Commission on Risk Assessment and Risk Management

Risk Assessment and Risk Management in Regulatory Decision-Making

DRAFT REPORT
FOR
PUBLIC REVIEW AND COMMENT

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COMMISSION ON RISK ASSESSMENT AND RISK MANAGEMENT

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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, 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 efficient, more effective, 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. With this draft report, we introduce a framework for making risk-management decisions; we evaluate and 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. The Commission continues to seek comments as we refine our recommendations for the final report to Congress and the president of the United States.

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):

- 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 Commission's Risk Management Framework

The framework explicitly embraces collaborative involvement of stakeholders; the process can be refined and its conclusions can be changed as important new information is acquired.

The framework requires first 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. For example, the risks associated with the hazardous air pollutants regulated at one industrial facility or category of facilities can be considered in context with the risks associated with other stationary and mobile sources that emit the same pollutants. The next layer of context would be provided by comparisons with risks associated with other important air pollutants, such as particles and carbon monoxide, emitted by the same sources. A multimedia context would lead to a comprehensive plan that includes risks associated with air, water, and solid waste in a particular geographic area.

The framework actively engages stakeholders, especially at the initial stage of formulating the problem; we want to go beyond worker and community right-to-know requirements and make stakeholders partners in risk assessment and risk management. In later stages of the framework, risk managers and stakeholders investigate the risks, including cumulative risks to human and environmental health; risk-reduction options are identified, and potential consequences evaluated, including the benefits, costs, and social, cultural, ethical, political, and legal dimensions of each option; and the responsible agency then makes a decision that reflects input from stakeholders, implements a risk-reduction action, and seeks credible evaluation of the outcome. As new information or new technology becomes available, the problem can be redefined, and the risk-management process repeated, if appropriate.

This 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 passed 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. The framework is also applicable to risk-management activities carried out by public and private entities at the state, regional, and local levels. 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.

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 might not be immediately helpful to risk managers. 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 understanding of what is needed to protect public health and the environment.

Use of Good Science 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, and we recommend the evaluation of a common metric to assist comparative risk assessment, risk communication, and risk characterization related to both carcinogens and noncarcinogens.

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 tied to 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 an 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.

Risk Management and Regulatory Decision-Making

Risk assessment and economic analysis provide only part of the information that risk managers use—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, and the use of risk assessment has differed in decision-making and regulatory programs.

Improvement of Risk Communication: In communicating to various audiences about risks, risk assessors 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 overprecise single estimates of risk is unwarranted.

We support the use of comparisons of specific risks related to a proposed action with emphasis on chemically related agents, different agents to which humans might be exposed in similar ways, different sources of exposure to the same agents, 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.

Bright Lines: Bright lines are specific exposure concentrations or levels of risk 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 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 do not support efforts by Congress to legislate particular bright lines.

Peer Review: We support efficient use of peer review, with care to exclude conflicts of financial interest, for both risk assessment and economic analysis. Peer-review quality and effectiveness should be evaluated regularly. 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 to their peer-review efforts.

Standards of 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 as is.

Recommendations for Agencies

The Commission developed findings and recommendations about several federal agencies and programs, partly to illustrate our general recommendations, partly to address inconsistencies,

and partly to try to assist Congress and the agencies on particular matters.

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 treatment 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. 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 and in the context of other risks to health.

We recommend more frequent determinations of future land use at the start of Superfund-site risk assessments, and updating of the Toxic Substances Control Act to reflect advances in the understanding of chemical toxicology. We endorse a comprehensive watershed-management approach to managing risks under the Clean Water Act.

Food and Drug Administration: We propose a substantial modification of the "Delaney clause", 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.

Department of Energy and Department of Defense: We propose further development and evaluation of risk-based approaches to priority-setting and budget-making.

* * *

NOTE: The entire report is a draft. Four critical monthly meetings scheduled to take place from October 1995 through January 1996 were canceled because of the budget negotiations. The Commission is particularly eager to have substantial public comment by August 9 and to modify its report for public release in October 1996.

1

Introduction

The Commission on Risk Assessment and Risk Management was mandated by Congress in the 1990 amendments to the Clean Air Act to address risks that are regulated under the many laws aimed at protecting the environment and protecting the health and safety of the American people from potentially dangerous exposures to chemicals and other hazardous substances and objects in air, water, food, the workplace, and consumer products. Of the 10 members of the Commission, 3 were appointed by the president, 6 by the majority and minority leaders of the House and Senate, and 1 by the president of the National Academy of Sciences.[1] The Commission's mandate[2] is summarized in the following phrases:

- Assess uses and limitations of risk assessment.
- Evaluate exposure scenarios for risk characterization.
- Determine how to describe and explain uncertainties.
- Enhance strategies for risk-based management decisions.
- Review desirability of consistency across federal programs.

The Commission was also asked to comment on the conclusions of *Science and Judgment in Risk Assessment* (NRC 1994a) (see appendix A.3) 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 technology-based controls are implemented to reduce hazardous-pollutant emissions from stationary sources and, if so, what to do about those residual risks. There was disagreement about the risk-assessment techniques and assumptions that should be used to estimate residual risks, about the benchmarks that should be used to distinguish between negligible and unacceptable risks, and about the risk-management methods that should be used to mitigate unacceptable risks. But the Commission's mandate was not restricted to evaluating air pollution, the particulars of the Clean Air Act, or the EPA. Rather, it was limited to "cancer and other chronic human health effects," so we did not address environmental problems, such as global climate change, ozone depletion in the stratosphere, or protection of wetlands and other habitats. We do note, however, that human health depends on a healthy environment, that the general approaches of health risk assessment are applicable to ecological risk assessment, and that benefit-cost analyses should assess all benefits, not just human-health benefits.

[1]Biographies of Commission members are provided in appendix A.1.

[2]A copy of the Commission's mandate is included as appendix A.2.

Vision

Through its deliberations, the Commission developed a shared vision of sustainable goals for our environment, our economy, and our 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 recognize that special sensitivity is required to encompass the diverse socioeconomic status and cultural practices of this nation. We seek a comprehensive, risk-based approach that puts specific actions in a public-health and ecological context.

Background

As a result of public recognition of environmental problems and translation of that recognition into effective action, tremendous progress has been achieved during the last 25 years in improving 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 health effects and ecological effects of chemicals, radiation, and microorganisms. Improvements in public health historically have come primarily from environmental interventions, such as proper waste disposal and hygiene, quarantines, clean water, and vaccines. Although many federal environmental laws share a primary goal of protecting the public's health and the environment, most environmental statutes have been media-specific and have relied on regulatory approaches rather than public-health approaches.

We know that the gains of the last 25 years can be sustained only by continued action, especially as the economy and the population grow and new technologies are introduced, and we believe that the effort to sustain them will be most effective if regulatory and public-health agencies work together.

Risk Assessment

Risk is a combination of the probability of an event—usually 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, 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 those assessments, 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 events involved in the risks, leading to conflict and litigation over proposed actions. Risk assessment itself has become controversial because of its important role in the protection of human health and the environment.

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.

- Hazard identification: Determine the identities and quantities of environmental contaminants present that can pose a hazard to human health.

- Dose-response assessment: Evaluate the relationship between contaminant exposure concentrations and the incidence of adverse effects in humans.

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

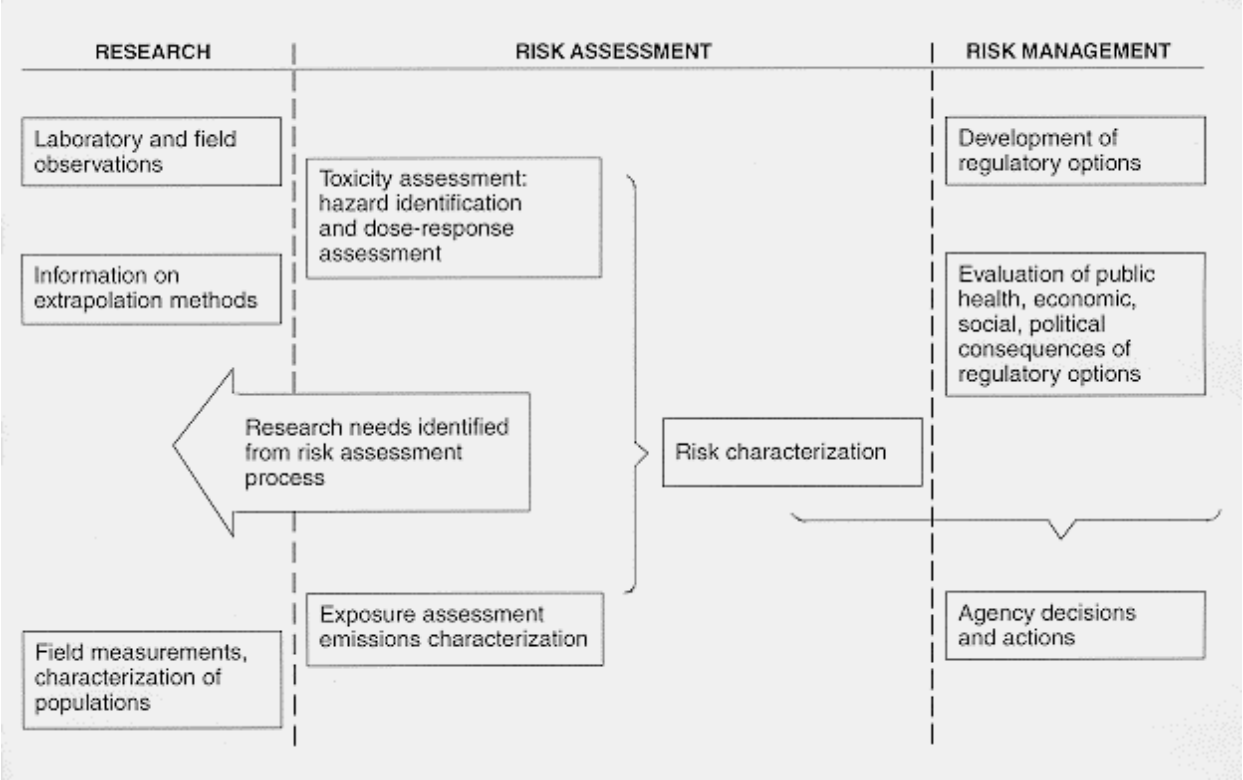
- Risk characterization: Describe the nature of adverse effects that can be attributed to contaminants, estimate their likelihood in exposed populations, and evaluate the strength of the evidence and the uncertainty associated with them.

The Commission was directed to focus on what Congress called “chronic health effects”, meaning effects that do not occur immediately—like injuries from falling off a construction platform—but that are the cumulative result of repeated exposures that might take months, years, or decades to become 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 (McGinnis and Foege 1993). Use of alcoholic beverages accounts for about 100,000 deaths, and motor-vehicle collisions for about 25,000 deaths. As many as 60,000 deaths per year are estimated to be attributable to airborne fine particles. Many activities individually contribute little to overall public-health risks but substantially when viewed collectively. For example, 60,000 deaths per year have been attributed to occupational and environmental chemical exposures of all types.

Of all causes of death, the most salient for most people is cancer; it is important to recognize that cancer has multiple causes and is not a single disease. However, cancer is not the only cause of health concerns associated with environmental pollutants. Reproductive impairments, birth abnormalities, asthma and other forms of airway hyperactivity, and effects on all the organ systems of the body warrant serious attention from a risk-management perspective. Even if those health effects have modest impacts on mortality, they are important determinants of our quality of life.

Risk assessment goes beyond scientific observations of exposures and effects in people,

Figure 1.1 Elements of risk assessment and risk management



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

animals, or test systems to try to answer 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.

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. Our regulatory agencies are expected to control, down to an extremely low level, the potential cancer risks, for example, associated with each of those individual activities; a limit of less than 1 extra cancer death from a particular chemical per million persons exposed over a 70-year lifetime is generally used for screening purposes and when exceeded, might serve as a justification for seeking exposure monitoring data to more accurately characterize risks. Risk criteria used in regulating occupational exposure to specific chemicals often correspond to about 1 extra cancer death out of every 1,000 workers exposed over a working lifetime. For noncancer risks, regulatory agencies aim to reduce exposures to below presumed thresholds 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. How do we use the tools of risk assessment and of economic analysis and consider social and cultural information to make better, more-efficient, more-understandable, and less-costly decisions about reducing risks that are judged to be too high? How do we compare risks and risk-reduction actions of various kinds to determine which deserve higher priority? What are the community, public-health, and environmental contexts for formulating a particular problem, characterizing its risks, deciding what to do about it, and evaluating the impact of actions taken? 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, the Commission proposes 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 salient 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 salient feature is the integrated, multimedia approach the framework takes to address multiple risks instead of individual risks.

Our Report

This report is the product of the Commission's deliberations and evaluations since May 1994

and constitutes a response to concerns of those who provided testimony before the Commission[3] and issue papers prepared for the Commission by several experts.[4] Section 2 describes the framework and its application, setting the stage for the rest of the report. Sections 3 and 4 provide guidance on how to approach the risk and cost components of the framework. Section 5 addresses ways to improve risk communication and risk management. Section 6 provides recommendations for specific federal regulatory agencies and programs.

This report is a draft intended to elicit public review and comment. The draft and the reports abstracted in appendix A.5 are available from the internet at http://www.riskworld.com. The Commission welcomes written comments addressed to its office at 529 14th St. NW, Suite 452, Washington, DC 20045—preferably by July 17, so that they can be considered in a public hearing on July 23 in Boston, but as late as August 9, so that they can be considered in the preparation of the final report. The Commission's final report will be issued in October 1996 and will be followed by additional hearings and presentations at meetings.

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

[4]Abstracts of the issue papers prepared for the Commission are included as appendix A.5.

2

Framework for Risk Management

It is time to change the traditional approaches to assessing and reducing environmental, health, and safety risks, which have relied on a chemical-by-chemical, medium-by-medium, risk-by-risk strategy. That strategy evolved from multiple, unrelated statutory requirements from the various Congressional subcommittees that have jurisdiction over agencies responsible for protecting health and the environment. The result is our highly fragmented and adversarial system of conflicting actions that ignores the interdependence of environmental components, emphasizes the differences instead of the similarities between cancer and other health effects, and investigates risks associated with individual purified chemicals instead of environmental mixtures of chemicals.

Many effective risk-management decisions certainly have been made, but many other decisions have left stakeholders unhappy or problems only partly addressed. Testimony received from the U.S. Department of Energy (DOE) Office of Integrated Risk Management, the U.S. Environmental Protection Agency (EPA) deputy and assistant administrators, and the public repeatedly emphasized the need to address multiple chemical exposures and called for our environment to be addressed as a system, not as a fragmented collection of individual risks. A related difficulty is the need to combine characterizations of risks to health and the environment with values, perceptions, and concerns of affected parties, especially nontechnical people and communities.

Moving toward integrated, effective environmental management requires a risk-management framework that can engage a wide range of stakeholders and address the interdependence and cumulative effects of various problems. The framework must have the capacity to address various media, contaminants, and sources of exposure and an array of public values, perceptions, and ethics. It should be sufficiently understandable to be adopted and used by risk managers in a wide variety of situations and lead to acceptable and effective decisions. It should be flexible so that its use can be matched to the importance of the decisions to be made. Full implementation of the framework for federal programs will lead to a need for Congressional authorization and funding; however, much progress can be made with existing statutes.

The overarching goal of the Commission's framework for integrated risk management is to move beyond "end-of-the-pipe" command-and-control approaches to environmental protection toward means of achieving sustainable development. Such an ethic of environmental stewardship requires an understanding of 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 believes that the integrated risk-management framework described here is timely. It is consistent with regulatory-reform goals of stimulating economic progress while improving the effectiveness of environmental protection and sustaining the accomplishments of the last 25 years of environmental regulation. Thus, it is consistent with the goals of the President's Council on Sustainable Development—to ensure that every person enjoys the benefits of clean air, clean water, and a healthy environment while maintaining economic prosperity and creating full opportunity for citizens, businesses, and communities to participate in and influence the natural-resource, environmental, and economic decisions that affect them (PCSD 1996). Its insistence on collaborative stakeholder involvement and empowerment, its commitment to place each problem in a public-health context, and its use, when appropriate, in an iterative manner to refine regulatory decisions make it applicable to diverse environmental regulatory problems. Although the Commission's mandate was to evaluate risk-management decision-making at the federal level, the framework is applicable to all levels of decision-making.

The framework reflects the importance of "participatory democracy" in resolving environmental dilemmas (Ruckelshaus 1995). It is consistent with testimony calling for risk-management partnerships among government, industry, and the public. For example, Walter Fields, of the National Association for the Advancement of Colored People (NAACP) in New Jersey, urged the Commission to define specific steps needed to bring communities into the risk-assessment and risk-management processes and to enable communities to engage in honest dialogues with industries. The Commission received similar testimony from a variety of people all over the United States, including Michael McCloskey, chairman of the Sierra Club; Linda Greer, of the Natural Resources Defense Council; Mark Van Putten, of the National Wildlife Federation; Peter Raven, of the Missouri Botanical Garden; Ronald Selph, mayor of Granite City, Illinois; Carol Henry, director of the DOE Office of Risk Management; and Phillip Lewis, of Rohm and Haas Company, Philadelphia. The framework incorporates various principles and recommendations set forth by the Carnegie Commission report *Risk and the Environment: Improving Regulatory Decision Making*, the National Commission on the Environment report *Choosing a Sustainable Future*, the National Research Council report *Science and Judgment in Risk Assessment*, the Annapolis Accords for Risk Analysis, the Harvard Group on Risk Management Reform, and the National Academy of Public Administration report *Setting Priorities, Getting Results.*

FINDING 2.1: After many years of management of environmental, health, and safety risks in the United States, there is still no generally accepted or uniformly applied framework or set of principles for making risk-management decisions. Current efforts to manage risks are often fragmented and sometimes in conflict, often reflecting different statutes. In addition, there is no systematic process for integrating public values, perceptions, ethics, and other cultural considerations into risk-management decisions.

RECOMMENDATION: A systematic, comprehensive risk-management framework should be used to reduce environmental, health, and safety risks. The Commission's framework comprises six stages (figure 2.1): formulating the problem in broad context, analyzing the risks, defining the options, making sound decisions, taking actions to implement the decisions, and evaluating the

Figure 2.1. Framework for Risk Management

effects of the actions taken. The framework can be used iteratively and must embrace collaborative involvement of stakeholders.

RATIONALE

The Framework

The Commission's risk-management framework constitutes a comprehensive strategy for reducing risks to public health, safety, and the environment. Each stage involves a different set of questions. The following is a description of how the six stages would operate and the collaborative and iterative processes that would occur throughout them.

1. Problem/Context: *What is the problem? What is its context? Who is responsible for managing the problem, and who are the stakeholders?* A potential or existing problem might be identified on the basis of environmental monitoring; emissions inventories; disease surveillance and epidemiologic observation; unexplained illnesses; a permit application; a bad odor; a need for national standards to control contaminant concentrations in air, water, soil, or food; or some other public concern. Attention might be focused on a "symptom" of an underlying problem.

The problem would be examined not just in a medium- and pollutant-specific manner, but in a comprehensive, multimedia, public-health context. Potential relationships among different problems are identified and considered. For example, the degradation of an aquatic ecosystem can be caused not only by point sources of water pollution but also by nonpoint sources, such as urban and agricultural runoff. It can also be affected by land-disturbance activities, including logging and grazing, construction of dams and reservoirs, diversion of surface-water and groundwater flows for domestic and agricultural uses, overfishing, and introduction of exotic species. Deposition of air pollutants—such as nitrogen, lead, cadmium, chromium, mercury, and radionuclides—can also contribute to the problem (see section 6.1.4).

Stakeholders are identified at the problem/context stage and are relied on heavily for problem identification and characterization. Risk managers can be people or institutions at the federal, state, or community level, depending on the problem's context. Once there is collective appreciation of (and possibly consensus on) the characterization of the problem, risk-management goals and objectives can be defined and pursued.

Appropriate contexts for a problem are likely to be situational. In some cases, the context can be overall public health. In other cases, it might be other risks (see section 5.1 for a discussion of risk comparisons). In still others, it might be its relationship to the interdependence of different problems (such as the degradation of an aquatic ecosystem, as described above).

An example of formulating a problem in its context might start with the consideration of the risks associated with hazardous air pollutants regulated at one industrial facility or category of facilities in the context of risks associated with stationary and mobile sources that emit the same pollutants in the same geographic area. The next layer of context would be comparisons with

risks associated with other important air pollutants, such as particles and carbon monoxide. A multimedia context would lead to a comprehensive plan that includes risks associated with air, water, and solid waste in the region.

Putting a problem in its context will be needed when residual risks associated with hazardous air pollutants are characterized after technology-based controls are implemented under the Clean Air Act (see section 6.1.1). For example, EPA has promulgated a maximum-available-control-technology (MACT) standard for the petroleum refinery industry. That standard was promulgated partly on the basis of EPA's finding that emissions from petroleum refineries potentially pose a leukemia risk to exposed populations because they contain benzene, a known human carcinogen. The standard will reduce the emissions of benzene and other hazardous air pollutants emitted by the source category. After the standard is implemented, residual-risk assessments will include a calculation to determine whether a leukemia risk that can be attributed to benzene remains. In addition to being emitted from petroleum refineries, benzene is emitted as exhaust from motor vehicles. In fact, emissions from mobile sources represent the largest single source of airborne benzene in the United States. Residual risks associated with the benzene emitted from a particular petroleum refinery could be compared with those associated with benzene from mobile sources and any other important sources that might exist in the geographic area of interest, including consumer products used in the home. The advantage of considering the risk in that context is that if the residual leukemia risk contributed by the petroleum refinery proves to be significant in comparison with the leukemia risk contributed by other sources, risk-reduction efforts can be focused on modifying the refinery further. If it proves insignificant in comparison, more effective and more efficient means of risk reduction that focus on the larger contributors of risk might be possible.

2. Risks: *What risks does the problem pose to public health?* Risk would be determined by considering the nature, likelihood, and severity of adverse effects on human health, the environment, or public welfare (such as economic well-being or aesthetics). Risks would be evaluated primarily by scientists and risk managers with input from stakeholders. Community stakeholders should be consulted at this stage to help to identify groups with high exposures so that appropriate exposure assessments can be designed (see section 3.2). The factual and scientific basis of the problem would be articulated and incorporated, along with subjective perceptions of the problem, into a characterization of the risks to human and environmental health and consideration of cultural and societal values, quality of life, and environmental equity (see section 5.1). Health and ecological risks would be treated both qualitatively and quantitatively. The nature of the adverse effects, their severity, their reversibility or preventability, and the possibility of multiple effects must be understood before complex estimates of the magnitude of the risks and their uncertainties are presented (see section 3.5). Cumulative risks associated with related problems would be identified, where possible. Indirect effects on human health through disruption of the environment also would be considered.

3. Options: *What can and should be done about the problem? What are the potential consequences and expected benefits of intervention? Are there other ways to reduce similar health effects in the same population or similar ecological effects in the same region? What are*

the estimated costs of each option? Approaches to addressing the problem would be identified by stakeholders, regulators, and scientists. A variety of regulatory and nonregulatory alternatives would be considered, such as permits, enforcement actions, pollution prevention, recycling, market incentives, voluntary reductions, and education (see section 5.4). Institutional, financial, and other arrangements for implementing each approach would be identified. The extent of risk reduction expected and the relationship between the costs and benefits of each approach would be determined and compared (see section 4). Cultural, ethical, political, and legal dimensions would be considered. Potential impacts of each approach would be characterized, including possible adverse effects on workers, the community, or the environment.

4. Decision: *What is the best solution to the problem? How can that decision or set of decisions be reached? Who should make that decision? Will the actions required be compatible with the Unfunded Mandates Act of 1995?* The most feasible, effective, acceptable, and cost-effective approaches to mitigating the problem would be identified, with the participation of affected and responsible parties. A mechanism for conflict resolution, or for reaching closure in the absence of consensus, might be needed. It is important to acknowledge that this framework will not always result in a consensus among those involved in the process. In fact, participation, negotiation, and attempted compromise sometimes can result in a hardening of opposite positions, a breakdown in negotiations, frustration with the process, and an inability to reach agreement. Those difficulties in reaching a decision should be viewed not as a failure of the process envisioned by the framework, but simply as a recognition that in some instances, notwithstanding the best efforts of all affected parties, consensus will not be achievable. At some point, the responsible regulatory authority must make its decision, including a decision to defer, if opposition is too strong or too credible. Deferral would require a later decision of whether to repeat the process from the beginning or to go on to other pressing needs.

5. Actions: *How can the decision be implemented rapidly and flexibly?* The action that has been chosen to address the problem is explained and taken. Several actions might be needed in various circumstances. Actions might be taken by public agencies, businesses, industries, and private citizens, alone or in combination. Objections or reassessments, even at this stage, may trigger an iteration of the process.

6. Evaluation: *How effective are the actions?* Too often, actions are mandated but there is little followup to ensure that they are taken, to analyze effectiveness and cost, or to compare the findings with estimates made in the decision-making stage. The effect of a chosen action on the problem can be characterized through monitoring and surveillance, through discussions with stakeholders, and through analyses of relationships between interventions and trends in health or environmental indicators. Criteria should be specified in advance. On the basis of evaluation, the original problem can be redefined, the actions reconsidered, and the various stages repeated if appropriate.

If the evaluation of the impact of the actions on a problem finds it unsatisfactory, another iteration of the process might be needed. But few effects on risk lend themselves easily to measurement and validation. To some extent, monitoring and surveillance can enable the study

of relationships between action and effect, but often such relationships are detectable only when the margin between actual exposures and exposures associated with the health or ecological effect of concern is narrow or the health effect of interest is particularly rare. Most public-health risks are already low, compared with such measurable effects as occupational injuries or motor-vehicle collisions. For example, suppose an action lowers the lifetime incremental risk of developing cancer because of a particular exposure from 1 in 10,000 to 1 in 1,000,000. No health study or surveillance activity could be designed to measure the effectiveness of an action with such a small change, because cancer would be the cause of death in 24% of the population in either event. Conclusions about effectiveness in such a case would have to rely on environmental monitoring, changes in biologic markers of exposure, or some other indirect measure of impact on disease incidence. Developing good baseline and surveillance information about disease incidence, linking health and environmental data, and determining regional differences in disease prevalence, trends, and risk factors would improve the ability to implement effective public-health interventions and enhance our confidence that they are effective.

Collaboration

The Commission's framework is intended to be implemented collaboratively, with some level of participation of stakeholders or other affected parties at each stage. Figure 2.1 shows a particularly prominent role for stakeholder involvement in the first stage, formulating the problem in context. Such partnerships can facilitate the exchange of information and ideas that all parties need if they are to make informed decisions about reducing risks. Regulatory actions or decisions are more likely to be successful if affected parties are involved in scoping and decision-making than if they are not (Richards 1993). As NAACP representative Walter Fields testified at the Commission's meeting in New Jersey, if people are not included in risk-management decisions, such as facility siting, from the very start, they feel excluded from important decisions that affect their communities, and emotional, not rational, reactions govern their response. The importance of stakeholder participation was emphasized by the President's Council on Sustainable Development (PCSD 1996) and the National Research Council Committee on Risk Characterization (NRC 1996a).

Including stakeholders in the processes of defining a problem and assessing its risks can provide a forum in which to clarify the technical data and science-policy assumptions used in risk assessment. Our recommendation for serious involvement of stakeholders in active protection of ecologic and human health, especially at the community level, is well-supported by recent public-opinion poll results. For example, results from a survey in mid-March 1996 suggest that 80% of Americans think that government at all levels should encourage citizen involvement in health and environmental protection (Council for Excellence in Government 1996). They do not want government to do less about risks to health and the environment than it does currently, but they want government action to be more efficient and effective. They also think that responsibility for controlling risks should be shared by government, business, communities, and individuals.

Collaboration also plays a central role in effective implementation, especially if environmental protection is no longer considered solely a government-industry responsibility and the public is expected to participate directly in implementation of risk-management steps (McCallum and Santos 1995). Public actions include reduction and recycling of wastes at home, on farms, in offices, and in recreation, as well as bearing some of the cost. Public comment and public meetings are not adequate substitutes for collaborative approaches to problem-solving, although they can be useful in gaining broader participation. Effective stakeholder involvement in regulatory decision-making requires a shift in attitudes so that affected members of the public are seen as partners in the problem-solving process, rather than as obstacles to it (Van Horn 1988, Chess et al. 1995). It might also require a modification in the timelines that regulatory agencies must satisfy to meet statutory or court-imposed requirements.

A potential disadvantage of our framework might be the investments of time and money required to implement a collaborative, systematic process. Even if the process might lead to long-term savings, the up-front costs could be considerable. Moreover, there is no guarantee that consensus on a risk-management decision will be reached. However, the time and expense required are unlikely to exceed the experiences of the Occupational Safety and Health Administration and EPA, which have sometimes required years in preparing agency risk assessments, in notice-and-comment rule-making, and in litigation over the resulting decisions.

Implementing a collaborative decision-making process should include incentives for participation. An industry or municipality might be more inclined to participate willingly and cooperatively if it were to receive some relief in exchange, such as reduced reporting requirements, suspension of punitive damages, or elimination of parties' abilities to sue after a decision is reached.

Iteration

The framework is intended to be implemented iteratively; that is, the process can be refined and its conclusions can be changed on the basis of research, new data, and new views. Iteration could apply to a rule that has already been promulgated or to a new rule or a new approach to a problem that is being developed. Public comment, negotiation, or analysis can redefine the problem or identify other issues of concern in a broader context. Research and information-gathering performed to clarify a problem or a risk might lead to a focus on a somewhat different problem. Analyzing risks and options can lead to a better understanding of how a problem should have been defined and scoped at the outset. However, iteration must not be allowed to become a device for indefinite delay. Using an iteration to scope a problem might actually speed up the risk-management process, as goals and issues are clarified, and possibly lead to a quicker and more cost-effective resolution than expected initially if it becomes apparent that proceeding with the entire framework is no longer necessary.

Using the Framework

The proposed framework is intended to be a guide for an approach or thought process for risk-

management decision-making. It is unlikely that all aspects of the framework would be required for every problem and some might be inconsistent with certain statutory requirements. Different levels of decision-making will require different levels of analysis. Risk managers should apply this process flexibly to accommodate the needs of individual circumstances.

A number of criteria might be used to determine when applying the framework would be most useful. A problem worth addressing according to the framework should involve achieving an agreed-upon goal, the optimal path to which is controversial. The problem should require resolution of interdependent or related issues. Enough facts should be available to permit meaningful discussion and resolution. Participants in the process should be representative of those affected by the outcome of problem resolution. In some cases, it might be particularly important for elected officials or their representatives to be included in the process so that their support of the result is likely. For example, including members of Congress in the stakeholder deliberations about Superfund reauthorization in 1994 might have enhanced the prospects for the success of that effort.

The framework can be applied at several levels.

National level. Congress could apply the integrated, multimedia approach of the framework to its future risk-management legislation and to its oversight of existing agency programs. For example, Congress could modify the Clean Water Act to establish a comprehensive, integrated, multimedia watershed-management approach and to provide for the development of state watershed programs (see section 6.1.4). The current EPA watershed-protection approach could be expanded with additional authorization and funding from Congress to accomplish multimedia environmental-risk management under the Clean Water Act and possibly under the Clean Air Act. In fact, using the current watershed-protection approach, EPA-sponsored estuary programs in Tampa Bay and Galveston Bay are good examples of how state and local governments and citizens can participate in a process that identifies high-priority, multimedia environmental problems and take action to ameliorate the problems.

EPA can use the framework to support its development of an integrated air-toxics strategy for urban areas, to link decisions on residual risks from major sources with risk-driven decisions on smaller stationary sources and mobile sources. Section 6.1.1 has a detailed discussion of the application of the Commission's risk-management framework to the determination of residual risks. EPA can also use the framework to support its Common Sense Initiative to integrate all the permitting that is required of individual manufacturing facilities, overcoming conflicting and redundant requirements.

State and regional levels. Under existing federal and state laws, states and regional airshed or watershed authorities can use the framework approach to address various environmental problems in an integrated manner, where applicable and feasible. Both the Michigan Department of Environmental Quality and EPA Region 5 have organized themselves into multimedia teams to facilitate integrated approaches to risk management. Several states have initiated programs to resolve and integrate potentially conflicting permitting requirements.

One example of how the problem/context and risks stages of the framework could be applied at the state level is the case of oxygenated and reformulated fuels. The 1990 Clean Air Act Amendments required that new vehicle fuels be introduced by 1992 in communities with of carbon monoxide concentrations exceeding national ambient air-quality standards. The new fuels contain the additive methyl *tert*-butyl ether (MTBE). In some states—particularly Alaska, Montana, Wisconsin, and New Jersey—there have been numerous complaints of unexplained symptoms of health effects. More that 70 million Americans are potentially exposed to evaporative emissions from oxygenated and reformulated fuels. MTBE has been singled out as potentially responsible for the symptoms. Assessing potential risks associated with these fuels in a public-health context should include evaluating not only MTBE toxicity but also risks associated with increased concentrations of nitrogen oxides, formaldehyde, and acetaldehyde. The health benefits of the MTBE-related reductions in carbon monoxide and benzene concentrations would also have to be considered, as would the role of ambient temperature and engine performance in exposures (HEI 1996). The risk characterization should also consider the different strengths of evidence for health risks associated with carbon monoxide, benzene, and MTBE. Using a common metric to compare the health effects of each chemical, such as a margin-of-exposure approach (see section 3.1), would be useful.

The following is an example of the framework in action at the regional level.

Beginning in 1978, the Association of Bay Area Governments (ABAG) developed and adopted an integrated, comprehensive environmental-management plan for the San Francisco Bay region (ABAG 1978). The plan recommended actions to improve and manage the region's air-quality, water-quality, water-supply, and solid-waste problems in an integrated, comprehensive manner. ABAG was designated as the lead agency by the state of California under various federal and state laws. The plan was developed to meet the requirements of the Air Quality Maintenance Plan under the Federal Clean Air Act Amendments of 1977, of the areawide plan under the Federal Water Pollution Control Act Amendments of 1972, of the Federal Resource Conservation and Recovery Act of 1976, of the California Solid Waste Management and Resource Recovery Act of 1972, and of California Senate Bill 424 of 1977.

- Collaboration. The plan was developed through an extensive collaborative process that involved a broad range of stakeholders, including representatives of federal, state, and local regulatory agencies, business, labor, environmental groups, ethnic minorities, and city and county governments. A 46-member environmental-management task force charged with plan preparation was formed by ABAG with the stakeholders well represented. The task force was chaired by Dianne Feinstein, then mayor of San Francisco. Community outreach was extensive, and several hundred roundtables, meetings, and formal public hearings were held.

- Problem/Context. Stakeholders were involved at the beginning of management-plan development to identify environmental problems in the region. For example, photochemical oxidants in the air, toxic materials in the San Francisco Bay, and inadequate solid-waste disposal practices were identified as some of the important problems. Potential relationships among the problems were also identified so that they could be considered in a multimedia, integrated

manner. For example, solid-waste disposal sites could cause surface-water and groundwater contamination and could produce dust, gases, and odors that affected air quality. Therefore, properly managed landfills were considered to be control measures for air and water pollution, as well as for solid-waste disposal problems.

• Risks. Risk information was compiled and communicated to the stakeholders. For example, health effects of photochemical oxidants and harmful effects of toxic materials on aquatic life were described to the stakeholders at various meetings. However, risk assessment was not performed extensively, because control measures were chosen on the basis of federal and state requirements.

• Options. Options for control measures were developed with extensive input from stakeholders. The most controversial measure was land-use controls for maintenance of air quality after 1985. The proposed control measures were evaluated for their environmental benefits, consequences, and costs and for their probable social and economic effects on the region.

• Decisions. Control measures were selected by the environmental-management task force, which was composed of locally elected officials and other stakeholders. Many of the control measures were voted on and adopted by the task force. However, after many months of discussion and the expression of substantial concern by labor, business, and many of the cities and counties in the region, the land-use control measure for maintenance of air quality was eliminated from the plan. In the decision-making process, several important issues were raised, including federal-state-local relationships, the social and economic impact of land-use controls, the extent of air-quality improvement likely to be obtained, and the suitability of including these measures in an air-quality plan.

• Actions. Because so much care that was taken to analyze problems and solutions and to make decisions with broad stakeholder participation, many of the actions recommended by the plan were taken by public agencies, businesses, industries, and private citizens. The plan continues to serve as a blueprint for environmental-management activities in the bay region. For example, a state implementation plan for air quality was developed in response to the plan and, as a result, the region was designated as an attainment area for ozone under the federal Clean Air Act 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 has been formed and has engaged in cooperative efforts, such as the development of a drought-response strategy for the region. Hazardous-material spill response teams have become available at the city and county levels. ABAG also provided technical assistance to local agencies to initiate recycling programs.

• Iteration. The plan recommended procedures for continual adjustment as new information or new technologies became available. Iteration was, in fact, carried out over the years.

• Evaluation. As a result of this collaborative, integrated environmental planning effort, the San Francisco Bay region has enjoyed substantial environmental improvement over the last 15 years. Although ABAG's designation as lead agency has expired, a planning process was continued by state and local agencies. Although no formal evaluation of the plan has been performed, much of the environmental improvement in the region can be attributed to implementation of the plan. The San Francisco Bay region is now considered by many to be one of the environmentally best managed metropolitan areas in the country, as a result of the comprehensive, integrated, collaborative environmental-management effort started almost 20 years ago.

Local and Community Levels. A city or a community can use the framework to address risks to its citizens. For example, radioactive-waste cleanup is a community-level, multimedia problem and should include effective local stakeholder involvement. When DOE began to address the cleanup problem at Hanford, the surrounding community was not adequately informed or involved, and that led to outrage and distrust. Involvement of the community as partners in risk management at the site since then has led to improved cooperation and more readily accepted decisions.

Other uses of the framework at the local level include the development and operation of industrial facilities or waste-disposal facilities.

Summary

Our risk-management framework constitutes a major shift in the emphasis that risk assessment plays in risk-management decision-making and has three critical advantages. First, it is consistent with using an integrated, holistic, top-down approach to a public-health or environmental problem instead of a chemical-by-chemical, medium-by-medium, bottom-up approach to characterizing individual risks; decisions about how to use risk assessment, and how extensively, are made from the perspective of risk management. Second, it emphasizes collaboration, communication, and negotiation in an open and inclusive process among stakeholders so that public values can influence the shaping of risk-management strategies; the results are intended to be decisions that are more pragmatic and more easily implemented than those made in the absence of consensus and solutions that incorporate the diversity of interests, knowledge, and technical expertise represented among stakeholders. Third, like the scientific process, the proposed risk-management process is iterative; at any stage of the process, the discovery of new information can change conclusions and decisions and lead to reformulation and re-evaluation of the problem at hand.

The Commission emphasizes that the proposed framework will need to be refined with experience. As illustrated by the examples described above, some elements of the framework, such as stakeholder involvement and multimedia analysis, have been tried. However, no risk-management effort to date has used all aspects of the framework. Many of the questions and concerns associated with this framework will be clarified as it is more widely used. We recommend that evaluation be an integral component of the process.

3

Uses and Limitations of Risk Assessment in Regulatory 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 middle 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 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 add individually so little to the background rate of about 240,000 cancer deaths out of every 1 million people who die every year in the United States. The ultimate goal is, of course, to lower the background rate itself, 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 (OSTP) 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, of emissions, or of exposures (Calkins et al. 1980) (see table 3.1).

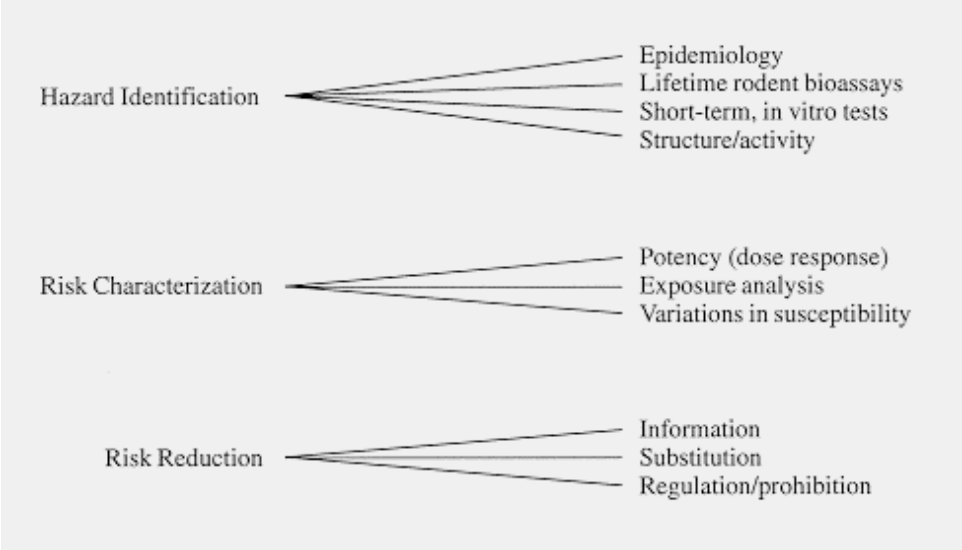
That scheme makes clear that information about potential hazards can come from epidemiologic studies of workers and other people who are exposed to hazards, from direct experimental tests in animals and in cells in the laboratory, and from comparisons of chemical structures. The next stage involves the 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.

Table 3.1 Framework for Regulatory Decision-Making.



3.1

Toxicity Assessment

Science and Judgment in Risk Assessment (NRC 1994) evaluated EPA's cancer risk-assessment practices and concluded that, although they could use fine tuning, they were fundamentally sound. EPA responded promptly to many specific recommendations of that report and has just issued *Proposed Guidelines for Carcinogen Risk Assessment* (EPA 1996). The Commission evaluated cancer risk-assessment practices at EPA and other federal regulatory agencies from a risk-management perspective—a broader context. We identified several aspects that we believe can be improved further. We address here the need for a common metric to compare reduction of risk of cancer and noncancer effects, how to evaluate chemical mixtures, and how to clarify factors that affect susceptibility to toxicity resulting from chemical exposures.

FINDING 3.1.1: Scientific information on a chemical's mode of action is used to make weight-of-evidence decisions about the relevance of toxicity-test results to humans and to extrapolate doses from laboratory animals to humans. Quantitative assessment of the relationship between dose and response is a mathematical procedure that has suffered from a regulatory policy dichotomy: chemicals that are suspected of causing cancer are regulated by assuming that every exposure has some risk, but chemicals suspected to cause 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 for either carcinogens or noncarcinogens. It has resulted in health risk assessments for carcinogenic and noncarcinogenic chemicals that cannot be compared and in striking discrepancies among maximal exposures considered to have negligible risk.

RECOMMENDATION: To assist in comparative risk assessment and risk characterization, a margin-of-exposure approach should be evaluated as an addition to current methods for expressing risks for carcinogens. The margin-of-exposure approach that is currently used by EPA for noncarcinogens and is proposed for carcinogens with nonlinear dose-response characteristics should be extended to carcinogens with linear dose-response characteristics, for comparison. For all types of cancer and noncancer health effects, risk assessments should use all relevant scientific information about a chemical's mode of action and disposition in the body.

RATIONALE

The distinction between "nonthreshold" carcinogens and "threshold" noncarcinogens is increasingly blurred. The standard assumption that all carcinogens are mutagens and that their dose-response relationships can be modeled by assuming low-dose linearity is inconsistent

with a variety of "secondary" mechanisms of carcinogenesis now identified. Meanwhile, knowledge of mechanisms of toxicity and of variation in susceptibility undercuts the standard assumption that all noncarcinogens have a definable threshold dose below which there is no effect. Disputes over the existence of a threshold for the activity of a particular chemical or over its dose-response characteristics below what can be observed in rodent bioassays or in biologic-marker studies are unlikely to be resolved experimentally. The result of this regulatory dichotomy is that carcinogens tend to be regulated more stringently and noncarcinogens less stringently than would be the case if there were a consistent method to compare them.

A large part of the debate about cancer risk assessment has focused on identifying and arguing over the best mathematical dose-response models to apply to rodent bioassay or epidemiologic data to extrapolate, for protection of the general population, often far below the range of effects that can be observed only at high doses. Because effects of such low exposures cannot be directly observed, the accuracy of those models beyond the observable range cannot be validated experimentally. Consequently, the accuracy or validity of the potency estimates derived from the models will remain in dispute. Public-health protection is not well served by unresolved debates about mathematical dose-response models, which delay or paralyze a regulatory agency's ability to evaluate toxicity or set standards. No similar extrapolation is performed for chemicals that can cause other effects, such as lung damage or reproductive toxicity.

A margin of exposure is 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 (EPA 1996). The risk manager evaluates a particular margin of exposure and decides whether it provides an appropriate level of protection given the relevant risk-management criteria. Stakeholders can make their own judgments. The margin-of-exposure approach is similar to, but more flexible than, the method EPA uses to derive estimates of reference doses or concentrations (RfD, RfC) for noncancer effects. Criteria for evaluating the acceptability of a margin of exposure include the slope of the dose-response relationship in the observable range, the nature and extent of the uncertainties, human variability to the response of concern, and human sensitivity as compared with laboratory animals.

Crump et al. (1996) advocate harmonization of cancer and noncancer risk-assessment practices through the use of techniques that do not rely on predicting low-dose risks. They state that the hope that dose-response models consistent with knowledge of the mechanisms of carcinogenesis would provide better estimates of low-dose cancer risk is unlikely to be realized in the near future. Because there is still so much uncertainty about low-dose mechanisms, even biologically based dose-response models must rely mostly on assumptions and generally predict risks similar to those predicted using completely empirical models such as the linearized multistage modeling procedure. The questionable biologic basis of current methods for estimating carcinogenic potency is suggested by the correlation that has been described between maximum tolerated doses (MTDs) and potency (NRC 1993). The observation that

MTDs of carcinogens are about 400,000 times the concentrations of carcinogens estimated to be associated with a 10^{-6} upper-bound risk level is a direct arithmetic result of the linear extrapolation, not a confirmation of a biologic mechanism.

Using a margin-of-exposure approach to evaluate risks from diverse toxicants might have some advantages. First, the distinct but complementary roles of risk assessment and risk management would be transparent: identifying an appropriate effect and dose to use as the basis of risk assessment would be a science-based activity (as it is now), and identifying appropriate margins of exposure would clearly be a risk-management responsibility, requiring consensus as to the level of protection that is desired and feasible for different effects or situations. For example, FDA uses a larger margin of exposure for a substance in food that is consumed by most of the U.S. population compared to what OSHA might use for protection of workers exposed to a solvent used in only one process in one industry.

Second, a margin-of-exposure approach for all carcinogens could improve risk communication. The information base on carcinogens is often restricted to observable dose-response data from bioassays. In only a limited number of cases do additional mechanistic data aid in extrapolating between species and from high to low exposures. It therefore seems misleading to express cancer risk in terms of predicted incidence or numbers of deaths per unit of the population when cancer risk often is based on no more information than is available on noncancer effects but is expressed in a manner that implies an unwarranted degree of precision. Third, harmonizing risk assessment methods for carcinogens and noncarcinogens might permit noncarcinogens greater emphasis than they now tend to receive. And finally, it would be easier to compare cancer risks to noncancer risks for making risk-management decisions. It is difficult to know whether cleaning up 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 than cleaning up a site classified as having a noncancer hazard index of 10. The same problem will emerge when residual risks are characterized and compared (see section 6.1.1).

EPA's *Proposed Guidelines for Carcinogen Risk Assessment* (EPA 1996) use that very approach for carcinogens with nonlinear dose-response characteristics, with a margin of exposure generated from the lowest effective dose (LED) associated with a 10% response rate (LED_{10}) or another point of departure, such as a no-observed-adverse-effect level (NOAEL). The LED_{10} concept is similar to the BMD_{10}, or benchmark dose for a 10% response rate, widely recommended for developmental effects but not yet rigorously evaluated for other types of effects.[1] The toxicology and risk-assessment communities are currently engaged in a major debate about whether the benchmark-dose approach should be used for evaluating the dose-response characteristics of other types of toxicity, especially neurotoxicity; about the comparability of standards based on benchmark doses and reference doses; and about the appropriateness and consequences of using lower confidence intervals on benchmark doses

[1]For a detailed discussion of the benchmark dose, see the report prepared for the Commission by Elaine Faustman (abstract found in appendix A.5).

derived from bioassays conducted with different testing protocols.

European countries use a margin-of-exposure approach for nongenotoxic carcinogens, and the Commission was told by Daniel Krewski, acting director of Health and Welfare Canada's Bureau of Chemical Hazards, that Canada is expected to adopt that approach for all carcinogens in the near future. Canada uses a risk measure similar to the margin of exposure called the exposure potency index, defined as the margin between estimated exposure concentrations and the dose that produces a 5% response rate (TD_{05}).

A disadvantage of a margin-of-exposure approach is that it produces results that are considered inconsistent with the needs of current methods used to perform economic analysis. We address this matter in section 4.3.

Instead of relying on estimates of cancer potency, FDA has used a "threshold of regulation" method for many years to regulate chemical additives that can migrate into foods from packaging material. FDA compiled a computerized database on hundreds of carcinogens, found that their potencies were lognormally distributed, and chose a concentration that generally would be associated with a cancer risk of 10^{-6} or less no matter how potent a carcinogen might be (Rulis 1989). According to FDA's testimony before the Commission, that concentration, 0.5 part per billion, is a concentration that generally represents a "reasonable certainty of no harm"; if a compound were present in food at that concentration, even if it were found to be a carcinogen, its risk to humans would be well below the highest risk that is considered negligible. To protect at a level sufficient to ensure less than an upper-bound lifetime risk of 10^{-6} associated with carcinogens as potent as the dioxin 2,3,7,8-TCDD or the fungal toxin aflatoxin B_1, however, the threshold of regulation would have to be so low (lower than 1 part per trillion in the diet) that virtually nothing would be able to pass the threshold-of-regulation criterion. (If an additive is *known* to be a carcinogen, it is regulated under the "Delaney clause" or another authority and is not permitted to be added to food at any concentration.) The advantage of the threshold-of-regulation approach is that regulatory activity for additives present below the threshold concentration is avoided; resources are focused instead on substances that might be of greater concern (see section 5.3 on bright lines).

Consideration of the relationships between dose and response is the fundamental principle of toxicology. Regulatory priority should be given to incorporating information about mechanisms of action and disposition to override default assumptions used to estimate small risks. We are hopeful that biologic markers of early effects can be validated as essential intermediate points in the pathophysiologic pathways of carcinogenesis and thereby provide more information about dose-response relationships and a better basis for relating animal and human responses.

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FINDING 3.1.2: Chemicals that cause cancer in rodents are appropriately considered potentially carcinogenic in humans. However, some chemicals elicit tumors in rodents through mechanisms that are unlikely to have any corresponding effect in humans. Others elicit tumors only at very high doses that are unlikely to be relevant to human exposures. Lingering controversies about those responses undermine the general reliance on rodent-bioassay results. Regulatory agencies have been cautious in recognizing the distinctions and in issuing guidance on when such rodent responses should be discounted or disregarded. As this report was going to press, EPA released its *Proposed Guidelines for Carcinogen Risk Assessment*, which include a category "not likely" to be carcinogenic in humans that includes chemicals with irrelevant modes of action.

RECOMMENDATION: Although the results of rodent bioassays provide valuable information about chemicals' potential risks to humans, some rodent cancer responses should be classified as irrelevant to human cancer risk assessment. If, after adequate testing, a chemical is found to produce only tumors that occur as a result of mechanisms or doses that have been deemed not relevant to humans, it should be unnecessary to generate cancer-potency estimates. Regulatory agencies should develop consistent criteria for making those distinctions, and the criteria should be updated as scientific knowledge about the mechanisms responsible evolves.

RATIONALE

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. That policy is undercut, however, when rodent tumor responses that can be shown to be irrelevant to humans are not excluded from consideration. Furthermore, from a risk-management perspective, it is wasteful to expend risk-assessment resources, risk-management time, and public and legal involvement nonproductively revisiting such policy issues chemical by chemical.

Table 3.2 lists examples of rodent mechanisms and tumor responses that are leading candidates for classification as "not likely" to be carcinogenic in humans according to EPA's *Proposed Guidelines for Carcinogen Risk Assessment.* 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. Chemicals that produce tumors only in rodents because of striking pharmacokinetic differences can also be addressed. In general, the chemicals listed in table 3.2 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 might be associated with a low incidence of tumor formation because of chronic overstimulation.

Some chemicals are recognized to induce the accumulation of large amounts of a protein containing α-2u globulin in the male rat kidney. Most scientists agree that this accumulation

Table 3.2. Rodent tumor mechanisms not likely to be relevant to human cancer risk if they are the only responses observed and are due to the mechanisms listed.

Tumor Site	Tumor Mechanism	Rodent Carcinogens
Male rat kidney	α-2u globulin-induced nephropathy	D-limonene, unleaded gasoline, isophorons
Forestomach	Local hyperplasia	BHA, propionic acid, ethyl acrylate (administered by gavage)
Male rat bladder	Reactive hyperplasia from cytotoxic precipitated chemicals	Saccharin, cyromazine, melamine, nitriloacetic acid, fosetyl-Al
Lung	Overwhelming of clearance mechanism	Various particles, including titanium dioxide and carbon black
Thyroid	Sustained excessive hormonal stimulation	EBDC fungicides, goitrogens, amitrol, sulfamethazine

leads to damage to the kidney tubules, cell death, sustained cell proliferation, and tumor formation (see Melnick et al. 1996 for alternative viewpoint). It does not occur in female rats or in other species, including humans. It was extensively studied and reviewed by EPA's Risk Assessment Forum and Science Advisory Board from 1988 to 1991, and it was 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 other adverse effects, including kidney tumors not due to this protein-mediated mechanism. Two problems remain, however: the very long time that it took to reach a decision, and the reluctance to apply the decision to the tumor response instead of to individual chemicals producing the response.

Another tumor response that is irrelevant to humans is that which occurs 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 it can result in local cytotoxicity and hyperplasia. At least three commercially important chemicals (table 3.2) have been found to produce tumors only in the forestomach. 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 effect, 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.

Rodent bladder tumors became famous during the saccharin debate of 1978-1979. Regulatory agencies later supported an International Life Sciences Institute panel on rodent bladder carcinogenesis, which 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. Bladder tumors can arise by other mechanisms (Cohen et al. 1995).

Grossly overloading the lung's clearance mechanisms by administering particles directly to the lung was considered irrelevant to humans by EPA in the case of titanium dioxide, which was delisted from the Toxic Release Inventory in 1988 for this reason (Fed Reg 53:23107-23202, 1988). The phenomenon is 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. Criteria are needed to determine what are "gross" particle overloads. Ultrafine preparations of carbon black or other materials might present a risk at lower concentrations.

Thyroid tumorigenesis in the rat has been under review by EPA at least since 1988. Various pesticides and fungicides induce liver enzymes or thyroid enzymes that affect thyroid hormone levels and lead to hyperplasia and ultimately tumor formation in rodents. The response might be evoked by high doses only. The feedback and transport systems for rodent thyroid hormones are very different from those in humans (McClain 1994). Although there is no doubt that humans are far less sensitive to this response, agency consensus appears to be that

the animal model cannot be disregarded.

Finally, there have been many challenges to the interpretation of mouse liver-tumor formation (not listed in table 3.2). At least six potential mechanisms have been described, some of which occur in humans and some of which do not. Mouse liver tumors are among the most common seen in bioassays and pose particularly vexing problems for interpreting effects of chlorinated organic solvents.

Bringing a risk-management perspective to the scientific-review process might galvanize action in a way that normal agency procedures have not. At least 10 years passed before EPA acted on the male rat kidney-tumor response. Over 15 years have passed since the human relevance of saccharin's carcinogenicity was doubted, but packages of sugar substitutes including saccharin still carry warning labels required by Congress. Banning the detergent nitriloacetic acid, a rodent bladder carcinogen, led to increased use of phosphate detergents, with serious ecological effects. 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.

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FINDING 3.1.3: Current regulatory approaches for reducing risks associated with chemical exposures generally do not reflect differences in individual susceptibility or encourage getting evidence to identify them. 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.

RECOMMENDATION: Risk assessments should include consideration of genetic and other host differences in susceptibility and identify especially susceptible human subpopulations for specific chemical exposures. Available information on the range of a population's susceptibility should be considered. Where appropriate, knowledge of differences in susceptibility should be used to support additional "bright lines" or standards for chemical exposure concentrations, to protect especially susceptible subpopulations (see section 5.3).

RATIONALE

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 modes of action; people are not hypersusceptible to all kinds of

exposures (Omenn et al. 1982). The influence of concurrent exposures on risk is discussed in section 3.2. 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
Elderly	Diminished detoxification and elimination mechanisms

There are opportunities to identify, evaluate, and reduce risks to sensitive people. Asthmatics, for example, make up 5-10% 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, 2-4 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.

Congressional amendments to the Safe Drinking Water Act, amendments to the Federal Insecticide, Fungicide and Rodenticide Act, regulatory-reform legislation, and other bills would require such recognizable subpopulations as the elderly, children, and women of child-bearing age to be identified and considered in risk characterization and in standard-setting. Recognition of subgroup susceptibility does not necessarily result in more stringent regulation.

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 risk and describing the risk peculiar to that population during risk characterization, perhaps relying on 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.

3.2

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 contamination 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, which the Commission's risk-management framework will stimulate. 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 also recommends that agencies exhibit an active preference for actual exposure data for communities and populations at risk.

FINDING 3.2.1: Because of statutory requirements and the desire not to underestimate maximal 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. Congress 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 maximally exposed individual (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 for any segments of the population that have unusually high exposures. Exposure assessments should emphasize the characteristics of actual or potential future populations in relation to specific sources of exposure and should reflect multiple sources of exposure, as appropriate in each case.

RATIONALE

With the intention of protecting public health, past exposure-assessment and health risk-assessment practices have relied on exposure estimates derived from a hypothetical maximally exposed individual (MEI). An MEI is a person who might spend a 70-year lifetime living at the point of greatest deposition from a plume of contaminant emissions from an industrial facility or a person who might spend a 70-year lifetime drinking only groundwater 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 high-end exposure estimates (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 section 5.1 and the discussion of variability and uncertainty in section 3.5). 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 90th 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 might be useful for simple 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 focusses attention on the characteristics of the population. Exposure estimates derived primarily from the emission or other characteristics of a particular source of contamination are incomplete. Exposure is experienced by individual members of populations and should be assessed

accordingly. A population-based approach can be source-specific but should include information on the variables that affect exposure characteristics, such as activity patterns 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, in which representative members of several urban populations used small personal samplers to measure individual exposure to airborne chemicals (EPA 1987a), is an example of a community-based approach to exposure assessment. Monitoring blood lead in a community's children and tracing the sources of lead is another example.

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 (if any) on actual population exposures exist. Such datadeficiencies create problems, as emphasized by Ellen Silbergeld, of 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 framework for risk management. Exposure assessment must begin to address aggregate exposure. Stimulated in part by Toxics Release Inventory reports, communities are interested not just in what a particular industrial facility exposes them to, 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.

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FINDING 3.2.2: 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, occupational 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 as a result, have not explicitly considered specific exposure conditions that might be present in minority-group communities, particular occupational settings, or areas of low socioeconomic status.

RECOMMENDATION: Risk assessments should be conducted so as to identify increased

risk to particular 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 on all known sources of exposure to a particular chemical and to related chemicals and to characterize exposure factors peculiar to particular subpopulations and link them with host susceptibility factors (see section 3.1).

RATIONALE

Increased risks of adverse health effects of contaminant exposures can result from increased doses and from increased susceptibility, which was discussed in section 3.1. Dose is a function of the concentration of a substance in the environment and the extent of exposure that a person has with the substance. Advances in the use of biologic markers will help to define relationships between exposure and dose. The following is a list of some factors that can increase risk as a result of increased exposure.

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

The Clinton Administration, the 103rd and 104th Congresses, several 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 into account health risks to children and infants associated with environmental hazards in the air, in food, and in water (EPA 1995b). That policy followed a National Research Council report that variations in dietary exposure to pesticides related to differences in food and beverage 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, 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.

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 parts of seafood 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. In contrast, 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.

Using 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 framework for risk management (section 2), calls for stakeholders to be involved in every step of the process, including evaluation of the actions taken.

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FINDING 3.2.3: 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-definition stage of the risk-management process.

RATIONALE

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/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 basis of the planning of 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 as a default 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 availability 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.

3.3

Uncertainty in Estimating Risk and Risk Reduction

The National Research Council report *Science and Judgment in Risk Assessment* (NRC 1994a) addressed the extensive uncertainty and variability associated with estimating risk and concluded that 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. The Commission concurs that qualitative descriptions of risk-related uncertainty are needed, but it does not agree that formal, quantitative uncertainty analyses are either necessary or useful for most risk assessments. When the Commission's risk-management framework is implemented, nonquantitative methods of communicating information about uncertainty to participants are likely to be more effective than quantitative methods. There are, of course, situations in which quantitative uncertainty analyses are likely to provide information that is useful in a decision-making process, and the Commission encourages the continued development and application of quantitative methods. There are also likely to be situations in which a quantitative uncertainty analysis can be used to improve qualitative information about uncertainty, even if the quantitative information is not what is communicated to the risk manager.

FINDING 3.3: The best way to present the results of a risk assessment so as to acknowledge variability and uncertainty is controversial. There is also confusion regarding the differences between variability and uncertainty. Variability comprises a population's natural heterogeneity or diversity, and it does not change through further measurement or study, although better sampling can improve knowledge about variability. Uncertainty reflects gaps in information about scientifically observable phenomena. Uncertainty sometimes can be reduced through further measurement or study. Several quantitative methods to describe risk-assessment uncertainties are being explored. Although there is general agreement as to the value of qualitative statements describing critical uncertainties in health risk assessments, formal quantitative approaches to uncertainty analysis are complex, difficult to perform, difficult to understand, and often unnecessary. Variability, in contrast, can be described much more readily and can be based on actual measurements.

RECOMMENDATION: Qualitative descriptions of the primary sources of uncertainty and the weight of the evidence associated with exposure, toxicity, and susceptibility should be included in risk characterizations intended for risk managers and the nontechnical public. Quantitative methods of describing the variability associated with exposure can yield useful information for risk management and should be included with qualitative descriptions in risk characterizations (see sections 3.2 and 5.1). However, a formal quantitative analysis of the

uncertainties in risk estimates is not needed for most risk assessments.

RATIONALE

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 and that fail to convey any sense of the confidence that the risk assessor has in the estimates or their inherent complexity. Providing a numerical range of possible risks that reflects uncertainty and variability is thought to allow more-informed and more-transparent decisions than are possible when only a single point estimate of risk is generated.

In the absence of some explanation of the weight of scientific evidence, communicating a range of population risks might be misconstrued by those unfamiliar with quantitative methods as implying that all the numbers in the range are equally likely or plausible and therefore equally valid for regulation. 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 just want to know, "Is it safe or not?" In this context, the routine provision of a distribution or range of possible risks might only confuse and delay the regulatory process.

Generating ranges or probabilistic distributions of risk estimates instead of point estimates is thought to portray more accurately the range of possible risks experienced by an exposed population. When data are scarce, assumptions about the underlying shape of the risk distribution dominate; that is, when uncertainty is great, a range of probabilities based on assumptions would replace point estimates based on assumptions. As Thomas Starr, of ENVIRON, testified before the Commission, formal uncertainty analyses are not useful if there are disagreements 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. Approximating uncertainty thus introduces yet another source of uncertainty.

A report prepared by Cambridge Environmental Inc. for the Commission, *Health Risk Assessments Prepared per the Risk Assessment Reforms under Consideration in the U.S. Congress* (see appendix A.5 for abstract), showed that when chemicals that are not known human carcinogens are evaluated, most of the uncertainty in risk estimates results from uncertainty about a substance's toxicity. The probability distributions generated to account for that kind of uncertainty can take a variety of shapes, depending on the assumptions made and the data used—for example, whether a chemical that tested positive for carcinogenicity in a rodent bioassay is or is not a human carcinogen and whether some tumor rates were reduced, not increased. Methods for quantitatively describing the uncertainties associated with toxicity are still under development.

Providing distributions of risk is thought to counteract the perceived bias toward overestimating risk that is due to a compounding of conservative default assumptions.

However, any range of a population's risks inevitably will include estimates in the upper end of the distribution that are at least as stringent as currently provided by point estimates. 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 is unlikely to lead to less-stringent regulation. If the risk-management process is perceived to be too stringent, the risk-management process, not the risk-assessment method, should be modified.

3.4

Chemical Mixtures

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 by the Commission 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 Commission's risk-management framework is implemented and experience with testing and evaluating multiple chemical risks increases, it should be feasible to move beyond fragmentation.

FINDING 3.4: 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 the toxicity of or risk associated with individual chemicals and then combine them by simple addition to estimate risk related to chemical mixtures. However, adding risks ignores potential synergistic or antagonistic interactions that could lead to underestimation 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 attendant risks should not be added, they should be considered separately.

RATIONALE

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 toxicity of the mixtures themselves can be tested and their risks characterized on that 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 the Commission 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 of tests of 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 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 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 section 3.5) 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).

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.

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. Dose is important because 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, for example, cancer incidence, 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 difference between exposures observed to cause adverse effects and actual environmental exposures is called the margin of exposure (EPA 1996) (see section 3.1.1).

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 all chemical-biological interactions are the result of reactions of many molecules at many cellular sites, a mathematical dose-response model of a response that depends on such mechanisms would have to be nonlinear at low doses. Such logic strongly suggests that any disease process that depends on such interactions is only marginally important in small exposures. 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 greater than the sum of the individual effects. For example, occupational exposure to asbestos is associated with a mortality ratio for lung cancer of 5 (that is, in comparison to persons not occupationally exposed to asbestos) and smoking with a mortality ratio for lung cancer of 10; but asbestos workers who smoke have a mortality ratio for lung cancer of 50, not 15. The risk of liver cancer risk 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, risk is not equal to the sum of the individual risks, each risk should be considered independently. 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-observed-adverse-effect levels), no effects were observed; each chemical acted independently, not additively or synergistically (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, not additivity or synergism, is the usual outcome (Falk and Kotin 1964, Schmähl et al. 1977), thereby reducing the effect expected from even a single one of those chemicals.

3.5

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, forests, or fiber, or for recreation and pleasure in the out-of-doors.

FINDING 3.5: There have been a number of attempts to develop a uniform ecological risk assessment approach. EPA's framework for evaluating ecological risk (figure 3.1) 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. Guidance for implementation of the EPA framework is needed.

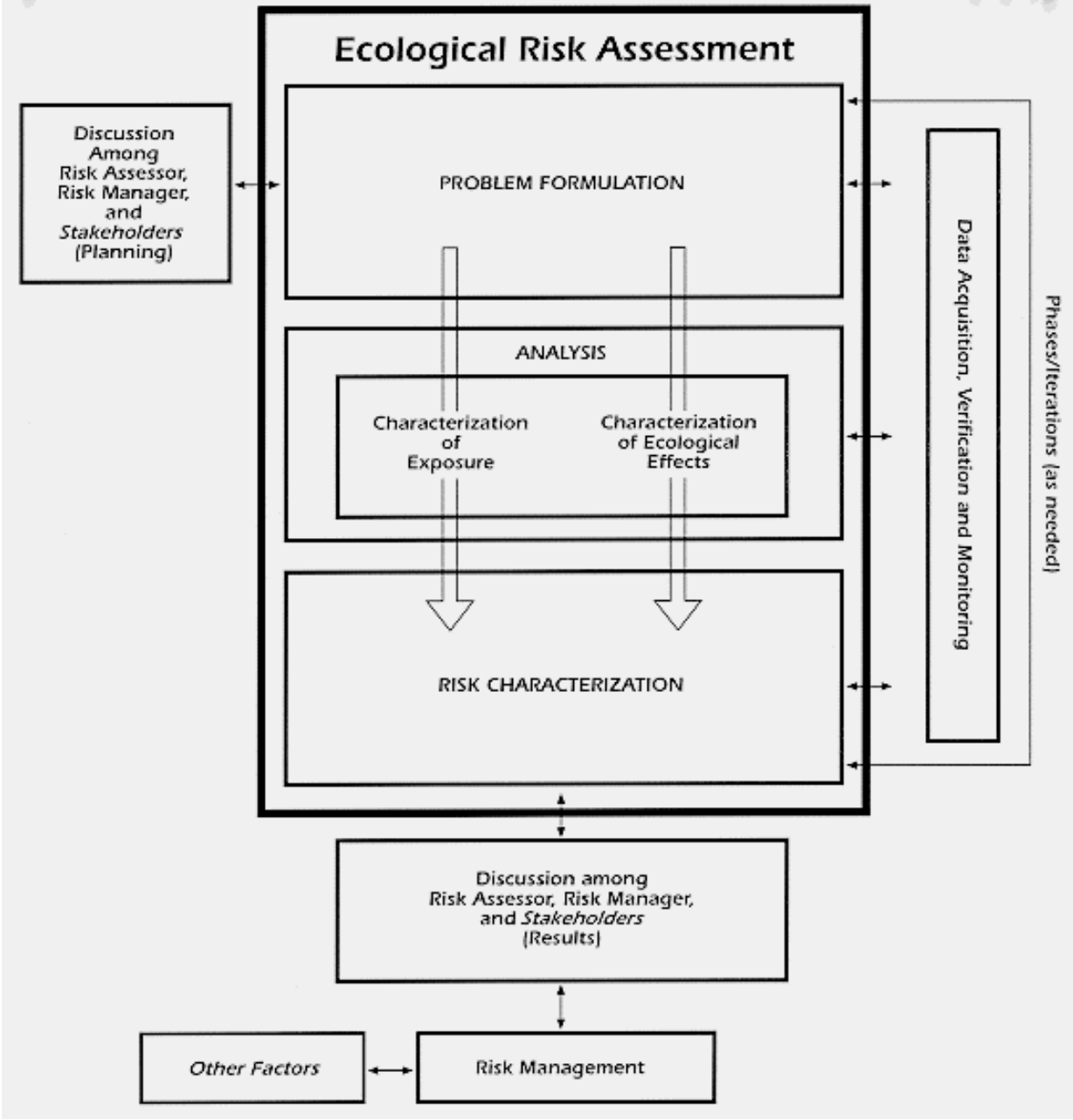
RECOMMENDATION: EPA and other agencies should continue together to implement EPA's ecological risk assessment framework. EPA and other agencies should develop clear guidance for putting various problems into context, choosing methods and tools for characterizing exposure and effects, characterizing uncertainty, and applying weight-of-evidence evaluations. For consistency with the Commission's risk-management framework, the critical addition of stakeholder involvement should be highlighted, starting with the problem-formulation stage.

RATIONALE

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 A.5 for abstract), there is a growing consensus that the EPA ecological risk-assessment framework (EPA1992b), 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.

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

Figure 3.1. EPA's framework for ecological risk assessment, modified to include stakeholders and factors in addition to risk. (Additions in italics.)



problem identification in a holistic context. 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 or potential receptors of stress, and the ways to measure the end points must be identified. Thus, this approach is consistent with the Commission's proposed framework for risk management.

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 3.1 reflects the Commission's proposal to add stakeholders, explicitly, to the participants in the problem-formulation stage of EPA's framework. Many small or well-defined assessments can be parts of established regulatory programs in which it might not be practical 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 a review of ecological risk-assessment case studies (EPA 1993), EPA concluded that the strengths and weaknesses of the studies seemed to originate, in large part, from decisions made during the problem-formulation stage. However, there is very little guidance on how this process should occur and who should be involved in it. The addition of stakeholders in this stage requires guidance from EPA on which parties to include and when and how to include them. In particular, it is important 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. Consideration of economic and legal issues will also be facilitated by the early inclusion of stakeholders. 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. An important 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, the index of biotic integrity is in use by more than 30 states in their water-quality programs. Guidance is needed on when to use it and other tools of varied complexity, such as fate and transport models, toxicity tests, and field studies for a given problem. In its 1996 report *Ecological Risk Assessment: Sound Science Makes Good Business Sense*, the American Industrial Health Council suggests 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. The Commission agrees. Because ecological risk assessments can be data intensive, guidance on when to conduct a tiered, iterative approach is needed. The intensity of data collection should be commensurate with the environmental benefits of greater certainty and the needs of stakeholders involved in the decision-making process.

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. For example, there are many sources of uncertainty in ecological risk assessment. Guidance in the use of qualitative and quantitative descriptions of uncertainty is needed. The strengths and weaknesses of the analyses must be described, together with the assumptions and uncertainties. Explicit directions and examples could greatly improve the conduct of risk characterization in ecological risk assessment.

In some cases, risk characterization is presented simply as a restatement of test results. In other cases, it is viewed as the final stage of a weight-of-evidence evaluation, a process of evaluating the underlying data and studies for accuracy, reliability, and relevance. There is no consensus on how to evaluate the weight-of-evidence in the context of ecological risk assessment or how it should be applied. The approach reflects one person's professional judgment, and the conclusions might not be transparent to others. The professional judgments that underpin weight-of-evidence evaluations should be examined and be made more explicit. Guidance in conducting both quantitative and qualitative weight-of-evidence evaluations should then be developed. The risk characterization must synthesize and provide information that can be applied to risk-management decisions, again with extensive consultation with stakeholders (figure 3.1).

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 section 6.1.3). In addition, the recently formed Office of Sustainable Ecosystems and Communities is leading an effort to focus on ecological risk assessment beyond toxic effects to individual organisms rather 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 ecological risk-assessment framework must be refined as agencies gain experience with its application to include biological, physical, and social stressors if it is to assist in addressing 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 while the development of the paradigm is still in its infancy in the United States and abroad. As the Organization for Economic Cooperation and Development noted in its report *Environmental Performance Review of the 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.

3.6

Radiation Risks and Microbial Risks

Public concern about risks associated with radioactive-waste disposal, recent large-scale outbreaks of serious disease from microorganisms such as *Cryptosporidium* in drinking water, and disasters from natural hazards such as floods, earthquakes, and hurricanes, are reminders that chemicals do not constitute the only environmental threats to public health. In many situations, people (and ecosystems) are exposed to combinations of radiation, chemicals, and infectious agents—a mixtures problem (see section 3.3). In many others, comparisons and tradeoffs among types of risk are necessary (for example, risks associated with byproducts of drinking-water disinfection versus those associated with microorganisms contaminating drinking water). Concurrent chemical, radiation, and microbial exposures will have to be evaluated in some situations when the risk-management framework is implemented.

It is surprising that environmental protection seems to be focused so predominantly on chemicals and so little on ionizing radiation and microorganisms. There is no doubt about the many serious health effects of exposure to radiation and microorganisms, whereas the effects of many regulated chemicals are of uncertain importance for humans. 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, in view of the public outrage that is rightly engendered by the deaths and other effects caused by microbial contamination of food, such as the recent, toxic *E. coli* contamination of under-cooked hamburger. The public-health consequences of exposing patients and workers to ionizing radiation and of exposing the general population to infectious agents are so well established that they might be 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. 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 a deep concern about our country's ability to manage its radiation hazards and particularly the anticipated decommissioning of nuclear power plants at the end of their useful lives.

FINDING 3.6.1: 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 for Radiation Protection and Measurement and the International Council for Radiation Protection; lead agencies are the Nuclear Regulatory Commission, Department of Energy, EPA Office of Air and Radiation, and FDA Division of Radiological Health. Scientists and regulators dealing with chemical hazards or with radiation hazards have been remarkably independent of each other and have given little attention to medical, industrial,

disposal, nuclear power, and nuclear weapons production settings when radiation exposures and chemical contamination co-exist.

RECOMMENDATION: A concerted effort should be made to relate the methods, assumptions, mechanisms, and standards for radiation risks to those for chemicals, to enhance the comparability of risk-management decisions and investments.

RATIONALE

The radiation-protection literature began with devastating accounts of early neglect of the health hazards of a new technology—the use of Roentgen rays (x rays), discovered in 1895 and immediately introduced into medical practice. Pioneering scientists and workers developed internal cancers and radiation burns of the skin. Radiation can affect genes, chromosomes, cell survival, and regeneration of rapid turnover tissues. The skin, bone marrow, intestine, oocytes, spermatogonia, lens, and respiratory tract are most typically affected.

Natural sources of ionizing radiation include cosmic rays; radium and other radioactive elements in the earth's crust; internally deposited 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 inhaled 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 polonium-210—another decay product of radium—in tobacco at up to 0.2 Sv/year, or 20 rems/year.

There appears to be a disparity between the levels of risk that are considered negligible for radiation exposures and those considered negligible for chemical exposures. In the case of chemicals, exposure limits are generally set to keep incremental upper-bound lifetime cancer risks for workers below one per thousand and for the general population below a range of one per 10,000 to one per million. In the case of radiation, the current occupational exposure limit is a whole-body-equivalent external dose of 50 mSv/year or 5 rems/year (10CFR20, 1990 revisions), which is equivalent to a lifetime cancer risk of more than one in ten, assuming a linear dose-response relationship (Upton 1996). That risk is far above those associated with lifetime exposure to chemical carcinogens at the level of their occupational standards. However, radiation-exposed workers are constantly monitored and large exposures are detected almost immediately and corrected. Health physicists have assured us that protective actions and the application of ALARA (as low as reasonably achievable) workplace practices lead to actual exposures for workers that are much smaller than occupational standards. Monitoring and job change lead to similarly lower actual exposures for chemically exposed workers.

The limit for unrestricted radiation exposure of a member of the public is now set at 1 mSv/year effective dose equivalent (100 mrems), only one fiftieth of the occupational exposure limit. In contrast, the difference between occupational and general population exposure limits for chemicals is usually much greater than a factor of 50.

FINDING 3.6.2: Methods for anticipating and assessing microbial hazards on a population basis (versus a clinical basis) are less developed than those for chemicals or for radiation; microbial risks generally are not evaluated using the dose-response modeling techniques used to evaluate chemical and radiation risks.

RECOMMENDATION: Refinement and application of epidemiologically based and other types of risk assessment methods for microbiologic hazards, and the collection of data and monitoring to validate and support those methods, should be encouraged.

RATIONALE

The emergence and resurgence of infectious agents ranging from the HIV-AIDS and Ebola viruses to tuberculosis mycobacteria, and the importance of antibiotic resistance mechanisms as a result of medical and veterinary overuse of antibiotics, have revived interest in the public-health aspects of infectious diseases. As seen in recent outbreaks of diarrhea caused by *Cryptosporidium* in Milwaukee's drinking water and of kidney failure in children caused by *E. coli*-contaminated hamburger meat in Seattle, our inability to assess health risks associated with microorganisms and inattention to risk reduction can lead to disaster. Those deaths, unlike theoretical low-dose cancer risks, are observable and countable. However, as with chemicals, most exposures to pathogens are below those associated with death or disease, because the body has effective defense mechanisms, so long as white blood cell and immune systems are intact. Empirical studies usually cannot produce sufficient information to assess a dose-response relationship in people, so methods for microbial risk assessment 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). Variation in susceptibility should be an important and specifiable aspect of infectious-disease risk assessments.

Models for assessing microbial risks include static models based on individual risks and population-based models that account for changes over time (Haas 1983, Haas et al. 1993, Eisenberg et al. 1996a,b). However, such epidemiologic factors as secondary spread of waterborne microorganisms, the effects of such host factors as the development of immunity, and the risk of death or disease resulting from bacterial contamination of meat at the slaughterhouse or from infected food handlers cannot be described fully with traditional dose-response modeling techniques. Static and dynamic models have complementary attributes, and different microbial-risk problems are likely to require different methods or combinations of methods.

A systematic examination of the applicability of existing models and of the need for new

models to assess microbial risks is needed. Monitoring and the collection of data on the characteristics of microorganism behavior, toxicity, dose-response relationships, and risks comparable with data on chemical hazards are also essential. (See discussions of risk associated with waterborne microorganisms in section 6.1.4 and of risks associated with food-related pathogens in section 6.4). The International Life Sciences Institute recently convened a working group that is seeking an appropriate risk-assessment paradigm for microorganisms in drinking water and defining the important data gaps and research needs.

4

Uses and Limitations of Economic Analysis in Regulatory Decision-Making

The regulatory-reform debate in the 104th Congress has 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 how and to what extent regulatory decisions are determined by economic considerations remains controversial.

Risk-assessment results can be used as the basis for estimating costs and benefits for the purpose of economic analysis, and the results of both risk assessment and economic analysis can contribute to or possibly even determine a regulatory decision. Both risk assessments and regulatory analyses can help improve risk management decisions. However, risk assessment and economic analysis can involve large investments of resources and multiple assumptions, 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 it was not explicitly mandated to do so. The Commission relied on an invited issue paper by Alan Krupnick, Michael Toman, and Ray Kopp of Resources for the Future (see appendix A.5 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.

4.1

Benefit-Cost Analysis and Cost-Effectiveness Analysis

This section briefly addresses the role of benefit-cost analysis (BCA) and cost-effectiveness analysis (CEA) (hereafter referred to as "economic analysis") in regulatory decision-making. Some health and environmental statutes requirethe 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 and 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.

FINDING 4.1.1: The role of economic analysis in regulatory decision-making is controversial. There is a concern that economic analysis places too much emphasis on assigning dollar values to aspects of health and the environment, which are difficult, if not impossible, to quantify and there is also a 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 cannot be assigned monetary values should be addressed and considered explicitly. Assumptions should be specified.

RATIONALE

Economic analysis plays an important role in our risk-management framework (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 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 goals and objectives of the tools of economic analysis differ. In cost-effectiveness analysis, which is a particular form of benefit-cost analysis, one of several options that achieves a

specified regulatory goal with the smallest loss in overall social well-being is selected (while acknowledging that costs and benefits might be inequitably distributed; see section 4.1.2). CEA begins with an assumed goal and then explores the methods that could achieve that goal to identify the least-costly one. 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 all of which are expected to attain the 0.1-ppm standard but use different approaches which give rise to different costs.

CEA also can be applied to assess the relative cost of 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.

BCA has a different role: it can be used to 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	50	150	100	0.2
5 ppm	990	40	500	350	9
1 ppm	999	9	2000	1500	170

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, and that it is possible, in principle, to infer how much people will give up to gain

environmental improvements. In this hypothetical example, if economic analysis indicated that the public were willing to pay up to $5 million per averted health effect, the "efficient" standard would be between 5 and 20 ppm. This approach might be rejected if willingness-to-pay is unknown, BCA is considered inapplicable, or benefits are nonquantifiable. 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, guided by what members of society are thought to be willing to pay to reduce risk, it can be used to help make choices among policies and actions with quite different benefits and costs. It is no small challenge to compare, for example, costs and benefits of reducing lead derived from paint contamination in houses with those ambient of ozone reduction. Thus, BCA applied in a strict quantitative sense can be used only to the extent that costs and benefits can be monetized. 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 who bears the costs of the policy so, for example, it does not explicitly weigh

consequences by income category or ethnic group.[1]

A benefit of CEA, in contrast, is that it does not require monetized benefits (although they can be monetized when appropriate).[2] 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. There is, however, a problem with CEA that its proponents sometimes overlook. If a proposed program has more than one favorable effect—for example, it saves lives, reduces illness, and provides ecological or aesthetic benefits—it is difficult, if not impossible, to compare it to other proposed programs on the basis of cost per one of the beneficial effects. If the other favorable effects can be monetized and subtracted from the costs, then a net cost-per-life-saved calculation could be made. By the same token, an estimate of the net costs of ecological or aesthetic benefits can be made by deducting estimates of reduced morbidity and mortality risk.

Despite its limitations, BCA can provide useful information to help to 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. As the recent report *Benefit-Cost Analysis in Environmental, Health, and Safety Regulation* put it, "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). But because estimates of costs and benefits are uncertain, BCA cannot be used to "prove" that the benefits of a policy outweigh its costs, nor should it be used as the only basis of a decision. However, providing information about the costs and benefits associated with a regulatory decision serves the public interest and, in fact, is mandated in the unfunded mandates reform act and 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 costs and benefits that can be quantified but also identify those which are less quantifiable. A clear rationale should be provided for a regulatory decision based on both quantifiable and nonquantifiable elements. All economic analyses should include explicit information about the assumptions and uncertainties that underlie estimates of costs and benefits.

✳ ✳ ✳

[1]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 (see issue 4.4).

[2]If benefits are not monetized, they cannot be aggregated, which is an advantage of using a money metric.

FINDING 4.1.2: 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.

RATIONALE

CBAs generally do 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 poor people and increases the welfare of rich people, but the rich people's gain outweighs the poor people's loss, CBA would show the policy to lead to an improvement in aggregate social welfare while acknowledging the disproportionate or inequitable distributions of costs and benefits. For example, cutbacks in spending for abatement or control of lead-based paint might put poor people at greater risk for lead toxicity but result in lower taxes for rich people.

CBAs need not incorporate equity considerations quantitatively, however. Deciding how different groups should be weighted for equity in economic analysis would be highly value-laden. No objectively correct weightings can be substantiated. However, if groups or individuals within a societal group potentially affected by a policy are likely to feel the impact differently, they can be identified, and that information can be communicated to risk managers or regulatory decision-makers and considered as policies are formulated.

Human-health risk assessments often consider especially susceptible population groups (see sections 3.1 and 3.2). For example, a risk assessment might give children or pregnant women special consideration because they can suffer the adverse effects of toxicant exposure to a greater degree than the general population. Quantifying that special susceptibility and deciding how it should be reflected in standard-setting is usually highly subjective. But regulators have to recognize and identify the extent of protection for relevant subpopulations.

By analogy, identifying particular population segments that will no longer be able to afford particular fruits or vegetables because of a policy that reduces permissible pesticide residues, for example, while identifying other population segments whose health risks from pesticides are reduced because of that policy but that can afford to continue to buy those fruits and vegetables should be relatively straightforward. Evaluating such differences quantitatively would be problematic, but revealing them qualitatively would provide important information that could be considered in the regulatory decision.

4.2

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 reflects, in part, the uncertainty associated with valuing such a quantity.

FINDING 4.2.1: 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 data are available, relevant, and reasonably precise, but they 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, communicated clearly, and quantified where appropriate. The results of economic analyses should not be expressed as though they are precise measures of actual economic costs and benefits.

RATIONALE

As inputs to economic analysis, the results of health risk assessments contribute a large degree of uncertainty. The uncertainty associated with an upper-bound point estimate of individual risk 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 in section 4.3.

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 whose degradation people would be willing to pay to avoid. 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") and because "they are there" ("non use value"); quantitative estimates of value in both cases can be highly variable and often controversial.

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 and possibly biased information, which might tend to overestimate or underestimate costs. The Office of Technology Assessment (1995) evaluated a variety of examples that illustrated 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, costs are initially overestimated, not underestimated, according to MIT Professor Nicholas Ashford's testimony to the Commission, 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 rule-makings 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 included large volumes of lower-risk materials inadvertently; as compared to EPA's estimate, the regulation of those materials under the rule substantially increased the actual costs of the rule.

The assumptions upon which economic analysis is based are associated with many sources of uncertainty, so it is misleading to express the results of economic analyses as single quantitative estimates of costs or benefits. Results of analyses should often include more than single estimates of costs and benefits, expressed in a manner that reflects their inherent uncertainty. In some cases, probabilistic techniques can provide a sense of the distribution of possible outcomes. In other cases, it might be possible to assess only a few alternative scenarios with some qualitative information about their relative plausibility. In all cases, however, it is essential to identify the primary sources of uncertainty.

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FINDING 4.2.2: 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. The development of federal guidelines for benefit valuation involving stakeholder input should be considered.

RATIONALE

Although a succession of 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 a death risk reduction (or "statistical life" saved) or to establish a basis for evaluating estimates of the cost statistical life saved associated with a policy option. As a result, under current guidance, agencies may choose not to value death risks (or "lives") explicitly or choose not to subject their regulations to comparison with a benchmark for cost effectiveness.

That kind of valuation inconsistency takes several forms, including whether an analysis even includes explicit values for death risk reductions, how such values are incorporated, and what values are chosen. For agencies that 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 over $50 million per life saved. The 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. 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 carcinogenic test strategies (Lave et al. 1988, Omenn and Lave 1986, Omenn et al. 1995).

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. "Best estimates"[3] can be devised within an

[3]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 A.5). However, to economists, best estimate is a well-defined and accepted concept, referring to central tendency or expected value.

interagency process that takes into account consensus and the range of uncertainty around published values, including the comparability of various types of risks. Government and private resources are less likely to be wasted when agency rule-making consistently reduces death risks at costs that reflect the value of the risk reduction. Explicit valuation of reductions in death risks also makes it easier to compare regulatory alternatives when expected benefits are nonquantifiable.

4.3

Linking Risk Assessment and Economic Analysis

Implementing the Commission's risk-management framework and using information on both risks and economics to make decisions require some consistency between risk-related 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. This section highlights some of the incompatible and contradictory approaches that will have to be reconciled if risk assessment and economic analysis are to be used together to support effective risk-management decision-making.

FINDING 4.3.1: 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 should collaborate more to minimize 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.

RATIONALE

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 needs of economists who are asked, at least implicitly, to provide information on individual preferences for avoiding health risks. For example, a 10% improvement in lung function is not meaningful to most 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% improvement in lung function. In addition, adverse effects other than cancer are generally regulated by comparing a chemical's exposure concentration to its standard, or "safe," concentration, not by calculating an estimate of risk based on probability (such as 10^{-6}). Economists have not yet developed methods for evaluating risks that are not expressed as probabilities. Closer collaboration between economists who are familiar with the valuation literature and scientists who are estimating concentration-response functions could help to avoid such mismatches and perhaps lead to the development of new methods, by seeking end points that can be evaluated in terms of both their risk and their economic value.

Another conflict between the needs of economists and the results of risk assessments is that health risk assessments generally focus on individual risk estimates rather than population risk

estimates. Economic analysis focuses on estimating 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 (hypothetical "maximally reasonably exposed") person. 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. 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 when there is uncertainty about aspects of 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 BCA standard practice, an analyst attempts to describe the distribution of risks (or the distribution of risk reductions) in the population and leaves it to a decision-maker to decide what is an acceptable level of protection and which strategies deliver that level of protection. Current trends away from expressing risk-assessment results in terms of upper-bound point estimates and instead using distributions of risks might overcome this inconsistency and should be pursued further.

Finally, inconsistency can result from the tendency of risk assessment to rely more on expert opinion and the tendency of economic analysis to rely more on the perceptions of nontechnical people. An economist's job is to characterize individual preferences for products or activities associated with risks where those preferences are conditional on individual risk perceptions; economic estimates of damages are based on individuals' willingness to pay to avoid risks. Individual risk perceptions are often inconsistent with expert opinion (see section 5.1), so using one as the basis for evaluating the other is also inconsistent. Resolving these inconsistencies will require judgments regarding the appropriate weighting of the opinions of experts and of informed, nonexpert people.

The use of margins of exposure by EPA to compare cancer and noncancer risks (see section 3.1 and 5.1) has been criticized as being unsuited to economists' needs for specified, extrapolatable (but not necessarily linear) dose-response curves down to very small exposures. That problem has always existed for any effect thought to exhibit a threshold, no effect below a particular dose. Putting aside the issue of defining that threshold, economists could use their "willingness-to-pay" methods to put values on the range of margins of exposure. 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 5.1 to guide assessment of the amount of risk reduction gained as exposure levels were reduced progressively.

5

Risk Management and Regulatory Decision-Making

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

This section examines some of the issues that have arisen as the use of risk assessment in regulatory decision-making has evolved and matured. Characterizing risk and communicating information about risks to affected parties have become complex and confusing. Decisions about how to allocate resources to reduce risks can be made partly on the basis of risk comparisons. The use of "bright lines", benchmarks to distinguish negligible from unacceptable risks, has led to questions about what those lines should be, who should decide what they should be, and which situations they should be applied to. Moving from command-and-control regulation to nonregulatory approaches to risk reduction can increase both efficiency and effectiveness. Peer review of the technical, scientific, and economic information that underlies risk-management decisions can help ensure reasonable, supportable decisions. Judicial review is a common element in major regulatory actions. This section offers recommendations on each of those issues in the hope of contributing to the evolution and improvement of risk-based decision-making.

5.1

Risk Characterization: Communicating and Comparing Risks

Risk communication engages both the communicator and the audience in listening and in explaining information and opinions. Effective risk communication requires effective risk characterization. Risks have sometimes been communicated to the nontechnical public as single numerical estimates, which are easily misinterpreted and misused. Effective risk communication must involve much more than numeric estimates. Risk communication should include clear messages about the nature, severity, and likelihood of risk and other messages, not strictly about risk, that express concerns, opinions, or reactions to risk messages (NRC 1989). Congress has considered various proposals to increase the transparency of risk assessments and to require the use of risk comparisons. Transparency is generally equated with revealing and characterizing the assumptions, uncertainties, default factors, and methods used to estimate risks. Requiring risk comparisons would compel agencies to compare a risk to be regulated with other risks also regulated by the agency and other risks experienced by the public. This section discusses communicating about risk in the risk characterization stage of the risk assessment and other risk communications with the public, including the use of risk comparisons. Section 5.2 discusses comparative risk assessment for risk management, the process of comparing and ranking risks to identify priorities and make resource allocations.

FINDING 5.1.1: Risk characterization is the primary vehicle for communicating health risk-assessment findings. Many risk characterizations have relied primarily on quantitative estimates of risk to communicate risk-assessment findings. Often they convey an unwarranted sense of precision while failing to convey the range of scientific opinion. They are particularly difficult for nontechnical audiences to comprehend. 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, effective risk management is impeded. Risk management is also complicated by the question of how much information is enough. A practical process is needed for determining when risks have been sufficiently well characterized to reach a decision and to justify it.

RECOMMENDATION: Risk characterizations must include information that is useful for all parties participating in a risk-management decision-making process. Quantitative estimates of risk are important and should be included, but qualitative information on the nature of adverse effects 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. During the problem-formulation stage of a risk-management process, participants should agree on criteria for the

value of acquiring additional information so that endless data-gathering does not become primarily an instrument for delaying or obstructing a decision or increasing costs.

RATIONALE

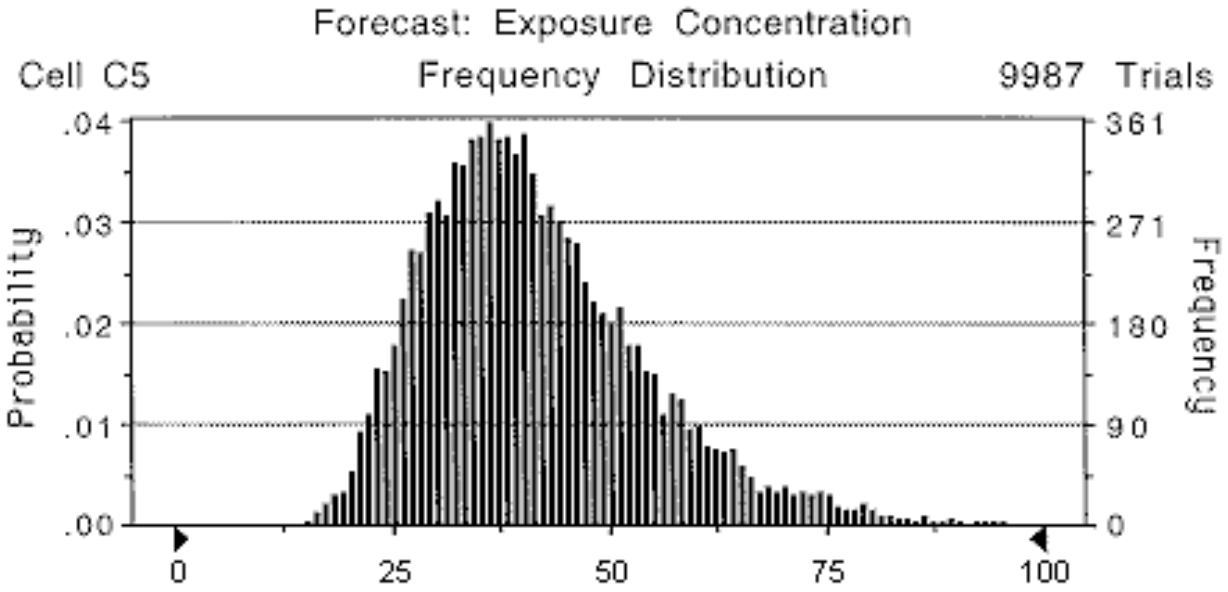
Risk assessment is an uncertain process that requires both scientific data and science-based assumptions. Risk assessments are conducted to infer risks below the range of observable events in people or in studies of laboratory animals. For example, 10-100% of laboratory animals exposed to a relatively 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 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 3-1). 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 they are not expressed as numerical risk estimates. Noncancer risk is determined by comparing a human exposure to a dose that is considered to be a "safe" standard concentration; that is, exposure to a dose below that standard is considered unlikely to present any risk and exposure just above that standard might be less safe. The quantitative likelihood that adverse effects will occur at exposures above the standard but below exposures observed to cause adverse effects is generally not known. Using a margin-of-exposure approach to cancer risk assessment instead of current methods would result in similar nonprobabilistic expressions of risk (see section 3.1).

More useful and understandable than speculative quantitative estimates of risk is qualitative information. Qualitative information includes 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 also includes 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. The discussion might conclude that because the weight of the scientific evidence supports the substance's classification, the agency has chosen to regulate it as a carcinogen in the interest of protecting public health. 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.

As discussed in section 3.3 on uncertainty, communicating a range or distribution of risks reflecting uncertainty is likely to be perplexing to risk managers or nontechnical stakeholders, who often want to know from technical staff whether an exposure is safe or unsafe. There will be complex risk questions that require complex quantitative analysis, but today many risk-management issues are unlikely to be illuminated by intricate quantitative analyses of uncertainty. Federal and state contractors have told the Commission that when they perform comprehensive quantitative analyses of risk-related uncertainty or variability, they are ignored or misunderstood. Of course, as quantitative methods to describe uncertainty and stakeholders' understanding and perceptions of uncertainty and risk evolve and mature, quantitative uncertainty analysis might well attain more general usefulness. Meanwhile, resources would be better 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."

In contrast, as discussed in section 3.2, we believe that using distributions to reflect the variability in a population's exposure characteristics can be useful now. Nontechnical stakeholders will certainly 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 toxicity standards could be compared to a distribution of a population's exposures like the following, derived using Monte Carlo techniques and exposure data from a hazardous-waste site.



(μg/m^3)

If the concentration of a chemical associated with a 10^{-5} cancer risk were 80 $\mu g/m^3$, for example, the risk manager and other decision-makers would see that most of the population is exposed to less than that concentration. The participants might decide that there is no 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 segment. If the concentration of concern were 20 $\mu g/m^3$, participants would see that most of the population is exposed to concentrations exceeding that, 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 toxicity standards conveys information that is more useful for decision-making than a single point estimate of risk or a hazard index. 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 discussion of bright lines in section 5.3) also conveys information to a risk manager that is less complex than a distribution of risks. In contrast with estimated risk levels, exposure standards are concentrations that can be measured; measurements facilitate implementation, evaluation, and compliance. The risk manager and the public can see clearly what the relationship between a protective exposure standard and a particular population's or subpopulation's exposure is likely to be. That information can be used to make decisions about the need for exposure or risk reduction that can be directed at those who are likely to need it most.

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 would probably 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. Ellen Silbergeld, representing the Environmental Defense Fund, emphasized in her testimony before the Commission that the greatest barrier to credible risk assessment is the absence of data and that if an iterative approach to risk assessment is required, guidelines are needed for deciding how much information is enough to conclude the process and support a decision. Likewise, Warner North, of Decision Focus, Inc., recommended both incentives for data collection and incentives for speedy risk-management decisions. At some point, continuing to collect and refine will yield considerably diminished returns with respect to improved risk estimation but could effectively stall a risk-management decision that would require capital investment on the part of the facility owner. Before the risk-management decision-making process proceeds, therefore, preferably in the problem-formulation stage, criteria must be established for determining what constitutes enough information. The nature of

the criteria will probably be controversial, but some controversy at the beginning of the process is better than a lot of controversy at the end.

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FINDING 5.1.2: Stories abound of misunderstandings about risks and risk-reduction proposals. We know very little about how to ensure effective risk communication that gains the confidence of stakeholders, incorporates their views and knowledge, and influences favorably the acceptability of risk assessments and risk-management decisions.

RECOMMENDATION: Regulatory agencies should adopt comprehensive risk-communication programs that emphasize both the learning and explaining activities of communication, 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.

RATIONALE

The Commission's risk-management framework (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 that 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 technical and nontechnical 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. 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 A.5 for abstract). Our discussion here is not comprehensive; rather, it is intended to indicate the importance of effective risk communication and the potential for mistakes and misunderstandings.

Risk-communication research suggests that people interpret and use new information in the context of their existing beliefs. People need a basic understanding of the exposure, effects, and mitigation processes relevant to making decisions about a hazardous process. Responding to 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 is a two-way street, however—it means both listening and speaking. Risk communicators should learn about the concerns and values of their audience, their relevant knowledge, and their experience with risk issues. Stakeholders might have knowledge of sources and patterns of exposure that risk assessors do not have. That knowledge needs to be integrated

into a risk assessment and risk management. 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. 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, and not just 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 Superfund program and the Department of Energy. Many corporations work continuously with citizen advisory panels in their communities. For example, in his testimony to the Commission, a representative of Rohm & Haas Company, noted that the citizen advisory panels that the company works with give it a better understanding of the questions and concerns of the community and an opportunity to test its risk-communication messages before using them with the general public. Not all citizen advisory panels develop a trusting relationship with the company they are advising or are trusted by the community of which they are a part.

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. 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, such as 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). A forthcoming Research Council report from the Committee on Risk Characterization also will address the role of stakeholders, especially the public.

The art of risk communication is moving from trying to explain risk information to citizens to a building of 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 considered cleaner and 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.

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FINDING 5.1.3: 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 and should compare risks associated 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. The margin-of-exposure approach (see section 3.1.1) can be applied to such comparisons across similar and different types of adverse health effects.

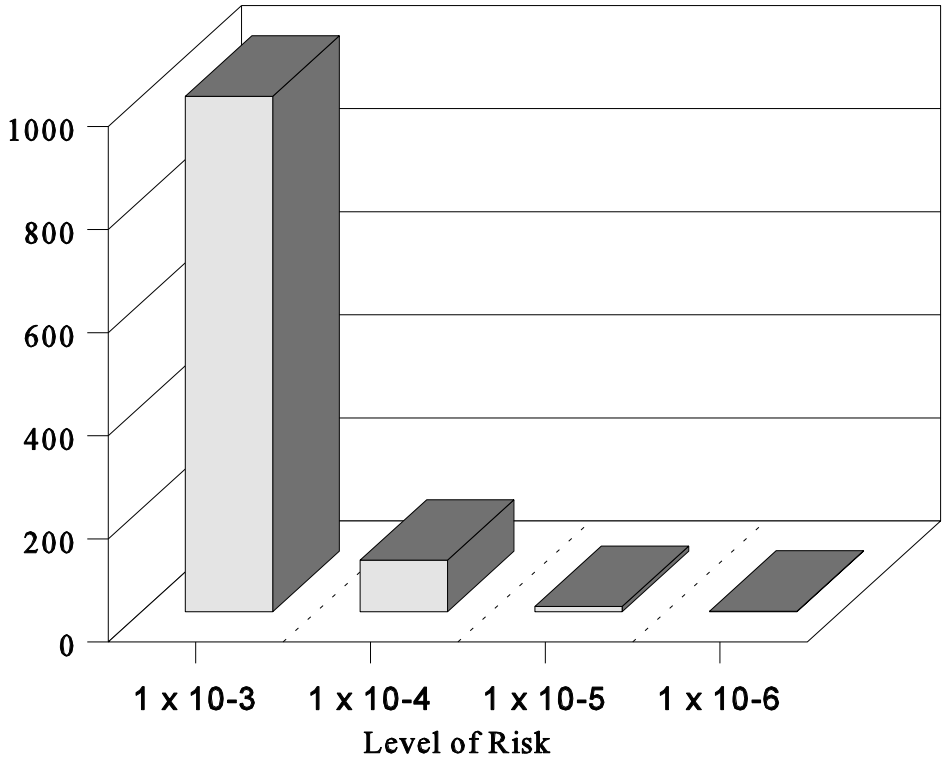
RATIONALE

Risk comparisons can be of many kinds. At the simple end of the spectrum are comparisons of magnitude, such as a one-in-a-million cancer risk compared with the 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 moter-vehicle exhaust and from broiled meat; comparisons of different agents with the same exposure pathway, such as carcinogenic components of natural foods and synthetic additives in food; and comparisons of different agents that produce similar effects, such as the risk of lung cancer from radon inhalation and from smoking a particular number of cigarettes. Toward the complex end, multiple risks are compared across a variety of dimensions, such as the hazards of different energy-producing or Superfund cleanup technologies to the public, workers, and ecosystems.

In general, risk comparisons can help people to comprehend probabilities or magnitudes. Most people, including physicians, often cannot 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 an order of magnitude as though it were a linear reduction. A better way to illustrate orders of magnitude of risk reduction is shown in Figure 5.1, in which a bar graph depicts better than words that a reduction in risk from one in a 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%. The percent of the risk that is reduced.

Figure 5.1 Reducing risk by orders of magnitude is *not* equivalent to linear reductions.



by reducing emissions and exposures is a much easier concept to communicate than reductions expressed in terms of estimated 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. 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. in press). The city of Columbus, Ohio, did an analysis indicating 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 as numbers of events in an actural exposed community or on an annual basis, not just 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, to which 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 risks of diverse character, especially when the intent of the comparison is seen as minimizing a risk (NRC 1989). One difficulty in using risk comparisons is that 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 have often been either confusing or irritating because they were seen as unfair or manipulative. Research on risk perception has suggested that directly comparing voluntary and involuntary risks or natural and technologic risks does not improve understanding of risks. However, 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.

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

5.2

Comparative Risk Assessment for Risk Management

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 have recommended comparative risk-assessment approaches for priority-setting.[1] The comparative-risk process includes a variety of tasks, from 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. Most of the comparative-risk projects for priority-setting have been initiated by state, local and tribal governments and typically by one or more of the environmental protection, natural-resource, or health agencies. Our recommendation here is directed at federal agencies.

FINDING 5.2: 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. State, local, and tribal comparative-risk projects have been useful in addressing such mismatches and in refining the comparative risk process to better manage risks.

RECOMMENDATION: Agencies should use a comparative-risk assessment approach for risk-management on an experimental or demonstration basis to test the effectiveness of seeking consensus on setting priorities for environment, health, and safety hazards. The priorities, reflecting diverse stakeholder values and opinions, should influence agency resource-allocation decisions.

RATIONALE

The Environmental Protection Agency (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* (SAB

[1] Section 5.1 of this report considers comparisons of specific risks for the purpose of communicating about risk.

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 would be supported widely. 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 might have been more successful in influencing agency priorities and resource allocations. Unfortunately, Congressional proposals to institute comparative risk assessment reports by federal agencies along with appropriate adjustments in budget requests have not reflected the experience and enhanced understanding of the role of public values in priority-setting gained from the state, local, and tribal comparative risk assessment for risk management projects.

Comparative risk assessment 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 that use graphics in a shared decision-making process, decision-seeking consensus, and bargaining or tradeoffs among stakeholders. That approach to comparative risk assessment 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 Congressional staff of authorizing committees of Congress for state and local representatives and can identify as participants internal agency and affected stakeholders 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.

Benefits other than priority-setting often justify putting time and effort into the comparative-risk assessment process for priority-setting (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. In fact, Charles Kleeburg, director of the Seattle Drainage and Wastewater Utility, explained to the Commission that the city's success in forging consensus on 10 priority problems that were acted on by the city government was a direct result of the influence and effectiveness of the comparative risk assessment process. 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 told by Congress to address.

There are a number of challenges to and limitations to the usefulness of the process as pointed out by Patricia Buffler and Carl Craner, in their testimony before the Commission about the California Comparative Risk Project. For example, there is no guarantee that the process will produce consensus among stakeholders, agencies, and funding authorities. Resolving inconsistent data across problems, forcing all risks into a common measurement, and integrating problems into a single list are important methodologic challenges. The degree of uncertainty varies across problems, making comparisons 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 federal agencies, there may be additional problems of having to propose changes to statutory mandates when priorities for resources change and the difficulty 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 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 testing how well identification, analysis, and comparison of risks and remedies can be translated into budget decisions. The Commission encourages federal regulatory agencies to use comparative risk for priority-setting on an experimental or demonstration basis.

5.3

Bright Lines

A "bright line" is a single numerical value between unacceptable and negligible magnitudes of risk or exposure concentrations of concern. Bright lines are chosen to provide pragmatic definitions of "safe" and "unsafe" for those making risk-management decisions and for those implementing or enforcing decisions. An example of a bright line is an excess-cancer risk of about 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 is judged unacceptable and protective action is required; a predicted risk of less than 10^{-5} is considered negligible and requires no protective action. Risk-based decisions are generally converted to measurable exposure or emission limits for implementation and compliance. Regulated parties are expected to demonstrate that estimated exposures or risks are below the bright line to operate a manufacturing facility, introduce a new product to the market, or sell foods with low concentrations of contaminants.

Bright lines are generally used with single point estimates of risk to judge safety; *Science and Judgment in Risk Assessment* characterizes bright lines and point estimates of risk as "magic numbers" whose use is inconsistent with knowledge about the distributions of risk and their inherent uncertainty (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. Bright lines that are health-based standards provide useful goals, however, to guide a decision-making process.

FINDING 5.3: Risk managers have often relied on clearly demarcated bright lines, defining boundaries between unacceptable and negligible exposures or risks, to guide their decisions. Congress has occasionally sought to include specified bright lines for risk in legislation. However, 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, all of which is required by the Commission's risk-management framework.

RECOMMENDATION: Bright lines or ranges of bright lines should be used as guideposts or goals for decision-making but should not be applied inflexibly. In addition to bright lines intended to protect the general population, bright lines to protect especially susceptible subpopulations—such as young children, pregnant women, or adults with lung disease—should be considered. Congress should leave the establishment of specific bright lines or ranges of bright lines to the regulatory agencies.

RATIONALE

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

There are several potential problems in the use of specified bright lines. Bright lines are burdened by all the uncertainty, variability, and assumptions inherent in risk estimation; thus, 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. 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. Implementing the Commission's risk-management framework will require the consideration of bright lines as a source of information about risk that is useful in the decision-making process, but they would not be the sole determinants of the outcome of that process. Roger Pryor, executive director of the Missouri Coalition for the Environment, testified before the Commission that although bright-line standards should be established on the basis of health considerations, other factors, such as cost and the role of cultural differences, should also play a role in risk-management decisions.

Congress has included bright-line risk provisions in several legislative bills in recent years. Not until the 1990 Clean Air Act Amendments, however, did Congress pass legislation specifying a quantitative risk, 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}.

Bright lines have been well established by regulatory policy despite their absence in legislation. For example, the Food and Drug Administration regulates intentional and unintentional additives in food by calculating an "estimated daily intake" and comparing that value to a previously established "acceptable daily intake". When the ratio exceeds 1.0, the agency considers the exposure unacceptable (Flamm and Lorentzen 1988). Noncancer health effects are evaluated similarly under Superfund; contaminant doses are compared to bright-line values called reference doses. If the ratio is less than 1.0, adverse effects are considered unlikely, and no action is required.

Ranges of bright lines have also 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.

In addition to ranges of bright lines, multiple bright lines should be considered. For example, section 3.1.3 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.

Bright lines expressed as contaminant concentrations are easier to implement than bright lines expressed as risks.[1] Although concentration-based bright lines are derived from some judgment about what exposure constitutes negligible risk (or, in some cases, technologic feasibility), risk managers or compliance officers can easily determine whether they are being adhered to because concentrations can be measured. When bright lines are expressed as risks, uncertain and variable risk estimates must be compared to determine compliance. Comparing risks will become even more difficult as distributional approaches to risk estimation are implemented.

[1]Examples of bright lines based on contaminant concentrations are maximum contaminant levels (MCLs) for drinking water, which, although derived from some estimate of risk, can be easily measured and therefore enforced. Expressing MCLs in terms of risk would be more difficult to enforce because risks would have to be estimated from contaminant concentrations and other variables at each drinking-water source; this would be a cumbersome and uncertain way to determine compliance.

5.4

Alternatives to Command-and-Control Regulation

In the last quarter-century, the United States has made extraordinary progress in 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 and enforcement that has established a floor for environmental protection.

In some cases, OSHA may be an exception, we may have reached a point of diminishing returns, in that each incremental improvement in human health- and environmental-risk reduction comes only with a large increase in control costs, or benefits of additional regulation may be slight because so much has already been invested in environmental risk reduction. In still 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 sanctioning 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. For some, especially small businesses, there may be a preference for design standards because resources for research and innovation are limited.

For progress to continue, we must look beyond command-and-control regulatory programs. The call for alternatives to command-and-control regulations was particularly strong in presentations received by the Commission outside of Washington, D.C. In addition, federal agencies emphasized their commitment and cited their projects aimed at finding effective alternatives to command-and-control regulation. This subsection discusses several analytic tools for identifying when environmental protection is improved and risk reduced, and endorses a number of alternatives to command-and-control regulation that should be considered when there is interest in going beyond current levels of protection and risk reduction.

FINDING 5.4: 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 testing requirements for newly developed chemical products. However, serious problems in the regulatory system have developed in some situations: delays in human-health and environmental protection, litigation, and compliance costs that are often out of balance with their benefits. Executive Order 12866 stresses the use of performance goals for environmental protection to increase the flexibility industry has to pursue the most effective and efficient solutions.

RECOMMENDATION: Regulatory agencies and affected communities should aggressively consider alternatives to command-and-control regulation using the Commission's risk-

management framework to improve the efficiency and effectiveness of protecting human health and the environment and to reduce compliance and litigation costs. A sense of experimentation and a commitment to evaluation are key elements.

RATIONALE

Government must set environmental protection standards, but there are important economic and environmental benefits in allowing companies and communities 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 equity 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. Jonathan Howes, Secretary of the Noth Carolina Department of Environment, Health, and Natural Resource, in reporting to the Commission on the work of the National Academy of Public Administration, said they concluded that many businesses have found it in their interest to meet or exceed environmental standards, particularly if they can use their own strategies to achieve the pollution reduction targets that are established.

Environmental accounting, industrial ecology and life-cycle analysis, and environmental audits are emerging analytic tools that can assist in understanding the consequences of economic activity and environmental-protection efforts. Alternatives to command-and-control regulation that are being tested include market-based incentives, taxes and subsidies, right-to-know laws and other incentives to encourage pollution prevention, alternative compliance, and consensus, mediation and dialogue projects. Those tools are options to be used when and where they make sense in responding to additional risk reduction opportunites. As the alternatives are being tested, it is important to evaluate them for reliability in meeting or exceeding environmental goals, feasibility of implementation, and general effectiveness and efficiency.

Tools for Understanding the 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;* 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 in overhead, and effects on and uses of 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 probabilitiesis 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. Bankers and investment advisers have been slow to encourage up-front investments in those 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.

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, and 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. Nevertheless, industry representatives emphasize that life-cycle analysis relies on many assumptions and needs further research and development before it can be a reliable tool.

Environmental Audits. Audits by industry and by third parties are a powerful tool for influencing corporate compliance with command-and-control regulations by easing penalties 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.

Alternatives to Command-and-Control Regulation

Market-based Incentives. Market-based incentives rely on economic motivations 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 emission 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 sulphur dioxide emission allowances has fallen 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 localized risks.

Right-to-Know and Other Incentives to Encourage Pollution Prevention. 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 could be given priority for approval if they were deemed safer for human health and the environment, and thereby reach the marketplace faster than other pesticides. If regulations control the labeling of a product, safer products could receive more favorable treatment, such as authority to use a special label, to give them greater prominence in the market. To encourage pollution prevention by manufacturing facilities, businesses might 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 Research Center. 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.

The Toxic Release Inventory and California Proposition 65 have proved effective pollution prevention incentives by requiring the disclosure of information about chemical releases to the environment and labeling of chemicals in products, respectively. Those right-to-know laws rely on the public's attitudes toward toxicants to encourage industry to reduce or eliminate their use or release. 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 reproductinve 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 informed the Commission that Proposition 65, once enacted and implemented, has had widespread support from environmental and business communities and has had few legal challenges. A key element was the decision by the state agency, accepted by environmentalists and business, to put the bright line for cancer risk at 10^{-5}, rather than 10^{-4} or 10^{-6}, as proposed by contending parties. He estimated that under this system, the state of California completed the necessary regulatory work for 282 chemicals at a cost of about one-tenth of what EPA was spending on risk assessment during the same years.

Taxes and Subsidies. Tax and subsidy programs that encourage and discourage economic activity can be powerful motivators, either encouraging or discouraging use of natural resources

and production or reduction of pollution. For example, agricultural land-retirement programs have prevented excessive soil erosion and damage to waterbodies and wildlife habitat, and promoting agricultural production through implicit and explicit subsidies for inputs, such as pesticide and water use, can contribute to environmental damage. Elimination or amelioration of negative-tax and subsidy programs can have a positive impact on the protection of human health and the environment, as can carefully targeted increases in subsidies for the provision of some environmental benefits. 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 attribure but other unfavorable characteristics.

Alternative Compliance. Alternative compliance provides greater flexibility to industry by allowing choices of methods for achieving emission-reduction or risk-reduction specifications. It is designed to achieve higher levels of environmental protection at lower cost and to foster integration of local concerns in environmental risk-management decisions. Alternative compliance gives regulated entities the ability to choose among a broad range of management alternatives instead of being subject to prescriptive command-and-control requirements. 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. 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 provided flexibility in compliance, also.

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. 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. Several industrial sectors have launched their own intitiativces such as Responsible Care by the Chemical Manufacturers Association.

The Commission joins with the President's Council on Sustainable Development (1996) in endorsing alternatives to command-and-control regulations. Wise use of a variety of alternatives might provide increased human-health and environmental protection with greater efficiency and lower cost to regulatory agencies, industry, the economy, and society, than command-and-control programs.

5.5

Peer Review

The importance of peer review in regulatory decision-making has been highlighted recently by the prominence of requirements for peer review in several regulatory-reform bills before Congress. Earlier versions of those bills included prescriptive instructions regarding the nature and duties of peer-review panels. Later versions of the bills have been less prescriptive. Peer review is an important and effective mechanism for evaluating the accuracy or validity of technical data, observations, and interpretations, and the scientific and economic aspects of policy recommendations and regulatory decisions.

FINDING 5.5: Peer-review activities in federal regulatory agencies are generally devoted to evaluating the quality of the science and the scientific interpretations that underlie a regulatory decision. The quality and interpretation of other technical information, especially that related to economic analysis and the social sciences, are generally ignored. Peer review has not been used to evaluate the use of scientific and economic information in regulatory decisions, however, and there are no procedures for evaluating the effectiveness of peer review itself. Several agencies do not have official guidelines or policies for peer review. Of course, peer review can be overdone; 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.

RECOMMENDATION: The role of peer review should be expanded to consider not only the quality of technical information, but the use of that information 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. Clear, written guidelines for peer review should be established by regulatory agencies, and the effectiveness of agency peer-review programs should be evaluated regularly. The level of peer review should be commensurate with the level of scientific or economic importance and regulatory impact of the decision to be made. Peer review should be conducted not simply to seek legitimacy for agency decisions and positions, but to improve their quality. When peer review is judged to be unnecessary, an agency should provide an explanation and justification.

RATIONALE

Peer review provides independent views of an issue. When used well, peer review can serve as a system of checks and balances for the regulatory process. In the context of risk analysis, an open process for peer review can increase the credibility of and confidence in an assessment. Peer review can make important contributions to a collaborative decision-making process that involves stakeholders. Administrative details—such as how peer reviewers are

selected, which agency products, 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 called for by its peer-review policy (EPA 1994) are examples of useful guidelines for peer review. Peer review of the output of the risk-assessment and options stages in the Commission's risk-management framework (section 2) is essential for all major rules under development. In some cases, peer review might be useful in the problem-formulation stage.

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 peer review of the use of technical information at the policy stage. Perhaps scientific advisers to the EPA administrator, the FDA commissioner, or the OSHA administrator 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. A mechanism for evaluating the descriptions and uses of scientific and economic analysis in the decision-making stage should be sought. The Commission does not suggest that the regulatory decision itself should be peer-reviewed, which, of course, is the purview of the judiciary.

Agency peer-review policies should include a regular evaluation process in which specific examples of an agency's use of peer review in its regulatory decision-making are examined. That evaluation would ask questions about how a peer review was conducted, whether and how the outcome of a peer review was used in a regulatory decision, whether the peer review was considered useful, and finally, how the process could be improved. A good example of agencywide evaluations of the role of peer review is described in the EPA publication *Safeguarding the Future: Credible Science, Credible Decisions* (EPA 1992b). Evaluations could be organized by the agency, such as EPA through its Science Advisory Board, or across agencies, such as by the Office of Science and Technology Policy or the risk-assessment subcommittee of the administration's Committee on Environment and Natural Resources.

Potential peer reviewers with clear conflicts of financial interest should be disqualified from service on peer-review panels that could directly influence regulatory decisions related to the products or interests of their organizations. However, it is difficult, if not impossible and unwise, to eliminate bias, which reflects views or positions taken that are largely intellectually motivated or that arise from a person's close identification or association with a particular point of view or with the position or perspectives of a particular group. The Commission believes that expertise, balance of biases, and inclusion of active, younger, and culturally diverse scientists, economists, and social scientists should be among the criteria for constitution of peer review panels. Explicit criteria for revealing and evaluating conflicts and biases are needed.

The person(s) responsible for selecting peer reviewers can have a great deal of influence on the

nature and biases of the membership, the expertise represented, and, by extension, 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 a small number of people do not have undue influence on reviewers' characteristics or decisions or on what is chosen for peer review.

Full peer review is unlikely to be needed for every regulatory decision. The most-effective and most-efficient use of peer review should be made case by case, taking into account such issues as the extent to which the scientific information on which a decision is to be based 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.

5.6

Judicial Review

Introduction

Issues of judicial review that were raised by the 104th Congress—in the context of what was termed "regulatory reform" legislation and amendments to 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 of, and limit the extent of, review of agency action by courts. Both agency action and judicial review of regulatory rule-making 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. However, 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, 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 and hold such 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 the issues raised by proposed legislation and the effect of each of the regulatory rule-making process. In short, and as discussed below, the Commission submits that legislative initiatives should not provide for premature interruption of the administrative process, should not 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, and should consider the use of alternatives that assure rational and cost-effective regulatory action.

Premature Interruption of the Administrative Process

FINDING 5.6.1: Interlocutory, or intermediate, appeals of discrete issues prematurely interrupt the administrative process.

RECOMMENDATION: Final agency action must, in fact, be final. Judicial review should be available only after agency action is complete and all administrative remedies have been exhausted. Amendments to the Administrative Procedure Act should not contemplate the premature interruption of the agency decision-making or rule-making process.

RATIONALE

Historically, provisions for judicial review under the APA grant review of the rule-making 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 establishment of a rule-making 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 if judicial review is invoked, there is a full record upon which a court can adjudicate.

Administrative procedure and practice require a party to challenge issues within the internal agency 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, 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—and prematurely—out of the administrative context, where issues could be developed fully, and into the judicial arena, under the guise of final agency action. Considering this scenario in the context of drafting and implementing agency regulations, interested parties could prematurely, and in piece-meal fashion, seek judicial review of discrete issues and effectively delay and hamstring the regulatory process.

Allowing premature interruption of the administrative process limits—if not impedes—the rule-making 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.

Interlocutory review is inconsistent with notions of litigation reform, which were also major goals of the 104th Congress.[1] In addition, new opportunities for judicial review would result in costly and unacceptable delays in the rule-making process. Simply stated, interlocutory appeals of agency actions are not supported historically and limit the development of regulatory initiatives by prematurely interrupting the regulatory rule-making process.

* * *

The nature and extent of judicial review

FINDING 5.6.2: Recent proposed legislation included detailed requirements governing the content of risk assessments and cost-benefit analyses, the procedures for preparing the analyses, and the regulatory decisions based on the analyses. Under accepted administrative law requirements, all those new requirements would be judicially reviewable, potentially leading to increased and more complex litigation over agency decision-making on highly scientific substantive matters.

RECOMMENDATION: Provisions that would make substantive risk assessments and cost-benefit 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 onto existing enabling statutes. Instead, a legislative program-by-program approach would assure that such requirements fit the statutory scheme and would help tailor such requirements to that scheme, thereby reducing the potential for unnecessary litigation. Court review should remain confined to questions of law, constitutional and procedural issues, and whether the agency's finding, determination, or decision was arbitrary or capricious under the traditional deferential standard (unless the enabling legislation otherwise provides). Following that standard, courts should continue to defer to agency expertise and peer review in areas involving highly scientific analysis.

RATIONALE

Courts are the appropriate reviewers of statutory and regulatory limitations of rights and obligations, of broad process and procedural rights and, of course, of legal issues and the interpretation and application of precedent. In general, courts are not best equipped to assess in detail and delve deeply into the technical science that supports much agency decision-making. Although all issues of scientific method and factual support for findings are currently subject to judicial review, courts instead typically have undertaken broad oversight of agency scientific findings under the "arbitrary and capricious" standard of review. This standard is deferential to agency scientific decision-making and allows agencies substantial flexibility in drawing upon their specialized expertise, while ensuring judicial oversight to ensure that administrative agencies follow accepted procedures and standards and do not, broadly

[1]Congress overrode a presidential veto to enact securities-reform legislation and also seriously considered and debated tort reform to decrease the amount of litigation.

speaking, act in an improper manner (i.e., arbitrarily or capriciously). Indeed, one of the primary reasons administrative agencies were created in the first place was to bring specialized expertise to bear on complex issues.

Some proposed legislative initiatives would change the nature and extent of judicial review of agency decisions in a number of ways. A legislative mandate to agencies to follow intricate, detailed procedures in developing cost-benefit 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 (discussed in more detail in section 5.6.3), inevitably would involve courts in an investigation of much more than whether a "rational basis" exists to support an agency rule. In addition to examining agency compliance with detailed substantive and procedural requirements contained in the legislative proposals under a broadened "substantial evidence" standard, courts would likely be required to delve far more deeply into the many complex scientific issues affecting a rule. That would create not only increased opportunities for litigation, but much more complicated and expensive litigation. The end result may well be that courts, without any significant scientific expertise in the subjects being adjudicated, would replace administrative agencies as the ultimate decision-maker on many highly technical, specialized issues.[2]

In addition to requiring risk assessments and cost-benefit analyses, some proposed legislation would establish criteria ("decisional criteria") that would be used to evaluate the validity of a rule, and would supplement all enabling statutes. Consequently, the findings of cost and risk evaluations, conflicts with regard to scientific data, the 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 inexorably part of the agency record and, therefore, the subject of judicial scrutiny. Some statutes administered by federal agencies now preclude reliance upon benefit-cost analyses or risk assessments in regulatory decision-making. For example, when EPA sets national ambient air quality standards (NAAQS) under section 109 of the Clean Air Act, it must rely on technology and cost considerations, and not the results of risk assessments (section 112 provides for risks to be considered at a second, later regulatory phase). Because many of the legislative proposals would overlay these laws with new requirements that decisions be based on benefit-cost analyses and risk assessments, they would greatly expand the number of issues that the Agency would have to analyze and that could be presented, in turn, to courts. Rather, we suggest the policy of including risks, costs, and benefits as decision criteria be established and pursued on a legislative program-by-program basis to ensure that the administrative rule-making process does not itself increase in complexity and duration, consuming more agency resources and time to complete individual rule-makings.

We recommend that courts should focus on that for which they are best equipped—reviewing agency compliance with the broad procedural requirements that currently govern agency

[2]Unless the enabling legislation otherwise provides.

action and reviewing whether an agency decision is arbitrary and capricious in light of the goals of the underlying statute.

* * *

Standard for Judicial Review

FINDING 5.6.3: Enhanced 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 expanded.

RATIONALE

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 the case of *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

[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.

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 rule-making. 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 those 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]

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[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).

Proposed legislation appeared to greatly expand the 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 substantial evidence standard apparently would be expanded beyond formal hearings to all rulemakings.

While the substantial evidence standard is not a new standard of review, it typically (although not exclusively; see, for example, TSCA) has been reserved for formal rule-making and hearings. Courts have expressed some question about the application of the substantial evidence standard to informal rule-makings where the evidentiary standards and record development are different than in formal hearings (see, for example, *Aqua Slide 'n' Dive v. CPSC*[14]). Courts that have historically deferred to agency interpretation and action under an arbitrary and capricious standard[15] would, instead, have to find substantial support for that action in the agency file. Inherently, requiring a court to find substantial evidence lessens its ability to defer to agency decisions.

The Commission submits 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.

* * *

Impact of increased litigation on agencies, parties, and the courts

FINDING 5.6.4: Our court system is backlogged and agencies are heavily burdened. Each is often incapable of handling its caseloads. Consequences of increased judicial review through interlocutory appeals and an expanded scope and standard for review could include a new wave of litigation causing more delay and more costs to agencies and parties, without producing improvements in the quality of the decisions or benefits to the parties involved.

RECOMMENDATION: Initiatives that are likely to increase litigation and the role of the courts should not be undertaken.

RATIONALE

[14]569 F.2d 831 (5th Cir. 1978)

[15]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.

As already noted, expanded judicial review under the proposed legislation would represent an historic retreat from precedential notions of judicial deference and restraint. The APA provides procedural avenues that are aimed at preventing arbitrary or capricious action by an agency. Moreover, under the APA, judicial intervention is called for, appropriately, at the end of the administrative process, when the record is full, developed, and complete, not near the beginning or in the middle of that process. The wave of science- and medicine-based litigation involving, among other things, asbestos and lead-based paint, that flooded the courts in the 1980s and early 1990s provides meaningful examples of how questions of science can open up a universe of litigation that results in massive delay and massive costs, without necessarily producing improvements in the quality of decisions or benefits to the parties involved.

We are not suggesting that courts steer away from science issues when considering those questions in the regulatory context. The question is not whether but to what degree a court reviews science-based regulatory decision-making. Increasing judicial involvement as described above act only to delay, burden, and increase costs to agencies and parties.

Alternatives to increased judicial review

FINDING 5.6.5: Consensual approaches to decision-making that would help assure rational and cost-effective regulatory actions affecting health, safety, and the environment as alternatives to increased judicial review are not commonly used.

RECOMMENDATION: Regulatory agencies should maximize consensual approaches to decision-making such as negotiated rule-making, alternative dispute-resolution techniques, expert peer review, and informal practices such as meetings with groups of representatives of interested parties, involvement of community stakeholders, and workshops to explore alternative regulatory approaches. Congress, in turn, should explore with the agencies removal of possible obstacles to these practices that may exist under current law.

RATIONALE

Alternatives to judicial review that promote dialogue, interplay, and negotiation between regulators and the regulated community are not commonly used, other than in the context of agency policy initiatives. While variations of alternative dispute resolution (ADR) procedures are sometimes used in the rulemaking and enforcement arenas, they 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 rule-making process work together to analyze and discuss proposed regulatory initiatives. Those negotiated rule-making sessions allow the promulgating agency to understand fully and develop possible alternatives to a regulatory initiative. The development of achievable standards or alternatives to regulatory controls are contemplated, tested, and implemented, and regulatory goals are achieved rather than violated.

EPA has embraced this concept with its Common Sense Initiatives, and for those stakeholders involved, the process has opened up communications with the regulatory agency. In turn, fewer legal challenges are filed in the course of the rule-making process.

In some instances, current laws may stand as obstacles to consensual approaches in regulation. For example, the Federal Advisory Committee Act prohibits federal agencies from organizing groups of interested but unrelated parties to seek consensus, unless the groups are chartered by the Office of Management and Budget (OMB) as advisory committees and detailed procedures, including notice of meetings in the Federal Register, are followed. As a result, agencies are faced with either resorting to the inefficient practice of meeting one by one with affected groups, or accepting the substantial delays associated with chartering advisory committees.

Similarly, agencies that seek to gather information on a voluntary basis from the regulated community or others are often prohibited by the Paperwork Reduction Act from doing so—even on a voluntary basis—unless they seek and obtain clearance from OMB. Other statutes that require publication and formal notice of meetings, such as the Government in the Sunshine Act, may unintentionally chill efforts by agencies such as the Federal Energy Regulatory Commission and the Consumer Product Safety Commission to use informal consensus-building approaches.

Congress might explore with affected federal agencies whether it would be useful to relax some of these restrictions to make consensus-building approaches more readily available. Agencies such as EPA have demonstrated their readiness to use these techniques and the law should not restrict their use unnecessarily.

6

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 the Environmental Protection Agency (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. And 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 and preferences. 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, and safety 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 be an exhaustive evaluation of all the federal agencies that assess and manage risks, but to highlight those that provided testimony to the Commission.

FINDING 6.1: 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.

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 or a scientific disagreement, which should be explicated.

RATIONALE

The primary reason for differences among agencies in performing risk assessments 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 remains 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.

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 effect of the diversity of methods among federal regulatory agencies is to make it difficult to compare risks, or the actions taken to mitigate those risks, from one regulatory program to another. For example, EPA and the Consumer Product Safety Commission (CPSC) differ on several critical aspects in the performance of a quantitative risk assessment, including reliance on the "maximally exposed individual" or other upper-end exposure estimates at EPA versus the average population exposure at CPSC and the use of upper-bound risk estimates at EPA versus maximal-likelihood estimates at CPSC. EPA occasionally uses pharmacokinetic information for cross-species extrapolation, but CPSC has declined to do so.

Although defaults and standard methods are necessary in the face of uncertainty and lack of case-specific knowledge, variation among agencies and programs increases the sense of arbitrariness in risk analyses. In cases where regulatory responsibilities overlap or different groups have cause to assess the same exposures, differences in assessment outcome can lead to conflict and confusion among the public and the regulated community. 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 A.6).

6.1

Environmental Protection Agency

EPA has played a critical role in facilitating the substantial improvements in our environment that we have enjoyed over the last 25 years. The major sources of pollution contaminating our air, water, and soil have been greatly mitigated, largely as a result of its efforts. The complex and intransigent problems that remain will require continued creativity and, in some cases, improved efficiency. This section addresses several of EPA's programs and offers recommendations that are aimed at improving the identification and management of risks.

6.1.1

Office of Air and Radiation

The Clean Air Act Amendments of 1990 contain several provisions of particular relevance to the Commission concerning the assessment and control of criteria air pollutants (section 109) and hazardous air pollutants (section 112). The same sources often contribute pollutants of both types. For example, motor vehicles are major contributors of the criteria air pollutants ozone, carbon monoxide, and particles, and they are also the source of about one-third of all hazardous air pollutants, including benzene, 1,3-butadiene, and formaldehyde. Similarly, point sources, especially those which use large quantities of volatile organic compounds, contribute to both the regional ozone air-pollution problem and increased concentrations of hazardous air pollutants in the local environment.

The 1990 amendments to section 112 established an entirely new program to control hazardous air pollutants from point sources through the promulgation and implementation of technology-based standards embodied in what is known as maximum available control technology (MACT). Congress required that the need for further control be determined through risk-based approaches after implementation of MACT. The MACT strategy was mandated because the regulation of hazardous air pollution from point sources with a purely risk-based approach seemed to be ineffective and inefficient. Difficulty in setting new standards was attributed to “paralysis by analysis”, according to the National Resources Defense Council’s David Hawkins, who was assistant administrator for the Office of Air and Radiation under President Carter. Although most air pollution had been regulated, there had been relatively little impact on the tonnage of pollutants released into the air, as was evident from Toxic Release Inventory data. It is not known whether a technology-based approach will be more effective in protecting public health than a risk-based approach.

As of May 1996, EPA had promulgated 27 MACT standards (including 10 in the overall category of hazardous volatile organic chemicals) and had proposed four more; a total of 174 source categories need one or more MACTs each. Full MACT implementation is projected by EPA to cost about $600 million per year and to reduce hazardous air-pollutant emissions by 880,000 tons and criteria air-pollutant emissions by 1,900,000 tons per year.

The risks that will remain after MACT standards are in place (residual risks) have not yet been determined. Preliminary analyses are being conducted at EPA. The agency is applying a case-study approach to assess data availability and to evaluate screening methods and models that might be used in the residual-risk program. Criteria that will be used to choose screens include ease of use (so that “nonexperts” can conduct screening assessments) and extent of conservatism. The goal is to find a method or methods that will eliminate from further analysis sources that are clearly of no concern and focus attention on sources that need

further, more-rigorous analysis. One potential screening method is EPA's three-tiered analysis described in appendix J of *Science and Judgment in Risk Assessment* (EPA 1992d, NRC 1994a). Tier 1 is a conservative screen that requires only stack heights, distances to fence lines, emission rates, and "lookup tables" to obtain maximal off-site concentrations. Tier 2 is also conservative, adding to tier 1 data only some generalizations about stack characteristics and a distinction between urban and rural environments. EPA's preliminary evaluations using the tiered approach demonstrate the enormous data gap that must be filled even to perform screening analyses, much less estimate residual risks reliably; there were enough data to evaluate only seven source categories at tier 1 and for only two of those were there enough data to proceed to tier 2.

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

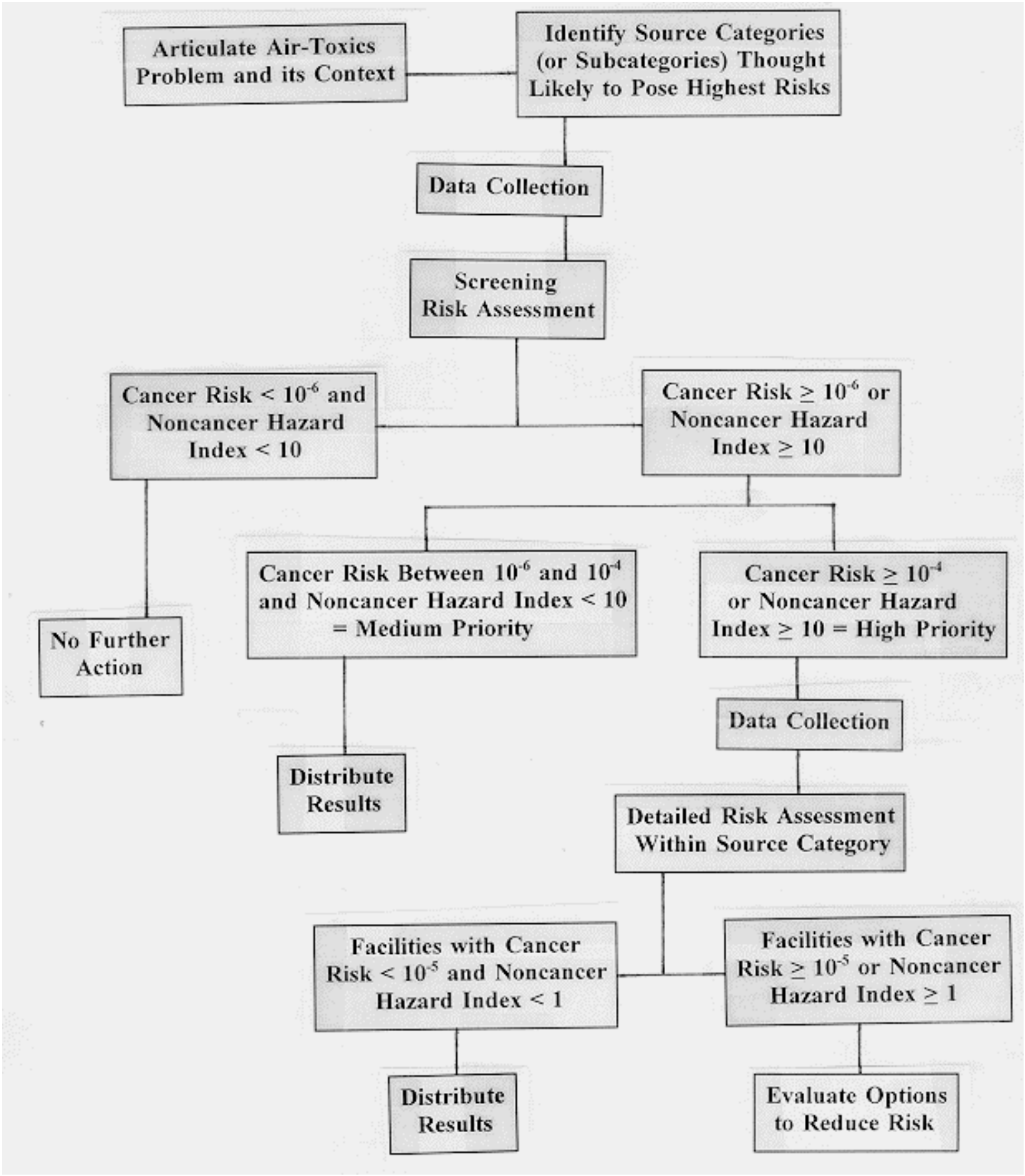
FINDING 6.1.1.1: EPA needs and wants guidance on how to implement the residual-risk provisions of the 1990 amendments to the Clean Air Act after controls have been put in place to meet technology-based standards. The current Clean Air Act requirements can be interpreted to imply that if even a single facility within a source category is found to pose a residual cancer risk of 10^{-6} or more after maximum available control technology (MACT) has been implemented, EPA must set new standards for the source category. That policy could lead to devoting extensive resources to pollution controls where there are no important risks.

RECOMMENDATION: To determine and manage residual risk after implementation of MACT, the Commission proposes a specific tiered scheme (see figure 6.1): characterize and articulate the scope of the national, regional, and local air-toxics problems and their public-health and environmental contexts; obtain necessary data and perform screening-level risk assessments to identify sources with the highest risks; conduct more detailed risk assessments of sources and facilities with the highest risks; evaluate risk-reduction options at facilities that have incremental lifetime upper-bound cancer risks greater than one in 100,000 persons exposed or, for noncancer risks, concentrations greater than reference standards, using the Commission's risk-management framework set forth in section 2; and determine the need to evaluate residual risks from less high-risk source categories. The scheme is described in detail below.

1. Problem/Context Characterization. To provide guidance for stakeholders and for implementing the residual risk-assessment and risk-management scheme, the scope of the local, regional, and national air-toxics and air-pollution problems are characterized. The problems are put in context by comparing air-toxics issues to air-pollution issues in general and to other, multimedia sources of exposure to the same chemicals. The goal is to build an understanding among stakeholders about the health context of residual risks from regulated point sources of emissions.

2. Screening Risk Assessments. Priority source categories or subcategories are identified that

Figure 6.1. Scheme for determining and managing residual risk after MACT.



the agency considers likely to pose the highest residual risks. Screening risk assessments of facilities are performed by source category (or subcategory), starting with those which the agency has identified. Screening risk assessments can follow methods such as EPA's tier 1 or tier 2 procedures for assessing risks from hazardous air pollutants (EPA 1992d, NRC 1994a). Screening risk assessments must rely on many default assumptions and the defaults must be realistic and chosen with care. The specific methods, criteria, and assumptions for performing screening risk assessments should be developed by EPA in partnership with state environmental regulatory agencies, with appropriate peer review and stakeholder input in an open and transparent process.

Successful implementation of screening risk assessments will require more and better data than are now available to EPA. EPA should establish a miminal data-quality requirement for source-category emissions to be used in residual-risk assessments and, where that requirement is not met, initiate a data-gathering effort supported by states and regulated parties. Initial data-collection efforts for screening assessments will need the cooperation of states, and data collection for refined risk assessments will require the cooperation of regulated parties. Data should be gathered during MACT development through the section 114 questionnaire and the information collection request, when collaboration with regulated parties is already taking place. Modifying Toxic Release Inventory reporting requirements so that what is reported is more consistent with data needs should be considered, such as reporting average emission rates, not total emissions in pounds.

3. Detailed Risk Assessments. If source categories considered in the screening risk-assessment phase are found to pose an incremental lifetime cancer risk that exceeds 10^{-6} for a reasonable upper-bound-exposed person in an affected population or if a noncancer hazard index—sum of the ratios of exposure concentrations of noncarcinogens to their Reference Concentrations (RfCs)—exceeds 10, the categories should be further classified. Those values are proposed as potential bright lines (see section 5.3), but some experience with source categories will be needed to see how well they serve in forming appropriate categories.

If a cancer risk is $\geq 10^{-4}$ or a noncancer hazard index is ≥ 10, the source category is considered to have high priority. More detailed risk assessments should be performed first within that category. Those risk assessments should be facility-specific and should be performed in partnership with regulated parties and other stakeholders as appropriate.

If a cancer risk is between 10^{-6} and 10^{-4} and a noncancer hazard index is less than 10, a source category is considered to have less-high or "medium" priority. Risk-assessment results should be distributed to the affected industries and other interested parties so that voluntary process changes or other actions can be evaluated to reduce emissions or risks associated with those sources.

4. Risk Reduction. Additional controls or process changes should be evaluated if more detailed risk assessments performed within source categories found to have high priority yield incremental lifetime cancer risks of $\geq 10^{-5}$ or noncancer hazard indices of ≥ 1 to reduce them to

below 10^{-5} or 1, respectively. If the more detailed risk assessments yield incremental lifetime cancer risks of $< 10^{-5}$ and noncancer hazard indices of < 1, no further action should be required. To the extent practical, when more than one source category of high priority is found at the same facility their risks should be evaluated together.

Identifying and implementing changes to reduce risk, where required, should be performed as part of a local or regional risk-management process conducted with the Commission's framework. Establishing risk-management goals with that framework should include consideration of not only the individual facility of concern, but also its context, including pathways of exposure to hazardous air pollutants besides inhalation (such as water or soil), the air-quality characteristics of the region, other sources of pollutant emissions, and considerations in addition to human health risk such as costs, benefits, equity, and values. The process must be conducted with full stakeholder participation.

5. Iteration. On the basis of learning from the risk assessments for the source categories considered by the agency to pose the greatest risks, the agency should determine the need for proceeding with assessments of medium-priority and low-priority source categories.

RATIONALE

Several aspects of the preceding scheme require elaboration.

Identification of High-Priority Source Categories

The Commission believes that EPA—through the experience gained during the first stages of implementing the 1990 amendments to the Clean Air Act, developing MACT standards, and setting priorities among hazardous air pollutants—has acquired enough information to identify the source categories most likely to pose residual risks. High-priority source categories should be identifiable on the basis of quantitative information, such as emissions data and how many people are exposed, where available, and also on the basis of qualitative considerations, such as whether high-priority hazardous air pollutants are present, whether there are sensitive subpopulations, and whether there are highly exposed populations, or "hot spots".

Screening Risk Assessments

Figure 6.1 describes a process whereby priority is given to sources likely to pose the highest risks. Subjecting source categories to a priority ranking requires the development of a screening risk-assessment model. Screening is based largely on some consistently applied estimate of exposure. At each step in the screening assesment, some decision must be made about the priority to give the categories and what actions to take. The Commission recommends integration of this screening process within its framework for risk management described in section 2.

Performing screening risk assessments at every facility within a source category would be

prohibitive, so a screening model that can be used to generalize risks for a source category or for types of facilities within a source category is needed. The screening model must be able both to account for differences among facilities and to provide results that can be used as a guide to making decisions about the need for further analysis. EPA should develop useful screening methods in partnership with state regulators and with input from regulated parties and other stakeholders.

Upper-end point estimates of exposure can be appropriate for screening risk assessments, but the use of the hypothetical maximally exposed individual (MEI) yields such an unrealistic overestimate of exposure that it should not be used (see section 3.2). Screening risk assessments should rely on more-representative estimates of exposure, such as EPA's "high-end exposure estimate" (HEEE) or an estimate based on a highly exposed actual person or reasonable worst case. More-detailed risk assessments should consider the entire exposure distribution (see section 3.2).

The goal of a screening risk assessment is to ensure protection of any especially susceptible subpopulations by using conservative assumptions to estimate toxicity, such as cancer potencies and RfCs. Detailed risk assessments should reflect the multiple pathways by which exposure to hazardous air pollutants can occur, obtain population- or ecosystem-specific exposure data to the extent feasible, and consider in more detail the health status of the community and specific population subgroups for health effects of particular concern.

Decision Threshold After Screening Risk Assessment

Within the decision-making framework, a threshold is needed to discriminate between sources that should be considered further and sources that need not. The Commission opposes the inflexible use of bright lines for regulation, but using a bright line to guide a decision-making process is necessary for efficient risk management.

The 1990 amendments to the Clean Air Act set 10^{-6} as the threshold for considering source categories for reduction of residual risk. Those with screening risk estimates that fall within the 10^{-6}-10^{-4} range might not require high priority because of the conservative nature of the assumptions used in screening risk assessments. The Commission therefore recommends that an intermediate category of "medium" priority be established for source categories with estimated risks between 10^{-6} and 10^{-4} on the basis of screening assessment. Sources that fall within that range might consider voluntary engineering improvements to reduce emissions and risk. Using a flexible 10^{-6}-10^{-4} approach is consistent with the permitting strategy already in place in a number of states, according to testimony received by the Commission from Joann Held and Tad Ahern, who manage air toxics programs in New Jersey and Maryland, respectively, 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 noncancer 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. A screening-level hazard index is calculated by dividing the exposure concentration of each noncarcinogen by its reference concentration (RfC) and then adding those ratios together. Detailed risk assessments might rely on several hazard indices, determined by adding together ratios only for chemicals with similar health effects.

Decision Threshold after Detailed Risk Assessment

The Commission prefers a 10^{-5} flexible bright line for actions to reduce residual cancer risk based on detailed risk assessments. That action level is consistent with Congressional guidance to use 10^{-6} for screening purposes. The choice of that decision threshold will be better informed after some experience is gained across source categories, including replacement of 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. In fact, within the Clean Air Act, there is a striking contrast between permissible margins of exposure for section 112 carcinogenic air pollutants and ubiquitous section 109 criteria air pollutants. For a lifetime upper-bound risk of 10^{-6}, the permissible margin of exposure for carcinogenic air pollutants is greater than 100,000-fold. For lead, carbon monoxide, small particles, and other criteria air pollutants, the permissible margin of exposure of recognized susceptible populations is below exposures associated with adverse effects by less than a factor of 2.

Section 112 addresses other serious hazards besides cancer, such as reproductive, developmental, and neurologic impairments. California's Proposition 65 labeling regulations similarly cover carcinogenic and reproductive effects. In that state, environmental activists and businesses accepted an agency decision to put the action level for carcinogens at 10^{-5} and the action level for reproductive toxicants at one thousandth of the no-observed-adverse-effect level. Those action levels for labeling apply to products to which very large numbers of people are likely to be exposed. For many section 112 source categories, in comparison, relatively few people are within exposure range of the point sources. Expressing risks in terms of numbers of persons who might be affected per year or per hypothetical lifetime, as well as the probabilistic estimates per 100,000 persons exposed, can help in risk communication (see section 5.1).

Risk Management

Implementing a tiered or phased approach to assessing risk, such as that recommended here and in *Science and Judgment in Risk Assessment* (NRC 1994), 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. 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 and that screening assessments do not assess the magnitudes of likely risks. 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).

When a facility is identified as having high priority and posing potential risks to health, a participatory, community-based approach to managing those risks should be used. Involving stakeholders in the risk-management process described in section 2 can identify additional factors that should be addressed, improve the quality of risk assessment, and increase the likelihood that the results of risk assessment and any decisions made with regard to managing risks will receive broad acceptance.

Application of the Commission's Risk-Management Framework to the Determination of Residual Risks

The Commission recommends that the risk-management framework described in section 2 be used to guide the design and implementation of strategies to address residual risks associated with sources subject to MACT standards. A goal of this framework is to involve stakeholders in the process early. As the process becomes more and more specific to local situations, however, so will the involvement of different stakeholder groups. For example, in the early stages of the process, when procedures for defining MACT subcategories and screening models are being developed, stakeholders might include the regulatory agencies, industries, and environmental or public-health organizations that address national issues. During later stages of the process, when the risks and risk-reduction options associated with individual pollutant sources are being considered, stakeholders might involve other participants from the community, such as health-care providers, plant managers, local politicians, and other citizens concerned about the outcome.

Problem/Context. Implementation of the decision tree for evaluating the problem of residual risks should begin by defining the scope of the national, regional, and local air-toxics problem. The public-health and environmental contexts include other sources of emissions of the same pollutants and risks associated with other regulated—and not-yet regulated—pollutants. The goal is to build a consistent understanding among stakeholders about the health context in which a particular pollution problem is being addressed and to provide guidance for the rest of the decision tree.

Risks. Once the problem is defined, the next stage of the process involves estimating the potential health risks associated with source categories that have implemented MACT. First, priorities are set among them. As of May 1996, 27 source categories had MACT standards. However, their relative hazard potential is largely unknown, and a process for identifying potentially high-risk sources has not been articulated. Including stakeholders at this stage

might involve establishing basic criteria for defining MACT subcategories and developing a strategy for obtaining the necessary information to perform a screening risk assessment. EPA could develop a draft plan and make it available to the public through a variety of mechanisms (e.g., dissemination through the Internet or through regional offices, state air agencies, and state environmental and health organization). Public dissemination could provide two benefits: obtaining input to the draft criteria-development and information-gathering strategy and identifying potential stakeholders for future steps in the process. Indeed, EPA is already working with state agencies to develop presumptive MACT standards; thus, the groundwork has been laid for expanding this effort during the stage of residual-risk determination in the hazardous air-pollutant program.

The goal of performing screening assessments of the MACT categories and subcategories is to determine whether they warrant further attention. The basis for the screening assessment is a screening model that relies on production, emissions, meteorologic, and demographic data. Peer review is necessary to ensure the integrity of the model among stakeholders. If the process of identifying MACT subcategories has been effective, there should be little disparity between the screening-model findings and the results from individual facilities. However, if a large number of sources have individual screening results that are either much higher or much lower than source-category screening model results, that could provide important risk-management information.

For sources identified as having high priority, a local stakeholder process would be set up—presumably from a subset of previously identified stakeholders—as well as newly identified participants. The stakeholder group would monitor the development and results of the detailed risk-assessment process. The group could provide useful input to the risk assessment and economic analysis by posing specific questions for the analysts to consider and by identifying exposure-assessment data needs and potentially vulnerable subpopulations.

Options. As in the risk-assessment stage of the framework, stakeholders could pose questions concerning economic impacts and technical details associated with various alternative options for pollution control or risk reduction. Care should be taken to ensure that the quality of this information is acceptable to the stakeholders, including use of peer review.

Decisions. Following the framework will not change the decision-making responsibilities of the regulatory agencies. However, the decision-making process should become better informed, include more explicit information on the costs and benefits of the actions chosen, and, if implemented properly, gain more public support than decisions that are made without stakeholder participation.

Actions. Traditionally, ensuring that actions are taken has been the responsibility of the licensing and enforcement divisions of regulatory agencies. Despite the importance of this activity, public involvement is generally at its lowest at this stage of the process. A solid oversight effort by stakeholders could ensure that actions are taken in a timely manner and are maintained and that implementation problems are properly identified and addressed.

Evaluation. In general, although there is often much criticism of risk-management decisions and actions, there is little evaluation. For example, was a decision responsive to the problem that was identified? Did the actions taken achieve the intended results? What recommendations could be made for addressing similar problems in the future? What were the critical information needs or gaps? Were the benefit and cost estimates reasonable?

It should be recognized that environmental risk management deals centrally with the need to make and implement decisions in the face of much uncertainty. If the overall process of risk management is to move forward, careful and thoughtful evaluation must take place. If done routinely and consistently, the results of such evaluations could provide valuable information concerning research needs and the development of better analytic methods, and could form the basis for improving the risk-management process as a whole.

* * *

FINDING 6.1.1.2: In carrying out its hazardous-air-pollutant program, EPA has attempted 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 optimize the amount of knowledge, skills, and resources devoted to the development of a MACT standard.

RECOMMENDATION: The partnership program should continue and be expanded to facilitate a stakeholder-based approach to setting MACT standards, including health and environmental organizations and community representatives. should establish an evaluation process for the partnership program. If it is found to be useful and effective, the Commission further recommends that it be used to facilitate decision-making related to residual-risk determinations.

RATIONALE

The hazardous-air-pollutant provisions of the Clean Air Act require EPA to promulgate standards for 174 source categories over a clearly defined timetable. 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 through a partnership framework, decisions can be made in a more timely and effective manner than has occurred thus far. At least points of disagreement could 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. It is important to determine whether the decision-making mechanism can be improved, however, both to expedite the promulgation of standards and to yield starting points for issues concerning residual-risk determinations.

* * *

FINDING 6.1.1.3: Many emissions sources can be subject to multiple MACT standards, as well as to additional Clean Air Act provisions (such as those addressing ozone control), 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. In particular, 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 timeframe. It should also focus on the pollution-reduction benefit that a more-comprehensive regulatory program could achieve.

RATIONALE

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 systems operating within a facility. Generic pollution standards for individual processes might neglect how the processes interact with other systems 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 systems. Emphasis should be given to applying MACT throughout a facility with control-technology requirements and timelines set to optimize both the effectiveness and the efficiency of pollution-reduction measures. The partnership program should help facilitate an integrated approach.

* * *

FINDING 6.1.1.4: 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. EPA's efforts to address indoor air pollution reportedly have been thwarted by its lack of statutory authority, by the lack of agreement on the nature of the problem and its solutions, and by the fact that jurisdiction over indoor air pollution is shared by several regulatory agencies.

RECOMMENDATION: Congress should direct EPA, OSHA, and other federal agencies to develop a coordinated strategy that addresses the growing problem of indoor air pollution. In developing this strategy, the agencies should consider implementing the Commission's risk-management framework as outlined in section 2 of this report. Until a coordinated regulatory strategy that addresses the problem of indoor air pollution is developed and implemented, EPA should continue to encourage the formation of building and safety committees to address indoor-air quality concerns.

RATIONALE

Over the last 2 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 and pressed-wood products and carpeting. The National Institute for Occupational Safety and Health (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 their 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 2 decades. They include effects of environmental 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. 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.

There is no risk-management framework for addressing indoor-air pollution concerns. There are essentially no enforceable standards, and EPA’s regulatory attention is focused mainly on outdoor air, despite research findings on total exposures. The attention of the Occupational Safety and Health Administration (OSHA) is focused mainly on industrial environments. Meanwhile, problems in offices, public buildings, and homes remain relatively unrecognized and unaddressed. Both agencies recognize the growing importance of the problem, but neither has the regulatory mandate to address it fully. There is an interagency task force that has begun to address the problem but it, too, lacks a statutory mandate.

Approaches to indoor-air pollution assessment and education generally remain 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. However, there is much political opposition to the development of a regulatory program: a recent OSHA public hearing on restricting smoking in the workplace and developing basic ventilation requirements was strongly dominated by the tobacco industry and various building-owner organizations.

Indoor air-quality problems are often complicated by their complexity and by their wide variation 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. For example, the agency produced 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 and conducts evaluations of the effectiveness of their activities.

6.1.2

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. In particular, there is greater focus on brownfields created by the stigma of contamination that can be restored and employed in the local economy. Many states now administer voluntary cleanup programs that can efficiently return contaminated lands to productive reuse. Nonetheless, the shadow of liability under the Superfund statute hangs over all those sites.

Over the years, EPA has identified more than 40,000 potentially contaminated sites in its Comprehensive Environmental Response, Compensation, and Liability (CERCLIS) database. After site-specific evaluations, EPA recently announced that more than 27,000 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 just over 25% of the 1,300 have been cleaned up. Although each of the last 2 years has produced more completed cleanups than the entire first decade of the program, progress is slow. With an average cleanup cost of $30 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 is also a relevant criterion.

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 groundwater 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 must face the challenge of implementing these improvements and goals consistently in its 10 regions and in states, territories, and tribal jurisdictions and ofmeeting 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 under RCRA 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.

FINDING 6.1.2.1: Superfund can be said to have caused more frustration than any other environmental, health, or safety regulatory program, because of unexpectedly large numbers of sites, high costs associated with clean up of individual sites, high transaction costs caused by disputes about responsibility and liability, excessive delays, and until recently, a limited number of sites cleaned up. Some remedies have been technically ineffective or so expensive as to be financially punitive. Remedy selection has not consistently considered future uses or realistic exposure scenarios. In contrast, the highly successful emergency removal actions of Superfund are not well appreciated, despite its timely and major contribution to reduction of public-health and ecologic risks.

RECOMMENDATION: 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, those sites in urban areas where economic use is avoided because of liability concerns. Also, Congress should grant EPA broader authority to develop

enforceable institutional controls.

RATIONALE

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 one 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, although it might seem to impose an additional step and concomitant delay, can improve the likelihood that the choice of remedy will reflect reasonably anticipated uses of the site and wishes of the community and reduce the dissonance and long delays often observed if goals and costs are debated only after EPA has proposed a remedy. Such a process is consistent with the Commission's risk-management framework.

Use of enforceable institutional controls, such as hazardous-substances easements, can make it feasible to protect health and the environment reliably into the future at cleanup levels that are less stringent than 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 redevelopment. Such redeveloped sites might provide economic-development opportunities in depressed areas and save pristine areas elsewhere. 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 a site can be predicted, detected, and remedied before substantial risks to health or further environmental contamination can occur. Hazardous on-site exposures due to changes in land use or failure to control access must also be prevented.

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FINDING 6.1.2.2: EPA needs additional guidance about choosing risk-based cleanup standards. Remedy selection and cleanup standards are complicated by innumerable and sometimes conflicting ARARs (applicable or relevant and appropriate state, or other federal requirements), including state legal requirements to clean up to "background."

RECOMMENDATION: EPA should continue to use its $10^{-6} > 10^{-4}$ risk range as a guide for site-specific risk-based cleanup goals. 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 about choice of data sets, 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 ARAR provision of the Superfund law should be amended to delete the "relevant and appropriate" language because it is subject to wide differences in interpretation, while retaining "applicable requirements."

RATIONALE

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 section 3.2).

There has been too much confusion and conflict over the ARAR provision and little use of the ARAR-waiver clause. The state and federal regulations that can serve as ARARs were often not written for conditions at Superfund sites, and they greatly complicate remedy selection and implementation. We support retaining applicable state and federal requirements as long as they do not conflict with the risk-based goals tied to future land use, as recommended in the preceding section.

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FINDING 6.1.2.3: There are many difficulties in the implementation of the balancing criteria of the National Contingency Plan for Superfund. 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. Especially at nonresidential sites, interruption of exposure pathways and other controls might be more appropriate than treatment. Worker protection and cost containment require more attention.

RECOMMENDATION: The mandate to use permanent solutions "to the maximum extent practicable" should be changed in the law to assurance of long-term reliability of protection of health and the environment. The preference for using treatment for the reduction of toxicity, mobility, or volume as a principal element should be targeted at highly hazardous material to ensure long-term reliability and should be overridden when no effective treatment remedy is available. EPA should continue to develop better 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.

RATIONALE

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 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 numerous truck trips 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, such as 30 - 50 years of pumping and treating groundwater contaminated by dense nonaqueous-phase liquids or construction of major terrain changes. On-site technologies that reduce toxicity, mobility, or volume should be used when appropriate. They should not be labeled as "innovative," which is a kiss of death for decision-makers; instead, 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. The least-expensive remedy is not always the most cost-effective; multiple health and ecologic effects might 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 discourage intrasite movement of wastes for less-intensive—yet efficient—treatment on-site. EPA has taken steps to reduce the problem via its Corrective Action Management Unit Rule and soon through its Hazardous Waste Identification Rule for contaminated environmental media, but the 104th Congress should remove the impediment to effective and efficient cleanup. Enactment in April 1996 of H.R. 2036, the Land Disposal Program Flexibility Act, provides a platform for complementing RCRA remediation reforms.

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FINDING 6.1.2.4: Superfund program costs have exceeded billions of dollars over 15 years and will increase. A budget process is needed to assure taxpayers and consumers that costs are being controlled. In general, decisions seem to be made without consideration of the aggregate effects, as though the capacity of taxpayers and consumers to support the federal and industry costs, as well as costs of responsible municipalities, is unbounded.

RECOMMENDATION: The entire national Superfund program— whether funded from the Superfund, private parties, municipalities, or some combination of those sources— should have an overall annual budget estimate so that Congressional appropriation and taxation decisions and EPA program actions can be better informed on a national scale. EPA's recently initiated risk-based allocation of cleanup funds should be developed for use in a budgeting and regulatory-impact analysis.

RATIONALE

The Commission believes that decentralized decision-making in regional EPA offices and in various states under authorized programs or Superfund cooperative agreements has led to many impractical and unduly expensive remedies, inconsistency, and limited learning from experience. Because potentially responsible parties must cover the costs of many remedial actions, there is little incentive for federal and state agencies to define a maximal cost when the record of decision (ROD) is made.

In the Bush Administration, EPA Administrator William Reilly proposed a "worst risks first" approach, but implementation has been inconsistent. Current EPA Administrator Carol Browner's policy and program initiatives have helped but could be enhanced by an assessment of aggregate needs and priorities. It will be difficult to propose and implement a budget plan for Superfund. The DOE Environmental Management Program constitutes an emerging example.

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FINDING 6.1.2.5: Once a record of decision (ROD) has been issued at a Superfund site, it has been difficult to revise the remedy selection, even when better and cheaper remedies have been identified later. In addition, changing policies on consideration of future land use could make it possible to alter the remedy in favor of a less expensive and smaller risk reduction.

RECOMMENDATION: EPA should expand and implement its new policy directive to address some general problems in older RODs. The agency should initiate changes in those RODs, or in response to petitions, and establish criteria for selective revision of RODs for particularly inappropriate remedies required in the past.

RATIONALE

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 - 50 years of pumping and treating of groundwater after initial reduction in contamination levels seems appropriate for reopening RODs. Protections must be included to avoid an avalanche of petitions to an agency without sufficient resources to respond and to avoid triggering unintended litigation. 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, such as containment and removal of dense nonaqueous-phase liquids.

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FINDING 6.1.2.6: 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 for hazardous-waste workers training programs 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.

RATIONALE

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 the American people want risk estimates and remedies that are based on sound science, not default assumptions, support for research programs that address them 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 clean up of sites are continuing responsibilities.

EPA's Technology Innovation Office has a private-public partnership program coordinated by Clean Sites 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.

6.1.3

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 section 5.4 of this report. This section focuses on issues related to the toxicity and registration of pesticides and on toxic substances.

FINDING 6.1.3.1: When EPA is precluded by the "Delaney clause" from issuing a tolerance for a pesticide, that pesticide cannot be used on a crop even if it meets all the requirements for registration under FIFRA and for a tolerance under section 408 of FFDCA. Thus, the Delaney clause effectively pre-empts the risk-benefit framework for regulation established in FIFRA and section 408 of FFDCA.

RECOMMENDATION: Pesticides should be exempted from regulation under section 409 of FFDCA and be regulated solely under FIFRA and section 408 of FFDCA. The standard of protection specified in section 408 should be changed 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 should be improved to allow for advances in scientific understanding and by requiring the consideration of potential highly exposed populations such as children.

RATIONALE

Together, FIFRA and section 408 of FFDCA establish risk-benefit comparison as the basis for pesticide regulation. Section 3 of FIFRA states that the administrator of EPA shall register a pesticide, provided that, among other requirements, "when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment" [section 3(c)(5)(D)]. "Unreasonable adverse effects on the environment" is defined in section 2 as "any unreasonable risk to man or the environment, taking into account the economic, social and environmental costs and benefits of the use of any pesticide" [section 2(bb)].

Section 408 of FFDCA provides requirements for establishing tolerances for pesticide residues in both raw agricultural commodities and processed foods. When a pesticide residue concentrates in processed food to greater than its section 408 tolerance concentration for the raw agricultural commodity, however, the processed-food tolerance is established under

section 409 of FFDCA. Section 409 (and not section 408) contains the Delaney clause, which is a proviso to the general safety standard. The Delaney Clause provides that "no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal." Interpreted literally, the Delaney clause requires application of a zero risk standard, which precludes consideration of risks and benefits. In practice, a pesticide can meet the standard for a tolerance under section 408, but can't be granted one if it is banned completely from processed foods under section 409 (the "Delaney paradox").

The conflicting requirements for pesticide regulation under FIFRA and FFDCA are not always in the interests of public and environmental health. Pesticides should be uniformly regulated according to risk-based standards and risk-benefit comparisons, such as those already provided for under FIFRA and section 408 of FFDCA. These issues are addressed more broadly in section 6.3 of this report, which focuses on the FDA.

If pesticides are to be regulated solely under FIFRA and section 408 of the FFDCA, Congress should also consider improvements to the existing safety standard. The standard should be flexible enough to account for changes in scientific understanding and to address emerging risk issues. For example, the National Research Council report *Pesticides in the Diets of Infants and Children* (NRC 1993) concluded that current tolerance-setting practices might not adequately protect children. The safety standard in section 408 of the FFDCA should be amended to require appropriate agency actions to ensure the adoption of the key recommendations of the NRC study.

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FINDING 6.1.3.2: 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 and to compare the risks and benefits associated with alternatives, provide a more complete evaluation of exposures and risks. Furthermore, to encourage development of safer pesticides and reduction in 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.

RATIONALE

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. For the agency 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 long-standing 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.

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FINDING 6.1.3.3: In recent years, review requirements for new chemicals and advances in the understanding of chemical toxicology have made important contributions to a lower incidence of new findings of carcinogenicity and other adverse effects among chemicals marketed. The Toxic Substances Control Act (TSCA) has not been reauthorized since its enactment in 1976, however, and EPA is mostly limited to review of data submitted, without being able to specify what studies should be conducted.

RECOMMENDATION: TSCA should be updated to reflect advances in toxicology and regulation over the last 20 years. Congress and EPA should clarify what kinds of toxicity, clinical, and exposure data should be generated as required under section 4 and reported under section 8 of TSCA.

RATIONALE

To help EPA with the continuous review of chemicals, manufactureres are responsible for reporting studies and other information that indicates the likelihood of adverse effects associated with their products. However, the extent of company responsibilities for reporting information on chemicals proposed to be marketed and chemicals not further developed is not

always clear. EPA/OPPTS is seeking to clarify both under TSCA 8(e) and FIFRA 6(a)(2) what studies and human adverse-event reports must be submitted to the agency.

OPPTS should devise means of analyzing technical information submitted under section 8, to address generic scientific and policy questions. For example, does use of a second species in toxicology tests add sufficient information to influence risk-management decisions? Are there biologically important correlations between the occurrence of tumors and other end points? TSCA potentially could provide a richer database than the National Toxicology Program (NTP), although without the systematic quality control of NTP bioassays. An analysis of new and old data that are required to be submitted under section 8(e) and 8(d) should be a joint effort of OPPTS and the Office of Research and Development/NCEA. Requirements to test chemicals have seldom been imposed; the threshold for issuing such a test rule is considered to require more extensive data than are available to justify it. Together, EPA and Congress should clarify section 4. Companies are required under TSCA 8(c) to retain files with reports of health effects in people exposed, but are not required to submit such files. EPA, industry, academics, and worker and consumer representatives could be brought together to propose criteria for making use of such information, relating it to use and exposure data to generate estimates of incidence rates, and developing practical analogies to the FDA adverse drug reaction reporting and analysis scheme.

The OECD recommends a basic set of testing requirements for new chemicals that are to be introduced to the market in member countries. Testing requirements are tiered and increase as the market for a product develops. Given the limitations of EPA's ability to require testing under TSCA and the absence of data accompanying new submissions, Congress should consider providing EPA with similar authority to specify what studies should be conducted by the manufacturer.

EPA is expected to propose testing protocols and testing requirements for effects of chemicals on endocrine functions, especially estrogenic, anti-estrogenic, and androgenic effects. At the first meeting of the Commission in May 1994, we invited Theo Colburn to discuss 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). Some, but not all, are mediated by or attributed to compounds that bind to estrogen receptors. Some are chlorinated compounds, but many others are not (alkylethoxylate plasticizers, for example).

Many scientific issues related to endocrine "disruptors" 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 and antagonists interact (estrogens and antiestrogens)? 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? Even higher than dietary doses of estrogenic chemicals are ingested in the form of oral contraceptives and post-menopausal hormone replacement therapy. The National Research Council has established the Committee on Hormone-Related Toxicants in the Environment to assess their known and suspected modes of action and potential toxicity and 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.

6.1.4

Office of Water

The EPA Office of Water has responsibility for protecting the nation's surface water and groundwater 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 1993). 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 on either available technology or 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 as amended 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. For each regulated pollutant, EPA publishes an unenforced maximum-contaminant-level goal based solely on health considerations and promulgates a standard that includes both health and feasibility considerations. Feasibility is determined by considering available technology and cost. The importance of safe drinking water was driven home in April 1993, when *Cryptosporidia* in the Milwaukee water supply caused an epidemic resulting in death and severe intestinal disorders.

The following recommendations are intended to build on the important improvements of the last 25 years in surface water, groundwater, and drinking water.

FINDING 6.1.4.1: 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 that uses ecological risk assessment and biotic-integrity measurements and 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.

RATIONALE

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. However, 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. And it can also be affected by activities that disturb the land, including logging and grazing, construction (especially of dams and reservoirs), diversion of surface-water and groundwater 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. 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 section 3.4) 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 organization, including individuals, communities, habitats, landscapes, ecosystems, and combinations of these. 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 state- and local-governments 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, in that 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.

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FINDING 6.1.4.2: Regulation of water pollution under the Clean Water Act is implemented generally 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. However, risk-based effluent limits should not yet supplant technology-based and quality-based techniques for reducing water-pollutant discharges and protecting water quality.

RATIONALE

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 section 3.4). For example, the impacts of endocrine "disruptors" on fish and on the offspring of fish-eating animals 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.

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FINDING 6.1.4.3: 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 and to the development of data for assessing relationships among the occurrence of microbial contamination, the use of disinfectants, and the formation of potentially hazardous disinfection byproducts.

RATIONALE

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 has 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 before new drinking-water standards are promulgated. 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 potential risk reduction.

6.2

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 disease and injury. In 1994, occupational injuries alone were responsible for an estimated $120 billion in lost wages and 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 Occupational Safety and Health Administration (OSHA), established in 1970 as a part of the Department of Labor, was charged with the responsibility of reducing worker injury, illness, and death caused by workplace hazards and exposures to toxic substances and harmful physical agents. The Occupational Safety and Health Act of 1970 directed OSHA "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 several means, including "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 providing for the development and promulgation of occupational safety and health standards". The mandate specifies that workplace standards that OSHA promulgates must be economically feasible, be technologically feasible, and have demonstrable benefits.

The National Institute for Occupational Safety and Health (NIOSH) was established by the Occupational Safety and Health Act as a part of the Department of Health and Human Services to conduct scientific research in occupational safety and health; to develop innovative methods, techniques, and approaches for addressing problems in occupational safety and health; to train a workforce of professionals in occupational safety and health; and to make recommendations to OSHA about standards for occupational safety and health. NIOSH identifies the causes of work-related diseases and injuries and the potential hazards of new work technologies and practices. With this information, it determines new and effective ways to protect workers from exposure to toxic substances, harmful physical agents, machine- and equipment-related hazards, and hazardous working conditions.

FINDING 6.2.1: The nation's recordkeeping system for job-related injuries is widely accepted although underreporting is considered as substantial. In contrast, 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, and the cost of occupational illnesses is believed to exceed that attributable to injuries. For example,

including lost work days and reduced productivity, the costs of occupational skin diseases alone might reach $1 billion a year. 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 occupational risks cannot be assessed in the absence of adequate national surveillance data.

RECOMMENDATION: To assess the effects of OSHA's regulations on workplace health and safety for the purpose of guiding NIOSH and OSHA research and regulatory priorities, Congress should direct NIOSH to strengthen its surveillance and intervention-effectiveness research and OSHA to expand its evaluation program.

RATIONALE

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 agents. Many cases of fatal, chronic, and disabling occupational diseases develop over 10-30 years and are poorly counted by employer reporting or workers-compensation systems. For the cases that are reported, the attributable costs underestimate costs due to lost productivity and reduced earning potential, and 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 2 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, however, can be assessed and, hopefully, verified through an effective surveillance program.

In a similar process over the last year, NIOSH led 500 federal agencies, industries, associations, labor unions, academics, and private citizens in the development of the National Occupational Research Agenda. The agenda 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. Risk assessment

itself was identified through testimony as a priority.

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 that they were 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.

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FINDING 6.2.2: 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.

RECOMMENDATION: OSHA and NIOSH should focus on ways 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. Current programs focused on cooperation between the organizations should be strengthened.

RATIONALE

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 have different responsibilities and play different roles in protecting worker health and safety, but they are clearly interdependent. NIOSH provides OSHA with scientific criteria and recommendations in support of OSHA's mandate to set health and safety standards. NIOSH identifies health-based exposure limits, and OSHA uses them to develop occupational standards that reflect feasibility considerations.

An interagency task force was formed to conduct the priority-planning process. There is an exchange of senior staff, who serve as full-time liaisons within the agencies' directors' offices. Because their risk-assessment and risk-management responsibilities are closely linked, it is important that they seek ways to ensure an effective interaction.

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FINDING 6.2.3: 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—might 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. The guidelines should, at a minimum, cover the following: 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.

RATIONALE

Risk-assessment guidelines have served EPA well over the years. OSHA has similar needs but its analyses are sufficiently different that it cannot simply 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 should be 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.

6.3

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 are considered in conjunction 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.

FINDING 6.3.1: 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. Prohibition was an appropriate 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.

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, as is in keeping with well-established FDA statutory language.

RATIONALE

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. 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. (See also the discussion in section 6.1.3 of this report about the inconsistencies between FIFRA and sections 408 and 409 of FFDCA in the case of pesticides.)

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 as 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 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 section 3.1). However, even in 1958, 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 botulism in 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.

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FINDING 6.3.2: 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 and properly evaluated by disinterested experts.

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 post-marketing 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. And FDA should continue to work with other countries to harmonize procedural and paperwork requirements, as well as the protocols. Such efforts should be broadened beyond HIV-AIDS and cancer treatment agents to other classes of therapies.

RATIONALE

There is an inevitable tension 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 reviews must be accompanied by requirements for strict 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.

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FINDING 6.3.3: 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 substantial scientific evidence 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 Dialog 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 of lack of benefit of and probable harm from beta-carotene supplements in smokers at high risk of lung cancer and heart disease illustrate 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.

RATIONALE

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 trails 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.

6.4

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, 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, that the statutory requirements of the act are met. This section offers several recommendations that should be considered as the office's activities take shape.

FINDING 6.4.1: USDA's Office of Risk Assessment and Cost Benefit Analysis (ORACBA) has the statutory authority to review a major regulation before it is submitted to the Secretary of Agriculture, but only at the end of the regulation-development procedure.

RECOMMENDATION: ORACBA should become involved in regulation development as soon as the impetus for a regulation is identified.

RATIONALE

Waiting 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 does not make sense. Considerations of context, 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 much time and resources will already have been invested in the outcome.

* * *

FINDING 6.4.2: 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.

RATIONALE

As noted in section 5.5 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 a regulatory decision. Involving independent peer reviewers in the regulatory process can help to clarify the objectives and scope of rule-making 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 5.5. 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.

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FINDING 6.4.3: 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 the University of Washington's School of Public Health, which relied on modern genetic techniques for detecting and tracing contamination. Salmonella contamination of chicken and 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 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.

RATIONALE

A key responsibility of USDA, together with FDA, is protecting the nation's food supply from microbial contaminants. USDA's meat and poultry inspection program and FDA's food inspection program were not designed to prevent food-safety problems. 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 food-industry 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, prevention's key elements are anticipation of the problems to be prevented and design of appropriate preventive methods. These require a useful knowledge base and continuous scientific progress from research on such topics as viable-but-not-cultural microorganisms, 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 information 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. 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 in section 3.6 of this report. 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 section 6.1.4).

6.5

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 the World War II and of the Cold War. The purpose of environmental management at DOE is to reduce health and safety risks associated with radioactive and hazardous waste and contamination resulting from the production, development, and testing of nuclear weapons. This section offers recommendations on the use of comparative risk for priority-setting and budgeting.

FINDING 6.5.1: 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 2½-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 (see section 6.1.2.4).

RATIONALE

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 beginning a "down-sizing." 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 know-how at 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 DOE needed to identify new institutional mechanisms to develop "objective, neutral, systematic, and iterative risk-based analysis" for DOE sites. Within 60 days, the Research Council committee issued *Building Consensus Through Risk Assessment*, supporting the DOE plan (NRC 1994b). That 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.

Simultaneous with this long-term institution-building, 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 now rank the significance of each DOE activity in terms of seven considerations, the first three of which 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 develop 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.

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FINDING 6.5.2: DOE sites represent an important opportunity to evaluate potential risks to workers from remediation activities.

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.

RATIONALE

EPA has seldom evaluated worker risks at Superfund sites. This omission results partly because workers often do not reside locally and therefore do not participate in the risk-assessment or remedial decision, and partly because workers receive a benefit—their jobs and their pay—which does not accrue to the community at risk. In contrast, DOE sites are generally in remote communities where the remediation workers are or become part of the community at risk, during what is expected to be longer, sustained efforts at remediation in comparison to Superfund sites. The employment provided by the need to remediate is considered a benefit to the community.

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.

6.6

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 for environmental security about DOD's strategy for implementing a relative-risk-based ranking 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.

FINDING 6.6: The contaminated sites that DOD is legally bound to clean up are not all sites that pose the worst risks to health or the environment. DOD has developed a relative-risk ranking procedure to facilitate 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.

RATIONALE

Listing procedures for the 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 DOD's contaminated sites, a means to focus remedial activity that is consistent with relative risks to health and the environment was needed.

To assess relative risks at sites to help in the sequencing of remedial work, DOD developed the Relative Risk Site Evaluation Concept. The concept categorizes sites as of high, medium, or low risk on the basis of three factors: a hazard factor (a combined measure of contaminant concentrations in a given environmental medium), a migration-pathway factor (a measure of movement or potential movement of contaminants away from the original source), and a receptor factor (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 regulatory-agreement status and public health

recommendations. A special consideration with regard to cleanup practices and community involvement arises 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.

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Commission on Risk Assessment and Risk Management

Risk Assessment and Risk Management in Regulatory Decision-Making

DRAFT REPORT
FOR
PUBLIC REVIEW AND COMMENT

Appendices

June 13, 1996

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Appendix A.1

Biographies of Commission Members

COMMISSION ON RISK ASSESSMENT AND RISK MANAGEMENT

Member Biographies

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. He was appointed to the Commission by President Clinton.

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 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 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. 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 pharmacology, 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 A.2

Mandate of the Commission on Risk Assessment and Risk Management

United States Environmental Protection Agency
Advisory Committee Charter

Risk Assessment and Management Commission

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

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

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

The Commission shall consider:

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

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

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

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

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

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

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

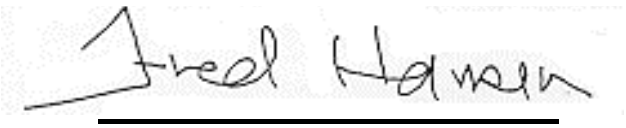
(b) The Commission may appoint and fix the pay of such staff as it deems necessary in accordance with the provisions of title 5, United States code. The Commission may request the temporary assignment of personnel from the Environmental Protection Agency or other Federal agencies.

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

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

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

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



NOV 14 1994
Agency Approval Date

Deputy Administrator

NOV 15 1994
Date Filed with Congress

Appendix A.3

Comments on
Science and Judgement 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.

Appendix A.6 of the Commission's report 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 5.3 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 upper 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 3.3 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 A.4

Individuals Who Presented Testimony at Commission Meetings

Speakers 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

Russell Jim
Manager
ER/WM Program
Yakama Indian

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

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
President
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 A.5

Abstracts of Reports Prepared at the Invitation of the Commission

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1. **A Survey of Methods for Chemical Health Risk Assesment among Federal Regulatory Agencies, prepared by Lorenz R. Rhomberg**

2. **Health Risk Assessments Prepared per the Risk Assessment Reforms under Consideration in the U.S. Congress, prepared by Cambridge Environmental Inc.**

3. **Cost-Benefit Analysis and Regulatory Reform, prepared by Resources for the Future**

4. **An Assessment of the Risk Assessment Paradigm for Ecological Risk Assessment, prepared by Menzie-Cura & Associates Inc.**

5. **Review of Noncancer Risk Assessment: Applications of Benchmark Dose Methodologies, prepared by Elaine M. Faustman**

6. **Comparative Risk Analysis for Priority Setting, prepared by David B. McCallum and Susan Santos**

7. **Communicating to the Public: Using Risk Comparisons, prepared by David B. McCallum and Susan Santos**

To obtain copies of the complete reports, circle those desired and facs to 202-233-9540 with your name, address, and phone written below, or obtain them over the internet at the *RiskWorld* website, http://www.riskworld.com, after they become available on July 1, 1996.

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 National 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 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 choice 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 simple 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 such 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[1] 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 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 required (1) significant research in the scientific literature, and (2) not a small amount 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.

[1] In particular, bills S 343 and HR 1022.

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-DOE, standard	1.2×10^{-9}	1.6×10^{-6}	1.7×10^{-6}	1.3×10^{-4}
1,1-DOE, 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-DOE workers	1.4×10^{-6}	3.6×10^{-3}	8.4×10^{-3}	2.7×10^{-2}

Several comparisons are noteworthy. In the first case study, U.S. 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 distribution. 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 upperbound -- would likely indicate dramatically different intervention strategies. Risks 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 three-fold 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 over-exposed 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 a 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

Cost-Benefit Analysis and Regulatory Reform

Raymond Kopp, Alan Krupnick, and Michael Toman
Senior Fellows, Resources for the Future

Executive Summary

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 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 can 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 outcome, 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* (Figure 1). The National Research Council (1993) published a similar paradigm.

The USEPA (1992) paradigm for ecological risk assessment expands upon the NRC's (1983) 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 assessors. 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 stage - 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 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 (Figure 10).

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 communication 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 judgement 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 judgements 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 stage 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 than 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

Abstract

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

Abstract

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

Abstract

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 seem 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 radon 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.

Appendix A.6

Federal Agency Risk Assessment and Risk Management Practices

Federal Agency Risk-Assessment and Risk-Management Practices[1]

Introduction

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

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

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

The basic issues of chemical health risk assessment and the role of risk assessment methods, default assumptions, and conservatism have been discussed in the National Academy of Sciences Report, *Science and Judgment in Risk Assessment* (NRC, 1994). This document builds on earlier works taking a comprehensive view of risk assessment and the principles underlying its conduct, especially *Risk Assessment in the Federal Government: Managing the*

[1]This appendix was prepared using material taken from a report prepared for the Commission by Dr. Lorenz Rhomberg of the Center for Risk Analysis at the Harvard School of Public Health.

Process (NRC, 1993), widely known as the "NAS Red Book," and *Chemical Carcinogens: A Review of the Science and Its Associated Principles* [50 FR 10371-10442], widely known as the "OSTP Principles."

These documents epitomize an ongoing discussion that has largely succeeded in defining a common framework and structure for risk assessment. Within this framework, however, there continues to be vigorous debate about the most appropriate risk assessment approaches, the bearing of various kinds of data on risk projections, and the degree and appropriateness of conservatism in risk assessment methods. Faced with this continuing disagreement about methods, various Federal regulatory agencies have adopted somewhat different procedures. In part, this diversity can be attributed to the different questions being asked of the risk assessment process in different regulatory contexts by different 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 of methods among Federal regulatory agencies is to make it difficult to compare risks, or the actions taken to mitigate those risks, from one regulatory program to another. One program's concern for a one-in-a-million cancer risk, say, may be based on an upper bound low-dose extrapolation to an average person in the exposed population extrapolated from mice based on a presumption of equal toxicity when daily doses are scaled by surface area, while another program's one-in-a-million is for a hypothetical person exposed to an agent at the regulatory limit for 45 years based on a maximum likelihood low-dose extrapolation and the presumption that equitoxic doses are proportional to body weight.

Although defaults and standard methods are necessary in the face of uncertainty and lack of case-specific knowledge, variation from group to group in these defaults enhances the sense of arbitrariness in risk analyses. In cases where regulatory responsibilities overlap or when different groups have cause to assess the same exposures, differences in assessment outcome can lead to conflict and confusion among the public and the regulated community.

This chapter attempts to sort out some of those sources of confusion by analyzing the public health mandates and regulatory powers of a number of risk-related regulatory programs' enabling statutes (see Table A.6.1), along with risk assessment and risk management practices as they have evolved in response to those statutes. Special attention is focussed on the laws' requirements about who in the exposed population is to be protected, and how sufficiently protective standards are defined. A summary overview of Federal risk-based regulations, mandates, statutory language, and principal differences in risk assessment methods is provided in Table A.6.2.

Table A.6.1. Environmental regulatory statutes addressed in this report.

Abbreviation/ Citation	Statute Title	Responsible Federal Office
CAA 42 U.S.C.A. §§ 7401 to 7671q	Clean Air Act	EPA, Office of Air and Radiation (OAR)
CWA 33 U.S.C.A. §§1251 to 1387	Clean Water Act (Federal Water Pollution Control Act)	EPA, Office of Water (OW)
SDWA 42 U.S.C.A. §§300f to 300j-26	Safe Drinking Water Act (Public Health Service Act)	EPA, Office of Water (OW)
RCRA 42 U.S.C.A. §§ 6910 to 6992k	Resource Conservation and Recovery Act (amending Solid Waste Disposal Act)	EPA, Office of Solid Waste and Emergency Response (OSWER), Office of Solid Waste (OSW)
CERCLA 42 U.S.C.A. §§ 9601 to 9675	Comprehensive Environmental Response, Compensation, and Liability Act	EPA, Office of Solid Waste and Emergency Response (OSWER), Office of Emercency and Remedial Response (OERR) ["Superfund"]
TSCA 15 U.S.C.A. §§2601 to 2692	Toxic Substances Control Act	EPA, Office of Prevention, Pesticides, and Toxic Substances (OPPTS), Office of Pollution Prevention and Toxics (OPPT)
FIFRA 7 U.S.C.A. §§ 136 to 136y	Federal Insecticide, Fungicide, and Rodenticide Act	EPA, Office of Prevention, Pesticides, and Toxic Substances (OPPTS), Office of Pesticide Programs (OPP)
FFDCA 21 U.S.C. §§ 321 to 394	Federal Food, Drug, and Cosmetic Act	Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition (CFSAN); *and* EPA, Office of Pesticide Programs
OSHAct 29 U.S.C.A. §§ 650 to 683	Occupational Safety and Health Act	Department of Labor (DOL), Occupational Safety and Health Administration (OSHA)
CPSA 15 U.S.C. §§ 2051n to 2084	Consumer Product Safety Act	Consumer Product Safety Commission (CPSC)
FHSA 15 U.S.C. §§ 1260 to 1278	Federal Health and Safety Act	Consumer Product Safety Commission (CPSC)
APA 5 U.S.C.A. §§ 551 to 559	Administrative Procedures Act	

Table A.6.2 Summary overview of Federal regulation of potentially toxic chemicals, including risk mandates, key statutory language, and principal differences in risk assessment methods among Federal regulatory programs.

Program Office	Statute/ Activity	Risk Mandate	Role of Carc Class.	Special Quant Methods	Individual Risks Considered	Population Risk Considered	Special Groups	Usual Acceptable Residual Risk	Practical Regul. Trigger or Criterion
OPPTS-OPPT "Toxics"	TSCA	avoid and mitigate "unreasonable risk" via risk-benefit balancing	no	"additional" cancer risk above background	yes, "reasonable worst case" for occup expos	yes, indirectly	workers, consumers, genl popn	unstated, but usually 10^{-5} to 10^{-6} for non-occup-ational, 10^{-4} to 10^{-5} for occup	
OPPTS-OPP "Pesticides"	FIFRA (registr.; use limits)	balance risks, benefits, social & economic costs; efficacious yet w/o "unreasonable risk to man or environment"	no QRA for *some* "C's"		yes, broadly, assume max permissible residues, but average food consumptions	yes		unstated, but usually 10^{-5} to 10^{-6} for non-occup-ational, 10^{-4} to 10^{-5} for occup	interplay of efficacy and tolerances for residues; registrant proposes use limits
	FFDCA (residue tolerances)	"Delaney Clause," no additives that are animal carcin.; "reasonable certainty of no harm" for residues	any pos cancer assay triggers Delaney		no for carcinogenic additives; yes for residue tolerances	yes for residue tolerances	demogr. sub-population diets considered	zero for additives; 10^{-6} for assumed max residues in average diet, 10^{-6} for non-dietary exposure	Delaney prohibition of carcinogenic additives
OW	SDWA (drinking water)	for carcinogens, unenforceable max contam limits (MCL) of zero, but enforceable goals (MCLG) set by technology if within adequate margin of safety	yes, "C's" may be treated as threshold	extra UF on NOAEL for "C's"	a standard exposure scenario in middle range	no	no	10^{-4} to 10^{-6} is range considered to be adequate	MCLG's primarily based on technical, cost feasibility if risk range hit.
	CWA (waterway water qual)	protect public health and welfare with non-enforceable, health-based water quality criteria and enforceable "best" technology based effluent standards	no	conserv. water transport models determine acceptable daily loading of water bodies	a standard exposure scenario in middle range	no	no	10^{-5} to 10^{-7}	standards set by states with EPA guidance; some consideration of residual risk after best avail tech effluent limits

Program Office	Statute/ Activity	Risk Mandate	Role of Carc Class.	Special Quant Methods	Individual Risks Considered	Population Risk Considered	Special Groups	Usual Acceptable Residual Risk	Practical Regul. Trigger or Criterion
OSWER	RCRA (haz waste handling, active disposal)	aim at "cradle-to-grave" stewardship; technology- and process-based, but also risk-triggered corrective action, to be protective of human health and the environment, excluding costs	in some haz waste ID criteria; C's may be treated specially	uses OW MCL's or its own QRA to list or delist as a haz waste	yes, a rather conservative estimate of hypothetical transport and exposure near a problem site, but uses some Monte Carlo modeling	no	hypothetical populations around haz waste facilities	listing: 10^{-5} corrective action: 10^{-4} to 10^{-6} incinerators: 10^{-5}	cleanup strategy chosen with site-use, feasibility considerations as long as within risk range of 10^{-4} to 10^{-6}
	CERCLA Superfund, abandoned and active haz waste site monitoring and cleanup	applicable other laws plus cleanup to be protective of human health and environment; risk-based but consider feasibility	no	consider cumulative risk of mixtures (but not exposure to multiple sites)	"reasonable maximum exposure" using mix of midrange and conservative assumptions	high population around site prompts listing on NPL	hypothetical populations around site, scenarios for special groups (real or hypothetical)	10^{-4} to 10^{-6}, depending partly on anticipated future use of site	site-specific "ranking" QRA for listing, prioritization of site; then more detailed risk assessment to choose actions reaching target risk range of 10^{-4} to 10^{-6}
OAR	CAA Criteria pollutants	adequate margin of safety to protect public health	non-cancer only	extensive data, including on humans	yes	yes			without harmful effects on most people
	CAA Hazardous Air Pollutants	Must apply Max Avail Control Technology; If residual risk to MEI >10^{-6}, further regulate to provide adequate margin of safety to protect public health, considering costs	no	Maximally Exposed Individual for each source can trigger residual risk provision	Only after MACT; MEI >10^{-6} triggers further action; MEI <10^{-6} before controls yields de minimis exemption	presumably yes, when assessing residual risk	populations around sources	<10^{-6} ??	apply best controls as default, then consider further regulation if needed

Program Office	Statute/ Activity	Risk Mandate	Role of Carc Class.	Special Quant Methods	Individual Risks Considered	Population Risk Considered	Special Groups	Usual Acceptable Residual Risk	Practical Regul. Trigger or Criterion
FDA	FFDCA (food additives, colors & contam-inants; cosmetics)	“Delaney Clause,” no additives that are animal carcin.; "reasonable certainty of no harm" for residues, no cost considerations	any pos cancer assay triggers Delaney	"modified" Gaylor-Kodell procedure for carcinogens, body weight dose scaling	no for carcinogenic additives; yes for additives, contaminants	no	demogr. sub-population diets considered	zero for additives; 10^{-6} for assumed max residues in "high use" diet	Delaney prohibition of carcinogenic additives
OSHA	OSHAct (occup. exposures)	"no employee will suffer material impairment of health," considering feasibility of stds	no, frequent use of human data	MLE of multistage model, body weight dose scaling	yes, for full working life at permissible exposure limit	no	no	feasible controls	"significant" risk (in practice, 10^{-3})
CPSC	CPSA FHSA (consumer products)	"to protect...against unreasonable risk of injury" with "reasonably necessary" standards, considering cost/benefit	scheme similar to EPA's, focus on agents with "sufficient evidence"	MLE if linear, surface area dose scaling, combine tumor types	not explicitly	yes, in context of cost-benefit analysis	impact of regulation (not risk) on elderly, handicapped	unclear	"reasonably necessary," least burdensome standards with benefits "bearing a reasonable relationship" to costs

Survey of Practices

Food and Drug Administration

The Food and Drug Administration (FDA), which resides within the Department of Health and Human Services, has a number of divisions. The primary one of interest to this report is the Center for Food Safety and Applied Nutrition (CFSAN); most of the FDA's assessment of potential human health risks from exposure to chemical substances is conducted by CFSAN in conjunction with its regulatory responsibility over additives and contaminants of foods and cosmetics.

The principal legislation on which FDA's authority is based is the Federal Food, Drug, and Cosmetic Act (FFDCA). Although it has been much amended over the years, the original act dates to 1906, making it by far the oldest among federal laws concerned with the regulation of public health risks from toxic substances. As such, much of the methodology for safety evaluation and risk assessment had its origin and early evolution in the implementation of parts of the FFDCA. The act had its origin in response to widespread scandals and "muckraking" exposés of poisonings from dangerous patent medicines, unwholesome meat packing, adulterated foods, and misrepresentations in labeling. Accordingly, the provisions of the act stress avoidance of "filthy, putrid, or decomposed" ingredients, sanitary conditions for processing and packing, proper identification and labeling, and strict limits to prevent "adulteration" of foodstuffs. It is in these adulteration provisions that toxicological risk assessment issues arise—foods are considered adulterated under the act when they contain "added substances" that are poisonous or injurious to health. The application of the act becomes somewhat arcane because the law distinguishes several categories of added substances: food additives, color additives, pesticides, and animal drugs. The question of pesticides is further complicated by the fact that regulatory authority over pesticides is shared by FDA under the FFDCA and the Environmental Protection Agency under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

"Food additives" (regulated under §409) exclude adequately tested substances listed by the agency to be recognized as safe "among experts qualified by scientific training and experience to evaluate its safety" (§201); otherwise, the safety of additives is established by the agency's granting of a petition by the would-be user (although agency initiative is also allowed and pursued in practice). The petition must contain experimental and toxicological data bearing on the evaluation together with a statement of the conditions of proposed use. In its response, the agency specifies conditions of permissible use (which may differ from those proposed) and maximal concentrations that may remain in the food when marketed. Section 409 specifies that, in considering what uses are safe, "the Secretary shall consider among other relevant factors...the probable consumption of the additive,...the cumulative effect of such additive in the diet..., taking into account pharmacologically related substances,...[and] safety factors which in the opinion of experts qualified by scientific training and experience...are generally recognized as appropriate for the use of animal experimentation data." (Although this is phrased quite generally, this still ranks as one of the more specific statements about risk

assessment methods to be found among environmental laws.) Section 409 also stipulates that tolerances should be set no higher than is "reasonably required to accomplish the physical and other technical effect for which such additive is intended" notwithstanding the fact that higher levels might be deemed safe. "Color additives" are regulated under a separate section of the act (§721); other than some procedural differences, however, the risk assessment provisions are similar to those applying to additives.

This methodologic prescription applies only to non-cancer toxic effects, however, because at §409(c)(3)(A) the FFDCA contains a very specific statement about how the safety of potentially carcinogenic food additives is to be treated. This is the well known "Delaney Clause," named after the sponsor of the 1958 amendment under which the provision was included in the act. It states that "no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal." The rationale cited at the time of the Delaney Clause's adoption was that carcinogens may be without a threshold concentration of toxic action; thus no exposure level could be declared "safe." This stipulation prohibits consideration of the quantitative level of risk that an additive might pose, effectively avoiding the quandary faced under other environmental laws of defining "acceptable" levels of cancer risk.

The Delaney Clause specifically exempts "the use of a substance as an ingredient of feed for animals which are raised for food production" if it is found that "no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary...) in any edible portion of such animal after slaughter...or in any food...derived from the living animal" [§409(c)(3)(A)]. This so-called "DES proviso" was added (in 1962) to allow the use of potentially carcinogenic animal drugs (such as diethylstilbestrol, or DES) as long as they did not harm the treated animals and left "no" residues in the derived food products. The weakness of this formulation became evident as methods for detection of chemical residues became more and more able to detect tiny, even infinitesimal amounts. This led to a quandary: the Secretary could fail to specify the most sensitive existing methods (thereby technically avoiding "detection" of chemicals known scientifically to be present) or he could specify that technical advances in detection should be used (thereby indirectly reversing decisions about "safety" of additives even though knowledge about their safety was not what was changing). Debate about the Sensitivity of Method standards produced the realization that the true issue was not about changing detectability, but about the potential for minute quantities of the agent to cause meaningful risk. This debate led to the development of the first methods for quantitative risk assessment of carcinogens at the FDA.

As with most environmental laws, the mandates in the FFDCA about risk are phrased generally and depend on interpretation. Section 409, applying to additives, requires that only uses that may be demonstrated to be "safe" be permitted. Soon after this section's addition to the FFDCA in 1958, the agency officially defined "safe" as meaning "that there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use" but recognized that absolute safety could not be definitively

guaranteed (21 CFR 170.3). (This has commonly been codified into the phrase "a reasonable certainty of no harm," which is widely regarded as a quotation from §409, although it does not in fact appear in the act.) Under §409, consideration of benefits and costs is not allowed.

Section 408, applying to non-concentrating pesticide residues, requires setting tolerances "to the extent necessary to protect the public health," but also states that "appropriate consideration" be given "to the necessity for the production of an adequate, wholesome, and economical food supply." That is, costs and benefits are to be weighed, albeit in an unspecified way.

As with other environmental laws with generally phrased mandates about risk, the specifics of how risk assessment is conducted in practice at the FDA depends on the particular procedures put in place to implement the mandate. Remarkably little of this implementation is firmly documented in citable policy documents, guidelines, or standard operating procedures. This is particularly true of the FDA. Some ascribe this to a desire to maintain as much flexibility as possible in the face of the rigidity and draconian nature of decisions mandated under the Delaney Clause, but it is perhaps more reasonable to note that the history of risk assessment at FDA is long and represents a period of considerable evolution of the role of risk considerations in regulation, from qualitative, *ad hoc*, and peripheral to quantitative, codified, and central. Much of the methodology was invented in attempts to respond to new and emerging needs from the regulatory process. In any case, the methods are codified largely in the history of evolving practice at the agency and in the documentation of regulatory actions (e.g., in the preambles to rules, laying out methods of analysis, in *Federal Register* notices).

To a great extent, the FDA relies on seminal publications outlining risk assessment principles as the grounding for its methods. These include the Red Book and the OSTP Principles. These expert consensus documents largely reflect compilation of insights and approaches first developed at FDA along with their elaboration and further development by the agency and other risk-assessing institutions. Unlike the EPA, however, the FDA has no officially published "guidelines" that establish standard methods for conducting risk assessment.

Occupational Safety and Health Administration

OSHA was created by, and has its regulatory authority under, the Occupational Safety and Health Act of 1970. (Because the agency and the act share the same acronym, the act is typically abbreviated as "OSHAct" and the agency itself as "OSHA.") The act's stated purpose is "to assure so far as possible every working man and woman in the Nation safe and healthful working conditions" by several means, including "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" (OSHAct §2). It was passed during the heyday of public concern about environmental health that also saw the founding of the Environmental Protection Agency. Regulatory decision-making under the OSHAct is formally invested in the Secretary of Labor.

The act mandates in §5(a) that "Each employer...shall furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm." The regulatory authority of OSHA is provided by §6 of the act, which sets out methods and criteria for issuance of occupational safety and health standards. In particular, §6(b)(5) states that "The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents...,shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard...for the period of his working life." This paragraph further states that "In addition to the attainment of the highest degree of health and safety protection for the employee," the Secretary must consider "the feasibility of the standard" and that "Whenever practicable, the standard promulgated shall be expressed in terms of objective criteria and of the performance desired."

In other words, the achievement of safe and healthful workplaces is to be brought about by the setting of enforceable workplace standards, in practice framed primarily in terms of allowable limits to employee exposure. For a workplace to be considered healthful, the limits to exposure are to be set so that an employee could be exposed at the limit for an entire working life without suffering harm. The authority is over the exposure limits, not over how they are achieved. In practice, engineering controls are preferred to respirators, where feasible. In §6(b)(7), however, it is stated that "Where appropriate, such standards shall also prescribe suitable protective equipment and control or technological procedures to be used in connection with such hazards." (This paragraph goes on to prescribe labels, warnings, and provisions for ongoing monitoring of employee exposure.)

The OSHAct does not mention risk assessment as such, nor does it say much about the establishment of safe exposures. It is more explicit than some other laws about what constitutes an adverse health effect, however. In §2 it refers to "diminished health, functional capacity, or life expectancy" while §6 mentions "material impairment of health or functional capacity" as outcomes to be avoided. The mandated focus is on individual risk to a hypothetical employee experiencing an agent at the permissible exposure limit for a working lifetime, with regulation set "to the extent feasible" so that such an employee will suffer no impairment. The interpretation of these provisions has undergone considerable evolution as the result of some key judicial challenges. A full account is beyond the scope of this report, but the history and issues are reviewed by Graham et al. (1988).

Initially, the mandate was interpreted as essentially a health-based standard with an added proviso that health-based regulations could not be set so low as to be infeasible, interpreted as meaning having significant financial impact on the industry. For carcinogens, the lack of demonstrable exposure thresholds for toxic effect was interpreted to mean that no workplace exposure standard, however low, could assure that "no employee will suffer material impairment of health." Accordingly, the "feasibility" provision becomes the limiting factor, and workplace standards for carcinogens were set as low as was deemed to be technically feasible at reasonable cost. Under this interpretation, in a proposed "carcinogen policy" (42

FR 54148, 1977), risk assessment for carcinogens played a rather minor role in OSHA's setting of workplace standards, and OSHA staff generally argued that the uncertainties of quantitative cancer risk assessment precluded its use as a basis for regulation.

A proposed 1 ppm standard for workplace benzene exposure set under this interpretation was challenged in court, eventually leading to a 5-4 Supreme Court decision [Industrial Union Department v. American Petroleum Institute, 448 U.S. 607 (1980)], commonly known as the "benzene decision," which imposed fundamental changes in the interpretation of the OSHAct mandate. The court ruled that, before issuing a standard, OSHA must first demonstrate that the chemical posed a "significant risk." Unless the risk is significant, the material does not become a "toxic material" or "harmful physical agent" controllable under the act, and its presence cannot be said to meaningfully lead to an unhealthy workplace. A key part of this finding was that the §3(8) definition of a standard as a "reasonably necessary or appropriate" action was taken as grounds that action under §6(b)(5) must be shown to be necessary in some quantitative sense. While stating that "OSHA is not required to support its finding that a significant risk exists with anything approaching scientific certainty," the court ruled that the case for significant risk could in principle be made using quantitative risk analysis. On the question of how large a cancer risk is "significant," Justice Stevens, in his opinion, stated that this was OSHA's responsibility, conceded to be a matter of policy, but that "If, for example, the odds are one in a billion..., the risk clearly could not be considered significant. On the other hand, if the odds are one in a thousand..., a reasonable person might well consider the risk significant and take appropriate steps to decrease or eliminate it."

In effect, the benzene decision prompts OSHA to conduct quantitative risk assessment in order to set standards for carcinogens. The court declined to address the related question about whether the "feasibility" and "reasonably required" standard-setting issues should be interpreted to require cost-benefit analysis of proposed standards. In a later supreme court decision, the "cotton dust decision" [American Textile Manufacturers Institute v. Donovan, 452 U.S. (1981)], the court ruled that OSHA may set a level as protective of health as feasible, even if a less stringent one has a more favorable cost-benefit ratio.

One further court case of note is the recent ruling [AFL-CIO v. OSHA, 965 F.2d. 962 (1992)] that OSHA must make its risk case for each chemical according to its own analysis. The practice of adopting outside standards, and of setting standards based on general risk arguments rather than case-by-case demonstration of significant risks, was struck down, invalidating 428 OSHA permissible exposure limits.

Since the benzene decision, risk assessment at OSHA has been dominated by the question of showing "significant" risk from exposure to workplace carcinogens. The question that Justice Stevens threw back to OSHA in his benzene opinion—what constitutes a "significant" risk (within the limits he set)?—has never been fully answered. Justice Stevens' statement that a lifetime risk of one in a thousand is clearly significant has served as something of a benchmark; in practice risks below 10^{-5} are rarely given much significance, but the lower bound on risks considered significant is hard to define because it is difficult to show. There is

no real case to date where OSHA did not pursue a standard because cancer risks were calculated to be low. In this case, the "significance" question is one of individual risk (rather than of public health impact on the whole exposed population), because the question is still posed in terms of the hypothetical worker exposed at the permitted limit. (OSHA has a policy of forbidding rotation of employees through jobs with high carcinogen exposure as a work practice to ensure no employee experiences a PEL for a 45 year working life. The grounds are that this strategy would only increase the number of workers exposed. In essence, this is a population risk argument.)

In practice, the technical and financial feasibility of achieving a standard is usually the limiting factor in choosing a permissible exposure level (P. Infante, personal communication). That is, limits are usually proposed under which a worker exposed to that limit would be calculated to experience risk in the upper end of Justice Stevens' range. (This is not to say that real workers with their actual exposures are necessarily suffering significant risk.) Under these conditions, the particular numerical estimate of risk level is not the driving issue in regulation, only the more general argument that "significant" risks could be generated. OSHA is able to entertain a variety of risk analyses based on somewhat different data sets and assumptions without muddying the regulatory decision with questions about which single analysis is the "right" one to choose to set a standard.

In the analyses that in practice drive the permissible levels specified in standards—that is, the determination of what levels are feasible to achieve—the costs and performances of various technical control options are considered. In these analyses, actual worker exposure levels and durations of exposure can be considered, including the resulting changes in residual risk to be expected after various regulatory options. Thus, there is opportunity, albeit indirect, for information on distributions of actual exposure to come into play in determining OSHA regulations. Nonetheless, the key consideration in feasibility is not risk, but rather the costs and technical ability needed to reach various ambient concentration levels.

Although the benzene decision has profoundly affected OSHA's approach to the analysis of risk, the practical result is that decisions are not very different from what would have been done under the pre-1980 carcinogen policy. The benzene decision stated that OSHA could not simply limit exposures according to feasibility of control without first showing that lack of control leads to significant risk. In practice, this is usually shown, at least for the standards that OSHA has pursued since 1980, so controls are set primarily on feasibility all the same. The role of risk assessment in this process is largely to establish (1) that significant risks exist under current exposures, and (2) that reducing the exposure as proposed in the standard will reduce the risk. The major practical impact is that the case for significant risk must be made for each compound, focusing the agency's activities and resources to pursue regulation on those compounds where risk can be clearly shown. Feasibility is a particular problem for OSHA because the characteristics of the indoor environment make it very difficult to control exposures to levels that other agencies might seek.

The principal notable features of risk assessment at OSHA are that the size of the risks in

question are a good deal larger than those encountered in other regulatory programs. Frequently, risks may be assessed on human data directly relevant to the regulatory interest; in recent years about one-half of OSHA PELs have been based primarily on human data. Even when animal data are used, human exposures of interest are often not far below the tested levels. Real, directly relevant exposure data are often available, and they are often quite defined and less variable compared to environmental exposures for the general population. As a consequence, OSHA risk assessments have to grapple much less with extrapolation questions, and OSHA's methods have less built-in conservatism (for example, use of maximum likelihood estimates instead of upper bounds). Since PELs are in practice set by feasibility, with risk assessment determining the need for controls, OSHA is able to entertain a variety of risk analyses without settling on a single "number" as the canonical one for its regulatory activities. The regulatory focus is on the risk to a worker exposed to the permitted level for a full working life; although in practice and for a variety of reasons, this hypothetical exposure may not be much higher than that actually experienced by many workers, and indeed some workers (those doing overtime or previously exposed under a higher standard, for example) may exceed this theoretical "maximum."

Consumer Product Safety Commission

The Consumer Product Safety Commission is an independent agency charged with regulatory responsibility over the safety of consumer products (which are defined by law to exclude foods, drugs and pesticides, regulated under FFDCA, as well as tobacco and certain other products regulated elsewhere). The commission was established by the Consumer Product Safety Act (CPSA) of 1972. The regulatory authority over hazardous substances in consumer products derives from the CPSA and the Federal Hazardous Substances Act (FHSA), which has existed since 1960. The FHSA was formerly administered by the Food and Drug Administration, but authority was transferred to the commission by §30(a) of the CPSA.

The CPSA establishes the Consumer Product Safety Commission with the mandate "to protect the public against unreasonable risks of injury associated with consumer products" and "to develop uniform safety standards" [§2(b)]. The agency is run by a five member commission appointed by the president (with the consent of the Senate) for seven-year terms. (In recent years, only three commissioners have been appointed, and in this circumstance, two constitute a quorum.) Decision-making by the commission is by majority vote among commissioners who may have been appointed by different administrations. This makes the development of analyses to support decisions somewhat different at CPSC than at agencies answering to a single administration appointee. Staff develop positions and options for the commission's consideration, laying information out for a final, publicly held, sometimes contentious debate.

The impetus is on the commission to promulgate consumer product safety standards when it is deemed necessary to protect the public against unreasonable risks of injury. That is, its task is to identify and act against hazards as opposed to endorsing products as "safe." Although much of the focus of the CPSA is on acute hazards, there are specially mentioned provisions for chronic toxicity, as discussed below. The commission has a wide variety of regulatory options

that can be applied as deemed necessary, including labeling, mandating other provision of information, endorsement of voluntary standards, manufacturing standards, product performance standards, bans, and recalls [CPSA §§7,8,15].

The FHSA defines a hazardous substance (or mixture) as one that is corrosive, an irritant, a strong sensitizer, or flammable, or one that "may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children" [FHSA §2(f)(1)(A)]. Section 3 of this act gives authority to "declare by regulation any substance or mixture of substances which...meets the requirements" of this definition to be a hazardous substance. (Section 3 specifies a series of procedures which includes the right to petition for hearings; it is these more extensive procedural requirements, in addition to the focus on chemical hazards, that chiefly distinguishes regulation under the FHSA from that under the CPSA.) Labeling of substances declared to be hazardous is mandated. However, if "notwithstanding such cautionary labeling...the degree or nature of the hazard...is such that the objective of the protection of the public health and safety can be adequately served only by keeping such substance...out of the channels of interstate commerce," the substance can be declared a "banned hazardous substance" [§2(q)(1)].

Many of the provisions of the CPSA and the FHSA apply to both acute and chronic hazards. There is a particular provision in the CPSA regarding chronic hazards, however. Before any rule "relating to a risk of cancer, birth defects, or gene mutations" can be proposed, the commission must appointment a Chronic Hazard Advisory Panel of independent scientific experts [§28] from nominations by the president of the National Academy of Sciences; "the Commission shall request the Panel to review the scientific data and other relevant information...to determine if any substance in the product is a carcinogen, mutagen, or a teratogen." If so, "the Panel shall include in its report an estimate, if such an estimate is feasible, of the probable harm to human health that will result from exposure to the substance" [CPSA §31(b)].

In promulgating a rule, the commission must make findings regarding "the degree and nature of risk...; the need of the public for the consumer products subject to such rule, and the probable effect...upon the utility, cost, or availability of such products...; and...any means of achieving the objective of the order while minimizing adverse effects on competition or disruption or dislocation of manufacturing and other commercial practices consistent with the public health and safety" [CPSA §9(f)(1)]. The final regulatory analysis of the rule must contain "A description of the potential benefits and potential costs of the rule, including... [those] that cannot be quantified in monetary terms, and the identification of those likely to receive the benefits and bear the costs" [§9(f)(2)]. Such analysis must also be included for "alternatives to the final rule which were considered, together with...a brief explanation of the reason why these alternatives were not chosen." The commission is prohibited from promulgating a rule unless it finds "that the rule...is reasonably necessary to eliminate or reduce an unreasonable risk of injury; that promulgation of the rule is in the public interest;...that the benefits expected from the rule bear a reasonable relationship to its costs;

and...that the rule imposes the least burdensome requirement which prevents or adequately reduces the risk of injury" [§9(3)]. It must also find that no currently implemented voluntary standard will suffice and that, if the rule is a ban, no other reasonable rule would protect the public. (As with most risk analyses, these findings are protected from judicial review unless the final rule itself is challenged.)

The requirements of the CPSA for rulemaking to include a statement on "the degree and nature of risk" [CPSA §9(f)(1)] and for each Chronic Hazard Advisory Panel to "include in its report an estimate, if such estimate is feasible, of the probable harm to human health" [§31(b)] constitute a fairly clear statutory call for the conduct of risk assessment. In addition, however, perhaps more than any other agency, the CPSC is explicitly required to justify its regulation in terms of costs and benefits. Whereas other cost-benefit balancing laws (e.g., FIFRA) merely make brief mention taking costs and feasibility into account, the consumer product laws lay out a series of specific findings that must be made.

The extensive need under the existing consumer protection statutes to cast regulatory risk analyses in terms of costs, benefits, impact on consumers, and the least burdensome regulatory approach among many options focuses attention of CPSC analyses on typical uses at typical levels under various regulatory options. The mandate for protection against "unreasonable risk" has an element of protecting individuals, but the mandated consideration of the costs and benefits of options means that the main concern is for how the number of users and the typical exposure during use will be affected by the various control options. That is, once the product has been determined to be toxic, the main focus is on population rather than on individual risk.

The statutes make no mention of protection of sensitive subpopulations from injury, although the CPSA [§9(e)] does mandate that the special needs of the handicapped and elderly be taken into account regarding the disruption to consumer convenience resulting from a potential rule.

Environmental Protection Agency

The Environmental Protection Agency (EPA) was created by executive order by President Nixon in 1970. The EPA was set up as an independent Federal agency to be the administrative home for a number Federal environmental programs that had previously been scattered over the Executive Branch. The programs out of which the EPA was cobbled had their own legislative authorities and histories. Because the consolidation was by executive order (and not through a new environmental act specifying a melding and recasting of these programs), the various components of the new EPA retained their different legislative mandates, regulatory powers, and scopes. Many of the laws were amended during the early years of the EPA, tailoring their treatment of issues of particular concern. In addition, new laws were added to bring additional environmental problems into the ambit of the Federal environmental effort.

The result is that, even twenty-five years later, the EPA represents a collection of

environmental programs that has only partly been consolidated and centralized. Risk analysis is used in support of regulation and rulemaking under a half-dozen major environmental laws and a number of minor ones. Although the role of risk assessment, particularly quantitative risk assessment, has grown largely since EPA's founding, the separation of regulatory programs has had an effect on risk assessment practices in various parts of the agency. The history of risk assessment at EPA has been marked by ongoing issues of consistency versus case-specificity of risk assessment methods and analyses, and consolidation versus dispersion of the conduct of risk assessment.

The dispersion of risk assessment activity over parts of the EPA makes the issue of coordination and maintenance of consistency particularly important to this agency. There are several means in place toward this end. They include the publication of a series of risk assessment guidelines, development of methodology documents, the chartering of several cross-agency groups to coordinate and harmonize practices and to resolve methodologic and policy questions that may arise, the reliance for advice and scientific guidance on external experts through the EPA Science Advisory Board, and the maintenance of a computerized, publicly available data base of agency-wide consensus on risk assessments.

The risk assessment methods employed by the Environmental Protection Agency have much in common with those used elsewhere, reflecting the general practices, standards, and precepts of the field. Risk assessment is a practical field, and the principles that have evolved reflect the concerns and ends of practitioners, including regulatory agencies and public health institutions, both national and international. The EPA has been an influential player in this development because of its major role in environmental regulation, the growing role of risk assessment in that regulation, and because the agency has made special efforts to define and develop the underpinnings of its methods through the promulgation of risk assessment guidelines and promotion of scientific discussions about risk assessment methods.

EPA's risk management practices are guided primarily by President Clinton's executive orders (Executive Order 12866 on Regulatory Planning and Review and Executive Order 12875 on Enhancing Intergovernmental Partnership). These revoke and replace executive orders from President Reagan, but include many provisions on similar matters. The EO 12866 directs agencies to conduct cost-benefit analysis for all "significant regulatory actions" and to promulgate regulations only when necessary due to "compelling public need." Regulatory approaches should be chosen to maximize net benefits, minimize the overall regulatory burden on society, and to be the most cost-effective means of achieving the desired end.

Office of Pesticide Programs

The regulation of pesticides is carried out by EPA's Office of Pesticide Programs (OPP), which is a part of the Office of Prevention, Pesticides, and Toxics (OPPT). Pesticides are different than other potentially toxic compounds in that they are intended to be poisonous, at least to the pests they are designed to control, and they are intentionally introduced into the environment for that purpose. This situation naturally calls for the consideration of both costs and benefits,

and the statutes under which pesticides are regulated provide for such analysis.

Pesticide regulation falls into two parts, and each part is accomplished under a different statute. The *registration* of pesticides (i.e., licensing for sale and use in agriculture or extermination) is carried out under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). No chemical may be sold in the U.S. as a pesticide without such registration, which establishes the conditions of legal use. The question of *tolerances* for pesticide residues on foods as encountered by the consumer is regulated under the FFDCA.

FIFRA (7 U.S.C.A. §§136 to 136y) provides for the regulation of sale and distribution of pesticides, where pesticide is defined as "any substance or mixture...intended for preventing, destroying, repelling, or mitigating any pest, [or]...intended for use as a plant regulator, defoliant, or desiccant" [FIFRA §2(u)]. No pesticide may be introduced into commerce without obtaining a registration from the EPA. Registration is obtained through petition to the agency, with the petitioner providing information on the intended use, data on efficacy of the pesticide and its toxicological properties. The agency is empowered to ask for the provision of additional data, including the requirement for more toxicological testing, if the information is deemed necessary for the registration decision.

The Administrator may approve the petition if the pesticide "will perform its intended function" [§3(c)(5)(C)], and "when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment" [§3(c)(5)(D)], which are defined as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of ...use" [§2(bb)]. Pesticides are registered either for general use or for "restricted use" [§3(d)], with the latter category specifying conditions of use such as application methods, amounts used, target pests, geographic restrictions and so on.

Once granted, registrations expire after 5 years, at which time the petitioner can apply for renewal of registration [§6(a)]. There are provisions for EPA to cancel a registration early [§6(b)] if the Administrator finds adverse effects could indeed be caused, but a decision to cancel must take into account "the impact...on the agricultural economy." Much of the modern registration framework was introduced into FIFRA by 1972 amendments (the Federal Environmental Pesticide Control Act, 7 U.S.C.A. §136), and a large number of previously registered pesticides had been "grandfathered in" under the lax pre-1972 procedures. Further amendments in 1988 required re-registration (or cancellation) of these within 9 years, a large burden on the agency's risk assessment apparatus.

In sum, the registration process under FIFRA amounts to the granting of a license for sale and distribution of a potentially dangerous chemical. The license is not unlimited; it specifies the conditions of use that are permitted, potentially including restrictions on the target pests, the amounts of pesticide used, the application method, frequency, and timing of use, training of applicators, the time that must elapse after application before workers can reenter a treated field, and the time that must elapse after application before the crop can be harvested.

Importantly, the registration also includes restrictions on which specific crops may be treated. Once registration is granted, however, all uses that fall within the specified restrictions become legal and permissible. That is, the regulatory power of registration is over permissible uses, not over actual practice within the permissible range.

To be granted a registration, the petitioner must demonstrate that the pesticide, when used on the proposed crops at the proposed levels, is effective at controlling pests and that, when used according to the restrictions, it will not cause unreasonable risk to humans or the environment. The definition of such adverse effects in FIFRA is very vague, but in practice it includes risk to the applicators and farmworkers, ecological risks, risks to homeowners from extermination procedures, and (through interaction with the tolerance setting process of the FFDCA, as discussed below) risks to consumers of treated foodstuffs. The mandate in FIFRA for balancing costs and benefits is similarly vague, comprising only the statement that "economic, social, and environmental costs and benefits" are part of the definition of what adverse effects are to be deemed "unreasonable." (The FFDCA is at least somewhat more specific on matters of both costs and benefits in regard to tolerances for residues on food.)

The FFDCA (21 U.S.C.A. §§321 to 394) provides for regulation of permissible contents of toxic substances in or on food, and pesticides are explicitly considered in its provisions. While primarily an FDA statute, the parts of the FFDCA applying to pesticides are administered by the EPA. The FFDCA is discussed in the section on FDA, but some key provisions are briefly reiterated here.

Tolerances are the concentrations (on a per weight basis) permitted to remain in or on food as it is available to the consumer. The process of setting tolerances is also by petition, with the petitioner submitting proposed tolerance levels along with toxicological information to demonstrate that such tolerances will be sufficiently protective. Tolerances of pesticides on raw, unprocessed agricultural commodities are regulated under FFDCA §408, which mandates that tolerances should be set "for pesticide chemicals which are not generally recognized, among experts qualified by scientific training and experience..., as safe for use, to the extent necessary to protect the public health." However, "appropriate consideration" must be given "to the necessity for the production of an adequate, wholesome, and economical food supply."

The processes of petitioning for registration and petitioning for tolerances are interconnected, and in practice they often occur concurrently. Although regulated under separate laws and following different procedures, the two processes have a practical linkage in that the conditions and limitations for use of the pesticide established during registration must clearly lead to residues experienced by the consumer that will be below tolerances that can be approved on health grounds. The approval of tolerances is based on exposure from the total diet, so each new approved use of a pesticide in the registration process leads to potential residues that "use up" part of the total allowable intake. Because each use of a pesticide must employ enough of the agent to be effective against pests, a registrant must carefully choose the particular crop and use restrictions for which registration is being sought to ensure that the sum of resulting residues will be below the level for which a tolerance can be approved on

consumer health grounds.

Because registration is regulation of a prospective activity, much of the analysis of exposures, use levels, benefits, and costs must be based on professional judgment. In many cases, the rigorous analysis of costs and benefits, and the economic and agricultural effects of using various alternative pesticides and pest control practices, arises when a registration renewal is in question or when a cancellation of registration is being considered.

OPP considers three categories of exposure: to consumers, to those occupationally exposed (which in practice focuses on applicators, but also includes farmworkers generally), and the general public exposed via non-dietary means (i.e., through environmental contamination). As with most regulatory programs, there is no written rule or policy regarding the level of risk that must be deemed acceptable, but (also as with most agencies) there is understood unwritten practice that is revealed in the examination of regulatory decisions taken by the agency.

OPP generally tries to ensure that individual risks in all three categories do not exceed 10^{-6} for lifetime exposure. Until recently, the goal for occupational exposures was somewhat higher, closer to 10^{-4}, but this was lowered to match the other categories during the tenure of Assistant Administrator Linda Fisher, and has remained so since. In the case of consumers, the 10^{-6} risk applies to cumulative exposure to the pesticide from all dietary sources, with these estimates usually being based on conservative residue estimates but population average rates of consumption of food types. As noted earlier, it is difficult to determine when this combination is conservative, especially vis-à-vis the high end of levels of consumption of particular foods. For pesticide applicators, the exposure assumptions are not particularly conservative in terms of exposure per treatment, but there may be assumptions about maximum allowable use of the agent that are not met in reality.

These risk criteria are nominally for individual risk levels. However, the fact that consumer risks are calculated based on consumption levels averaged over the entire population makes these risk calculations apply to the whole population (at least on average, and bearing in mind the conservative residue assumptions). Thus, the criterion really hinges on a kind of population risk measure. High individual cancer risks that result because of high consumption of the affected food products is not captured because of the nature of the exposure analysis.

For non-cancer risks, many of the same considerations apply; high end individual exposures are not captured by the exposure assessment. However, differences in average exposure in each of 22 demographic subgroups are considered.

The consideration of costs and benefits is vaguely specified in the pesticides statutes, but registrations and tolerances are set bearing in mind the balancing of the risks engendered with the costs to agriculture and food prices. As registrants tailor their petitions for which crop treatments are to be approved, limitations on uses, and tolerances, they consider the economic and agricultural benefits to be gained by different combinations of uses that might be

approvable. Those specific uses that are most efficacious and economically favorable to agriculture are more likely to be proposed by the registrant because they will lead to a better market for the pesticide once registered.

Office of Pollution Prevention and Toxics

The EPA's Office of Pollution Prevention and Toxics (OPPT) is a relative newcomer among EPA regulatory programs, having been founded (under the original name of the Office of Toxic Substances) to implement the 1976 Toxic Substances Control Act (TSCA). In addition to its original role as implementer of TSCA, OPPT has been given responsibility for pollution prevention programs, regulation of certain abatement programs (such as that for asbestos), and the administration of the Toxics Release Inventory, mandated under amendments to the Superfund law. The focus of risk assessment in OPPT, however, is under TSCA.

TSCA (15 U.S.C.A. §§2601 to 2692) was conceived of as a "gap-filling" statute; Congress recognized that the existing array of environmental legislation covered risk posed by chemicals only under those particular exposure conditions each program was mandated to regulate. Moreover, this regulation was often in reaction to existing pollution, and its efficacy was hampered by lack of information on the chemicals in question. TSCA was passed in 1976 as an attempt to take a comprehensive approach to regulation of toxic substances, stressing properties of the chemical rather than of particular exposures to the chemical, and encouraging the development of information regarding toxic properties and exposures. The aim was to prevent risks from toxic substances that might "fall through the cracks" between other environmental statutes. This cross-cutting role has meant that throughout its history, there have been ongoing questions about TSCA's overlap with other environmental statutes.

The provisions of TSCA implement a set of policy statements set out at the beginning of the act [TSCA §2(b)]. First, "adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment." Moreover "the development of such data should be the responsibility of those who manufacture and...process such chemical[s]." Second, the government should have adequate authority "to regulate chemical substances...which present an unreasonable risk of injury to health or the environment," including imminent hazards. Finally, exercise of this authority should "not...impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose...to assure that...such chemical substances...do not present an unreasonable risk." Section 2(c) goes on to require that "the Administrator [of EPA] shall consider the environmental, economic, and social impact of any action" taken under the act.

Section 4 of TSCA relates to testing and gathering of information on chemicals. It authorizes rulemaking requiring manufacturers to conduct toxicological testing for "carcinogenesis, mutagenesis, teratogenesis, behavioral disorders, cumulative or synergistic effects, and any other effects with may present an unreasonable risk of injury to health or the environment" [§4(b)(2)(A)]. The burden is on EPA to show that such testing is necessary, however. (This is unlike testing mandates under FIFRA or FFDCA, in which the agency can

without rulemaking call for all information needed to grant or deny petitions.) The substance must present possibilities of unreasonable risk, "enter the environment in substantial quantities," or be likely to have "substantial human exposure" [§4(a)], all criteria that require the agency to do some preliminary risk assessment. An Interagency Testing Committee is established to set testing priorities. (Through this means, §4 is a vehicle for various Federal regulatory groups to obtain testing mandates, as long as their interests parallel those of EPA.) In practice, testing is done through enforceable negotiated consent agreements ever since a lawsuit challenged the earlier practice of negotiated voluntary testing [NRDC v. EPA, 595 F.Supp. 1255 S.D.N.Y.1984)].

TSCA makes a distinction between new and existing chemicals. The latter are those on a “list of each chemical substance which is manufactured or processed in the United States”, which EPA is required to compile and maintain. Anyone proposing a new chemical (i.e., one not yet on the list), or to undertake a “significant new use” of an existing chemical, must give notice to EPA, along with test data and information bearing on its potential risk. EPA reviews the submission and permits the chemical’s manufacture, suspends its manufacture or distribution, restricts its use pending the provision of further data, or initiates rulemaking to regulate its manufacture or distribution. Once a chemical enters commerce, it becomes an “existing” chemical.

In essence, the Toxic Substances Control Act aims at establishing a system of both public and private vigilance against health and environmental risks from chemicals in commerce that might not be noted or covered by other regulatory authorities. The mandate is to avoid "unreasonable risk of injury to health or the environment," while balancing the benefits of any controls against "unnecessary economic barriers" [§2(b)]. The onus is on EPA to show that unreasonable risk exists, but if it does so, controls are to "protect adequately" against the risk [§6(a)]. In promulgating any such rule, the Administrator must "consider and publish a statement with respect to...the effects...on health and the magnitude of the exposure of human beings,...the effect on the environment,...the benefits of such substance...for various uses and the availability of substitutes..., and...the reasonably ascertainable economic consequences of the rule, after consideration of the effects on the national economy, small business, technological innovation, the environment, and public health" [§6(c)(1)].

In other words, EPA is given rather general authority to seek out and regulate any "unreasonable risk" wherever it may be found, but what might otherwise be sweeping authority is reigned in by the requirement to consider economic and social impact. The act also offers a myriad small checks on this authority in addition to one major one—"If...a risk of injury to health or the environment could be eliminated or reduced to a sufficient extent by actions taken under another Federal law" [§6(c); §9(a)(1)], that other law must be deferred to unless it can be shown to be in the public interest to regulate under TSCA. In practice, this "hand-off" to another regulatory authority almost always happens, and most assessments of risk due to major "existing" chemicals (as opposed to "new" chemicals, as discussed above) are referred to the CPSC, OSHA, or another part of EPA.

In the analysis of new chemicals, OPPT generally seeks margins of exposure relative to NOAELs of 100. Cancer risks are generally ruled acceptable if they fall below 10^{-4} lifetime individual risks for occupational settings and below 10^{-5} for general population exposures. It should be borne in mind that these are rough criteria, given the screening nature of new chemical assessments.

TSCA is a cost-benefit balancing statute, but a rigorous analysis of costs and benefits is usually only possible for actions contemplated under §6. The much more frequent new chemical analyses and development of risk justifications for test rules employ a more qualitative consideration of costs and benefits.

Office of Air and Radiation

Until about the 1950's, air pollution regulation was framed in terms of control of public nuisances; local and state laws aimed to control particular emissions sources that created visible and direct public annoyance. Growing awareness of the chronic health effects of air pollution, and a growing concept of unsullied air as a public resource held in common and in need of public protection, led to various control measures, including the passage of the Clean Air Act (42 U.S.C.A. §§7401to7671q) in 1963. Initially, the Federal role was largely limited to research, with primary responsibility for control left to the states. It became evident, however, that state control alone was insufficient to deal with cross-boundary movement of polluted air. Moreover, states varied widely in the vigor of their enforcement, prompting fears that states would vie to attract industry by providing lax regulatory environments. The inherent conflict is that the sources of air pollution are local, and hence properly in the realm of state and local regulatory control, but the effects are on the common resource, so that irresponsibility of the few despoils the air for all—a classic "commons" problem.

This initial, desultory phase of air pollution control ended in 1970 with the passage of amendments to the Clean Air Act that for the first time created a strong Federal role. Implementation of pollution control plans, issuance of emissions permits, and enforcement were still the province of the states (as they continue to be today), but these state activities had to accomplish the meeting of Federally mandated and uniform standards for air quality, with provisions to ensure that the states would rigorously enforce the standards.

The Federal standards are of two basic kinds: standards for air quality and standards for the performance of pollutant sources in terms of allowable emissions. Standards for air quality specify uniform national definitions of what constitutes acceptably clean air, and regulatory programs (much of which occur at the state level with EPA oversight) covering the spectrum of sources of the pollutant by a variety of means are then aimed at achieving air quality at least up to those standards. Performance standards for sources are aimed at establishing uniform national limits on the emissions from particular kinds of sources, including motor vehicles (mobile sources) and stationary sources. (For some purposes, the CAA distinguishes among "major" and "minor" sources based on amounts of emissions, and on "point" and "area" sources based on whether the emissions come from a specific, identifiable facility or from

more general human activity not easily localized to a few geographic coordinates.)

Sections 108 and 109 of the CAA call for the development of air quality criteria for the widespread "criteria pollutants." Criteria pollutants include sulfur dioxide, particulates, ozone, nitrogen dioxide, carbon monoxide, and lead. (The criteria pollutants are not named in the statute, but are those with "emissions which...may reasonably be anticipated to endanger the public health or welfare...[and] result...from numerous or diverse mobile or stationary sources" [§108(a)(1)]. Over time, lead has been added to the list and hydrocarbons dropped.) The criteria "shall accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health and welfare" [§108(2)]. So-called "primary" ambient air quality standards are to be standards which, "allowing for an adequate margin of safety, are requisite to protect the public health" [§109(b)(1)]. (There are also "secondary" standards that consider non-health effects.) Legislative history has led the "ample margin of safety" mandate to be interpreted as requiring protection of most of the population, including sensitive population groups (e.g., asthmatics, the elderly) but not the most exposed individual or the most sensitive member of a sensitive group. These are to be purely health-based criteria, and are not dependent on costs or technical feasibility.

It is up to the states to provide plans for controlling pollution so as to attain these National Ambient Air Quality Standards (or NAAQSs); section 110 calls on each state to submit to the EPA for approval "a plan which provides for implementation, maintenance, and enforcement of such primary standard in each air quality control region (or portion thereof) within such State" [§110(a)(1)]. Such State Implementation Plans (SIPs) are to include "enforceable emission limitations and other control measures...(including economic incentives such as fees, marketable permits, and auctions of emissions rights)...as may be necessary" [§110(a)(2)(A)] and must provide for monitoring and enforcement. Section 111 provides for Federal standards of performance for new sources of criteria pollutants "which may reasonably be anticipated to endanger the public health or welfare." Sections 160-169B provide for the prevention of significant deterioration of air quality in regions that are already in attainment of the NAAQSs.

Mobile source emissions are addressed in §202; emissions standards for new motor vehicles may be set for "any air pollutant...which may reasonably be anticipated to endanger public health or welfare" [§202(a)(1)]. Although the main concern has been motor vehicles as a source of criteria pollutants, mobile source toxics are also addressed in §202(l), which calls for study of "emissions that pose the greatest risk to human health or about which significant uncertainties remain" and calls for standards for these, including explicit requirements for regulation of benzene and formaldehyde. Fuel formulation may be regulated under §211, and manufacturers of additives may be required to conduct "tests to determine potential public health effects...including...carcinogenic, teratogenic, and mutagenic effects." Such regulations must consider technical and economic feasibility.

Air toxics are regulated under CAA §112. The amendments of 1990 added a list of 189 compounds designated as hazardous air pollutants [§112(b)]. Chemicals may be added to this

list by rule if found to "present...a threat of adverse human health effects." Compounds may be deleted from the list by petition if "adequate data" determine that "emissions, ambient concentrations, bioaccumulation or deposition of the substance may not reasonably be anticipated to cause any adverse effects to human health or adverse environmental effects" [§112(b)(3)(C)]. The EPA must build and maintain a list of the principal areas sources and of "major sources" of these pollutants (i.e., those emitting more than 10 tons/year of any one listed chemical or 25 tons/year of any combination). §112 mandates that emissions of compounds on its specified list be controlled to the extent feasible on technical and economic grounds, regardless of the risk they may pose (excepting the *de minimis* delisting). Section 112(f) calls for the examination of risks that may remain after such technical controls are in effect; EPA must develop methodology to estimate such "residual risk" and recommend legislation to address any such risk that may be found. If Congress does not act on this recommendation, the EPA must promulgate emissions standards "with an ample margin of safety to protect the public health." That is, if residual risks exist after Maximum Available Control Technology (MACT) standards are in effect, there is a fallback to the pre-1990 basis for air toxics regulation. In particular, the promulgation of such standards is triggered if MACT controls "do not reduce lifetime excess cancer risks to the individual most exposed to emissions from a source...to less than one in one million" [§112(f)(2)(A)]. The standards adopted need not protect this maximally exposed individual (MEI) to the 10^{-6} level—the criterion is instead the "acceptable risk" policy developed after the vinyl chloride decision [54 FR 38044]—but the existence of a 10^{-6} risk triggers the consideration of residual risk regulation.

Thus, despite the fact that the 1990 amendment of §112 was designed to reduce the role of risk assessment in air toxics regulation (and the consequent questions and delays as uncertainties in those assessments are debated), there are several places where risk assessment is called for in evaluating the technology-based controls. These include (1) the listing and delisting of hazardous air pollutants, which depends on whether a chemical may "present...a threat of adverse human health effects;" (2) the *de minimis* delisting of source categories, which requires less than a 10^{-6} risk to the MEI; (3) the triggering of post-MACT standards to address residual risk, which also requires less than a 10^{-6} risk to the MEI; and (4) the offset trading of one pollutant for another based on whether the increased emission is "more hazardous." Of these, the third (the residual risk determinations) is the one based primarily on EPA initiative, but it is one that will require extensive analysis, because each source of each hazardous air pollutant should in principle be evaluated at a level of detail such that the individual near each source at highest risk can be characterized.

For criteria pollutants, standards are set by using a complex characterization of the distribution of exposure levels in the population that would be expected under a specified air quality criterion. When combined with the exposure-response relationships, this gives a projection of the number of health effects incidents to be expected in the exposed population. Both the exposure and dose-response components are estimated based on extensive data; they require little extrapolation and few default assumptions, and the estimates of health impact are thus characterized as unbiased estimates without added conservatism. Point estimates rather than

"upper bounds" are used. Ranges of risk are estimated corresponding to the experience of sensitive groups.

The risk mandate for protection of public health with an adequate margin of safety is accomplished by setting air quality criteria such that most of the population is protected, including sensitive sub-groups and highly exposed individuals, but not necessarily the most sensitive or most exposed person. There is no fixed level of acceptable risk, which depends on the nature of the health effect in question, the size of the group potentially affected, and the degree of uncertainty about effects and exposure. These decisions are prohibited from considering costs and feasibility.

Although the effects in question are non-cancer health effects, they are generally held not to display a practical threshold exposure for effects. The methods recognize that even quite protective standards do not banish the possibility of some few people being affected. In this way, the situation is similar to that of carcinogens, where "safety" cannot be absolute, and so a reasonable degree of protection must be defined. For criteria pollutants, the risk characterization focuses on population risk, that is, on the health impact on the population as a whole, recognizing that that impact is most likely to appear among the most sensitive and most exposed. There is no real individual risk criterion.

In the analysis leading up to the development of a proposed ambient air quality standard, an analysis may be done of the effects that would be expected if the whole population were exposed to air just at the limit of the standard. Although this is not the primary decision criterion, such an analysis provides an idea of potential impact if all the air were indeed as polluted as is being allowed. This situation is unlikely to occur in practice in a compliant area, since the air quality criteria represent the allowable maximum in what is always in reality a variable level of air quality. (It is interesting to compare the minor role this analysis plays for criteria pollutants to the major role that a similar analysis plays in the regulation of pesticide residues, as discussed in the section on the pesticides office. In that case, the regulatory decision is made on an analysis presuming that all foods contain their maximally allowed residues, even though a distribution with mostly lesser values is likely to be true. The chief difference, of course, is that pesticide residues are more readily manipulated up to their allowable level than is ambient air quality.)

In the case of air toxics, the application of analysis as now being formulated to regulatory decisions is still in the future, and so it is difficult to characterize with confidence. The presumption is that for most sources of most hazardous air pollutants, the maximally available control technology will be sufficient and further regulation not needed. Actual regulations of residual risk, where necessary, will be made under the criteria prevailing before the 1990 amendments, that is, the criteria mandated by the D.C. District Court's 1987 "vinyl chloride decision" [NRDC v. EPA, 824 F 2d 1146]. These criteria have an individual risk component, that an individual exposed to the maximum fenceline concentration for 70 years should not have a risk exceeding 10^{-4}. They also have a population risk component, that as few people as possible should have a risk greater than 10^{-6}. The 10^{-4} level is the policy definition of "safe,"

fulfilling the mandate for a regulation that "protects the public health." It is intended that this level of safety be guaranteed even to someone who chooses to fulfill the fenceline exposure scenario, whether or not someone actually does so. The aim to protect as many people as possible from the 10^{-6} risk level is interpreted as the provision of an "ample margin of safety" as provided for in the CAA. In the case of non-cancer effects, it is presumed that exposures below the reference concentration (RfC) fulfill both the mandate for safety and for an ample margin of safety. Given the amount and site-specific detail of exposure analysis required to trigger post-MACT regulation, it is likely that the exposure assessments for such regulations will be much less conservative and "worst-case" than may have been the case prior to 1990. Although the regulatory criteria are nominally the same, the risk outcome and the stringency of regulation may end up being somewhat different.

Office of Water

Regulation of water pollutants is carried out by EPA's Office of Water (OW). The Office of Water administers two major statutes, the Federal Water Pollution Control Act (better known as the Clean Water Act or CWA 33 U.S.C.A. §§1251 to1387) and Title XIV of the Public Health Service Act (better known as the Safe Drinking Water Act, or SDWA 42 U.S.C.A. §§300f to 300j-26). The Clean Water Act has as its goal to maintain and improve the cleanliness and biological integrity of the nation's waters, including lakes, rivers, and navigable waters. The aim is to make these waters "fishable and swimable." In many ways, the nature of the pollution problem and the nature of the statutory approach parallel that of the Clean Air Act, discussed in an earlier section; the nation's waters constitute a broadly distributed common resource the quality of which is impinged upon by the activities of many local sources of contamination. Each source of effluent is not solely responsible for the resulting water quality, but the collective burden of discharges may result in unacceptable deterioration of the resource as a whole. The regulatory approach is the promulgation of nationwide uniform criteria defining the degree of water quality that is compatible with intended uses and states of different water bodies. (The criteria are health-based, but they are not rules, and are themselves unenforceable.) These water quality criteria are coupled with enforceable technology-based standards for allowable discharges from point sources, which (also like the Clean Air Act) are implemented through permitting regulations by the states. It is the responsibility each state to conduct regulation of discharges such that the applicable water quality criteria are met for the state's waters.

The Clean Water Act opens with a "Congressional declaration of goals and policy" [CWA§101] that sets ambitious goals for the nation, declaring "it is the national goal that the discharge of pollutants into navigable waters be eliminated by 1985" and that "the discharge of toxic pollutants in toxic amounts be prohibited." The history of amendment of the CWA has been in part the history of rescheduling and delaying the milestones and timelines for achievement of the mandated complete solution to the nation's water pollution problems, as issues of feasibility and practical impediments are encountered. Nonetheless, the act has provisions for citizen lawsuits that has led to the agenda of water regulation being driven largely by court orders and consent agreements.

The CWA distinguishes "conventional" pollutants from "toxic" pollutants. The former are largely those associated with discharge of sewage and nutrients, such as fecal coliform bacteria, suspended solids, and sources of biological oxygen demand. In some ways, they are analogous to the criteria air pollutants, the inevitable, widespread products of human activity that are dangerous by virtue of their overproduction if uncontrolled. The present report will concentrate on the "toxic" water pollutants, analogous to the air toxics, that are treated and analyzed as exposures to toxic chemicals.

As enacted in 1972, the CWA required implementation of standards for toxic pollutants providing an "ample margin of safety;" that is, feasibility considerations were not allowed. For reasons similar to the difficulties seen in regulating air toxics under a similar standard, the CWA was amended in 1977 to include a named list of chemicals [§307(a)(1)] to be regulated within three year with regulation to be based on "best available technology" (abbreviated BAT, a feasible technology approach similar to the 1990 revision of the Clean Air Act). A residual risk-like provision permits the Administrator to set a more stringent "ample margin of safety" standard if necessary [§307(a)(4)].

Section 304 of the CWA calls on EPA to establish "criteria for water quality accurately reflecting the latest scientific knowledge...on the kind and extent of all identifiable effects on health and welfare," including ecological effects. That is, the criteria are to be entirely health- and effect-based. For carcinogens, no level can be named that fulfills the designation of "safe," so the criteria are presented as water concentrations that would be expected to lead to lifetime cancer risk levels of 10^{-5}, 10^{-6}, and 10^{-7} when consumed at the standard rate for a lifetime. For non-carcinogens, water quality criteria are developed that will not violate the RfD. (Cancer risks and RfDs are calculated by the standard methods.) These calculations are based on individual risk, but the criteria are to apply nationwide, so it is presumed that any criterion will apply to a significant number of people. Actual exposures for many people will of course be less, but exposures will be higher for a significant number, both because of the midrange nature of the consumption assumptions and because much surface water in the country is not in compliance with the water quality criteria which (despite the policy statements set out at the beginning of the CWA) remain goals to be striven for in many cases.

The second major statute administered by the water office is the Safe Drinking Water Act, which regulates the contamination of drinking water provided by public water systems. The act took its current form after 1986 amendments that followed a report from the Office of Technology Assessment documenting widespread serious incidents of contaminated drinking water (Findley and Farber, 1992). As with the Clean Water Act, there are a number of statutory timelines for promulgation of regulations that set a very ambitious schedule, one that has been difficult to meet in practice. Regulation is based on the permissible levels of contamination of finished water, that is, as it appears to consumers at the end of the tap. These standards, called national primary drinking water regulations, are promulgated by EPA [§1412(b)(3)] and enforced by the states, which can opt to set more stringent standards [§1413]. The standards apply to all public water supplies serving at least 25 people. Section

1412(b)(3)(A) calls on the EPA Administrator to "promulgate national primary drinking water regulations for each contaminant...which...may have any adverse effect on health of persons and which is known or anticipated to occur in public water systems." The standards are set on a health basis alone, but the requirement is to come as close to meeting them as is technologically feasible. Primary enforcement authority is with the states, which can opt for more stringent standards.

A standard specifies two levels of contamination of drinking water by the compound in question: a "maximum contaminant level goal" is set "at a level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety." For each standard with such a goal there is also specified "a maximum contaminant level which is as close to the maximum contaminant level goal as is feasible" [§1412(b)(4)], where "feasible" means "feasible with the use of the best technology, treatment techniques and other means which...are available (taking cost into consideration)." (In practice, achievability is judged by affordability of control technology to larger public water suppliers; smaller suppliers may have economic difficulty complying. If contaminant levels cannot be measured, a standard can specify a treatment technique to be used.)

In other words, maximum contaminant level *goals* (known as MCLGs) are to be set solely on health grounds to protect with an adequate margin of safety. Maximum contaminant *levels* (known as MCLs) are levels that are practically achievable. It is the technically feasible MCL, and not the health-protective MCLG, that is the enforceable standard. The level set for the MCL depends on available technology, and the appropriate level can change with technological advance. Section 1412(b)(9) provides for periodic revision of MCLs to address this.

The main reason for the MCLG/MCL distinction is that carcinogens, being presumed to be without a threshold, have no safe level. (Clearly, it is also possible that an agent with a threshold has that threshold level lower than is technically achievable.) That is, the common problem faced under all statutes requiring "safety" (especially with an "adequate margin") when dealing with non-threshold toxicants is addressed under the SDWA by controlling contamination to as low a level as technically and reasonably possible without particular regard for how much risk is estimated to remain. This is similar to the "carcinogen policy" at OSHA as it existed before the Supreme Court benzene decision and practice at the EPA Office of Air and Radiation before the vinyl chloride decision, both of which policies were overturned by those decisions, as discussed in the sections on those groups. The chief difference is that the SDWA explicitly decouples the risk and the feasibility issues.

It is important to remember that MCLs are set on a technical feasibility criterion, with the feasibility issue being affordability of controls by public water providers. In some cases, other regulatory programs (notably Superfund and Solid Waste) use the water office's MCLs as though they were health-based criteria, for example as standards to be attained for cleanup of or release into water. The entirely reasonable rationale is that requiring concentrations to be lower than allowable in tap water seems to be unwarranted, but the inappropriate implication is

sometimes made that attainment of the MCL is a standard of health protection.

Office of Solid Waste

The regulation of hazardous solid waste is the responsibility of EPA's Office of Solid Waste (OSW). The office implements the 1976 Resource Conservation and Recovery Act (RCRA 42 U.S.C.A. §§6901 to 6992k), which amended the Solid Waste Disposal Act. The purpose of the act is to develop mechanisms for ensuring stewardship over hazardous compounds from their generation to their proper disposal. The act's provisions set up an extensive set of requirements for reporting and record keeping in addition to standards for generators and transporters as well as treatment and disposal practices. That is, the aim is to ensure that hazardous wastes are kept track of—and that ownership and responsibility for those wastes are not lost or obscured—during storage, transportation, and disposal. The provisions can be seen as a means to avoid the processes leading to dangerous hazardous waste sites, especially those at which responsibilities for the wastes are no longer assignable.

RCRA declares it to be "the national policy of the United States that, wherever feasible, the generation of hazardous waste is to be reduced or eliminated as expeditiously as possible. Waste that is nevertheless generated should be treated, stored, or disposed of so as to minimize the present and future threat to human health and the environment" [RCRA§1003(b)]. Hazardous waste is defined as solid waste that may "cause or significantly contribute to an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness" or otherwise present a potential hazard to human health or the environment [§1004(5)].

Section 1003 requires EPA to identify hazardous wastes and to list those wastes that should be subject to RCRA's provisions. (There is a provision for delisting a waste as well [§3001(f)].) Listing is to take into account "toxicity, persistence, and degradability in nature, potential for accumulation in tissue" as well as factors such as corrosiveness and flammability. EPA is empowered to issue standards "as may be required to protect human health and the environment" in three broad areas: generation, transport, and disposal. Generation is covered by §3002, requiring standards for record-keeping, handling, labeling, and use of appropriate containers. Section 3002 sets up a manifest system to ensure that the waste is kept track of and responsibility for it assigned, from its generation to eventual disposal, even if this involves transactions and transfers of ownership of the waste. Transport standards are mandated in §3003, which also incorporates the manifest system, as does §3004, which governs storage and disposal. Disposal standards are largely framed in terms of technology that must be used. Land disposal is prohibited unless "to a reasonable degree of certainty,...there will be no migration of hazardous consituents from the disposal unit...for as long as the wastes remain hazardous." RCRA also provides for EPA regulation of cleanup of currently active industrial sites that hold RCRA permits and requires permits for waste incineration and other disposal methods in addition to land storage.

Given the largely technical and procedural nature of its provisions, RCRA has relatively little

to say about risks and risk assessment. It simply calls for EPA to act to ensure that hazardous waste management practices "are conducted in a manner which protects human health and the environment" [§1003(a)(4)]. Section 3019(b) states that when, in the Administrator's judgment, "a landfill or a surface impoundment poses a substantial potential risk to human health, due to the existence of releases of hazardous constituents, the magnitude of contamination,...or the magnitude of the population exposed", a request may be made for the Agency for Toxic Substances and Disease Registry (ATSDR) to conduct a health assessment of the site. Such a health assessment is not a risk assessment *per se*, but it contains many of the elements of one, including characterization of the exposures and potential exposures around the site, identification of potential exposure pathways, review of the known health effects of the hazardous constituents present, surveys of health complaints in the population in the vicinity of the site, and the review of applicable health-based exposure standards that may exist.

In practice, the evaluation of toxicity information and the potencies of substances is largely drawn from other EPA sources outside of OSW, including information on the IRIS database, reports produced by the EPA Office of Research and Development, maximum contaminant levels taken from the EPA Office of Water, and methods borrowed from the Office of Emergency and Remedial Response (Superfund). In fact, the analysis of hazards posed by inadequate waste disposal sites has much in common with the analysis conducted by Superfund for abandoned sites. OSW combines this information with its own exposure analyses and conducts risk characterization appropriate to its uses of risk analysis.

Risk calculations represent individual risks under exposures that are calculated with conservatism tempered where possible by the use of distributional and Monte Carlo analysis. Individual lifetime cancer risk levels of 10^{-5} or so from unregulated disposal trigger listing of a waste as a hazardous substance and hence subject to RCRA controls on handling and disposal. Newer methods are adopting a range of 10^{-4} to 10^{-6} as a range in which this decision can be made. Delisting a substance as a hazardous waste requires a risk estimate less than 10^{-6} for unregulated disposal. Incinerator permits have usually been granted if risks are below 10^{-5}. Remediation of active waste sites depends on many non-risk technical and other factors, but a post-remediation risk level of 10^{-4} to 10^{-6} is aimed at.

RCRA also has little to say about costs, neither requiring nor prohibiting their consideration (Schierow, 1994).

Office of Emergency and Remedial Response

The Superfund program was created by the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA, 42 U.S.C.A. §§9601 to 9675) of 1980 and its subsequent amendments, the 1986 Superfund Amendments and Reauthorization Act (SARA), to address the need for cleanup of the nation's hazardous waste sites. The program is administered by the EPA Office of Emergency and Remedial Response (OERR). With no state unaffected by past hazardous waste disposal practices, the Superfund program has

perhaps done more than other programs to make the use of risk assessment a local issue. At the same time, it has become a lightning rod for criticism of the U.S. EPA's use of risk assessment for regulatory decision-making in general.

Neither CERCLA nor SARA specifically mention risk assessment, when it is to be used, what procedures to follow, or what levels of risk warrant remedial action or (in the case of specific action) define what actions are to be deemed "protective." The statutes provide a broad mandate to pursue action on contaminated sites that "may present an imminent and substantial danger to the public health or welfare" [§102]. Risk assessment is used under Superfund to define hazardous substances and the amounts of release that must be reported to EPA ("reportable quantities"), rank the risks posed by hazardous waste sites and identify the action priorities among them, including the addition of sites to a National Priorities List (NPL) of high-priority sites, and evaluating the effectiveness of options for remediation (which are chosen on various non-risk grounds in addition to considering risk reduction effectiveness).

Specific policies on risk assessment have been laid out in the National Contingency Plan (NCP, the body of regulations implementing CERCLA and its amendments) and in numerous guidance and policy directives issues pursuant to the NCP. The NCP, like the statutes themselves, does not specifically define the use and form that risk assessment takes in the Superfund site assessment and remedy selection process. However, especially in the area of remedy selection, the NCP interpretation of SARA sets the criteria which must be met and balanced in remedy selection and can profoundly affect the role that risk assessment plays in cleanup of hazardous waste sites. It is important to recognize that although regulatory policy has given risk assessment a role in the evaluation and remediation of hazardous waste sites, it is one of many considerations in the selection of a final remedial alternatives. The NCP establishes nine criteria by which remedial alternatives must be evaluated:

- Overall protection of human health and the environment;
- Compliance with existing regulations and local requirements;
- Long-term effectiveness and permanence;
- Reduction of toxicity, mobility, or volume through treatment;
- Short-term effectiveness;
- Cost;
- Implementability;
- State acceptance; and
- Community acceptance.

The first two criteria are considered threshold criteria that must be met before a remedy can be evaluated fully by the other criteria. The "overall protection" includes consideration of risks that may be generated as a result of the remedial action (e.g., risks to remediation workers or to the public surrounding a site). However, the strong preference for permanent remedies voiced in SARA and codified in the NCP creates a more technology-based approach to remedy selection, which critics argue can override the implications of a risk assessment.

Nominal decisions about cleanup are influenced (to the degree they are based on risk at all) on individual risk levels. These risks are based on standard scenarios of exposure depending on the anticipated future land use, and on estimates (often upper end estimates) of the concentration of contaminants currently at the site. Exposures are often figured as RMEs, or reasonable maximum exposures. RMEs correspond to exposure scenarios in which some contributing variables are set at conservative, upper-bound values, but most are set at population average values.

Policies regarding the level of risk that constitutes a hazard have evolved in the Superfund Program. At the outset of the program, a 10^{-6} lifetime cancer risk was frequently the benchmark against which estimated risks for a site were judged. Under the current NCP and subsequent policy directives, estimated risks at a site are evaluated against a risk range of 10^{-4} to 10^{-6}. The NCP states: "For known or suspected carcinogens, acceptable exposure levels are generally concentration levels that represent an excess upper bound lifetime cancer risk to an individual of between 10^{-4} to 10^{-6} using information on the relationship between dose and response." The NCP does not address the definition of “protective” in the context of exposure to non-carcinogens. In practice, however, exposures to contaminants resulting in hazard quotients or hazard indices exceeding 1 are considered to carry an increased potential for adverse noncancer health impacts.

An important and unique feature of Superfund risk assessments is the consideration of exposure to many chemicals simultaneously. This practice is attributable to the need of risk assessment to evaluate waste sites as health hazards, and not particular chemicals. Superfund does not consider the possible exposure of some people to multiple hazardous waste sites, however.