIEHS programs for training hazardous waste workers, and applicable EPA research and demonstration activities. The Superfund program should make greater use of EPA's own Science Advisory Board. If, as expected, more responsibility and funding for site-specific decision-making are delegated to the states, research and public health assessment functions should continue to have high federal priority.

Despite extremely challenging deadlines and inadequate data at many sites, ATSDR has made a valuable contribution to the Superfund program through its toxicological profiles of various common contaminants at Superfund sites, its public health advisories (in collaboration with local and state health departments), and its establishment of several exposure registries. That work should continue. The Superfund basic research program administered by NIEHS under the Superfund appropriation has mobilized highly relevant interdisciplinary research at 17 universities. If Congress and citizens want risk estimates and remedies that are based on sound science, not just default assumptions, support for research programs is critical and is a federal responsibility. Good science does not of itself lead to application; Congress must also support EPA's research activities. Similarly, worker training and worker protection for the relatively high risks involved in the cleanup of sites are continuing responsibilities.

EPA's Technology Innovation Office has a private-public partnership program coordinated by Clean Sites, Inc., involving major companies with Superfund responsibilities, vendor companies with new or not widely used technologies, DOE or Department of Defense facilities, and state regulators. The program's demonstrations provide objective comparative assessments in real world circumstances. They should be expanded, and their findings should be widely disseminated.

Office of Prevention, Pesticides and Toxic Substances

The authority and mandates of the Office of Prevention, Pesticides and Toxic Substances (OPPTS) are included in the Pollution Prevention Act, the

Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), the Federal Food, Drug and Cosmetic Act (FFDCA), and the Toxic Substances Control Act (TSCA). The subject of pollution prevention is discussed in Risk Management Options: Alternatives to Command and Control on page 49 of this report. This section focuses on issues related to the toxicity and registration of pesticides and on toxic substances.

Delaney Clause

Finding

In August 1996, Congress passed the Food Quality Protection Act, modifying the pesticide residue provisions of the Delaney Clause. Other applications of the Delaney Clause were not modified (see Food and Drug Administration on page 136). The standard of protection specified in section 408 of FFDCA was changed from zero risk to "reasonable certainty of no harm" in keeping with the Food and Drug Administration's well established statutory language. At the same time, the safety standard was improved to allow for advances in scientific understanding and by requiring explicit consideration of potential risk for highly exposed populations, particularly young children. These changes are wholly consistent with the Commission's recommendations in our June 1996 Draft Report.

Recommendation

None. The Commission appreciates Congress' responsiveness to the recommendations included in our June 1996 Draft Report. We note, however, that because the new statute was effective immediately, EPA was allowed no transition time for making the adjustment to the new procedures and has experienced a difficult time, especially with so many pesticides already in the middle of the approval process.

Multiple Risks From Pesticides

Finding

Historically, EPA has made its regulatory decisions chemical by chemical, including pesticide registration decisions. That approach does not accommodate consideration of the potential effects of exposures to several chemically different pesticides with similar effects or of multiple exposures to chemically similar pesticides. EPA considers multiple exposures and multiple risks when it evaluates pesticides for the purpose of reregistering them, but it does not yet do so during the evaluation of new pesticides.

Recommendation

EPA should establish an integrated approach to the registration process to evaluate multiple risks and exposures to multiple agents. Risks and benefits associated with alternatives should also be compared. Furthermore, to encourage development of safer pesticides and reduce the use of more hazardous alternatives while avoiding market disruption, EPA should expand its accelerated registration program for the products that meet rigorous and well-defined criteria for high human health and environmental safety standards. Products that meet the high standards should be permitted to carry EPA-approved labels to communicate to the user that they meet high safety standards.

EPA has avoided using an integrated approach to registration, because of the potential for serious disruption of market forces, such as shortages due to the loss of minor use labels important to fruit and vegetable growers and pesticide resistance problems as the number of pesticide products on the market is reduced. Instead, the agency has encouraged the substitution of biologic pesticides for more hazardous chemicals and the use of formulation changes and equipment modifications to decrease exposure. It has canceled some of the uses of pesticides that are particularly hazardous, such as parathion. And it has established a restricted use category for needed but highly toxic pesticides to ensure that they will be used only by pest control operators and agricultural workers qualified by training and experience to use them properly. To improve the rational use of pesticides

and minimize their adverse effects by establishing an integrated approach to evaluation of multiple risks and of exposures to multiple agents, the agency should introduce the new approach on a demonstration basis, to avoid disruption.

EPA has a longstanding commitment to developing safer pesticides and alternatives to chemical pesticides. By creating a safer pesticide registration and pesticide labeling program, EPA can encourage development of safer alternatives and elimination of highly hazardous materials. A pesticide registration and labeling policy would give manufacturers an incentive to develop safer alternatives and and give consumers information on which to base informed choices. The marketplace can operate to reduce or eliminate exposures without the disruption and spot shortages that can be caused by an integrated approach.

Updating the Toxic Substances Control Act

Finding

In recent years, toxicologic testing and review requirements for new chemicals have made important contributions to a lower incidence of findings of carcinogenicity and other adverse effects among new chemicals marketed. The Toxic Substances Control Act (TSCA) has not been reauthorized since its enactment in 1976, although it has been subjected to numerous court interpretations, primarily over the process EPA must follow in order to request or require testing by companies. EPA and several consumer and environmental organizations consider the provisions of the law and the judicial interpretations of those provisions as constraining. Industry, on the other hand, believes that much of the information already requested is of little relevance.

Recommendation

TSCA should be updated to reflect advances in toxicology and regulation over the past 20 years. Given the differences in views among key parties, the Commission recommends a focused stakeholder process to review the act and its implementation and to seek consensus on the the best ways for EPA to obtain and interpret needed toxicologic data, especially as related to sections 4 and 8.

TSCA occupies an important position among the numerous health and environmental statutes. It is the only law that provides EPA with the authority to regulate new and existing chemical substances not otherwise regulated by other statutes (such as the laws governing regulation of pesticides, drugs, foods, and cosmetics). It authorizes EPA to gather chemical use, exposure, and toxicologic information; require testing; and regulate unreasonable risks.

At a 1996 conference marking the 20th anniversary of TSCA a divergence of views emerged about how well the processes of testing new chemicals, reporting findings of toxicity and potential risks, and making information available to the public were working. Lynn Goldman, EPA Assistant Administrator for Prevention, Pesticides and Toxic Substances, informed the Commission that judicial interpretations in response to suits over the 20-year history of TSCA have severely limited the agency in issuing requirements for minimal data sets. The agency faces a “catch-22” in that the courts require EPA to have extensive information to justify a testing request, yet EPA can only obtain such information by issuing a testing request.

The Environmental Defense Fund (EDF) has been evaluating the extent to which information is available for quantitative risk assessments of the approximately 2,900 chemicals in the TSCA high-production inventory; apparently not more than a few percent have adequate data for such assessments. INFORM (1996) has performed a study of information publicly available through the Substantial Risk reporting program of section 8(e), which requires chemical manufacturers, processors, and distributors to submit information to EPA concerning “substantial risks” posed by substances used in commerce within 15 days of learning of such risks. Since 1977 EPA has received 13,000 such notices.

According to INFORM (1996), such findings are not submitted in a standard reporting format, are often protected very broadly by Confidential Business Information provisions, lack information on uses and exposures, and are not readily available to the public. EDF objects to the presumption that chemicals for which data are not available should be considered free of risks.

The Chemical Manufacturers Association provided testimony to the Commission, in response to our Draft Report proposal that Congress consider amending TSCA, that no fundamental flaws exist in the law, that it provides EPA with the authority and flexibility needed to protect human health and the environment from unreasonable risk, and that problems in its administration and implementation are being addressed regularly by the agency, industry, and other stakeholders.

The underlying problem is that section 8(e) does not require companies to conduct tests, only to report risks that they do discover through their own testing programs. The result, as noted by David Sigman of Exxon Chemical, representing the Chemical Manufacturers Association, is that there are disincentives to conducting tests, especially exploratory tests. Those companies that do not test avoid reporting, while those that do extensive tests run the risk that any adverse data reported will be given undue weight when the overall "weight of the evidence" should indicate that such adverse findings are unlikely to be correct or plausible.

EPA would like to clarify under both TSCA 8(e) and FIFRA 6(a)(2) what studies and human adverse-event reports must be submitted to the agency. Also, EPA is awaiting results from voluntary participation by U.S. chemical manufacturers in an OECD exercise aimed at testing and reviewing test results for some 500 high-production chemicals, as part of a screening inventory. OECD has recommended a basic set of testing requirements, intended to facilitate decisions about testing in member countries and to generate comparable data for various chemicals. The Commission endorses timely completion of this cooperative effort. Such lists of tests will need to be amended as additional and better tests are developed.

OPPTS and EPA's Office of Research and Development should work together to define criteria for scientifically sound weight-of-evidence reviews of old and new data submitted under sections 8(e) and 8(d). These agencies are cooperatiing in addressing the 1996 Congressional mandate to develop testing protocols and requirements for detecting the effects of chemicals on endocrine functions. At the first meeting of this Commission in May 1994, Theo Colburn discussed observations in wildlife, fish, and humans of changes in reproduction, gender-specific behaviors, sperm count, and incidence of anomalies of the genitalia. The terms "endocrine disrupters" and "endocrine modulators" have emerged as descriptive of a wide range of such effects (Davis and Bradlow 1995, McLachlan and Korach 1995, Colburn et al. 1996), although the National Academy of Sciences committee that is evaluating these effects (see below) uses the term "hormonally active agents." Some, but certainly not all, are mediated by or attributed to compounds that bind to estrogen receptors. Some are chlorinated compounds, but many others, such as alkylphenolic ethoxylate plasticizers, are not.

A recent study of combinations of chemicals with estrogenic activity performed using cultured yeast cells containing the human estrogen receptor reported synergistic interactions at low concentrations in vitro (Arnold et al. 1996). A great deal of scientific, regulatory, and public concern about the potential adverse environmental and human health impacts from synergistic estrogen responses ensued. More recent studies conducted at four different institutions have attempted to reproduce those results in the yeast cell system, in human cells, and in mice (a total of ten different estrogen-responsive assays) (Ramamoorthy et al. 1997a,b). All of the studies failed to reproduce the original results, detecting only an additive response, which suggests that the public attention was premature.

Many scientific issues related to hormonally active agents are just being framed. This topic stands at the hazard identification stage of the Risk Assessment Framework (Section 1) and the Problem/

Context stage of the Commission's Risk Management Framework (Section 2): How do agonists (estrogens) and antagonists(antiestrogens) interact? How predictive are the complex endocrine assays? How do we estimate risks associated with exposure to very low doses of environmental estrogenic chemicals when dietary doses of naturally occurring estrogenic compounds (phytoestrogens, such as flavonoids) are so much higher? Still higher doses of estrogenic chemicals are ingested in the form of oral contraceptives and post-menopausal hormone replacement therapy. The National Research Council has established a Committee on Hormone-Related Toxicants in the Environment to assess their known and suspected modes of action and their potential impacts on wildlife and humans. EPA's Health Effects Research Laboratory has been working to identify those modes of action for some years, and the Chemical Industry Institute of Toxicology has announced that a portion of their budget has been reallocated to initiate a program of research on endocrine effects. The Commission supports giving priority to the scientific assessment of the potential toxicity of this class of chemicals.

Given the divergent views about the situation, the history of litigation, the advances in the world of testing and toxicologic interpretation, and the willingness of all parties to engage in dialogue, the Commission recommends that EPA, industry, academia, and worker, consumer, and environmental organizations be convened in a sustained stakeholder process to review TSCA and its implementation, to propose criteria for developing test batteries, to seek consensus on making weight-of-evidence judgments about such data, to define criteria for making data more accessible to the public, and to consider analogies to the FDA adverse drug reaction reporting scheme.

Office of Water

The EPA Office of Water has responsibility for protecting the nation's surface water and ground water and ensuring the supply of safe drinking water for the public. The Clean Water Act was enacted in 1972, soon after the dramatic incident in which the Cuyahoga River in Ohio caught fire because it was so polluted. Water quality has improved substantially since then; nevertheless, about 35% of America's surveyed rivers, lakes, and streams still do not meet standards for their designated uses (OECD 1996). Point sources of pollution have been controlled to a great extent; now state water quality managers have identified nonpoint sources, such as urban and agricultural runoff, as the largest contributors to water quality problems.

The Clean Water Act regulates point-source and nonpoint-source discharges of pollutants to the waters of the United States. States establish water quality standards based on the designated use of a water body—such as providing fish for consumption, agriculture, or drinking water—and on the quantitative or narrative water quality criteria that are required to support a particular use. Point sources obtain permits for discharges based on available treatment technologies and on the quality of the water receiving the discharge and its designated use. Effluent guidelines for a particular point source are based either on available technology or on water quality. Technology-based effluent guidelines set a consistent, industrywide level of control and are imposed at the point of discharge; if they prove to be inadequate to meet the water quality standards for a particular body of water, additional controls are implemented to meet effluent limits based on water quality. Effluent limits have been established for over 100 pollutants discharged by 51 categories of industry and are based on the best available technology that is economically achievable. For nonpoint sources of water pollution, states use grants from EPA to develop control programs, usually providing for implementation of best management practices.

The Safe Drinking Water Act of 1974, most recently amended in August 1996, requires EPA to set drinking water standards to protect human health from both naturally occurring and anthropogenic contaminants, and it specifies requirements for water treatment. Standards have been formulated for more than 80 contaminants. As a result of the 1996 amendments, EPA must

establish a priority list of unregulated contaminants and gather information on the magnitude of their risks and their occurrence in the water supply. Every five years, EPA must set standards for at least five of the unregulated contaminants that have been listed and studied. The new law also requires the agency to prepare a benefit-cost analysis, and benefits of new standards must justify their costs unless the agency determines that the risk to human health outweighs the cost justification. As recommended in the Commission's testimony to the Senate and citied in the Senate Committee report accompanying the 1996 amendments, the act also recognizes that cost and risk are not the only factors that need to be considered in evaluating environmental programs and that other factors, including values and equity, must also be considered. The importance of safe drinking water was brought home to the general public in April 1993 when *Cryptosporidia* in the Milwaukee water supply caused an epidemic, resulting in deaths and severe intestinal disorders throughout the city.

The following recommendations are intended to build on the important improvements of the last 25 years in surface water, groundwater, and drinking water.

Integrated Watershed Management Approach

Finding

The Clean Water Act regulates sources of pollution in a manner that has resulted in fragmented programs that do not adequately address the health of the watershed ecosystem or sufficiently involve communities, states, and others in multijurisdictional management and protection of water quality.

Recommendation

The Clean Water Act should be amended to establish a comprehensive, integrated watershed management approach to provide for the development of state watershed programs. The state programs should be subject to EPA approval and oversight and have substantial involvement by stakeholders and other appropriate federal, state, and local agencies.

Over the last 25 years, pollutant discharges into the nation's rivers, lakes, estuaries, coastal waters, and wetlands have been greatly reduced. Much of the success has been achieved through the control of municipal and industrial point-source discharges into water bodies under programs established by the Clean Water Act. The health of an aquatic ecosystem can be affected not only by point sources of pollution but also by nonpoint sources such as urban and agricultural runoff, as well as by activities that disturb the land, including logging and grazing, construction (especially of dams and reservoirs), diversion of surface water and ground water flows for domestic and agricultural uses, overfishing, introduction of exotic species into water bodies, and deposition of air pollutants. Russell Jim of the Yakama Indian Nation spoke to the Commission about the contribution of several of such phenomena to the decline of salmon populations in the Pacific Northwest. The clean water programs take a fragmented approach to those problems and do not provide for integrated environmental management of the watershed ecosystem. As noted in comments to the Commission from Michael Evans, general counsel for the Senate Environment and Public Works Committee, a multimedia approach to watershed management has been a priority of Senator Max Baucus (D-MT). With a watershed management approach, ecosystems and human health could be better protected from the cumulative effects of a multitude of natural and human activities.

The watershed management approach is a comprehensive, geographically based approach that recognizes all resources within a hydrologically defined watershed as parts of an interconnected system that depends on the health of the parts to sustain the healthy functioning of the ecosystem. Ecological risk assessment and the index of biotic integrity (see page 77) can be important tools in identifying stressors of the watershed and characterizing their impact on various plant and animal species. For

example, ecological risk assessment case studies being examined by the Office of Water include a wide array of ecological organizations, such as individuals, communities, habitats, landscapes, and ecosystems. The watersheds examined include the Snake River, the Middle Platte River, Waquoit Bay, and Big Darby Creek.

Watershed management should focus on identifying priorities and tailoring solutions to the specific set of problems found in a watershed. The estuary programs in Tampa Bay and Galveston Bay are good examples of government and citizen participation in a process that identifies high-priority environmental problems for the estuaries and institutes action to ameliorate the problems. Those two programs are also good examples of a multimedia approach to environmental problems, as atmospheric deposition was found to be an important source of potential water pollution in both locations.

Achieving greater efficiency and effectiveness through watershed management will depend on building partnerships and integrating federal, regional, state, tribal, territorial, local, and private programs within the watershed.

Implementing the Clean Water Act

Finding

Regulation of water pollution under the Clean Water Act is generally implemented through effluent limits based on technology and water quality. Ecologic and human health risk assessments provide information that is used to help set effluent limits based on water quality and criteria for receiving water quality. Risk assessments are also used to set regulatory priorities.

Recommendation

EPA and the states should continue to use receiving water quality and risk assessment results (and other considerations) to set priorities for the development of various water pollution control programs. Risk assessment should also be used, where appropriate, to establish water quality criteria and effluent limits based on water quality. Risk-based effluent limits should not yet supplant technology and water quality based approaches for reducing water pollutant discharges and protecting water quality, however.

Risk assessment provides useful information for making decisions about the best ways to control water pollution. EPA uses human health risk assessment to derive water quality criteria intended to protect human health. In contrast, ecologic risk assessment is not yet likely to afford adequate descriptions of risks to complex aquatic systems (see Ecological Risk Assessment on page 77). The impacts of endocrine "disruptors" on fish and on the offspring of fish-eating animals, for example, have not been fully assessed. As an emerging tool, ecological risk assessment has not yet reached the level of sophistication and reliability necessary to support its use as the primary determinant of effluent limits based on water quality.

Drinking Water Contamination

Finding

Methods to assess microbial risks associated with drinking water are too limited for general use, and data on risks associated with microorganisms, disinfectants, and disinfection byproducts are sparse.

Recommendation

EPA should give a higher priority to the improvement and application of methods for assessing waterborne microbial risks. The development of data for assessing the occurrence of and risks from microbial contamination and the relationships to the use of disinfectants that form potentially hazardous disinfection byproducts must also be given priority.

Evaluating drinking water quality includes assessing both microbiologic risks and risks associated with disinfectants and disinfection byproducts. Microbiologic contamination of drinking water supplies poses a clear threat to public health when treatment is inadequate. In response to the threat, EPA is developing a risk assessment paradigm for evaluating human risks associated

with waterborne pathogens. Efforts to reduce potential health risks associated with disinfection byproducts must not compromise the microbiologic quality of drinking water.

A 1992 regulatory negotiation effort recently produced the Information Collection Rule, which establishes monitoring and data reporting requirements for large public water systems for EPA to use in setting various drinking water standards. Implementation of the rule is hoped to lead to greater understanding and better characterization of the risks associated with microorganisms, disinfectants, and disinfection byproducts. Additional data and analysis of those risks are needed for the next generation of drinking water standards. Because implementing new standards is expensive and because a large proportion of the United States population is exposed, research should be focused on characterizing risks related to different disinfectants and disinfection byproducts and comparing them with microbial risks so that the agency can target its activities toward the greatest net risk reduction.

Occupational Safety and Health Administration and National Institute for Occupational Safety and Health

An estimated 60,000 deaths every year in the United States are related to occupational diseases and injuries. In 1994, occupational injuries alone were responsible for an estimated $120 billion in lost wages, lost productivity, administrative expenses, health care, and other costs, although the annual occupational fatality rate has been reduced from 18 per 100,000 workers in 1970 to 8 per 100,000 in 1993.

The purpose of the Occupational Safety and Health Act of 1970 is "to assure so far as possible every working man and woman in the nation safe and healthful working conditions." That is to be accomplished by supporting reseach in the field of occupational safety and health, providing medical criteria which "assure insofar as practicable that no employee will suffer diminished health, functional capacity, or life expectancy as a result of his work experience," and developing and promulgating occupational safety and health standards. Two agencies were established to accomplish the purposes of the act: the Occupational Safety and Health Administration (OSHA) in the Department of Labor and the National Institute for Occupational Safety and Health (NIOSH) in the Department of Health, Education and Welfare (now the Department of Health and Human Services).

OSHA is mandated, among other things, to establish and enforce workplace standards to effect the purposes of the act. Standards promulgated under the act are required to be based on the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws. This language and judicial interpretations require that OSHA standards must be both economically and technologically feasible and also have demonstrable benefits.

NIOSH is the only federal entity charged with conducting research in ocupational safety and health; developing innovative methods, techniques, and approaches for addressing problems in occupational safety and health; discovering latent diseases and establishing causal connections between diseases and work; responding to employer and worker requests to evaluate possibly unsafe or unhealthy working conditions; exploring new problems in occupational safety and health, including those created by new technology; and training a workforce of professionals in occupational research, demonstrations, and experiments to effect the purposes of the act.

Assessing OSHA's Regulatory Effectiveness

Finding

Although the nation's recordkeeping system for job-related injuries is widely accepted, underreporting is considered substantial. Furthermore, estimates of the incidence or prevalence of fatal and nonfatal work-related illnesses are very imprecise,

partly because there is no adequate national surveillance system and partly because of complexities associated with discerning cause and effect. The economic burden of occupational injuries amounts to almost half the total cost of all injuries in the United States. The cost of occupational illnesses is believed to exceed that attributable to injuries; for example, the annual costs of occupational skin diseases alone including lost work days and reduced productivity might reach $1 billion. The impact of occupational injuries, disabilities, and diseases spreads in ripples beyond the affected worker and employer to families and society at large in ways that are not easily measured or expressed in monetary terms. The effectiveness of OSHA's regulatory activities directed towards reducing chronic occupational risks cannot be assessed in the absence of adequate national surveillance data.

Recommendation

Congress should direct OSHA, NIOSH, and the Bureau of Labor Statistics to strengthen their surveillance and intervention-effectiveness research and evaluations. Congress should direct OSHA and NIOSH to increase the efforts they devote to quantifying risks, costs, and benefits; these activities, which will require additional resources, should help assess the effects of OSHA's regulations on workplace health and safety and to guide NIOSH research and OSHA regulatory priorities.

A substantial proportion of the estimated 60,000 worker fatalities each year is believed to result from occupational diseases associated with exposures to toxic substances and harmful physical and infectious agents. Many cases of fatal, chronic, and disabling occupational diseases develop over 10-30 years and are poorly counted by employer reporting or worker-compensation systems. For the cases that are reported, the attributable costs underestimate costs due to lost productivity and reduced earning potential; such human values as reduced quality of life are not considered. The lost work day is an inadequate measure of the impact of chronic diseases. Without accurate information on the incidence and prevalence of occupational illnesses, the effect of a regulation on incidence or prevalence cannot be assessed. Without information on the effect of regulations, it is difficult to target research and regulatory priorities toward the exposures and illnesses of greatest concern.

Over the last two years, a comparative risk analysis for priority-setting has been conducted by OSHA with strong participation from NIOSH and many stakeholders. The product of that effort, OSHA's priority-planning process, is the identification of 18 emerging or persistent occupational safety and occupational health issues most in need of agency action, both regulatory and nonregulatory. The results were unveiled in December 1995; work has begun on their implementation. The agenda outlines regulatory priorities based on objective data, subjective judgment, and expert knowledge. Whether workplace interventions based on the identified priorities will have the desired effect on occupational illnesses needs to be assessed and, hopefully, verified through an effective surveillance program.

In a similar process in 1995-1996, NIOSH led 500 federal agencies, industries, associations, labor unions, academics, and private citizens in the development of its National Occupational Research Agenda. The agenda from this stakeholder process outlines priorities for the nation's public and private research in occupational safety and health. It is intended to increase the efficiency and effectiveness of such research by focusing efforts on the most important current and emerging scientific needs for improving the safety and health of workers. It is also an important step in efforts by NIOSH to engage in and promote extensive research coordination and collaboration among organizations and scientists throughout the public and private sectors. Testimony from the stakeholders identified risk assessment methods as a research need of such importance that it was included in the final list of 21 priority research areas.

In both the OSHA and NIOSH priority-setting projects, information on the incidence and prevalence of occupational injuries and illnesses was used to the extent available. However, both OSHA and NIOSH drew heavily on the expert judgment and experience of the stakeholders who participated in the open and iterative processes by which the final products were developed.

OSHA has dedicated a major effort to stimulating state-level and private-sector voluntary initiatives. Priorities and data should assist such devolution and delegation of responsibility.

Improved Cooperation Between OSHA and NIOSH

Finding

The Occupational Safety and Health Act institutionalized the clear separation of health research (NIOSH) and science-based policy decisions (OSHA). Although it is important that OSHA and NIOSH have distinct responsibilities, it is also critical that these interdependent organizations work closely together. For example, OSHA and NIOSH have recently coordinated their regulatory and research agendas through the OSHA Priority Planning Process and the NIOSH National Occupational Research Agenda.

Recommendation

OSHA and NIOSH should continue to facilitate effective collaboration so that OSHA's regulatory needs guide NIOSH's research efforts and NIOSH's contributions to OSHA are well targeted toward OSHA's regulatory and science policy needs, as well as towards serving private-sector worker protection programs. Conversely, NIOSH research findings and risk assessments should be a strong influence on OSHA priority-setting for regulatory and other interventions to address workplace safety and health.

As the 1994 National Research Council report *Science and Judgment in Risk Assessment* emphasized, 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 and building more productive linkages to risk management were both considered essential. OSHA and NIOSH are clearly interdependent: NIOSH identifies health-based exposure limits and provides OSHA with scientific criteria and recommendations in support of OSHA's mandate to set health and safety standards, OSHA uses this information to develop occupational standards that reflect feasibility considerations.

The risk assessment and risk management responsibilities of OSHA and NIOSH are closely linked, so it is important that they ensure an effective interaction. The interagency task force formed to conduct the priority-planning process and the exchange of senior staff, who serve as full-time liaisons within the agencies' directors' offices, are good steps.

Guidelines for Risk Assessment

Finding

OSHA seems to have relied upon a case-by-case approach for performing risk assessment and risk characterization in support of risk management policy decisions. Its 1980 "cancer policy" is rarely used and was written before the many scientific advances of the 1980s and 1990s. Its risk management targets—for example, reducing cancer risk to less than one case per 1,000 workers exposed—reflect the difficulty of demonstrating technical or economic feasibility at lower risk levels.

Recommendation

OSHA should publish, after appropriate public involvement and review, one or more sets of guidelines that lay out its scientific and policy defaults. At a minimum, the guidelines should cover an explicit rationale for choosing the defaults and an explicit standard for how and when to modify them; methods for assessing risk for noncancer health effects of concern in occupational settings; methods for quantifying and expressing uncertainty and individual variability

in risk; and a statement of the magnitude of individual risk that it considers negligible for the various adverse health effects. The guidelines should help OSHA decide how extensive a risk assessment is needed in different situations. Finally, OSHA should explain and justify its actions when it evaluates or regulates a substance differently than other federal agencies that regulate the same substance.

Risk assessment guidelines have served EPA well over the years, with guidelines evolving as knowledge is gained (see, for example, the 1996 Proposed Guidelines for Carcinogen Risk Assessment). OSHA has similar needs but its analyses are too different to adopt EPA's guidelines or the recommendations of *Science and Judgment in Risk Assessment* (NRC 1994a). In their testimony before the Commission, Adam Finkel, director of OSHA's Directorate of Health Standards Programs, and Frank White, vice president of Organization Resources Counselors, Inc., agreed that articulated risk assessment guidance is urgently needed. They also agreed with the testimony of Frank Mirer, director of the Health and Safety Department of the International Union of United Auto Workers, that OSHA's risk assessment procedures should not be uniform but consistent with the magnitude of effect or controversy that a particular standard is likely to generate. To be useful, OSHA's guidelines must recognize that OSHA cannot treat each risk assessment with the same degree of rigor and detail, particularly as it seeks to make up the ground lost in a 1992 court decision vacating more than 400 permissible exposure limits (PELs). Because of the large number of PEL risk assessments that are needed and the fact that substances regulated via PELs will not be subject to the numerous ancillary provisions of OSHA's substance-specific rule-makings (such as medical surveillance and worker training), OSHA should outline a less exhaustive risk assessment template for this category of analysis.

Updating Workplace Permissible Exposure Limits for Air Contaminants

Finding

OSHA's limits for chemical exposures (permissible exposure limits, PELs) are out-of-date, not readily updated, and not sufficiently protective of worker health for millions of American workers. The OSHA PEL update process has been slowed to a crawl by a series of legal challenges. A chemical-by-chemical PEL-setting process, based on intensive assessments of toxicity, exposure, risk, and feasibility, has proved impractical for any but the highest use chemicals. A more constructive and streamlined process is needed for regulating workplace exposures to a large number of air contaminants.

Recommendation

Labor, industry, and OSHA should develop a science-based stakeholder process for updating workplace PELs and for developing new PELs for air contaminants. The process should begin by bringing the PELs up to date with the changes that have been made over the last 30 years in consensus standards. Then, a longer phase of selecting high-priority substances for more thorough analysis, using analytical methods chosen in consultation with stakeholders, could begin. Congress should provide authorizing language required to give standing to the process and the PELs so chosen.

When the Occupational Safety and Health Act was enacted in 1970, the new Occupational Safety and Health Administration promptly adopted existing workplace threshold limit values (TLVs) as permissible exposure limits (PELs). Those TLVs had been established by the non-government organization known as the American Conference of Governmental Industrial Hygienists (ACGIH) in 1968, based on then-available scientific information and best professional judgment. The ACGIH TLV Committee periodically re-evaluates and updates the TLVs,

based on professional judgment and new information, but uses no explicit risk-based or feasibility-based methodology.

In 1986 OSHA mounted a PEL update project, with considerable industry support for the adoption of consensus exposure limits, again largely based on TLVs, for over 400 industrial chemicals. The extent of the scientific evidence supporting the TLVs was highly variable, however, and no uniform criteria for choosing them could be cited. Many academic and labor occupational health specialists criticized the TLVs for permitting too much exposure. When the PELs were proposed in 1989, litigation was filed by several industry groups and by labor. A court ruled in 1992 that this rulemaking was flawed and unacceptable, due to inconsistent and unclear determinations of risk and insufficiently elaborate assessments of feasibility. However, stringent requirements for detailed toxicologic, epidemiologic, exposure, cost, and feasibility information to support many specific rulemakings would far exceed available budgetary and staff resources of OSHA and of NIOSH.

In 1996, OSHA identified a subset of about 20 substances for the first phase of a new PEL update and held a public meeting for comment. Industry criticized this renewed effort, preferring a labor/management/OSHA advisory process and offering to provide exposure data as part of such a process. Labor has been skeptical about such an arrangement, fearing industry domination.

The Commission believes that the tension between the amount of scientific, engineering, and economic analysis required and the need for timely updates and new standards could be resolved in two phases.

Phase I would consist of updating the original OSHA PELs (based on the TLVs of 1968) with current TLVs established by the ACGIH. To do so may require legislation to overcome the criticisms of the court about the previous PEL update. Presumably there could be a rebuttable presumption that the current TLVs are not unduly stringent and have been judged to be technologically and economically feasible.

Phase II would consist of selective attention to those substances, in groups of 10 to 30 chemicals, where estimated risks, known exposure levels, widespread use, or other considerations justify a high priority for further exposure reduction. This process is similar to OSHA's recent effort with the set of 20 chemicals and would allow labor, industry, OSHA, and NIOSH to have an opportunity to agree on the criteria for nomination and selection of chemicals and on a template for risk and feasibility analysis. OSHA and its stakeholders should seek agreement on a template for analysis. Perhaps OMB and the Small Business Administration could assist with guidance on how best to meet their criteria for reviews under Executive Order 12866 and under the Small Business Regulatory Enforcement Fairness Act of 1996, respectively.

This two-phase process should begin by trying to generate consensus about phase I and exploring the need for legislation authorizing the adoption of current TLVs. Similarly, recommendations to Congress might emerge for the phase II process to facilitate negotiated rulemaking and the necessary reviews.

We believe Congress would prefer that such stakeholder consensus emerge before Congress moves into what have been minefields. The precedents include the process that led to modification of the pesticide residue provisions of the Delaney clause in the Food Quality Protection Act of 1996. We have made a similar recommendation for a stakeholder process to define desired legislative action for updating the Toxic Substances Control Act.

It should be noted that PELs are distinct from OSHA's comprehensive health standards, such as those for asbestos, benzene, and recently proposed for methylene chloride. The comprehensive standards include a PEL but may also include implementation requirements such as monitoring, training, and use of protective equipment. About

25 chemicals have been regulated by OSHA with comprehensive standards. Candidates for comprehensive standards have been chosen primarily as a result of petitions from stakeholders and also on the basis of considerations of toxicity, exposure, and number of workers exposed.

Food and Drug Administration

The Food and Drug Administration (FDA) promotes and protects the public health by regulating a wide variety of consumer and medical care products. FDA is responsible for ensuring that human food, animal feed, and cosmetics are safe and truthfully labeled; that human and animal drugs, medical devices, and biologics are safe, effective, and truthfully labeled; and that radiation from x-ray equipment and electronic products (such as television receivers and microwave ovens) does not exceed acceptable limits. FDA is now exercising its responsibility to protect minors from chemicals in cigarettes. Thus, a wide array of safety issues is considered, with a broad spectrum of benefits. FDA also conducts research on risk assessment methods and mechanisms of adverse health effects. In this section, the Commission offers recommendations about food safety, drug approval, and dietary supplements.

The Delaney Clause

Finding

The Delaney clause of the Federal Food, Drug, and Cosmetic Act prohibits FDA approval of food additives (section 409) and color additives (section 721) that have been shown in appropriate studies to cause cancer in laboratory animals (or humans). Exactly what is covered by the Delaney clause is very complicated. Pesticide residues that are considered food additives were recently exempted from the Delaney Clause by the 1996 Food Quality Protection Act (see EPA Office of Prevention, Pesticides and Toxic Substances on page 124). Prohibition was an appropriate precautionary response to unknowns about cancer-causing chemicals when FFDCA was enacted in 1958, but it is inconsistent with modern analytic detection methods and current scientific knowledge. The Delaney Clause illustrates what can happen when Congress legislates scientific judgments, however well intentioned, in a manner that cannot evolve with advances in scientific knowledge.

Recommendation

The language of the Delaney clause should be modified to permit consideration of the quantitative risk that a covered food additive or color additive might pose, specifying that direct or indirect addition of carcinogens to foods should be prohibited to the extent needed to provide reasonable certainty of no harm, in keeping with well-established FDA statutory language.

The Delaney clause, inserted in 1958 into section 409 of the FFDCA specifies that "no [food] additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal"; equivalent language in section 721 specifies that "a color additive shall be deemed unsafe . . ." In fact, definitions of food additives are extremely complicated. Excluded from the category of food additives under the Delaney clause are uses of substances generally recognized as safe (GRAS), ingredients sanctioned before 1958 (such as sodium nitrite and BHA in some uses), and pesticide residues on raw agricultural commodities. All intentionally added substances and uses not excluded are covered, such as artificial sweeteners and pesticides that concentrate in processed food. Pesticides occuring in raw or processed foods have now been exempted by the 1996 Food Quality Protection Act. Color additives, covered separately from food additives, may be added to foods, drugs, cosmetics, and even devices. Indirect additions to the food supply are covered by the Delaney clause, including chemicals that migrate into foods from packaging or other food contact surfaces. Although FDA has been a leader in developing methods for quantitative risk assessment of carcinogens, under the

prohibition of the Delaney clause the methods cannot be used.

In 1962, Congress enacted an amendment to the Delaney clause known as the diethylstilbestrol (DES) proviso. This amendment permitted the use of carcinogenic compounds as animal feed additives and veterinary drugs so long as "no residue of the additive shall be found by methods approved by the Secretary by regulation in any edible portion of the animals after slaughter or in any food such as milk or eggs yielded by or derived from living animals." To define no residue, FDA developed a quantitative, negligible risk standard known as the sensitivity-of-method standard. The FDA commissioner is authorized to specify which analytic detection method should be used to characterize concentrations of additives. The methods chosen typically have a sensitivity corresponding to detection of a concentration associated with an upper-bound lifetime incremental cancer risk of one in a million (10^{-6}).

The Delaney clause does not define what is found to induce cancer and therefore does not invite exceptions for substances that induce tumors in rodents by mechanisms that are not relevant to human cancer risk (see Using Rodent Tests to Predict Human Cancer Risk on page 64). Even in 1958, however, Delaney required the FDA to determine whether evidence of carcinogenicity in animals had been obtained in "appropriate studies," with emphasis on feeding studies for obvious reasons of relevance. Because the clause focuses on the potentially carcinogenic properties of additives, it does not consider risks of other adverse health effects that can far outweigh risks of cancer—such as risks of developmental or neurologic toxicity—although those risks do get full attention from FDA under other authorities. Nevertheless, the requirement under the Delaney clause to reach a decision on animal carcinogenicity and appropriateness of studies makes a disproportionate claim on agency and petitioner resources, which might better be spread over investigations and reviews of all serious health effects and over decisions of whether any proposed uses of an additive would be deemed safe. Quantitative risk assessment methods are applied routinely to determine acceptable concentrations of natural, unavoidable food contaminants (such as aflatoxin in peanuts and corn, or mercury in swordfish) or of trace contaminants of food and color additives, and to determine the urgency of regulatory actions.

To its credit, adoption of the Delaney clause called attention to substances that might cause cancer and to the importance of caution when knowledge is limited. The Commission has concluded from various testimony, however, that the direct impact of the Delaney clause on reducing cancer risks for the public has not been large, partly because most food protection decisions are governed by other strong provisions of the food safety laws and partly because the clause has been invoked decisively only a few times. Furthermore, FDA's efforts to regulate sodium nitrite in 1979 (under multiple provisions of FFDCA) highlighted the need to balance risks and benefits at different concentrations when a chemical has major health benefits (in this case, prevention of potentially lethal botulism from stored meats).

Debate about the role of food additives and pesticide residues in relation to the role of other dietary factors that increase or decrease cancer risk led to the National Research Council report *Carcinogens and Anticarcinogens in the Human Diet* (NRC 1996b). That report concluded that calories, fat, and fiber are more important for overall cancer risk than individual food constituents, whether synthetic or naturally occurring.

Rate of Drug Approval

Finding

Despite acceleration of the drug approval process, especially for HIV-AIDS and cancer treatment agents, and despite providing guidance to pharmaceutical and biotechnology firms during various stages of drug development, FDA is often criticized by patient groups eager for access to new agents or agents approved in other countries. At the same

time, FDA bears a heavy responsibility to assure the public that the risks of serious adverse effects have been fully investigated, properly evaluated by disinterested experts, and weighed against the benefits of the drug.

Recommendation

FDA should sustain its efforts to provide early guidance on appropriate studies and to complete reviews and necessary inspections expeditiously. Accelerated reviews and approvals should be linked to rigorous postmarketing surveillance. In keeping with its counterpart agencies in other countries, FDA should update criteria for toxicity testing and clinical trial protocols so that properly documented studies meeting those criteria in other countries can be used as evidence for FDA review. Also, FDA should continue to work with other countries to harmonize procedural and paperwork requirements, as well as the protocols. Such efforts should include all classes of therapies.

An inevitable tension exists between careful premarketing assessment before regulatory approval of drugs, vaccines, and other medical products and the desire to make important advances in patient care available to patients. The Commission supports FDA efforts to accelerate the review process, use fee-based enhancement of FDA staff resources, and give guidance to firms and their clinical and biostatistical investigators. Moving towards accelerated approvals must be accompanied by requirements for effective postmarketing surveillance, perhaps including restriction of early prescribing rights to qualified and certified specialists who must closely study their patients' side effects and report them promptly.

In this global economy, FDA is building on many years of public and private international partnerships seeking harmonization of testing protocols and risk assessment methods to make appropriate use of studies and documentation from other nations that meet mutually agreed-on regulatory standards. Nevertheless, approvals in other countries with different benefit and risk criteria and with different degrees of reliance on postmarketing surveillance cannot automatically lead to approval by FDA. More attention in this country to off-label use and postmarketing surveillance of both benefits and risks would be desirable.

Regulating Dietary Supplements

Finding

The Nutrition Labeling and Education Act of 1990 set up a framework for justifying health claims on food labels, including those for dietary supplements. This framework requires significant scientific agreement and review and approval by FDA. FDA published the mandated regulations in January 1993 and approved several health claims. Soon thereafter, however, the Dietary Supplement Health and Education Act of 1994 (DSHEA) changed FDA's authority to regulate the safety and labeling of dietary supplements. The agency now has the burden of proving that a dietary supplement is adulterated before it can act to protect public health. DSHEA also created a presidential commission that was directed to reconsider what evidence would be necessary to make health claims for vitamins and other dietary supplements. Today, dietary supplements can carry FDA-approved health claims. DSHEA also permits manufacturers to make statements of nutritional support without prior approval from FDA. A Keystone Center dialogue report (1996) on health claims for foods and dietary supplements supported the 1990 act and the 1993 FDA regulations and made additional suggestions.

Recent evidence of hazards from herbal supplements promoted among young people for a "natural high" illustrates the consequences of allowing biologically active substances on the market without adequate evidence of safety. Also, evidence from clinical trials indicating probable harm from beta-carotene supplements in smokers at high risk of lung cancer and heart disease without any corresponding benefit illustrates the importance of assuring that health claims are supported by sound science before they are used to promote the sale of products.

Recommendation

FDA's authority to require scientific evidence to justify manufacturers' claims of safety of and health benefits from nutritional supplements should be reaffirmed and strengthened.

Vitamin supplements, herbs, and "natural" foods are increasingly marketed with claims of health benefits, reflecting preliminary data from epidemiologic analyses or medical testimonials. Evidence from clinical trials is rarely available. Since 1994, overwhelming evidence has been published that one of the most popular and most promising supplements, beta-carotene, previously considered anticarcinogenic, does not reduce risks of lung cancer and heart disease; instead, beta-carotene is associated with increases in those risks in people at high risk (ATBC 1994, Omenn et al. 1996). In light of the public's and scientists' desire to prevent cancer, heart disease, and other major diseases, we should strengthen the scientific basis of public health advice, regulatory approval, and product marketing.

Department of Agriculture

The U.S. Department of Agriculture (USDA) Office of Risk Assessment and Cost-Benefit Analysis (ORACBA) was established by the Federal Crop Insurance Reform and Department of Agriculture Reorganization Act of 1994. The office's primary role is to ensure that major human health, safety, and environmental regulations proposed by USDA are based on sound scientific and economic analysis. A major regulation is one that is projected to have an incremental economic cost of at least $100 million per year. The office is responsible for providing technical assistance, for coordinating risk-analysis activities across USDA, and ensuring that the statutory requirements of the act are met. Risk analysis activities take place in many USDA agencies, including the Food Safety and Inspection Service, the Animal and Plant Health Inspection Service, the Agricultural Research Service, and the Economic Research Service. This section offers several recommendations that should be considered as the office's activities take shape.

Development of Regulations

Finding

ORACBA has the statutory authority to review a major regulation before it is submitted to the Secretary of Agriculture.

Recommendation

ORACBA should become involved in the regulatory development process as soon as the impetus for a regulation is identified.

It does not make sense to wait until a regulation has been under development for a year or more and is virtually complete to determine whether it meets risk and cost criteria. Considerations of context, as well as risk and cost, should be included in the regulation development process from the start and, to the extent that they are consistent with statute, should help guide it. Risk and cost evaluations performed only when a regulation is almost complete are unlikely to be useful because too much time and too many resources will already have been invested in the outcome.

Peer Review

Finding

USDA has no formal procedure for external peer review of its risk assessments or economic analyses.

Recommendation

ORACBA should establish formal guidelines for peer review of the procedures, practices, and products of risk assessment and economic analysis at USDA.

As noted in Section 6 of this report, peer review is an essential part of the regulatory process. Peer review should encompass review of the raw technical data that underlie a risk assessment or benefit-cost analysis, the models and assumptions used and their interpretation, and how those data were cited in regulatory decisions. In-

volving independent peer reviewers in the regulatory process can help to clarify the objectives and scope of rulemaking and verify the quality of the technical information considered. It can also ensure that the information evaluated at the start of the process has been used in a technically defensible manner. More detailed recommendations about the role of peer review panels in regulatory decision-making are in section 6. When USDA's regulatory actions involve some types of pesticide or food safety issues, it might be appropriate to coordinate their peer review with EPA or FDA.

Microbial Risk Assessment

Finding

In January 1993, pathogenic *E. coli* caused at least four deaths, dozens of cases of kidney failure in children, and over 600 illnesses in one outbreak linked to undercooked, contaminated ground beef. This toll would have been far greater had an excellent public health science base and surveillance and investigation activity not been in place at the local and state health departments and at the University of Washington's School of Public Health, which relied on modern genetic techniques for detecting and tracing contamination. *Salmonella* or *Campylobacter* contamination of chickens or eggs has also led to fatal illnesses. Those and similar incidents focused public attention on the protection of our food supply from microbial contamination. However, the methods currently used by USDA and the food industry to assess microbial risks for the purpose of evaluating and regulating food safety are rudimentary, conflicting, and based on inadequate data.

Recommendation

USDA should develop and improve methods for assessing microbial risks for food safety evaluation. It should also develop information and data reporting requirements to gather data to support those risk assessments.

A key responsibility of USDA is protecting the nation's food supply from microbial contaminants, together with FDA. USDA's meat and poultry inspection program and FDA's food inspection program were not designed to prevent food safety problems, however. Inspections involve visual reviews of operating procedures, with little knowledge of conditions prior to the inspection or ability to predict future conditions. Agencies and industries have been expanding their use of the concept of hazard analysis and critical control points (HACCP). Pathways for contamination are identified, controls are designed and installed, monitoring is supposed to be performed, and records are made available for audits. Problems are expected to stimulate a feedback to critical control points and control measures. This program is a counterpart to manufacturing aspects of Responsible Care in the chemical industry; combining this preventive approach with an effective public health surveillance scheme could raise public confidence in the safety of our food supply domestically and help set an international standard for safe food. For example, beginning in 1995 all seafood exported to the European Community had to be produced under standards certified by the exporting country and accepted by the EC as equivalent to their HACCP standards. At the state level, HACCP plans are being used to update and unify ordinances regarding retail food handling and sanitation, together with such industry groups as the National Fisheries Institute, the National Food Processors Association, public health agencies, and consumer groups. As emphasized by Michael Taylor, formerly of FDA and now at USDA, the key elements of prevention are anticipation of the problems and design of appropriate preventive methods. These require a useful knowledge base and continuous scientific progress from research on such topics as growing microorganisms that have not yet been cultured, biofilms that harbor microorganisms shielded from sanitizing techniques, emerging foodborne pathogens, and conditions that affect the virulence (hazard) of potentially pathogenic microorganisms. Also, there is need for more informa-

tion about food processing, packaging, and distribution techniques.

Risk assessment should play a key role in this activity, but methods of evaluating risks associated with microbial contaminants are in their developmental stages and require more rigorous application and evaluation. Many microbial risk problems require the development of new methods and models, particularly for early stages of food production where pathogen prevention might occur. In addition, there are no databases on microbial diseases and risks comparable with those on chemical hazards. More detailed recommendations on the development of microbial risk assessment methods are found in Risks From Microorganisms on page 84. Collaboration with the EPA Office of Water, whose Information Collection Rule establishing monitoring and data reporting requirements for public water supply systems might be a good model for a similar USDA rule, would be appropriate (see page 130).

The Food Safety and Inspection Service of the USDA has recently developed the Public Health and Science Program, which includes a quantitative risk assessment capability and has made significant progress in this area. One of the goals of that program is to aggressively develop data to be used in microbial risk assessments and models for performing those assessments. The National Microbiological Baseline Data Collection Programs were begun in 1992 to collect data on microbiological profiles of inspected carcasses and ground product. Baseline data have been collected for steers and heifers, cows and bulls, broiler chickens, market hogs, ground poultry, ground turkey, and ground beef. Those data have been used to establish performance criteria and standards for raw products in the HAACP final regulations. The Public Health and Science Program has also initiated, in collaboration with the Centers for Disease Control and FDA, the Sentinel Site Surveillance Program. That program is tracking foodborne diseases of public health significance in five states. It is expected to provide, for the first time, a good estimate of the incidence of sporadic foodborne illness due to the major enteric pathogens (*Salmonella*, *Shigella*, *Yersinia*, *Campylobacter*, *E. coli* 0157:H7, and possibly *Vibrio*). The Public Health and Science Program has also begun to develop refined models for quantitative risk assessments and is presently working in collaboration with others inside and outside USDA to develop a dynamic fault tree model for the risk presented by *E. coli* 0157:H7 in ground beef.

President Clinton has highlighted in public pronouncements the need for more vigilant food protection and use of modern scientific methods. His concern resulted in increased fiscal year 1997 funding of the Sentinal Sites Surveillance Program and other FDA and USDA hazard identification and risk assessment research programs.

Evaluating the Benefits of Conservation Practices

Finding

There is no formal plan to monitor and evaluate the benefits of all the conservation practices managed or encouraged within USDA, whether on public or private lands.

Recommendation

USDA should develop and implement methods for monitoring and evaluating benefits of all conservation practices managed under the auspices of USDA. These include programs managed by the Forest Service as well as the Natural Resources Conservation Service and Farm Services Agency.

A key responsibility of USDA is assuring natural resources are conserved through a variety of programs. This includes assuring that:

- The natural resources necessary for food and fiber production are conserved in a way that farming can continue indefinitely into the future.
- The effects of farming do not degrade the natural resources which we all share and need

in our daily lives, nor do they threaten the public health.

- The use and management of the national forests and forest lands do not jeopardize the other resources or the future health of the forests and lands.

Assessing whether these programs are achieving their goals is essential to USDA's accountability and to ensuring the wise use of scarce resources. As discussed in Section 2 of this report, the Commission's Risk Management Framework emphasizes the importance of the Evaluating Results stage of risk management. Plans for evaluation should be built into every program's overall implementation plan to specify when evaluation will be conducted, who will conduct it, and what will be evaluated. Without evaluation, the success or failure of a program cannot be determined, its cost-effectiveness cannot be assessed, and future programs cannot benefit from lessons learned.

Department of Energy

The Department of Energy (DOE) manages one of the largest environmental programs in the world, including 130 sites and facilities in over 30 states and territories, the legacies of World War II and the Cold War. The purpose of environmental management at DOE is to reduce health, safety, and ecological risks associated with radioactive and hazardous waste and contamination resulting from the production, development, and testing of nuclear weapons. Risk assessment for radiation sources has been a tool developed and effectively used by DOE, the Nuclear Regulatory Commission, and their predecessor agencies for many decades (see Risks From Radiation Hazards on page 82). This section offers recommendations on the use of comparative risk for prioritysetting and budgeting.

Risk-Based Nuclear Weapons Site Cleanup

Finding

The massive program of cleanup of nuclear weapons production and waste sites has historically lacked a risk-based approach. Since late 1993, DOE has established a process that is committed to relating risks and risk reduction to budget and programmatic priorities. DOE's Environmental Management Program (DOE/EM) established six strategic goals: to address truly urgent risks, to ensure worker safety, to assume managerial and financial control, to become outcome oriented, to focus on technology development, and to become more customer and stakeholder oriented. The effort is experimental and is a highly desirable input to the annual budget request and appropriation.

Recommendation

The 3 1/2-year initiative of DOE/EM, stimulated by Congress, to learn to assess and manage the entire environmental program from a risk perspective should be continued and should be examined as a model for the EPA Superfund program. Stakeholder related efforts, such as DOE's site-specific advisory boards, require long-term budgetary support.

The DOE sites are large, numerous, and complex; they include radioactive wastes, diverse chemical wastes, mixed radioactive and chemical wastes, and contaminated and dilapidated facilities, and they have special nuclear materials that need to be decommissioned. The program is one of the largest "discretionary" federal budget items, having grown from $2.3 billion in FY 1990 to $6.5 billion in FY 1994 before "downsizing" to $5.7 billion for FY 1997. It is complicated by signed agreements with numerous states and EPA (tri-party agreements) and signed agreements with American Indian nations that have treaty rights to large areas of particular sites. Those agreements, a legacy of

the Bush Administration, used technical expertise of the time and empowered the states to make potent claims on federal responsibility. All parties acknowledge that there remain major uncertainties about the nature, extent, and remediability of major components of those sites, let alone a final selection of a permanent nuclear waste repository site.

DOE Secretary Hazel O'Leary, at Hanford Summit I in September 1993, committed the department to complying with occupational and environmental requirements of sister federal agencies (OSHA and EPA) and to taking dramatic steps to override the 50-year history of secretive operation of the nuclear weapons program. She and Assistant Secretary Thomas Grumbly called on the scientific community to join the effort with fresh ideas and capabilities. Grumbly reiterated that request at a National Research Council workshop commissioned by DOE to determine whether they needed to identify new institutional mechanisms to develop "objective, neutral, systematic, and iterative risk-based analysis" for their sites. Within 60 days, a National Research Council committee issued *Building Consensus Through Risk Assessment*, supporting the DOE plan (NRC 1994b). The report highlighted the inclusion of cultural, socioeconomic, historical, and religious values in a new risk-based approach that incorporated public involvement at each step. Eventually, DOE funded the Consortium for Risk Evaluation With Stakeholder Participation (CRESP) and several smaller academic groups and consulting firms to work with all stakeholders, including DOE. Commissioners Goldstein and Omenn are among the founders and leaders of the consortium.

At the same time that this long-term institution-building was occurring, the conference report of the Energy and Water Development Appropriations Subcommittee for FY 1994 stated that DOE "needs to develop a mechanism for establishing priorities among competing clean-up requirements" and submit a report to Congress by June 30, 1995. DOE mobilized a major effort to describe and characterize its major activities on risk data sheets and submitted its summary of the results in *Risks and the Risk Debate: Searching for Common Ground, The First Step* (DOE 1995) in timely fashion. The DOE Environmental Management Advisory Board endorsed this draft risk report as an important first step in linking risk data with compliance considerations for use in budget decisions; it also recommended improvements in data quality, review, public involvement, and consistent interpretation of data in light of future land-use planning and long-term cost projections.

DOE/EM followed up in late 1995 and early 1996 by substantially reworking its risk data sheet approach and then integrating it with the EM 1998 budget process. Risk data sheets rank the significance of each DOE activity in terms of seven considerations, of which the first three are specific risk factors: public safety and health; site personnel safety and health, environmental protection; compliance with applicable laws and regulations; mission impact; reduction of the "mortgage"of remaining cleanup obligations; and social, economic, and cultural impacts. For every activity, each of the seven considerations is ranked high, medium, or low; definitions of those evaluations are somewhat uncomfortable and cumbersome. DOE regional and site managers developed the rankings and data to support the 1400 risk data sheets, but substantial efforts to involve stakeholders in both criteria definition and risk data sheet quality assurance are evolving. The entire risk-ranking process is being reviewed externally and internally at DOE. Congress, this Commission, and most others regard this unprecedented process as a worthy start. DOE should balance the need to formalize the process quickly with the need to keep it fluid until its elements became coherent. Many suggestions for improvement are being assessed for incorporation. A sustained evolutionary effort is needed.

Worker Safety at DOE Sites

Finding

DOE sites represent an important opportunity to evaluate potential risks to workers from remediation activities. Worker safety is an important responsibility of DOE and its contractors.

Recommendation

DOE should actively develop means to integrate and evaluate worker risk into their decision-making process concerning the choice and timing of remediation options.

Historically, DOE's approach to managing worker health and safety risks has suffered from problems of fragmentation. Work planning had typically been a sequential process involving many levels of review and delays. Safety and health professionals were simply one of many inputs to the reviews, which often produced conflicting comments or work plans that were disconnected from actual conditions. Workers were rarely involved in either preparation or review of work plans, so problems that could have been averted because of the workers' extensive experience and unique knowledge of work conditions were not discovered and corrected until after a plan was released. As a result, most workplace deaths and serious injuries at DOE sites over the past five years can be attributed to inadequate hazard identification and control within the work planning process.

Over the last two years, DOE has launched an enhanced work planning initiative that brings together all the personnel who need to provide input to the work planning process as an integrated, multidisciplinary team to develop, review, and approve the work plan in one step. Health and safety considerations are identified by professionals such as health physicists, industrial hygienists, safety engineers, and occupational medicine specialists, who participate in the team along with managers, planners, and maintenance and operations supervisors. Workers also participate as members of the team, ensuring timely input and the benefit of their hands-on experience. Demonstration pilots of the enhanced work planning initiative have shown exceptional results: increased productivity, greater awareness of health and safety, decreases in safety and health incidents (e.g., a 61% drop in recordable incidents at Hanford Tank Farm), and cost savings (e.g., a greater than 25:1 dollar savings per dollar spent at Fernald). Backlogs, planning time, and working time have been reduced substantially as well. These savings have resulted from the exchange of expertise, improved communication, and increased up front health and safety professional and worker involvement. Nevertheless, extensive efforts are still needed to build an informative database on all workers, including subcontractor employees, and to link job hazard analyses, industrial hygiene, radioactivity monitoring, health surveillance, and occupational medical services for worker protection and program evaluation.

Integrating community and remediation worker risks provides challenges. For example, the risk to those who remove hazardous chemicals and radioactive wastes occurs only between the time that the work begins and the end of their lifetimes, while the risk to community members extends into future generations if remediation does not occur or is ineffective or insufficient. In addition, much worker risk is due to injuries and occurs in early adulthood, while much of the risk of mortality in the community is due to cancer or other diseases occurring late in life. Integrating analyses of worker and community health risks thus presents the challenges of accounting for different health and safety effects, different periods of exposure occurring at different times in a lifetime, and different perceptions about the risks and benefits of remediation options and cleanup standards.

Department of Defense

The Defense Environmental Restoration Program was established by Congress in 1984 to evaluate and remediate sites that were contaminated as a result of Department of Defense (DOD) activities. The Commission received testimony from the office of the Deputy Under Secretary of Defense (Environmental Security) about DOD's strategy for implementing a relative risk-based sequencing procedure for setting priorities among the sites that

were to be addressed. This section discusses very briefly DOD's efforts to establish remediation priorities among its contaminated sites.

Risk-Based Priority-Setting at DOD Sites

Finding

Not all of the contaminated sites that DOD is required to clean up pose major risks to health or the environment. DOD has developed a relative risk ranking procedure to facilitate the process of priority-setting among contaminated sites.

Recommendation

DOD should continue its efforts to establish risk-based remediation priorities among its contaminated sites in collaboration with community advisory groups and state and federal regulatory authorities.

Listing procedures for the Superfund National Priority List establish entire DOD installations as single sites for the purpose of listing. DOD installations are generally large and varied, however, with locations of potentially high risk and locations of potentially low risk within a single installation. Since 1984, DOD has identified almost 20,000 potentially contaminated sites on some 1,700 current installations and about 8,000 potentially contaminated sites at formerly used installations in the United States. Given the large number and diversity of contaminated sites, DOD needed a means to focus remedial activity that is consistent with relative risks to health and the environment. Although cleanup of contaminated sites on closing bases is important, the total number of contaminated sites is so large that there is a need for setting cleanup priorities.

DOD is promoting the use of a risk management concept to evaluate the sequence of work at the environmental restoration program sites in conjunction with the regulatory agreement status of each site. The scheme was subjected to review by the National Research Council and was compared with other hazard ranking schemes. The relative risk site evaluation framework is a qualitative method used by all DOD components to evaluate the relative risk posed by a site in relation to other sites. It should not be equated with more formal risk assessments conducted to assess baseline risks. Relative risk site evaluations are required for all sites at active military installations, base realignment and closure installations, and formerly used defense properties that have future funding requirements that are not classified as:

- Having all remedies in place
- Response complete
- Lacking sufficient information
- Abandoned ornance

DOD and DOD components are using the relative risk site evaluation framework as a tool to help sequence work at sites and as a headquarters program management tool. As a program management tool, the framework is being used to periodically identify the distribution of sites in each of three relative risk categories—high, medium, and low. A series of discrete relative risk site evaluations provides headquarters program managers with a macro-level view of changes in relative risk distributions within DOD over time. The relative risk site evaluation framework and resulting data also provide DOD with a basis for establishing goals and performance measures for the environmental restoration program.

The relative risk site evaluation concept categorizes sites as high, medium, or low risk on the basis of three factors: hazard (a ratio of contaminant concentrations in an environmental medium to comparison values or standards), migration pathway (a measure of movement or potential movement of contaminants away from the original source), and receptor (an indication of the potential for human or ecological contact with site contamination). A site's category can change because of new or additional information or as a result of cleanup activities.

As in the Commission's Risk Management Framework, the rankings are performed in collaboration with community advisory groups at the sites. In

practice, decisions about which sites should be addressed first include considerations in addition to the rankings, such as the statutory and regulatory status of a particular installation or site, public concerns, program execution considerations, and economic factors. Cleanup practices and community involvement are given special priority at sites on the base closure list.

DOD's ranking procedure does not involve actual assessments of health risks, nor does it address the decision of whether work is necessary at a site. The procedure only provides relative risk information for use in determining the sequence in which sites will be addressed. A risk assessment is performed as an integral part of site characterization, however. In addition to human exposure assessments, biological and ecological impacts must be considered in the risk assessment. The information developed in the risk assessment provides the basis for developing and evaluating remedial action alternatives, focusing on specific contamination problems at the site, and refining the relative risk evaluation.

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Glossary

acceptable daily intake (ADI)	A routine approach of FDA and other U.S. and international governmental and nongovernmental organizations to set safe levels of oral intake for chemicals by dividing the no-observed-adverse-effect-level (NOAEL) by safety and uncertainty factors of two to four values of 10 (100 to 10,000).
affected parties	Individuals and organizations acted upon by chemicals, radiation, or microbes in the environment or influenced favorably or adversely by proposed risk management actions and decisions.
alternative compliance	A policy which allows facilities to choose among methods for achieving emission-reduction or risk-reduction specifications instead of command-and-control regulations that specify standards and how to meet them. An example of alternative compliance is the use of a theoretical bubble over a facility to cap the amount of pollution emitted while allowing the company to choose where and how within the facility it gets to or stays below the cap.
antagonistic interactions	An adverse effect resulting from exposure to two or more chemicals that is less than that predicted by adding their independent effects together, often due to interference with each other's action.
aquatic ecosystem	A water ecosystem, such as a stream, lake, or bay.
attainment area	A geographical area, such as a city, state, or regional airshed, that is meeting EPA clean air standards.
benchmark	A standard of evaluation.
benchmark dose	An exposure level that corresponds to a statistical lower bound on a standard probability of an effect, such as 10% of people affected.
benefit-cost analysis (BCA)	An economic method for assessing the benefits and costs of achieving alternative health-based standards with different levels of health protection.
bioassay	Evaluation of a chemical's toxicity using laboratory animals or other test organisms.
biologic markers	Changes in the characteristics of a biologic sample, such as changes in enzyme levels or mutations in specimens such as blood cells, that reflect a particular environmental exposure, a particular human or animal disease process, or evidence of increased or decreased susceptibility to adverse effects from such exposures.
bright line	Specific levels of risk or of exposure that are meant to provide a practical distinction between what is considered safe and what is not.
brownfields	Idle, contaminated urban properties.
carcinogen	A cancer-causing agent.
central tendency	The mean (average) or the median (midpoint) of a range of relevant risk estimates for a particular situation, exposure, or chemical hazard.
chronic health effects	Diseases occurring as a result of repeated or persistent exposures.
collaborative stakeholder involvement	Engaging interested and affected parties in the substantive work of risk management, through all 6 stages of the Commission's Framework.
command-and-control regulations	Specific requirements prescribing how to comply with specific standards defining acceptable levels of pollution.
Common Sense Initiative	A current EPA initiative that convenes teams of stakeholders in six major industrial sectors—automobile manufacturing, computers and electronics, iron and steel, metal finishing, petroleum refining, and printing—to find comprehensive and feasible strategies to reduce pollution.
comparative risk analysis	The process of comparing and ranking various types of risks to identify priorities and influence resource allocations.

comparisons of risk	Using two or several more-or-less similar or equivalent risks to assist in communicating information about risk estimates.
contaminants	Chemicals, microorganisms, or radiation found in air, soil, water, or food that are not normally constituents of these environmental media or are found at increased concentrations due to human activities.
context	Here refers to public health and ecological assessment of the contribution of any particular environmental hazard to health, safety, or the environment.
cost-effectiveness analysis (CEA)	An economic method to identify the least costly way to achieve a particular health protection goal.
cumulative	Enlarging or increasing by successive addition.
cytotoxicity	Causing harm to a cell.
disease incidence	The prevalence of new occurrences of a disease.
disposition	The transport and fate of chemicals, microbes, or other agents in the environment and inside living organisms, including humans.
dose-response relationship	The relationship between exposure level and the incidence of adverse effects.
ecological risk assessment	A process used to estimate the likelihood of adverse effects on plants and/or animals from exposure to stressors, such as chemicals or draining of wetlands. The process includes problem formulation, characterization of exposure, characterization of ecological effects, and risk characterization.
economic analysis	Used here to refer to an analysis in monetary values of the costs and benefits of various actions to protect health or the environment.
end-of-the-pipe	Relying on technologies, such as scrubbers on smokestacks and catalytic converters on vehicle tailpipes, to reduce emissions of pollutants after they have formed.
environmental accounting	Incorporating all costs involved in design, production, use, disposal, and reuse of resources contrasted with traditional methods of accounting in which energy costs are assigned to overhead, and effects on and uses of air, water, and soil are ignored.
environmental audits	An examination of records or accounts relating to corporate or public sector activities that may adversely affect or protect the environment.
environmental indicators	Measures reflecting the health of the environment locally, nationally, or internationally.
environmental justice	Concern about the disproportionate occurrence of pollution and potential pollution-related health effects affecting low-income, cultural, and ethnic populations and lesser cleanup efforts in their communities.
epidemiology	The core public health science, investigating the causes and risk factors of disease and injury in populations and the potential to reduce such disease burdens.
equity	Just, fair, and impartial treatment of all people and population groups, including low-income, cultural, and ethnic populations potentially more affected by pollution.
exposure assessment	Determination of the sources, environmental transport and modification, and fate of pollutants and contaminants, including the conditions under which people or other target species could be exposed and the doses that could result.
exposure descriptors	Characteristic parameters measured, estimated, or assumed in assessing how much a population is exposed to contaminants. Breathing rate, daily food consumption, and contaminant concentrations in environmental media are examples .
exposure pathway	The path from sources of pollutants via air, soil, water, or food to reach people and other potentially affected species or settings.
extrapolation	Making inferences about the unknown by projecting or extending known information, using models and assumptions.
gavage	Introduction of material into the stomach via a tube through the mouth.

genotoxic	Capable of altering the structure of DNA and causing mutations.
hazard	A source of possible damage or injury.
high-end exposure estimate (HEEE)	Exposure levels at the higher end of a range of actual or estimated individual exposures, such as the 90th percentile level.
hyperplasia	A nontumorous increase in the number of cells in an organ or tissue with consequent enlargement of the affected part; sometimes a precursor to tumor formation.
industrial ecology	The analysis of an industrial system in which all materials, energy, and wastes are accounted for. An ideal system would reuse all materials, release no wastes, and minimize energy requirements.
interdependence	Mutual dependence.
interlocutory appeals	Legally challenging a regulatory rulemaking before that rulemaking is final.
international harmonization	Agreement across nations, as for toxicity testing protocols, clinical trials of pharmaceuticals, and even risk reduction requirements.
iterative process	Replication of a series of actions to produce successively better results, or to accommodate new and different critical information or scientific inferences.
judicial review	Acceptance by the courts of litigation challenging statutes and regulatory actions or proposals; the judicial branch check on legislative and executive branch actions.
life-cycle analysis	Tracking a product through all stages of its development, from extraction of fuel for power to production, use, and disposal.
lognormal	A logarithmic function with a normal distribution.
lower (and upper) confidence interval	Statistical parameters for a dose or a risk estimate indicating likely range of values, typically 95% range.
lowest effective dose (LED)	The lowest dose of a chemical that produced a specified level of an adverse effect when it was administered to animals in a toxicity study. For example, the LED_{10} is the lowest effective dose that produced an effect in 10% of the exposed animals.
margin of exposure	A ratio defined by EPA as a dose derived from a tumor bioassay, epidemiologic study, or biologic marker study, such as the dose associated with a 10% response rate, divided by an actual or projected human exposure.
margin of protection	A ratio of the estimated risks associated with two doses, such as the risk associated with a no-observed-adverse effect level compared to the risk associated with an estimated human exposure level.
maximally exposed individual	A hypothetical person whose exposure to a contaminated medium is assumed to occur at the highest levels possible throughout his or her entire lifetime.
maximum-available-control technology (MACT)	The emission standard for sources of air pollution requiring the maximum degree of reduction of hazardous air pollutants, taking cost and feasibility into account. Under section 112 of the Clean Air Act Amendments of 1990, the MACT must not be less than the average emission level achieved by controls on the best performing 12% of existing sources, by category of industrial and utility sources.
maximum tolerated dose (MTD)	The highest dose that can be administered to animals for two years without causing more than 10% loss of weight greater than controls or other evidence of significant systemic toxicity; the aim is to test chemicals at the highest dose feasible in laboratory animals, generally rats and mice.
measures of dispersion	The degree to which a characteristic, such as exposure level or benefits, is distributed across a population.
mechanisms of action	The sequence of a biologic process; the details of the process by which a chemical or other agent induces an adverse effect.
mechanistic data	Information about a chemical or other agent's mechanisms of action and about similarities and differences between rodents and humans, for example.

mitigate	To make an impact less severe.
mobile sources	Vehicular sources of air pollution, such as cars, trucks, buses, planes, boats, and motorcycles.
mode of action	The way in which a chemical elicits toxicity; does not complete characterization of the mechanisms of action.
multimedia approach	A process for considering several environmental media, such as air, water, and land, together, rather than in isolation.
multiple risks	Risks from several sources or many agents.
noncarcinogen	An agent causing effects other than cancer, such as neurological, reproductive, or pulmonary effects.
nongenotoxic carcinogen	Cancer-causing agents which act without altering the structure of DNA.
nonpoint-source pollution	Diffuse sources of water pollution, such as runoff from streets, farms, and mines.
no-observed-adverse-effect level (NOAEL)	The highest dose of a chemical that was administered to animals in a toxicity study without producing an observed adverse effect.
options	Choices of actions.
peer review	Evaluation of the accuracy or validity of technical data, observations, and interpretation by qualified experts in an organized group process.
pharmacokinetics	Study of the absorption, distribution, metabolism, and excretion of chemicals and the genetic, nutritional, behavioral, and environmental factors that modify these parameters.
point source	In the Clean Water Act, pollution from a discharge pipe.
precautionary principle	Decisions about the best ways to manage or reduce risks that reflect a preference for avoiding unnecessary health risks instead of unnecessary economic expenditures when information about potential risks is incomplete.
probabilistic approaches	Evaluating a range of possible risk estimates and their likelihood, tied to various mathematical models of the likely distribution of potential values, instead of relying on single numbers or point estimates.
Project XL	An EPA initiative to give (as of 1996) six companies (Intel, Anheuser Busch, HADCO, Merck, AT&T Microelectronics, and 3M) and two government agencies (California's South Coast Air Quality Management District and the Minnesota Pollution Control Agency) the flexibility to develop comprehensive strategies as alternatives to multiple current regulatory requirements to exceed compliance and increase overall environmental benefits.
public health context	The incidence, prevalence, and severity of diseases in communities and populations and the factors that account for such problems and that can be reduced or prevented; includes smoking, alcohol, diet, motor vehicle accidents, infections, chemical exposures, and other common voluntary and involuntary exposures or activities.
public health approach	A public health approach to risk management focuses on effective and feasible actions at the community level to reduce exposures and risks, with priority given to exposures with greatest impact (number of people and severity of effect).
record of decision	The cleanup actions agreed to by the principal responsible parties at a Superfund site.
reference concentration (RfC)	A concentration specified by EPA to limit human inhalation exposure to potentially hazardous levels of chemicals in air.
reference dose (RfD)	A dose specified by EPA to limit human oral exposure to potentially hazardous levels of chemicals that are thought to have thresholds for their effects (i.e., noncarcinogens).
residual risk	The health risk remaining after risk reduction actions are implemented, such as risks associated with sources of air pollution that remain after the implementation of maximum achievable control technology.

risk	The probability of a specific outcome, generally adverse, given a particular set of conditions.
risk assessment	An organized process used to describe and estimate the likelihood of adverse health outcomes from environmental exposures to chemicals. The four steps are hazard identification, dose-response assessment, exposure assessment, and risk characterization.
risk characterization	The process of organizing, evaluating, and communicating information about the nature, strength of evidence, and the likelihood of adverse health or ecological effects from particular exposures.
risk management	The process of analyzing, selecting, implementing, and evaluating actions to reduce risk.
salient	Prominent, having meaning to individuals or groups.
scoping	Defining the range of possibilities.
screening risk assessment	A risk assessment performed using few data and many assumptions to identify exposures that should be evaluated more carefully for their potential risks.
stationary sources	Fixed sources of air pollution, such as smokestacks and vents, contrasted with mobile (vehicular) sources.
susceptible populations	Populations which may exhibit a greater effect in response to particular exposures; generally, specific to the exposures or the effect.
sustainable development	Meeting the needs of the present without compromising the ability of future generations to meet their own needs; finding a convergence of environmental and economic goals.
synergistic interaction	An adverse effect resulting from exposure to two or more chemicals that is greater than the effect predicted by adding the effects of each.
threshold	The level of exposure above which adverse health effect is thought to occur, and below which no adverse effect is thought to occur.
tiered approach	A series of assessments of increasing complexity.
toxicity	The adverse effects of chemicals on living organisms.
transparency	Readily understandable, clear, not hidden.
tumorigenesis	Formation of tumors.
uncertainty analysis	Analysis of information about risks that is only partly known or unknowable. Mathematical uncertainty analyses can be used to generate probabilistic distributions of risk estimates that reflect the extent to which the information used to assess risk is uncertain.
variability	A population's natural heterogeneity or diversity, particularly that which contributes to differences in exposure levels or in susceptibility to the effects of chemical exposures.
value of information	Value-of-information techniques provide an analytic framework for deciding whether it is better to make a decision now based on an inherently uncertain risk assessment or to collect additional information first and then decide.
weight of the scientific evidence	Considerations involved in assessing the interpretation of published scientific information—quality of methods, ability of a study to detect adverse effects, consistency of results across studies, and biological plausibility of cause-and-effect relationships.

Appendix A1
Biographies of Commission Members

Dr. Gilbert S. Omenn, Chair

Dr. Omenn is Professor of Environmental Health and of Medicine and Dean of the School of Public Health and Community Medicine at the University of Washington, Seattle. His research and public policy interests include genetic predisposition to environmental and occupational health hazards, chemoprevention of cancers, health promotion for older adults, and risk analysis. From 1977 to 1981, Dr. Omenn was a Deputy Science and Technology Adviser in the White House Office of Science and Technology Policy and then an Associate Director of the Office of Management and Budget. As the first Science and Public Policy Fellow at The Brookings Institution in Washington, DC, he coauthored the influential 1981 study, Clearing the Air: Reforming the Clean Air Act. The author of 380 research papers and scientific reviews, as well as author/editor of 14 books, Dr. Omenn received his A.B. from Princeton University, his M.D. from Harvard, and a Ph.D. in genetics from the University of Washington.

Alan C. Kessler, Vice-Chair

A partner in the Philadelphia office of the law firm of Buchanan Ingersoll Professional Corporation, Mr. Kessler has extensive experience in the defense and litigation of major class action toxic tort suits in federal and state courts, as well as experience in the successful defense and prosecution of major federal antitrust and securities class action suits. Three times elected as a Township Commissioner for the Lower Merion Township in Montgomery County, Pennsylvania (population 58,000), Mr. Kessler also has been appointed by three successive Philadelphia mayors to various city boards and commissions. He also has been an advisor to a number of mayoral, gubernatorial, senatorial and presidential campaigns, and served on President Clinton's transition team. Mr. Kessler received his B.A. from the University of Delaware and his law degree from the University of Maryland.

Norman T. Anderson

Mr. Anderson is Director of Research for the American Lung Association of Maine. President of the Maine Biological and Medical Sciences Symposium, he also is a member of the American Association for the Advancement of Science. He was a regional air toxicologist for the U.S. Environmental Protection Agency in Boston; a regulatory toxicologist for the Maine Bureau of Health, and an environmental health scientist for the Maine Department of Environmental Protection. He also has served on numerous environmental health advisory committees at the state and local level. Mr. Anderson received his B.A. from Brown University and his Masters of Science in Public Health from the University of North Carolina in Chapel Hill. He also has studied immunology and pathology at the Boston University School of Medicine.

Dr. Peter Y. Chiu

Dr. Chiu is Senior Physician for The Kaiser Permanente Medical Group in Milpitas, CA, and an Assistant Clinical Professor at the Stanford University Medical School. Dr. Chiu has been a Fellow of the American Academy of Family Physicians since 1989, and also has been a registered civil engineer in California since 1972. He served as the principal environmental engineer for the Association of Bay Area Governments between 1976 and 1979 and was responsible for planning, organizing and directing environmental management programs for the San Francisco Bay area. He also served on the California Regional Water Quality Control Board from 1979 to 1984. Dr. Chiu received his B.S. in Civil Engineering, his Masters of Public Health degree, and his Doctor of Public Health degree from

the University of California, Berkeley; and his M.D. degree from Stanford University.

Dr. John Doull

Dr. Doull is a Professor of Pharmacology and Toxicology and Therapeutics at the University of Kansas Medical Center. A former president of the American Board of Toxicology and the Society of Toxicology, Dr. Doull served on the boards of the American Academy of Clinical Toxicology and The Toxicology Forum. Dr. Doull has also served as a consultant to numerous government agencies, private institutes, foundations and businesses. He is the recipient of many professional honors, including one named for him, the John Doull Award presented by the Mid-America Chapter of the Society of Toxicology. Dr. Doull received his B.S. in Chemistry from Montana State College, and his Ph.D. in Pharmacology and M.D. degrees from the University of Chicago.

Dr. Bernard Goldstein

Dr. Goldstein is Director of the Environmental and Occupational Health Sciences Institute, a joint program of the University of Medicine and Dentistry of New Jersey-Robert Wood Johnson Medical School and Rutgers University, and Chairman of the Department of Environmental and Community Medicine at the medical school. He is a former member of the New York University faculty and a former president of the Association of University Environmental Health Sciences Centers. Dr. Goldstein has undertaken many major consultation and committee assignments. He has published more than 200 articles and book chapters related to environmental sciences and public policy. Dr. Goldstein received his B.S. degree from the University of Wisconsin and his M.D. from New York University School of Medicine.

Dr. Joshua Lederberg

Dr. Lederberg, a Noble Prize winning research geneticist, is President Emeritus of The Rockefeller University and remains a professor and Sackler Foundation Scholar there. He received the 1958 Nobel Prize in Medicine for studies on the exchange of genetic material in bacteria and the U.S. National Medal of Science in 1989. Dr. Lederberg was a professor of genetics at the University of Wisconsin and Stanford University School of Medicine before becoming president of The Rockefeller University in 1978. A member of the National Academy of Sciences since 1957 and a charter member of its Institute of Medicine, Dr. Lederberg has been active on many government advisory committees and boards and served as Chairman of the President's Cancer Panel from 1979 to 1981. Dr. Lederberg received his B.A. from Columbia College, was a medical student at Columbia University College of Physicians and Surgeons, and obtained his Ph.D. from Yale.

Dr. Sheila M. McGuire

Dr. McGuire is president of the Iowa Health Research Institute and an expert in the epidemiology of oral diseases, geriatrics research, and fluoride research. A former Assistant Professor in the Harvard Medical School's Department of Dental Care Administration and adjunct faculty member at the University of Iowa College of Dentistry, Dr. McGuire was a member of the Health Professionals Review Group for the White House Task Force on National Health Care Reform. She also served a two-year term as chair of the Massachusetts Public Health Association's Legislative Committee. Dr. McGuire received her Doctor of Dental Surgery degree from the University of Iowa; her Master's in Epidemiology from the Harvard School of Public Health; and her Doctorate of Medical Sciences in Epidemiology from Harvard.

Dr. David Rall

Dr. Rall is the former Director of the National Institute of Environmental Health Sciences (NIEHS) and is one of the world's leading authorities on toxicology and environmental health. He was the founding Director of the National Toxicology Program, the largest toxicity testing program in the world, and has authored and co-authored approximately 170 papers relating to comparative pharma-

cology, cancer chemotherapy, pesticide toxicology, drug research and regulation, among other topics. Dr. Rall has served on and/or chaired numerous interagency and international committees on toxicology and environmental health, and now is serving as foreign secretary for the National Academy of Science's Institute of Medicine. Dr. Rall received his B.S. degree from North Central College and his M.S. and Ph.D. degrees in Pharmacology, as well as his M.D. degree, from Northwestern University.

Dr. Virginia V. Weldon

Dr. Weldon is Senior Vice President, Public Policy, for Monsanto Company. Her overall responsibilities include identifying public policy issues affecting the company, setting priorities, and implementing Monsanto's approach to these issues. Prior to joining Monsanto in 1989 as Vice President, Scientific Affairs, Dr. Weldon was a professor of pediatrics, deputy chancellor for medical affairs, and vice president of the Medical Center at Washington University School of Medicine and Medical Center. She is a member of the President's Committee of Advisors on Science and Technology, and a distinguished service member of the Association of American Medical Colleges, whose assembly she chaired in 1985-86. Dr. Weldon received her A.B. degree from Smith College and her M.D. degree from the State University of New York at Buffalo.

Dr. Gail Charnley, Executive Director

Dr. Charnley has 20 years of experience in environmental toxicology and risk assessment, including laboratory research focusing on the role of environmental factors in human cancers. She was most recently acting director of the toxicology and risk assessment program at the National Academy of Sciences, where she served as project director of several committees convened to evaluate methodologic questions related to evaluating human health effects from chemical exposures. She has performed health risk assessments and developed regulatory criteria for human exposure to environmental contaminants for a variety of regulatory agencies and has chaired several U.S. Army Science Board committees. She currently serves as a councilor of the Society for Risk Analysis. Dr. Charnley received her A.B. in Biochemistry from Wellesley College and her Ph.D. in Toxicology from the Massachusetts Institute of Technology.

Appendix A2
Mandate of the Commission on Risk Assessment and Risk Management

RISK ASSESSMENT AND MANAGEMENT COMMISSION

Sec. 303.

(A) Establishment.—There is hereby established a Risk Assessment and Management Commission (hereafter referred to in this section as the "Commission"), which shall commence proceedings not later than 18 months after the date of enactment of the Clean Air Act Amendments of 1990 and which, 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.

(B) Charge.—The Commission shall consider—

(1) the report of the National Academy of Sciences, authorized by section 112(o) of the Clean Air Act, the use and limitations of risk assessment in establishing emission or 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 the suitability of risk assessment for such purposes;

(2) the most appropriate methods measuring and describing cancer risks or risk 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 exposure reductions, effluent standards, ambient standards, 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;

(3) 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;

(4) 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

(5) and comment on the degree to which it is possible or desirable to develop a consistent risk assessment methodology, or a consistent standard of acceptable risk, among various Federal programs.

(C) Membership.—Such 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. Appointments shall be made no later than 18 months after the date of enactment of the Clean Air Act Amendments of 1990.

(D) Assistance from Agencies.—The Administrator of the Environmental Protection Agency and the heads of all other departments, agencies, and instrumentalities of the executive branch of the Fed-

eral Government shall, to the maximum extent practicable, assist the commission in gathering such information as the commission deems necessary to carry out this section subject to other provisions of law.

(E) Staff and Contracts.—

(1) In the conduct of the study 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.

(2) 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.

(3) 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 perdiem in lieu of subsistence as authorized by law for persons in the Government service employed intermittently.

(F) Report.—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. 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.

(G) Authorization.—There are authorized to be appropriated such sums as are necessary to carry out the activities of the Commission established by this section.

Appendix A3
Comments on *Science and Judgment in Risk Assessment*

Comments on the Conclusions of *Science and Judgment in Risk Assessment*

The primary message of *Science and Judgment in Risk Assessment,* the 1994 National Research Council (NRC) report to the Environmental Protection Agency (EPA), was that although EPA 's health-risk assessment methods were fundamentally sound, it needed to establish more clearly the scientific and policy basis for those risk assessments and describe the uncertainties and variabilities associated with health risk estimates. This appendix reviews the NRC report's primary conclusions in science, policy, and uncertainty and comments on them in the context of the Commission's mandate.

1. Uses and Limitations of Risk Assessment

The NRC report emphasized that risk assessment is a set of tools and that it should be an adjunct to the primary regulatory goal of safeguarding public health, not an end in itself. Health risk assessment is but one element of environmental decision-making—a component of decisions about whether, how, and to what degree the assessed risk requires reduction. The factors that might be considered by decision-makers depend on the requirements of applicable statutes, precedents established within the responsible government agencies, and good public policy. The limited resources available for environmental protection should be spent to generate information that helps risk managers to choose the best possible course of action among the available options.

The Commission agrees that risk assessment is but one of a number of risk-management decision-making tools. The results of a risk assessment are not scientific estimates of actual risk; they are conditional estimates of the risk that could exist under specified sets of assumptions and—with political, engineering, social, and economic information—are useful for guiding decisions about risk reduction. The risk-management decision-making framework that is discussed in section 2 of the Commission's report provides guidance for including those kinds of information in risk-management decisions.

2. Maximal Use of Scientific Information versus Plausible Conservatism

The NRC report stated that EPA operates in a decision-making context that imposes pressures on the conduct of risk assessments and that these contextual pressures have led to recurrent problems of scientific credibility. Criticisms of EPA's risk assessments focus on three basic decision-making structural and functional problems:

- Unjustified conservatism, often manifested as unwillingness to accept new data or abandon default options.
- Undue reliance on point estimates generated by risk assessment.
- Lack of appropriate conservatism due to failure to accommodate such issues as synergism, human variability, unusual exposure conditions, and ad hoc departures from established procedures.

The NRC report pointed out that whereas EPA's risk-assessment practices rely heavily on default options, EPA has never articulated the scientific or policy basis of those options. Because of limitations on time, resources, scientific knowledge, and available data, however, the report concluded that EPA should generally retain its conservative, default-based approach

to risk assessment for screening analysis in standard-setting. The authors offered several recommendations to make this approach more effective:

- Use an iterative approach to risk assessment.
- Provide justification for defaults and establish a procedure that permits departure from defaults.
- When communicating information about risks to decision-makers and the public, identify the sources and magnitude of the uncertainty associated with risk estimates.

The Commission concurs that default assumptions are a necessary part of the conduct of risk assessments. Risk assessments make predictions about the unknowable by using inferences that have not been or cannot be adequately tested with the scientific method. In the absence of adequate scientific information, science- and policy-based assumptions are appropriate. The Commission also supports the goal of transparency and believes that assumptions used in risk assessments and the uncertainty associated with their results should be clearly identified and justified.

An iterative approach to risk assessment also seems reasonable. An iterative approach would start with relatively inexpensive screening techniques and move to more resource-intensive data-gathering, model construction, and model application as the particular situation warranted. To guard against the possibility of underestimating risk, screening techniques must be constructed to err on the side of caution when there is uncertainty. In many situations, for example, gathering site-specific exposure information or investigating the human relevance of a particular toxicologic end point observed in rodents can reduce the extent to which default assumptions are required. Screening risk assessments that use assumptions instead of site-specific information might be used to set priorities by identifying the sites that are likely to pose the greatest risks to health or the environment. More refined risk assessments that use more sophisticated information could then be performed on the riskier sites to obtain better risk estimates. Such an iterative approach is intellectually satisfying.

However, the Commission is concerned about the possible public reaction to iterative determinations of risk. Suppose that a first-tier, screening risk assessment of a contaminated site concludes that an upper-bound incremental lifetime cancer risk greater than 10^{-6} is possible. Later refined risk assessments of the same site conclude that the risk is likely to be less than 10^{-6}. The residents of the surrounding community have been told first that the site poses a risk to their health and now that it does not. It is unlikely that such apparently conflicting conclusions will establish any credibility for the regulatory agency or other organization that has announced them. Citizens will remain suspicious and will probably believe that the site constitutes a health hazard, despite messages to the contrary.

Nonetheless, the NRC report concluded that neither the resources nor the necessary scientific data exist to perform a full-scale risk assessment on every potentially hazardous chemical. Nor, in many cases, is such an assessment needed. There might be a vast difference between having “the truth” and having enough information to enable a risk manager to choose the best course of action from the options available. The latter criterion is more applicable in a world with resource and time constraints. Determining whether “enough information” exists to support a decision implies the need to evaluate a full range of decisions. Further improvement of a risk-assessment estimate might or might not be the most desirable course in a given situation, especially if the refinement is not likely to change the decision or if disproportionate resources have been directed to studying the risk at the expense of creating a full set of decision options from which to choose.

Using an iterative approach thus could yield the risk-management decisions required under regulatory mandates in a resource-sensitive manner and at the same time provide incentives for further research without the need for costly case-by-case evaluations. But communicating iterative estimates of risk to the public without loss of credibility will require serious consideration.

3. Inter-agency and Intra-agency Consistency

The NRC report observes that it often seems safest for a regulatory agency to take refuge in established procedures even if they have begun to appear scientifically outdated. External pressures, such as the demands of state agencies for precise guidance, strengthen this tendency. These managerial problems are faced by any regulatory body that is responsible for rendering consistent decisions based on changing scientific knowledge. To remain accountable to the public, regulatory agencies must assess uncertain science in accordance with principles that are fully and openly articulated and applied in a predictable and consistent manner from case to case. Science-policy rules might ensure a valuable degree of consistency from one case to another, but they do so in part by sometimes failing to stay abreast of changing consensus in the scientific community. Bureaucratic considerations of consistency can sometimes override good scientific judgment.

The NRC report concluded that there is a need for a tradeoff between flexibility on the one hand and predictability and consistency on the other regarding departure from default options. Agencies should seek a middle path between inflexibility and ad hoc judgments, but steering this course is difficult. Consistency and predictability are served if an agency sets out criteria for departing from its guidelines. If such criteria are themselves too rigidly applied, the guidelines could ossify into inflexible rules; but without such criteria, the guidelines could be subverted at will with the potential for political manipulation of risk assessment.

A report prepared by Lorenz Rhomberg for the Commission (see abstract in Appendix A7) surveys risk-related consistency issues both within EPA and among several regulatory agencies. The survey notes that differences in how risks are calculated and how risk-assessment results are used in regulatory decision-making have evolved in different agencies and programs for a variety of reasons. Some of those differences are necessary because of the differing mandates or goals of the various programs, but risk-assessment and risk-management practices are in general poorly coordinated. Better coordination is needed to resolve inappropriate inconsistencies in situations in which two or more agencies regulate similar health or ecologic hazards. Some inconsistencies might be appropriate, however, in light of each agency's or program's own goals and mandates.

4. Bright Lines

In its discussion of bright lines, the NRC report concluded that judicial review has not established any particular method for EPA to use in determining what level of risk should be considered negligible. EPA in turn has decided that it cannot use any single metric as a measure of whether a risk should be considered negligible. Instead, it has adopted a general presumption that a lifetime excess risk of cancer of about one in 10,000 (10^{-4}) for the most exposed person constitutes negligible risk and that the margin of safety should reduce the risk for the greatest possible number of persons to an individual lifetime excess risk no higher than one in 1 million (10^{-6}). Such factors as incidence, the distribution of risks, and uncertainties are taken into account in applying those benchmarks.

The 1990 amendments to the Clean Air Act require that standards be set for emission sources if maximum achievable control technology allows a residual risk of greater than 10^{-6} to the person most exposed to emissions (the "maximally exposed individual", or MEI). Although that requirement appears to be an example of legislating risk-management decisions on the basis of the MEI, the 10^{-6} criterion in fact need be interpreted only as an upper-limit screening device. In addition, those standards need not be expressed in terms of quantitative risk. EPA may use the 10^{-6}-10^{-4} approach described above, but it is not required to do so. Any method that is consistent with the requirement that the standards provide an "ample margin of safety" and reduce risk to a level judged acceptable by EPA may be used.

As discussed in section 3 of the Commission's report, the Commission does not support legislating

reliance on specific bright lines for environmental regulatory decision-making, except as guideposts or goals for decision-making. If numerical targets are to be included in agency rules, the Commission prefers the use of ranges between bright lines as goals, which would permit flexibility in decision-making that reflects uncertain risk estimates, uncertain cost estimates, and local stakeholder preferences. Decision-makers should be expected to apply bright line ranges flexibly, such as using 10^{-6} as a benchmark for screening risk assessments, but not as a yes-or-no criterion for site cleanup decisions. Specific bright lines should not be mandated by Congress—they should be established, when appropriate, by regulatory agencies. Congress should continue to use qualitative language in legislation, such as "reasonable certainty of no harm."

5. Peer Review

The NRC report recommended that peer review, workshops, and other devices be used to ensure broad peer and scientific participation and guarantee, as much as possible, that EPA 's risk-assessment decisions are made with access to the best science available. It also recommended that EPA continue to rely on its Science Advisory Board and other expert bodies to determine when departing from a default option is warranted.

The Commission goes further in its recommendations about peer review, noting that peer review has not been used to evaluate the use of scientific or other technical information in regulatory policy and that there is no process for evaluating the effectiveness of peer review. The economic information used in regulatory policy is seldom peer-reviewed, and most agencies do not have official guidelines or policies for peer review. The Commission recommends several remedies for those problems while cautioning that the level of peer review should be commensurate with the importance or impact of the decision to be made. Peer review should not be used to stall the decision-making process.

6. Comparative Risk

The NRC report concluded that EPA should pay more attention than it now does to the appropriateness of various procedures for risk comparison. A scientifically sound way to do that would be to modify risk-assessment procedures to characterize more specifically the uncertainties in each comparison of risks—some larger, some smaller than the uncertainties in individual risk assessments. Because of the substantial and varied degrees of model and parameter uncertainties in risk estimates, it is almost impossible to rank relative risks accurately unless the uncertainty in each risk is quantified or otherwise accounted for in the comparison. If comparison of risks is imperative for regulatory purposes, the report suggested attempting to compute the uncertainty distribution of the ratio of two risks and choosing from it one or more appropriate summary statistics.

The Commission has addressed comparative risks from the perspectives of both risk communication and of conducting comparative risk projects for priority-setting. The Commission recommends that risk comparisons for risk communication help to convey the nature and magnitude of a particular risk estimate and be restricted to comparisons of risks associated with chemically related agents, different sources of exposure to the same agent, different kinds of agents with the same exposure pathway, and different agents that produce similar effects. The Commission also agrees that the appropriateness of procedures used to compare risks for priority-setting requires attention and evaluation and suggests that comparative risk-ranking paradigms are appropriate for guiding resource-allocation decisions.

7. Exposure Assessment

The NRC report noted that EPA has traditionally characterized exposure according to two criteria: exposure of the total population and exposure of a specified highly or maximally exposed individual (MEI). The MEI's exposure is estimated as the plausible up-

per bound of the distribution of individual exposures. The reason for finding the MEI, as well as population, exposure is to assess whether any individual exposure might occur above a particular threshold that, as a policy matter, is considered important. In its most recent exposure-assessment guidelines, EPA no longer uses the term MEI, noting the difficulty in estimating it and the variety of its uses. The MEI has been replaced with two other estimators of the upper end of the individual-exposure distribution, a "high-end exposure estimate" (HEEE) and the theoretical upper-bounding estimate (TUBE). The HEEE is not specifically defined ("the Agency has not set policy on this matter"), but it is a value in the upper tail of the individual-exposure distribution. The HEEE is based on the estimation of the distribution of exposures that people might actually encounter; from the individual exposures, it is possible to develop population exposure (and risk) distributions and include uncertainty estimation and personal-activity patterns. The exact percentile that should be picked for the HEEE is not specified, but it should be chosen to be consistent with the population size in a particular application. The TUBE is a calculated value that is expected to exceed the exposures experienced by all individuals in the actual distribution. Neither the HEEE nor the TUBE is explicitly related to the MEI.

The NRC report recommended that the underlying assumption that calculated exposure estimates are conservative be reaffirmed; if it is not, alternative exposure models whose performance has been clearly demonstrated to be superior should be used in exposure assessment. Those alternative models should be chosen to provide more accurate, scientifically founded, and robust estimates of pollutant-exposure distributions (including variability, uncertainty, and demographic information).

The Commission believes that the results of an exposure assessment can be a source of greatest uncertainty in a risk assessment and agrees that there is a need for more accurate, scientific, and validated models for exposure assessment. EPA should move away from estimates of exposure that are based on a mythical overexposed individual, which are likely to overestimate the exposures of most of the population and underestimate the exposures of special populations, such as subsistence fishermen. Point estimates of exposure convey no information about the extent to which they overestimate or underestimate exposures, and they should be used only for screening risk assessments. The entire distribution of a population's exposure concentrations should be used for more refined risk assessments, rather than just the exposures of a highly exposed subpopulation (although highly exposed populations, if they exist, should be identified and evaluated separately).

8. Differences in Susceptibility

The NRC report points out that EPA and the research community have thought almost exclusively in terms of the bimodal type of variation, with a normal majority and a hypersusceptible minority. That model might be appropriate for noncarcinogenic effects, but it ignores a major class of variability with regard to cancer (the continuous, "silent" variety), and it fails to capture some bimodal cases in which hypersusceptibility might be the rule, rather than the exception. EPA's 1986 cancer risk-assessment guidelines, however, are silent regarding person-to-person variations in susceptibility and thereby treat all humans as identical, despite substantial evidence and theory to the contrary. That is an important "missing default" in the guidelines. The NRC report recommended that EPA adopt an explicit default assumption for susceptibility and that the magnitude and extent of human variability due to particular acquired or inherited cancer-susceptibility factors be determined through molecular epidemiologic and other studies. Results of the research should be used to adjust and refine estimates of risks to individuals and estimates of expected incidence in the general population. In addition, EPA should continue and increase its efforts to validate or improve the default assumption that, on average, humans to be protected at the risk-management stage have susceptibility similar to that of humans included in relevant epidemiologic

studies, the most sensitive rodents tested, or both. EPA's 1996 Proposed Guidelines for Carcinogen Risk Assessment mention the importance of including information on susceptibility differences when available, but do not go so far as recommending an explicit default assumption.

The Commission agrees with the NRC report's conclusions regarding susceptibility. Risk assessments should be conducted so that populations with a special susceptibility or risk—whether because of greater exposures than the general population, because of other concurrent exposures, or because of some physiologic characteristic that increases sensitivity—are identified and the extent to which they are at greater risk determined.

9. Multipathway, Multisource, and Mixture Exposures

EPA currently adds the risks related to each chemical in a mixture to develop a risk estimate for that mixture. That approach is based on an assumption that doses of different agents can be treated as roughly additive with regard to inducing the end point; this assumption is reasonably consistent with much of the experimental evidence on the joint actions of chemicals in mixtures. The NRC report concluded that this additivity procedure is generally appropriate when the only risk characterization needed is a point estimate for use in screening. The Commission agrees that dose additivity of mixture components is an appropriate assumption for most cases, but it believes that the issue of dose additivity versus response additivity has not been adequately addressed.

The NRC report also concluded that any comprehensive assessment of health risk associated with environmental exposure to any particular compound must consider all possible routes by which people might be exposed to that compound, even if expected applications in risk management are limited to some particular medium or source. The report recommended that EPA consider using appropriate statistical procedures to aggregate cancer risks associated with exposure to multiple compounds. Aggregating risks associated with different exposures might not be possible, however, because the analyses for each exposure will produce risk estimates of differing accuracy and conservatism. The Commission agrees that procedures for aggregating risks must be explored. The issue of which end points or exposures can be aggregated appropriately is complex—for example, should different tumor types within the same organ or tumors in different organs be aggregated, or do these constitute different, independent responses? Considering multiple sources of contaminant exposure is particularly important in the context of environmental justice and identifying sensitive populations requiring special consideration, and methods to do so are needed.

10. Uncertainty

The NRC report concluded that it might be undesirable to reduce a risk characterization to a single number, or even to a range of numbers intended to portray uncertainty. Instead, the report recommended that EPA consider giving risk managers risk characterizations that are both qualitative and quantitative and both verbal and mathematical. The Commission concurs that better communication about risk-related uncertainty is needed, and it encourages regulatory agencies to explain the uncertainty associated with any numerical estimates of risk and to eliminate risk estimates with phony accuracy (e.g., 4.237×10^{-5}), which communicate a misleading confidence in accuracy. The Commission also believes that risk characterizations for routine risk assessments should emphasize qualitative information about risks more than quantitative information. Qualitative information is likely to be more understandable and useful than quantitative estimates or models to risk managers and the public. Qualitative information includes a careful description of the nature of the potential health effects of concern, of the strength and consistency of the evidence that supports an agency's classification of a chemical or other exposure as a health hazard, and of any means to prevent or reverse the effects of exposure.

The NRC report also concluded that any expression of probability regarding model uncertainties (i.e., inability to determine which scientific theory is correct or what assumptions should be used to derive risk estimates), whether qualitative or quantitative, is likely to be subjective. Subjective quantitative probabilities could be useful in conveying the judgments of individual scientists to risk managers and to the public, but the process of assessing subjective probabilities is difficult and essentially untried in a regulatory context. Substantial disagreement and misunderstanding about the reliability of quantitative probabilities could occur, especially if their basis is not set forth clearly and in detail.

As discussed in section 4 of the Commission's report, the Commission believes that, although there is general agreement as to the value of qualitative statements describing critical uncertainties in a risk assessment, there is opposition to the use of a more routine and formal mathematical approach to characterizing uncertainties. The opposition is based on the belief that a formal, quantitative approach is unnecessary, is difficult to perform, and will not improve risk communication. Uncertainty is inherent in any estimation procedure. Some sources of uncertainty, such as those related to estimating exposures, are likely to be relatively easily addressed through the use of statistical methods. Other types of uncertainty, such as those associated with species-to-species or high-to-low dose extrapolation, are less straightforward or quantifiable. Characterizing the uncertainty and variability that underlie a potential risks can generate a distribution of risks, instead of a point estimate, but it should be kept in mind that when data are scarce, assumptions about the underlying shape of a distribution will be needed—that is, when uncertainty is greatest, a range of probabilities based on assumptions would replace point estimates based on assumptions.

Providing a numerical range of risk estimates reflecting uncertainty and variability might allow decisions to be made in a more informed and more transparent manner than is possible when only a single point estimate is generated. However, communicating a range of risk estimates might be misconstrued by those unfamiliar with quantitative methods as implying that all the numbers in the range are equally likely or plausible and are therefore equally valid for regulation. Many risk assessments are crude yardsticks for decision-making. In this context, the routine provision of a range of risk estimates might only confuse and delay the regulatory process.

Appendix A4
Individuals Who Presented Testimony at Commission Meetings

Greg Adams
Regulatory Affairs
California Association of Sanitation Agencies

Tad Aburn
Manager of Air Quality planning,
Air Radiation Management Administration
Maryland Department of the Environment

June Andersen
Manager
Environmental Programs
IBM Corporation

Nicholas Ashford
Professor of Technology and Policy
Center for Technology Policy and Industrial Development
Massachusetts Institute of Technology

Michael Belliveau
Executive Director
Citizens for a Better Environment

Timothy Bingaman
Member, Leader
Risk Assessment Task Force,
Corporate Risk Network
New Jersey Chemical Industry Council, Dupont

Sue Briggum
Director
Government Affairs
WMX Technologies, Inc.

Walter Buchholtz
Manager
Government Relations and Issue Management
Exxon Chemical Company

Patricia Buffler
Dean
School of Public Health
University of California Berkeley

Paul Chrostowski
Principal
Weinberg Consulting Group

Jerry Clifford
Director of Superfund Task Force
Office of Solid Waste and Emergency Response
U.S. Environmental Protection Agency

Murray Cohn
Director
Division of Health Effects
U.S. Consumer Product Safety Commission

Josephine Cooper
Vice President
Environment and Regulatory Affairs
American Forest and Paper Association

Bertram Cottine
Executive Director
Division of Health Effects
U.S. Consumer Product Safety Commission

Carl Craner
Associate Dean
Faculty of Humanities and Social Studies
University of California Riverside

Edmund Crouch
Senior Scientist
Cambridge Environmental Inc.

Chris D'Alliene
Co-Chair
New Jersey Environmental Risk Assessment and Risk Management Commission

Tudor Davies
Director
Office of Science and Technology
U.S. Environmental Protection Agency

Terry Davies
Director
Center for Risk Management
Resources for the Future

Joseph Dear
Assistant Secretary for Occupational Safety and Health
U.S. Department of Labor

Fred Demmick
Group Leader
Environmental Protection Agency/ OAQPS

Michael Dourson
Director, TERA
Toxicology Excellence for Risk Assessment

Kay Drey
Member
Missouri Coalition for the Environment

Jerry Fitzgerald English
Environmental Attorney
Cooper, Rose, and English

Elaine Faustman
Professor and Associate Chair
Department of Environmental Health
University of Washington

Brian Ferguson
Vice President
Industry and Federal Affairs
Eastman Chemical

Patricia Ferrebee
Program Manager
Office of the Deputy Under secretary of Defense for Environmental Security
Department of Defense

John Festa
Senior Scientist
American Forest and Paper Association

Walter Fields
New Jersey Chapter
National Association for the Advancement of Colored People

Adam Finkel
Director, Directorate of Health Standards Programs
Occupational Safety and Health Administration
U.S. Department of Labor

Kate Fish
Executive Director
Earthways

Jack Fowle
Legislative Aide
Office of Senator Daniel Patrick Moynihan

Craig Gannett
Senior Counsel
Committee on Energy and Natural Resources
U.S. Senate

Thomas Gentile
Chief of Toxics Assessments
Division of Air Resources
New York

Barry Gold
Professional Staff Member
Subcommittee on Technology, Environment and Aviation of the Committee on Science, Space, and Technology
U.S. House of Representatives

Lynn Goldman
Assistant Administrator
Office of Prevention, Pesticides & Toxic Substances
U.S. Environmental Protection Agency

Laura Green
Scientist and President
Cambridge Environmental, Inc.

Linda Greer
Senior Scientist

Natural Resources Defense Council
Fred Hansen
Deputy Administrator
Environmental Protection Agency

Carol Henry
Office of Integrated Risk Management
Department of Energy

JoAnn Held
Chief
Air Quality Permitting Program

Jonathan Howes
Secretary
Department of Environment, Health, and Natural Resources
State of North Carolina

Robert Huggett
Assistant Administrator
Office of Research and Development
U.S. Environmental Protection Agency

Richard Jackson
Director
National Center for Environmental Health
Centers for Disease Control and Prevention

Sheila Jasanoff
Chair, Science and Technology Studies
Cornell University

Michael A. Jayjock,
Senior Research Fellow and Manager of Human
Health Risk Assessment, Rohm & Haas

Barry Johnson
Assistant Administrator
Agency for Toxic Substances and Disease Registry

Bruce Jordan
Office of Air Quality and Planning
U.S. Environmental Protection Agency

James Karr
Director
Institute for Environmental Studies
University of Washington

Bruce Kelman
National Director
Health and Environmental Sciences
Golder Associates

Nandan Kenkeremath
Minority Counsel
Committee on Energy and Commerce
U.S. House of Representatives

Donald Kennedy
Professor of Environmental Science
Institute for International Studies
Stanford University

Paul Kleihues
Director
International Agency for Research on Cancer

Raymond Kopp
Director and Senior Fellow
Quality of the Environment Division
Resources for the Future

Gregory Lashutka
Mayor
Columbus, Ohio

Lester Lave
University Professor
Carnegie Mellon University

Eugene Leong
Executive Director
Association of Bay Area Government

Karen Levy
Senior Policy Analysis
EPA/Air Policy Office

Steve Lewis
Member
Scientific Committee
American Industrial Health Council

Douglas MacLean
Professor and Chair
Department of Philosophy
University of Maryland

John Martonik
Acting Director
Health Standards Program
Occupational Safety and Health Administration

Roger McClellan
President
Chemical Industry Institute of Toxicology

Michael McCloskey
Chairman
Sierra Club

Bruce Means
Chief of Toxic Integration Branch
Office of Emergency and Remedial Response
U.S. Environmental Protection Agency

Daniel Mendelker
Washington University
St. Louis, Missouri

Frank Mirer
Director
Health and Safety Department
United Auto Workers

Jack Moore
Director
Institute for Evaluating Health Risks

Richard Morgenstern
Visiting Scholar
Resources for the Future on Sabbatical from EPA's Office of Policy Analysis

Mary Nichols
Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency

Warner North
Decision Focus, Inc.

James H. O'Brien
Environmental Planning Manager
Lukens, Inc.

Kenneth Olden
Director
National Institute of Environmental Health Sciences

Craig Oren
Professor, School of Law
Rutgers University

Walter Pettit
Executive Director
California State Water Resources Control Board

Daniel Phalen
Executive Director
Bay Area League of Industrial Association

Delores Phillips
Legislative and Policy Director
New Jersey Environmental Federation

Sharon Pinkerton
Legislative Director and Press Secretary
Office of Representative John L. Mica

Michael Pompili
Assistant Health Commissioner
Columbus, Ohio

Roger Pryor
Executive Director
Missouri Coalition for the Environment

Roger Randolph
Director
Air Pollution Control Program
Missouri Department of Natural Resources

Peter Raven
Director
Missouri Botanical Gardens

James Reisa
National Research Council
National Academy of Sciences

Lorenz Rhomberg
Assistant Professor
Center for Risk Analysis
Harvard School of Public Health

Kelly Rimer
Office of Air Quality Planning and Standards
U.S. Environmental Protection Agency

Don Ritter
President
National Environmental Policy Institute

David Roe
Senior Attorney
Environmental Defense Fund

Jim Russell
Manager
ER/WM program
Yakama Indian Nation

Mark Schaefer
Assistant Director
Office of Science and Technology Policy
Executive Office of the President

Ronald Selph
Mayor
Granite City, Illinois

Ellen Silbergeld
Professor of Epidemiology
University of Maryland

Deborah Stine
National Research Council
National Academy of Sciences

Gerhard Stohrer
Science and Environmental Policy Project

James Stratton
Interim Director
Office of Environmental Health Hazard Assessment
California Environmental Protection Agency

Robert Sussman
Deputy Administrator
U..S. Environmental Protection Agency

Dan Tarlock
Professor of Law
Chicago Kent College of Law

Craig Tarpoff
Alderman
Granite City, Illinois

Maria Tikkenen
Water Quality Specialist
Association of California Water Associations

Mark Van Putten
Eastern Division Staff Director
National Wildlife Federation

Peter Venturini
Chief
Stationary Source Division
California State Water Resources Control Board

Daniel Wartenberg
Associate Professor
Department of Environmental and Community Medicine
Environmental and Occupational Health Sciences Institute

Murray Weidenbaum
Director
Center for the Study of American Business
Washington University

Frank White
Vice President
Organization Resources Counselors

Terry F. Yosie
Executive Vice President and Managing Director of EDG
E. Bruce Harrison Company

Elizabeth Zimmermann
Director
Environmental Programs
Santa Clara County Manufacturing Group

Appendix A5
Individuals and Organizations Who Provided Comments on the Commission's June 1996 Draft Report

(Arranged in alphabetical order according to organization)

Stephen Greene
Boston, MA

Edward C. Leach
Pleasant Hill, CA

Donna J. Vorhees
Brighton, MA

Marion Harnois
Boston, MA

W. Gary Flamm
Washington, DC

Martin N. Haas
Las Vegas, NV

Jane Walker Pfister
Brookline, MA

Dirk Dunning
Gresham, OR

Elizabeth K. Weisburger
Bethesda, MD

David E. Burmaster
President
Alceon Corporation
Cambridge, MA

Steve C. Lewis
Chair
Science Policy Committee
American Industrial Health Council
Washington, DC

G. William Frick
Vice President
Health and Environment and Safety
American Petroleum Institute
Washington, DC

S.Y. Chen
Group Leader
Risk Assessment & Safety Evaluation
Environmental Assessment Division
American Water Works Association
Argonne, IL

John H. Sullivan
Deputy Executive Director
American Water Works Association
Washington, DC

Miley Merkhofer
Principal
Applied Decision Analysis, Inc.
Menlo Park, CA

Elizabeth K. Hunt
Executive Director
Basic Acrylic Monomer
Manufacturers, Inc.
Washington, DC

Ngozi T. Oleru
Director
Boston Office of Environmental Health
Boston, MA

David Ozonoff
School of Public Health
Boston University
Boston, MA

Edmund Crouch
Senior Scientist
Cambridge Environmental Inc.
Cambridge, MA

Richard Lester
Associate Scientist
Cambridge Environmental Inc.
Cambridge, MA

Laura Green
President and Senior Scientist
Cambridge Environmental Inc.
Cambridge, MA

Timothy Lash
Associate Scientist
Cambridge Environmental Inc.
Cambridge, MA

Bob Kociolek & Others
Executive Director
Cancer Prevention Coalition
Chicago, IL

Marvin S. Legator
Professor of Community Health
Cancer Prevention Coalition
Galveston, TX

Brian Leibovitz
Editor-in-Chief, Journal of Optimal Nutrition
Cancer Prevention Coalition
Davis, CA

M. Granger Morgan
Department of Engineering & Public Policy
Carnegie Mellon University
Pittsburgh, PA

Miranda Henning
Senior Health Scientist
Carol A. Gillis
Senior Associate Health Scientist
ChemRisk
Portland, ME

M.L. Mullins
Chemical Manufacturers Assoc.
Arlington, VA

Dale Hattis
Research Associate Professor
Clark University
Worcester, MA

Raymond Yang
Professor of Toxicology
Colorado State University, Foothills Campus
Fort Collins, CO

Thomas Bliley
Chairman
Committee of Commerce, House of Representatives
Washington, DC

Brian Toal
Epidemiologist
Gary Ginsberg
Toxicologist
Department of Public Health
State of Connecticut
Hartford, CT

Daniel M. Byrd
President
Consultants in Toxicology
Risk Assessment & Product Safety
Washington, DC

Annette Dickinson
Director of Scientific & Regulatory Affairs Council
Council for Responsible Nutrition
Washington, DC

Warner D. North
Senior Vice President
Decision Focus Incorporated
Mountain View, CA

Roger Randolph
Department of Natural Resources
Jefferson City, MO

Stuart G. Harris
Natural Resources Specialist
Department of Natural Resources
Pendleton, OR

Terry Yosie
Executive Vice President
E. Bruce Harrison Company
Washington, DC

Thomas Starr
Principal
Environ Corporation
Arlington, VA

William S. Pease
Staff Scientist
Environmental Defense Fund
Oakland, CA

Hugh Spitzer
Environmental Network
Bethesda, MD

John M. Hunter
Environmental Working Group
Sacramento, CA

William G. Kelly
Federal Focus, Inc.
Washington, DC

Peter A. Valberg
Principal
Gradient Corporation
Cambridge, MA

Stephen A. Ziller
Vice President
James H. Skiles
General Counsel
Grocery Manufacturers of America
Washington, DC

Peter E. Voytek
Executive Director
Halogenated Solvents Industry Association Inc.
Washington, DC

John Graham
Professor & Director
Harvard Center for Risk Analysis
Boston, MA

Kimberly Thompson
Harvard Center for Risk Analysis
Boston, MA

Richard Wilson
Mallinckrodt Professor of Physics
Harvard University
Cambridge, MA

Daniel Greenbaum
President
Health Effects Institute
Cambridge, MA

Charles A. Willis
Chairman, Legislative & Regulatory Committee
Health Physics Society
Potomac, MD

Vern R. Walker
Hofstra University School of Law
Hempstead, NY

Arthur Chan
House Water Res. & Environ Subcommittee
Washington, DC

Wayne D. Berman
Chief Scientist
ICF Kaiser Engineers, Inc.
Oakland, CA

Willard Chappell
Lawrence Gratt
IWG Corp.
San Diego, CA

Donald E. Stevenson
Dermigan Consulting Group
Largo Vista, TX

Rogene F. Henderson
Senior Scientist
Inhalation Toxicology Research Institute
Albuquerque, NM

Alan A. Moghissi
President
Institute for Regulatory Science
Columbia, MD

Lorenzo Tomatis
Past Director of the International Agency for Research on Cancer
Instituto pe l'Infanzia
Trieste, Italy

Jo Anne Shatkin
Senior Associate
JK Research Associates, Inc.
Worcester, MA

Frederick H. Degnan
Partner
King & Spaulding
Washington, DC

Gary E. Marchant
Kirkland & Ellis
Washington, DC

Charles B. Mosher
Head Officer
Mariposa County Health Department
Mariposa, CA

Carol Rowan West
Paul Locke
Massachuetts Department of Environmental Protection
Boston, MA

Arnold Wendroff
Mercury Poisoning Project
Brooklyn, NY

Jay I. Goodman
Professor
Michigan State University
East Lansing, MI

Ron Melnick
White House
Washington, DC

George W. Lucier
Natl Inst of Environ Health Sciences
Research Triangle Park, NC

Gina M. Solomon
Senior Staff Scientist
Natural Resources Defense Council
San Francisco, CA

Al Meyerhoff
Senior Attorney
Natural Resources Defense Council
San Francisco, CA

Rae Zimmerman
Professor of Planning & Public Administration
New York University
New York, NY

Angus E. Crane
Director, Regulatory Affairs & Counsel
North American Insulation Manufacturers Association
Alexandria, VA

Christopher Frey
Assistant Professor
Department of Civil Engineering
North Carolina State University
Raleigh, NC

David C. Kocher
Oak Ridge Laboratory
Oak Ridge, TN

Terry Davies
Director
Resources for the Future
Washington, DC

James D. Wilson
Senior Fellow
Resources for the Future
Washington, DC

Ann Holbrow
Resources for the Future
Washington, DC

Kate Probst
Resources for The Future
Washington, DC

Gerhard Stohrer
President
Risk Policy Center
Larchmont, NY

Michael A. Jayjock
Rohm and Haas Company
Spring House, PA

Elisabeth Paté-Cornell
Professor
Stanford University
Portola Valley, CA

Harrison Schmitt
Chair & President
The Annapolis Center
Annapolis, MD

Richard I. Sedlak
Technical Director
The Soap and Detergent Association
New York, NY

Michael L. Dourson
Director
Toxicology Excellence for Risk Assessment
Cincinnati, OH

Douglas M. Brugge
Tufts School of Medicine
Boston, MA

Eric Rubel
General Counsel
U.S. Consumer Product Safety Commission
Washington, DC

Sherri W. Goodman
Deputy Under Secretary of Defense
U.S. Department of Defense
Washington, DC

Kaye Wachsmuth
Assistant Deputy Administrator
U.S. Dept of Agriculture
Food Safety and Inspection Services
Washington, DC

Nell Ahl
U.S. Department of Agriculture
Washington, DC

Tara O'Toole
Assistant Secretary
U.S. Department of Energy
Washington, DC

Clark D. Carrington
U.S. Dept. of Health & Human Services
Washington, DC

John Bowers
U.S. Department of Health & Human Services
Washington, DC

Sarah Henry
Executive Secretary
U.S. Department of Health & Human Services
Washington, DC

Richard Williams
Chief, Economics Analysis Branch
U.S. Department of Health & Human Services
Washington, DC

Clark Nardinelli
Economics Analysis Branch
U.S. Department of Health & Human Services
Washington, DC

Michael Bolger
Chief, Contaminants Branch
U.S. Department of Health & Human Services
Washington, DC

Dorothy E. Patton
U.S. Environmental Protection Agency
Washington, DC

Timothy Barry
U.S. Environmental Protection Agency
Washington, DC

Stephen D. Luftig
Director, Office of Emergency & Remedial Response
Environmental Protection Agency
Washington, DC

Bryan Hardin
U.S. National Institute for Occupational Safety & Health
Atlanta, GA

James Taylor
Executive Director for Operations
U.S. Nuclear Regulatory Commission
Washington, DC

Franklin E. Mirer
Director, Health & Safety Department
United Auto Workers
Detroit, MI

David Okrent
Professor Emeritus
University of California
Los Angeles, CA

Richard A. Merrill
Daniel Chaplin Professor of Law
University of Virginia School of Law
Charlottesville, VA

Amy Bonomi
University of Washington
Seattle, WA

Sandra Smith
University of Washington
Seattle, WA

Joe Yetter
University of Washington
Seattle, WA

James Hudson
University of Washington
Seattle, WA

Martha Shinkle
University of Washington
Seattle, WA

Pat Degracia
University of Washington
Seattle, WA

Carolyn B. Strong
University of Washington
Seattle, WA

Barbara Pierce
University of Washington
Seattle, WA

Jeanie Bjerke
University of Washington
Seattle, WA

Pia Fish
University of Washington
Seattle, WA

Raymond Galley
University of Washington
Seattle, WA

Maria Soval
University of Washington
Seattle, WA

Jeff Clark
University of Washington
Seattle, WA

Paula McMeen
University of Washington
Seattle, WA

Laura Whitman
University of Washington
Seattle, WA

Daniel Jorgensen
University of Washington
Seattle, WA

Thomas Kinane
University of Washington
Seattle, WA

Bradford Gessner
University of Washington
Anchorage, AK

Tom Kerns
University of Washington
Seattle, WA

Thomas Murray
University of Washington
Seattle, WA

Arthur Watanabe
University of Washington
Seattle, WA

Gerald Van Belle
University of Washington
Seattle, WA

Boni Stout
University of Washington
Seattle, WA

Mary Riveland
Director
Washington State Department of Ecology
Olympia, WA

Marva Kalish
President
Woods of Windsor
Roslyn Heights, NY

Appendix A6
Differences Between the Draft and Final Reports

Including A Representative Sample of Comments Organized by Table of Contents Along with Commission Responses (in Italics)

Fundamental Difference in Organization of Final Report

• We recommend separating the Commission's work products into two publications. Many of the Commission's more detailed suggestions raise complicated issues that are not thoroughly addressed in the draft report. These sections detract from the Commission's principal product: its risk management framework. The report would be strengthened if it focused on laying out why this framework is needed and what we need to do to implement it. This offers the best approach for ensuring the Commission's recommendations become the "Red Book" for risk management in the 1990s.

The Commission created a two-volume final report, the first volume devoted exclusively to the Commission's Risk Management Framework and the second to a more comprehensive revision of the 1996 Draft Report. We also moved the risk management chapter from chapter 5 in the Draft to chapter 3 in the Final, to put greater emphasis on risk management and to save some readers from an early immersion in more technical risk assessment issues.

1. Introduction

We added a box defining risk, risk assessment, and risk management.

2. Framework for Environmental Health Risk Management

• We strongly support the Commission's call for a more systematic, consistent, and disciplined approach to risk management, but the recommendations fall considerably short of what is necessary to develop a coherent risk management program across federal agencies. The Commission needs to propose an adequate strategy for addressing statutory constraints that would limit implementation of its recommendations and establish a guiding set of risk management principles.

• The stakeholder involvement framework as set out in the draft report would be extremely resource-intensive for both agencies and stakeholders, and may not always be workable. While communication with all stakeholders throughout the regulatory development process is paramount, it is neither practical nor constructive to have the same level of involvement at all levels of the process by all.

• As a state agency, we see little new or unique guidance in this framework which will aid us in our day-to-day tasks. We have struggled with difficult risk management decisions for many years and would like practical guidance to help us coordinate our efforts. This chapter discusses only generalities with little practical guidance. It is always a good idea to put a problem into context relative to other sources of similar exposure or even background exposure. However, what is a state regulator to do if residual risks from sources outside of his control exceed a source within his control? Such comparisons often anger the public by belittling their local problem and saying it is insignificant compared to some larger problem beyond their control.

• While the Commission stresses that the appropriate contexts for a problem are likely to be situational, we are concerned that risks associated with individual sources or sites will be inappropriately compared with unrelated exposures. The Commission should recognize that many of the issues suited to analysis by comparative risk are best addressed at the program level, in the decision to regulate a process, release, or exposure, and not in individual risk assessments conducted as part of that program.

• We strongly support the comission's recommendation to increase public participation in risk assessment and risk management processes. Recommending public involvement early in the risk assessment process is an important step forward from the guidance to separate risk assessment from risk management, as per the Red Book. However, the final report should address the increased funding required for meaningful stakeholder participation at the local level. For example, stakeholder participation from exposed citizens is extremely important in many situations, yet citizen groups do not usually have individuals with the appropriate technical background to educate stakeholders or to argue effectively for their position. These groups need funding to hire technical expertise.

• The scope and content of the proposed risk management framework are of limited value. The proposal breaks no new ground and does not assist risk managers, the professional community, or stakeholders in thinking about risk

management in a different way. A more productive path would be the development of a companion set of principles, procedures, recommended practices, and case studies to complement those already in existence for risk assessment.

• Increased stakeholder involvement in both risk assessment and risk management is both necessary and inevitable, but the Commission provides no clear reasoning process or clarity about how the elements of stakeholder participation are to be effectively managed. The Commission could have presented a synthesis of best practices of incorporating stakeholder perspectives into both risk assessment and risk management decisions.

• The Commission should abandon its proposed risk management framework, which fails to address many of the major practical and scientific/analytical issues involved in identifying and implementing risk management options.

• We strongly support the Commission's conclusions that an increased emphasis on explicit consideration of total environmental exposure is needed in the risk assessment process, that affected populations should be consulted about routes of exposure, that all stakeholders must be brought into the decision-making process from the beginning, and that there is a need for developent of better disease surveillance data.

• A clear strength of the report is the broad risk-management framework. The framework is compelling because it is flexible enough to allow consideration of a diversity of decision strategies, ethical perspectives, and types of technical guidance. It also calls for early stakeholder involvement, use of sound science, and good-faith efforts at consensus formation, features of decision making that are not always evident today.

• We are gratified to note that the Commission recommends enhanced stakeholder involvement and collaboration in its draft report. Our concern, however, is that the Commission does not give practical guidance on how to implement stakeholder involvement throughout the process of risk assessment and risk management. We urge the Commission to carefully expand upon its guidance on how to involve stakeholders and to clarify the nature of interactions between interested and affected parties. Most importantly, mechanisms of stakeholder involvement should be designed with the goal of preserving the critical role of science in risk assessment.

• The Commission report codifies the importance of stakeholder participation and explicitly anticipates a role for stakeholders in all phases of the risk assessment/risk management process. In light of the apparent increased importance of stakeholders there is a need to clarify their role, addressing: (1) criteria for determining both balance and legitimacy in the choice of representative stakeholders, and (2) power sharing, i.e., whether legislative changes are needed to give stakeholders advisory status or grant them the power to approve or disapprove regulatory decisions.

• The report falls short of providing a concrete scheme or evidence to support the conclusion that the projected process would actually provide time savings in the long run. Other issues not adequately addressed include the effective coordination among federal agencies, which requires changes in how government operates; the new directions in research, which require more funding support; and more stakeholder interactions, which require more time and resources. It is appropriate to lay down some alternatives leading to potential future implementations.

• We commend the Commission's efforts to present a framework for risk management that incorporates a rigorous science-based approach to problem solving as well as full consideration of societal, economic, and cultural conditions and needs. With the goal of accounting for the connections between environmental health, human and economic well-being, and the processes by which our society's actions create long-term changes, both beneficial and adverse, the Commission established an intriguing framework for making decisions on the reduction of risks to public health, safety, and the environment.

• We support the report's recommendations on the inclusion of stakeholders in risk management processes conducted by any regulatory agency with jurisdiction over health, safety, and environmental issues. One of fundamental tenets of our organization's Risk Principles is the need for an open public process with participation by stakeholders at every stage of the process. It is incumbent on stakeholders to clearly communicate their views and to provide information and analyses. We suggest that the Commission address the process for stakeholder selection and the means for participation.

• We compliment the Commission on recognizing that everything is connected. Tribal health and environmental equity are essentially synonymous, as our elders have said for thousands of years. They have also said that yes, everything is connected.

• We agree that an integrated approach to risk is needed. To do this, however, we should turn the entire paradigm around, and concentrate less on building a comprehensive set of micro-exposures (such as the TEAM approach, although this does, of course, provide useful information), and concentrate more on describing what we want to protect and all the ways it might be at risk.

• This report defines risk solely in terms of public health. This definition is too narrow. Our tribal risk model recognizes that contaminants pose risks to tribal rights, resources, health, and culture. Discussion should be added that recognizes that risk has broader definitions than simple mechanistic human exposure assessment.

• We strongly endorse the emphasis on stakeholder involvement at each step in the risk assessment and risk management process, although this was not carried through the report. Most of the document, while raising many important points, tends to remain within the conventional risk paradigm (hazard id, dose response, exposure assessment, and risk characterization). We would prefer to step a little further out of the "box" and add a component of cultural toxicity to the paradigm along with human and ecological toxicity.

• We strongly support the key observation that environmental problems must be addressed comprehensively rather than on a chemical-by-chemical, media-specific basis. The draft report almost completely fails to address solutions to the problems it identifies. Implementation deserves sustained attention in the report. The proposed risk management framework should be modified to (1) incorporate a more comprehensive approach to hazard identification, (2) incorporate effective incentives for generating the scientific information required for sensible decision-making, (3) address the resource constraints that bias and limit stakeholder participation in regulatory decisions, and (4) recognize and counteract the risk of increased transaction cost and "paralysis by analysis" that the framework poses in its current form.

• The framework is an important step in the direction of providing the components and philosophy of a decision-making approach, but a greater degree of specification would prevent unintended outcomes from occuring where the wrong process was taken.

• Advocating public involvement without establishing a process for involvement is politically and managerially unsound. The discussion of public involvement should be expanded to include elements of or alternatives for such a process or at least how such a process would be developed.

• The report underscores multimedia approaches and the provision of contexts for exposures. Without further development, however, it is too easy for this to be interpreted as the larger the problem, the less the marginal impact of any incremental additional contamination or exposure. This can obscure situations in which the mountain of contamination is increasing and any given addition has to be continually larger to be acknowledged.

• Ever since the environmental movement began, integration to avoid the pitfalls of categorical thinking and fragmentation has been a constant battle cry. No one denies that in many circumstances integration is absolutely critical to effective management. Most importantly, identifying how the institutional barriers to integration can be overcome is more significant than acknowledging that integration should occur.

• I would like to commend the Commission for its bold proposal of a new risk management framework. Given [our federal agency's] environment, safety, and health challenges, complex web of stakeholders, and technical, budgetary and regulatory constraints, this risk management framework will be very useful.

• There is utility to the collaborative framework concept outlined in the report. If inflexible and prescriptive federal rules remain, collaboration at the local level will be meaningless. New statutory and regulatory flexibility for state and local decision making will be necessary to implement any such framework.

• The draft report suggests making stakeholders partners in risk assessment and risk management. This should not mean that risk assessment becomes a political process. Risk assesssment must be science based. Stakeholders can contribute by providing scientific information.

The Framework is reaffirmed and supported considerably better than in the draft report with principles, guidance regarding implementation, and examples. For example, Principles for Risk Management Decision-Making have been added, as have Guidelines for Stakeholder Involvement. Each of the six stages of the framework is described in detail, including questions to ask and considerations to address. The role of stakeholders in each stage of the Framework is explained. The connection of each stage to the Principles for Risk Management Decision-Making is clarified. The different contexts that should be considered (multisource, multimedia, multichemical, and multirisk) are clearly described. Examples are given that illustrate different contexts and indicate how creative, integrated strategies to risk reduction can be implemented.

We recognize that regulatory agencies operate under the constraints of their enabling statutes and regulatory policies and we recommend that to address environmental problems more comprehensively and in context, Congress should initiate joint oversight hearings and agencies should fully use their discretionary authority to expand stakeholder involvement and to address the most significant sources of risk. We also recognize that local stakeholders may need technical and sometimes financial assistance to be effective participants in risk management decisions. To avoid having risk assessments become too politicized, however, we note that stakeholders can contribute valuable information (about exposures, for example) to risk assessors but should not participate directly in the assessment itself.

We acknowledge the important role that cultural considerations play in risk management decision-making in addition to considerations of risk, feasibility, cost-effectiveness, etc., but we have chosen to restrict our definition of risk to that of human and ecological health in the mechanistic sense. We emphasize, however, that cultural considerations should be included in risk assessments, especially in terms of their impacts on exposure and susceptibility.

3. Risk Management and Regulatory Decision-Making

Communicating and Comparing Risks

■ Identifying Risk Communication Needs

• There is little or no discussion of the role of the media in developing and shaping of perceptions of risk and of the need to bring reporters and others into the process in a way that recognizes their role but that reflects accurate and thoughtful information.

• We agree that better risk communication is needed. However, it is far harder for decision makers to understand other perspectives (once they're convinced that their computer has provided them with the "right" answer) than it is for tribal technical staff to understand the details of risk assessment. As you are all too well aware, any disagreement with the computer's answer, or with the assumptions of the modeler who designed the code, is labeled junk science. From a tribal perspective, over-reliance on numerical results is irrational and might be labeled junk ethics. Science should be done in service to values. Data are subservient to wisdom.

• Risk communication is a two-way process, and just as much emphasis needs to be placed on communicating tribal and community risks to managers and assessors as risk managers place on communicating probabilities to the public. Please do not overestimate the ability of risk managers to understand either the details of risk assessment or of tribal/community concerns, and do not underestimate the expertise of tribal technical staff. This applies not just to explaining risk results, but also (and even more importantly) to the improvement of the risk assessment methods themselves. We don't need to be communicated at; we need to be able to use risk assessment as equal partners and peers.

• We would prefer to see less emphasis on funding risk communication and more on funding tribes to develop in-house technical expertise.

We strongly support two-way communication and a sense of respectful partnership. We have tried to avoid recommending greater quantitation than is needed for understanding risks and examining options for action. We added recognition of the important role that the media play in risk communication.

■ Communicating About Risk by Comparing Different Kinds of Risk

• We fully support the report's recommendations regarding the value of using comparative assessments of risk to convey information about the nature and magnitude of risks. We agree with the types of comparisons that the report recommends but suggests some additional information. Information about the benefits associated with the risk should also be provided along with information about "substitution" risks. That information is necessary to place the risk fully in context and to identify the potential tradeoffs inherent in any risk management decisions.

• When used appropriately, comparisons of unlike risks can be illustrative in certain situations and can convey a sense of magnitude in terms familiar to the recipients of that information. The Commission should acknowledge the potential usefulness of such risk comparisons and suggest appropriate scenarios for their use.

The Commission acknowledges the useful role that risk comparisons can make in risk communication, but we believe that comparing unlike risks is generally inappropriate. There are other useful methods of communicating a sense of magnitude, which we discuss. We also recognize the importance of understanding "substitution" risks, but have chosen to emphasize their consideration when we address examining options for risk management actions, not as a tool for communicating about the nature and magnitude of a particular risk.

■ Need for a Common Metric

• We agree with the finding that the dichotomy in methods for assessing cancer and non-cancer risks causes inconsistencies in risk management actions and makes comparisons of risk difficult. A margin-of-exposure approach for carcinogens may be useful in addressing this dichotomy but potential confusion may arise when a risk manager is presented with somewhat inconsistent measures of risk for linear and non-linear carcinogenic agents. In addition, such a method must be clear about whether methods or assumptions are based on science or policy (i.e., defining an acceptable margin of exposure).

• A margin of exposure approach is a major departure from the standard risk assessment/risk management practice used in the evaluation and regulation of carcinogens. The draft document does not adequately describe the disadvantages of such a practice. The discussion overlooks the limitations of cancer bioassays and fails to put into perspective the purpose and utility of probabilistic cancer risk estimates.

This [probabilistic] approach is very useful for risk management and should not be written off as "speculative." The nonprobabilistic margin of exposure approach is useful in pointing out the dosage gap between animal testing and human exposures, but it does little to clarify whether there is a plausible risk for humans and how large this risk might be.

• There is no scientific evidence for potential risk and it should not be used in public policy. Evidence for health effects at low dose, by traditional scientific interpretation, is negative. We believe public policy in the United States and Europe would have followed a different course if the public had been told about the successful experience regulating the natural carcinogens arsenic, radon, and aflatoxin. Restoring public trust after years of misleading science advice and failing policy is the most urgent issue. The U.S. National Institutes of Health should lead the science advice. EPA should not be involved in risk assessment or in science advice in the future.

• The draft report strongly supports margin of exposure as a cancer risk characterization tool but fails to provide any guidance on how to use such a comparison in risk management.

• When providing guidance to regulatory agencies, the document contradicts itself by relying solely upon probabilistic estimates of cancer risk for decision making, rather than also using the margin of exposure approach.

• Its use should be limited to helping to provide perspective on probabilistic risk estimates for non-genotoxic carcinogens whose mechanistic database is sufficiently developed to demonstrate a strong likelihood for a threshold dose for cancer.

• We strongly support the Commission's recommendations to develop compatible protocols for evaluating cancer and noncancer health effects, so that the two types of risks may be compared. However, the Commission should stress the importance of being able to use all available scientific information and, in the absence of data to the contrary, to incorporate conservative toxicity and exposure assumptions to protect human health.

• The recommendation to adopt a "margin of exposure" type analysis for carcinogens essentially gives up on producing quantitative estimates (uncertain though they are) of the consequences of interest for policy how many cases of cancer do we expect may be caused by a specific exposure, and how may cases might we be able to prevent by various measures to control that exposure? What we need to do for nongenetically acting carcinogens and for the array of noncancer effects is to do the fundamental research to eventually convert the old NOAEL/uncertainty factor system into one that makes quantitative predictions of the likely incidence of harm.

• The draft report leaves readers with the impression that margin of exposure is essentially interchangeable with the margin of protection. Using a margin of exposure for comparative risk purposes presumes that exposure is a perfect surrogate for response; thus, it assumes, albeit implicitly, that all dose-response relationships are linear. Although the margin of exposure approach would give both cancer and noncancer endpoints a common metric, it provides us with an essentially linear metric, the worst possible metric to be using for noncancer endoints, thereby trivializing all of toxicology.

This section was changed to emphasize that we recommend common metrics as risk communication tools and not necessarily as a substitute for current regulatory practices. We note that the U.S. Environmental Protection Agency recommends and uses a margin of exposure approach. We also point out that a margin of protection approach is used everywhere (except in the U.S.) to evaluate both carcinogens and noncarcinogens. Probabilistic estimates of risk are, after all, upper bounds on expected risk, not estimates of actual risk or of the number of cases of cancer we expect to occur. We strive to indicate that the margin of exposure is not the same as the margin of protection, and that basing risk management decisions on such metrics must include evaluations of the available scientific information.

Comparative Risk Analysis for Risk Management Priority-Setting

■ Risk-Based Priorities and Resource Allocation

• We share the Commission's support for the use of comparative risk assessment by federal agencies for prioritization purposes but disagree with the Commission that comparative risk should be conducted only on a demonstration or experimental basis. We believe that there has been enough experience with comparative risk to begin using it now to set priorities among agency activities.

• The procedure for comparative risk assessment for priority-setting, while intuitively appealing, is extremely problematic. As an example, consider the problem of ranking the relative importance of controlling endocrine disruption and particulate air pollution. The former is poorly undertood, but has the potential to impact the entire human race and all living animals. The latter problem is fairly clear, and we have quite precise estimates of the number of deaths annually attributable to particulate pollution. Which poses the greater risk? That question is currently impossible to answer. Because of the reliance on data availability, a precautionary

approach is generally not supported by comparative risk assessment.

This section now acknowledges the disparate views on the utility of comparative risk analysis, but retains the recommendation that comparative risk analysis should be conducted on a demonstration basis, which seems appropriate in light of those disparate views.

Strategies for Managing Risk

■ Risk Management Options: Alternatives to Command and Control

• We strongly support the Commission's recommendation that there should be increased reliance on market-based alternatives to command and control regulation.

• We agree with the need to explore alternatives to command-and-control regulations. The tools identified in the report as alternatives to command-and-control systems should be risk-based or used to identify and respond to risk reduction opportunities. The report did not adequately emphasize the goal of risk reduction as a key component in each of these tools. The usefulness of a tool should be measured by its ability to identify, compare, and reduce risks in a way that permits the optimal use of resources.

This section now acknowledges the important role that command-and-control regulation has played in environmental protection. The importance of evaluating alternative tools for reliability, feasibility, effectiveness, and efficiency is emphasized. Material on the roles that research, monitoring, and surveillance play in managing risks was added.

■ Bright Lines and Regulatory Standards for Risk Management

• The recommendation on bright lines is equivocal and needs further clarification. Bright lines may be successfully used only as a criterion to differentiate those problems, issues, sites, etc., that do not require further inquiry from those that require further evaluation by a more exhaustive and extensive analytic process to determine if action is necessary. They should be used only for screening, and not for risk management decision-making.

• We do not oppose the use of bright lines when they are used only for screening purposes and are based on scientifically sound methods. The final report should include language warning against the inappropriate use of bright lines for non-screening purposes.

• The Commission should endorse the use of bright lines only in screening analyses to determine whether a more detailed risk assessment is required, and clarify its discussion on the use of bright lines as screening tools and specify how to use these tools flexibly.

• We commend the Commission for recognizing both the benefits and limitations of bright lines and concur that bright lines are necessary as guidelines in exposure limits and that agencies need to be flexible in their interpretation of bright lines. However, the Commission should recognize that qualified staff are needed to interpret and qualify the range of uncertainty and variability that underlies the bright line. The less we depend upon bright lines, the greater our costs will be.

• The Commission should give more thought to its recommendation about multiple bright lines and ranges of bright lines. It is our experience that given a range of "acceptable risks," the upper end of a risk range becomes the de facto bright line. This practically eliminates the flexibility that in thoery results from the use of a range. Further, the use of a risk range may result in inconsistent application of the range and questions of fairness, both real and perceived.

This section was changed to clarify that the Commission opposes the use of inflexible risk-based bright lines because risk estimates are so uncertain and variable, but that we believe measurable, concentration-based bright lines (standards) can be useful. We note, however, that bright lines or ranges of bright lines tied to specific exposure concentrations should be used only as guideposts or goals for decision-making, and should not be applied inflexibly. We also note that risk-based bright lines can be useful for screening, but should not be the sole basis of risk management decision-making.

Judicial Review of Regulatory Decisions to Manage Risk

• This section reflects the personal views of the Commission members on legislative initiatives considered by the 104th Congress. The legislative mandate creating the Commission did not envision comments on pending legislation as an appropriate issue for Commission consideration. It would be useful to revise the section on judicial review to assess the impact of the process on risk assessment/risk management practices historically. It would also be of value to assess judicial review in the context of the internal debate within EPA between those advocating inclusion of alternative interpretations and uncertainties in a regulatory document and those who believe such inclusions weaken the agency's position during judicial review.

• We find the report's section on judicial review to be very good and agree with most of its recommendations, for example, that final agency action must be final, that a Congressional mandate to all agencies to follow detailed cost-

benefit and risk assessment requirements that would then be judicially reviewable is unwise and inappropriate, and that the standard of judicial review should not be expanded.

• This section should be refocussed away from issues raised in specific past legislative proposals toward articulating the general principles that should govern judicial review in the event Congress adopts a new framework for risk assessment and risk management decisions. The Commission's generalizations simply do not represent an accurate description of the proposals that have received most serious consideration. This issue lies outside the scope of the Commission's mandate and fails to recognize the extensive oversight role that the courts now play under existing health, safety, and environmental statutes.

• The judicial review chapter of the draft report is a great disappointment and should be deleted or revised substantially. The chapter is extremely one-sided and simply adopts the administration's position on the regulatory reform debate without providing a useful analysis to illuminate the issues.

The judicial review section was changed to de-emphasize previously proposed regulatory reform legislation, but the Commission believes that the issues raised in those earlier proposals may very well surface again in future proposals and, more importantly, that those issues go well beyond any particular legislation. Those issues served to focus the debate on the appropriate role of judicial review of agency action in the regulatory process. The section does not intend to overlook or impugn the important oversight role that the courts play at present, and we believe that failing to address judicial review-related issues in our report would constitute failing to acknowledge that important role.

The section has been changed to clarify that the Commission does not support strict decisional criteria. The section addressing the impact of increased litigation on agencies, parties, and the courts has been deleted.

■ Premature Interruption of the Administrative Process

• The regulatory reform bills did not call for the interruption of the administrative process by premature judicial review. Instead, the bills would have required that risk assessments and benefit-cost analyses be made part of the rulemaking record, to be considered in connection with judicial review of final rules.

This statement is not true. Early proposals would have redefined final agency action. Final agency action must be final, and should not be redefined to permit review of agency action and discrete issues until after agency action is complete.

■ The Nature and Extent of Judicial Review

• All environmental laws, including recent safe drinking water and food safety legislation, employ risk assessment and scientific terminology that are ultimately reviewable in courts. The Commission's recommendation is one-sided and fails to consider the need for accountability of federal programs. Arguably, smarter programs may result in less litigation. Nonetheless, any statutory change is likely to increase litigation at first.

• If the well-established principles for judicial review developed under the APA and individual laws are reflected in regulatory reform legislation, the courts would continue to perform their long-standing responsibility to assure principled decision-making by agencies without creating new litigation opportunities or subjecting rules to unproductive judicial oversight.

• If an environmental rule were based on more sound science and greater consideration of costs and benefits, industry may well find that the final rule is reasonable enough that it should not be challenged. Thus, litigation actually may decrease.

New litigation opportunities would not result from the appropriate application of the APA. They could result from the establishment of detailed decisional criteria and procedural requirements that would supplement all existing enabling statutes, which were included in versions of the draft regulatory reform legislation.

■ Standard for Judicial Review

• The general principles that govern judicial review should be based upon current standards of judicial review of administrative action.

• The attack on the "substantial evidence" test is impassioned but misguided. There is no evidence to support that under the substantial evidence test, courts would replace administrative agencies as the ultimate decision-maker on highly technical issues.

The Commission believes that proposals to require substantial support and in the rulemaking file for agency findings and conclusions at the expense of the arbitrary and capricious standard could be interpreted to mean that the substantial evidence standard would be expanded beyong formal hearings to all rulemakings, reducing a court's ability to defer to agency decisions.

■ Consensual Approaches as Alternatives to Increased Judicial Review

• Our agency makes extensive use of consensual approaches as regulatory alternatives. For example, through

meetings and cooperation with industry, we have addressed a number of safety hazards. This has allowed us to address these hazards quickly and without resorting to rulemaking. We also work extensively with consensus voluntary standards groups to develop effective voluntary standards.

Consensual approaches as alternatives to increased judicial review would involve stakeholders in decision-making, as recommended by the Commission's Risk Management Framework.

4. Uses and Limitations of Risk Assessment for Risk Management Decision-Making

Toxicity Assessment

■ Using Rodent Tests to Predict Human Cancer Risk

• There are many important chemicals that are candidates for a future version of the table listing potentially irrelevant mechanisms, tumors, and chemicals. Further research may show that tumors observed in rodents or even in humans at extremely high doses are not relevant to human cancer risk at low doses by obtaining the understanding that different biological mechanisms govern the development of these tumors and that these mechanisms are not operative for humans at low doses.

• If animal models are wrong, deficient, limited, etc., then addressing these concerns, i.e., what criteria or research is needed to identify when the models are wrong, should be a major focus of the report, not that the results of animal models should be discarded when they are not relevant to humans. Can the report provide criteria or guidelines as to when results can or cannot be used? Most, importantly, what are the alternatives to animal models?

• We concur with the recommendation to classify as irrelevant to human cancer risk assessment a limited set of rodent cancer responses where the physiological mechanisms for tumor development in the rodent do not have a corresponding human mechanism. Some education and risk communication may be required on this point, however, so that the public does not lose confidence in other rodent bioassay data. We strongly support the Commission's recommendations to focus on testing

• We agree with the recommendation that certain rodent responses should be classified as irrelevant to human cancer risk assessment. This recommendation is particularly applicable in cases where there are tumors that result from mechanisms that are unlikely to occur in humans or that occur at very high doses that are irrelevant to human exposures.

• The Commission's recommendation is critically important to ensure that risk assessments are realistic and to help policymakers understand true human cancer risks and set priorities among their efforts accordingly.

This section was changed to emphasize the importance of rodent bioassay results and the role that they can play in identifying carcinogens, along with knowledge of mechanisms of action. A table listing known human carcinogens was added. Material was added that describes weight-of-evidence considerations for evaluating a chemical's or a tumor's human relevance.

■ Evaluating Chemical Mixtures

• We strongly support the Commission's recommendations to focus on testing chemical mixtures. This type of research will provide better information on potential interactions among chemicals and help reduce uncertainty. However, testing mixtures adds costs and the results are hard to generalize to slightly different mixtures in different settings.

• We agree with the recommendations to test mixtures and that, in some cases, adding together risks from individual chemicals is generally appropriate and is unlikely to result in an underestimate of risk.

• It is neither appropriate nor workable to test environmental mixtures that exist at low concentrations. As the Commission itself notes, for "environmental" mixtures (as distinct from consumer or occupational exposure), effects of mixtures seen at high doses are probably inappropriate for conducting risk assessments for much lower levels of actual exposure because the interactions that may occur experimentally at high doses would not occur at low doses. Furthermore, mixture permutations are infinite and their variability huge.

• We agree with the finding that dose response data are needed for mixtures. However, we urge caution about the recommendation to consider risks separately if mechanisms are different. Chemicals do not usually act through single mechnisms, and secondary mechanisms may exist. The same is true of primary and secondary target tissues and primary and secondary effects.

• The draft report is a bit too strongly slanted toward the contentions that: (1) at low doses (i.e., environmentally relevant exposure levels), toxicologic interactions are unlikely, and (2) at low doses, interactions, if present, are mostly likely additive in nature. These contentions, in my view, are not necessarily true.

The Commission disagrees that testing environmental mixtures is of no utility; we recognize that testing at high doses may not be relevant in a dose-response sense to low environmental doses but it would certainly be useful as a screening tool, to help identify exposures that should be examined or controlled more carefully. We also recognize that mixtures are highly variable and

suggest that methods such as Monte Carlo analyses may prove useful in attempts to generalize testing results. We added material suggesting how a coordinated research program could facilitate enlarging the mixture toxicity data base.

The Commission continues to support the view that low-do0se interactions, if they occur, are unlikely to be detectable and that assuming response additivity is precautionary. The data submitted by commenters supported our conclusions.

■ Accounting for Differences in Susceptibility

• We agree with the recommendation that risk assessments should include considerations of differences in susceptibility. Population subgroups must be considered and we agree that recognition of subgroup susceptibility should not "result in more stringent regulations." However, we object to the reference to additional "bright lines." Instead of using the most susceptible subpopulations to justify the most stringent bright lines, we believe that knowledge about differences in susceptibility should be used to identify where more stringent restrictions may be needed. Such situations should be dealt with on a case-by-case basis and considering all aspects of the situation. Thus we believe that where appropriate, knowledge of differences in susceptibility should be used to tailor risk management responses for identified susceptible subpopulations.

• Environmental equity needs further interpretation. Suggesting separate bright lines for protecting susceptible subgroups should not inadvertently impede their economic development or career opportunities. Further deliberation is needed to avoid unintended consequences.

• Susceptible subpopulations should not become a vehicle for maintaining the conservatism of the maximally exposed individual. The Commission should make it clear that risk assessments that include susceptible subpopulations should not be used as the basis for risk management actions that treat all exposed individuals as members of the susceptible population. Actions should be specifically targeted towards the susceptible subpopulation.

• This finding and recommendation imply that risk assessments do not take into consideration host susceptibility factors. Standard risk assessment practice for noncancer endpoints is to include a 10-fold safety factor for inter-individual differences in susceptibility to the chemical. This approach should be pointed out and its merits/faults discussed.

We now indicate in our finding that current regulatory approaches for reducing risks associated with chemical exposures generally do not include information on differences in individual susceptibility or encourage getting evidence to identify them, and note that in the absence of specific information about differences in susceptibility, risk assessments rely on assumptions and safety factors that are presumed to be protective of sensitive individuals. We concur that susceptible subpopulations should not be used as the basis of risk management actions that treat all members of an exposed population as especially sensitive, and that risk management responses should be tailored for specific identified subpopulations.

Exposure Assessment

■ Design of Exposure Assessments to Meet Risk Management Goals

• We agree that exposure assessments should be designed to be commensurate with the needs of the risk management decisions at issue and that the use of a tiered approach in exposure assessments is a good strategy for effective resource allocation.

■ Using Realistic Exposure Scenarios

• We agree that exposure assessments should not be based on a maximally exposed individual. Using high-end exposure estimates for screening assessments and distributions of a population's exposures for more refined assessments is reasonable.

• We commend the Commission on its recommendation regarding population-based exposure. Another terminology might be receptor-based as opposed to source-based exposure assessment. The TEAM studies have clearly demonstrated that source-based exposure assessment can be seriously misleading when compared to personal measurement results.

We clarified our recommendation to indicate that exposure assessments should rely on population exposure data where possible instead of assumptions about exposure derived from sources and models. We include the terms receptor-based and source-based and refer to the TEAM study as a good example of receptor-based exposure assessment. We emphasize that considering the size of an exposed population is important in addition to considering the distributions of its exposures.

■ Identifying Highly Exposed Populations

A reference to the Food Quality and Protection Act of 1996 and its role in addressing susceptible populations was added. Our reference to education as a risk management tool was clarified to indicate that there are other alternatives and that education might not be considered appropriate by stakeholders in all cases.

Ecological Risk Assessment

■ Framework for Evaluating Ecological Risk

• We agree that EPA and other agencies and interested parties should continue to work together to refine ecological risk assessment and risk management approaches. Guidance on problem formulation, methods, characterization of uncertainty, and the appropriate role of stakeholder participation in the process is necessary and should incorporate the views and expertise of all practitioners of ecological risk assessment/risk management.

• We applaud the Commission for including a discussion of ecological risk asssessment. However, ecological receptors will continue to be underrepresented in environmental regulations as long as there is a lack of focus on this topic. This section should be expanded and revised in keeping with the level of discussion on direct human health issues. Formal recommendations on support for basic research tools and data should be included in the final report.

• This report does not engage in a robust and comprehensive discussion of ecological risk assessments, alluding to only a single purpose for conducting an ecological risk assessment protecting resources in terms of their direct human uses. There are multiple and legitimate purposes that various constituencies may have in conducting ecological risk assessments. This subject needs more evaluation and discussion.

• The limited scope of the Commission's review is illustrated by the sole identification of the index of biotic integrity as an "important diagnostic tool," giving the impression that Karr's index is a preferred choice. There are numerous other diagnostic tools available that may be equally or more applicable and useful.

• The link between the discussion phase and the risk management phase in the framework should be illustrated with only a downward arrow. An arrow going in both directions communicates that a risk management decision is never final or complete.

The Commission has not expanded this section, although we continue to refer the reader to other excellent sources of information. We were not mandated to address ecological risk assessment, but we would have been remiss not to include it. An acknowledgment and analysis of the U.S. Environmental Protection Agency's new ecological risk assessment guidance was added and the arrow on the framework was modified. We acknowledge that there are other purposes for conducting ecological risk assessments besides protecting resources in terms of their direct human uses.

Environmental Hazards Other Than Chemicals

■ Risks from Radiation Hazards

• The report focuses on the differences between radiation and chemical standards and the level of cancer risks at the exposure limits. There is no discussion of differences in methodology, data, and assumptions from which standards are derived. Harmonization of the fields of radiation and chemical risk assessments will remain an illusive goal without these basic differences being articulated and discussed.

• The Commission did not recognized standards recommended by authoritative bodies in radiation health protection such as the ICRP and the NCRP.

• The report downplays the ALARA principle that underpins all radiation standards.

A discussion of the differences in approaches to deriving radiation and chemical standards, a reference to the ICRP and NCRP standards, and an emphasis on ALARA were added to the section.

■ Risks from Microorganisms

Material has been added that describes ongoing efforts intended to strengthen microbiological risk assessment.

Risk Characterization

■ Effective Risk Characterization to Support Decision-Making

• Risk managers and the public need to understand, and have the right to know, what the weight of the scientific evidence says about a given health or environmental risk. Unfortunately, current agency practice and EPA's recent cancer guidelines appear to ignore the weight-of-the-evidence approach; as a result, decision makers and the public will continue to be misinformed and billions of dollars will be wasted on excessively hypothetical and exaggerated statements of cancer risks.

• Failure to achieve a clear separation of scientific evidence from policy considerations has negative implications beyond impaired credibility: it inevitably obscures the overall level of uncertainty in the assessment and will influence consideration of societal tradeoffs and ultimate decision-making. The Commission recommends "weighing the evidence," but weighing the evidence cannot be done unless it is kept separate from assumptions. Clear understanding of uncertainties is a key component of considering tradeoffs because the public may often opt for deferring measures to address very uncertain gains in order to devote scarce resources to achieve more pressing and certain gains.

This section was changed to emphasize the role of the precautionary principle and the importance of considering the weight of the scientific evidence. Material on uncertainty was moved to the uncertainty section (next) and material on resolving the need for decision-making versus collecting more data was moved to the

new value-of-information section.

■ Characterizing the Uncertainty Associated with Risk Estimates

• The emhasis of your major statement on uncertainty that most risk assessments do not need quantitative uncertainty evaluation is discouraging to those of us who believe that making our best efforts to fairly and honestly express uncertainties is a prime duty of any technical analyst. It is probably quite literally true that most risk control decisions would not be changed by a quantitative uncertainty analysis. But we should be encouraging risk managers to face the facts of the imprecision of our estimates as a fundamental part of appropriately communicating the limitations of our available information.

• The report is a step backward in regulatory decision-making because of a serious inconsistency. The Commission recommends against performing full analyses of uncertainties because it would be difficult and confusing to the decision-maker, but at the same time they encourage risk comparison, risk ranking, and cost-effectiveness or cost-benefit analyses that are meaningless without explicit treatment of uncertainties. The issue is not so much the treatement of variability, which is sometimes currently done in exposure assessment, but of fundamental epistemic uncertainties, for example, about dose-response relationships.

• We urge the Commission to reconsider its preference for providing qualititative descriptions of the range and distribution of risks over quantitative ones. Risk assessors should provide such quantitative estimates where appropriate. Qualitative information, including descriptions of the major assumptions, uncertainties, and policy judgments embodied in a risk assessment, are always necessary to more clearly describe a risk and place it in context. However, a point estimate accompanied by qualitative information describing uncertainties does not sufficiently inform the risk manager or the public. The apprehension of risk managers regarding quantitative estimates of the range is understandable. Point estimates provide a sense of certainty and the appearance of consensus on the estimate, but that sense is unreal. The Commission should suggest a paradigm for how risk management decisions can be made from ranges and distributions of risk. At a minimum, the Commission should recommend that if a full range and distribution of estimates are not going to be provided, more than one point should be identified, including a central or most plausible estimate along with a high-end estimate.

• Formal uncertainty analyses have much to add to the risk assessment and risk management process. If risk managers' eyes start to glaze over when they are presented with such information, the fault is ours, not theirs, and the obligation is ours to improve communication and raise their level of awareness and appreciation for the real value contributed by such analyses.

• The Commission should recommend that uncertainties be quantified for both exposure and dose response when comparing risks. If uncertainty is not quantified, then it is not possible to know whether one risk is truly higher or lower than the other. When uncertainty is quantified, it is possible to determine whether one risk is likely to be higher or lower, or whether the risks are indistinguishable from each other given scientific uncertainties. This information is useful to policy-makers. In the former case, the risk assessment may be influential in the decision process. In the second case, other factors, such as equity issues, economics, etc., may provide a stronger basis for making a decision.

• As long as cancer risk calculations are being made by risk assessors and used by risk managers, these calculations need to be made by appropriate methods and uncertainties need to be carefully explained by the risk assessors to the risk managers and to stakeholders. I do not believe progress will be made by retreating to qualitative discussions of uncertainty, especially if the use of a quantitative point estimate of cancer risk is retained.

• While it is appropriate to avoid excessive use of complex probabilistic methods, quantitative methods for uncertainty analysis can enable improved communication between scientists/risk assessors and the decision-makers and stakeholders. The draft recognizes this potential for economic analysis and exposure analysis. The draft should be revised so that this point is also made for uncertainties about the dose-response relationships for cancer and other health effects.

• Quantitative uncertainty analysis may not be necessary in all instances, but should be conducted for risk assessments underlying major regulatory decisions that include parameters with significant uncertainty.

This section was changed to clarify that the Commission supports using probability distributions of the variability in a population's exposures as appropriate to enhance characterization of exposures and communication of risks. We continue to recommend against routine use of formal quantitative analysis of uncertainties in risk estimation, particularly that related to evaluating toxicity, relying on narratives instead.

■ Value of Obtaining Additional Information

• The major analytic weakness of the report is its silence on the promise of formal "value of information" methods to enhance the quality of risk management decisions when the

stakes are high and the quality of available information is low.

This section was added to clarify the conflict between the need to make decisions in the face of uncertainty and the need to gather more information on which to base decisions.

5. Uses and Limitations of Economic Analysis for Risk Management Decision-Making

Benefit-Cost and Cost-Effectiveness Analysis

Only minor additions and clarifications have been made.

■ Useful Roles in Regulatory Decision-Making

• We strongly support the report's conclusions regarding the importance of benefit-cost and cost-effectiveness analysis in making regulatory decisions. We also agree that not all costs and benefits can be assigned monetary values; nonmonetary values should be included in decision-making nonetheless. When making regulatory decisions, the decision-maker should be able to determine whether the benefits of a rule including non-quantifiable factors justify the costs.

• Protecting people's health and safety and the environment should always be the primary goal of risk management regulation but economic analysis should always be a factor in deciding when and how to take regulatory action. The role of economic analysis in regulatory decisions should be clearly set out by the law.

• The report does not take a strong enough position on the appropriate role that cost-benefit analysis can play in regulatory decision-making, and does not confront existing statutory barriers to the use of economic analysis in policy-making. The final report should call for expansion of the use of cost-benefit analysis in risk management decision-making.

• The report inappropriately lumps benefit-cost analysis and cost-effectiveness analysis under the single heading of "economic analysis" and often refers to them jointly. In fact, these two policy-making tools are very different and the report should clearly distinguish between them. The final report should make clear the primary role benefit-cost analysis can play in formulating policies that maximize net benefits to society, unlike cost-effectiveness analysis.

• We recognize the necessity to convert all of our risk concerns into dollars if they are to play any real role in cost-benefit analysis. We also recognize, however, that risks and lives are not linear functions. There are miminum units of aggregation that must be evaluated (entire habitats, for instance, rather than cubic meters of soil). The inevitable consequence of setting a monetary value on a human life is the reductionist conclusion that a value per minute of life lost is a valid application.

■ Distributions of Costs and Benefits

• Weighting benefits and costs quantitatively based on equity would be highly subjective and inappropriate. The better approach is to inform the decision-maker about who receives benefits and who pays the costs in a more appropriate way, to be used explicitly in making the regulatory decision.

Uncertainty and Inconsistency in Economic Analysis

■ Characterizing the Uncertainty Associated with Cost and Benefit Estimates

• We agree that the preference for transparency in risk assessments applies to economic analyses as well as risk assessment and that there is a need to develop consistent methods for conducting such analyses for use in regulatory decisions. The value of risks should be stated explicitly and valued using best estimates or ranges of estimates and using consistent procedures and basic assumptions.

■ Inconsistencies in Monetary Valuation of Benefits

• We agree in part with the recommendation to state explicitly the value of mortality risks but we would also recommend more emphasis on the use of illness risks and ecological risks. The costs of medical care and workdays lost to illness are probably large by comparison to mortality costs, and these are worth considering despite some added controversy. We hope to see a caution in the final report against too-rigid protocols, which reduce economists' flexibility to choose the data and analytical approach that best fit the problem.

■ Linking Risk Assessment and Economic Analysis

• Willingness to pay should be applied to the precautionary principle, so that regulation for protectiveness reasons (beyond a statistical NOEL level) should include a monetary penalty for data gaps when used in CBA.

• The problem with the cost-per-life-saved approach is that protecting small groups of people would be cost-ineffective. The population risk might be a more relevant measure in some situations. Other measures might be total environmental contaminant burden, total mutation burden on a small tribal gene pool, etc.

• There is a need to more closely coordinate the analyses of the risk assessors and the economists. There is a need to find ways to present risk information and to craft economic analyses to use that information in a way that will best en-

able a risk manager to determine which risk management alternative is the most cost-effective or provides the best balance of benefits and costs.

6. The Role of Peer Review in Regulatory Decision-Making

This section was changed to three findings and recommendations instead of one, targeting and clarifying the specific issues raised by commenters.

Improving the Quality of Regulatory Decisions

• We have serious concerns regarding the recommendation on the effect of potential conflicts of interest on the eligibility of potential peer reviewers. The recommendation to exclude potential peer reviewers with financial conflicts of interest is wrong. Full disclosure of all financial or organizational interests best serves as a criterion for selection of peer reviewers. Peer reviewers are not judges or juries, they are expert witnesses.

• We disagree with the recommendation that calls for the disqualification of any potential peer reviewer with "clear conflicts of financial interest." It is important to recognize that federal agencies use scientists with expertise in specific technical disciplines who are employed by industry, consulting firms, advocacy groups, and academia. All of these affiliations could be construed to constitute a potential conflict of financial interest.

• We strongly endorse the report's recommendation to expand the use of peer review to economic analyses, social science information, and the use of scientific and economic data in decision-making.

This section was changed to clarify which kinds of financial conflicts we believe should disqualify peer reviewers and which kinds do not.

The Conduct and Effectiveness of Peer Review

This section was not substantially changed.

Evaluating the Use of Peer Review and of Scientific and Economic Analysis in Regulatory Decision-Making

This section was changed to clarify that we think advisory groups should review the use of peer review information in regulatory decisions, not review the decisions themselves.

7. Recommendations for Specific Regulatory Agencies and Programs

Environmental Protection Agency

■ Office of Air and Radiation

• We agree with the Commission's support of the use of screening assessments to determine which facilities within source categories or subcategories need to take additional risk assessment or risk management steps. We believe MACT standards will greatly reduce emissions of hazardous air pollutants, and that further reductions should be based on site-specific considerations of remaining risk. We agree with the proposal of a tiered scheme to determine and manage residual risk after implementation of MACT.

• The report should acknowledge that although many questions still remain about indoor air quality, that significant progress has been made. Because consumer products used in the home may release chemical and biological pollutants, and the design of the home itself may contribute to indoor air quality problems, CPSC has taken an active role in protecting consumers from illnesses and deaths associated with poor indoor air quality.

The tiered scheme for assessing residual risks proposed by the Commission was revised, clarified, and streamlined. A section addressing critical data gaps and needs was added. The recommendation regarding risks from indoor air was expanded to include other regulatory agencies besides EPA and to acknowledge the work that CPSC has done in this area.

■ Superfund

• It is inaccurate to say that it has been difficult to revise remedies. Revisiting remedies has always been possible, and is in fact being encouraged at sites with ground-water contamination where new science or remediation technologies hold promise for cost savings.

• Preparing an overall annual budget estimate, presumably including actions at sites by other federal agencies, would obscure the Commission's emphasis on risk-based planning and actions in a fog of numbers of widely differing scales. EPA is committed to risk-based priority-setting, planning, and budgeting. At the same time, our experience to date in the risk-based allocation of cleanup funds, which the Commission commends, has demonstrated that there is great difficulty using one risk algorithm in considering emergency responses and long-term cleanup actions.

• We support Superfund's goal of protecting human health and the environment, and agree with the Commission that Superfund should be amended to require site-specific and risk-based remediation standards. The remedy process should

provide protection of human health and the environment through methods that are practical and achievable in a cost-effective fashion.

• We agree that the interpretation of ARARs has caused problems and led to needless cleanup. ARARs dramatically affect the final cost of remediation. They can result in remedy selection that is overly costly and technically infeasible. We believe that the "relevant and appropriate" language should be deleted from the law and that "applicable" requirements should be subject to a specific set of remedy-selection balancing criteria.

This section now acknowledges EPA's new policies on revising remedies. We clearly distinguish between emergency responses, applauding their goal of expeditiously removing obvious sources of exposure, and long-term cleanup. The costs and disputes about remedy selection apply almost entirely to the long-term cleanup. The recommendation about brownfields was caveated to note that purchasers of brownfields cannot add to or exacerbate contamination and that access must be provided to authorities to ensure that no migration or increase in contamination occurs. The recommendation regarding an overall annual budget for Superfund has been deleted.

■ Office of Prevention, Pesticides and Toxic Substances

• We do not support the Comission's recommendation that TSCA be reopened and updated. Although we agree that TSCA should be administered to reflect advances in toxicology over the last 20 years, legislative action is not necessary to effect these changes. The current statute provides sufficient flexibility to update the TSCA requirements. Sufficient flexibility exists under section 4 to update tests that are being mandated. EPA is already updating requirements for reporting under sections 8(a), (d), and (e), and the agency is considering several changes to the section 4 requirements.

This section now acknowledges the changes in the Delaney clause that were made with the Food Quality and Protection Act of 1996, noting their responsiveness to the recommendations in our Draft Report. Instead of asking Congress to update TSCA, the Commission recommends a focussed stakeholder process to review the Act and its implementation.

■ Office of Water

This section acknowledges the Safe Drinking Water Act amendments passed in 1996 after our Draft Report was released. As recommended in the Commission's testimony to the Senate, which was cited in the report accompanying the 1996 amendments, the act recognizes that cost and risk are not the only factors that need to be considered in evaluating environmental programs and that other factors, including values and equity, must also be considered.

Occupational Safety and Health Administration

• We support the recommendation that OSHA and NIOSH facilitate effective collaboration to help guide OSHA's regulatory needs and NIOSH's research efforts. A cooperative and integrated approach to the nation's occupational issues would result in more cost-effective actions.

• The allegation in the report that there is substantial underreporting of job-related injuries is unfounded. The Commission offers no evidence to support this statement.

• We support the Commission's recommendation that OSHA develop a guideline that lays out scientific and policy defaults. Currently, we are supporting a larger industry intitiative to develop a process to update the outdated permissible exposure limits. One part of the industry-identified process is the development of guidance to assist the agency in risk assessment and cost-benefit analysis.

• The report makes three valuable recommendations for improving the administration of the Occupational Safety and Health Act, calling for better surveillance and intervention-effectiveness research, better coordination between NIOSH and OSHA, and creation of health assessment guidelines. We support these recommendations.

• Recommendations for additional OSHA and NIOSH actions, such as increased surveillance, intervention effectivess research, evaluations, and guidelines for decision rules should be accompanied by recommendations to Congress for additional resources to carry these steps out.

• The report should be amended to clearly state that OSHA needs to reduce the permissible exposure limits to many common chemicals. Risks to workers from prevailing chemical exposure levels are thousands to a million times greater than those addressed by controversial actions in the environmental health arena. Efforts to update these limits have been stalled for decades, although public health actions addressing those few substances for which OSHA has set standards have been successful. The OSHA PEL update project of 1984 had considerable industry support for adopting tighter consensus exposure limits for several hundred common substances. Nevertheless, this modest improvement in protection was blocked by the courts because risk assessment and feasibility analysis were judged to be insufficiently elaborate.

This section was modified to include some minor additions and modifications to the text supplied by OSHA and NIOSH staff. The statement that job-related injuries are under-reported was made by OSHA staff, so we changed our statement to read that such injuries are "considered" to be under-reported. We acknowledge that additional OSHA and NIOSH actions such as increased surveillance will require additional resources. A new finding and

recommendation to design a streamlined PEL update process, involving stakeholders and possible Congressionial action, was added.

Food and Drug Administration

• Given the continuing vagaries and ambiguities of risk assessment, fully recognized in this draft report, including the rather systemic inability to address cumulative exposure to multiple carcinogens, there are no policy jusfications for interfering with the applications of the Delaney clause [besides those covered by the Food Quality and Protection Act of 1996].

• The Food Quality and Protection Act of 1996 leaves the text of the Delaney clause unchanged and thus leaves unaddressed the issues surrounding its application to substances that fall within the statutory definition of "food additive." My concern is that passage of legislation freeing EPA from the constraints of the Delaney clause will be cited by defenders of the clause as confirmation that action by Congress is necessary to permit FDA to take into account any of the scientific advances that are discussed in the toxicity assessment section of the Commission's draft report. This could leave FDA even more constrained than it has been in the past. The Commission's recommendation may be cited in support of this result. It will be more difficult to muster congressional support for any change now, precisely because the coverage of the Delaney clause has shrunk.

• By limiting the Delaney clause to additives "found" to "induce cancer," Congress clearly contemplated that the responsible agency would conduct a meaningful, rigorous evaluation of evidence concerning carcinogenicity. The statute does not prescribe how to conduct this evaluation and this comports with a clear Congressional expectation that the nature of the inquiry will evolve as scientific understanding of carcinogenesis advances. For this reason, although one may most certainly contest the scientific underpinnings of the Delaney clause and call for its modification, such criticism should not overlook the reality that decisions leading to the implementation of the clause were never meant to be simplistic, legalistic, or non-scientific. Rather, decisions were intended to be based on the most convincing scientific evidence and the very best exercise of scientific judgment. The Commission could enhance federal food safety decisionmaking by, in addition to endorsing reform or modification of the Delaney clause, underscore the value of and need for sound science in the implementation of the Clause in the absence of such reform.

• It would be a mistake to modify the Delaney clause to permit consideration of quantitative risk. This would make matters worse. The Delaney clause is not appropriate in light of today's knowledge and it should simply be repealed. In carcinogen risk assessment, as in risk assessments focused on noncancer endpoints, we should call for the best scientific judgment as to whether harm is likely to occur to people under realistic conditions of exposure.

The Delaney clause is quite complex. We strongly support the use of the best available science and believe that the Delaney clause illustrates what can happen when Congress legislates scientific judgments, however well intentioned, in a manner that cannot evolve with advances in scientific knowledge. We understand that "found" to "induce cancer" should be open to rigorous evaluation of scientific evidence concerning likely human carcinogenicity, but must point out that the courts have interpreted it otherwise. Minor additions and corrections were made to the text at the suggestion of FDA staff.

Department of Agriculture

• It appears that information about risk assessment and risk management in USDA came principally from ORACBA. Risk assessment activities are currently underway in many USDA agencies, including FSIS, the Animal and Plant Health Inspection Service, the Agricultural Research Service, and the Economic Research Service.

• Half of USDA's 100,000+ employees are engaged in service with the Forest Service, Natural Resources Conservation Service, or Farm Services Agency. That means that we have a very large share of the resource conservation activities in the federal government. Because of that, some mention must be included in the Commission's report.

This section was modified to include minor corrections and additional information submitted by USDA staff, including acknowledgment of risk assessment activities taking place in offices in addition to those at ORACBA. A recommendation was added to develop and implement methods for monitoring and evaluating benefits of USDA's conservation practices. We are gratified that the Administration has instituted substantial funding for improvements in testing for microbial contamination, as we urged in 1996.

Department of Energy

This section was modified to include information about DOE's work planning procedures for managing worker health and safety risks.

Department of Defense

The section was modified to include minor corrections and additions suggested by the Office of the Undersecretary of Defense.

Appendix A7
Abstracts of Reports Prepared at the Invitation of the Commission

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A Survey of Methods for Chemical Health Risk Assessment among Federal Regulatory Agencies

Lorenz R. Rhomberg, Ph.D.
Harvard Center for Risk Analysis
Harvard School of Public Health
Boston, MA

According to its charter, the Commission on Risk Assessment and Risk Management is charged with investigating "the policy implications and appropriate uses of risk assessment and risk management in regulatory programs under various Federal laws." The demands of the risk assessment process far outstrip the ability of scientific investigation to give firm answers. Environmental statutes, however, place responsibility on certain Federal agencies to set regulatory limits on human exposure to potential environmental toxins so as to ensure public safety. The practical need remains, then, to make characterizations of the risk consequences (including the uncertainty about those consequences) of various potential actions. Faced with this practical problem, regulatory agencies have arrived at practical methodology. This methodology includes 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.

On the broad scale, Federal risk assessment practices follow the structure and methodological recommendations of the 1983 National Academy of Sciences report *Risk Assessment in the Federal Government: Managing the Process*. In detail, however, current practices in these areas vary among Federal agencies and even among regulatory programs within the US Environmental Protection Agency)EPA), reflecting the lack of a single, agreed-upon scientific procedure for the assessment of health risks from chemical exposures. In part, the diversity of methods can be attributed to the different questions being asked of the risk assessment process in different regulatory contexts by different environmental 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 choices made for the sake of consistency within each organization (which, owing to independent histories, becomes inconsistent among organizations). The effect of this diversity is to make it difficult to compare risks, or the actions taken to mitigate those risks, from one regulatory program to another.

The present report comprises a survey of chemical health risk assessment methodology among the Federal agencies primarily charged with regulating the production, use, emissions, and disposal of potentially toxic chemicals. The primary focus is on differences in standard methodology for assessment of potential chemically induced chronic health effects, examined in the context of each group's legislative mandates. The groups included are the Food and Drug Administration (Center for Food Safety and Applied Nutrition), the Occupational Safety and Health Administration, the Consumer Product Safety Commission, and the Environmental Protection Agency, with special attention given to the various regulatory programs within the last agency. In conducting this survey, each regulatory program's enabling legislation—the statutes that mandate regulatory activity—was examined regarding legislative purposes, mandates, and the nature of the regulatory powers granted as they affect the conduct of risk assessment by particular groups. Special attention is focused on the laws' requirements about who in the exposed population is to be protected, how the distribution of exposures among people comes into play, and how sufficiently protective standards are defined. Each organization's principal documentation on risk assessment policy and methodological guidance was examined. Many of the specific procedures are not clearly codified, however; office-specific practices are to be found in the patterns of analyses used in particular cases as documented in specific rulemaking actions. To develop information on these practices, and to gain a perspective on the operation of each regulatory office and its activities, a series of interviews was conducted with 23 key officials, risk assessors, and scientists in each of the offices covered by this survey.

Many of the methods of quantitative risk assessment, in the face of usually incomplete case-specific data, make conservative assumptions, on the grounds that "worst-case" analyses will at least not underestimate the true human risks. An application of the worst-case principle that has received considerable attention is the emphasis on risks calculated for the "maximally exposed individual" or MEI.

The notion is that, in order for a regulatory action to protect the entirety of an exposed population, it must protect the person with the most exposure; hence, the most exposed person's potential risk serves as a benchmark for the adequacy of a proposed strategy to control, restrict, or ameliorate environmental concentrations of a chemical agent. The questions arise how often in current EPA practice and policies does the risk to the MEI actually form the basis of a regulatory decision and whether any such use follows from specific mandates in the regulatory statutes. Accordingly, particular attention is focused on the question of how various programs characterize exposure, on how individual risk versus population risk play in setting regulatory levels, and in particular on the role of estimates of the high end of individual exposure in this process.

The results of the survey are presented in discussions of each regulatory program's practices. Within the discussion of each program are sections on the program's enabling legislation and its risk mandates, notes on implementation of these mandates, and discussions of program-specific issues in hazard identification, dose-response analysis and characterization of quantitative potency, exposure assessment, and risk characterization and regulation. The main differences among agencies and EPA regulatory programs are summarized in tabular form.

To a large degree, the body of environmental laws that seek to establish practices that will ensure safety (or at least mitigate risk) of chemical exposures were established before risk assessment was a well recognized and codified discipline. Most of the methodology of risk assessment has been invented in reaction to the calls by these laws to define limits on exposure that will "protect the public health" or lead to "a reasonable certainty of no harm." That is, in passing the laws, Congress called on the regulatory agencies to develop means to assess risks so as to define exposure levels that would achieve the stated qualitative goals of health protection. The presumption in this approach (which is not always borne out) is that there will be relatively few such exposures in need of control and that controls that are clearly sufficient to achieve protection can be had at reasonable cost to those responsible and to society as a whole.

The present report has attempted to examine the major environmental laws for their mandates on risk and for their calls for risk assessment to address these mandates. Since the laws largely precede risk assessment methodology, there is little call for specific analytical actions on the part of regulatory agencies. Nonetheless, the need for risk assessment is implicit in every call to define levels of exposure in regard to the potential health effects they may cause.

The different risk mandates are all rather vaguely worded, and it is not possible to discern calls for different methods of risk estimation from a mandate to assure "reasonable certainty of no harm" and one to "protect the public health with an adequate margin of safety." The chief difference among mandates is whether they call for balancing costs and benefits or whether they account for feasibility of controls, issues that affect the uses to which assessed risks are to be put in regulation but that do not affect the conduct of risk estimation itself. Only in the Consumer Product Safety Act are the criteria for balancing risks and benefits, and the particular findings in this regard that must be made to justify regulation, explicitly spelled out.

The environmental laws do not allow the regulatory agencies any action to control risks—they specify the nature of the regulatory actions to be undertaken, whether these be the issuance of permits or registrations, the definition of acceptable ambient concentrations, the limitations of discharges, and so on. The nature of the regulatory actions required vary more among laws than do the risk mandates, and the regulatory powers under each law are tailored to the nature of the regulated enterprise or activity, hinging largely on practical questions regarding where regulatory control can be effectively administered to accomplish the ends and purposes intended.

From the point of view of risk assessment, this variation in regulatory powers tends to manifests itself in different exposure assessment methods. Consequently, there is more variation among regulatory agencies and programs in exposure assessment methods procedures than in assessment of toxic effects. In this report, an attempt has been made to relate the methods used in risk assessment (and in particular, exposure assessment) to the nature of the law's regulatory activities. Given these differences in the regulatory powers granted by the various laws, it is unreasonable to expect exposure and risk assessments to be equally realistic across regulatory groups. By their nature, laws acting through permits will define exposures above those usually seen in compliance since they regulate by specifying maxima; laws acting through ambient concentration standards that represent ambitions to control pollution will define exposures below those typically seen, since they regulate by specifying goals to be striven

for; and laws acting through specification of difficult to achieve technical controls will define exposures (or at least emissions) close to that actually achieved, since they act by imposing uniformity in control.

Some regulatory activity must be prospective, aiming at controlling potential risks from activities yet to occur, while others focus on mitigation of current risky activity. Some laws empower regulators to require data on toxicity and exposure from petitioners, while in other settings risk analysts must make do with whatever existing data can be identified. Some laws permit regulatory control of many aspects of potentially risky activity, while others must allow for considerable unregulated variation in the public's activities regarding frequency, manner, and magnitude of exposure to compounds as a consequence of variation in lifestyles and preferences.

When the express aim of a law is to *manage* risks to the population, the exposure assessment should attempt to characterize the full distribution of exposure levels in the population as accurately as possible, so that the distribution of risks can be examined (and changes or shifts in the burden of risk under different regulatory options noted). In this circumstance, it is important to attend not only the existence of high individual risks, but also to the total burden of risk on the population. Many current environmental laws, however, are written so as to require *protection* from risk. Permits are issued, standards are set, conditions of use are defined, or cleanups are mandated so as to set limits on exposure such that few if any of the population of concern will experience risk levels that are "unacceptable." In this setting, the focus is on setting regulations to protect those at the high end of the risk distribution. This focuses the attention of the assessment on defining the upper end of the range of exposure scenarios for which it is intended to furnish protection. Depending on the law, this may be the top end of the actual distribution of exposures near a source (as in the Clean Air Act §112), a person of somewhat above average consumption of a medium contaminated up to a limit deemed permissible (as in the Safe Drinking Water Act), or an especially frequent consumer of a foodstuff containing an additive (as in the Federal Food, Drug, and Cosmetic Act). The present survey found much emphasis on high-end exposures and hypothetical exposures that would be the maximum allowable under a proposed regulation, but the only instance where a true "maximally exposed individual" serves as the basis of regulatory decision is in the Clean Air Act's provisions for triggering further risk analysis owing to "residual risk" after technical engineering controls on emissions have already been applied.

Whether the protected exposure is actual or hypothetical (and whether a hypothetical exposure is high or low compared to the upper end of actual exposures) may have less to do with data availability or willingness to use different exposure estimation techniques than with the intent of the law. A key factor is which parts of the exposure equation are under regulatory control and which are not. For instance, in setting pesticide tolerances, the assumption is made that all foods on which the agent is permitted in fact bear it, and at the maximally permissible level, when conducting initial exposure assessments. This is done not simply to be "conservative," but because the law requires setting levels that will be safe for consumers of the foods, and this must include protection of someone who chooses to eat all the foods containing the agent, even though few people may actually do so. Moreover, since permitting residues up to the tolerance level implies that all such levels are acceptably safe, the tolerances have to be set such that they would be safe *if* they occur, irrespective of whether they in fact occur.

In other words, much of the attention to estimates of risk that are conservative in the face of uncertainty about potency and much of the focus on the upper end of exposures arise because these methods were invented to implement the calls from the statutes for defining regulatory actions that would ensure safety. As notions of effective risk management evolve, it is becoming clear that such methods are less well suited for estimating the actual burden of exposure and risk in populations. The discussions of each statute and regulatory program in this report attempts to examine how the methods that have evolved in each program reflect the tasks set for regulators, either explicitly or implicitly, by the various statutes as they set mandates about what is to be accomplished and by what regulatory actions.

The inconsistency of methods for dose-response assessment cannot be so easily explained in terms of response to different regulatory needs. The variety of methods seems to reflect the somewhat separate history of development of potency estimation in the different groups and the lack of a definitive scientific basis to guide these independent evolutions along exactly the same path. The variety of methods correctly reflects the uncertainty about the best or most appropriate procedures, but it results in the awkward result that different agencies can arrive at

different characterizations of an agent's carcinogenic potency from the same set of data, based only on differences in preferred methods and precedents from earlier analyses. It would seem that harmonization of these methods to the extent achievable would be beneficial. At the same time, harmonization achieved through rigidity in rules for choice of methods would falsely imply that the mandated set of approaches is more correct than others and would stultify application of case-by-case judgment.

As with exposure assessment, the focus of much potency analysis is on defining levels of exposure that can be more or less assured of posing "acceptable" risk. The methods that are used in the face of uncertainty can usually be understood in this light. As the questions being asked by the risk management process move beyond such issues of assurance of safety, existing methodology and practices established in response to current environmental statutes become less appropriate.

Fundamentally, risk assessment methods are practical inventions put in place to address the kinds of questions asked of regulatory analysis by the mandates of the environmental laws. These laws and their mandates can be changed, and the methods for assessing risks will have to change with them, to respond to new needs.

Health Risk Assessments Prepared per the Risk Assessment Reforms under Consideration in the U.S. Congress

Cambridge Environmental Inc.
58 Charles Street
Cambridge, MA 02141

1 Summary

The Commission on Risk Assessment and Risk Management retained Cambridge Environmental Inc. To conduct case studies of health risk assessment that conform with proposed regulatory reform legislation and to comment, as risk assessors, on the required methods. The principal relevant mandate in these legislative proposals is that the conservative point estimates of risk currently generated and relied upon be augmented with estimates that are in some sense "best"—that are central tendency estimates, generated by taking better account of the uncertainties and variabilities in the underlying data and assumptions.

To illustrate the techniques required to satisfy such a mandate, we studied four cases. The objective of the first case study was to estimate incremental lifetime risk of cancer to an individual in a population whose water supply had been contaminated with part-per-billion levels of 1,1-dichloroethylene (1,1-DCE). The second case study differed from the first only in that 1,1-DCE was allowed, consistent with its dose-response data, to have either an anticarcinogenic or a carcinogenic potency, rather than being constrained to have only a carcinogenic potency, as is the current regulatory norm. The third case study differed from the first only in that it considered exposure to similar levels of vinyl chloride, a potent and known human carcinogen, rather than exposure to the equivocally carcinogenic 1,1-DCE. The fourth case study estimated incremental lifetime risk of cancer associated with occupational exposures, rather than low-level environmental exposures, to 1,1-DCE.

For each case study, we first estimated the incremental lifetime risk of cancer to a "reasonably maximally exposed individual" using the methods currently recommended by U.S. EPA. We then prepared a distribution of risk estimates by choosing parameter values for each variable from the distribution defined for that variable and combining these choices in the risk equation. These latter tasks require (1) significant research in the scientific literature, and (2) a great deal of statistical and computational expertise. Using computer software we created, we repeated the risk calculation about 20,000 times, gathering up each estimate of incremental lifetime risk of cancer to define its distribution. From the distribution, we could estimate the mean, median, and 95th percentile (and other statistics) of the distribution for the incremental lifetime risk of cancer. Each of these might be considered a "best" estimate of risk.

The results of the four case studies are summarized in the following table (Table 1).

Several comparisons are noteworthy. In the first case study, EPA methods (specifically, those used for risk assessment of Superfund sites) yielded a point estimate of risk of 1.3×10^{-4}. Although such an upper-bound point estimate is typically assumed by many to be at about the 95th percentile of the risk estimate distribution, it corresponded here to the 99.8th percentile of such a distribu-

Table 1 - Statistics of the distributions of risk estimates from the case studies

Case	Median (50th percentile)	Mean	95th percentile	Current EPA-style Point-estimate(reasonably maximum exposure)
1,1-DCE, Standard	1.2×10^{-9}	1.6×10^{-6}	1.7×10^{-6}	1.3×10^{-4}
1,1-DCE, non-standard	-2.0×10^{-9}	-9.5×10^{-6}	1.7×10^{-6}	-
Vinyl chloride (standard)	1.4×10^{-6}	8.8×10^{-5}	2.0×10^{-4}	4.1×10^{-4}
1,1-DCE workers	1.4×10^{-8}	3.6×10^{-3}	8.4×10^{-3}	2.7×10^{-2}

tion. The probabilistic method employed here found that the 95th percentile of the distribution was about 80-fold lower—1.7×10^{-6}. These two different estimates—both upper bound—would likely indicate dramatically different intervention strategies. Risk as high as the former often require extensive remediation, whereas risks as low as the latter usually do not.

The second case study, in which exposures to 1,1-DCE were allowed to confer either beneficial or detrimental effects on cancer risk, yielded two central tendency estimates of risk that were negative—so suggested that low levels of 1,1-DCE might confer no excess risk of cancer, and might even confer a small benefit. Nonetheless, the 95th percentile of the distribution of risk estimates in the second case study was identical to that estimated in the first case study (1.7×10^{-6}). Thus, allowing the relevant portions of the bioassay data themselves to define the slope and bounds of the dose-response curve—as opposed to imposing standard, regulatory restrictions on that curve—yielded both dramatically different central tendency estimates and identical upper-bound estimates.

The third case study, in which exposures to vinyl chloride were substituted for dose-equivalent exposures to 1,1-dichloroethylene, yielded a point estimate of risk (4.1×10^{-4}) that was only three times larger than the point estimate generated in the first study for 1,1-DCE. Such a minor difference belies the substantial differences in the quality and quantity of data surrounding the carcinogenicity of these two chemicals. In contrast, the probabilistic methods yield a 95th percentile estimate for the risks from vinyl chloride that is some 120-times larger than the estimate from 1,1-DCE.

Finally, the fourth case study suggested that (1) occupational exposures to 1,1-DCE were, as expected, substantially riskier than low-level environmental exposures, and (2) that the point-estimate of risk is only some threefold larger than the 95th percentile estimate. Under certain circumstances, such as relatively high exposures, the deterministic and probabilistic methods may thus yield reasonably similar upper-bound estimates of risk.

Working through these case studies, we have reached certain conclusions about the proposed risk assessment reforms. Among these opinions are:

- Performing risk assessment holistically and probabilistically is not easy. Considerable research must be made into the ranges of plausible estimates for a vast number of inputs. Considerable quantitative expertise, including computer-programming skills, are required to design and Implement the method. The risk assessor must genuinely understand—as opposed to merely use—many sorts of models—and perhaps be able to create some anew. He or she must combine distributions in valid manners.
- Current point-estimates of risk may obscure underlying scientific complexities and other important information. Public health policy demands upper-bound estimates of risk; but if these are calculated too crudely, they prevent efficient, health-protective decision-making.
- Under various circumstances, probabilistic risk assessment may indeed be informative and worthwhile. Techniques used to generate risk estimates should scale with the situation to be assessed. Some situations can be shown to be harmless under almost any method of risk analysis; running full Monte Carlo analyses on these would be inefficient. Other situations are much harder to call, have high stakes, or otherwise demand more sophisticated analysis. For such situations, probabilistic methods, carefully and honestly implemented, may offer the best current hope.
- Health risk assessment is typically dominated by uncertainty, rather than by variability. Distributions of estimates of health risk are remarkably broad; and most of that breadth is due to our fundamental uncertainty about the health effects of low-level exposures to environmental chemicals, not to variations in people's exposures. The high ends of a risk distribution are driven primarily by "pessimistic" interpretations of, but consistent with, the dose-response data. These data typically derive from overexposed rodents whose responses may or may not predict human responses in the situation under analysis.

- Central tendency, mean or median estimates of risk are unlikely to provide a full, useful basis for public health decision-making. One really needs the full distribution. However, a properly derived 95th percentile estimate of risk, supplemented with mean and median estimates, may provide a set of three bottom lines that can indeed be a basis for sound public policy. There is no single estimator of risk appropriate to all situations, and the definition of the estimator matters greatly. Further, no matter what estimator of risk might be chosen, the estimate must be compared with some standard for decision-making, and that choice of standard is also crucial.
- An entirely scientific risk assessment is a mirage. There is no single right way to do it. Sound policy should indeed rest on sound science. But risk assessment is not and cannot be wholly scientific undertaking. Risk assessment often turns upon details that are inherently unknowable. In general, probabilistic and holistic risk assessments could lead to improved decision-making. Whether such assessments prove to be more defensible than the status quo is harder to say.

Cost-Benefit Analysis and Regulatory Reform

Resources for the Future
1616 P Street, NW
Washington, DC 20036

The ongoing efforts in the 104th Congress to legislate requirements for cost-benefit analysis (CBA) and the revised OMB Guidelines for the conduct of such assessments during a regulatory rule making process, highlights the need for a comprehensive examination of the role cost-benefit analysis can play in agency decision-making. This white paper summarizes the state of knowledge and offers suggestions for improvement in the conduct and use of cost-benefit analysis, especially in the context of environmental regulations. Its scope is not confined to assessments of cancer risks or other toxic substances concerns , but rather, addresses the entire range of environmental policy issues.

CBA is a technique intended to improve the quality of public policy decisions, using as a metric a monetary measure of the aggregate change in individual well-being resulting from a policy decision. Individual welfare is assumed to depend on the satisfaction of individual preferences, and monetary measures of welfare change are derived by observing how much individuals are willing to pay, i.e., willing to give up in terms of other consumption opportunities. This approach can be applied to nonmarket "public goods" like environmental quality or environmental risk reduction as well as to market goods and services, though the measurement of nonmarket values is more challenging. Cost-effectiveness analysis (CEA) is a subset of cost-benefit analysis in which a policy outcome (e.g., a specified reduction of ambient pollution concentration) is taken as given and the analysis seeks to identify the least-cost means for achieving the goal (taking into account any ancillary benefits of alternative actions as well).

To its adherents, the advantages of CBA (and CEA) include transparency and the resulting potential for engendering accountability; the provision of a framework for consistent data collection and identification of gaps and uncertainty in knowledge; and, with the use of a money metric, the ability to aggregate dissimilar effects, such as those on health, visibility, and crops, into one measure of net benefits. Criticisms of CBA hinge on questions about a) the assumption that individual well-being can be characterized in terms of preference satisfaction; b) the assumption that aggregate social well-being can be expressed as an aggregation (usually just a simple summation) of individual social welfare; c) the empirical problems encountered in quantifying economic value and aggregating measures of individual welfare.

We take a) as axiomatic, noting also that because CEA is a subset of CBA, philosophical objections to the use of a preference-based approach to individual welfare measurement apply equally to both. For b) we agree that CBA does not incorporate all factors that can and should influence judgments on the social worth of a policy, and that individual preference satisfaction is not the only factor. Nevertheless, we assert that CBA must be included as a key factor. Other arguments under c) are measurement problems how choices based on preferences permit one to infer economic values in practice.

The state of the science of measuring such economic values is exceedingly active. Estimates of the willingness to pay for reductions in mortality and morbidity risks, for avoiding environmental damages to recreation opportunities, and for avoiding visibility degradation, are the most active and successful areas of valuation. Issues of a higher order stalk the estimation of nonuse values, and a variety of mostly empirical concerns have left materials damages

poorly understood. Estimation of the costs of reducing environmental effects, while generally thought to be relatively straightforward, are found to be at least as challenging as estimating the benefits, although there are easy-to-estimate, but perhaps, poor proxies for the loss in social well-being such costs represent.

The white paper offers a number of suggestions to regulatory agencies in conducting CBA, drawing upon the "best practices" identified in the new OMB Guidelines. These include the use of clear and consistent baseline assumptions; the evaluation of an appropriately broad range of policy alternatives, including alternatives to new regulation; appropriate treatment of discounting future benefits and costs, and accounting for the cost of risk-bearing; the use of probabilistic analyses and other methods to explore the robustness of conclusions; the identification of nonmonetizable or nonquantifiable aspects of a policy, and the potential incidence of all effects; and, last but not least, the use of benefit and cost measures that are grounded in economic theory (i.e., measures of willingness to pay and opportunity cost).

The paper also argues that from an economic perspective, risk assessment is a subset of benefits analysis in that quantitative relationships between pollution exposure and some human or ecological response are needed to estimate the population response and thus the marginal change in welfare resulting from a policy. The culture of risk assessment is not generally oriented towards this role, implying that risk assessments do not always provide the necessary input to an economic benefits analysis. Suggested changes in risk assessment practices include: estimating population risks, not just individual risks; providing information on the entire distribution of risks, including central tendencies, rather than just upper-end risk measures based on conservative assumptions about the potential threat; providing as much information as is practicable about how risks vary with exposure, rather than just identifying "safe" or "acceptable" threshold levels of exposure; and considering substitution risks as of equal importance to direct risk reductions. Economists and risk assessors together must also address how to give appropriate attention to both lay perceptions and expert assessments of risks.

The improvements in the methodologies for estimating the costs and benefits of regulatory activities discussed above are necessary but not sufficient for significantly improving regulatory decisions. Several more overarching issues involving the role of cost-benefit analysis in public decisionmaking must also be debated and resolved. These include:

Decision Rules and Cost-Benefit Analysis: While decisions should not be based solely on a simple cost-benefit test, a cost-benefit assessment should be one of the important factors in the decision. This approach is entirely consistent with Executive Order 12866. A rule with negative measured net benefits could still be promulgated under this approach if it could be shown that other factors (such as an improvement in the equity of the income distribution or an enhancement of environmental justice) justified the action. A discussion providing the justification would help ensure accountability.

Quantifiable Benefits and Costs: CBA needs to have standing as a part of all major regulatory ***and legislative*** decisions. In particular, CBA must have standing to implement the decision approach outlined above. Administrative reforms could accomplish much, but legislative changes will be needed to implement this suggestion where the use of CBA currently is precluded.

Nonquantifiables and CBA: We recommend a value of information approach. This involves estimating the net benefits for the quantifiable elements and asking how large the nonquantifiable elements would have to be to reverse the conclusion of the analysis or, as a broader measure, the regulatory decision. This provides information about nonquantifiables (beyond their enumeration and description) in a useful format for the decisionmaker.

Goals and Standards Marrying Efficiency and Equity: CBA can be given appropriate standing and introduced systematically into goal setting without compromising other social concerns by first developing regulatory goals or aspirations, ideally expressed as ranges of acceptable risk, based on health or other criteria that reflect equity or fairness concerns. Then CBA, defined broadly, would be used to justify where the standard would be set within this range or, to the extent that the range expressed aspirations versus more concrete requirements, how far toward the stated goal the regulation should go. An example of this approach can be seen in the Senate reauthorization of the Safe Drinking Water Act.

Insuring Credibility of Analysis: Agencies need to be clear about their justification for proceeding with a regulatory action, especially when the regulation fails an implicit or explicit cost-benefit test. They should have the scientific and economic assessments underlying major rules peer-reviewed, and both the analysis and peer review should be done early enough to influence the out-

come, not as a rubber stamp to decisions made on other grounds. Peer review can be inside the agency (although EPA has recently dismantled this function), part of an interagency process, part of an expanded role for OMB, or even be privatized. The combination of expanded peer review and timely completion of analysis would also greatly support and enhance the performance and perceived credibility of the existing Executive Branch regulatory review process managed by OMB.

An Assessment of the Risk Assessment Paradigm for Ecological Risk Assessment

Menzie-Cura & Associates Inc.
1 Courthouse Lane #2
Chelmsford, MA 01824

Summary

This document reviews the strengths and limitations of the paradigm for ecological risk assessment and its implementation. The review is derived from discussions with government and professional organizations, recent literature, and attendance at various relevant symposia, workshops, and other meetings. The prevailing paradigm for ecological risk assessment is reflected in the U.S. Environmental Protection Agency's (1992) *Framework for Ecological Risk Assessment*. The National Research Council (1993) published a similar paradigm.

The USEPA (1992) paradigm for ecological risk assessment expands upon the NRC's (1993) four-step paradigm presented in *Risk Assessment in the Federal Government: Managing the Process*. One of the earliest adaptations of the 1983 paradigm for use in ecological risk assessment is presented in Barnthouse and Suter (1986) and their work provided a starting point for the development of the *Framework*. Consisting of Problem Formulation, Analysis, and Risk Characterization components, the *Framework* illustrates the importance of communication between risk assessors and risk managers and the role of monitoring and other data collection efforts.

Strengths

Perhaps the *Framework's* greatest strength is that it is sufficiently flexible to apply to a broad range of environmental problems. In particular, the *Framework* attempts to broaden the conceptual approach beyond a perceived narrow view of risk assessment as the evaluation of a chemical's effect on a few species. The *Framework* has gained wide acceptance as the basis for developing ecological risk assessment methods and organizing risk assessments within many federal and state agencies. Most people surveyed by us found that the *Framework* provided an acceptable conceptual structure for developing more detailed guidance or for organizing ecological risk assessments.

An important characteristic and potential strength of the *Framework* is its introduction of the term "Problem Formulation" in place of "Hazard Identification" to characterize the nature of initial activities that should occur as part of the risk assessment process. Problem Formulation is the most critical step in ecological risk assessment because it provides direction for the analysis and should take into account the ecological, societal, and political issues related to the questions being addressed. Ecological problems can range from simpler analyses involving a single chemical and a limited number of species to more complex issues such as watershed-level assessments of multiple physical, chemical, or biological stressors. Ecological stressors may include an overabundance of essential nutrients (e.g., nitrogen loading), chemical contaminants, physical alterations (e.g., temperature, water levels, soil type), radionuclides, habitat loss or modification, oxygen consuming substances, introduced species, and genetically-engineered organisms. Ecological receptors affected by one or more of these stressors could include individual organisms, species, communities, habitats, and ecosystems. The diversity of potential stressors and receptors indicates the care that must be taken at the problem formulation stage and its importance for structuring the assessment.

The problem formulation stage is also important because it attempts to integrate the perspectives of stakeholders, risk managers, and risk accessors. People do not have a common value system or knowledge base with respect to ecological or environmental issues. Communication among stakeholders, risk managers, and risk assessors at the problem formulation state—as well as during the assessment—is, therefore, important for formulating the questions, identifying differences in perspective, and resolving issues.

The development of the *Framework* and the discussions related to its implementation have fostered the use of a common language for discussing the ecological risk assessment process. In addition, the *Framework* has helped

define what is meant by an ecological risk assessment. This has been especially useful inasmuch as a diversity of terms and approaches have arisen to serve various environmental programs.

Limitations

The major limitations related to the paradigm regard knowing how and when to use it. The USEPA, other federal agencies, states, industry, and professional organizations are currently grappling with the development of guidance or approaches for conducting assessments. Much of the discussion in forums related to guidance development centers on fundamental components of the analyses, indicating that we are still at a basic level in understanding how to conduct ecological risk assessment. Further, while there is a growing recognition that the ecological risk assessment process should include ongoing communication among ecological risk assessment process should include ongoing communication among stakeholders, risk managers, and risk assessors, there is little guidance on how this should occur. The importance of communication with stakeholders is not identified within the prevailing *Framework* paradigm.

Risk assessments are tools and as such are better suited for some environmental problems than others. In most cases, risk assessments are used to help answer questions related to decisions. The choice to use risk assessment to answer the questions or help with the decisions will depend on the ecological issues and on other factors that may affect the decision. In this same vein, the complexity of the risk assessment should be appropriate to the question or decision and the level of uncertainty that can be accepted. To this end, a number of groups have identified the need for tiered or phased approaches for conducting assessments leading from simpler to more complex analysis. Finally, there may be cases where risk assessment *or any other technical assessment* can not meet expectations within an acceptable level of uncertainty due to limits in our understanding of environmental processes and predictive abilities. In such cases, risk assessment may still have value in identifying the extent of uncertainty and gaps in knowledge. However, it would be inappropriate to think that risk assessment has provided a clear "answer."

Recommendations

This review makes the following recommendations:

1. The USEPA's *Framework* should be accepted as the paradigm for most ecological risk assessments. However, the *Framework* could be augmented to: a) reflect the importance of communication among stakeholders, risk managers, and risk assessors throughout the process, and b) identify the iterative nature of risk assessments. The report presents a modified framework to address these issues.

2. Guidance should be developed for implementing components of the *Framework* through a series of case studies. This should be undertaken as a collaborative effort involving stakeholders, risk managers, and risk assessors. Guidance is especially needed in the following areas:

Problem Formulation: This critical step establishes the direction and scope of the ecological risk assessment. The process by which this is done involves identifying the actual environmental value(s) to be protected (Assessment Endpoints) and selecting ways in which these can be measured and evaluated (Measurement Endpoints). The selection and articulation of Assessment Endpoints is the key starting place for the assessment. However, there is very little guidance on how this process should occur and who should be involved. Because of the fundamental importance of this step to the overall assessment, this process should be given the highest priority for guidance development. The selection and articulation of assessment endpoints is a focus of communications between stakeholders, managers, and assessors, and, therefore, guidance should be developed through a process that involves representatives from all of these groups.

Weight-of-Evidence Approach: Many ecological risk assessments involve the conduct of a "weight-of-evidence approach." However, there is no consensus on the definition of weight-of-evidence" or how such an approach should be applied. Often the approach reflects an individual's professional judgment and the conclusions reached may not be transparent to others. A definition should be established for use in ecological risk assessment. Further, an effort should be undertaken to examine the professional judgments that underpin weight-of-evidence approaches and how they can be made more explicit. Finally, guidance for conducting quantitative and qualitative weight-of-evidence approaches should be developed. The 1995 report prepared by the Massachusetts Weight-of-Evidence Workgroup (contact Nancy Bettinger at Massachusetts Department of Environmental Protection) is an effort to address this need.

Tiered or Phased Approaches: There is general agreement that risk assessments are best conducted using tiered or phased approaches. There is a need to establish how these should be structured and linked to management decisions. Because tiered assessments are imbedded within

management strategies, guidance development should include both risk assessors and risk managers. Related to the implementation of a tiered strategy is addressing the uncertainties inherent in the various levels of analyses. There are many sources of uncertainty in ecological risk assessment. These should be presented and discussed as part of the assessment. Methods for quantifying these uncertainties should be identified and evaluated. The uncertainty in the analysis should be addressed in a manner appropriate for the parties involved in the decision. For example, one goal of uncertainty analysis could be to insure that the decision is "protective" within a reasonable level of uncertainty.

Risk Characterization: Many of the groups surveyed by us identified this component as an area where guidance was needed. Available methods are considered to be limited and often overly simplistic. In some cases, risk characterization is interpreted simply as a restatement of test results. Risk characterization can be viewed as the final state of a weight-of-evidence approach that relates the analysis results to the Assessment endpoints. In screening level assessments, simple methods might be employed if these are adequate to answer questions with an acceptable level of protection. In more complex situations, it may be necessary to employ more sophisticated risk characterization tools. Guidance is needed both on when to use tools of varying complexity as well as which tools are most appropriate for a given problem. Ultimately the risk characterization should synthesize and provide information that can be understood and applied to risk management decisions. Identifying and characterizing the uncertainties in the analyses are important aspects of characterizing risks. These are often overlooked or excluded. Guidance is needed on how best to characterize and discuss uncertainty as part of risk characterization.

Communication: Ecological issues can pose communication difficulties among stakeholders, risk managers, and risk assessors. These individuals do not share common language systems and may not share common value systems. These differences are often not recognized and this can lead to problems throughout the assessment process. A better understanding of these differences is needed in order to learn how the groups can communicate more effectively. Discussions concerning the development of assessment endpoints is a useful place for exploring the nature of these differences and identifying methods for bridging gaps in understanding among the groups. This could be accomplished by working through a number of case studies.

3. Stakeholders should have greater involvement in the ecological risk assessment process. However, guidance is needed on how and when to involve stakeholders. For example, 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. Stakeholder involvement should be considered when generic guidance and guidelines are being developed for broad application. Stakeholder involvement should also be considered for larger local or regional assessments where the interests of stakeholders could be affected by the decision(s). The need for stakeholder involvement at early stages within an ecological risk assessment is more important for human health risk assessment because of greater diversity of values the public places on natural resources. Ultimately, it is the risk manager's responsibility to determine how to consider and incorporate the interests of stakeholders. This too is an area where guidance is needed.

4. Scientists, policy makers, and the public should be educated on the ecological risk assessment process, its strengths and limitations, and how and when it can be used as a tool to help answer questions or make decisions.

Review of Noncancer Risk Assessment: Applications of Benchmark Dose Methodologies

Elaine M. Faustman, Ph.D, DABT
School of Public Health and Community Medicine
University of Washington
Seattle, WA 98105

The overall goal of this project is to evaluate risk-assessment methods traditionally used for noncancer health risks and to compare these methods with newly developed approaches. The report gives a brief economic rationale for preventing noncancer health effects, using figures for years of potential life lost, which reveal that noncancer health effects, such as birth defects, are of the same national economic magnitude as cancer and heart

disease. Traditional methods for assessing noncancer risks include identification of no-observed-adverse-effect levels (NOAELs). Reference doses (RfDs) and acceptable daily intakes (ADIs) are derived by dividing NOAELs by uncertainty or modifying factors. Those factors represent a default approach to account for animal-to-human and average-to-sensitive population extrapolation or extrapolation from inadequately designed experiments. If all doses tested produce a response a lowest-observed-adverse-effect level (LOAEL) is used and a safety factor of 10 is applied. Those traditional approaches are compared with benchmark-dose methods in which a curve-fitting procedure is used to find a dose that produces a specific effect. Confidence limits are generated around that dose, which is set at the lower confidence limit to produce a specified percentage change in response. The benchmark dose (BMD) is used to calculate a reference dose.

The method is used for noncancer end points. Although the majority of applications of the BMD approach are related to developmental toxicity, it has also been applied to reproductive toxicity, neurotoxicity, and cancer. The method has been most thoroughly evaluated with reference to developmental toxicity in a series of 4 papers and technical documents by Faustman, Allen, Kavlock, and Kimmel that analyzed over 1825 experimental end points. The BMD method offers an alternative to traditional NOAEL approaches and is in general no more conservative than the use of NOAELs and includes a confidence-limit calculation. A log-logistic model for developmental toxicity has several advantages, and BMD values based on a safety factor of 5 with this model are similar to both continuous and quantal NOAEL values (without confidence limits). Traditional safety-factor approaches used for RfD calculation based on LOAEL values are over-conservative; a factor of 5 is more appropriate than a factor of 10. NOAEL values are not "riskfree" but represent effect levels ranging from below 5% up to 20% effect. That illustrates an important advantage of BMD approaches: a regulatory limit can be consistently set at a given response level rather than being dictated by study design. The BMD method rewards adequately designed experiments by setting higher BMDs, which is in direct contrast to the NOAEL approach. With curve-fitting procedures, the calculation of RfDs is no longer constrained to be one of the experimental doses tested. BMD methods will allow for easy transition to truly biologically based dose-response models when such models are developed.

Comparative Risk Analysis for Priority Setting

David B. McCallum and Susan Santos
Focus Group Inc.
Tilghman, MD 21671

Risk-based priority-setting has been accepted by many as the preferred strategy for deciding how to deal with resource-allocation issues. Supreme Court Justice Stephen Breyer, in a book before his appointment, analyzed the cost per death averted for various regulations and concluded that "the entire nation could buy more protection by refocussing regulatory efforts." The Carnegie Commission on Science, Technology, and Government encouraged greater use of comparative risk assessment (CRA). The National Academy of Public Administration, in reviewing Environmental Protection Agency (EPA) practices, suggested that risk-based priority-setting should be increased. Congress has mandated that comparative risk be used in determining which problems to address first.

CRA has evolved, and so has its definition. EPA defines it in a Guidebook to Comparing Risk and Setting Environmental Priorities (September 1993) as both an analytical process and a set of methods used to systematically measure, compare, and rank environmental problems. It provides a common basis for evaluating net benefits and costs of different strategies for reducing or preventing ... risks.... Rankings can provide an important input to the priority-setting and budget processes when possible risk reduction and prevention strategies are considered in the context of other relevant non-risk concerns, such as economic viability, technological feasibility, and social equity.

CRA projects at the state level have involved hundreds of people from the public and private sectors. Typically, CRA projects at the state level have been carried out by several committees working in concert. These usually include a management committee (often from state or local government), a technical work group (scientists and researchers from the academic and activist communities and potentially industry), and a public advisory committee (representing interest groups). CRA is based on the analytic principles and approaches of rational public-policy analysis dating from the early 1970s. However, CRA has not been neatly, firmly, and finally established. The strength of the comparative-risk process is its ability to "frame" public-policy questions consistently and to

engage people productively in addressing them. Its weakness is that the answers can be uncertain, unwelcome, or both. The ultimate goal for government officials, the CRA community, and the public, in using CRA as a tool for environmental planning and protection, is to synthesize the power of the scientific method with the insight of democratic participation.

There is still a high level of experimentation with the process. Indeed, too much standardization at this point could lead to the application of poorer methods. Also, CRA and goal-setting have not been institutionalized in federal or state agencies.

Recommendations

The following actions are recommended:

- Implement CRA for priority-setting in stages so that it does not overwhelm the human and technical resources.
- Keep CRA process flexible so that innovations can occur and priorities are not distorted by flawed rankings.
- Encourage innovation in CRA at the federal, state, and local levels and allocate resources for evaluation of process and outcome.
- Provide resources to train competent professionals to perform CRA.

Legislative

The role of comparative and traditional risk assessment, cost-benefit analysis, and risk communication in shaping priorities has been the focus of congressional debate. These tools can provide insight into the effectiveness of regulatory and nonregulatory approaches to health and environmental protection, but they do not yield prescriptive guidance for decision-makers and can be resource-intensive and contentious among stakeholders. Resources must be provided to train professionals in these activities and to allow government, scientific, and public organizations to adequately carry out the analytic and stakeholder participation processes.

Legislation should set high thresholds for requiring complex analyses; doing a good job on a few assessments is important as the agencies build capacity to do more. It should also recognize the role of expert opinion and should give the risk manager discretion. The comparisons and tradeoffs are complex, and the uncertainty is often high. Allowing discretion and providing active oversight can be more effective than prescriptive guidance.

Federal Executive Branch

The Office of Science and Technology Policy and the Office of Management and Budget can identify opportunities for collaboration among agencies and encourage the development and transfer of expertise across the executive agencies. The main thrust must be at the agency level, where cross-program activities and multiagency involvement need to be encouraged. Problem-oriented temporary task groups from various agencies should be formed to coordinate on specific issues. The EPA-FDA task group on the effects of pesticide residues on children is a good example.

The interagency Task Force on Environmental Heart and Lung Disease and Cancer had a productive working group on risk communication that developed many effective workshops and publications. It provided a mechanism for interagency funding of projects of common interest and could be a model for interaction on risk-assessment issues.

Support of Future State and Local Efforts

Flexibility is crucial. EPA has adopted more flexibility in negotiating specific objectives with each state. Block grants have been proposed for other federal-state activities and are not new (health programs were funded through block grants in the 1970s). Block grants provide flexible funding and cut administrative costs. However, there is a need to guard against consumption of money by routine activities at the expense of innovation.

In South Carolina in the 1970s the development of preventive public-health programs for chronic diseases would not have been possible without special funding outside the block-grant program. Special funding was provided through grants and cooperative agreements with NIH and CDC. With the special funding came a great deal of interaction with other states and experts from the science community. The CDC programs actually assigned a public-health advisor to the state. Technical support was also provided by such programs as the National High Blood Pressure Education program.

Those research and demonstration funds provided funding to define the problems and evaluate the effectiveness of intervention strategies. The efforts encouraged state funding for services and provided an effective means for building capacity at the state level.

Communicating to the Public: Using Risk Comparisons

David B. McCallum and Susan Santos
Focus Group Inc.
Tilghman, MD 21671

Ever since risk assessment has been used in the federal government to support decision-making, there has been a recognition that government agencies had no choice but to communicate with stakeholders, including the public. In 1987, William Ruckelshaus, former EPA Administrator, noted that the question is not whether to involve the public in decisions about risk, but how. In 1989, the National Research Council produced a report on risk communication and offered the following definition:

Risk communication is 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 reactions to risk messages or to legal and institutional arrangements for risk management.

The risk communication process must address the following questions: Who will make the decision? How will technical estimates of risk and other factors be evaluated? How, when, and where will stakeholders' concerns be managed? What information do the stakeholders want or need?

Several characteristics of risk comparison and communication should be considered when evaluating the effectiveness of approaches for the study and practice of risk communication. Risk comparison can be a simple one-dimensional comparison or a more complex multidimensional comparison. At the simple end, similar risks and only a few aspects of each are compared. At the complex end, multiple risks are compared across a variety of dimensions. The simpler the comparison, the easier it is to communicate and produce a more predictable response. However, a simple comparison might not represent the situation accurately. If the risk comparison is more complex, it can yield richer perspective for the decision-maker and public, but might also be an attempt to relate risks that are so dissimilar that, to some target audiences, comparison does not seem relevant.

Several approaches, both theoretical and empirical, have been used to understand how target audiences respond to risk messages and to improve the quality of communication. Psychometric models have examined the effect of qualitative risk characteristics, such as whether a risk is new or familiar, in explaining how groups respond to risk messages. Other models are more econometric; they are based on contingent evaluation of perceived threats and perceived benefits. The latter seems more explanatory, but the amount of comparative research is very limited.

The mental-models approach seeks to understand how people use information to make decisions by using a structured-interview technique to identify knowledge, beliefs, missing information, and misconceptions. Providing information in a manner that conforms to the audience's "mental model" improves comprehension. Providing missing information and correcting misconceptions make decisions more consistent between lay and expert groups.

Because our theoretical understanding of risk communication is not full, a practical empirical approach is most effective. Focus-group and survey research suggests that a variety of qualitative characteristics of risk can influence the response to risk comparisons and that risk comparisons can exacerbate or trivialize concerns. Therefore, formative research, including message testing, should be a part of any risk-communication activity.

The research on risk communication provides insights into the utility of risk comparisons. They can be useful but only when they are a part of an overall communication strategy. This strategy requires that the communicator: understand the nature of the risk—both the hazard that it presents and the qualitative attributes that influence perception by the target audience; understand the audiences that are being addressed and their relationship to the hazard; understand how the risk comparison interacts with other components of the message; and have a way to evaluate the audiences' response.

Experience from risk communication suggests that risk comparisons should be made in ways that provide cues to action and that respect the values of the participants in the process. Failure to consider social and political issues and values will diminish the quality of the discussion. That does not mean that the scientific components should be de-emphasized in deference to values, but the technical components and their implications for risk management must be effectively and persuasively conveyed to all stakeholders, including the public.

Most research has been descriptive rather than experimental. It has been focused on specific risks, such as ra-

don and toxic substances, rather than taking a more comprehensive view of environmental risks. The kind of community-based research in the 1960s and 1970s that has underpinned the prevention movement in health care has not been done for the environment. Some of our pressing environmental problems are more amenable to a broad public-health approach than to the traditional command-and-control regulatory approach.

The complex nature of risk communication calls into question the value of requiring simple comparisons of risk end points with either common risks of daily life or other chemical or physical risks. Without a context, this information might yield wrong or confusing messages for the public. For most listeners, it evades the primary questions, "Will it hurt me?" Therefore, risk-communication efforts should provide both comparisons and context, which can depend on factors beyond risk numbers.

Recommendations for Practice

Include communication as a specific component of all risk-management plans and budgets (10% of available resources is a good rule of thumb).

• Hold risk-program managers accountable for meeting communication objectives.

• Use appropriate formative research to underpin communication efforts.

• Communicate uncertainty with care. Because stakeholders, including the public, might react to uncertainty in unpredictable ways, ensure that a good mechanism to evaluate what has been communicated is in place.

• Use effective communication strategies to build and extend the consensus among stakeholders, including the public. Clear consensus-building (e.g., with comparative risk assessments) can provide support for using more persuasive communication techniques.

Recommendations for Research

• Conduct experimental studies on the influence of risk comparisons on attitudes and behavior of stakeholders, including the public.

• Fund innovative demonstration efforts at the national, state, and local levels.

• Conduct research on the effectiveness of various techniques for presenting uncertainties in environmental risk assessment.

• Conduct research on strategies that make regulatory standards flexible.