

PART V

RISK-BASED DECISION MAKING

Introduction to Part V

Part V of this Reference Manual provides an overview of three components of risk-based decision making.

- Risk Management (Chapter 27) refers to the regulatory and other actions taken to limit or control exposures to air toxics, including the role of risk management in regulating hazards.
- Community Involvement (Chapter 28) is an integral part of many risk management strategies because good community involvement helps ensure that the strategy selected will have the highest likelihood of success. Various levels of community involvement are also required by many laws.
- Risk Communication (Chapter 29) describes the process of planning the risk assessment (during scoping) and conveying the results of the risk assessment in a way that meets the information requirements for the risk management decisions. This chapter discusses the importance of risk communication, and planning and implementing a risk communication strategy.

Chapter 27 Risk Management

Table of Contents

27.1	Introduction	<u>1</u>
27.2	Role of Risk Management in Regulating Hazards	<u>1</u>
27.3	Types of Risk Management Decisions Related to Air Toxics	<u>4</u>
27.4	Use of Risk Estimates in Decision-Making	<u>5</u>
27.5	Process for Making Risk Management Decisions	<u>9</u>
	27.5.1 Define the Problem and Put it in Context	<u>9</u>
	27.5.2 Analyze the Risks Associated with the Problem in Context	<u>9</u>
	27.5.3 Examine Options for Addressing the Risks	<u>11</u>
	27.5.4 Make Decisions about Which Options to Implement	<u>12</u>
	27.5.5 Take Actions to Implement the Decisions	<u>13</u>
	27.5.6 Conduct an Evaluation of the Action's Results	<u>14</u>
27.6	Information Dissemination	<u>14</u>
	References	<u>15</u>

27.1 Introduction

This chapter introduces risk management, focusing on its role in addressing the risks that air toxics pose. It provides an overview of the types of risk management decisions related to air toxics, a discussion of how risks to individuals and populations are presented to the public, and options for implementing decisions (e.g., regulation, voluntary risk reduction activities).

Specifically, **risk management** refers to the regulatory and other actions taken to limit or control exposures to a chemical. **Risk assessment**, on the other hand, is a tool used to support risk management decisions by providing quantitative and qualitative expressions of risk, along with attendant uncertainties. Specifically, the risk assessment conveys a quantitative and qualitative description of the types of impacts that may occur from exposure to an air toxic, the likelihood that these impacts will occur given existing conditions, and the uncertainties surrounding the analysis. Risk management considers these principle factors along with a variety of additional information (which may include the cost of reducing emissions or exposures, the statutory authority to take regulatory actions, and the acceptability of control options) to reach a final decision.

27.2 Role of Risk Management in Regulating Hazards

Risk management may include implicit or explicit policy and value judgments. Therefore, one would expect there to be differences of opinion concerning what represents an appropriate risk management action. Even the most basic risk management decision can be highly controversial. A classic example is the decision(s) needed to answer the question **how clean is clean?** This question refers to a risk management decision that must establish a target level to which existing levels of contamination/pollution should be reduced. Establishing this level is not a trivial matter. Working through these issues can be complicated by the different values of the stakeholders and debates over individual perceptions about risk. As discussed below, many authors and organizations stress the importance of understanding risk management mandates, options, and concerns throughout the risk assessment process, from the initial problem formulation steps to the final risk characterization and risk communication. Many of the critical decisions in structuring the technical risk assessment depend on risk management concerns (e.g., what risk management options are feasible, what level of certainty in the risk estimate is acceptable).

Although the National Academy of Sciences and others stress the **distinction** between risk assessment and risk management, they also stress the **integration** of the two efforts (see Exhibit 27-1). Risk assessments are often designed and conducted with awareness of the risk management options available to decision-makers and the social, economic, and political context in which those decisions are to be made. Likewise, periodically reviewing the risk management options during the risk assessment effort ensures that the results of the risk assessment will provide meaningful input into the decision-making process. The National Research Council (NRC) of the National Academy of Sciences (NAS), in their 1983 study entitled *Risk Assessment in the Federal Government: Managing the Process* (the “Red Book”),⁽¹⁾ advocated a clear conceptual distinction between risk assessment and risk management, noting, for example, that maintaining the distinction between the two would help to prevent the tailoring of risk assessments to the political feasibility of regulating a chemical substance. However, the NRC also recognized that the choice of risk assessment techniques could not be isolated from society’s

risk management goals. Ultimately, the risk assessors should be aware of risk management goals; however, the fundamental science performed in the risk assessment should be impartial and based on the factual base of information, to the extent possible.

Use of the Term “Safe”

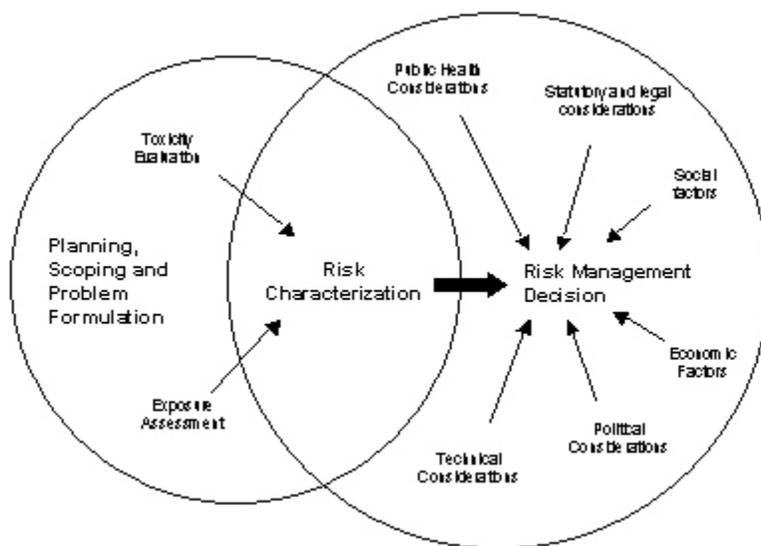
Safe: Condition of exposure under which there is a practical certainty that no harm will result to exposed individuals (as defined in EPA’s *Terms of Environment*).

Safe: Free from harm or risk (as defined in the Merriam-Webster Collegiate Dictionary).

During government and community interactions and risk communication, it is important to be sensitive to perceived meanings of the term “safe.” Regulators and scientists are often reluctant to use the term “safe,” because many people understand “safe” to mean “zero risk.” Ideally, one would like to eliminate all risks, but this is usually not a realistic expectation. Regulators commonly work to address the most important risks and decrease them to the level at which they believe the risks are smaller than the benefits of the activity causing the problem (in this case, risk from exposure to air toxics). They commonly refer to this level as “acceptably low risk.”

However, community members may become frustrated with regulators who are reluctant to use the term “safe,” potentially perceiving the regulators’ choice of words as a dodge of the issue. Therefore, it is important for government representatives to address perceptions of the meaning of safe during risk communication and, as appropriate, use risk comparisons to help in communicating the concepts of safe versus acceptably low risk. Information on risk communication is provided in Chapter 29, and Section 29.4 provides specific information about risk comparisons.

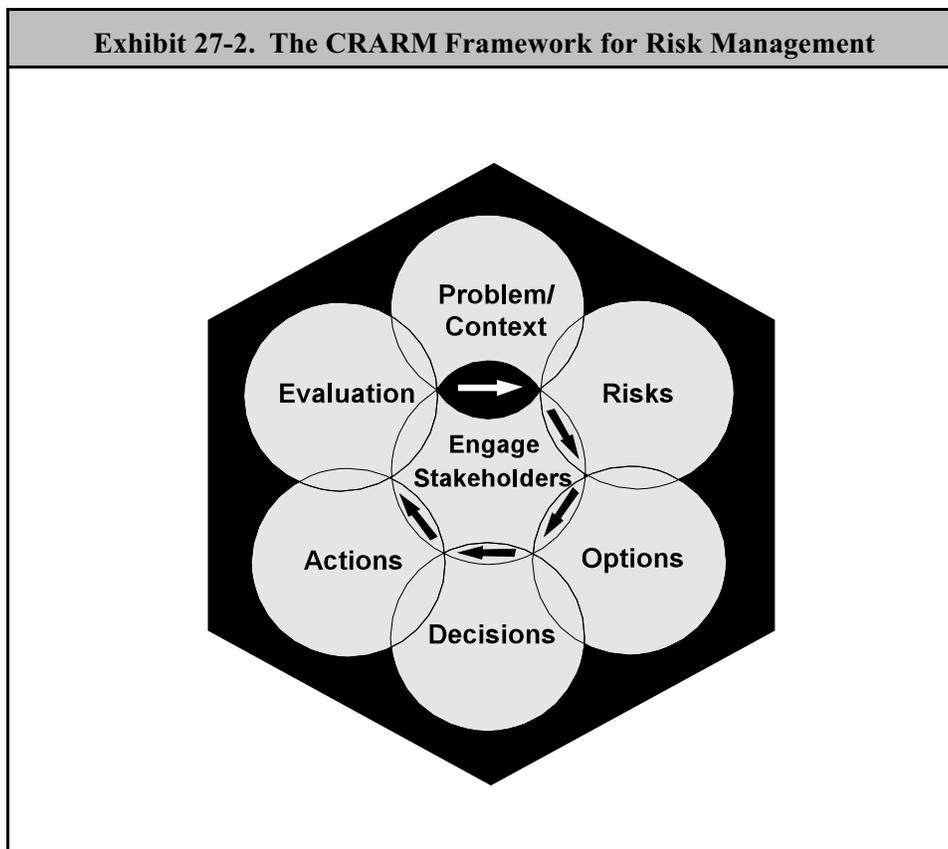
Exhibit 27-1. Illustration of the Integration Between Risk Assessment and Risk Management



The NRC, in their 1994 report, *Science and Judgment in Risk Assessment* (the “Blue Book”),⁽²⁾ noted that, while the Red Book emphasized the distinction between risk assessment and risk management, the purpose of separation was not to prevent any exercise of policy judgment when evaluating science or to prevent risk managers from influencing the type of information that assessors would collect, analyze, or present. The Blue Book concluded further that the science-policy judgments that EPA makes in the course of a risk assessment would be improved if there were more clearly informed by the Agency’s priorities and goals in risk management. Protecting the integrity of the risk assessment, while building more productive linkages to make risk assessment more accurate and relevant to risk management, is essential.

The integration between risk assessment and risk management also has been emphasized by Presidential/Congressional Commission on Risk Assessment and Risk Management. In their Reports *Framework for Environmental Health Risk Management* and *Risk Assessment and Risk Management In Regulatory Decision-Making* (the two-volume “White Book”),⁽³⁾ the Commission developed a six-stage integrated framework for environmental health risk management that can be applied to most situations (Exhibit 27-2):

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



The Commission noted that the process of examining risk management options does not have to wait until the risk analysis is completed, although a risk analysis often will provide important information for identifying and evaluating risk management options. In some cases, examining risk management options may help refine a risk analysis. The Commission also recommended that all of these steps involve stakeholders (see Chapter 28).

When discussing risk management, it is important to consider **where** and **how** changes or interventions may occur in the causal sequence of environmental impacts since interventions may reduce pollutants a number of ways along the critical path of environmental impacts. For example, interventions such as changing manufacturing processes, implementing emissions controls, or influencing worker behaviors that actively reduce exposure may have a positive mitigating effect on environmental impacts. In the discussion of risk management that follows, it is critical to keep in mind the range of ways in which environmental risks can be mitigated; it is up to the risk managers to determine the most feasible and critical “points of entry” along the path when developing a risk management strategy.

27.3 Types of Risk Management Decisions Related to Air Toxics

Two general categories of risk management decisions are relevant to air toxics: emissions control and siting.

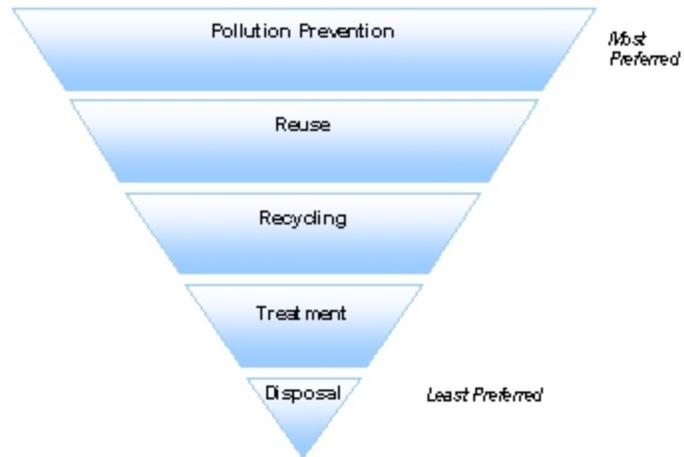
- **Emissions control.** Emissions control decisions may involve “command-and-control” decisions (e.g., emissions limits) or incentives (e.g., tax credits for reduced emissions). EPA’s preference is to encourage pollution prevention whenever feasible (see Exhibit 27-3). Emissions control decisions are most likely to involve formal risk assessments.
- **Siting/locating.** These decisions involve where to locate industrial facilities, businesses, waste disposal facilities, and transportation routes. Siting decisions are typically made by S/L/T governments through mechanisms such as zoning, deed restrictions and other property controls, and in some cases regulation. Many of these decision-making processes include public involvement in which citizens may seek to influence the final decision. Siting decisions may involve assessment of environmental impacts pursuant to the National Environmental Policy Act, other federal statutes, or similar state statutes. Siting decisions may increasingly involve air toxics risk assessments.

Not All Risk Management Decisions are Regulatory

Some risk management decisions are made by EPA or state, local and tribal (S/L/T) regulators pursuant to specific statutory criteria. However, government agencies may have limited authority to impact many other decisions. For example, some decisions are made by the individuals who own or operate the facilities that release air toxics, while others are made by citizens who are being impacted by emissions. Risk management decisions may need to consider looking beyond technological solutions.

Exhibit 27-3. Pollution Prevention Hierarchy

In the Pollution Prevention Act of 1990, Congress established a hierarchy for the handling of pollution (see graphic). The Act established as United States policy that pollution should be prevented or reduced at the source whenever feasible, that pollution that cannot be prevented should be recycled in an environmentally safe manner whenever feasible, and that pollution that cannot be prevented or recycled should be treated in an environmentally safe manner whenever feasible. Disposal or other release into the environment should be employed only as a last resort and should be conducted in an environmentally safe manner.



Pollution prevention is the reduction or elimination of pollutants at the source. As defined in the Pollution Prevention Act, “source reduction” means any practice which (1) reduces the amount of any hazardous substance, pollutant, or contaminant entering any waste stream or otherwise released into the environment (including fugitive emissions) prior to recycling, treatment,

or disposal, and (2) reduces the hazards to public health and the environment associated with the release of such substances, pollutants, or contaminants. It includes equipment or technology modifications, process or procedure modifications, reformulation or redesign of products, substitution of raw materials, and improvements in housekeeping, maintenance, training, or inventory control. Examples of the value of pollution prevention for reducing environmental risks at the community level are demonstrated by EPA’s Environmental Justice through Pollution Prevention (EJP2) grant program. EPA encouraged community groups, tribes, and local governments to identify environmental problems and generate potential pollution prevention solutions for their communities.

Source: U.S. Environmental Protection Agency. 2002. *Environmental Justice Through Pollution Prevention Program*. Updated July 9, 2002. Available at: <http://www.epa.gov/opptintr/ejp2/>. (Last accessed April, 2004.)

27.4 Use of Risk Estimates in Decision-Making

Decision-makers have a number of options when deciding what types of risk estimates to consider as inputs to risk management decisions. Estimates of human health risk generally fall into two categories, estimated **cancer risk** and the estimated **noncancer hazard** magnitude of exposure concentration or dietary intake greater than a pre-established reference exposure level), as described in more detail in Chapters 13 and 22. Non-cancer hazard may be considered for both acute (short-term) and chronic (longer-term) exposures. In some cases, **ecological risk** may be a factor in decision-making.

In some situations, risk managers may choose to consider EPA’s approach for assessing an “ample margin of safety.” For cancer risks, EPA generally considers incremental risk (or probability) of cancer for an individual potentially exposed to one or more air toxics. In protecting public health with an ample margin of safety, EPA strives to provide maximum feasible protection against risks to health from HAPs by (1) protecting the greatest number of

persons possible to an individual lifetime risk level no higher than 1×10^{-6} (one in one million) and (2) limiting to no higher than approximately 1×10^{-4} (one in ten thousand) the estimated risk that a person living near a source would have if exposed to the maximum pollutant concentrations for 70 years. These goals are described in the preamble to the benzene National Emissions Standards for Hazardous Air Pollutants (NESHAP) rulemaking (54 *Federal Register* 38044, September 14, 1989) and are the goals incorporated by Congress for EPA's residual risk program under Clean Air Act (CAA) section 112(f). Exhibit 27-4 describes some of the key steps in the development of the 1×10^{-4} to 1×10^{-6} carcinogenic risk range.

For non-carcinogenic substances, on the other hand, risk managers may consider a reference level that is developed based on data from laboratory animal or human epidemiology studies (see Chapter 12), and to which uncertainty factors are applied. The reference level is usually an exposure level below which there are not likely to be any adverse effects from exposure to the chemical. Exposures above the reference level may have some potential for causing adverse effects. This concept may also be applied generally to ecological risks.

Risk estimate options generally revolve around estimates of individual risk, the number of people at different risk levels (population risk), and occasionally include the expected incidence of disease in the entire population. Risk estimates can be derived for the current population as currently distributed in an area or for a population size and geographic distribution that might occur in the future; similarly, they may focus on risk estimates for persons currently exposed or possible risks calculated for a hypothetical individual located where exposures are expected to be relatively high. It is important to note that risk estimates should strive to take into account both **indoor** and **outdoor** exposure to toxics, when possible.

- **Risk to a specified individual.** Most risk assessments focus on estimating individual risk rather than the incidence of adverse effects (e.g., numbers of predicted cancer cases per year) in a population. There are two general estimates of individual risk:
 - **High-end** risk estimates seek to determine a “plausible worst case” situation among all of the individual risks in the population. This estimate is meant to describe an individual who, as a result of where they live and what they do, experiences the highest level of exposure within some reasonable bounds. Reasonable maximum risk estimates are often defined conceptually as “above the 90th percentile of the population”⁽⁴⁾ but not at a higher exposure level than the person exposed at the highest level in the population. When calculated using deterministic methods, the high-end individual is calculated by combining upper-bound and mid-range exposure factors (e.g., an average body weight, but high-end ingestion rate) so that the result represents an exposure scenario that is both protective and reasonable, but not higher than the worst possible case.
 - **Central-tendency** risk estimates seek to determine a reasonable “average” or “mid-range” situation among all of the individual risks in the population. Many risk management decisions related to exposure to radioactive substances (e.g., in nuclear power plants) are based on central-tendency risk estimates.

Exhibit 27-4. Development of the 1×10^{-4} to 1×10^{-6} Carcinogenic Risk Range

The 1970 CAA established Section 112 to deal with hazardous air pollutants. Once the EPA Administrator had identified such a pollutant and “listed” it, he/she was directed to set emission standards for sources emitting it at levels that would “provide an ample margin of safety to protect the public health.” The regulation of benzene pursuant to Section 112 illustrates the evolution of risk-based decision-making for carcinogens and the consideration of the “ample margin of safety.”

- EPA listed benzene as a HAP in June 1977 and indicated that the “relative risk to the public” would be considered in judging “the degree of control which can and should be required.”
- In 1980, the first round of benzene standards followed the proposed procedures in EPA’s 1979 draft airborne carcinogen policy, which reflected a technology-based approach to emission standard development with a limited role for quantitative risk assessment in establishing priorities and ensuring that the residual risks following the application of “best available technology” (BAT) were not unreasonable.
- In 1984, after “weighing all factors,” EPA made several changes to the proposed benzene rules, arguing that the risks were “too small to warrant Federal regulatory action.” These decisions were promptly challenged by the Natural Resources Defense Council, who argued about the uncertainties in the risk estimates and the inappropriate consideration of cost in regulatory decisions made under Section 112. The issues raised were similar to litigation already pending on amendments to the original vinyl chloride standards.
- On July 28, 1987, Judge Robert Bork, writing for the D.C. Circuit Court of Appeals, remanded the vinyl chloride amendments to EPA, finding that the Agency had placed too great an emphasis on technical feasibility and cost rather than the provision of an “ample margin of safety” as required by the statute. The opinion also laid out a process for making decisions, consistent with the requirements of the law. The Bork opinion held that EPA must first determine a “safe” or “acceptable” level considering only the potential health impacts of the pollutant. Once an acceptable level was identified, the level could be reduced further, as appropriate and in consideration of other factors, including cost and technical feasibility to provide the required ample margin of safety. The Court also held, however, that “safe” did not require a finding of “risk-free” and that EPA should recognize that activities such as “driving a car or breathing city air” may not be considered “unsafe.”
- In September of 1989, after proposing several options and receiving considerable public comment, EPA promulgated emission standards for several categories of benzene sources. EPA argued for the consideration of all relevant health information and established “presumptive benchmarks” for risks that would be deemed “acceptable.” The goal, which came to be known as the “fuzzy bright line,” is to protect the greatest number of persons possible to an individual lifetime risk no higher than one in 1,000,000 and to limit to no higher than approximately one in 10,000 the estimated maximum individual risk. The selection of even “fuzzy” risk targets placed greater emphasis on the development and communication of risk characterization results.

Source: National Academy of Sciences’ *Science and Judgment in Risk Assessment* (The Blue Book).⁽²⁾

Note that, when calculating deterministic risk estimates, both a high end and central tendency estimate of risk give the risk manager some sense of the range of risks in the population. When risks to a population are developed using probabilistic methods, this becomes a moot point, since the result is a distribution of risks across the population, which necessarily includes information about the full variability of risk across the population – including both high and central tendency risks. See Chapter 31 for more information on probabilistic approaches to risk assessment.

- **Risk to the total population.** Whether or not risk to the total population is considered by EPA may depend on the regulatory authority provided by the CAA. For example, Section 112(k) of the CAA requires EPA to develop an Urban Air Toxics Strategy to reduce HAPs from area sources to achieve a 75 percent reduction in cancer incidences attributable to such sources. Two general types of descriptors are used for population risk. One, sometimes termed **population at risk** is derived by determining the number of people in a population with a particular individual risk level (e.g., “1,340,000 people are exposed at the 1×10^{-6} level, and 320 people are exposed at the 1×10^{-4} level”). This is a useful estimate of the variability of risk in a population.
- **Incidence**, another descriptor used for population risk, is an estimate of the total number (incidence) of adverse effects in a population over a specified time period (e.g., a period of 70 years). A screening approach to deriving this estimate for a 70-year period involves multiplying the estimate of individual risk (central tendency and/or reasonable maximum) by the number of persons for which that risk estimate was predicted. For example, in a population of 200 million persons, an individual cancer risk of 1×10^{-4} (i.e., one in ten thousand) for everyone in the population would translate to an incidence of hundreds or thousands of excess cancer cases over a 70-year period (depending on the exposure assumptions). However, in a small population (e.g., a town of 200 persons), the same individual cancer risk to everyone would translate to an excess incidence of cancer of less than one over a 70-year period.
- **Present versus future scenarios.** Risks may be characterized using present or future scenarios. Use of present scenarios involves predicting risks associated with the current exposures to individuals (or populations) that currently reside in areas where exposures are predicted to occur. For example, a current population risk estimate would use the existing population within some specified area. The resultant risk estimates are associated with the presumption that the current exposure conditions exist for the current population over the period of time associated with the assessment (e.g., into the future). Use of future population scenarios involves estimating risks associated with exposure conditions to individuals that might reside, at some future point, in areas where potential exposures may occur (e.g., if a housing development were built on currently vacant land).
- **Potential risk.** Risks may be sometimes be characterized for hypothetical exposures. For example, in a screening air toxics modeling application, a potential risk estimate may be derived using the location where the maximum modeled exposure concentration occurs, regardless of whether there is a person there or not. This estimate may be considered along with the predicted individual risk associated with a currently populated area, such as the MIR, which reflects risk associated with the maximum exposure concentration at an actual residence or in a census block with a non-zero population (see Chapter 11).

27.5 Process for Making Risk Management Decisions

A number of different authors and organizations have identified key steps or factors to consider in making risk management decisions. The discussion in this section is taken largely from the risk management framework developed by the Presidential/Congressional Commission on Risk Assessment and Risk Management.⁽³⁾ The Commission's framework has six stages, each of which is briefly described below. The Commission also noted that the framework is conducted:

- In collaboration with stakeholders; and
- Using iterations if new information is developed that changes the need for or nature of risk management.

27.5.1 Define the Problem and Put it in Context

The problem/context stage is the most important step in the Risk Management Framework. It involves:

- Identifying and characterizing an environmental health problem, or a potential problem, caused by chemicals or other hazardous agents or situations;
- Putting the problem into its public health and ecological context;
- Determining risk management goals;
- Identifying risk managers with the authority or responsibility to take the necessary actions; and
- Implementing a process for engaging stakeholders.

These steps are all important, but may be conducted in different orders, depending on the particular situation. For example, when a federal or S/L/T regulatory agency is mandated by law to take the lead on an air toxics issue, the steps they take often will proceed in the order listed above, with the identity of the risk managers already clear, since the agency will have assumed that role from the start. On the other hand, in a community based effort to characterize the cumulative risk posed by multiple sources of air toxics in a neighborhood, stakeholders might have to engage in a collaborative stakeholder process first to identify resources as well as risk managers with the needed authority to act before the other steps can take place.

27.5.2 Analyze the Risks Associated with the Problem in Context

The nature, extent, and focus of a risk assessment should be guided by the risk management goals. The results of a risk assessment – along with information about public values, statutory requirements, court decisions, equity considerations, benefits, and costs – all can influence whether and how to manage the risks.

Risk assessment can be controversial, reflecting the important role that both science and judgment play in drawing conclusions about the likelihood of effects on human health and the

environment. Often, the controversy arises from what we do not know and from what risk assessments cannot tell us, because our knowledge of human vulnerability and of environmental impacts is incomplete, especially at the relatively low levels of chemical exposure commonly encountered in the general community.

Some Factors to Consider in Defining the Problem for an Air Toxics Risk Assessment

- **Risk.** The specific estimates of risk to be used as inputs to the decision should be defined as explicitly as possible. Are acute risks (e.g., short-term exposures) the primary concern, or are exposures over the longer-term more important? Are ecological risks a concern? How certain are we that our risk estimates are an accurate reflection of true exposure and risk?
- **Air toxics of concern.** What are the primary air toxics of concern? Are they more prevalent in indoor or outdoor environments? How many individual chemicals contribute to the risks that need to be managed? Do these chemicals exert their effects independently, or are some acting in a synergistic (or antagonistic) manner? Are all equally important, or will reducing exposures to a subset of these air toxics result in adequate risk reduction? How important is it to manage every chemical of concern versus only those that pose the greatest risk?
- **Sources.** What are the primary sources of the air toxics that need to be managed? Where are these sources located? How many are there? Are they all equally important, or will controlling a subset result in adequate risk reduction?
- **Exposure pathway considerations.** What exposure pathways/routes are most important? Are all equally important, or does a subset represent the greatest risk? Does control of each pathway require controls over all components of the pathway (e.g., emissions, exposure), or can the pathway be controlled by controlling a subset of these components?
- **Amount of emissions reduction desired/achievable.** What is the overall target for emissions/exposure reduction? How does this relate to risk reduction by the estimates identified above? Will partial reductions result in significant risk reduction, or is it more of an all-or-none situation? What technologies are available to achieve the desired level of risk reduction? How much do the various options cost?
- **Spatial and temporal factors.** Are releases of concern limited to a relatively brief period of time, or do data support the emissions being relatively continuous over a longer period of time? Are the released toxics specific to a single location or are there several wide-spread emission points? What is the fate and transport of the released chemicals? How does background risk relate to the risk reduction strategy?
- **Data gaps and uncertainties.** What are the main sources of uncertainty in the data used in the risk assessment? How do these uncertainties affect the risk management decision? Will more information reduce these uncertainties and can the uncertainty be addressed with available time and resources? Approaches for identifying and managing uncertainties associated with risk assessment are discussed in Chapters 13 and Part VII.

27.5.3 Examine Options for Addressing the Risks

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

The Commission noted that stakeholders can play an important role in all facets of identifying and analyzing options. They can help risk managers:

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

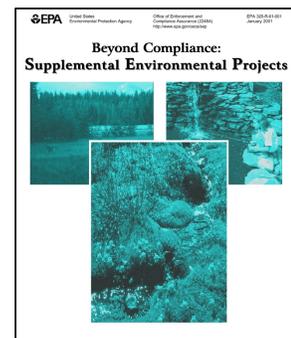
Chapter 28 provides an overview of community involvement and its role in risk assessment and risk management.

Alternative Solutions to Unique Problems

Project XL, which stands for “eXcellence and Leadership,” is a national pilot program that allows state and local governments, businesses, and Federal facilities to develop with EPA innovative strategies to test better or more cost-effective ways of achieving environmental and public health protection. In January 2001, EPA signed the 50th XL Final Project Agreement. Although EPA is no longer accepting proposals for new XL projects, EPA will continue to fulfill each of its commitments under Project XL and will track and monitor the progress of each XL pilot for the duration of the project.

See www.epa.gov/projectxl for more information.

Supplemental Environmental Projects (SEPs) are part of enforcement settlements connected with violations of an environmental statutory or regulatory requirement. As part of the enforcement settlement, a violator voluntarily agrees to undertake an environmentally beneficial project in exchange for a reduction in the penalty. See www.epa.gov/compliance/civil/programs/seps for more information.



27.5.4 Make Decisions about Which Options to Implement

In most risk management situations, decision-makers will have a number of options from which to choose. Which option is optimal depends on the particular situation (and in some cases may be driven by statutory requirements). The following seven are fundamental characteristics of sound risk management decision making:

- Base the decision on the best available scientific, economic, and other technical information;
- Be sure the decision accounts for the problem's multisource, multimedia, multichemical, and multirisk contexts;
- Choose risk management options that are feasible, with benefits reasonably related to their costs;
- Give priority to preventing risks, not just controlling them;
- Use alternatives to command-and-control regulation, where applicable;
- Be sensitive to political, social, legal, and cultural considerations; and
- Include incentives for innovation, evaluation, and research.

Options to be considered for air toxics fall into the following general categories:

- **Regulatory approaches.** Pursuant to various sections of the CAA, Congress has authorized EPA to regulate air toxics. Many S/L/T governments have also authorized agencies to regulate air toxics. Regulatory approaches include enforceable requirements that identified sources must meet (or else be subject to legal action, such as fines) as well as emissions-trading type requirements that focus on controls over sources in total while allowing flexible emissions among individual sources.
- **Voluntary approaches.** EPA and other regulatory agencies are looking beyond regulatory approaches to reduce risks from air toxics. Non-regulatory (voluntary) approaches are frequently the preferred option in a number of cases. Decision-makers at S/L/T agencies may not currently have specific regulatory authority to address specific air toxics problems identified in a risk analysis (particularly in a novel analysis such as a multi-source, community-based risk assessment). The types of problems identified may not lend themselves to regulatory solutions (e.g., they may require changes in the behavior of the exposed population). Voluntary programs may also allow sources to significantly reduce overall risk at much lower cost than various regulatory options. Various incentives such as tax reductions or consumer rebates can be used to encourage voluntary responses.
- **Permits and related authorities.** Permits offer opportunities for both regulatory and voluntary risk-management strategies. Many sources release air toxics to the atmosphere pursuant to permits and related authorities. Permits generally need to be renewed periodically and/or modified if conditions at the source change beyond some specified

amount. This may provide an opportunity to re-write permit conditions so as to reduce high-risk emissions. This might be coupled with voluntary measures or other flexible solutions to result in overall risk reduction (see box). Agencies may also work with emission sources to incorporate voluntary measures or other flexible solutions into the permit.

Example Factors to Consider When Evaluating Risk Management Options

- **Risk reduction benefits to be realized.** Risk management decisions often focus on the *incremental* risk associated with the chemical or other hazard being regulated in the absence of background risks. However, background risk may be important in certain situations. For example, if a monitoring program measures concentrations of air toxics being transported into a given study area that result in risks above an “acceptable” level, no level of emissions control within the study area will be able to reduce risk to an “acceptable” level, and the community may wish to address the incoming air toxics via discussions beyond the local community.
- **Level of uncertainty in the analysis.** In the face of highly uncertain risks, decision-makers have to carefully weigh the consequences of two or more options: making a decision to control emissions or exposures only to find out later that there was little actual risk (e.g., incurring unnecessary “cost” to the community), or making a decision *not* to control emissions or exposures only to find out later that the risks were real and large (e.g., incurring potentially preventable harm to the community).
- **Implementation costs,** both for voluntary approaches (e.g., marketing, process changes, tax incentives) as well as to regulatory agencies, the regulated community, and the general community (consumers).
- **Technical feasibility.** Short of shutting down the emission source altogether, is there an available technology to reduce or eliminate emissions?
- **Legal feasibility.** Does the decision-making body have legal authority to both establish and enforce requirements?
- **Effectiveness/timing.** Will the option provide effective management of the problem within a reasonable time-frame?
- **Political feasibility.** Does the option have the necessary political support?
- **Community Acceptance.** Do the stakeholders buy-in to the proposed risk reduction alternatives?

Each of these factors may be more or less important depending on the context for the risk management decision. For example, the risk manager may be required by statute to weigh economic factors less than technical factors.

27.5.5 Take Actions to Implement the Decisions

Traditionally, implementation has been driven by regulatory agencies’ requirements. Businesses and governments (e.g., local municipalities) are generally the implementers. However, the chances of success may be significantly improved when other stakeholders also play key roles. Depending on the situation, action-takers may include public health agencies, other public

agencies, community groups, citizens, businesses, industries, unions/workers, and technical experts. These groups can help:

- Develop and implement a plan for taking action;
- Explain to affected communities what decision was made and why and what actions will be taken; and
- Monitor progress.

27.5.6 Conduct an Evaluation of the Action's Results

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

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

27.6 Information Dissemination

The Presidential/Congressional Commission on Risk Assessment and Risk Management noted that effective risk communication is critical to successful implementation of the risk management framework.⁽³⁾ Risk communication engages both the communicator and the audience in listening and in explaining information and opinions about the nature of risk and other topics that express concerns, opinions, or reactions to risk messages.⁽⁵⁾ The Commission made the following recommendations with respect to risk communication:

- The complex and often confusing process of communicating information about risks to diverse affected parties must be improved;

- Decisions about how to allocate resources to reduce risks can be made and explained partly on the basis of risk comparisons;
- The use of “bright lines” which distinguish between contaminant emissions and exposures associated with negligible risk levels and those associated with unacceptable risk levels, needs to be clarified;
- Moving from command-and-control regulation to non-regulatory approaches to risk reduction can increase both efficiency and effectiveness; and
- Criteria for judicial review, a common element in major regulatory actions, should be reaffirmed.

Chapter 29 provides an overview of risk communication and it’s role in risk assessment and risk management.

References

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