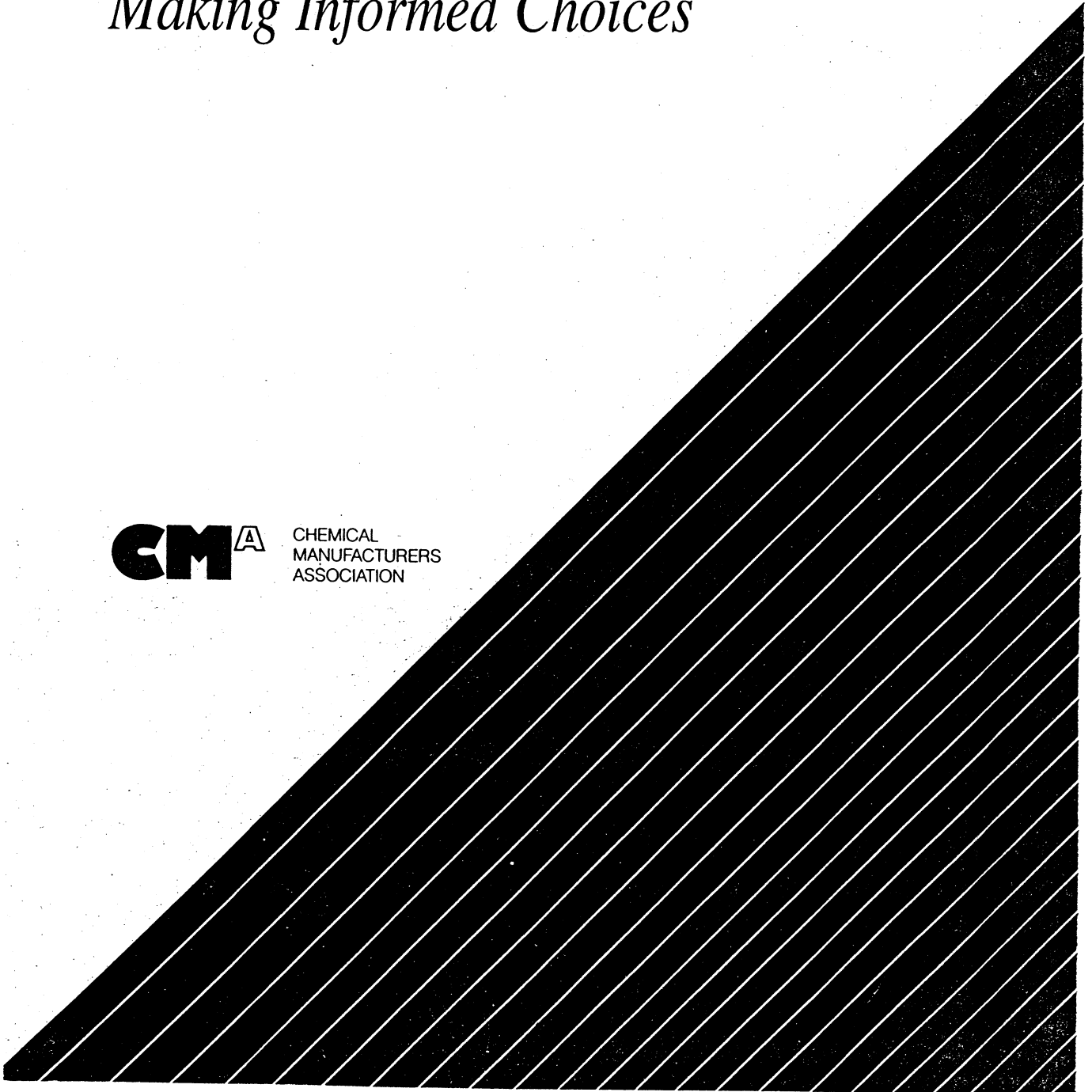


RISK ANALYSIS & PUBLIC POLICY

Making Informed Choices



CHEMICAL
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ASSOCIATION





"The environment is an interrelated whole, and society's environmental protection efforts should be integrated as well. Integration in this case means that government agencies should assess the range of environmental problems of concern and then target protective efforts at the problems that seem to be the most serious. It means that society should use all the tools—regulatory and non-regulatory—that are available to protect the environment.

...One tool that can help foster the evolution of an integrated and targeted national environmental policy is the concept of environmental risk.

...The concept of environmental risk...helps people discuss disparate environmental problems with a common language. It allows many environmental problems to be measured and compared in common terms, and allows different risk reduction options to be evaluated from a common basis."

Reducing Risk: Setting Priorities and Strategies for Environmental Protection,
The U.S. Environmental Protection Agency, Science Advisory Board, 1990.



RISK ANALYSIS AND PUBLIC POLICY

Introduction

Environmental, health and safety regulations have led to dramatic improvements in the environment and have significantly reduced human health risk. Even so, the Federal and State regulations that have led to these improvements have been more costly and less effective than they could have been. Too often, regulatory priorities have not been based on realistic considerations of risk nor have the opportunities for risk reduction been fully considered.

Resources to address health, safety and environmental issues are limited. Those resources need to be allocated carefully so that we address the greatest needs in the most cost-effective manner.

To provide more cost-effective protection to human health and the environment, regulatory priorities should be based upon realistic consideration of risk. The priority-setting process must include scientifically-based risk assessments, comparative risk analysis that incorporates societal values, and risk management choices that consider cost-benefit analysis.

The public must be fully involved in risk decision-making. They have a right to know about the threats addressed by regulation, the level of risk reduction and the quality of the science used to support decisions. They also deserve information concerning the cost of implementing and complying with regulations versus the benefits of those regulations. This knowledge will allow for public scrutiny and will improve the quality and outcome of regulatory decisions.



RISK ASSESSMENT



RISK ASSESSMENT

Introduction

While risk assessments are useful tools for regulatory decisions, there could be some improvements made to the way they are used.

First, there is a need to improve how we incorporate new scientific information in the risk assessment process.

Second, the critical information resulting from risk assessments should be effectively communicated to decision makers and to the public.

EPA has acknowledged that they need to use state-of-the-art risk assessment practices in order to lessen challenges for having overstated or understated risk. This is true for other agencies that rely on risk assessment for their regulatory processes. They need to enhance the scientific basis of the risk assessment process by making it more open and more transparent, allowing more public input and presenting realistic estimates of risk.

The public is best served if the results of risk assessments are presented more clearly, separately identifying and explaining the policy decisions used in risk assessments. In addition, when communicating with the public, agencies should place estimates of risk in an understandable context, comparing risks within the field they regulate and to the everyday risks faced by the public.

John Graham of the Harvard School of Public Health, Center for Risk Analysis, has written, "There are genuine problems with current risk assessment practice that need to be corrected. Some flaws in the current practice lead to neglect of significant risks which need to be reduced." Improving the accuracy and relevance of these assessments is essential to achieving the greatest benefit to society. It will lead to better use of our funds budgeted for environmental regulation and avoid undue costs by state and local governments and industry.

Questions & Answers on Risk Assessment

What is risk assessment?

Risk assessment evaluates the probability and consequences of a risk. It includes the use of data or expert judgment to identify, characterize and, to the extent possible, quantify the potential



adverse effects of exposure of people to hazardous materials, activities or situations. It is the process of deciding how dangerous something is by estimating the form, size and characteristics of a risk. Chemical risk characterization combines information about toxicity and human exposure data.

How are risk assessments used?

Risk assessments help to better understand the nature and significance of risks. Risk assessments allow us to judge the acceptability of risk probabilities and outcomes. They can be used in the analysis that allows us to compare risks with benefits. This kind of information helps set priorities for addressing health, safety and environmental risks. Realistic estimates of the size or seriousness of a problem are necessary to make intelligent choices about solutions.

Do all risk assessments require the same level of effort?

No. A full-blown risk assessment is not needed for every potential threat. Simple screening-level risk assessments can identify insignificant risks. More complex assessments can be conducted when screening indicates a more significant risk. The level of detail and amount of resources devoted to a risk assessment should be commensurate with the problem that risk assessment is intended to address.

Which government agencies conduct risk assessment?

Risk assessments are used to make regulatory decisions on the federal and state levels. Many agencies use some form of risk assessment, but those that deal with complex environmental and human health issues are more deeply involved. They include the Consumer Product Safety Commission, the Environmental Protection Agency, the Food and Drug Administration, the Nuclear Regulatory Commission, the Occupational Safety and Health Administration, the Department of Agriculture, the Department of Transportation and the Mine Safety and Health Administration. At the state level they include those agencies involved in administering laws and regulations in these areas.

The mission of these environmental and risk-related agencies overlap to a great extent. A large part of what each does is to protect the public from the risks posed by potentially hazardous situations and exposure to low levels of hazardous substances.



What is the result of risk assessment?

Risk assessment organizes and analyzes all available scientific information relating to the specific chemical or situation. It evaluates hazards and relates them to human exposure. Risk assessment provides information about the type of hazard expected. It provides a characterization of the risk.

How realistic are estimates of risk?

Sometimes risk estimates are not very realistic. In most cases the predicted risks are so small that they cannot be measured. Often risks are purposely overstated to be "safe" or conservative.

What can the government do to make its risk estimates more realistic?

The government needs to be more open about its risk assessment process and needs to accept new scientific information that will modify its assumptions.

Regulators need to explain more carefully the assumptions and uncertainties inherent in their risk estimates. They need to make the risk assessment process more open by fully describing the assumptions, defaults, and models they used. They must also describe the range of the risks (e.g., between 1 in 1 million and 1 in 100,000) and determine a central estimate within that range rather than provide only the purposefully exaggerated "upper bound" risk, or "worst case" risk.

If risk assessments are uncertain, why use them for setting public policy?

While risk assessments need to be improved in certain areas, they remain an invaluable tool to organize information for the regulatory and public policy process. It is a better approach than the alternative: protection by arbitrarily attempting to minimize all environmental risks, regardless of the costs or demonstrated impact to human health and the environment. Public policy decisions are being made all the time and often involve scientific issues. Even though risk assessment is not perfect, it is better than setting policy based only on emotional or political considerations.

What are default assumptions?

A 1983 National Research Council report defines default assumption or default option as "the option chosen on the basis of risk assessment policy that appears to be the best choice in the



absence of data to the contrary.” Default assumptions are standard, conservative estimates designed to fill gaps in the risk assessment process when situation-specific information is not available. Most default assumptions are based on very conservative scientific estimates and policy judgments. They are also used when the assessor does not know which of several plausible models or assumptions is correct for a particular case.

EPA’s risk assessment practices rest heavily on default assumptions or “inference guidelines,” as they are often called.

Why can’t we eliminate the use of default assumptions?

Default assumptions are necessary when the situation-specific information is unknown or uncertain. Using sound default assumptions in risk assessment can generate useful information for regulatory or policy decisions. It permits the process of risk assessment and risk management to proceed.

Are all default assumptions realistic?

Regulatory agencies generally select default assumptions that are conservative — designed to overstate risks. This practice may be prudent in some cases. But sometimes assumptions are so conservative they are completely unrealistic. For instance, cleanup requirements for toxic materials at waste sites can use an assumption that children will be eating dirt from the site every day. The site cleanup, therefore, must be adequate to protect the health of those dirt-eating children. No one considers that there may not be any dirt-eating children playing in the area. This default assumption naturally will require lots of money and delay an acceptable cleanup — all to protect the health of non-existent, dirt-eating children.

What is transparency?

Transparency means that the process of risk assessment should be open and available to everyone. Agencies should be required to report the results of risk assessment by fully describing the assumptions, defaults, and the models they used. They should also describe the range of the risk so that variability and uncertainty of the risk estimate are clear.

Why is transparency important?

In the decision-making process, risk managers and the public need to understand the strengths and limitations of the assessment. They need to understand how reliable the data were and the degree of scientific confidence or uncertainty in the process. Risk managers and the public are



likely to give higher priority to a problem whose risk is well supported by data than to a risk that is highly speculative.

How can transparency be achieved?

Risk assessments should include discussions about confidence and uncertainties in describing risks. Numerical risk estimates that provide upper bound estimates of risk (like a one-in-a-million chance of contracting cancer) should be accompanied by descriptive information that provides the decision-maker with middle and lower bound estimates, as well as the range of uncertainty.

How do risk assessors get toxicity information?

Toxicity can be manifested in many ways: disease, injury and disability to humans; effects on laboratory animals or wildlife, or damage to plants. Risk assessors depend on laboratory experimentation with animals as one of the most common ways to predict biological risks to humans. Toxicity information is also derived from non-animal studies. These include comparing toxic effects from similar compounds and observing the incidence and distribution of effects on human populations.

How reliable is toxicity information from animal experimentation?

In the absence of human data, results of animal experimentation are typically used to predict how humans will respond. These predictions are usually valid, but in any particular case they may not be. The reliability of conclusions drawn from animal experimentation and translated to humans depends on a number of factors. These include anatomical and physiological similarities or differences, the number of animals used in test and control groups, and the levels and length of exposure to the substance. There needs to be validation (e.g., information on mechanisms of an action, differences in metabolism, etc.) that the system being studied accurately reflects what might occur in humans exposed to the same test agent. Laboratory testing typically uses high concentrations and short-term exposures compared to the actual low levels and longer duration exposures for humans. Thus, additional data clarifying the relevance to humans may sometimes be needed.

What are chemical exposure assessments?

Exposure assessments are estimates of the amounts of a chemical an individual is likely to be exposed to, the frequency and duration of that exposure and the number of individuals likely to be exposed.



Exposure assessments usually identify potential ways by which people could come into contact with chemicals, and estimate exposure concentrations and time of contact. Exposure assessment can also be done by measuring exposure while it is taking place (point-of-contact measurement) or by reconstructing exposure through certain physiological indicators or tests (reconstruction).

How are chemical exposure assessments used?

Exposure assessments determine the contact between humans and the air, water, soil or even the diet containing the toxic chemical. The exposure assessment is combined with the toxicity evaluation to estimate the actual or potential risk.

What factors are considered when making human exposure assessments?

The factors considered include: the concentration of a chemical in the environment (determined by either direct measurement or by using mathematical models); the magnitude of the intake or contact with the chemical per unit of time; frequency and duration of exposure; when the exposures take place; age; sex; health; and exposures other than the chemical, such as medicines, cigarettes, occupation, etc. For example, the amount of contaminated water ingested per day or the amount of contaminated soil coming into contact with the skin can be part of an exposure assessment evaluation.

What is IRIS, and does it provide useful information for the risk assessment process?

IRIS (or Integrated Risk Information System) is EPA's public access database of chemical hazard information about hundreds of substances. It is used by risk assessors for toxicological information. There is a need for this type of central repository of data so that risk assessments can be based on standardized data.

There are problems with the IRIS database. The information in IRIS does not undergo peer review by scientists outside of EPA. Further, there is no effective mechanism for the public to add new information or to have existing health or environmental information in this database reviewed or revised.



COMPARATIVE RISK AND PRIORITY SETTING



COMPARATIVE RISK AND PRIORITY SETTING

Introduction

Risk assessment can be used to compare risks posed by different environmental problems. It will help us set priorities for addressing health, safety and environmental risks. Unless we have realistic estimates of the size of a problem, we will find it virtually impossible to make informed choices about solutions. Risk assessments and comparative risk assessments are simply tools that can help us better understand a particular threat. The more reliable, credible and relevant the risk assessment, the better our understanding — and the more informed our policy response can be.

Comparative risk considerations can serve as a tool for setting priorities for health and environmental regulation. A 1990 EPA study, *Reducing Risk: Setting Priorities and Strategies for Environmental Protection*, found that EPA was directing resources to relatively low-risk concerns while other more serious risks received little attention. This cannot continue. We must move in the direction that gives us the greatest benefit — that is, the greatest protection — for our efforts. We will achieve far more environmental and public health protection if we are more discriminating and use comparative risk to prioritize our problems and allocate our resources. Focusing resources on problems which pose lesser risks will divert resources from actions that would protect human health and the environment more.

Questions & Answers on Comparative Risk and Priority Setting

What is risk comparison?

Risk comparison puts a risk into perspective by comparing it to other risks that may be more familiar. We need to compare risks to understand their relative impacts on the decision-making process. Risk comparisons give us a yardstick for measuring risks.

How can risk comparisons be useful?

Risk comparison helps people understand the important decisions about whether, and how, to regulate. It can provide information in terms that non-experts can understand. Unfamiliar risks proposed for regulation can be compared to familiar risks, allowing a better understanding of the size of the risk. The goal of risk comparison should be to permit the risk manager and the public to understand where and how to spend money to effectively reduce risk.



What is comparative risk assessment?

Comparative risk assessment estimates the relative levels of risk posed by substances, products and activities, and it can be used to establish priorities for determining whether, and how, to regulate. Comparative risk assessment compares the magnitude of risks and can be used to set priorities for the greater protection of human health, safety and the environment in the most cost-effective manner.

How can comparative risk assessment be used for priority setting purposes?

Comparative risk assessment can allow agencies to estimate the size of various risks so that rational priorities can be established. It can be a balancing process in which various combinations of risk reduction schemes are compared and evaluated against various societal needs.

Should comparative risk assessment be applied by different agencies and their different regulatory programs?

Ideally it should be. Comparative risk assessment is used most often when comparing different risks within the same context of products, risk management actions or activities. A broader use of comparative risk assessment would be to consider various threats across different regulatory programs. Such consideration is difficult, however, especially when dealing with the priorities of different agencies or even with different statutes within the same agency. Nevertheless, the difficult decisions about priority setting and resource allocation do take place, and comparative risk assessment serves as a useful tool to help make those decisions.

How have agencies used comparative risk information in setting regulations?

Statutory deadlines and specific requirements set by Congress seldom permit the time or flexibility for agencies to use comparative risk assessment to prioritize their regulatory activities. Congress makes this even more difficult when it sets separate risk standards for different regulations. For example, while the Toxic Substances Control Act (TSCA) specifies protection in a cost-effective manner, the Clean Air Act requires protection of sensitive populations with an "ample margin of safety." In other cases, policymakers are prohibited from using cost/benefit information in their decisions, thus further limiting their ability to prioritize.

Have states or localities conducted comparative risk assessment?

Yes, this is where most comparative risk assessment takes place. Six states have completed comparative risk ranking studies and are now implementing their findings. Sixteen additional



states have studies in progress, and ten states are in the planning stages. In addition, several localities (cities, groups of counties, Native American tribes) have completed or are carrying out studies. EPA has set up two centers as clearing houses for analysis of comparative risk analysis approaches by various states.

Does EPA recognize the need to prioritize risks?

Yes. The Environmental Protection Agency has recognized the urgent need for a risk-based regulatory approach employing comparative risk assessment. In its landmark report, *Reducing Risk*, EPA warned: "There are heavy costs involved if society fails to set environmental priorities based on risk. If finite resources are expended on lower-priority problems at the expense of higher-priority risks, then society will face needlessly high risks. If the priorities are established based on the greatest opportunities to reduce risk, total risk will be reduced in a more efficient way, lessening threats to both public health and local and global ecosystems."

How do you compare different kinds of risks?

It can be difficult. Comparative risk assessment is a political process, not a science. When it is applied to risks that are very different (e.g., comparing the risk of flying to the risk of chemical exposure) there is certainly less precision in the assessment than when it is applied to similar risks. However, the comparative risk process still provides a better system than one that does not integrate scientific information or consider any prioritization. It also can allow the public to help determine priorities. Public values are key to setting priorities among diverse types of risk.

How accurate is comparative risk assessment?

When risks are similar, as they might be with air or water emissions, evaluating trade-offs and deciding which risks should have priority is relatively easy. When the risks are in different areas, the analysis and evaluations are more complex, more subjective and less precise. It does, however, provide a mechanism for separating risks into high, medium and low categories.

Is comparative risk assessment an excuse to ignore problems?

No, it is a better method for addressing and prioritizing problems than a system that does not provide any evaluation and is responsive only to special interests. People and agencies make choices and set priorities all the time. The question is whether these will be informed or uninformed. Comparative risk assessment helps us to use our resources where they will do the most good and give us the most protection.



RISK MANAGEMENT



RISK MANAGEMENT

Introduction

Society needs a smarter, more cost-effective approach to regulation. We need to spend our money more effectively in addressing health and environmental problems. We need freedom to find innovative approaches that lead to the greatest reduction of risk to health and the environment. Congress should encourage performance-oriented rules that result in cost-effective risk reduction.

Risk management ultimately aims to evaluate the balance between health or environmental consequences over and against other effects of specific regulatory actions. Risk management weighs policy alternatives, selects the most appropriate regulatory action and integrates the results of risk assessment into social, economic and political concerns.

Specifically, the regulatory risk management process should be used to consider:

- to what extent a regulatory action will actually reduce a specific risk, or if the regulation itself will actually cause different risks;
- to what extent the regulation will increase costs and create or reduce benefits;
- the difficulty of enforcing a regulation or the political reaction that a regulation might create; and
- the relative risk reduction a regulation could achieve versus potential increased benefits of alternative regulation.

Questions & Answers on Risk Management

What is risk management?

Risk management decides what to do about a risk or threat. It is primarily a policymaking process where government and the public use the information from risk assessments to decide if they are willing to spend money to reduce a risk.



How is risk assessment used in risk management or decision-making?

Once the risks are assessed then risk managers weigh policy alternatives and select the most appropriate action to reduce risk. It integrates the results of risk assessment with social, economic and political concerns to reach a decision. Risk assessment, a scientific process, should remain distinct from risk management, a political process.

How are regulatory priorities set?

The current system for setting regulatory priorities infrequently takes risk into consideration. It is a command and control process where legislation dictates the regulatory control. With limited exception, agencies do not have the freedom to determine their regulatory priorities or to consider the consequences of a particular regulatory action.

How much flexibility do agencies have for crafting regulations?

Flexibility for most regulatory actions is very limited. People believe risk assessments are done for most regulations or projects and are part of the decision-making process. That is not the case. Only one federal statute, TSCA, calls for risk to be used to determine whether, and how to regulate. In most cases, regulators do not have such flexibility. For most laws, the course of regulatory action is prescribed by the law itself.

Are risk assessment or risk management activities considered when setting regulatory budgets and personnel allocation?

Agencies do not routinely use comparative risk to decide where to put their resources. Agency budgets do not break out and prioritize relative risk assessment or risk management from other activities. As a result, their ability to identify resources necessary for such risk analysis activity is inhibited.



PUBLIC PARTICIPATION



PUBLIC PARTICIPATION

Introduction

Regulatory priorities have too often reflected misguided perceptions of risk. Policymakers, risk managers and the public need better information and a better framework for evaluating and comparing health, safety and environmental risks. To achieve progress, the public must be involved but today is often left out of the decision process.

The public is also left out when federal laws and regulations mandate how cities and states must spend large portions of their limited budgets, ignoring high priority local needs. Cities often are forced to spend their money on negligible or non-critical risks, rather than on greater local needs, such as more police officers or firefighters. "There is no acceptable way to make...(risk management) choices without involving the citizens who will be affected by them...(we) need to take steps to enhance public understanding," says Professor Granger Morgan of Carnegie Mellon University.

The public's involvement is central to the whole process of risk management. An informed, fully engaged public is necessary to both establish risk-based priorities that are acceptable and to allocate resources appropriate to each issue. The public needs, deserves and expects to receive accurate risk information in order to make informed decisions. This means that government, industry and the environmental community all have the responsibility to accurately inform the public about risks and to minimize distortion and exaggeration.

Questions & Answers on Public Participation

Does the public have a role to play in risk assessment and risk management?

Absolutely. Those who face the risk should contribute to the risk assessment and risk management process. The public can provide information about behavior, habits, etc., that will help estimate exposure. They should be allowed the opportunity to determine the importance of the hazards from their point of view, to prioritize risks, and to determine where we, as a society, should spend our money.



Is the public currently involved in the risk assessment process and subsequent risk management decisions?

The public has little opportunity to participate in the risk assessment process or to decide how and which risks should be managed. The public thus has limited opportunity to provide information about health or environmental effects related to the risks being assessed.

Why is it important to inform the public about relative risk?

An informed, fully engaged public is necessary both to establish risk-based priorities they will find acceptable and to allocate appropriate resources to manage those risks. Knowing about how big a risk is compared to other risks will help to make informed decisions.

Can the people who use risk assessments tell what assumptions have been made?

This is often a problem if the risk assessors (regulators) do not provide the public or risk managers with enough information. For example, regulators typically provide only upper bound estimates of risk, leaving to the imagination the middle and lower bound estimates, as well as the range of uncertainty. Regulators must provide a fair and full characterization of the risk.

How can the public provide input into the risk assessment process?

While much of the risk assessment process relies on scientific activity and scientific judgment, there is a significant amount of evaluation within the assessment process that relies on societal needs and political judgments. The public should be involved in deciding what risks to accept and how much money to spend to reduce risks.

What is peer review, and why is it important?

Peer review is the accepted process in scientific research of subjecting one's findings to a critical review by others of equal scientific standing. It is important to validate the work of one scientist, investigator or laboratory. It establishes the reliability of the assessed information.

What kinds of peer review do risk assessments get?

It depends. Some agencies such as EPA have an elaborate structure for peer review — most of it internal. Others use essentially none. A peer review process that provides an independent assessment would ultimately enhance the quality of the risk assessment process.