1 Defining the Field

Risk assessment is the product of a shotgun wedding between science and the law.

William Ruckelshaus

"Technical support for decision making under uncertainty" is the only definition of risk assessment that describes its many uses. As Bernstein (1996) plausibly argues, the use of rational methods for dealing with the uncertain future in place of prayers, prophecies, traditions, auguries, and hunches is the hallmark of modern culture. Risk assessment began with the need to calculate odds for gamblers, and subsequently, in seventeenth-century England and the Netherlands, with the need to determine premiums on annuities and the probability that a ship sent on a trading voyage would return successfully (Hacking 1975; Bernstein 1996). Most risk assessors are still involved in finance and insurance (Melnikov 2003). Risk assessment has since spread to many spheres of human endeavor including engineering, wildfire management, medicine, and environmental regulation. The general definition indicates that two features are common to all of these enterprises: a decision to be made and uncertainty concerning outcomes.

The conventional, objectivist definition of risk is: a combination of the severity (nature and magnitude) and the probability of effects from a proposed action. Severity may be variously described depending on the situation, e.g., the number of deaths, the reduction in abundance, and the reduction in areal extent. Probability may be derived from an estimate of the frequency of an effect among individuals in an exposed population or a hypothetical frequency of effects if the same decisions were made multiple times. For example, a risk might be a 0.3 annual frequency of mass mortalities in an exposed population, or a probability that an effluent will reduce the number of fish species in a lake by as much as 15%. Alternatively, risk may be defined subjectively as a state of mind of an individual making an uncertain decision or of those exposed to the consequences of a decision. This subjective risk is an important issue when assessing risks to humans, who are subject to anxiety and dread, but is less relevant to the topic of this book. Note that subjective risk is fundamentally different from the Bayesian, subjective interpretation of probability in estimates of objective risk (Chapter 5).

The terms "environmental risk" and "ecological risk" can cause confusion because of their similarity. In the United States, the term environmental risk has been used to describe risks to humans due to contaminants in the environment. Ecologists subsequently invented the term ecological risk to refer to risks to nonhuman organisms, populations, and ecosystems (Barnthouse and Suter 1986). However, the term environmental risk is commonly used in Europe in the way that ecological risk is used in the United States.

The decision to be supported is too often neglected in risk assessment. "It is hard to imagine risk analysis existing without the need for decisions, without the need for a systematic approach to aiding those who make decisions" (Crawford-Brown 1999). Yet, the most influential guidance for environmental risk assessment (ERA) has stressed the need to isolate risk assessors from the influence of decision makers in order to avoid bias (NRC 1983).

ERA practice has tended to emphasize the risk assessment process in the abstract without a grounding in a decision-making process. For example, due to the peculiarities of Superfund regulations, the guidance for baseline ERA at contaminated sites in the United States does not address the consequences of remedial decisions (Sprenger and Charters 1997). This situation is changing with the realization that the highest-quality assessment is worthless if it does not address the needs of the decision maker (National Research Council 1994; The Presidential/Congressional Commission on Risk Assessment and Risk Management 1997). Risk-based environmental decisions generally fall into three categories: should we permit x (e.g., use of a new chemical, release of an effluent, or increased harvest of a resource); what should we do about x (e.g., remediate, treat, or restore); should we do x, y, or z (e.g., which pest management method poses the least risk)?

Probability, the other core concept in ERA, has also been surprisingly neglected. The probabilities that characterize risks may result from variability or uncertainty (Chapter 5). Although quantitative methods for analyzing uncertainty and variability in terms of probability have existed for centuries, most ERAs treat them qualitatively or in nonprobabilistic terms. This does not mean that uncertainty and variability are ignored or that, as some have contended, most current risk assessments are not truly assessments of risk. Rather, they are often dealt with by semiquantitative precautionary practices. That is, conservative assumptions and safety factors have been assumed to provide sufficient safety to avoid the need for a formal probabilistic analysis. However, formal probabilistic analysis of uncertainty is increasingly common. This is because the semiquantitative practices are subject to criticism that they are insufficiently precautionary, excessively precautionary, or precautionary to an undefined degree.

Risk assessment uses science, but is not science in the conventional sense, i.e., it does not seek to develop new theories or general knowledge. It rather uses scientific knowledge and tools to generate information that is useful for a specific purpose. In this sense, risk assessors are like engineers, and in fact much of the practice of ERA has been developed by engineers (see, e.g., Haimes 1998). However, contrary to some critics, risk assessment is based predominantly on factual information and scientific theory, and is not simply a scientific smoke screen for policy. Typically, risk assessments and their components are intensely and publicly reviewed and are often challenged in court. As a result, the use of bad science to justify a preordained decision is likely to be detected in contentious cases.

1.1 PREDICTIVE VS. RETROSPECTIVE RISK ASSESSMENT

The EPA's framework and guidelines for ecological risk assessment and the previous edition of this text distinguish retrospective from predictive risk assessment. This distinction has created some confusion, because it is nonsensical to speak of risks of events in the past. This text eliminates that distinction and focuses instead on the decision-supporting function of risk assessment. Hence, when assessing risks from spills or other past events, we are assessing risks associated with future consequences of those events. They include ongoing toxic effects, the spread of toxic levels of contaminants to other areas, loss of habitat due to failed restoration, and other sequela. Even when performing assessments to set monetary damages for past actions, we are not assessing risks of past events. For example, during the Exxon Valdez oil spill, a certain number of sea otters, bald eagles, and other wildlife were killed. The natural resource damage assessment (Section 1.3.8) did not assess risks to those organisms. Rather, to the extent that the uncertainties in the damage assessment could be interpreted as risks, they should be interpreted as risks that the level of monetary damages assessed will be either insufficient or excessive with respect to the cost of restoration of the populations of those species, making good lost services of nature, and otherwise remediating ecological and economic injuries.

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Although all risk assessments are in some sense predictive, it does not mean that information concerning the past is irrelevant. Analyses of such data may be used to help formulate the assessment problem, elucidate trends that may extend into the future, identify causal relationships between agents and injuries, and define a baseline for remediation and restoration. By analogy to human health epidemiology, analyses of past ecological effects and their causes are termed ecological epidemiology (Chapter 4). Hence, what the US Environmental Protection Agency (US EPA) terms retrospective assessments should be thought of as predictive assessments of the future consequences of past actions.

1.2 RISKS, BENEFITS, AND COSTS

When assessing an action, it may be necessary to consider the risks associated with the action, the potential benefits, and the costs of carrying out the action. For example, when considering whether to apply a remedial technology to a contaminated site, it is important to consider the risks of ecological injury from the contaminants and from the remedial action itself (e.g., injuries to benthic communities due to dredging), the benefits of the action (e.g., reduced contaminant risks to epibenthic fish), and the cost of carrying out the remediation. Which of these dimensions is formally analyzed and how they are compared depends on the context. Some laws require consideration of costs while others do not allow it. Further, there is considerable variation in whose benefits, costs, and risks are considered. For example, the registration of pesticides or biocontrol agents in the United States may consider costs and benefits to farmers if there are no good alternatives to the pesticide in question, but not the costs to the manufacturer. Although the primary focus of regulatory agencies is on the risks from new chemicals, effluents, spills, and exotic organisms, the consideration of benefits and costs as well as ethical concerns and public preferences can provide a more complete basis for decision making (Chapter 36). Although costs to the regulated party can be readily identified and relatively easily estimated, the benefits to the environment are always incompletely identified and are difficult to quantify. Hence, cost-benefit analysis tends to be biased against environmental protection.

1.3 DECISIONS TO BE SUPPORTED

The form and content of an ecological risk assessment is determined by the decision to be supported. This is true not only because different decisions require different sorts of information, but also because of the different formal and informal traditions and constraints that have developed in the various decision-making cultures. For example, the assessments of new industrial chemicals in the United States must be performed within 90 days and normally cannot demand data generation. On the other hand, assessments of contaminated sites may require years of effort involving expensive field surveys, sample collection, analysis, and testing.

1.3.1 Prioritization of Hazards

In the United States and many other countries, priorities for environmental management have been set in a highly inconsistent manner, based primarily on public pressures as translated by legislators into laws and budgets. Because resources for environmental management are limited, it would be desirable to devote them to the highest priority hazards rather than the ones that were given a strong mandate some decades ago. This concept of using risk assessment to prioritize hazards is appealing (Grothe et al. 1996), but controversial in practice (Finkel and Golding 1995).

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The US EPA and its Science Advisory Board have performed comparative risk assessments for the purpose of prioritization (SAB 1990, 2000; MADEP 2002). The results have been controversial and have not greatly influenced the EPA's regulatory and management practices. However, they have led to the development of guidance for comparative assessment and to the performance of such assessments in most states of the United States (Bobek et al. 1995; EPA 1997a; Feldman et al. 1999). The performance of such assessments is difficult because of the paucity of information and the difficulty of comparing risks to disparate entities and processes over large ranges of spatial and temporal scales. As a result, expert judgment has been used in the absence of data analysis, as in the case of Harwell et al. (1992), and even that has been largely replaced as a means of prioritization by consensus of representatives of stakeholders and the public (EPA 1997a). Consensus-based assessments have some potential benefits beyond prioritization itself, such as better understanding of environmental issues and promotion of coordinated action by the participants, but they have not been followed and implemented by prioritized risk management programs (Feldman et al. 1999). Prioritization based on actual estimation of risks must await further development of assessment methods and a willingness to devote sufficient resources to the problem.

The need to replace expert judgment with technical approaches is illustrated by the consideration of oil spills in the prioritization of environmental hazards by the US EPA's Science Advisory Board. They gave a low rank to oil spills because of the perception that ecological effects of oil in the marine environment were short term (SAB 1990). However, that perception seems to be a result of a lack of high-quality long-term monitoring. It has been reported that some detectable effects of the Exxon Valdez spill persisted for at least a decade

(Peterson et al. 2003).

Beyond the technical difficulties, risk-based prioritization has had little influence in regulatory agencies, in part because it may be considered illegal or immoral. The potential illegality arises because environmental laws in the United States and most other countries require protection independent of other laws. For example, the US EPA cannot decide to stop enforcing the Clean Air Act because resources would be more effectively spent enforcing the Clean Water Act. In addition, prioritization may assign high priority to hazards for which no legal authority for action exists. The accusations of immorality most commonly arise from the accusation that technical analysis is used to minimize the legitimate subjective concerns of citizens or to ignore risks to small groups with particular exposures (e.g., indigenous people consuming traditional foods). On the other hand, consensus-based prioritization may also provide unequal protection. When prioritization is based on a stakeholder process, there is a potential for higher ranking of the risks that concern the most articulate and influential segments of the population. Because of these issues, the potential benefits of a rational prioritization process must await a mandate from the highest levels of government to overcome the technical, social, and legal impediments (Davies 1996).

COMPARISON OF ALTERNATIVE ACTIONS 1.3.2

As discussed above, risk assessment is performed to inform decisions concerning alternative actions. Unfortunately, the range of alternatives is often small and the range of issues considered is often narrow. For example, registration of a pesticide often does not include consideration of the risks from the alternatives, existing pesticides that may be more persistent or toxic, and nonpesticide pest control techniques that have their own potentially severe ecological risks. Rather, the alternatives are typically restricted to registration, registration with restrictions, or rejection of the new pesticide. It is clear that the decision-making process can meet the legal mandate and be rational within its scope, but result in a less than optimum decision for the environment.

Comparative risk assessment raises two complications. First, it is not adequate to estimate risks; one must also estimate the benefits of the alternative actions. A relatively low-risk alternative action may be undesirable, because it produces small benefits or even net decrements. The comparison of risks and benefits (not just costs and benefits) is important in any case, but is essential when comparing a set of alternatives. Second, comparison of risks often involves the common units problem. That is, if the alternatives involve disparate risks and benefits, they may not be directly compared by simply quantifying future ecological conditions. The temporal integration of expected benefits and decrements of each action, expressed in common units, is termed net environmental benefit analysis (Efroymson et al. 2004). If the comparison must consider the costs of implementation, the net benefits must be monetized to yield a cost—benefit analysis (Chapter 36).

Comparative risk assessment is a different way of looking at any of the decisions discussed in this chapter. Although all risk-based decisions involve the comparison of at least two alternatives (e.g., permit an action or not), a more comparative approach opens up the process to a range of potentially desirable alternatives. However, it complicates the assessment and decision-making process. Approaches to these issues are discussed in Chapter 34.

1.3.3 PERMITTING RELEASES

Ecological risk assessments have been concerned primarily with two activities: determining whether releases of chemicals or other agents should occur and determining how to deal with the releases that have already occurred. Clearly, we should do a better job of the former to reduce the need for the latter. Ecological risk assessments for permitting releases are distinguished by the type of agent released (i.e., chemicals, effluents and other wastes, and exotic organisms) and by whether the agents are novel or have been permitted before and are being reconsidered.

1.3.3.1 Chemicals

In the United States, new chemicals are regulated as pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as industrial chemicals under the Toxic Substances Control Act (TOSCA) or under the Food, Drugs, and Cosmetics Act (under which ecological concerns have received little attention). The difference in ERA under FIFRA and TOSCA serves to illustrate the importance of legal constraints on assessment practices. Because pesticides are designed to be toxic, FIFRA allows the government to require relatively extensive characterization and testing of new chemicals by the manufacturer and allows the government time to complete the assessment. TOSCA does not allow characterization and testing requirements beyond basic descriptions of the compounds and allows only 90 days for assessment and decision making. As a result, assessment of pesticides has been based on a fairly elaborate tiered scheme and is moving to a system of probabilistic assessment (Urban and Cook 1986; Ecological Committee on FIFRA Risk Assessment Methods 1999a,b). The pesticide industry has responded with its own tiered and probabilistic ecological risk assessments of products such as atrazine (Section 32.4.4). In contrast, ERA under TOSCA relies on small data sets, quotient methods, and assessment factors of 10, 100, or 1000 (Zeeman 1995; Nabholz et al. 1997). Assessments of new chemicals in the European Union and elsewhere have their own testing requirements and schemes, but in general they rely on tiered testing approaches and simple methods using factors and quotients (RIVM 1996; Royal Commission on Environmental Pollution 2003). Similar assessment approaches have been developed by responsible chemical manufacturers to assure that their products "are safe for the environment" (Cowan et al. 1995). Methods for ecological assessment of chemicals are rapidly

developing because of advances in science such as computational toxicology and because of renewed interest in existing chemicals, particularly the European Community's REACH regulations (Bradbury et al. 2004).

1.3.3.2 Effluents and Wastes

The release of aqueous and gaseous effluents and other waste streams is regulated in the United States and most other countries through a permitting process. The most important of these from an ecological perspective is the permitting of aqueous effluents, by a process known as National Pollutant Discharge Elimination System (NPDES) in the United States. This is accomplished primarily by specifying that the effluent will not violate water quality standards. Standards include concentrations, durations, and frequencies of exceedence that must not be violated (Section 2.2). In most states, standards are based on National Ambient Water Quality Criteria published by the EPA (1985). Equivalent criteria and standards are used in other nations (Roux et al. 1996; CCME 1999; ANZECC 2000). Alternatively, permits may specify that the toxicity of the effluent be tested using standard acute or subchronic tests (Section 24.2) or that the receiving community achieve biological criteria (EPA 1996a; Ohio EPA 1998).

1.3.3.3 New Organisms

Organisms may be deliberately imported for horticultural use, biological control, pets, or other purposes. Determining whether an importation should be permitted is conceptually difficult because organisms are complex and can display unexpected properties or may evolve new properties. Risk assessments in support of the regulation of importation of foreign organisms may be based on structured expert judgment as in the United States (Orr 2003) or more objective analyses. An example is the assessment of import of shrimp for aquaculture that may carry a virus, which is pathogenic to native shrimp (Fairbrother et al. 1999). Genetically engineered organisms are regulated in the United States as though they are chemicals. That is, novel biocontrol agents are regulated by the pesticides office of the EPA, and other novel organisms are regulated like industrial chemicals by the toxic substances office.

1.3.3.4 Items in International Trade

The World Trade Organization (WTO) 1995 Agreement on the Application of Sanitary and Phytosanitary Measures and some regional trade agreements require that a risk assessment be performed if a nation excludes an item from importation due to risks that it poses to human health, animals, or plants. The exclusion may be based on the determination that the item may be toxic, a pathogen, a pest, or otherwise pose an unacceptable risk, or there is a significant risk that an item may be a carrier of such a hazardous agent. Items that have been excluded from import range from controversial genetically modified crops to wood and plant products that may contain exotic pests. The WTO agreement is more demanding than most legal bases for risk assessment, in that risks must be expressed in terms of probabilities or likelihoods, not possibilities (Codex 1997; OIE 2001). New Zealand provides an excellent guide for conducting probabilistic risk assessments for imports of animals, animal products, and associated pathogens and pests (Murray 2002).

1.3.4 LIMITING LOADING

The regulation of the uses of chemicals and their disposal in effluents or solid wastes fails to be protective because of the effects of multiple releases from multiple sources. One solution is to define the rate at which an ecosystem may receive a pollutant from all sources without unacceptable effects. For atmospheric deposition, this is referred to as the critical load (Hettelingh and Downing 1991; Holdren et al. 1993; Hunsaker et al. 1993; Strickland et al. 1993). The same term is applied to aqueous pollution (Vollenweider 1976), but for water quality regulation in the United States, it is referred to as the total maximum daily load (TMDL) (Houck 2002). Setting limits on loading requires defining the resources to be protected (e.g., water quality, biotic communities, or human health) and the endpoints to be measured for each (e.g, water quality criteria, benthic invertebrate species richness, and soil pH). A mixture of field measurements and modeling is then used to determine whether a limit is exceeded, whether a new source will cause exceedence, the relative contributions of existing sources to an exceedence, or the likelihood that a remedial action will result in acceptable loading. In some cases, this is relatively straightforward. For example, if a persistent and soluble chemical is released at multiple points in a stream or watershed, simple transport and fate modeling can be used to determine contributions to exceedence of a water quality criterion at a downstream point. However, other cases are complex and difficult. For example, NOx deposition in a watershed is difficult to trace back to point and nonpoint sources in the atmosphere, and effects on terrestrial and aquatic ecosystems are difficult to measure or predict because of the complexity of nitrogen cycling and acidification and eutrophication processes.

1.3.5 REMEDIATION AND RESTORATION

The predominant use of ecological risk assessment in the United States has been to support the remediation of contaminated sites under Superfund (Suter et al. 2000). A full ecological risk assessment for a contaminated site would consider the risks from the existing contamination (the no action alternative), from the remedial actions themselves, from residual contamination, and from subsequent land uses. In addition, if ecological restoration activities may be performed after remediation, risks associated with restoration must be considered.

In the United States, remedial assessments are performed in two stages: a baseline assessment that determines whether the unremediated contamination poses a significant risk and an assessment of remedial alternatives termed the feasibility study. Procedural and technical guidance are available for baseline assessment (Sprenger and Charters 1997) (see also the EPA's Environmental Response Team and Office of Solid Waste and Emergency Response web sites), and these assessments are often well performed and based on ample data. Because there is a contaminated site to be sampled, surveyed, and tested, the full range of assessment techniques is available to the assessor (Suter et al. 2000). In contrast, there is little guidance for the assessment of risks from dredging, soil removal, capping, construction of roads and other support facilities, chemical or thermal treatment of media, spills of treatment chemicals, and other remedial activities that pose obvious ecological hazards. Remedial decisions tend to focus on the efficacy of technologies in reducing the contaminant risks and on their costs rather than the risks from remediation. The ecological risks of remedial alternatives are usually given a serious assessment only when, as in the polychlorinated biphenyl (PCB) contamination of the Hudson River, New York, the remediation is particularly costly or controversial.

Restoration involves recreating to some extent the ecological structure and function of a site disturbed by a remedial action or any other action. Hazards associated with restoration include erosion and siltation, introduction of exotic species (e.g., as ground covers) with undesirable properties, use of pesticides and fertilizers, and conversion to parks with associated mowing and trampling. In addition to these risks from restoration, planted trees may die, instream structures may wash away, and for other reasons restoration activities may fail. Therefore, it may be appropriate to adapt engineering risk assessment techniques to restoration projects. As with other sorts of risk assessments, assessments of restoration should

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to is compare the risks of alternatives. For example, after the eruption of Mount St. Helens, parts of the area were seeded with exotic herbaceous plants. Although these plants reduced erosion of the ash, they apparently slowed the reestablishment of the native forest. Hence, the risks to stream and river ecosystems from eroding ash could be compared with the risks from delayed recovery of the native terrestrial community.

1.3.6 PERMITTING AND MANAGING LAND USES

The conversion of one land use to another, particularly the conversion of land supporting a natural community to agricultural, residential, or urban uses, is one of the most severe anthropogenic hazards that ecosystems face. However, land use conversion is little regulated in the United States, where land use permitting is usually performed at the local level of government. Hence, ecological risk assessment is seldom involved in land use decision. The exception is the major action of the United States federal government, which is subject to environmental impact assessment (Section 2.12). Nevertheless, the ecological risk assessment framework can be applied to land management decisions, even the complex decisions concerning land development and water use in South Florida (Harwell 1998).

Land use also involves decisions concerning the intensity of use: How many cattle should be allowed to graze on an area of rangeland? How often should a forest be logged? These decisions are the subject of their own well-developed assessment practices (Davis et al. 2000; Holchek et al. 2003). Although they make little use of risk assessment concepts and terminology, to the extent that they have clear quantifiable goals and analyze uncertainty to inform decision makers, they are ecological risk assessments.

1.3.7 SPECIES MANAGEMENT

Risks to species or species populations are estimated for the management of resource species and endangered species. The techniques developed for these purposes have been adapted for estimating risks to populations from pollutant chemicals and introduced organisms, and risk assessment concepts have been adapted to resource management (Chapter 27) (Francis and Shotton 1997). Management of game species, fisheries, timber trees, and other harvested plants requires assessments to determine harvest levels that do not pose unacceptable risks of extirpation. Probabilistic modeling has been particularly important in fisheries management. Other innovations in the assessment of resource management include modeling populations in a community or ecosystem and adaptive management (Walters 1986). Management of threatened or endangered species is often based on a form of population modeling termed population viability analysis that estimates the time to extinction or the probability of extinction within a prescribed time period such as the next 50 years (Sjogren-Gulve and Ebenhard 2000; Beissinger and McCollough 2002; Keedwell 2004). These two assessment practices overlap when harvesting is forcing a population to extinction (Musick 1999). Assessment of species management becomes particularly complicated when the valued species is potentially damaging to the ecosystem or to other valued species (Box 1.1). Risk assessment lends itself to species conservation, and ecological risk assessment for conservation and for pollution regulation have developed in parallel (Burgman et al. 1993; Burgman 2005).

1.3.8 SETTING DAMAGES

When ecological injuries occur due to negligence or criminal activities, the responsible parties may be required to pay monetary damages. These damages are used to restore the damaged ecosystems, or, when that is not possible, to acquire and protect other areas. In the United States, natural resource trustees are required to seek damages from polluters under the Clean

BOX 1.1 Elephant Management, Risks, and Environmental Ethics

The management of populations can have implications for co-occurring populations and communities that result in difficult decisions. This issue is particularly stark in the case of elephant management described by Whyte (2002). Elephants are potentially highly destructive of their habitats. They are capable of grazing, including uprooting entire tussocks of bunch grasses; of browsing, including ripping off branches or knocking down trees to feed on branches and roots; and of feeding on bark torn off with their tusks. In addition, they have no significant predators except humans. Hence, they are capable of destroying woodlands before succumbing to starvation, particularly during droughts, as occurred in Tsavo National Park, Kenya, in 1974 (Whyte 2002). On the other hand, elephants are quintessential charismatic megafauna, so they attract the concern of animal rights advocates. These conflicts became particularly acute in Kruger National Park, South Africa, which is a closed system where poaching is well controlled.

An ecological risk assessment of elephant management in Kruger National Park could be formulated in various ways. Elephants could be treated as agents that can cause risks of effects on woodlands and woodland-associated wildlife populations including extinction of some communities and populations within the park. This formulation could result in identification of an elephant population level that would maximize biodiversity by creating intermediate disturbance. Alternatively, an assessment could mix animal rights concerns with ecological concerns by comparing the risks to individual elephants with risks to populations and communities. Finally, it could take an organism rights approach to all species comparing risks to individuals of charismatic megafauna (elephants) with risks to individuals of other species, including charismatic megaflora (baobab trees).

If risks to individual elephants are admitted as an issue, it is not clear which management alternative is best for them. Conventional culling involves a shot in the brain, which is brutal but quick. Anesthesia followed by shooting is slower and potentially more cruel. Contraception requires frequent harassment of the females to administer the drug, can cause females to be harassed by males during pseudo estrus, and can upset the demographics of family units. In addition, it is tremendously expensive, since it requires repeated treatment of at least 70% of adult females that would require radio-collaring them so that they could be relocated. Finally, one could let nature take its course, which would result in slow and painful but natural deaths of elephants. Hence, the goals of minimum suffering and minimum interference could lead to different solutions.

The policy in Kruger was to maintain a population of 7000 elephants by culling, based on conventional analyses of habitat carrying capacity. This policy ended in 1994 due to animal rights protests. The compromise was to divide the park into six zones: two "high-impact" zones in which elephants would be undisturbed; two botanical reserves, which would preserve rare or ecologically important plants; and two "low-impact" zones. The various zones are monitored, and control implemented when damage is sufficient. The monitoring includes abundances of plants, frogs, birds, reptiles, and mammals, and some abiotic measures such as erosion rates. When changes exceed a threshold of potential concern in a low-impact area, the managers and stakeholders will consider management actions. For example, one threshold of potential concern is an 80% reduction in the number of mature trees. Hence, the abundance of mature trees is a measure of effects. Monitoring of elephants and the other biota should eventually yield empirical models of the biotic community's response to exposure to elephants. Although management decisions are currently made ad hoc, this experience could provide a basis for managing elephants based on clear biodiversity and elephant protection goals and endpoints. However, that will require reconciling the views of elephants as individuals with rights vs. elephants as components of an ecosystem with other species worthy of protection, even from elephants. The same ethical dilemma faces managers of other animals that are capable of detrimentally modifying ecosystems such as feral horses and donkeys in the western United States or whitetail deer in the eastern United States. Risk assessment cannot solve such dilemmas, but by clarifying the valued attributes of the system (endpoints), i.e., the causal relationships (conceptual models), the relationships between exposure and response, and the uncertainties involved, it can support decision making.

Water Act (1977 amendments), the Outer Continental Shelf Act (1989 amendments), the Oil Pollution Act of 1990, and the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA). Natural resource trustees are public land managers such as the US Bureau of Land Management or managers of biological resources such as the US Fish and Wildlife Service. However, a forest owner or any other private owner of natural resources could sue for damages under civil laws. An assessment for setting damages must determine that a natural resource has been injured and that the injury is potentially associated with a responsible party. After this screening phase, the nature and extent of the injury must be quantified and the actions of the responsible parties must be demonstrated to be the cause. Conventionally the next step is to convert the injuries to the resource into monetary damages based on lost services of the resource, which are to be paid to the resource manager or owner by the responsible party. It is intended that the resource manager will use the damages to restore or replace the resource. Alternatively, the responsible party may be charged to restore the resource. This requires that an assessment of alternative restoration approaches be performed so that their costs and expected efficacies can be compared. Regulations and guidance for natural resource damage assessment for public resources in the United States are available at the Department of Interior (40 CFR 11 and http://www.doi.gov/oepc/frlist.html). Damage assessments in general are a subset of ecoepidemiological assessments (Chapter 4).

1.4 SOCIOPOLITICAL PURPOSES OF RISK ASSESSMENT

The primary purpose of risk assessment is to inform a decision-making process, but, because decision making is inevitably a sociopolitical process, risk assessment also serves sociopolitical purposes. First, a risk assessment provides a record of the technical basis for a decision. Second, it provides information on the legitimacy of stakeholder and public concerns. Third, it reduces controversy by providing a technical forum for resolving contentious issues. Finally, it provides a means for stakeholders to participate in framing and informing the decision-making process. Clearly, these functions are ideals that are not always achieved in practice. However, it is important for risk assessors to be aware that good decisions must be viewed as legitimate decisions, or the environmental management process will fail. Hence, they must be willing to participate in the ancillary activities such as public meetings and reviews that provide legitimacy. To that end, they must understand their role in the drama of environmental decision making.

1.5 CAST OF CHARACTERS

1.5.1 Assessors

Risk assessors are technical experts who perform assessments so as to support a decision. Ecological risk assessors typically work in teams that may include health risk assessors, ecologists, toxicologists, chemists, hydrologists, statisticians, system modelers, engineers, and other relevant technical experts. While most practitioners have learned risk assessment concepts and methods on the job, universities are increasingly providing training in risk assessment. Assessors may be employed by a regulatory agency, an applicant for a permit, a party responsible for a spill or dump, a local citizen's group, or an environmental advocacy organization. In any case, they are technical consultants, translating available science and practice into useful information.

1.5.2 RISK MANAGERS

Risk managers are individuals or teams with the responsibility and authority for making a decision that involves risk. In some cases, the role is clearly assigned. For example, in the remediation of contaminated sites under Superfund, the Remedial Project Manager is the US

Defining the Field 13

EPA official responsible for deciding what remedial actions should be taken. Risk assessors are clearly responsible for providing technical support to that individual. However, in other cases the role is less clear. For example, in both the United States and Europe, risk assessments of new chemicals are performed using a standard approach which leads to a conclusion that the chemical is acceptable or unacceptable in a proposed use. As a result, although individual risk assessors do not have decision-making authority, their analyses generate a decision, not simply a risk estimate. However, the authorized officials will step in when decisions are not routine or when new methods are proposed.

The relationship between risk assessors and risk managers is highly variable among nations and regulatory contexts. One reason is the relative concern in different risk assessment contexts for relevance and independence from biases. Clearly, if a risk assessment does not provide the information needed by a risk manager, it is largely a wasted effort. Therefore, the risk manager must provide the charge to the risk assessors, and should be available to inform the judgments that must be made on the basis of policy rather than fact in the course of the assessment. On the other hand, risk managers have biases that cause them to prefer certain outcomes to risk assessments a priori. Therefore, if a risk manager is too involved in the technical analyses, the results will appear biased and may in fact be biased. Therefore, the original guidance for risk assessment in the US federal government emphasized the need to isolate the risk manager who is politically accountable from the technical experts who must provide a credibly unbiased application of science (NRC 1983). Since then, the pendulum has swung to the other extreme so that the same august body has called for extensive input by risk managers and stakeholders (NRC 1994). As suggested in the previous paragraph, the relationship is also influenced by the extent to which the risk assessment is routine. Site-specific assessments and unconventional or high-profile assessments are more likely to receive attention from a risk manager.

The US EPA's framework for ERA, in keeping with the 1983 National Research Council guidance, shows the risk manager outside the risk assessment box (Figure 3.1). However, practice is highly variable, even within the US EPA. Risk assessors should be aware of who has the authority to make the risk management decision and how they prefer to receive technical support.

1.5.3 STAKEHOLDERS

Stakeholders are people or organizations that have a particular interest in the outcome of an environmental management decision. Examples include people who live on or near a contaminated site, parties responsible for contamination, environmental advocates, fishermen and other harvesters of biotic resources, manufacturers of a new chemical, and recreational users of a resource. Although the public as a whole has a stake in environmental management decisions, the stakeholders in a decision are a much smaller group with particular concerns. Therefore, the risk manager must consider public interests as distinct from stakeholder interests.

The role of stakeholders has been emphasized in recent risk assessment guidance (NRC 1993; The Presidential/Congressional Commission on Risk Assessment and Risk Management 1997). That emphasis is more appropriate for human health risk assessment both because stakeholders are typically focused on health or economic concerns, and because the stakeholder input is usually more relevant to those concerns.

Stakeholder involvement is important when remediation or treatment is driven by fears rather than risks or observed effects, and those fears differ among communities. For example, in most communities public fears could force remediation of radionuclides to levels "as low as reasonably achievable," even when those levels are far below background. However, in some communities such as Oak Ridge, Tennessee, or Los Alamos, New Mexico, risk assessments

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can be more influential because the public is well educated, knowledgeable, and familiar with radiation issues. Such differential fears do not occur among nonhuman organisms, but levels of concern for nonhuman organisms and ecosystems vary greatly among communities and interest groups.

Economic considerations associated with issues of fairness are also important stakeholder inputs. Some will bear the cost and others, the benefits of a decision. These issues are complicated by the problem of environmental justice, the concern that some racial or ethnic groups bear an unfair burden of environmental pollution. There are no such feelings of victimization or inequity among plants and nonhuman animals.

Although different levels of risk may be appropriate for different human communities because of differences in their risk aversion, stakeholder preferences do not necessarily provide a basis for differential protection of birds or plants in different communities. Agencies must enforce requirements of environmental laws, whether or not the local human community is concerned. For example, cranes are a national and world heritage resource, but local communities on the Platt River want to withdraw water that is needed for crane habitat. Those stakeholder preferences should not trump the legal protections or ethical obligations applied to those birds. However, if stakeholders are ignored or thwarted, they will, as in the Platt River case, use legal or political processes to achieve their aims. Alternatively, stakeholders may raise specific and legitimate community concerns for the nonhuman environment that would not be raised or given great significance by risk assessors or risk managers. For example, indigenous peoples along the Columbia River attribute religious and cultural as well as economic value to salmon. Similarly, fishermen are concerned about lesions, tumors, and deformities in fish that would not concern many ecologists.

In many cases, ecological risk assessors are in the position of educating stakeholders concerning the attributes of the environment that are at risk and their relationship to human welfare. However, assessors must also be open to learning from stakeholders who may have knowledge or concerns that are relevant to the assessment.

Risk assessors should realize that stakeholders might have agendas that are not consistent with increasing the understanding of risks to improve the rationality of decisions. Usually, some parties will have a stake in ignorance, because additional data and analyses are likely to weaken their position. Who they are depends in part on who bears the burden of proof. If regulators must prove that risks are excessive before taking action, the manufacturers of new products have an interest in limiting information. However, if manufacturers must prove the safety of a new product, the manufacturers of existing competitive products and environmentalists who are opposed to new technologies have an interest in limiting information. Similarly, if people feel that they have been injured by a product, and have attained public and political sympathy, they have an interest in rapid judgment rather than study and analysis. Some stakeholders will advocate additional data gathering and assessment as a delaying tactic rather than from a desire to improve the quality of the decision. For example, manufacturers of a hazardous product are likely to argue that there is not enough information to regulate it. An awareness of these unstated agendas is important when stakeholders participate in the planning of assessments or influence the information provided to risk managers.

Finally, stakeholders may be more than sources of goals or issues of concern. In some cases, stakeholders will generate data and even conduct their own risk assessment. Those risk assessments may be used as a basis for legally challenging a risk manager's decision or may be presented to the risk manager as an alternative to the assessment performed by his own assessors.