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Planning for Ecological Risk Assessment: Developing Management Objectives

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CONTENTS

LIST OF TABLES

LIST OF TEXT BOXES

LIST OF EXAMPLE BOXES

LIST OF FIGURES

LIST OF KEYS

NOTE: Page numbers to be added.

Executive Summary

The purpose of any risk assessment is to inform a risk-management decision, that is, determine whether there is in fact a problem, how significant it is, and what factors most influence it, in order to decide what to do about it. Although planning is important for any risk assessment, ecological risk assessment merits especially thoughtful consideration: In human-health risk assessment and risk management, we are dealing with a single, well-studied organism, and everyone generally agrees that humans and their health are important and effects such as cancer, deformities, functional deficits, and death should be avoided. Goals such as "minimize cancer" and "prevent birth defects" are so well accepted that they have become implicit and are rarely challenged.

Unfortunately, it is not so easy for ecosystems. To begin with, it can be difficult to choose which of many organisms to study. In addition, we understand ecosystem processes and interactions much less well than we do humans, and we seldom have as much toxicological, behavioral, physiological, or ecological data as we would like for our analyses. Moreover, there is little agreement on which (if any) organisms or ecosystems are important enough to single out for protection, especially when we routinely choose human activity over ecosystem protection (e.g., for agriculture). And even when risks can be well-described, they are not necessarily met with sympathy or understanding. These factors make evaluation and management of ecological risks more complicated and time-consuming.

Some have also observed that ecological risk assessments done in isolation from the decision they are meant to inform may miss the mark if they fail to link their results to a decision, examine a question that is not relevant to the decision, or evaluate a particular (but unarticulated) risk-management option.

This document responds to a survey that asked what topics should be pursued as follow-on to the 1998 *Guidelines for Ecological Risk Assessment*. It is designed to help decisionmakers work with risk assessors, stakeholders, and other analysts to plan for ecological risk assessments that will effectively inform the decisions they need to make. It presents the three steps of Planning: Identify Decision Context, Develop Objectives, and Identify Information Needs. It also describes how planning fits into the overall risk-assessment process and provides several case examples showing how the process might be applied in EPA programs. We do not propose an Agency-wide set of objectives (although we may wish to do so after we gain experience). And although planning clearly influences risk communication and risk management, we do not address these topics here.

The guidance first discusses how to frame the decision context, and examines how to articulate the decision to be made and how to describe the fabric of public values; legal, regulatory, and institutional context; risk-management options, and the place and time in which the decision is framed. It also describes the typical players–risk managers, risk assessors, interested parties, and other analysts–and their roles, and suggests a process for reaching consensus.

Once the decision context has been examined, management goals and objectives can be developed. To accomplish this, planners explore three questions: What do we want to protect? (how to identify important resources), What do we mean by "protect?" (stating goals specifically enough to take action), and What's really important, and how do we get there? (prioritizing, and separating ends from means). Objectives should be complete, compact, controllable, measurable, and understandable.

When identifying information needs, planners are encouraged to think ahead about everything that will be needed to decide what to do about identified risks; ecological risk is part of the picture, but issues such as feasibility, practicability, cost, and acceptability also need to be factored into the decision. They should also consider who and what resources are available to perform the ecological risk assessment. The aim of this step is to narrow down which questions the risk assessment should address and identify those that will be addressed elsewhere.

Although there is no longer a distinct boundary between planning and problem formulation, the two processes must be linked to set the stage for an informative ecological risk assessment. Management objectives are by definition closely related to the assessment endpoints evaluated in ecological risk assessment, and it should be possible to characterize them using the measures described in the *Guidelines*. There are many potential applications for this guidance in EPA and other environmental-management programs. An appendix provides four examples of how the principles might be applied.

1. INTRODUCTION

Ecological risk assessment is a process that evaluates the likelihood that adverse effects may occur as a result of an ecosystem's (or a component's) exposure to a stressor. Like human-health risk assessment, its purpose is to provide information to help decide whether and what action is needed to avert or reduce risks. Ecological risk assessments, however, typically involve several challenges not at issue in human-health risk assessment. Human-health risk assessments deal with one species (humans), and there is general agreement that health is valuable and should be protected; effects such as death, cancer, deformity, and reproductive change are undesirable and should be minimized. In contrast, ecological risk assessment examines many different species and multiple levels of biological organization, from individual to population, community, and ecosystem. Not everyone values organisms or ecosystems equally, and there is no general agreement on the level of protection they should be afforded. Moreover, a stressor or ecological change may harm some species but benefit others, making it more difficult to decide whether the effects should be avoided. Ecological risk assessments may also consider species interactions, indirect effects, and the significance of non-chemical stressors.

Because of these complexities, the process for planning an ecological risk assessment and deciding on priorities for protection is particularly important. Careful consideration of what should be protected and who should be involved–before the ecological risk assessment begins–can greatly improve its usefulness. Although the laws that direct EPA's activities provide general goals, they do not specifically tell the Agency what to protect. This document is intended to aid in the planning process by bridging the gap between EPA's general statutory mandates and the specific priorities that should be established to conduct an effective ecological risk assessment.

Note that this guidance describes a process for developing robust ecological risk-management objectives; we do not propose an Agency-wide set of objectives here. However, it has been suggested that EPA develop such a set (see Section 3.3), and the Agency may wish to generate them after we gain experience and become more familiar with the development process. And although the planning process clearly influences how risk assessors convey their results to risk managers, risk communication in general, and risk management, we do not treat these topics here as they are significant enough to merit separate guidance of their own; some are also being addressed in other efforts.

1.1 HISTORY

In 1998, the United States Environmental Protection Agency (EPA) published its *Guidelines for Ecological Risk Assessment* (U.S. EPA, 1998). The *Guidelines* were developed to provide an in-depth overview of the three phases of ecological risk assessment established in the Agency's (1992) Framework for Ecological Risk Assessment: Problem Formulation, Analysis, and Risk Characterization. They also took the first steps in addressing related activities and decisions that take place outside the process of developing the ecological risk assessment, such as planning for the assessment, monitoring, and other data acquisition.

After completing the *Guidelines*, the EPA's Risk Assessment Forum distributed a survey asking respondents in the Agency's Program and Regional Offices to prioritize topics for future ecological risk assessment (ERA) guidance development. "Priorities for Protection" was ranked one of the top-priority issues. As one respondent observed, "There are no consistent agency-wide priorities [for protection].... Without them, we will move along with risk approaches that satisfy regulatory requirements that have little or no relevance to actual environmental or natural resource protection. I believe developing understanding [about what to protect] is crucial." This need, coupled with information from earlier works such as *Priorities for Ecological Protection* (U.S. EPA, 1997a) and *Managing Ecological Risks at EPA* (U.S. EPA, 1994), has inspired EPA to develop this document, *Planning for Ecological Risk Assessment: Developing Management Objectives*. A cross-program work group sponsored by EPA's Risk Assessment Forum and the Science Policy Council developed the document.

To better identify the specific areas the guidance should address, the workgroup organized three colloquia for audiences consisting of EPA (the document's primary audience), other government, and private-sector users, respectively. Participants from the EPA colloquium asked for advice such as criteria for deciding what to protect, types of ecosystems or ecological values to protect, how to define "protect," and how to engage interested parties. Colleagues in other government agencies expressed wide support for coordinating objectives and suggested that EPA review existing objectives from other agencies. Participants in the private-sector colloquium advocated that the guidance take a holistic approach, that EPA recommend proactively involving interested parties and engaging tribes, and that broad, flexible criteria be developed for selecting and prioritizing what was to be protected. The work group used this input to identify areas in which it needed additional information and subsequently commissioned six issue papers to explore specific topics. The papers address examples of decision analysis (McDaniels, 2000), interested-party involvement (Glicken, 2000), a comparison of several countries' approaches to ecological risk management (McCarty & Power, 2000), high-risk ecosystems (Noss, 2000), ecosystem services (Daily, 2000), and a private-sector approach to prioritization (Valutis & Mullin, 2000). EPA Region 5 staff also developed a seventh paper to document practices used or being developed in its offices (Mysz et al., 2000). The papers were later published as a group in a special issue of *Environmental Science and Policy* (December 2000) along with an introduction that solicited discussion (Sergeant, 2000). This work laid the foundation for developing the current document.

1.2 INTENDED USE AND AUDIENCE

Figure 1 (Figure 1-1 from the *Guidelines*; U.S. EPA, 1998) depicts the ecological risk assessment in three phases: problem formulation, analysis, and risk characterization. The *Guidelines* focus on these elements, but acknowledge that considerable planning precedes the risk assessment and that risk management follows it. This document focuses on the planning that is performed prior to risk assessment itself and how it feeds into Problem Formulation. (Note that when the *Guidelines* were written, there was more of a distinction between Planning and Problem Formulation than at present.)

Where the audience for the *Guidelines* was Agency risk assessors who primarily focus on science issues, the audience for this document is Agency risk managers or decisionmakers, who, regardless of discipline, must make decisions in light of science and policy issues, legal requirements, potential economic impacts, public scrutiny, and resource and other constraints. Risk assessment alone cannot address these issues. The assessor and manager collaborate (and in many cases solicit input from interested parties) to ensure that the assessment addresses the manager's needs and makes the most of available information. This approach should provide useful information for developing strong, defensible decisions about the future of a site, action, event, or proposal.

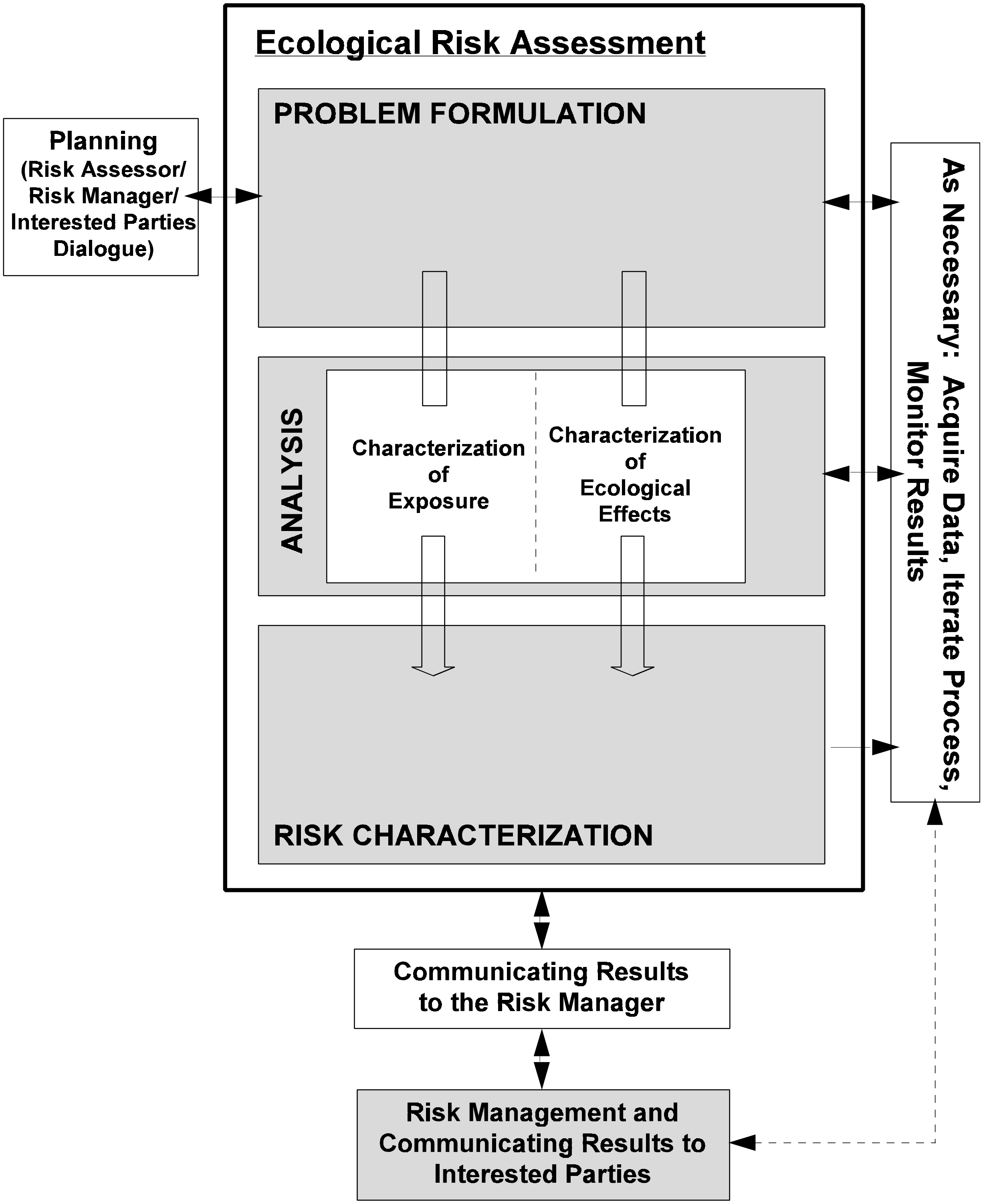


Figure 1. The framework for ecological risk assessment (U.S. EPA, 1998).

This document focuses on how to incorporate risk managers' concerns in two key elements of the planning process: how to decide what to protect; and how to translate these priorities into management goals and objectives that will serve as a basis for the risk assessment. Robust goals and objectives can:

- Ensure that risk assessments provide information relevant to the risk manager's decisions;
- Help decision makers set specific, measurable objectives that can be used to track progress and document success;
- Provide an opportunity to incorporate public values into decisionmaking;
- Focus risk efforts (planning, communication, management) on resources that are truly valued;
- Provide transparency to both ecological risk assessment and the decisions it informs;
- Identify knowledge gaps and future areas for research; and
- Promote consistency within the Agency and inform others about our methods

This guidance examines risk-management strategies, describes the questions to be answered in developing ecological risk-management decisions, explores how to develop risk-management options, and shows how the results of planning are used in problem formulation. While it was written for risk managers, we hope it will also prove useful to risk assessors and interested parties who help plan ecological risk assessments. All three groups can contribute to the development of risk-management goals and objectives that address a variety of concerns.

1.3 OVERVIEW AND DOCUMENT STRUCTURE

Planning for ecological risk assessment includes three primary steps: [1] defining the risk-management decision to be made, the context in which it will be made, and its purpose; [2] developing objectives, and [3] identifying what information is needed to inform the decision (see Figure 2). Discussions and chapters are arranged so users can go directly to specific sections that correspond to the topics to be addressed. This is an important feature because planning an ecological risk assessment may not require every step described here. Similarly, planning is not necessarily a linear process and may follow a different order than that presented, or may need to be repeated as the process develops.

1.4 KEY CONCEPTS

The terminology we use here builds upon and refines concepts set forth in the *Guidelines*. Note that we distinguish the terms "management goal" and "management objective." For the purpose of this document, management goals are defined as "general statements about the desired condition of ecological values of concern." Management objectives, while similar to management goals, differ in that they should be specific enough to use when developing assessment endpoints and measures. Chapter 3 provides more detailed information and examples of moving from a goal to an objective. Table 1-1 provides a summary of definitions and short examples for easy reference.

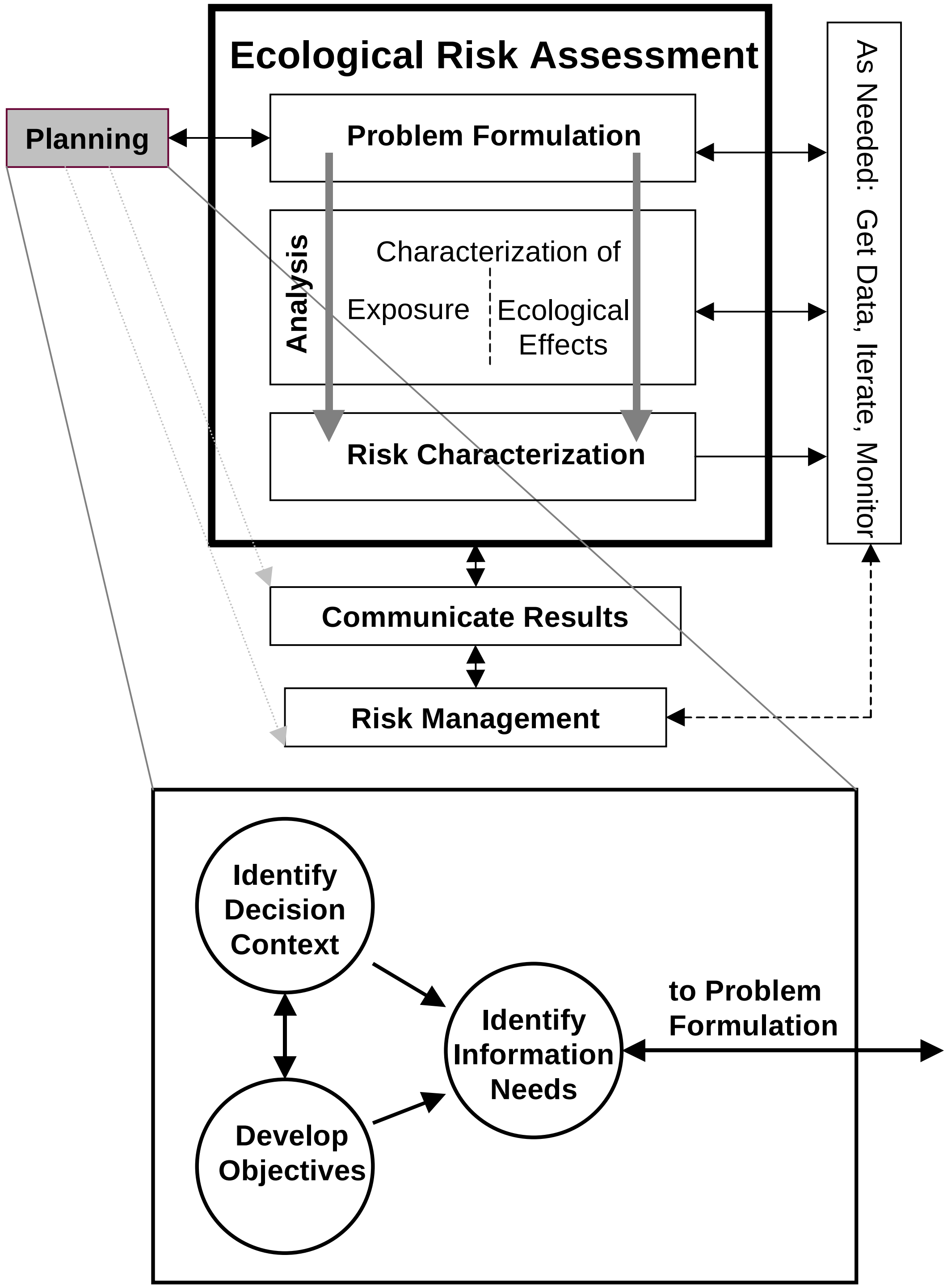


Figure 2. Planning for ecological risk assessment.

Table 1-1. Definitions.

Concept	Definition	When and how developed	Examples
Management Goal	*General* statement about the desired condition (or direction of preference) of ecological values of concern	1) Usually in legislation or regulation	Protect and restore the chemical, physical, and biological integrity of the nation's waters (from the Clean Water Act)
		2) Sometimes by risk managers and others on an assessment-specific basis when planning an ERA	Reestablish and maintain water quality and habitat condition for a particular water body
Management Objective	*Specific* statement about the desired condition (or direction of preference) of ecological values of concern	By risk managers, with participation by risk assessors and others, when planning an ERA	Restore and maintain self-sustaining native fish populations and their habitat
Assessment Endpoint	An explicit expression of what is to be protected, defined by an ecological entity and its attributes	By risk assessors, with input from the planning process, during ERA problem formulation	Salmon reproduction and age class structure

2. IDENTIFY DECISION CONTEXT

A useful way to develop management objectives and plan the subsequent risk assessment is to begin by identifying and documenting the decisions to be made and the context in which they will be made (NRC, 1996; Presidential/Congressional Risk Commission, 1997). This includes articulating the decision or problem that the risk manager faces, understanding the social and legal context for the decision, placing preliminary boundaries on the scope of the risk assessment, and identifying who needs to be involved (Figure 3). Appropriately framing the context will help ensure that management objectives are relevant to the risk manager's decision and increase the likelihood that the information generated by the risk assessment will be useful.

The decision-context questions presented in this chapter need not be addressed in any particular order and may involve several iterations. Their answers will be useful in developing management objectives (Chapter 3) and completing the risk-assessment planning process (Chapter 4), and they may be evaluated as objectives are developed. Risk managers may work with risk assessors, interested parties, and other analysts to identify the decision context; we refer here to these groups collectively as "risk-assessment planners" or "planners."

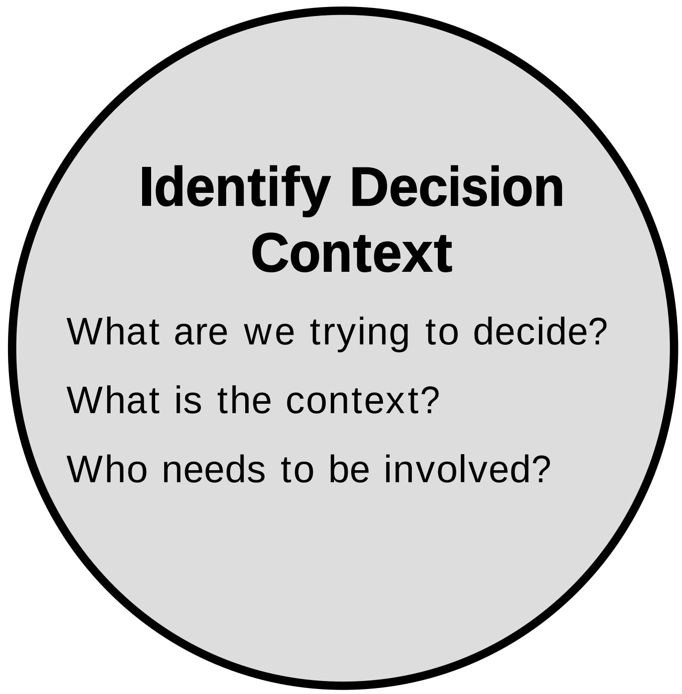


Figure 3. Identify Decision Context

2.1. WHAT ARE WE TRYING TO DECIDE?

The National Research Council (NRC, 1996) stated that the process for analyzing and characterizing risks "should be a decision-driven activity, directed toward informing choices and solving problems." To be successful, a risk assessment must answer questions that help risk managers decide what to do about a problem. Thus, the risk-management decision context may be defined by questions such as What is the decision to be made?, Why is it being made?, Who has authority to make it?, and Who will be affected? The nature of the decision influences the risk assessment's scope and who needs to be involved: Unique and wide-impact decisions consider risk on a large social and geographic scale and may affect many people and ecological entities. They are likely to involve substantial time and effort in planning, setting management objectives, and engaging the public. At the other end of the spectrum, routine and narrow-impact decisions are more amenable to standardization. Between these lie repeated, wide-impact decisions, which may also be subject to wide attention but that can be evaluated using somewhat standardized routines (NRC, 1996).

In many cases, the risk-management decision to be made can be clearly and simply described (although not necessarily easily made). EPA has well-defined authority and precedent for decisions such as:

- Superfund site cleanup.
- Pesticide or new-chemical approval or registration
- Allowable air-pollutant emission levels.
- Water-pollutant discharge limits for industrial facilities.

In other cases an ecological risk assessment is conducted to identify what caused an observed problem. The risk assessment might then be designed as a community-based effort with EPA assistance rather than directed by the Agency for traditional regulatory purposes. Examples of these situations include:

- Pollution is suspected of reducing wildlife populations.
- A community wishes to prioritize and address environmental threats in its vicinity.
- Review of an industry's overall or cumulative environmental impacts.

In these cases, it may not be possible to define the risk-management decision to be made until the situation is better understood. Moreover, the risk-management approach may not rest with a single agency, but could involve decisions and voluntary actions by governmental and private organizations, businesses, and individuals. In such cases, it is useful to begin by summarizing the problem. Questions to consider include: What is the problem?, Why is it a problem?, How was it first recognized?, What adverse impacts might occur, or how imminent might any impacts be?, Are they reversible?, How urgent is the need for action?, and What might have caused the problem? (Presidential/Congressional Commission, 1997). Once the problem has been described, the risk manager can lay out the possible decisions to be made and the reasons for making them; remember that both are likely to be refined as planning and analysis proceed.

There are many ways to organize decisions. Some decisionmakers may wish to frame and structure the decision using a formal decisionmaking process such as that described in Keeney (1992). Hammond et al. (1999) provide a simplified approach to structured decisionmaking. Finally, Schwartz (1996) describes techniques for long-term or "futures" planning.

Example Box 1. Waquoit Bay: What Are We Trying to Decide?

The Waquoit Bay Ecological Risk Assessment was one of five case studies sponsored by EPA to determine whether ecological risk assessment would work on a watershed scale. It provides an example of planning and setting management objectives. It will be used throughout the document to illustrate steps in planning; the case is also summarized in Appendix A, Case Examples.

Waquoit Bay is a small estuary on Cape Cod, Massachusetts that is showing signs of degradation, including loss of eelgrass, fish, and shellfish and increased algal mats and fish kills. The case study was initiated to better understand these problems. No specific pending decision such as a regulatory action by EPA or other organizations was driving the risk assessment. The study was designed to help the community identify and evaluate risk-management decisions to solve these problems rather than assessing the causes of the problems. It confirmed that nutrients (i.e., nitrogen) were important stressors on the estuary and identified restoration measures that could reduce nitrogen inputs, such as improving sewage treatment and reducing fertilizer use. Community- or watershed-based risk assessments like this one often begin with a problem to be assessed rather than a decision to be made. Program-specific risk assessments are usually oriented toward a specific regulatory decision, such as how a Superfund site should be cleaned up.

2.2 WHAT IS THE CONTEXT?

Once the risk-management decision has been defined, the scope of the risk assessment to inform that decision can be refined by considering the context in which the decision will be made and the risk assessment will be conducted. The context includes the values held by those affected by the decision; established laws, regulations, and institutions; and the suite of risk-management options available. It also includes the geographic and temporal context, or the space and time in which the decision may be made, and aspects of the natural environment and society that may be affected by the decision. Context also helps identify critical assumptions about the problem and alternate risk reduction strategies.

In addition to the areas of context discussed below, it may be helpful to consider the decision or problem of concern within the broader risk context. This could include the multisource context (other sources or stressors to which ecosystems are exposed), the multimedia context (exposure via other media such as water, air, and soil), and the multirisk context (other risks that ecosystems may face) (Presidential/Congressional Commission, 1997).

2.2.1. Public values

To be effective, a risk-management decision should protect or restore those aspects of the environment that people value. Risk-assessment planners should consider these values before a risk assessment begins to ensure that the assessment provides information relevant to public concerns. Understanding public values is likely to involve interaction with interested parties, a topic discussed in more detail in Section 2.3. Values are then incorporated into management objectives, as discussed in Chapter 3. People value the environment and its attributes for many reasons, ranging from immediate commercial benefits to preserving options for future generations. Table 2-1 describes some common values that people attribute to ecosystems.

Table 2-1. Values that people attribute to ecosystems and their components. Adapted in part from Daily, 2000.

Type of Value	Explanation	Examples
Consumptive	Ecosystems produce water, food, durable materials, energy, medicinal sources, and other consumable products.	Products: drinking water, fish, game, forage, timber products, pharmaceutical products or precursors, industrial products
Functional	Ecosystems perform valued functions or services.	Functions: air and water purification, moderation of weather and climate extremes, waste detoxification, soil regeneration, pollen and seed dispersal, pest control.
Recreational	Ecosystems provide valued opportunities for recreation and enjoyment.	Recreation: hiking, boating, birding, hunting, fishing, photography, viewing scenery, biking.
Educational	Ecosystems are valuable as a teaching tool and source of knowledge.	Education: nature and scientific study, research projects, field trips, and outdoor classrooms.
Ethical, Aesthetic, Religious, and Spiritual	Ecosystem or their components have intrinsic value beyond direct, immediate human economic benefit.	Inherent values: non-human living creatures' existence rights; source of spiritual fulfillment, moral lessons, and beauty; source of undiscovered future value.

These categories are not mutually exclusive: For example, salmon are valued both as sport fish and as food. Native Americans and others value them for their cultural significance. As is the case for salmon, these values often converge in special places or species that are widely recognized as being important for both economic and cultural reasons. Planners should identify such places and species within the area that may be affected by the decision.

On the other hand, these values sometimes contradict each other or values not directly related to the environment. The environment or its components may be perceived as interfering with food and fiber production, as a source of disease and harmful pests; causing natural disasters such as flooding; or interfering with transportation and property use. This can lead to ambivalent or divided attitudes toward particular places, habitats, or species. For example, the predator admired by some for its beauty, power, and role in the ecosystem may be despised by others for its attacks on domestic animals. Although they may complicate efforts to reach consensus, these views also should be recognized and understood.

Values may differ among different people and geographic areas and can change over time. Planners should focus on understanding the values held by those affected by the risk-management decision. The interested or affected group may be only a few people (e.g., a specific Superfund site) or the entire nation (e.g., a household pesticide). However, planners should keep in mind that, to the extent that a decision sets a precedent for other decisions, it should reflect either values beyond individuals in the immediately affected area or the set of chosen values and its implications should be discussed.

Economists, psychologists, anthropologists, and others have developed methods for understanding values and social preferences. Some have developed tools for measuring or estimating the economic value or ranking societal preferences for the attributes described in Table 2-1 (see also U.S. EPA, 2000a) that may be useful when prioritizing management objectives. However, quantification methods are limited by factors such as the difficulty of assigning monetary value to ecological services that do not enter into markets and of eliciting values on benefits that are not as obvious as more typical goods and services (U.S. EPA, 2000b).

Finally, while understanding public values is important, this information is considered in light of scientific, legal, and other factors. For one, public perceptions may diverge from established scientific thinking. Some individuals may not realize the wetlands' capacity to purify water supplies, for example, and thus may place less value on their importance than if they were more fully informed. EPA decisions should also conform to federal laws and regulations (see next section), whether or not such rules precisely correspond to local values. As a result, management objectives for risk assessment should reflect current public preferences but cannot be dictated solely by them.

2.2.2. Legal, Regulatory, and Institutional Context

Federal, state, tribal, and local requirements comprise another major contextual component, and define both opportunities and constraints concerning decision authority. They can also be considered an expression of public values in a democratic society. Federal laws provide EPA with the overall framework of environmental attributes that should be protected. However, they rarely provide direction on how to establish management objectives for a given risk assessment. But because they form the basis for more detailed EPA regulations, guidance, and policies and because their interpretation in a court of law becomes the ultimate arbiter of Agency decisions, risk-assessment planners need to understand how these statutes can inform the management decision and management objectives.

Laws governing EPA vary widely in specificity. At a general level, most of these laws mandate that EPA "protect the environment," with "environment" often defined very broadly. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and Toxic Substances Control Act (TSCA), for example, define the environment simply as water, air, land, living things, and their interrelationships. These laws provide little guidance on what should be targeted for protection or how much it should be protected. Other laws direct EPA to more specific ecological concerns. The Clean Water Act repeatedly mentions fish, shellfish, and wildlife; it also refers to specific types of aquatic ecosystems, including rivers, lakes, and estuaries. The Clean Air Act mentions "regionally representative" and "critical" ecosystems, refers to wildlife protection, and (like the Clean Water Act) refers to specific places such as Chesapeake Bay and the Great Lakes. And although EPA does not promulgate it directly, the Endangered Species Act contains detailed protection provisions for designated species.

Although individual laws generally do not provide specific, quantifiable ecological objectives, taken as a whole they provide EPA and other agencies with a broad environmental-protection mandate; they also deem a number of environmental entities as being worthy of protection. Table 2 presents some aspects of the environment that merit protection under Federal laws. This may provide a useful context for planners in identifying what should be protected, as discussed further in Section 3.2.

EPA regulations established to carry out these laws, as well as policies, guidance, and precedents, provide a more detailed context and should be examined during this step. Some programs have in fact considered risk-management issues and developed policies: Superfund, for example, specifies nine criteria for remedy selection (see Text Box 2-1), and RCRA has similar requirements (Text Box 2-2). And the Office of Radiation and Indoor Air incorporated the philosophy that if we protect humans from the harmful effects of ionizing radiation, we also protect the environment (Text Box 2-3) in its policies. *Managing Ecological Risks at EPA: Issues and Recommendations for Progress* (U.S. EPA, 1994) is also a valuable source of information about EPA authorities and precedents for risk-management decisions. State, tribal, and local requirements may also be important factors.

Tribal requirements may comprise a mixture of legal, cultural, and institutional concerns. They are based in the larger, more complicated context of inter-governmental and cross-cultural relationships that exist between tribes, the federal government, and the states, and they may be influenced by long-standing (but not necessarily fully realized) commitments. In addition, tribal values integrate aspects of the environment with human health and other cultural concerns distinctive to their societies.

The institutions involved in the risk-management decision are an important part of the context for developing risk-management objectives. The government agencies involved in or affected by the decision, their mechanisms for taking action, their policies and positions, and their jurisdictions all may affect the development and implementation of risk-management objectives. One way to learn about state, tribal, and local requirements and decisionmaking is to seek out interested parties (also known as stakeholders) as described in Section 2.3.3.

Table 2-2. Ecological Entities Targeted for Protection by Law.

Ecological Entities / Federal Laws	Clean Air Act	Clean Water Act	Coastal Zone Management Act	Comprehensive Envir. Response, Compensation, & Liability Act (Superfund)	Endangered Species Act	Fed. Insecticide, Fungicide, & Rodenticide Act	Marine Mammal Protection Act	Marine Protection, Research, & Sanctuaries Act	Migratory Bird Treaty Act	National Environmental Policy Act	Resources Conservation & Recovery Act	Toxic Substances Control Act
Environment												
Natural resources												
Ecosystems												
Marine ecosystems												
Biota/living things												
Aquatic or marine life												
Endangered species												
Wildlife/animals												
Fish												
Birds												
Marine mammals												
Shellfish												
Plankton												
Plants												
Land												
Soil												
Water												
Coastal waters												
Wetlands												
Shorelines, beaches												
Estuaries, flood plains, dunes, barrier islands, coral reefs												
National parks, wilderness areas, and other special areas												
Great Lakes, Chesapeake Bay, Lake Champlain												

Text Box 2-1. Ecological Risk Management in Superfund

Superfund decisionmakers must consider several criteria when developing their risk-management decisions. Threshold criteria (obligatory requirements) are:

1. Overall protection of the environment
2. Compliance with applicable or relevant and appropriate requirements (ARARs)

Balancing criteria (technological and institutional considerations) include:

3. Long-term effectiveness and permanence
4. Reduction in the toxicity, mobility, or volume through treatment
5. Short-term effectiveness
6. Implementability
7. Cost

Modifying criteria (political and public considerations) are:

8. State and/or support agency acceptance
9. Community acceptance

In addition, OSWER Directive 9285.7-28P, *Ecological Risk Assessment and Risk Management Principles for Superfund Sites* (U.S. EPA,1999) presents six principles for managing ecological risks:

1. "Superfund's goal is to reduce ecological risks to levels that will result in the recovery and maintenance of healthy local populations and communities of biota."
2. Coordinate with federal, tribal, and state Natural Resource Trustees
3. Use site-specific ecological risk data to support cleanup decisions
4. Characterize site risks
5. Communicate risks to the public
6. Remediate unacceptable ecological risks

2.2.3. Risk-Management Options

Depending on the program, risk managers may have a variety of options for preventing, controlling, or remediating ecological risks. The choices may include engineering controls, regulatory approaches, communication and education, or market-based incentives, and choices are often limited by the program's enabling legislation. Risk-management options and management objectives are interconnected, and setting management objectives without understanding if or how they can be achieved may result in unrealistic objectives. For example, if a risk manager in the Office of Pesticides Programs (OPP) chooses the management objective "minimize harm to bird populations," risk-management options might include such strategies as using less toxic formulations and reducing exposure. They would not include actions such as reducing lead shot use by hunters or limiting development near wetlands (even if these activities have greater effects than do pesticides), not because these activities don't affect bird populations, but because FIFRA (OPP's enabling legislation) does not regulate them. At the same time, defining risk-management options before ecological goals have even been established may lead one to overlook potentially useful approaches. In the extreme, it could lead to remedies that cause more ecological damage than the original stressor of concern.

Text Box 2-2. Ecological Risk Management in RCRA

RCRA decisionmakers must consider several criteria when evaluating final corrective measure alternatives and in making their risk-management decision. The remedy must comply with the following four specific standards:

1. Protect [human health] and the environment
2. Attain media cleanup standards set by the implementing agency
3. Control the source of releases so as to reduce or eliminate, to the extent practicable, further releases that may pose a threat to [human health] and the environment
4. Comply with any applicable standards for management of wastes

In addition, the implementing agency must consider, as appropriate, the following five other factors when selecting a remedy:

5. Long-term reliability and effectiveness
6. Reduction in the toxicity, mobility, or volume of wastes
7. Short-term effectiveness
8. Implementability
9. Cost

Following selection of a preferred alternative for proposal in the Statement of Basis, the implementing agency must request public comment on the administrative record and the proposed corrective measure(s). A public meeting or other public-involvement activities may be necessary, based on facility-specific circumstances. (Source: RCRA Corrective Action Plan, Final, OSWER Directive No. 9902.3-2A, May 1994.)

Text Box 2-3. Ecological Risk Management for Radiation Exposures in the Environment

EPA's Office of Radiation and Indoor Air (ORIA), part of the Office of Air and Radiation, is responsible for developing generally applicable standards for releases of radioactivity to the environment. The prevailing philosophy in radiation protection has been that if we protect humans from the harmful effects of ionizing radiation, we have also sufficiently protected the environment. For releases to air, which are controlled under the Clean Air Act's National Emissions Standards for Hazardous Air Pollutants (NESHAPS), this dictum likely holds true. Ecological harm is typically measured by such indices as species survivability, ecosystem diversity, and other macro-level indicators. Since exposures high enough to affect these indices would be orders of magnitude larger than those allowed under NESHAPS, ecological risk is not considered important for permitting routine releases of radioactivity to air.

It follows from the preceding argument that the ecological risks of concern will be those where biota, but not humans, are exposed to a radioactive source (such as in aquatic environments or unpopulated areas). Generally, Safe Drinking Water Act Maximum Contaminant Levels (MCLs) for radionuclides in water ensure that contaminated ground water and surface water are cleaned up to levels where ecological effects would be unlikely to be observable (i.e., concentrations that are a fraction of the natural background levels of radioactivity). For contaminated soil, ORIA typically uses the CERCLA process to determine cleanup levels. Thus for ecological risk assessment, ORIA's recommended approach would be identical to that described for the Superfund Program (Text Box 2-1). ORIA's standard for uranium mill-tailings cleanup does not specify an ecological risk assessment, but requires cleanup to levels near those found in nature.

When soil cleanup is performed under the authority of the Atomic Energy Act (AEA), the philosophy of ALARA is typically employed (As Low As Reasonably Achievable). Although protecting human health is the benchmark for radiation protection under the AEA, ALARA usually results in cleanup levels well below regulatory limits and thought to be protective of the environment. Although this approach is different from Superfund's, where threshold and balancing criteria are used to modify cleanup objectives, both approaches are intended to optimize cleanup results. National and international advisory bodies are now examining whether ALARA-based cleanups sufficiently protect the environment, or whether ecological risk should be considered separately.

Planners may wish to begin by laying out the preliminary suite of management options for the decision to be made or problem to be addressed. The options can help make the risk assessment more manageable by limiting the range of conditions it considers, and by setting practical boundaries on the time and resources that will be required. This will help ensure that the management objectives are "controllable," or able to be influenced by feasible risk-management options, as described in Chapter 3. If a management objective cannot plausibly be accomplished, then a risk assessment based on that objective is unlikely to help the risk manager make an effective risk-management decision. For example, a management objective that can only be achieved by controlling agricultural runoff will not be helpful to a risk manager whose authority is restricted to controlling industrial discharges.

There is no need to evaluate or select risk-management options at this time, because their eventual selection will be informed by the risk assessment and other factors. Options may go beyond those directly available to the EPA risk manager (such as placing conditions on a permit or regulating a chemical's use) and include those available to others (such as authorities of state agencies or voluntary actions by businesses or citizens). The risk manager should examine the options used in similar risk-management decisions that were successfully implemented, as well as setting forth innovative options for managing risks. The risk manager will probably want to revisit management options after interested-party deliberations (if these take place), after management objectives have been established, and after a risk assessment has been conducted to see if other approaches for controlling risks may be useful. Management options may be analyzed separately from the risk assessment in some EPA programs (e.g., Feasibility Studies conducted under Superfund). Issues that can be considered when evaluating management options include effectiveness, feasibility, costs, benefits, unintended effects, and social impacts (Presidential/Congressional Commission, 1997).

2.2.4. Geographic and Temporal Context

The more clearly risk-assessment planners can define a decision's geographic and temporal dimensions, the easier the risk assessor's task will be. This context can also be valuable in identifying which interested parties should be involved and what state and local requirements apply. Defining the scope is likely to be an iterative process: It begins when the decision context is identified, and may be further refined when setting management objectives (Chapter 3) and during the actual risk assessment. Clearly, EPA management decisions vary greatly in scope: Some affect a single facility, Superfund site, or chemical with limited uses. Others are much broader, such as those involving widely used pesticides, industrial chemicals, or consumer products. Generally, the broader the scope, the more complex and uncertain the resulting risk assessment.

As a preliminary step, planners tentatively identify the general geographic area likely to be affected by the risk-management decision or environmental problem. They should consider broad questions such as What spatial boundaries seem most relevant for the decision and the risk assessment? Do natural boundaries (e.g., a watershed, airshed, or ecological region) or political boundaries (e.g., city, county, state, nation) exist that best frame the issue? For example, a project defined by a specific watershed (like Waquoit Bay in Appendix A.3) has its boundary defined at the outset. In other projects, the boundary may initially be defined more generally (like the Salton Sea area in Appendix A.1) until later in the planning and assessment process. The boundary for a decision based on a widely dispersed stressor like a pesticide or effluent might be first defined as the area in which it will occur at significant levels, in which case no specific geographical boundaries need be defined at this time. In addition to spatial issues, planners should also consider the temporal aspect: How far into the future is the risk-management decision likely to have ramifications?

The preliminary scope will be refined as the risk manager focuses on what to protect (Chapter 3) in setting management objectives. For example, the risk manager's initial decision-context definition may be a specific Superfund site and the area that a site-cleanup decision will affect. As management objectives are defined, a stream that runs through the area and other nearby special natural areas may be defined as high priorities for protection. The subsequent risk

Example Box 2. Waquoit Bay: What is the Context?

The Waquoit Bay analysis showed that the context of a watershed-based risk assessment is likely to involve many values, involved organizations, and potential risk management options. It can be a major challenge to set priorities and agree on roles. But such assessments benefit from having a clear geographical scope. The legal/institutional context and the risk-management options may be easier to identify for national-level risk assessments designed around EPA regulatory decisions, but defining their geographical scope may be difficult. The context for Waquoit Bay includes:

- **Public values:** The estuary is habitat for several recreationally or commercially important fish and shellfish. Residents and tourists value it for its scenic beauty and recreational opportunities; they also appreciate the estuary and its associated watershed for their wildlife.
- **Legal, regulatory, and institutional context:** At least 14 local, regional, and national resource-management agencies share jurisdiction over the Bay. Other considerations include local zoning and land-use restrictions, regional planning, state regulations, and other federal activities (such as a nearby military reservation).
- **Risk-management options:** Options included upgrading septic systems or community sewage treatment plants, reducing fertilizer inputs, modifying land development, increasing vegetated buffers, and controlling boating.
- **Geographic and temporal scope:** The geographic scope was initially defined as the Waquoit Bay watershed, and was subsequently refined by the risk-assessment team. Stressors included land development that could have impacts for many years, so the temporal scope extended into the foreseeable future.

assessment may further refine the scope by clarifying how far contaminants are transported and how long they will persist.

2.3. WHO NEEDS TO BE INVOLVED?

At a minimum, both risk managers and risk assessors should be involved in developing management objectives and planning the risk assessment. Often, it will be helpful to obtain input or participation from other interested or affected parties, and in some EPA office policies require this. This section describes potential participants and their likely roles.

The extent and nature of public involvement, and the disciplines and groups that are represented, will vary depending on the risk assessment. Risk assessments supporting unique, wide-impact decisions may require extensive public involvement (NRC, 1996) and it may be advisable to develop a detailed strategy for engaging the public. Routine assessments may not need as much involvement, but the planners should still consider who needs to be involved and how they will participate early in the process.

2.3.1 Risk Managers

Risk managers determine how a potential risk will be controlled, mitigated, or avoided. (The term “risk manager” as applied to EPA refers not only to executives at the highest levels of the Agency with final authority for making risk-management decisions, but also the broad range of staff with day-to-day influence on these decisions.) They rely on information from science, technology (or risk-management options), law, political representatives, social values, economics, public opinion, and interested parties. Within EPA, risk managers rely on analyses by risk assessors, economists, engineers, and other experts. Risk managers are typically responsible for determining the goals for public participation in risk assessments. As described in section 2.3.3, in some cases interested parties may also function as risk managers.

2.3.2 Risk Assessors

Risk assessors are usually scientists with training in toxicology, statistics, environmental chemistry, and other disciplines. They determine how the risk assessment will be conducted, collect and qualify data, estimate and describe risks, and characterize the strengths, assumptions and uncertainties of the risk assessment for the risk manager and interested parties. They may also collaborate, for example, with economists on benefits assessments and with engineers on risk-management options. Their input may also shape data collection and analysis for the risk assessment.

2.3.3 Interested Parties

Interested parties (also known as “stakeholders”) may include other government agencies, private industry, environmental groups, landowners, and others concerned about an environmental issue or who wish to influence risk-management decisions. In some cases they also may be risk managers because the choices they make will affect ecological risks, especially in the case of community-based assessments. There are many published definitions, but EPA’s Draft Policy on Public Involvement (U.S. EPA, 2000c) defines stakeholders as “individuals and organizations who have a strong interest in the Agency's work and policies,” and adds “Stakeholders also may interact with EPA on behalf of another person or group that seeks to influence the Agency's future direction. Some stakeholders are, or believe they are, affected parties, that is, individuals or groups who will be impacted by EPA policies or decisions.”

EPA is committed to full and meaningful public involvement in Agency activities (U.S. EPA, 2000c), with “the public” defined broadly to include the general U.S. population and representatives of any public or private organization. Recent reviews (NRC, 1996; Presidential/Congressional Commission, 1997 [cite 2001 SAB report if completed] - U.S. EPA, 2001a) have also called for early and substantial involvement of interested parties during the risk management-risk assessment process. Interested-party participation helps ensure that the risk assessment targets aspects of the environment that those affected by the decision care about. In addition to providing technical data, interested parties can clarify those aspects of the environment that are most valued and other concerns that may compete with ecological considerations. Participation can also foster EPA’s trustworthiness and credibility, and reduce the overall time and expense in decisionmaking (U.S. EPA 2000c; NRC, 1996; Presidential/Congressional Commission, 1997 [U.S. EPA, 2001a?]).

Interested parties should be engaged as early as possible and their involvement tailored to the specific ecological risk assessment and any program-specific requirements that may apply. Six basic steps for involving interested parties are described in EPA's Draft Public Involvement Policy (U.S. EPA, 2000c):

1. Identify the interested and affected public.
2. Provide information and outreach to the public.
3. Conduct public consultation and participation activities.
4. Assimilate information and provide feedback.
5. Plan and budget for public participation.
6. Consider providing assistance to the public.

The contextual information described earlier in this chapter can help identify interested parties. An effort should be made to include people who may be affected by the risk-management decision; anyone who may have helpful information and expertise; or those who have been involved or expressed interest in similar decisions before (Presidential/ Congressional Commission, 1997). Clearly, interested-party participation should be planned in advance. If interested parties will evaluate a decision which has already been made, the process and expectations are very different than for a joint decision-making process. Both cases are legitimate opportunities for involvement, but the approaches and kinds of participants will likely be very different. Other considerations are presented in Text Box 2-4.

Involving the public is an integral part of defining the decision context. Just as examining the decision context is helpful for identifying interested parties, these parties can also provide part of the context. Risk managers, risk assessors, and interested parties can all bring useful information about the decision, the scope of the risk assessment, and potential management options and help refine the decision context.

However, such involvement is not always helpful or appropriate: Interested parties may not have the time or resources to contribute meaningfully to planning discussions (and the Agency may not be able to supply them). The Science Advisory Board has recommended that EPA develop guidance on how to use stakeholder processes appropriately ([U.S. EPA, 2001?]).

Text Box 2-4. Involving Interested Parties.

The National Research Council (NRC, 1996) states: "getting the right (i.e., broad enough) participation" and "getting the participation right" (a satisfactory process for deliberation) are both crucial in risk assessment. Glicken (2000) also states that an appropriate and effective inclusion process will require planners to consider several points:

1. Is it clear why interested parties are being asked for their input?
2. Are all the appropriate parties identified and included?
3. Are the right information-elicitation tools being used?
4. Are the tools rigorously applied?
5. Are the resultant data analyzed using appropriate techniques?
6. Is the entire process (including its methodology) documented?

2.3.4. Other Analysts

A risk assessment cannot provide all the information that goes into a risk-management decision. Other evaluations such as human-health risk assessments, economic analyses, engineering or feasibility studies, and legal analyses may also be needed to inform the decision (see Figure 4). It may necessary to include specialists from these areas in the planning process. The benefits of including or at least making an effort to coordinate with other analysts include saving time and money on data collection and increasing the probability that each evaluation informs its respective part of one coherent decision.

2.3.5. Reaching Consensus

Consensus–the situation where all participants feel that they have been heard and can live with the agreement reached–can be hard to reach in a group comprised of people from different areas of expertise, personal interests, motivations, and social groups. Facilitated **dialogue** is an excellent way to reach consensus on goals. This process is specialized, but briefly, its attributes are (1) equality and the absence of coercive influences (everyone has an equal standing and feels free to speak), (2) listening with empathy (everyone is heard and taken seriously), (3) bringing assumptions into the open (people explore and explain what's behind their positions) (see, for example, Yankelovich 1999 and Martin 1999). Goals developed by consensus are usually general, so the planning group should be prepared to spend some time making them specific and measurable enough to use in the ERA.

2.3.6 Application to Risk-Communication and Outreach Efforts

The issues discussed when framing the question will naturally reflect risk managers,' interested parties,' and other analysts' concerns about the potential problem and decision to be made. A summary of these issues can serve as a useful outline for describing risk-assessment results to decisionmakers. It can also be woven into the process described in Text Box 2-4 and used as a starting point for more general risk-communication and outreach activities and help document the stakeholder-involvement process. And the technical questions and data needs expressed by other analysts can guide later, tailored summaries of results for use in their investigations.

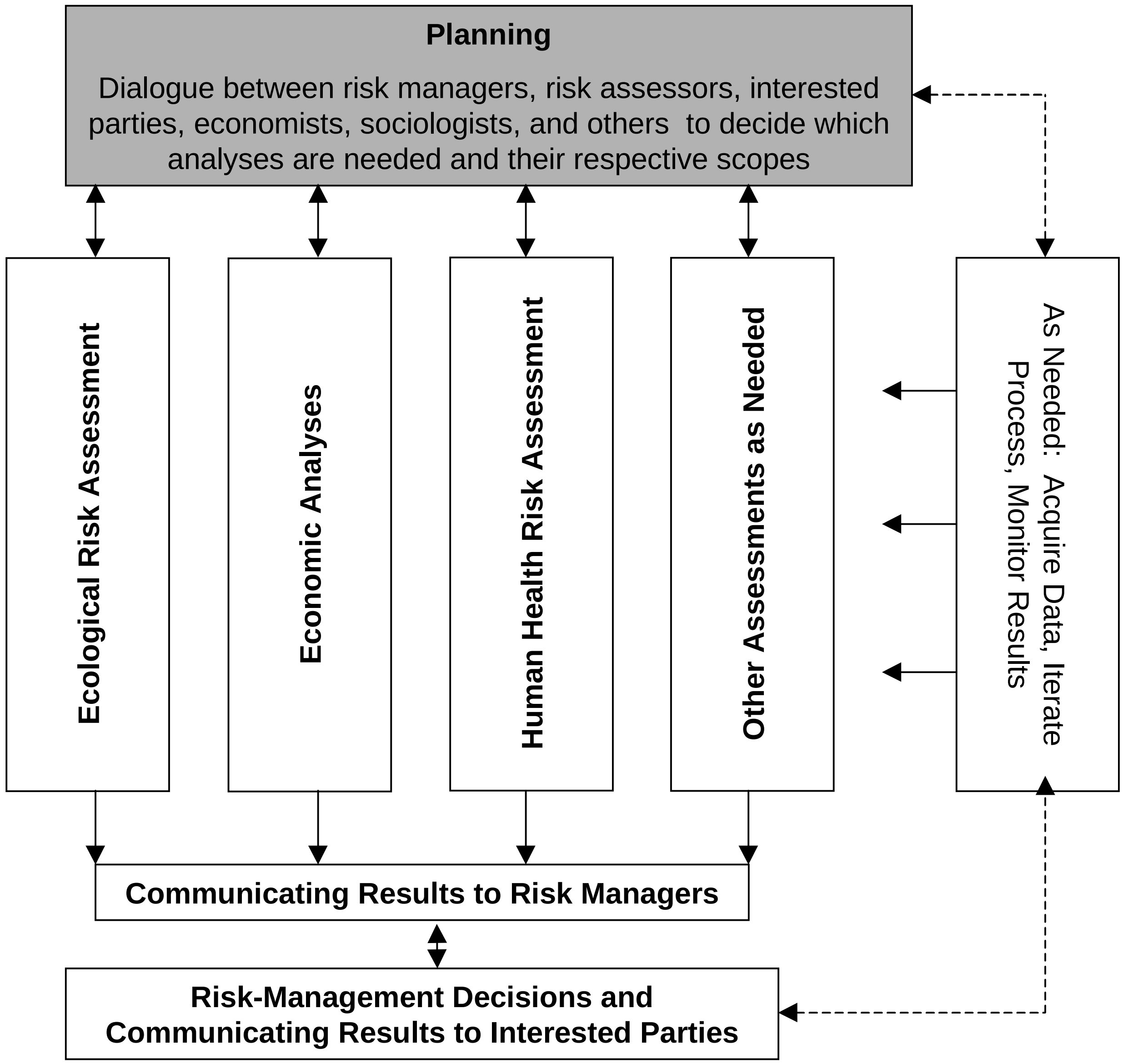


Figure 4. Environmental Decisionmaking Process (adapted from U.S. EPA, 2001b).

Example Box 3. Waquoit Bay: Who Needs to be Involved?

The Waquoit Bay risk-assessment team included representatives from EPA, the Waquoit Bay National Estuarine Research Reserve, and the National Marine Fisheries Service. At the beginning of the case study, the team held a public forum to learn what was valued about the Bay and identify interested parties. About 50 different organizations were identified, ranging from local property associations, environmental groups, and towns to universities and state and federal agencies; many of these also contributed to the risk assessment, and some had the authority to do something about stressors and were therefore risk managers. The breadth of interest in Waquoit Bay is typical of watershed- or community-based ecological risk assessments, and an active search for participants and contributors can improve an assessment's quality and usefulness.

2.4. SUMMARY OF DECISION, CONTEXT AND PURPOSE

Planning for risk assessment should conclude with a summary to document the results (see Section 4.4). Important aspects of the decision context described in this chapter can be captured in such a summary that includes:

- The decision to be made or problem at hand
- Values held by the people affected by the decision
- Relevant laws and other policy considerations
- Possible risk-management options that will be evaluated
- The general geographic and temporal scope of the issue or problem
- Who needs to be involved and how they will be engaged

Now that the context for the decision or problem has been explored, the risk manager is well-prepared to develop the management objectives for the risk assessment, as described in the next chapter.

3. DEVELOP OBJECTIVES

Chapter 2 dealt with the context for the risk-management decision and its associated risk assessment. This chapter describes the process and some concepts for developing objectives within that context.

McDaniels (2000) describes the importance of articulating ecological objectives:

> "Objectives define what matters, or what people care about, in any decision context. Achieving objectives (either getting more of what is desired or avoiding what is not) is the chief motivation for making any decision. Hence, objectives for ecological risk management should reflect what matters to society, and should form the basis for any decisions. In short, objectives are the fundamental motivation for [ecological risk management]."

Objectives Development starts with a clear statement of the problem, issue, or opportunity identified in the Identify Decision Context phase and ends with a set of specific objectives which will guide all of the remaining steps (see Figure 5). In this step we answer the "what to protect" question for ecological issues and lay out what is at stake. The substeps for this step are:

1. What do we want to protect? Define the entities, ecological processes, and geographic areas to be considered.

2. What do we mean by "protect?" Define ecological objectives.

3. What's really important, and how do we get there? Review and structure objectives.

4. Select objectives.

Figure 5. Develop Objectives.

3.1. WHAT ARE MANAGEMENT GOALS AND OBJECTIVES?

As explained in Chapter 1, we distinguish between the terms "goal" and "objective" in this document. A **goal** is a *general* statement of the desired outcome. **Objectives** are more specific statements of the desired outcome. They differ from the general goal in that they should be sufficiently specific to allow scientists to develop measures from them. In the Waquoit Bay example (a waterbody threatened by pollution and development in its watershed; see Appendix A), the overall goal was to "Reestablish and maintain water quality and habitat conditions in Waquoit Bay and associated wetlands, freshwater rivers, and ponds."

Keeney's definition of objectives (Keeney, 1992) applies to both goals and objectives as we are using those terms:

> "An Objective is a statement of something that one desires to achieve. It is characterized by three features: a **decision context**, an **object**, and a **direction of preference**. For example, with respect to traveling in automobiles, one objective is to maximize safety. For this objective, the decision context is automobile travel, the object is safety, and more safety is preferred to less safety."

In some cases, a **desired state** may take the place of the **direction of preference** (e.g., "sufficient habitat to support the 1970 population level," rather than "maximize habitat"). The choice of whether to use desired state or direction of preference will depend upon the decision context.

3.1.1 Identify the Overall Goal

Once the nature of the decision to be made is specified (in Identify Decision Context), a useful next step is to identify the overall fundamental goal for the decision at hand, at least in preliminary terms. For example, the overall goal for the Salton Sea project is "to maintain and restore ecological and socioeconomic values of the Salton Sea to the local and regional human community and to the biological resources dependent upon the Sea." Such an overall objective would naturally lead people to ask: What are these ecological and socioeconomic values? That question leads to thinking about the objectives (see also McDaniels, 2000). These more specific objectives are the topic of the following sections.

Example Box 4. Waquoit Bay: Identifying the Overall Goal

Part of the process for answering the question "what do we want to protect?" involves developing an overall risk-management goal. For the Waquoit Bay risk assessment, the risk-assessment team reviewed written goals that had been established by 14 local, regional, and national resource management organizations with jurisdiction in the watershed. They also held a public forum to identify valued amenities in Waquoit Bay. The team then drafted a management goal that was a qualitative statement capturing the essential interests expressed by the organizations and the public in the Waquoit Bay watershed. Finally, they presented the draft goal (and management objectives, as described in Example Box 5) to managers of concerned organizations. These risk managers modified and approved the overall goal, which in final form was:

> "Reestablish and maintain water quality and habitat conditions in Waquoit Bay and associated wetlands, freshwater rivers, and ponds to (1) support diverse, self-sustaining commercial, recreational, and native fish and shellfish populations, and (2) reverse ongoing degradation of ecological resources in the watershed."

3.1.2 Purpose of Objectives

Objectives indicate what is at stake in the decision to be made. McDaniels (2000) describes why objectives are particularly important for ecological issues:

> "Clarifying objectives is particularly important for ecological risk management (compared to, say, human health risk management) because human understanding of what constitutes ecological health (or ecological risk) is culturally and individually defined. For example, every individual has experience that provides a shared understanding of what it means to say someone is healthy. But given the role of disturbance and renewal in ecosystems, what may appear to a casual observer to be a healthy ecosystem could be seen as highly unhealthy or at risk to another observer."

> "There is, of course, no single definition of 'risk' in any context.... But the subjective nature of perceptions of ecological risk, and the many scientific perspectives on how ecological health should be defined, mean that defining ecological risk through the process of clarifying objectives is fundamentally value-laden, and particularly crucial to informed decisions about ecological risk-management activities."

Having objectives from the beginning provides clarity to the risk manager, the risk assessor, and the public about the ecological and other values at stake in the decision and the information which the risk assessment is intended to provide. As McDaniels (2000) points out, the lack of objectives leads to analysis of the wrong problem (or only a portion of the problem); inconsistent analyses; and difficulty in understanding and communicating the analysis.

3.1.3 Types of Objectives

This guidance focuses on ecological objectives and the issue of what to protect.

However, ecological objectives are not the only ones that need to be set. Economic, human health, political, social and other objectives should all be made explicit. There may be objectives for any of the decision drivers identified when the context was identified. By making all these objectives explicit the process maximizes the usefulness of the various analyses and provides a bases for making and communicating trade-off decisions. Objectives for the Salton Sea case study (Appendix A) included “Provide opportunities for economic development along the shoreline” (economic) and “Provide a safe, productive environment for resident and migratory birds and endangered species” (ecological).

Objectives do not prejudge the decision. Within the total set of objectives (including both ecological and other types of objectives), some are likely to be in conflict with others, because conflicting values are at stake for the decision. The objectives should reflect and clarify these conflicts, not attempt to cover them up or resolve them in advance of analysis and further deliberations.

Although many people and groups can be involved in setting these objectives, they are risk-management objectives and thus are ultimately the responsibility of the decisionmaker, which may be an individual, a group, a government department, or an *ad hoc* group.

3.2 WHAT DO WE WANT TO PROTECT?

This substep identifies entities, processes, or places that are susceptible to the stressor being considered or otherwise relevant to the problem at hand.

Objectives should reflect “what matters” to those whose views should be considered in a given decision. Of course, as McDaniels (2000) points out, “what matters is different for different people and a complete list of everything that matters in a given ecological risk-management decision will generally not be obvious, and often involve surprises or new insights. Significant creativity and hard thinking will be required to develop such a list.” Therefore, this step needs to be done with the help of the risk assessors (who can provide information on susceptibility to the stressor), the public (who can provide information on local values and conditions), and other experts such as economists. McDaniels suggests that a facilitator be used for this and subsequent steps. A facilitator is probably not necessary for the most routine and simple problems, but should be considered for those that are more complex and far-reaching.

For a **local or community-based project**, this substep involves defining the geographic limits for the project. These may be political or natural boundaries. They need to be broad enough to encompass all influential factors, but narrow enough to retain the focus of the effort. Once the boundaries are defined, the “what to protect” question needs to be considered within the limits of those boundaries. What are the ecosystems within the area? What makes them unique? What is the connection between organisms? Where is the energy flow? Key 1 (What We Protect at EPA; described below) can be helpful, but the individual project should include the resources in the area concerned, and may well go beyond what is listed there.

On the other hand, a **national** program level may begin with the type of ecosystems, stressors, or sources that are the focus of decision, instead of geographic boundaries. Keys 1 through 4 can help decisionmakers focus on the specific ecological objects relevant to these ecosystems, stressors or sources.

At the conclusion of this substep, you will have a list of ecological entities, processes, and places that are relevant to your problem.

3.2.1 Keys to What to Protect

Some risk managers find the setting of ecological objectives particularly difficult because there is such a vast choice of ecological resources and so many different ways of looking at them. For example, many of the laws that govern EPA's activities provide the general goal "protect human health and the environment" without further definition of what is meant by "the environment." This guidance is intended to help risk managers focus on what to protect in such circumstances. It is not intended to limit choices.

This set of keys described in this section is adapted from *Priorities for Ecological Protection: An initial list and discussion document for EPA* (U.S. EPA 1997a). It is presented as a tool to help risk managers think through the possibilities for ecological protection. The keys are organized into several increasing levels of specification.

Key 1. What We Protect at EPA - Three approaches to ecosystems:

The first level, shown in dark shading in Key 1, represents three approaches to deciding what to protect. This deals with different aspects of ecosystems in a way that is related to our various reasons for valuing them.

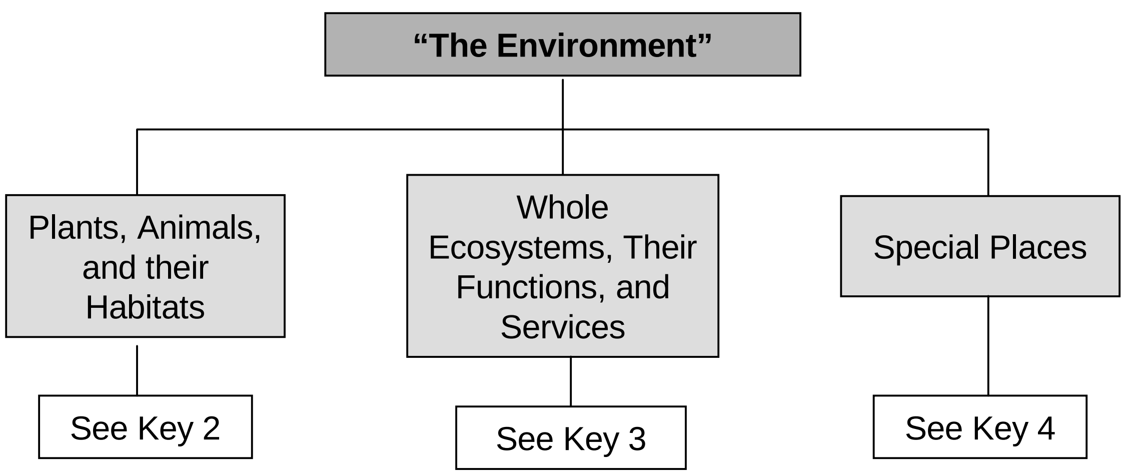
The first approach, "Plants, Animals, and their Habitats," deals with ecological protection in a way familiar to many EPA programs, according to the living components of ecosystems, which are valued in themselves, apart from their settings or their functions. An objective to protect endangered species might be developed through this approach.

The second approach, "Whole Ecosystems, Their Functions and Services," treats ecosystems as systems. These systems necessarily have both living and nonliving components, but in this approach, they are valued for the whole, not the components. The specific components (e.g. species of invertebrates) may change without changing the overall ecosystem as it is viewed in this approach. Objectives to protect ecosystem services could be developed through this approach. These are aspects of ecosystems that are very important to human functioning, but with the exception of wetland functions, they have not been the focus of regulatory actions.

The third approach, "Special Places," focuses protection on specific geographic localities.

Some specific localities are mentioned for special attention in EPA laws; many more are protected by our state and federal partners who may require assistance from EPA in protection from certain stressors. It can be argued that ecological place should be the primary consideration, since all ecosystems and their components exist in some defined boundary, at least some of the time. For decisions focused on a limited geographic area, it may be most useful way to organize objectives within an overall goal having to do to with a special place. This was the case for Waquoit Bay, where all the specific objectives were oriented toward the overall goal of protecting and restoring ecosystems within its watershed. However, programs with a national focus may need to form objectives that are not tied to any specific place (except perhaps the United States as a whole). For example, a pesticide decision may need to be made for all uses of the pesticide throughout the country and take into account the fact that migratory species may use agricultural fields in the US even though they neither breed nor winter here. These programs, however, may target some special places for increased protection or higher priority (in the way that endangered species habitat, for example, is given special consideration).

Key 1. What We Protect at EPA

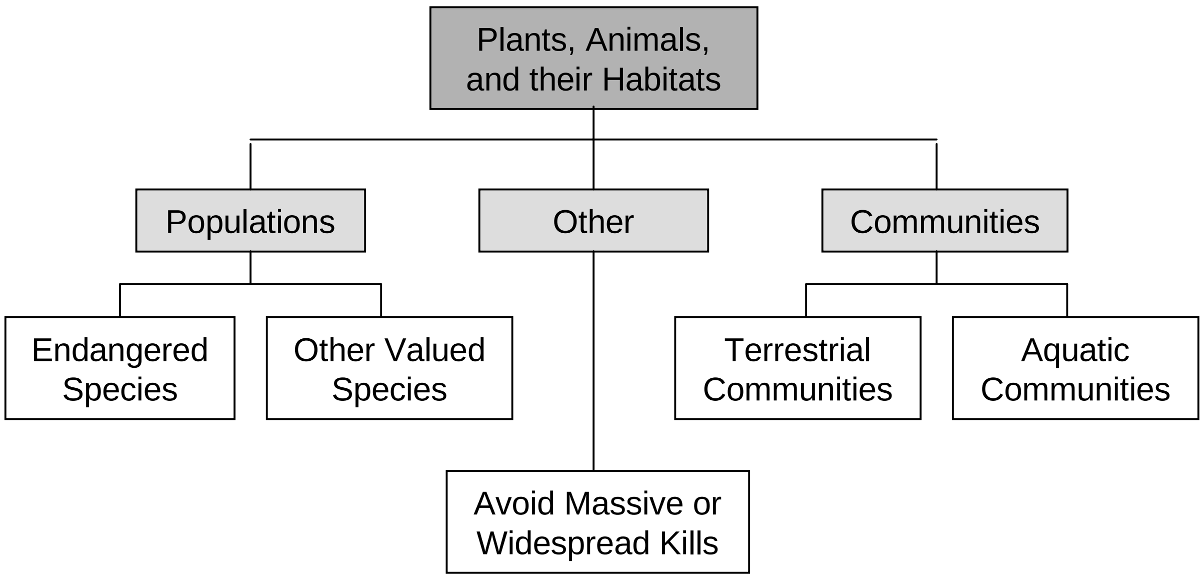


These three approaches do not divide ecosystems into mutually exclusive categories. In fact, any specific ecosystem may be approached through all three. However, the specific objective for the ecosystem may differ depending on the approach taken. Risk managers should consider possible objects for protection by all three approaches. Action to protect a particular species may not protect an ecosystem service, and vice-versa.

Keys 2-4. Categories of "What to Protect" within each approach:

This level, in light shading, provides some logical categories of things to protect within each approach. For example, plants and animals may be protected as populations, communities, or at something close to the individual level (as when action is taken to prevent widespread or massive wildlife kills). This level does not provide specific objects for protection as might appear in program-specific objectives, but rather provides some categories for risk managers to review in setting objectives. All of these categories may be appropriate across the Agency.

Key 2. Plants, Animals, and their Habitats



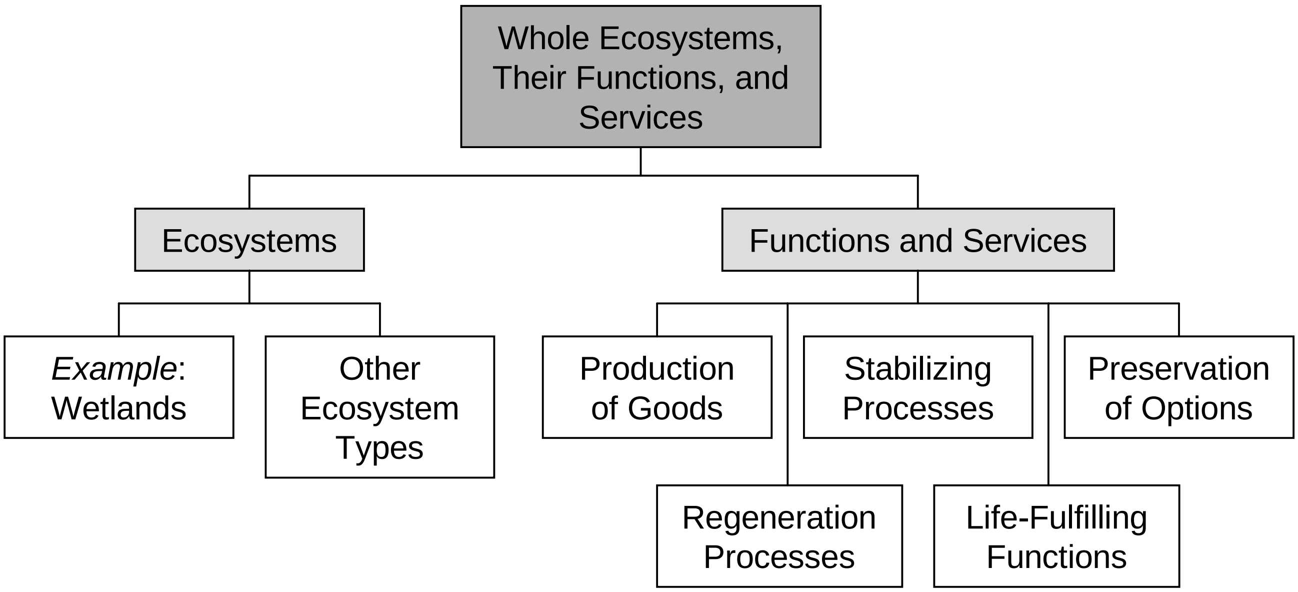
Keys 2-4. More specific designations of what to protect.

The unshaded areas represent more specific objects of protection. These may often be program specific, though some (like endangered species) could apply across the Agency. Specific designations in the Key are examples only, there is no attempt to list everything that might be considered.

There are many ways to classify and prioritize ecosystems. While we do not espouse a particular method here, helpful ideas may be found in several documents: Noss (2000) proposes a strategy for identifying high-risk ecosystems on the basis of rarity, biological distinctiveness, exhibiting major declines, containing high numbers of imperiled species, or facing greatest threats. Valutis and Mullen (2000) describe The Nature Conservancy's process for conservation planning at a large scale, with a goal of protecting a high degree of biodiversity and acting where both threats and potential for success are greatest. Mysz et al. (2000) present EPA Region 5's procedure for identifying Ecologically Rich Regions that have high ecological quality and have significant potential for collaborative partnerships with other organizations.

Daily's classification of ecosystem services (Table 1 in Daily, 2000) can serve to subdivide "Functions and Services"in Key 3. It is included here as Table 3. Her first level of classification has already been included in Key 3 (unshaded entries under "Ecosystem Services").

Key 3. Whole Ecosystems, Their Functions, and Services



Key 4. Special Places

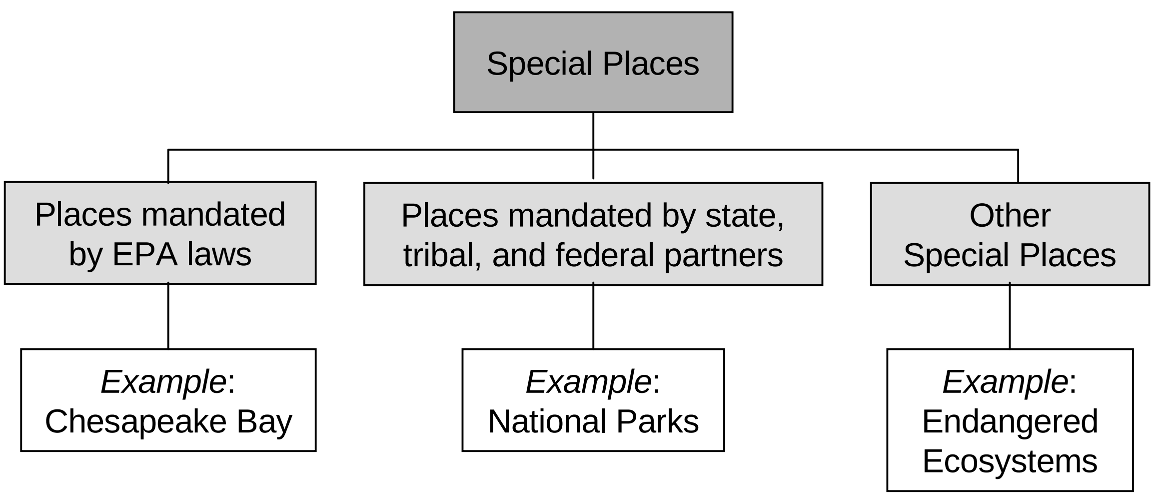


TABLE 3-1: Daily's Classification of Ecosystem Services with Illustrative Examples.

ECOSYSTEM SERVICE	EXAMPLES
Production of Goods	• food (terrestrial animal and plant products, Forage, Seafood, Spice) • pharmaceuticals (medicinal products, precursors to synthetics) • durable materials (natural fiber, timber) • energy (biomass fuels, low-sediment water for hydropower) • industrial products (waxes, oils, fragrances, dyes, latex, rubber, etc., precursors to many synthetic products) • genetic resources (intermediate goods that enhance production of other goods)
Regeneration Processes	• cycling and filtration processes (waste detoxification and decomposition; soil fertility generation and renewal; air and water purification • translocation processes (dispersal of seeds necessary for revegetation; pollination of crops and natural vegetation)
Stabilizing Processes	• coastal and river channel stability • compensation of one species for another under varying conditions • control of the majority of potential pest species • moderation of weather extremes (such as of temperature and wind) • partial climate stabilization • hydrological cycle regulation (mitigation of floods and droughts)
Life-Fulfilling Functions	• cultural, intellectual, and spiritual inspiration • aesthetic beauty • existence value • scientific discovery • serenity
Preservation of Options	• maintenance of the ecological components and systems needed for future supply of these goods and services and others awaiting discovery

(adapted from Table 1 in Daily, 2000)

3.3 WHAT DO WE MEAN BY "PROTECT?"

Ecological Objectives are set based upon the initial list of what to protect (generated by the steps just described) and the information gathered when identifying the decision context. In this substep, the decision context and desired state (or direction) are added to produce the full objectives. As stated earlier, these objectives should include the decision context (activity that requires decisions), the object (the entity, process, or place under consideration), and the desired state or direction (e.g., maintain a population at its current level, restore a function to a specific past state, no unreasonable risk). See Tables 5-1 and 5-2 in Chapter 5 for some examples.

The decision to use either a desired state or a direction will depend upon the specific program, policy, and issue. Sometimes a desired state is necessary to express the actual objective of the decision at hand. For example, the Waquoit Bay objective "Reestablish a self-sustaining scallop population in the bay that can support a viable sport fishery" includes a desired state for the scallop population. This could not be fully expressed through a simple directional objective such as “increase the scallop population.” On the other hand, the objective “Reduce or eliminate hypoxic or anoxic events” includes a simple direction (“reduce”) as an alternative to a desired state (no such events). Although the desired state implies a level of protection, the examples show that this need not be quantitative or even based upon ecological risk alone. The pesticide example of avoiding unreasonable risk (in Table 5-1) is based on balancing the risk to ecosystems against the benefits that pesticide use provides to agriculture.

In all cases the objective should include the decision context. In the Waquoit Bay example, the decision context is implied, rather than explicitly stated. All objectives are within the Waquoit Bay decision context. In the pesticide example from Table 5-1, the context is supplied by the term “no unreasonable effects.” Although not explicitly stated, this clearly means effects of pesticide use.

It is important to write the objective as explicitly as possible, even if the program has been working toward this objective for many years. Sometimes things are not as clear as they seem; for example, is the program really concerned with the entire aquatic community? Or are fish really the concerns, and the other members included because they affect fish? Furthermore, there may be reason to make some changes because of recently developed policies, new information, public opinion or other changes in circumstances. McDaniels (2000 - Section 3, Step 3) provides some suggestions for eliciting and clarifying objectives at this stage.

Some authors (e.g., U.S. Environmental Protection Agency 1994 and 1997a) have proposed that EPA develop Agency-wide ecological objectives that apply to all programs, and discussed the advantages of doing so. Although “Managing Ecological Risks at EPA” (U.S. Environmental Protection Agency 1994) pointed out both the advisability of Agency-wide objectives and the existence of some commonalities between programs, the actual development of an Agency set of objectives is beyond the scope of this document, which focuses on the planning process. Furthermore, the development of such a set might prove difficult at this time, when few program-specific ecological objectives have been made explicit. It will probably be easier to focus first on *what* to protect. Key 1 (What We Protect at EPA) may help by providing a common framework and language for deciding what to protect. Once some agreement has been reached on common objects of protection, the Agency can turn its attention to trying to agree on desired state or direction to develop full objectives. Even with such a set of Agency-wide objectives, however, each program will have to adapt the objectives to include the specific decision context.

3.4 WHAT’S REALLY IMPORTANT, AND HOW DO WE GET THERE?

The preceding steps lead to a list of unstructured concerns and issues that may include both ends and means. This step structures these into a hierarchal list of ends (fundamental) objectives. Text Box 3-1 summarizes the process.

McDaniels (2000) suggests first combining terms and ideas that basically mean the same thing or refer to the same concept. Once redundancy is thus reduced, the remaining tasks are to separate ends (fundamental objectives) from means and then to structure the fundamental objectives in a hierarchy. At the end of this step a structured set of fundamental objectives will be available for the final selection step.

Text Box 3-1. Structuring and Selecting Objectives

1. Separate ends (what we want) from means (how we might get there)
   - Objectives should be fundamental (i.e., ends).

2. Structure fundamental objectives in hierarchies of specificity.

3. Choose appropriate level of specificity
   - Specific enough to provide guidance
   - General enough to minimize number of objectives

4. Select a set of objectives
   - Complete
   - Compact
   - Controllable
   - Measurable and understandable

3.4.1 Separating Ends from Means

As defined earlier, objectives are statements of something that one desires to achieve. There are **fundamental** or **ends objectives** (what one wants to accomplish) and **means objectives** (how one might achieve it). For example, if your fundamental objective is to maximize automobile safety, one means of doing this is to minimize automobile accidents. This means objective can be further broken into means such as “minimize driving under the influence of alcohol.” There may be several means to accomplish an end, or fundamental, objective. This document focuses on setting fundamental objectives. Although means support the fundamental objectives and are in fact necessary to accomplish fundamental objectives, the analysis and discussion should always specify the fundamental objectives and distinguish them from the ends. Otherwise technical and value issues can become hopelessly confused to the detriment of both the risk assessment and the project goal. An approach to insuring that the objectives are fundamental by using a **means-ends network** is presented below

A set of objectives starting with fundamental objectives and ending with the means objectives most immediately related to a decision is a **means-ends network** (McDaniels, 2000; Keeney 1992). Sometimes the development of a means-ends network begins with a known fundamental objective for which means are developed (how can we accomplish this). This may be called “top-down” development. Often, however, the process begins with a stated means to accomplish an unstated fundamental objective. For example, a common EPA objective is to minimize emissions of harmful materials. Yet minimizing emissions is probably really a means to avoid adverse human health and environmental effects. Thus the fundamental objective is avoiding adverse effects, and minimizing emissions is a means for achieving that objective. Finding the fundamental objective requires a “bottom-up” analysis, as described below.

In a “bottom-up” approach, fundamental objectives can be discovered by repeatedly asking the question Why is this important? for any stated objective. The answer may be that it is one of the essential reasons for interest in the situation. In this case it is likely to be a fundamental objective. Very often, however, the answer is that it is important because of its implications for some other objective. In the latter case, it is a means objective and the response identifies another objective (which itself may be either a fundamental objective or another means objective).

3.4.1.1 Example: Using means-ends networks to uncover fundamental objectives

One specific example of a stated objective that appears to be a means objective is "Establish a NO_x trading program for the eastern U.S. that will cap NO_x emissions at a level 20% below existing levels by 2009."

To uncover the more fundamental objectives, we ask, Why is this objective important? One response might be that less NO_x would reduce summertime regional ozone formation. The question then is Why is it important to reduce summertime regional ozone levels? An answer could be to protect ozone sensitive vegetation (flora) from adverse effects of high ozone exposures (e.g., foliar injury, growth and/or yield reductions in crop/tree species). From this, the question Why is it important to protect ozone sensitive vegetation? follows. One answer might be that many of these sensitive species can be found in our national parks and other Class I areas, which have the mandate in national legislation to protect the current assemblage of plants and animals, as well as the aesthetic, historical and cultural values of the areas to the visitors. Alternatively, or in addition to the above, the answer might be to also protect the regional agricultural economic base by protecting crop and timber yields across the region, since several important crop and timber species have shown sensitivity to ozone. Thus, the fundamental objective(s) for reducing NO_x is that it will improve (preserve) the value(s) of both agricultural and natural systems which have been recognized as important to the people of the U.S.

Another answer to the same initial question Why is this objective important? might be that reduced NO_x levels would reduce wet and dry deposition of NO_x to ecosystems. Then follows the question, Why is it important to reduce wet and dry deposition of NO_x to ecosystems? The answer could be that the current levels of nitrogen inputs to many terrestrial ecosystems exceed the capacity of the ecosystems to utilize this nutrient so that over time these systems are becoming nitrogen-saturated. Alternatively, or in addition, the answer could be that coastal and fresh waters are experiencing acidification and/or eutrophication. The question would then follow Why do we care about systems becoming nitrogen-saturated or experiencing acidification and/or eutrophication? The answers could be that nitrogen-saturation can change the species composition of an area and affect the overall productivity of the system, while acidification and eutrophication ultimately harms aquatic life.

3.4.1.2 Advantages of Uncovering Fundamental Objectives

People are not going to want to ask themselves a long series of questions about why something is important unless they can see some benefit to it. The benefits to going through this process to try to identify fundamental objective(s) are several fold:

1) Fundamental objectives give a much stronger basis for a risk assessment. In the above example, the original statement of the objective does not provide any ecological (or human health) endpoint for the assessment. Even answers to the earlier iterations would fail to provide endpoints that would really deal with the risk-management issue. For example, the assessment could show that both ozone levels and NO_x deposition to ecosystems are affected by NO_x emissions but still leave unanswered the question of what damage this might do. Alternatively, the risk assessors might pick an ecological endpoint for the analysis, but this may not agree with what the risk manager sees as important. Thus the relationship to the important endpoints could be ignored.

2) By identifying the fundamental objective, it is easier to judge whether a particular course of action is likely to achieve what is needed (e.g., solve the pollution problem or simply shift it to another area). Concurrently, the underlying assumptions behind these decisions become more apparent and can be reevaluated.

For example, in the first discussion of the case study in Section 3.4.1.1, there is an inherent assumption that a NO_x trading program is the tool to use to achieve the desired NO_x emissions reductions. The reason this tool was originally selected may turn out to be that it was the most accessible or familiar alternative/technique to the risk manager. However, after going through the exercise of asking the series of Why ...? questions, the manager will see that there are a variety of different ecosystem types that need protection (e.g., forested, crop/field, and aquatic). At that point, he/she may realize that these ecosystems are not distributed equally across the landscape so that the southern and mid-Atlantic states have the majority of the field type agriculture while the Northeastern states of New York, Vermont, New Hampshire and Maine are mostly forested and contain the greatest number of sensitive aquatic systems. Since most of the NO_x pollution produced by this latter grouping of states travels out to sea or up into Canada, controlling NO_x pollution here is not going to benefit the sensitive ecosystems. However, that same subset of states bear the brunt of Ohio River Valley air pollution sources because the polluted air moves northeast. If New York reduces its emissions, a trading program may then allow Ohio to emit at its usual rate, which would not protect the sensitive ecosystems in the northeast. Therefore, this means-ends network would help the manager decide if he/she has selected the right tool or needs to craft the tool a certain way to achieve the fundamental objective(s).

3) Finally, going through the exercise of a means-ends network highlights for the risk manager who interested parties might be for that particular decision. Since risk managers are now encouraged to involve interested parties early in the decision-making process, this is a useful exercise in itself. In addition, in situations in which there appears to be significant disagreement on the problem or course of action among the interested parties, it may be useful to go through a means-ends network with them. This will clarify whether the disagreements are at the superficial level of means, or whether they stem from different fundamental objectives. There is no truly universally accepted root objective. For example, there may be one set of interested parties that hold to the “preservationist” value system for whom the fundamental objective is no discernable

impact on the environment. Another set of interested parties may share the "conservationist" view whose fundamental objective is to allow wise/sustainable use of the environment in question. The process of asking Why? can identify areas of agreement (it might be that the disagreement lies in the respective groups' means objectives) and, at a minimum, where any basic disagreement really exists. Though those groups may never agree on fundamental objectives, this process will still help the risk manager understand the differences and decide how best to manage the risks in light of them and the other constraints he/she should consider such as resources and time. Documentation of this process can help to further public dialogue, guide the risk assessment, and inform future actions.

3.4.2 Structuring Fundamental Objectives: How Specific Do They Need To Be?

Once the fundamental objectives are determined, they may be structured into an objectives hierarchy. This hierarchy does not deal with the priority or importance attached to the objectives. It deals instead with the level of specificity or generality of the objectives.

Objectives hierarchies organize objectives in such a way that the lower-level objectives are contained in and, in total, define the higher-level objective. One example (from Keeney, 1992) is in the decision context of setting a carbon monoxide air quality standard. If the overall objective is "Minimize carbon monoxide concentrations," objectives at the next lower level could be "Minimize carbon monoxide concentrations in industrial areas," "Minimize carbon monoxide concentrations in urban areas," and "Minimize carbon monoxide concentrations in rural areas." Or if a fundamental objective was to protect bird populations, a set of more specific objectives might further define the objective by specifying the types or groups of birds to be protected. These could specify birds by type of habitat (wetlands, grasslands) or by genus or species, or in any other way that is useful to the decision and analysis process.

Hierarchies can be made from the objects alone, instead of fully stated objectives, usually in fewer words. Daily's classification of ecosystem types discussed in Section 3.2 is based upon object hierarchies.

Some reasons to organize objectives or values into hierarchies is to ensure that nothing essential is omitted, to clarify and concretize the meaning of the higher level objectives or values, and to show the relationships among objectives (or values).

Objectives should be refined to the level that best facilitates discussion and analysis. For example, the objective "Protect Human Health and the Environment" is too general to provide useful discussion or analysis. People may use this term while having very different ideas of what it means. The ways in which risk assessors go about the assessment of such an objective may differ greatly from what risk managers have in mind. In order to avoid these problems, objectives (or their objects) should be specified to the point that the true objectives have been sufficiently defined. On the other hand, it is better to make the objectives no more specific than necessary in order to keep the total number of objectives to a number which makes it relatively easy to see the entire picture of what is to be accomplished (five to ten, say, rather than dozens). More specific levels will inevitably produce a greater number of objectives. For example, a list of objectives dealing with birds by genus or species would be much longer than the single objective dealing with birds in general. This issue is discussed further in the next section.

3.4.3 Minimizing the Number of Fundamental Objectives

The list of objectives may still be too long for easy implementation. When this occurs, the objectives hierarchies should be examined to determine whether a higher level objective might replace several lower level objectives. For example, in the Salton Sea example (Appendix A.1), the second objective is "Provide a safe, productive environment for resident and migratory birds and endangered species." This objective could have been broken down into many lower level objectives dealing with particular species of birds and endangered species. However, this was not necessary. The objective includes those birds that are resident or migratory in the Salton Sea area and the endangered species that exist there. There is no need to list them all (or even for decisionmakers to know what they are) at this point. The objective applies to all of them and the specific listing can be left for the analysis, or risk assessment phase. Unless there is some need to formulate different objectives or priorities for different species, most objectives could be stated at this less detailed level. Such an approach is likely to keep the fundamental objectives to a reasonable number.

If the list is still too long, decisionmakers could consider prioritizing the list of objectives or the objects included in them. Several of the issue papers suggests principles on which to prioritize.

Noss (2000) contains suggestions for prioritizing high-risk ecosystems. The Nature Conservancy (Valutis & Mullen, 2000) is based on the fundamental principle of conserving biodiversity. EPA Region 5 has developed criteria (Mysz, et al., 2000) that use a combination of diversity, self-sustainability, and rarity (relict native ecosystems) to identify what they have termed "critical ecosystems" that will help EPA coordinate with other organizations take an ecosystem-based approach to environmental problem-solving. This process, or a version of it, has also been applied in Region 1 and in Region 4's Southeastern Ecological Framework project.

In using these or similar approaches, decisionmakers should make sure that they understand the principle being used and that it is fundamental (in the same sense that the objectives are fundamental). Take, for example, the "high-risk ecosystems" discussed in Noss (2000). If a program or project adopts this approach, are they doing so because high risk ecosystems are fundamentally more important than others? Or is the protection of high risk ecosystems a means to some more fundamental priority, such as future provision of ecosystem services? These questions are asked just as described for "means vs. ends" objectives, as policy questions. Fundamental priorities, like fundamental objectives, cannot be scientifically derived, although science can be very useful in developing the means for attaining them.

Example Box 5. Waquoit Bay: Defining Management Objectives

The management goal for Waquoit Bay (described in Example Box 4) was used to draft 10 specific management objectives that served as a basis for planning the risk assessment. Like the goal, these were presented to risk managers and approved following modifications. These objectives were all ecological, but non-ecological objectives could also have been developed to reflect public values. The objectives define what must occur in the watershed for the goal to be achieved and provide the foundation for management decisions. The management objectives were:

- Reduce or eliminate hypoxic or anoxic events
- Prevent toxic levels of contamination in water, sediments and biota
- Restore and maintain self-sustaining native fish populations and their habitat
- Reestablish viable eelgrass beds and associated aquatic communities in the bay
- Reestablish and self-sustaining scallop population in the bay that can support a viable sport fishery.
- Protect shellfish beds from bacterial contamination that results in closures
- Reduce or eliminate nuisance macroalgal growth
- Prevent eutrophication of rivers and ponds
- Maintain diversity of native biotic communities
- Maintain diversity of water-dependent wildlife

Most of these objectives are "fundamental" in that they define protecting a valued ecological entity. Objectives to protect fish and scallop populations are examples. Several, however, appear to be means for accomplishing a more fundamental objective. Reducing hypoxic (low oxygen) events and preventing toxic levels of contamination are really means to protect fish, shellfish, and other valued resources, for example. As explained in section 3.4.1.2, we recommend using only fundamental objectives as final management objectives.

3.5 SELECT OBJECTIVES

This final substep of Objectives Development includes a review of the objectives to insure that they are well defined and the documentation of the completed list.

As mentioned earlier, a well-defined objective has three components: an object (what is being valued), a direction of preference, and a decision context. McDaniels' (2000) example "minimize adverse effects on ecological services in the Hood River basin" embodies all three: The object is "adverse effects on ecological services;" "minimize" means that less is preferred to more and "in the Hood River basin" is the decision context. Creating sub-objectives that each state what kinds of ecological services are important to maintain would further specify this objective.

In addition to the need for each objective to be well defined, McDaniels (2000) prescribes certain attributes for the set of objectives as a group. They should be **"complete, compact, controllable, measurable, and understandable**."

Complete: The objectives should cover everything that matters in making the decision. This means that they should include more than just ecological concerns. As McDaniels points out “The objectives that conflict with the efforts to address ecological concerns should also be included, such as costs, human health effects, economic development opportunities, private property rights, or any others. By including these kinds of conflicting concerns, the analyst ensures that the objectives address everything that matters in a given decision. Sometimes one sees analysis that ignores the conflicts involved in decisions, by simply adopting a “single objective” perspective in the analysis. There is little to be gained in making an analysis more tractable by ignoring the major conflicts that are inherent in the decisions.” The Salton Sea case study in Appendix A provides a good example of a set of objectives that includes potential conflicts (human development, recreation, and wildlife habitat).

Compact: The set of objectives should be non-redundant and concise. This means, among other things, that the set should contain fundamental objectives only, not the means for obtaining these objectives. McDaniels adds that “Separating ends and means is one of the most crucial aspects of structuring objectives, and also one of the most subtle. That is because an objective that is a means in one decision context can be an end in another related context.”

Controllable: Objectives involve only those ends that can be influenced by the decision at hand and the range of options available for that decision. This does not mean that the issues involved in the decision need to be the sole or even the primary influences on the end points. It does mean that they should not be outside the range of influence for the decision. It also means that the decision context is included in the objective to show the connection between the decision and the desired state. For example, the desired state for the pesticide example in Table 5-1 reads “*No unreasonable effects* on bird survival or maintenance of bird populations [emphasis added]. This acknowledges that the objective has to do only with the effects of pesticide use on bird survival and populations, not the full range of factors that might affect birds or their populations.

Measurable and understandable: Objectives do not have to be operationally defined or include specific measures. However, they do need to be clear enough so that the risk assessors can do their job of defining assessment endpoints and various measures, as described in Chapters 4 and 5. Thus, using “birds” as an object may be too ambiguous. Are individual birds or bird populations (or both) involved? If populations, are they local, regional, or national? Are we talking only about native birds? This clarity is required so that the risk assessors will know what links they need to make between the measures available to them and the decision objectives. For example, for practical reasons, assessors may need to use non-native, individual birds in devising effect measures. If the objective specifies populations of native birds, they will understand in advance that links need to be made to these valued entities.

These attributes can be applied to the objectives described in the Salton Sea example (see Appendix A.1). It is difficult for someone not closely involved in the issue to make a firm critical judgment of the extent to which a set of objectives is **complete,** because there may be issues of which the outside observer is unaware. However, the five objectives do appear to cover the issues mentioned by the two public laws and the summary from the public forum. Not every such issue is specifically mentioned, because some are subordinate to one or more of the five major objectives and others (salinity, for example) are related to means rather than fundamental objectives. The set of objectives is clearly **compact**. There are no redundancies among the objectives and all are fundamental, even though the laws specified some means objectives. There is sufficient authority to say that the objectives are **controllable**. The lead and cooperating agencies have the authority to take actions which would affect the objectives in the preferred direction (these include controlling salinity in the Sea, reducing wildlife disease, and improving recreational facilities). The objectives are clear and **understandable**. They are also **measurable,** although each objective had to be further divided into subordinate objectives and means objectives in order for specific measures to be devised. This included, for example, listing the particular species of birds, endangered species, and sport fish in the area.

Finally, the objectives should be documented, along with the results of earlier and later steps, to serve as a record of the decisions made in this step and a guide to subsequent steps. The next chapter deals with the subsequent step of planning the risk assessment.

3.5.1 Interpreting GPRA Goals to Develop Objectives

EPA's Strategic Plan (U.S. EPA, 2000d) contains some more specific ecological objectives within the very general GPRA goals. These objectives are also quite general, but often contain more specific subobjectives. In some cases no specific ecological goals are listed, but the discussion of what appear to be means objectives (reducing pollution, for example) indicates the more fundamental objective associated with the stated objective. This section shows how a few of EPA's GPRA goals may be interpreted to develop objectives that embody these attributes. Notice that the objectives are very general and sometimes contain more specific subobjectives. Although a specific goal is not always specified, the discussion of what appear to be means objectives (e.g., reducing pollution) indicates the more fundamental objective associated with the stated objective. Text Box 3-2 presents examples of some other Federal agencies' objectives.

- **Goal 1. Clean Air -** The air in every American community will be safe and healthy to breathe. In particular, children, the elderly, and people with respiratory ailments will be protected from health risks of breathing polluted air. Reducing air pollution will also protect the environment, resulting in many benefits, such as restoring life in damaged ecosystems and reducing health risks to those whose subsistence depends directly on the environment.

  Example objective - Objective 1.4 sets target reductions of ambient sulfates, total sulfur deposition, ambient nitrates, and total nitrogen deposition. These pollutants are major precursors of acid rain which causes **forest damage**, among other things. This connection is discussed in "Environmental Goals for America" (U.S. EPA, 1996a), although not mentioned in the discussion of Objective 1.4. The implied objective is **"Protect the nation's forests from damage caused by acid rain."** The object (what is being valued) is the nation's forests, the direction of preference is less acid rain damage, and the decision context is ambient air targets for acid rain precursors.

- **Goal 2. Clean and Safe Water** - All Americans will have drinking water that is clean and safe. Effective protection of America's rivers, lakes, wetlands, aquifers, and coastal and ocean waters will sustain fish, plants, and wildlife, as well as recreational, subsistence, and economic activities. Watersheds and their aquatic ecosystems will be restored and protected to improve public health, enhance water quality, reduce flooding, and provide habitat for wildlife.

  Example objective -**Conserve and enhance the ecological health of the nation's (state, interstate, and tribal) waters and aquatic ecosystems–rivers and streams, lakes, wetlands, estuaries, coastal areas, oceans, and groundwater–so that 75% of waters will support healthy aquatic communities by 2005.** The object is the nation's waters and aquatic ecosystems, the desired state is that 75% of waters will support healthy aquatic communities, and the temporal context is by 2005.

- **Goal 4. Preventing Pollution and Reducing Risk in Communities, Homes, Workplaces, and Ecosystems:** Pollution prevention and risk management strategies aimed at cost-effectively eliminating, reducing or minimizing emissions and contamination will result in cleaner and safer environments in which all Americans can reside, work and enjoy life. EPA will safeguard ecosystems and promote the health of natural communities that are integral to the quality of life of this nation.

  Example objective (from Subobjective 4.1.5) - By 2005, the use of pesticides in the U.S. that have high potential to cause significant acute toxicity to fish or wildlife will be reduced by 50% from 1995 levels. Although this is probably a means rather than a fundamental objective, the fundamental objective is clearly implied– it is "By 2005, reduce damage to fish and wildlife from toxic pesticides." The object is fish and wildlife, the direction of preference is less damage, the decision context is pesticide use, and the temporal context is 2005.

- **Goal 5. Better Waste Management, Restoration of Contaminated Waste Sites, and Emergency Responses** - America's wastes will be stored, treated, and disposed of in ways that prevent harm to people and the natural environment. EPA will work to clean up previously polluted sites, restore them to uses appropriate for surrounding communities, and respond to and prevent waste-related or industrial accidents.

Example objective - Discussion of the importance of Goal 5 mentions damage to **vegetation** and endangerment of **wildlife** among the risks to be avoided. An implied objective is "**Prevent harm to vegetation and wildlife from polluted waste sites.**" The objects are vegetation and wildlife, the direction of preference is less damage, and the decision context is waste site cleanup under CERCLA.

- **Goal 6. Reduction of Global and Cross-Border Environmental Risks:** The United States will lead other nations in successful multilateral efforts to reduce significant risks to human health and ecosystems from climate change, stratospheric ozone depletion and other hazards of international concern.

  Example objective (from Subobjective 6.1.5) - Restore and maintain the chemical, physical and biological integrity of the Great Lakes Basin Ecosystem, particularly by reducing the level of toxic substances and by protecting human health, restoring vital habitats (says "habits"), and restoring and mainlining stable, diverse and self-sustaining populations. The object is the Great Lakes basin ecosystem, the desired state is that the chemical, physical and biological integrity of the ecosystem would be restored and maintained. The temporal context is 2005.

Text Box 3-2. Selected Objectives from Other Federal Agencies.

U.S. Fish & Wildlife Service (USFWS): Through 2005, 20 percent of migratory bird populations demonstrate improvements in their population status. (USFWS Strategic Plan, www.fws.gov/r9gpra)

> The object is migratory bird populations, the desired state is that 20 percent demonstrate improvements in population status, and the temporal context is through 2005.

National Oceanic and Atmospheric Administration (NOAA): Protect, conserve, and restore coastal habitats and their biodiversity. (NOAA Strategic Goals; www.pmel.noaa.gov/noaa-strategic)

> The object is coastal habitats and their biodiversity and the desired state is that they be protected, conserved and restored.

National Park Service (NPS): Air quality in 70% of reporting park areas has remained stable or improved. (NPS Strategic Plan 2001, 2002; www.nps.gov/planning/NPS_strategic_plan.pdf)

> The object is air quality, the spatial context is the national park areas, and the desired state is that 70% of the reporting park areas have air quality that has remained stable or improved

USDA/Forest Service (USDA/FS): Improve and protect watershed conditions to provide the water quality and quantity and the soil productivity necessary to support ecological functions and intended beneficial water uses. (USDA/FS Strategic Plan [2000 Revision]; www2.srs.fs.fed.us/strategicplan/sp2000.pdf)

> The object is air quality in the national park areas and the desired state is that 70% of the reporting park areas have air quality that has remained stable or improved.

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4. IDENTIFY INFORMATION NEEDS

Chapter 2 explored the context for the risk-management decision to be made and its associated risk assessment, and Chapter 3 explained how to establish management objectives for the decision. This chapter describes the final steps to complete planning for a risk assessment (see Figure 6). It also explains how the planning results will be used, and what a risk manager can expect from a risk assessment.

4.1 WHAT QUESTIONS SHOULD THE RISK ASSESSMENT ADDRESS?

Ecological risk assessments evaluate the likelihood that adverse effects may occur as a result of exposure to a stressor. They examine the relationship between stressors and effects, and may be designed to predict the effects of a source or stressor, determine what might have caused an observed effect, or identify threats to a resource. They use information about stressors, receptors, and ecosystems to estimate effects under specific conditions.

Although every risk assessment will eventually describe stressors and their sources, organisms potentially affected by them (receptors), and what changes might occur, its specific questions depend on the reason it was initiated:

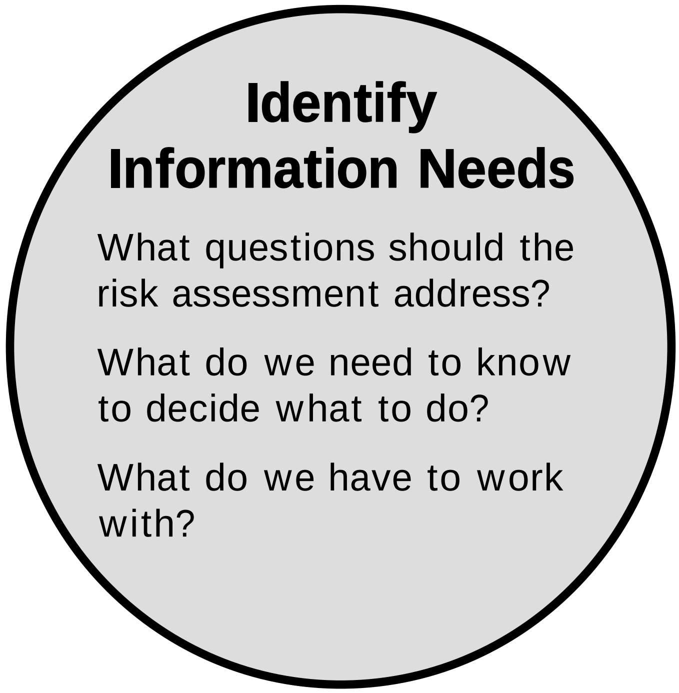

Figure 6. Identify Information Needs.

- If an effect such as a fish kill has been observed, we need to know what caused it. The risk assessment begins with the effect and examines what stressors could have produced it, how the affected organisms could have encountered them, and whether other stressors could have caused the same effect (and, if so, how they can be distinguished from each other).

- If we need to decide whether to allow some activity that might harm the environment, such as an incinerator or a discharge to water, the risk assessment begins with the stressor and examines how the stressor will behave in the environment and what organisms might be exposed, their sensitivity to the stressor, and the factors (behavior, etc.) that influence whether they will encounter it.

• If we are interested in a particular resource such as a waterbody and want to learn about the stressors to which it might be vulnerable to focus our protection efforts, the risk assessment starts with the resource, identifies potential stressors in the vicinity, and evaluates their presence and potential effects.

• If we want to know whether a particular action or regulatory program was effective, the risk assessment might start with what effects were observed before it was put into place and examine how they have improved since then. The analysis might look at effects or concentrations in organisms, media concentrations, and presence or absence of designated physical or chemical indicators of success as well as whether target concentrations have been met.

Example Box 6. Waquoit Bay: Identifying Information Needs

The risk-assessment question for the Waquoit Bay analysis was: What and how are human activities contributing to the ongoing degradation of valued ecological entities in the watershed? To answer this, risk assessors would need information about known and suspected stressors, organisms and other Waquoit Bay resources, effects that had been noticed, and whether any trends were evident.

The risk-management options developed to meet the objectives described in Example Box 5 included controlling nutrients by upgrading septic systems or modifying land development. Other information needed to make a decision about how to control identified stressors included the costs, feasibility, and acceptability of those options. Because the analysis was meant to explore whether ecological risk assessment could apply at the watershed scale, it did not analyze management options in depth, but it did examine the ecological changes that could be expected if those options were implemented. The planning stage involved only a preliminary exploration of information needs, which was substantially refined during problem formulation. It also considered the resources available for the risk assessment: Professional staff were available to participate on the risk assessment staff, but additional funding was limited. As a result, the team concentrated on evaluating available information.

The questions identified here as those the risk assessment should address will be examined in problem formulation. They should be linked to regulatory criteria as well as the assessment endpoints and various measures used in the ecological risk assessment itself. Text Box 4-1 shows how regulatory criteria correspond to management goals and objectives, and provides examples of assessment endpoints, measures, and risk-assessment questions that might be used to evaluate risks to waterbodies.

After this review of objectives, the risk manager and risk assessors should have a clear understanding of which questions the risk assessment should explore. Remaining steps are deciding the scope and resources for the risk assessment and translating the objectives into specific assessment endpoints for evaluation in the risk assessment, as described in the following sections.

Text Box 4-1. Regulatory Criteria, Assessment Endpoints, and Risk-Assessment Questions

EPA uses water quality criteria (U.S. EPA, 1999b) to protect aquatic life from chemical stressors; we assume that protecting a suite of test species protects those in the environment. We use the criteria to decide whether exposed organisms are at risk of adverse effects from chemicals discharged to waterbodies. Here is an example (adapted from U.S. EPA, 1998) of how the Clean Water Act and water quality criteria correspond to management goals, management objectives, assessment endpoints, and measures, and what questions a risk assessment can answer about whether aquatic organisms face risks from chemicals discharged to water.

Regulatory/Management Goal
- Clean Water Act, §101: Protect the chemical, physical, and biological integrity of the Nation's waters.

Management Objective
- Attain Ambient Water Quality Criteria, i.e., protect 99% of individuals in 95% of the species in aquatic communities from acute and chronic effects resulting from exposure to a chemical stressor.

Assessment Endpoints
- Survival of fish, aquatic invertebrate, and algal species under acute exposure
- Survival, growth, and reproduction of fish, aquatic invertebrate, and algal species under chronic exposure

Measures of Exposure
- Concentrations in water
- Concentrations in fish, aquatic invertebrates, and algae

Measures of Effect
- Laboratory LC_{50}s (lethal concentration for 50 percent of tested organisms) for at least eight species meeting certain requirements
- Chronic NOAELs (no-observed-adverse-effect levels) for at least three species meeting certain requirements

Measures of Ecosystem and Receptor Characteristics
- Water hardness (for some metals)
- pH
- Habitat requirements
- Behavior

Questions the Risk Assessment Can Answer
- What organisms are exposed to what chemicals?
- What adverse effects might these organisms suffer?
- Is any particular chemical responsible for most of the problem?
- What are the implications of the answers above for the stated management objective?

4.2 WHAT DO WE NEED TO KNOW TO DECIDE WHAT TO DO?

As described in Chapter 3, management objectives may be a mixture of ecological and other (such as economic) objectives. Ecological objectives can be used as the basis for the risk assessment by asking questions about the current state of knowledge for each. The basic question is: What are the impacts of our decision alternatives on our objectives?" (or perhaps Do we know whether our objective is likely to be achieved if we make this decision, and if so, will it be within an ecologically relevant time frame?) but is more likely to be manifested as something like: If we leave this Superfund site as is, how will that affect our objectives?; If we register this pesticide, how will that affect our objectives?; or If we grant this permit, how will that affect our objectives? Once the decisionmaker poses the question, risk assessors work with the risk manager to answer this question for each ecological objective given the current state of knowledge.

For example, suppose one ecological objective for clean-up of a Superfund site is "minimize ecologically significant impacts on native fish in Little Brook" which flows through the site, and that the available treatment options are (in addition to the no-action alternative) [a] dredging contaminated sediment from Little Brook and [b] treating surface soils to reduce further transport of contaminated soil into the brook. The questions we can pose are: If we do nothing, what will the impacts to fish be?; If we dredge Little Brook, what will the impacts to fish be?; and If we treat surface soils, will the impacts to fish be?

To answer these questions, several types of information will be needed: For example, we may need to know how fish respond to different contaminants and environmental conditions, the success rate of different soil and sediment treatments, how (if at all) habitat becomes re-established after dredging, how much money is available for remediation, whether the community will accept a dredging program, how much time is available to complete the work, and whether seasonal conditions affect our ability to complete work at the site. Questions may be grouped into convenient categories such as ecological, economic, engineering, legal, or sociological.

The risk assessment, then, will seek to answer ecological questions about the effects of doing nothing, dredging, and treating surface soils. It cannot answer questions such as whether is it economically or socially feasible to do any of those things. Note that these questions may be critical to the eventual decision, so they should be documented to be sure other analyses will address them. Example Box 6 shows how information needs were identified in the Waquoit Bay analysis.

Finally, as noted previously, some of the management objectives will not be ecological. For example, objectives such as fairness, creating jobs, or enhancing property values are beyond the realm of ecological risk assessment, but the risk manager should still ask the question of whether they are likely to be achieved by available risk-management options. Other tools, such as economic analyses, can be used to resolve uncertainties related to these non-ecological objectives. EPA has developed a Framework for the Economic Assessment of Ecological Benefits (U.S. EPA, 2001b).

4.3 WHAT DO WE HAVE TO WORK WITH?

A risk assessment's scope and complexity depend on factors such as regulatory constraints, how much uncertainty can be tolerated, and, of course, the resources available to do the job.

Program or other regulatory requirements are usually the first consideration: Many times they specify exactly what the risk assessment should address (scope and complexity), as well as how much time may be taken. Scope is also a function of ecosystem size and type, the type of analysis (e.g., watershed or airshed risk assessments necessarily cover a larger area than those designed for a Superfund site or RCRA facility). Regulations may also provide decision criteria.

Uncertainty–and how of it we can tolerate yet still feel comfortable with the risk assessment's conclusions and any decisions based on them–is a major limiting factor. Although we are never 100 percent certain about our conclusions or that our decision is in fact the correct one, it is possible to decide how much information is enough. This may be based on statistical analyses, review of similar decisions, whether decision criteria are already available, and whether the risk assessment and decision are unique or routine analyses. Note that there is usually a tradeoff between speed and certainty: It takes time to collect data, and sometimes decisions must be made before all the desired data can be acquired. In this case the risk manager should decide on how much uncertainty can be tolerated when making (and defending) the decision. EPA's guidance on developing Data Quality Objectives (U.S. EPA, 2000e) provides a seven-step process for determining data needs. Although it is intended for data collection, several of its steps are similar to those described here (see Text Box 4-2).

Text Box 4-2. The Data Quality Objectives Process (U.S. EPA, 2000e)

Step 1. State the problem. Review existing information to concisely describe the problem to be studied.
Step 2. Identify the decision. Determine what questions the study will try to resolve and what actions may result.
Step 3. Identify the inputs to the decision. Identify information and measures needed to resolve the decision statement.
Step 4. Define the boundaries of the study. Specify time and spatial parameters and where and when data should be collected.
Step 5. Develop a decision rule. Define statistical parameter, action level, and logical basis for choosing alternatives.
Step 6. Specify tolerable limits on decision errors. Define limits based on the consequences of an incorrect decision.
Step 7. Optimize the design for obtaining data. Generate alternative data collection designs and choose most resource-effective design that meets all data quality objectives.

Resources include time, money, and expertise. The risk assessor and decisionmaker may or may not have any control over how much time is available to complete the risk assessment and develop the decision: Pesticide registrations and new-chemical permits must be processed within a predetermined time, while other programs do not face such constraints. Seasonal factors such as field sampling season also determine what work can be done at what times. Money is another factor over which parties may or may not have any control. Finally, available expertise affects how much can be done: Seasoned technical staff may be able to produce more detailed analyses in less time than less-experienced people. This is not to imply that a given risk assessment must "make do" with available personnel; not every assessment needs the same level of detail, and an effort should be made to secure the appropriate skill mix for each assessment.

Resources are often the limiting factor, and often spur risk assessors toward creative approaches such as sharing data, collaborative field work, or using opportunistic data or novel analytical tools. Faced with similar constraints, risk managers may wish to consider how to streamline the decisionmaking process and incorporate past experience into it, for example, by developing personal rules of thumb or a network of colleagues who can offer advice and perspective. Whatever approach is chosen, risk managers should strive for clear, transparent, and defensible decisions.

4.4 PLANNING SUMMARY

There are many reasons to document the results of the planning process: If personnel change, new participants can review the "institutional memory" in the planning summary to see why objectives were selected and what information the risk assessment was intended to provide. If resources are reduced, the summary can be used to identify the most important decisions and questions to be sure they are addressed if at all possible. If program goals change, the summary can be used to determine what changes are needed to realign the objectives or the risk assessment with those new goals. Finally, as discussed in Section 2.3.6, the summary can serve as an outline for later risk-communication efforts. This need not be a lengthy document; all it need do is provide enough information for the reader to see what was important to protect, what objectives were chosen, and what questions the risk assessment was supposed to address.

In general, the planning summary should describe [1] management goals and objectives, [2] known management options, [3] specific objectives for the risk assessment, [4] the focus and scope of the assessment, and [5] resource availability. The summary may also include the risk assessment's technical approach, its reason for initiation, and the area and time over which stressors will be evaluated. The description should be clear enough so those new to the project or wanting an overview can understand the process.

Planning agreements may be required (as in Superfund's Scientific Management Decision Points; U.S. EPA, 1997b) to document decisions and ensure that the risk assessment remains consistent with its original intent. A summary can provide a point of reference for determining if early decisions need to be changed in response to new information.

Planning feeds into the Problem Formulation phase of ecological risk assessment, and there may not be a distinct boundary between the two processes. During problem formulation, risk assessors should continue the dialogue with risk managers (and, if appropriate, interested parties). This is especially important when selecting assessment endpoints and completing the analysis plan to ensure that potential problems are identified before the risk assessment proceeds.

5. INTEGRATING PLANNING AND PROBLEM FORMULATION

Previous chapters have explored the context for the risk-management decision context, how to establish management objectives, how to identify what information is needed to make the decision, and what information a risk assessment can provide. This chapter describes how planning feeds into the problem formulation phase of ecological risk assessment.

Although the decisionmaker may need a variety of information to decide what to do about a given ecological risk, the risk assessment cannot provide all the information and should be used in conjunction with analyses of topics such as economics, engineering, law, policy, and precedent. It is also worth examining data from any related human-health risk assessments. This is the place to make sure all participants understand what the risk assessment can do, the range of possible outcomes, and what information will come from other sources. Some participants may also request that the risk assessment collect data or provide information that they can use in their analyses.

Ecological risk assessments can describe the effects of stressors on an ecosystem, trace the source of adverse effects, and identify threats to ecosystems by evaluating stressors, exposed organisms, and the environment. Decisionmakers can expect conclusions such as "If current conditions continue, the native fish population may be reduced by as much as 50 percent over three years;" "If we register this pesticide for this particular use, we do not anticipate any significant adverse effects;" and "If we permit these air emissions, we expect to see tree growth in this forest region reduced by 30 to 50 percent."

Text Box 5-1. Definitions from the 1998 Guidelines for Ecological Risk Assessment

Assessment endpoints should be ecologically relevant (an important component of the ecosystem of interest), susceptible to the stressor (exposed to it as well as sensitive to its effects), and relevant to management goals. They include an entity and some attribute (and, ideally, spatial and temporal extent) and are quite similar to a management goal except that they do not include values such as direction of preference or desired state.

Measure of Effect: A measure that describes a change in an attribute of an assessment endpoint or its surrogate in response to a stressor to which it is exposed.

Measure of Exposure: A measure of stressor existence and movement in the environment and its contact or co-occurrence with the assessment endpoint.

Measure of Ecosystem and Receptor Characteristics: Measures that influence the behavior and location of ecological entities of the assessment endpoint, the distribution of a stressor, and life-history characteristics of the assessment endpoint or its surrogate that may affect exposure or response to the stressor.

5.1 HOW OBJECTIVES ARE USED IN PROBLEM FORMULATION

If the objectives are specific enough, the remaining steps can be completed by the risk assessors without the close involvement of risk managers. However, it is useful for all concerned, including risk managers, to review and understand each of the steps in at least the *problem formulation* stage of the risk assessment. Problem Formulation is the first phase of the risk assessment, followed by Analysis and Risk Characterization. The following sections demonstrate the close relationship between the objectives that are set by the risk manager and the subsequent risk assessment.

As defined in the *Guidelines for Ecological Risk Assessment* (U.S. EPA, 1998), an assessment endpoint is comprised of an entity and some attribute on which the assessment will focus. Assessment endpoints should be ecologically relevant, susceptible to the stressor, and valued by society (see Text Box 5-1). These three criteria are explicitly considered in Problem Formulation. If the objectives are specific, they will contain enough guidance on societal value so that the risk assessors can complete this step without further guidance from risk managers.

The risk manager and risk assessor should review the conceptual model (see U.S. EPA, 1998 for definition) together to ensure that there is general understanding about the relationship between the objectives, the assessment endpoints and the measures. Do some changes need to be made to ensure that the objectives are addressed? This is also a good time to identify all regulatory questions, the degree of certainty required, and other issues important to the assessment.

As described in the *Guidelines* (U.S. EPA, 1998), the analysis plan delineates the assessment design, including, for example, identifying data gaps and limitations. Are there aspects (entities, sources, or stressors) important to the goal that are impossible to address properly for scientific or other reasons? If so, these barriers should be explicitly discussed in all documentation of the process and a plan for overcoming them should be implemented. The documentation should include explicit relationships between the overall goal, the objectives, the assessment endpoints, the conceptual model, and the analysis plan. Example Box 7 describes how objectives developed in Planning were used to guide Problem Formulation.

Example Box 7. Waquoit Bay: Integrating Planning and Problem Formulation

How objectives were used: The objectives listed in Example Box 5 were used to define societal value during Planning. The risk assessors used that information, along with what was then known about stressors and the watershed itself, when developing a conceptual model (part of Problem Formulation) that illustrated the connections between sources (e.g., agriculture, residential development), stressors, effects, and assessment endpoints. The risk-assessment question described in Example Box 6 was used to develop an analysis plan (also part of Problem Formulation) that first called for a preliminary comparative risk analysis based on existing data and professional judgment. This identified nutrient loading as the single most important stressor in the watershed's aquatic habitats. Accordingly, the team focused subsequent analyses on nitrogen loading and eelgrass in the estuary.

The analysis plan (also part of Problem Formulation) discussed models that would be used to relate nitrogen loading to the identified sources and to eelgrass response, as well as associated model uncertainties. The risk-assessment questions about nutrients were more specific: How is nitrogen loading related to identified sources? and How does eelgrass respond to nitrogen in the estuary? The risk assessors also decided how to use the available professional staff, and to allocate the limited funds at hand between supporting academic researchers' participation and collecting new ground-water data.

The assessment endpoints are used to develop measures (see Text Boxes 5-1 and 5-2) to learn about how the assessment endpoint is affected by stressors. These measures will describe how the entity reacts to stressors (measures of effect), how it may contact or co-occur with stressors (measures of exposure), and how the ecosystem properties and receptor behavior influence risk (measures of ecosystem and receptor characteristics). Text Box 5-2 illustrates one assessment endpoint and several measures for the management objective “Maintain a viable, self-sustaining Coho salmon population that supports subsistence and sport fisheries.”

Text Box 5-2. Example Management Objective, Assessment Endpoint, and Measures
(adapted from U.S. EPA, 1998)

Management Objective:
- Maintain a viable, self-sustaining Coho salmon population that supports subsistence and sport fisheries

Assessment Endpoint:
- Coho salmon breeding success, fry survival, and adult return rates

Measures of Exposure:
- Numbers of hydroelectric dams and associated ease of fish passage
- Toxic chemical concentrations in water, sediment, and fish tissue
- Nutrient and dissolved-oxygen levels in ambient waters
- Riparian cover, sediment loading, and water temperature

Measures of Ecosystem and Receptor Characteristics:
- Water temperature, water velocity, and physical obstructions
- Abundance and distribution of suitable breeding substrate
- Feeding, resting, and breeding behavior
- Natural reproduction, growth, and mortality rates

Measures of Effects:
- Egg and fry response to low dissolved oxygen
- Adult behavior in response to obstacles
- Spawning behavior and egg survival with changes in sedimentation

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5.2 OUTPUTS FROM THE RISK ASSESSMENT

The risk assessment will eventually describe the relationship between stressors, effects, and organisms or functions of concern in terms of adverse effects. It also describes the severity and significance of predicted effects and describes any uncertainties associated with the analysis. Finally, it describes how much faith we may place in its conclusions. EPA has issued guidance that describes ideal features of risk characterization (see Text Box 5-3). Sometimes the decisionmaker may proceed with confidence, and in other cases he or she will want more information to be sure the decision is the correct one, or may opt to monitor the results of the decision over time. As noted earlier, risk is seldom the single determining factor; it is balanced with other information about, for example, economics, legal precedents, and engineering data to develop the risk-management decision.

5.3 EXAMPLES

Tables 5-1 and 5-2 provide brief examples of objectives and their relationship to the endpoints used in risk assessment. The first column identifies the decision context–a national or international program in some cases, a special local or regional project in others. The second column identifies the **object** (the entity or function) to be protected in the example. The next column states at least one objective (it may be only one of many entities for a given program or project). These examples are for illustration only; no attempt is made to describe any program in its entirety. The last two columns describe selected results of the problem-formulation phase of risk assessment. These are not a part of planning, but are based upon the objectives set during planning. The **assessment endpoints** describe the particular attributes of the entity that is to be protected (see Text Box 5-1), and are based upon the objective. Finally, the **measures of effect** are the measures used to evaluate the condition or response of the assessment endpoint.

Text Box 5-3. Risk Characterization

EPA's Risk Characterization Policy (U.S. EPA 2000f) states that four principles can be applied throughout risk assessment to improve the entire process: *transparency, clarity, consistency, and reasonableness*:

Transparency ensures that any reader understands all the steps, logic, key assumptions, limitations, and decisions that led to the risk assessment's conclusion.

Clarity means the process and rationale are described in easily understood language or diagrams.

Consistency ensures that the risk assessment is compatible with similar analyses. (This does not mean that one should blindly follow guidance at the expense of innovation.)

Reasonableness means that the risk assessment is based on sound judgment considering the information that is available, the assumptions that were applied, and logic of the analysis.

Table 5-1. EPA Examples of Ecological Entities and Assessment Endpoints

ECOLOGICAL RISK-MANAGEMENT OBJECTIVES			RELATED RISK ASSESSMENT COMPONENT	
Decision Context	**Object**	**Desired State or Direction**	**Assessment Endpoints**	**Measures**
Water Quality Criteria (U.S. EPA, 1999)	Aquatic Community	Protect 95% of aquatic species	Fish, aquatic invertebrate, and plant survival, development, and reproduction	Lab data on growth, mortality, development, and reproduction.
U.S. Pesticide Registration[1] (one of several objectives)	North American migratory and native birds.	No unreasonable effects on bird survival or maintenance of bird populations	Bird survival, development, and reproduction	Lab data on mortality and reproduction; field observations of bird kills
EPA Wetlands program	Wetlands and their services	No net loss of wetlands	Wetland extent	Extent of wetland plants and soil
Superfund (one of several objectives)	Fish populations	Minimize ecologically significant impacts on fish	Fish survival and reproduction	Lab data on mortality growth & reproduction
Waquoit Bay watershed (One of several objectives) (U.S. EPA, 1996b)	Scallops and their estuarine ecosystems	Re-establish a self-sustaining scallop population that can support a viable fishery	Scallop habitat (i.e., eelgrass) abundance and distribution; benthic invertebrate diversity, abundance, and distribution	Eel grass (% cover and distribution); benthic index

The entity described is only one of several entities targeted by the program.

Table 5-2. Non-EPA Examples of Ecological Entities and Assessment Endpoints

ECOLOGICAL RISK-MANAGEMENT OBJECTIVES			RELATED RISK ASSESSMENT COMPONENT	
Decision Context	**Object**	**Desired State or Direction**	**Assessment Endpoints**	**Measures**
Great Lakes Initiative (Ryder and Edwards, 1985)	Lake Superior, oligotrophic lake, lake trout	Maintain as oligotrophic[2] lake with lake trout as top predator	(Nutrient cycling?), lake trout abundance	(partial list) Average age and size; % of fishing harvest
Lake Washington (Edmundson, 1991)	Clarity and appearance of Lake Washington	Restore, maintain water clarity	Depth of visibility	Depth a white disc can be seen
U.S. Forest Service Northern Goshawk Guidelines (CEQ, 1993)	Northern goshawk and its old-growth habitat	Sustain goshawk population and benefit old-growth habitat	Goshawk abundance, extent of habitat	Measures of abundance and habitat for goshawks and their prey
National Marine Fisheries Management	Coho salmon population	Maintain viable, self-sustaining Coho salmon population that supports subsistence and sport fisheries.	Coho salmon breeding success, fry survival, and adult return rates	Egg survival, egg, fry, and adult responses, spawning behavior
Salton Sea Ecosystem Restoration	Salton Sea	Maintain Salton Sea for multiple uses (see Section A.1.2)	Not yet determined	Not yet determined
Hubbard Brook National Experimental Forest (New York Times, 1996)	Forest plants	Maintain plant abundance	Plant abundance	Total plant biomass

An oligotrophic lake is one with low nutrient and high oxygen levels.

5.4 SUMMARY

There are many advantages to planning for ecological risk assessment. Carefully developed management objectives can:

- Produce risk assessments that effectively inform risk-management decisions;
- Help decisionmakers follow progress and demonstrate success;
- Foster understanding among risk managers, various analysts, and those affected by risk-management decisions;
- Provide a process for incorporating public values into decisionmaking;
- Focus risk efforts (planning, communication, management) on valued resources;
- Make ecological risk assessment subsequent risk-management decisions more transparent and accessible;
- Identify data gaps; and
- Promote consistency in ecological risk assessment and management.

In this guidance we have presented a process for developing management objectives when planning for ecological risk assessment: "Identify Decision Context" explained how to identify the risk-management at hand; delineate the values, legal, regulatory, and institutional requirements, risk-management options, and temporal and geographic context; and decide who should participate in the planning process. "Develop Objectives"described how to identify the overall management goal and refine it into more specific objectives, decide what we mean by "protect," and decide what is most important and how to achieve it; we also describe the attributes of a good set of objectives and suggest some prioritization criteria (Keys 1-4). "Identify Information Needs" explored how to determine what questions the risk assessment should address, what resources are available, and what additional information would be needed to decide what to do about an identified problem. Finally, we describe the relationship between planning and problem formulation.

Appendix A. CASE EXAMPLES

This chapter provides examples of how the process described above can be used in several settings. We have tried to show the parallels between each example and the steps described above in stepwise fashion. Note that although we have tried to illustrate how the process might have been applied in real projects; the projects did not actually follow the process described in this document because they all took place before it was written. Their use should not be taken as criticism, but as examples of how we think the process might be used in planning for risk assessment and decisionmaking.

A.1 SALTON SEA: AN EXAMPLE OF CONFLICTING OBJECTIVES

The Salton Sea restoration effort provides a good example of possibly conflicting objectives. Two agencies, the Bureau of Reclamation (federal government) and the Salton Sea Authority (state government) are leading the effort to restore this, the largest waterbody in California. It is designated as a repository for agricultural drainwater; but agricultural pollutants are a danger to fish and wildlife, and rising water levels threaten human land uses.

A.1.1 Identify Decision Context

The Salton Sea was created by flooding after irrigation water was brought into the Salton Sink to support agriculture. Over the years, it became an important recreation area and wetland habitat, although agriculture remains the primary land use in the area. Today the water is rising and has flooded buildings, roads and agricultural lands. The water level is maintained mainly by agricultural drainwater, which also contributes nutrients, pesticides, and other contaminants (e.g. salts). Disease outbreaks among birds have increased in frequency and severity and recreational use has declined.

What are we trying to decide? A method or combination of methods to restore the Salton Sea area to meet the goals specified in two laws that explicitly mention the Sea.

What is the Context? The project is enabled by two public laws dealing specifically with the Salton Sea. Public Law 102-575 was passed in 1992 and the Salton Sea Reclamation Act (Public Law 105-372) in 1998. The public laws direct activities to "the area of the Salton Sea," but do not provide specific boundaries. (Geographical boundaries were set during the course of the project and are different for different stages.) The laws also direct the project to "provide endangered species habitat, enhance fisheries, and protect human recreational values" among other things. The project also needs to comply with the National Environmental Policy Act (NEPA) and the California Environmental Quality Act (CEQA). The Environmental Impact Statement (EIS) prepared in compliance with these laws provided most of the information for this summary. Public values identified during the scoping process included recreational, aesthetic and spiritual values.

Who needs to be involved? The Bureau of Reclamation (federal government) and the Salton Sea Authority (state government) are the lead Agencies and therefore serve as risk managers. A number of other state and local agencies are cooperating with them. The Secretary of the Interior established a Salton Sea Science Subcommittee to provide information and evaluations for the project. This subcommittee serves as the risk assessment team for the project. The project provides for input from federal, state, local, and tribal agencies that have jurisdiction by law or that have special expertise with respect to any environmental impact involved in a proposed action. It also provides for more general public input through public meetings and workshops and educational efforts.

A.1.2 Develop Objectives

The EIS lists both an overall goal and specific objectives, although its terminology differs from that of this guidance. The overall goal is called the "purpose" of the project, and the objectives are called "goal statements." Only the subordinate objectives (both fundamental and means) are called "objectives."

Overall Goal The overall goal is: "to maintain and restore ecological and socioeconomic values of the Salton Sea to the local and regional human community and to the biological resources dependent upon the Sea."

What do we want to protect? The objectives include resident and migratory birds, endangered species, recreational uses and sports fishing. These are based upon the enabling laws and public input. Although the Salton Sea project obviously did not use any of the keys to what to protect presented in Chapter 3, it included objective targets from all three major approaches: Plants and Animals (birds and endangered species), Ecosystem Services (recreation and sports fishing), and Special Places (the Salton Sea area itself).

What do we mean by protect? Define objectives The objectives include general desired states as described by the terms "maintain," "restore," and "provide."

What's really important, and how do we get there? Review and structure objectives.
Means vs Ends: Although the EIS does not specifically discuss means vs. fundamental objectives, it is clear that the project directors gave some thought to this. The final list of five major objectives for the project appears to be entirely composed of fundamental objectives, even though the enabling laws included some means objectives ("reduce salinity," for example). There are some means objectives among the subordinate objectives listed for each of the five major fundamental objectives (e.g., reduce salinity is included as a subordinate objective under "Maintain a viable sport fishery").

Objectives Hierarchies: The subordinate objectives also include some subordinate fundamental objectives. For example, the objective dealing with birds and endangered species lists the California brown pelican, the desert pupfish, and other species as targets of subordinate objectives.

Select objectives - Characteristics of a good set. The EIS states that the goal statements are consistent with the direction contained in the Public Laws, address the underlying purpose and need for the project, and provide guidance for developing project alternatives. The objectives include both ecological and economic objectives. The Objectives appear to have most of the characteristics of a good set (although the subordinate objectives do mix means and fundamental objectives without distinguishing between them). The five major objectives are brief and compact. The project directors obviously did structure and prune the potential list from the law and from public input.

The five major objectives are:

- Maintain the Sea as a repository of agricultural drainage from the Imperial and Coachella Valleys
- Provide a safe, productive environment for resident and migratory birds and endangered species
- Restore recreational uses
- Maintain a viable sport fishery
- Provide opportunities for economic development along the shoreline

A.1.3 Identify Information Needs

What do we need to know to decide what to do? The major purpose for the science component is to provide a sound scientific foundation on which to base management judgments on various alternatives to achieve project goals.

What do we have to work with? Time frames, resources available The lead agencies have developed a work plan which discusses the sources and amount of funding and estimates time frames for each task.

What questions should the risk assessment address? The first and major job of the science component is to evaluate the potential environmental impacts of each of five major alternatives listed in the EIS.

Use of Objectives in the process The Salton Sea EIS alternatives are evaluated for their effect upon the stated objectives. The initial evaluation has already been done and makes it clear that some objectives are likely to be promoted and others hindered by some of the alternatives. Therefore, this information is likely to be crucial in the public reaction to the EIS alternatives and the final decision.

Planning Summary A summary of the decision context, goals, objectives and decision alternatives was provided in the Draft Salton Sea Restoration Project Environmental Impact

Statement/Environmental Impact Report (Tetra Tech, 2000).

A.1.4 Comments

A.2 HOMESTEAD AIR FORCE BASE: AN EXAMPLE WITH LATE-APPEARING INTERESTED PARTIES

Homestead Air Force Base (HAFB) is an NPL Superfund site in Florida that is being partially closed under the Base Realignment and Closure program. The 482nd Air Force Reserve Fighter Wing will remain and occupy one-third of the original land area (3000 acres), with the remaining 2000 acres slated for transfer to Dade County after environmental restoration is completed.

A.2.1 Identify Decision Context

What are we trying to decide? The decisionmakers–EPA and the Air Force in this case–were trying to decide what and how much remediation was required to protect human health and the environment at HAFB.

What is the context? Superfund provided the legal and regulatory context–site sediments were known to contain metals, PAHs, and pesticides, and public values were implicit in the CERCLA requirement that EPA protect human health and the environment. The physical setting was a large, fenced area containing some terrestrial hazardous waste sites (already remediated) and drained by swales, ditches, and canals. These small waterways drain into the Boundary Canal and thence into a stormwater reservoir. The Outfall Canal is fed by pumped drainage from a reservoir and at one time carried treated wastewater. The Outfall Canal flows through about 2 miles of commercial agricultural area before discharging via a passive salinity barrier into Biscayne Bay National Park, an Outstanding Florida Water.

Who needs to be involved? The initial (early 1990s) ecological risk assessment was conducted by the U.S. Air Force with EPA concurrence. Other parties that might have been involved were then addressing the urgent problems associated with widespread environmental and social devastation in the wake of Hurricane Andrew.

A.2.2 Develop Objectives

The group of course did not use the process described in this document, but they did identify the items described here.

What do we want to protect? This was based on Superfund's mandate to protect (human health and) the environment, and implicitly translated into "aquatic organisms in Boundary Canal, the storm-water reservoir, and Outfall Canal."

What's really important, and how do we get there? Among several considerations were minimizing risk to aquatic organisms on the site canals and ditches and minimizing the costs of remediation.

How do we choose? The Air Force proposed that if sediment concentrations were below levels thought to cause harm to aquatic organisms and if water concentrations in onsite waterbodies were below Ambient Water Quality Criteria, then no further action would be needed.

A.2.3 Identify Information Needs

What do we need to know? The risk managers needed to know whether contaminant water concentrations in the Boundary Canal, storm-water reservoir, or Outfall Canal exceeded Ambient Water Quality Criteria. If they did, then some action such as dredging contaminated sediments would be needed to reduce water concentrations. If not, then no further action was required.

What do we have to work with? Since the decision criterion was already determined to be whether Ambient Water Quality Criteria were exceeded, decisionmakers needed contaminant concentrations collected from the three waterbodies (and the personnel to collect them) and scientists to perform an exposure analysis to determine whether aquatic organisms were exposed to concentrations exceeding the criteria.

What questions should the risk assessment address? The risk assessment examined contaminant concentrations in sediments and the water column and estimated exposure to aquatic organisms. No contaminants were detected in surface water.

Use of Objectives in the process Although the original HAFB risk assessment was prepared long ago, the risk assessors considered the no-action alternative (i.e., leave the site alone) in their analysis. The basic objective was to leave the Boundary Canal, storm-water reservoir, and Outfall Canal in a state that would not harm aquatic organisms.

A.2.4 Comments

After sediment exposure concentrations were compared to toxicological data, the risk assessment concluded that no adverse effects would be expected in Boundary Canal, the storm-water reservoir, or Outfall Canal. The Air Force recommended that no further action be taken, and EPA concurred.

However, other interested parties scrutinized this decision and objected because their interests had not been addressed. They had not been involved earlier because virtually all of them were responding to the aftermath of hurricane Andrew. Nevertheless, they were dissatisfied with the decision because it did not address other animals in the food chain or the possibility that chemicals could be transported to Biscayne Bay.

There are several valuable lessons to be learned from the above case study. First and foremost, early stakeholder involvement is crucial in situations like this, especially since HAFB is so close to a sensitive natural resource. In fairness to all, however, earlier stakeholder involvement would have occurred had the state and local environmental agencies as well as the National Park Service not been so involved in dealing with the immediate and pressing problems associated with widespread environmental and social devastation in the wake of Hurricane Andrew.

Of equal importance to early stakeholder involvement is the need to adequately scope and plan an ecological risk assessment, beginning with problem identification and setting environmental protection goals and objectives. Often in the Superfund program, environmental protection goals and objectives are implicit and narrowly focused, and sometimes devote more attention to human-health issues than to ecological concerns such as which resources or entities to protect (e.g., general or specific animals, plants or ecosystems), attributes of those entities needing protection (e.g., survival, reproduction, habitat extent for key species; also referred to as assessment endpoints) and the desired state or direction of change for the entities under consideration (e.g., maintain or enhance populations of key species, maintain or restore habitat, maintain or restore ecosystem function, also referred to as ecological risk-management objectives). A broader discussion of these concepts is presented in chapters 4 and 5 of *Priorities* (U.S. EPA, 1997a).

Another lesson learned from the HAFB ecological risk assessment experience is to consider the broader context of all statutory requirements and the differing risk-management goals of the agencies and organizations involved in the project. For instance, the Superfund program does not necessarily strive for environmental restoration, rather, program emphasis is on risk reduction. On the other hand, State and Federal Natural Resource Trustees are often more interested in resource restoration, whether the entity to be protected is a population of animals or a habitat which is critical to the survival of key species. This is not to say that risk reduction is not important to the Natural Resource Trustees; however, the focus of the Trustees' involvement in Superfund cleanups is on natural resource damage assessments and the restoration of impacted entities.

In summary, Homestead Air Force Base illustrates the value of early planning, identifying and including interested parties, and articulation of management goals and objectives. It also demonstrates that explicit management goals and objectives lead to effective risk-management decisions that are more likely to be accepted by interested parties than those "understood" or left to interpretation.

A.3 WAQUOIT BAY: A DEMONSTRATION PROJECT

The Waquoit Bay Watershed Ecological Risk Assessment Case Study is one of five watershed case studies jointly sponsored by the Office of Water and the Office of Research and Development. These case studies were designed to demonstrate the ecological risk assessment process in a community setting; therefore, the Waquoit Bay experience combines many features of both the risk-based national-program approach and CBEP. (U.S. EPA, 1996d). The project was conceived to examine whether the 1992 *Framework for Ecological Risk Assessment* (which was superseded by the *Guidelines* in 1998) could be applied to watersheds. The study was initially funded with $30,000 in the early 1990s, although more funding was secured over the ensuing years.

Several federal and state government agencies have been studying or working in the area. In 1979 Waquoit Bay was designated as an Area of Critical Environmental Concern by the Commonwealth of Massachusetts. In 1988 the State of Massachusetts and the federal government jointly established the Waquoit Bay National Estuarine Research Reserve (WBNERR). The estuary is also a study site under a research project funded by the National Science Foundation, U.S. EPA, and the National Oceanic and Atmospheric Administration. In April 1995 a new U.S. Fish and Wildlife Refuge was established that will provide a contiguous arc of undeveloped land on the bay.

EPA Region 1 formally nominated the Waquoit Bay watershed in 1993 for inclusion in an EPA-sponsored project to develop watershed-level ecological risk assessment case studies. Waquoit was selected as one of the five watersheds because of the interest by a variety of organizations, the type of watershed, the diversity of stressors and the existence of willing leadership and extensive data. The value added by conducting a risk assessment is based upon (1) a focus on multiple stressors and related risk, (2) identification of significant data gaps and (3) an interpretation of risk that is useful for pending management decisions.

A.3.1 Identify Decision Context

Waquoit Bay, on Cape Cod, has long been prized for its natural beauty and recreational value, and as a habitat for a diversity of plant and animal life. Lately it has been under heavy pressure from residential development and recreational industries. Fish are dying, scallops have been extirpated, and the aquifer underlying the watershed is contaminated. The public is concerned. Several federal and state government agencies have been studying or working in the area.

What are we trying to decide? A plan to protect or restore the valued natural resources of the Bay using approaches available to the organizations involved in the project.

Context This was undertaken as a watershed project, so the initial context is the Waquoit Bay watershed. The first step in establishing a goal for the project was a public meeting at which people were asked for their input on what was valuable to the public about the Waquoit Bay watershed. A wide range of amenities were suggested, including scenic views, recreation, and open space. Among these that would be considered ecological (include some non-human biological component), aquatic and wildlife habitats were the most frequently mentioned. Examples were indigenous wildlife, flyway integrity, and fish and shellfish. The legal and regulatory tools available were limited to those administered by the Agencies involved in the project, which included EPA.

Who needs to be involved? EPA and the WBNERR share the risk-management role for this project. Several other Federal, State, and local agencies are involved. The risk assessment resources are limited to those that the involved agencies can contribute to the project. The project provides for input from the general public at public meetings and the involvement of many interested groups as partners in the project.

A.3.2 Develop Objectives

The Waquoit Bay Watershed project was intended as a case study of the risk assessment planning and problem formulation process. Therefore it developed a set of explicit goals and objectives. The objectives were developed for the specific purpose of guiding the risk assessment.

Overall Goal The written goals established for Waquoit Bay by 14 local, regional, and national resource management organizations with jurisdiction in the watershed were collected by the team and summarized. These organizational goals were used to refine the risk assessment management goal and develop the 10 management objectives. The risk assessment team drafted an overall goal based on the results of the public meeting:

> "Reestablish and maintain water quality and habitat conditions in Waquoit Bay and associated wetlands, freshwater rivers, and ponds to (1) support diverse, self-sustaining commercial, recreational, and native fish and shellfish populations, and (2) reverse ongoing degradation of ecological resources in the watershed."

Specific Objectives Since this goal by itself was considered too general to serve as a basis for setting assessment endpoints, 10 more specific objectives were also established, based on the goals of 14 organizations working in the area.

What do we want to protect? Although this project obviously did not use the "Key to what to protect" it included objective targets from all three major approaches: Plants and Animals (fish, scallops), Ecosystems (rivers and ponds), and Special Places (the Waquoit Bay area itself).

What do we mean by "protect?" Define objectives The objectives include desired states as described ("maintain"and "restore") and direction of preference ("reduce").

What's really important, and how do we get there? Review and structure objectives.
Means vs. Fundamental Objectives The project did not specifically designate

fundamental and means objectives. Most of the objectives (listed below) appear to be fundamental but some of them (those dealing with eelgrass, for example) are means toward accomplishing other objectives, though they may also be fundamentally important.

Objectives Hierarchies Objectives are grouped hierarchically by the type of affected area (freshwater, estuarine, or both)

Select objectives - Characteristics of a good set. The working management goal, summary of organizational goals, and 10 proposed management objectives (all developed by the risk assessment team) were presented to managers of concerned organizations at a meeting in February 1995. The goal and objectives were modified and approved by the organization representatives at this meeting. Participants in this meeting are considered the risk-management team for the risk assessment.

The full set of objectives are listed in Table A.1. The project did not specifically apply the set of characteristics listed in Chapter 3, but the set of objectives seems to be reasonably compact and measurable. Given the limited authority of the organizations involved, the objectives may not all be controllable, but that is to be expected in a project like this whose aim is to see what needs to be done, without any specific legal authority. The set appears to be complete in so far as e*cological* issues are concerned, however, they are entirely ecological, although it is clear that the project needed to consider other types of issues, such as economic.

Table A.1. Objectives for Waquoit Bay

Affected Area	Management Objective
Estuarine and Freshwater	1. Reduce or eliminate hypoxic or anoxic events
	2. Prevent toxic levels of contamination in water, sediments and biota
	3. Restore and maintain self-sustaining native fish populations and their habitat
Estuarine	4. Reestablish viable eelgrass beds and associated aquatic communities in the bay
	5. Reestablish and self-sustaining scallop population in the bay that can support a viable sport fishery.
	6. Protect shellfish beds from bacterial contamination that results in closures
	7. Reduce or eliminate nuisance macroalgal growth
Freshwater	8. Prevent eutrophication of rivers and ponds
	9. Maintain diversity of native biotic communities
	10. Maintain diversity of water-dependent wildlife

A.3.3 Identify Information Needs

What do we need to know to decide what to do? Eight assessment endpoints were selected based on three criteria: how well they represent the management goal and objectives (societal value), how well they represent ecological integrity in the ecosystem (ecological relevance), and how likely they are to be exposed to and adversely affected by known stressors (susceptibility). The conceptual model for Waquoit Bay describes the relationship of various sources and stressors to each of the eight assessment endpoints. It also indicates what measures of effect will be used for each assessment endpoint. The task of the risk assessment will be to relate these sources and stressors to the assessment endpoints in order to determine their likely impact on the stated objectives.

What do we have to work with? Time frames, resources available During planning, participants recognized that the risk assessment would be restricted by severe resource limitations. All members of the risk assessment team were professionals from federal, state, and local organizations who provided their expertise and time without grant or contract funds. Limited contract support was used to provide some assistance to the team. No new data were collected to conduct the assessment, but best efforts were made to use available data effectively.

The Waquoit Bay risk assessment will not be able to assess most of the risk paths laid out in the conceptual model because the resources for the analysis are extremely limited. However, setting out the full range of objectives and examining the ways in which various risk models applied to each of them enabled the project leaders to make a considered choice of how best to use these resources.

What questions should the risk assessment address? The analysis will concentrate on nutrient loading, which is thought to be the most important stressor for most of the assessment endpoints. The Waquoit Bay problem formulation provides a thorough justification of this choice. It also gives considerable detail about the stressors and risk hypotheses. These will not be included in the analysis plan, but should be completed at some time.

Use of Objectives in the process The risk assessment team for Waquoit Bay selected assessment endpoints using the 10 specific objectives discussed above to guide them on what was of societal value; therefore, the risk-management team did not need to be so closely involved with this step as with previous steps. Relating the risk assessment conceptual models to the objectives also helped the project leaders make a reasoned choice about how to prioritize the risk analysis.

A.3.4 Comments

About context: The geographic boundaries were defined from the beginning by the watershed. One of the first steps in the process was a public meeting at which people were asked for their input on what was the Waquoit Bay watershed. Although the project was initiated organized by just two organizations, risk assessors and managers were selected from among a larger group of interested organizations working in the area.

About management objectives: The Waquoit Bay Watershed project was intended as a case study of the risk assessment planning and problem formulation process. Therefore it developed a set of explicit goals and objectives. The objectives were developed for the specific purpose of guiding the risk assessment. The entities that form the focus of the objectives are evidently based on concern for particular groups of plants and animals, but the objectives do not focus on these alone. Most types of aquatic ecosystems are included in the objectives, as are wetlands (for the water-dependent wildlife). Special places are represented by the endangered species habitat, and indeed by the bay itself. Some of the objectives are means for other objectives in the set. For example, objective 5 (reestablishment of scallops) would require achieving objective 1 (elimination of hypoxia), objective 2 (prevent toxicity, objective 4 (reestablishment of eelgrass, and objective 7 (eliminate macroalgae). However, it is possible that all the objectives are seen as fundamental (important in themselves) even though some would lead to the accomplishment of others. Some of the objectives which appear to be means are listed as ultimate objectives for organizations working within the Waquoit area. There is no evidence that the Waquoit team went through the questioning necessary to separate means from ends.

About questions for the risk assessment and resource needs: The risk assessment team for Waquoit Bay selected assessment endpoints using the 10 specific objectives discussed above to guide them on what was of societal value; therefore, the risk-management team did not need to be so closely involved with this step as with previous steps. Relating the risk assessment conceptual models to the objectives also helped the project leaders make a reasoned choice about how to prioritize the risk analysis.

The Waquoit Bay risk assessment will not be able to assess most of the risk paths laid out in the conceptual model because the resources for the analysis are extremely limited. The analysis was to concentrate on nutrient loading, which was thought to be the most important stressor for most of the assessment endpoints. The Waquoit Bay problem formulation provides a thorough justification of this choice. It also gives considerable detail about the stressors and risk hypotheses. These will not be included in the analysis plan, but should be completed at some time.

A.4 AN OPPT EXAMPLE

The OPPT process for PMN review was developed long before this guidance document was even conceived, and before any of the recent risk-management process proposals that discuss the need for early involvement by decisionmakers were developed. Therefore, it does not follow the process described in this document. In fact, unlike the other examples in this chapter, it does not even use specific objectives. However, it is useful because it is fairly typical of many EPA risk assessment practices in various programs. The PMN process probably works better than many similar processes because it is a screening process.

Under the Toxic Substances Control Act (TSCA), manufacturers and importers of new chemicals much submit premanufacture notification (PMN) to EPA before they can begin to manufacture or import the chemical. EPA's Office of Pollution Prevention and Toxics (OPPT) must assess the risks associated with the chemical and decide whether the chemical can be manufactured or imported and if there are conditions placed upon the manufacture or import of the chemical. A statutory requirement limits EPA's review time to 90 days. The manufacturer does not have to initiate any tests prior to submitting a PMN and so only limited exposure and effects data are provided. Coupled with the large number of submissions and amount of resources allotted toward review, OPPT must perform ecological risk assessments efficiently and effectively. EPA's review of a specific alkylated diphenyl is discussed below, although the particular chemical identity is confidential.

A.4.1 Identify Decision Context

What are we trying to decide? EPA must determine whether or not to allow manufacture of import of a chemical, and if so, whether there are conditions to be placed upon the manufacture or import of the chemical.

Context The general interest of the public in the protection of human health and the environment is considered by EPA during PMN review. The PMN submitter is one of the most obvious stakeholders in the outcome as EPA's analysis can determine whether or not a particular manufacturer can produce a chemical or under what condition. This can significantly affect the manufacturer's business. The chemical is reviewed under TSCA which allows that (with respect to ecological effects) EPA may issue requirements to prohibit or limit the manufacture of a new chemical if it may present an unreasonable risk to the environment. Affected ecosystems are generally not known specifically, although assumptions can be made based upon manufacturing and use information. The chemical is expected to affect aquatic life in rivers, streams and lakes.

Who needs to be involved? EPA risk managers are involved, however, decision making is fairly routinized due to the constraints on the risk assessments. Typical review of a PMN chemical estimates concern concentrations and compares it to predicted environmental concentrations or assesses the number of times per year the concern concentration is exceeded. EPA Risk assessors recommend courses of action to risk managers on the basis of these results. Input to specific PMN cases is limited to the submission by the manufacturer or importer and any follow-up information EPA requests from the submitter. The procedures and policies regarding human health and ecological hazard, exposure, and risk assessments have been presented to the public and stakeholder via EPA-sponsored workshops, Federal Register publications, and publication in peer-reviewed journals.

A.4.2 Develop Objectives

Overall Goal The goal as specified in TSCA is "to regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment, and to take action with respect to chemical substances and mixtures which are imminent hazards ..." Goals and objectives are not specified uniquely for each PMN.

What do we want to protect? Objective targets include plants and animals and are described as aquatic life in rivers, streams, and lakes.

What do we mean by "protect?" Define objectives The objective is to prevent "unreasonable risk of harm or injury to health or the environment," defined as "water, air, and land and all living things" by regulating regulate substances that are "imminent hazards."

What's really important, and how do we get there? One way to protect "all living things" is to protect aquatic life. A means to this end is to protect fish, invertebrates, and algae.

A.4.3 Identify Information Needs

What do we need to know to decide what to do? The risk assessment uses available data on the chemical and structure activity relationships to predict concentrations of the chemical that may be found in water. In addition, the same information is used to assess concentration levels that may cause concern for effects to fish, invertebrates, and algae.

What do we have to work with? Time frames, resources available EPA must make decisions on PMN chemicals within 90 days of receiving a submission. Given the short time frame coupled with the large number of PMNs processed by OPPT each year, limited time and effort are applied to each risk assessment.

What questions should the risk assessment address? The risk assessment needs to assess the concern concentration for the most sensitive species (fish, invertebrate, or alga) and the most sensitive effect, which is usually long-term change in growth and reproduction but can also include mortality. Risks for chronic effects are assessed via an exposure model that estimates whether the concern concentration is likely to be exceeded more than 20 times in a given year.

Use of Objectives in the process The basic objective is to develop assessment endpoints that will allow assessors to determine whether there might be a risk to human health or the environment. Risk assessors have chosen several assessment endpoints to determine this as shown Table A.2.

Table A.2. OPPT Assessment Endpoints.

ENTITY	ATTRIBUTES
Fish	survival, growth, reproduction
Aquatic Invertebrates	survival, growth, reproduction
Phytoplankton	survival, reproduction

Higher trophic levels (fish, birds, mammals)	survival, growth, reproduction

A.4.4 Comments

The objective given here is the very broadly defined TSCA goal to prevent unreasonable risk of harm or injury to health or the environment." There are no specific objectives stated, and the "environment" is defined only under the very broad TSCA definition of "water, air, and land and all living things." Nonetheless, the risk assessors have come up with specific assessment endpoints.

This is a not unusual situation where the burden of defining what is at stake and direction of preference or desired state has been left to the risk assessors and implicitly taken as a scientific process. Because this is a screening assessment and apparently does not require much in the way of weighing one objective against another, the process can work, although it would be desirable to make it more explicit.

The train of logic to reach the assessment endpoints could be something like this: If the risk to aquatic organisms is removed the entire environment will be protected. If risk to fish, aquatic invertebrates and phytoplankton are removed, then all aquatic organisms will be protected. Therefore, if the estimated concentrations of a chemical are below the levels specified on the screen for these organisms, all aquatic life and thus the environment as a whole will be protected.

The reason this can work is that a screening assessment passes only those cases which present virtually no risk. Any case not meeting this criteria requires further action. Therefore, no detailed, specific assessment is needed at this screening stage and a goal as broad as that given by TSCA can be the basis for evaluation. However, two points should be considered.

1. Under this approach, the risk assessment actually addresses the broad question of the risk of any environmental affects, not the narrow issues listed above (under "What questions should the risk assessment address?"). Discussion of results and uncertainty should revolve around the broader issue.

2. Once the problem goes beyond screening (i.e., when some risk is indicated), management objectives will be needed to guide the assessment and deliberation. This is true even though no additional data are available. Without such guiding objectives, the discussion of risks and trade-off with other issues (such as the cost of obtaining more data) will be subject to all of the ailments discussed earlier in this document. For example, discussion may center around effects on species similar to those tested even though these are not seen as particularly valuable by the decision makers. Meanwhile, highly valued objects (such as ecosystem services) may be left out of the analysis and discussion even though they are likely to be at risk. Given the fact that the objectives (like the general analysis scheme) will need to be developed generically (not separately

for individual chemicals), it may be preferable to develop objectives to guide the entire process.

GLOSSARY

Assessment endpoint–An explicit expression of the environmental value that is to be protected, operationally defined by an ecological entity and its attributes. For example, salmon are valued ecological entities, and reproduction and age class structure are some of their important attributes. So "salmon reproduction and age class structure" might form an assessment endpoint.

Desired state–A characteristic of a management objective that represents the condition of an entity that will be achieved or maintained following risk management.

Direction of preference–A characteristic of a management objective that represents the direction of change in an entity that is desired following risk management.

(Ecological) Entity–As used here to specifically refer to ecological entities, a general term that may refer to a species, a group of species, or a specific habitat. An entity and some attribute comprise an assessment endpoint.

Ecological risk assessment–The process that evaluates the likelihood that adverse ecological effects may occur as a result of exposure to a stressor.

Exposure–The contact or co-occurrence of a stressor with a receptor.

Fundamental objective–A "bottom-line" management objective for something that is valued in its own right (not just as a way to accomplish something else). Compare to "means objective."

Interested party–An individual or organization who has a strong interest in the Agency's work and policies. Interested parties (also known as stakeholders) may also interact with EPA on behalf of another person or group that seeks to influence the Agency's future direction. Some stakeholders are, or believe they are, affected parties–individuals or groups who will be impacted by EPA policies or decisions.

Management goal–A general statement of the desired condition or direction of preference for the entity to be protected; often developed independently of any risk assessment, such as part of federal legislation.

Management objective–A specific statement about something one desires to achieve that includes an object (in this case, the ecological entity targeted for protection), a decision context, and a direction of preference. It is typically derived from a management goal on an assessment-specific basis.

Management option–Any potential method for preventing, reducing, or controlling risk, including regulatory approaches, engineering controls, communication and education, behavioral choices, or market-based incentives.

Means-ends network–A way to identify fundamental objectives and distinguish them from means objectives by asking a series of "Why is this important?" questions.

Means objective–An objective that is used to accomplish another objective, rather than representing the desired state or direction of preference of the entity a risk manager wishes to protect. Compare to "fundamental objective."

Measure–An observation that may describe exposure, effects, or ecosystem or receptor characteristics, used to describe the assessment endpoint or factors affecting risk to it.

Object–An entity that is the target of a management goal or objective.

Objective–A statement of something that one desires to achieve that includes an object, a decision context, and a direction of preference. Objectives identify what is at stake; they do not prejudge decisions.

Planning–A process for preparing to conduct a risk assessment that involves establishing management objectives, reaching agreement on who needs to be involved as well as scope, timing, and resources, and identifying what information will be needed to inform a particular decision.

Risk assessor–An individual or group who carries out scientific or technical aspects of a risk assessment.

Risk management–A process of evaluating, selecting, and implementing actions to reduce risks.

Risk manager–An individual or group with authority to evaluate, select, or implement actions reduce risks.

Receptor–The entity exposed to a stressor.

Stakeholder–See Interested party.

Stressor–Any physical, chemical, or biological agent that can induce an adverse response.

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