3 Ecological Risk Assessment Frameworks

Whilst a few persons, by extraordinary genius, or by the accidental acquisition of a good set of intellectual habits, may profitably work without pre-set principles, the bulk of mankind require either to understand the theory of what they are doing, or to have rules laid down for them by those who have understood the theory.

John Stewart Mill

One of the defining features of ecological risk assessment is that it follows a procedural framework that has evolved from the National Research Council framework for human health risk assessment (NRC 1983). Frameworks serve as guides for performing risk assessments, show the reader how the assessment is structured, and provide a basis for quality assurance by ensuring that necessary components are included. The health risk assessment framework was adapted to ecological risk assessment (Barnthouse and Suter 1986; EPA 1992a). The ecorisk framework has since been adapted for other nations including South Africa (Claassen et al. 2001), Australia and New Zealand (ANZ 1995; NEPC 1999), Canada (CCME 1996), the Netherlands (Gezondheidsraad 2003), and the United Kingdom (UK Department of the Environment, Food and Rural Affairs 2000). It is employed for various uses and legal contexts (Menzie and Freshman 1997; Power and McCarty 1998, 2002). These frameworks tend to be similar in the core processes of estimating ecological risk, but differ greatly in the extent to which they attempt to specify the nature of the decision-making process and the involvement of stakeholders. This chapter describes the standard US EPA framework and some alternatives that are potentially useful. It ends with a discussion of circumstances that lead to iteration of the assessment process and problem-specific frameworks.

3.1 BASIC US EPA FRAMEWORK

The most commonly used ecorisk framework is the US EPA framework, which is portrayed in Figure 3.1. It consists of planning, problem formulation, analysis, risk characterization, and risk management (Norton et al. 1992; EPA 1998a). The framework is outlined here, and developed in detail later.

Planning is a stage prior to risk assessment in which the risk manager, in consultation with the risk assessors and possibly with stakeholders, provides input to the assessment process. That input includes:

- Management goals—the assessors must know the desired condition of the environment.
- Management options—the assessors must know what actions might be taken so that they can be assessed and compared.

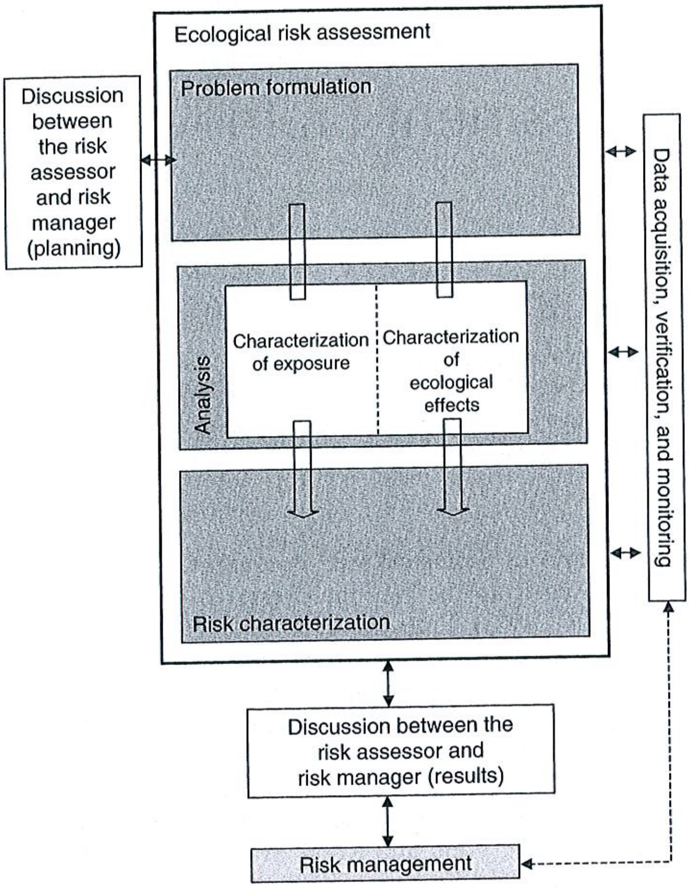

FIGURE 3.1 The US EPA framework for ecological risk assessment. (From US Environmental Protection Agency, *Framework for Ecological Risk Assessment*, EPA/630/R-92/001, Risk Assessment Forum, Washington, D.C., 1992; US Environmental Protection Agency, *Guidelines for Ecological Risk Assessment*, EPA/630/R-95/002F, Risk Assessment Forum, Washington, D.C., 1998. With permission.)

- Scope and complexity of the risk assessment—assessments are constrained by the nature of the decision (e.g., national or local), time, and resources to complete the assessment, and the risk manager's desire for completeness, accuracy, and detail.

Problem formulation is the phase in which the charge to the assessors from the risk manager is converted into a plan for performing the assessment. It includes:

- Integrating available information—assemble and summarize information concerning sources, contaminants or other agents, effects, and the receiving environment.
- Assessment endpoints—define in operational terms the environmental values that are to be protected.
- Conceptual model—develop a description of the hypothesized relationships between the sources and the endpoint receptors.
- Analysis plan—develop a plan for obtaining the needed data and performing the assessment.

Analysis is the phase in which a technical evaluation of the data concerning exposure and effects is performed.

Characterization of exposure component of the analysis consists of:

- Measures of exposure—results of measurements indicating the nature, distribution, and amount of the agent at points of potential contact with receptors
- Exposure analysis—a process of estimating the spatial and temporal distribution of exposure to the agent
- Exposure profile—a summary of the results of the exposure analysis

Characterization of effects component consists of:

- Measures of effect—results of measurements or observations indicating the responses of assessment endpoints to variation in exposure
- Ecological response analysis—a quantitative analysis of the effects data
- Stressor–response profile—the component of the ecological response analysis that specifically deals with defining a relationship between the magnitude and duration of exposure and the endpoint effects

Risk characterization is the phase in which the results of the analysis phase are integrated to estimate and describe risks. It consists of:

- Risk estimation—the process of using the results of the analysis of exposure to parameterize and implement the exposure–response model and estimate risks, and of analyzing the associated uncertainty
- Risk description—the process of describing and interpreting the results of the risk estimation for communication to the risk manager

Risk management is the process of making a decision concerning the need for regulation, remediation, or restoration, and of determining the nature and extent of the action. Risk assessors may interact with the risk management process in two ways:

- At the end of the assessment, the results of the risk characterization may be simply communicated to the risk manager, who determines the course of action.
- The risk assessors may interface with other analysts who contribute to the decision such as cost–benefit analysts or decision analysts to provide integrated decision support.

Data acquisition is outside the ecorisk box. However, risk assessors may make calls for data during any of the three phases. In addition, the risk manager may demand that more data be collected and the assessment process be reiterated.

3.2 ALTERNATIVE FRAMEWORKS

The US EPA framework for ecological risk assessment is intended to be flexible, so in theory it can accommodate the features of all the following alternative frameworks. However, when a particular aspect of an assessment situation requires that an assessment be performed in a manner that is manifestly different from that portrayed in the standard framework, it is only fair to the user of the assessment results to present a framework that actually shows the way the assessment was done. Much of the criticism and confusion associated with the US EPA framework has to do with trying to fit all assessments into an agent-focused formalism

(Fairbrother et al. 1997; Harwell and Gentile 2000). The following alternative frameworks contain features that are useful in commonly encountered situations. These features may be selected and combined to generate a framework that represents an appropriate assessment process for the case at hand. However, any alternative to an ecorisk framework must contain the basic features of problem formulation, analysis of exposure and effects, and characterization of risks, although the names applied to the features might differ.

3.2.1 WHO-Integrated Framework

The US EPA framework for ecological risk assessment is different from its framework for human health risk assessment, which is the 1983 National Research Council framework. However, there are numerous advantages to integration of health and ecological risk assessment. They include providing a more consistent and coherent basis for decision making; greater efficiency and quality of assessments from the sharing of data, models, and insights; and the potential for assessing the effects of ecological injuries on human health and well-being. The International Programme on Chemical Safety of the World Health Organization (WHO) has developed a framework for integrated health and ecological risk assessment (Figure 3.2) (WHO 2001; Suter et al. 2003). The framework was based largely on the US EPA ecorisk framework, because it is more flexible and inclusive than any of the frameworks for health risk assessment.

The WHO framework has an advantage over the standard ecorisk framework in its treatment of interactions among risk assessors, risk managers, and stakeholders. The US EPA framework limits the contribution of risk managers to providing questions and goals prior to the problem formulation and limits stakeholders to providing input to the risk

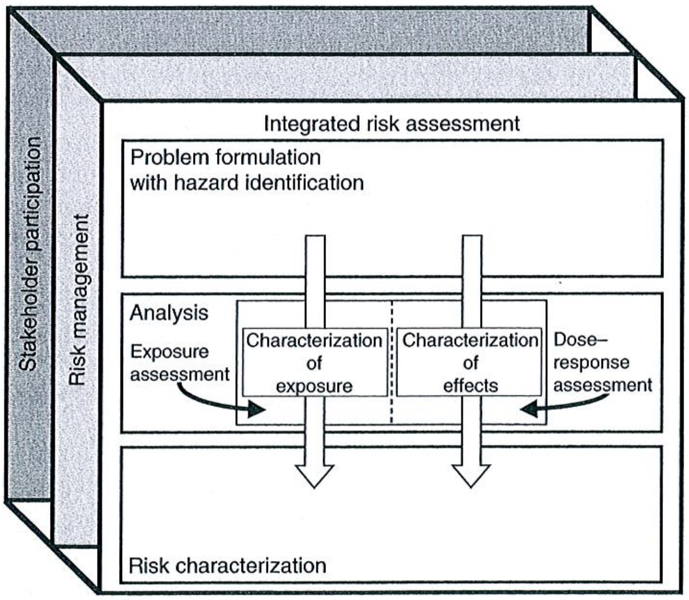

FIGURE 3.2 The framework of the World Health Organization (WHO) for integrated risk assessment. (WHO, *Report on Integrated Risk Assessment*, WHO/IPCS/IRA/01/12, World Health Organization, Geneva, Switzerland, 2001. With permission.)

manager's plans. This limited input is not consistent with all legal and regulatory contexts in the United States, and it is certainly not consistent with practices outside the United States. Hence, the WHO framework shows risk management and stakeholder processes as parallel with the risk assessment processes. Depending on the context, there may be a lot of interaction at numerous points in the process or none at all.

Even as a framework for ecological risk assessment in the US EPA, the WHO framework has the advantage of being consistent with advice from the Presidential/Congressional Commission on Risk Assessment and Management (1997) and National Research Council (1994). While the US EPA framework is designed to preserve the independence of the risk assessors from outside influences that might bias the assessment, these groups were concerned that the results of risk assessments have not been as useful as they should be because of insufficient input from decision makers and stakeholders, and that risk assessments performed in isolation have low credibility with the stakeholders and the public. The WHO framework accommodates those concerns by allowing for greater input and dialog among assessors, managers, and stakeholders. However, when implementing this framework in a particular context it is necessary to specify what interactions will actually occur. Otherwise, the assessment will not have sufficient procedural transparency to assure acceptance.

3.2.2 Multiple Activities

Most ecological risk assessments address a single activity, or a single chemical or other agent. However, some ecological risk assessments address risks from a set of activities, each of which may generate multiple agents at a site or in a region. Examples include military training exercises; management of a watershed with various land uses, effluents, and nonpoint sources; an energy technology; or the development of a transportation system. In such cases, the ecorisk process can become bogged down in its complexity if it is not broken down into modular components. Some examples are pasturage and confined feeding as activities within dairy farming, or mining, hauling, processing, combustion, condenser cooling, and ash disposal as activities within coal-fired generation of electricity. The framework shown in Figure 3.3 was developed for this purpose (Suter 1999a). An overall problem formulation is performed for the entire program which, in addition to the usual problem formulation components, divides the program into distinct activities. Each of these activities is then assessed with its own problem formulation, analysis, and characterization. Finally, the risk characterizations for the activities are combined to estimate the overall risk of the program. Clearly, this approach requires some insight in order to define activities that are either independent or dependent in such a way that their interactions can be modeled after their direct or principle effects have been estimated.

This framework also lends itself to ecosystem management. That is, rather than assessing risks from a particular chemical, waste, or even a complex program, one could assess risks to an ecosystem of all agents or activities that impinge upon it.

This framework also differs by including decision support systems and risks to humans and human activities resulting from ecological damage. Risks to human activities may be particularly important, because many activities that are the subject of risk assessment cause environmental effects that are detrimental to continuation of the activity. Obvious examples include overharvesting of fisheries, overgrazing, irrigation resulting in soil salinization, and tillage resulting in soil loss. Less obvious examples include overuse of military training sites resulting in the loss of a realistic setting, and overuse of parks resulting in the destruction of the natural resources and aesthetic qualities that attract users. This negative feedback between use of the environment and reduced utility of the environment for the users is hardly recognized in ecological risk assessments.

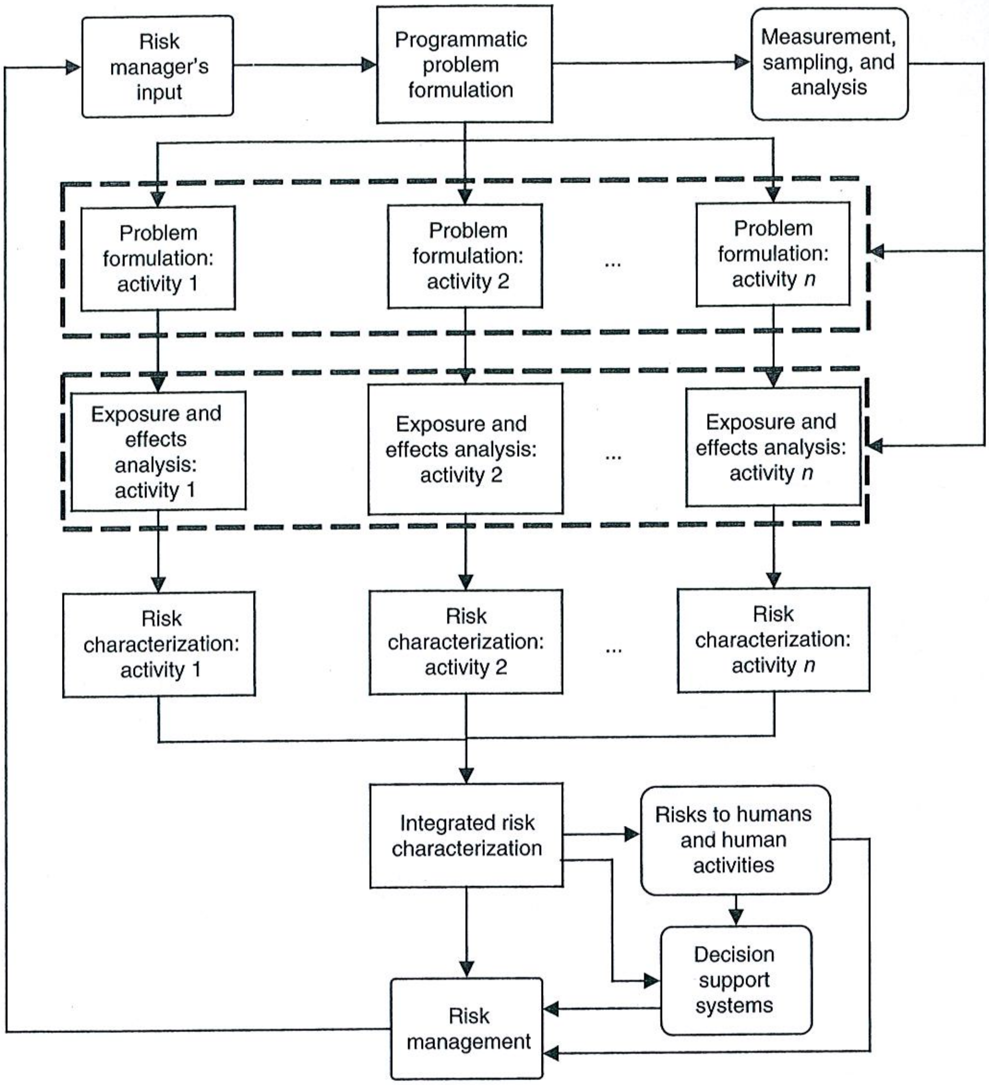

FIGURE 3.3 A framework for assessing a set of activities associated with a program. (From Suter, G.W., II., *Human and Ecological Risk Assessment*, 5, 397, 1999. With permission.)

3.2.3 Ecological Epidemiology

The standard framework presumes that the agents of concern and their sources are identified and the assessors' task is to estimate the risks that they pose to the environment. However, in some cases, effects are observed but their causes are uncertain, or exposure is observed (e.g., mercury in fish flesh) but the source is unknown. In such cases, the analysis phase must address sources, exposure, and effects (Figure 3.4). Such assessments are termed ecological epidemiology or ecoepidemiology (Chapter 4). The goal of these assessments is to characterize the causal chain from source to exposure and effects, so as to determine risks from allowing the current situation to continue or from alternative remedial or regulatory interventions. This framework may be useful even in cases that begin with an identified source and agent. For example, in assessments of contaminated sites, biological surveys may identify

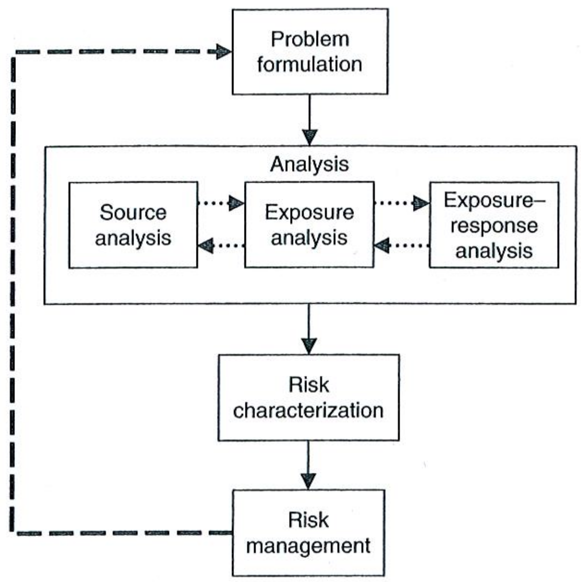

FIGURE 3.4 A framework for assessing ecoepidemiological risks in which the causal exposure or sources must be determined. (From Suter, G.W., II, Ed., *Ecological Risk Assessment*, Lewis Publishers, Boca Raton, FL, 1993. With permission.)

ecological impairments, but it may not be clear that the contaminants being assessed are the cause. Similarly, the observed toxicity of media may be due to contaminants or sources other than the subject of the assessment. For example, the waters of Poplar Creek on the Oak Ridge Tennessee Reservation, a Superfund site, were toxic, but so were the waters upstream of the reservation. The source of toxicity was an upstream municipal wastewater treatment plant. Hence, ecoepidemiological inference requires assessors to consider all credible causes of ecological effects, and not just the one that prompted the assessment.

While this ecoepidemiological framework provides considerable flexibility by simultaneously analyzing sources, exposures, and effects, it may not be the most efficient way to conduct such assessments. In many cases, an effect is observed but the cause is completely unknown, so it is not possible to reasonably formulate the problem. Rather, one should perform a causal analysis (Chapter 4) and then, once the cause is identified, perform a conventional risk assessment to determine the risks associated with remedial or regulatory alternatives.

3.2.4 Causal Chain Framework

The US EPA framework for ecological risk assessment, like its health risk predecessor, shows the analysis phase as consisting of an analysis of exposure and effects. This formulation is clearly appropriate to cases in which the endpoint entities are directly exposed to a chemical or other agent and in which the effect of concern is a direct result of that exposure. However, even in those cases, the division between exposure and effects is more pragmatic than inherent (Box 17.1). In ecological risk assessment, indirect effects commonly result in multistep causal chains. That is, toxic effects on one group of endpoint organisms such as forest trees must be estimated, but those effects in turn result in effects on other endpoint organisms due to loss of food or habitat structure or increased soil and nutrient export. Such indirect effects are identified during the development of the conceptual model for an assessment (Chapter 17). Indirect effects are recognized in the US EPA guidelines, but they are not explicitly incorporated in the framework.

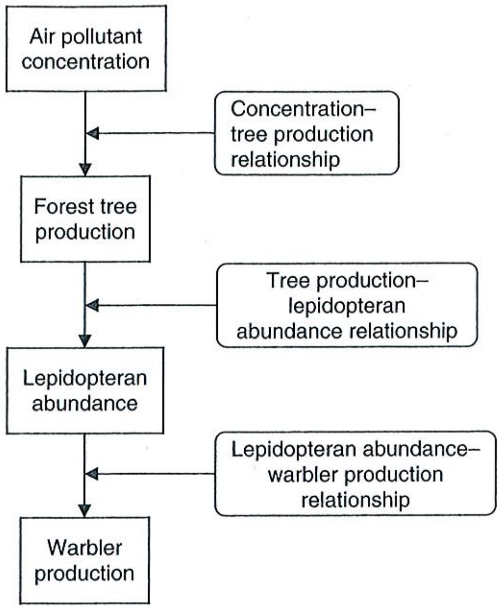

FIGURE 3.5 A hypothetical conceptual model of a risk assessment involving risks from air pollution on trees, lepidoptera, and birds.

An example of indirect effects is presented in Figure 3.5. Air pollutants damage forest trees, resulting in increased litter fall and tree mortality. This causes reduced abundance of forest lepidoptera, which in turn leads to reduced production of young birds that feed on lepidopteran larvae. Each of the system states (rectangles), except the pollutant concentration, is an endpoint effect, and each of the states except the last is an agent that may affect the succeeding states in the causal chain. Hence, the condition of the trees and the abundance of lepidoptera are both effects and causes. The probability that the effects (e.g., reduced bird production) will occur depends on the magnitude of exposure to the causal agent (e.g., the abundance of lepidopteran larvae) and an exposure–response relationship (e.g., productivity of birds as a function of larval abundance). Such chains of repeating units of cause and effect may be represented by a loop in which each effect may become a cause of additional effects (Figure 3.6) (Suter 1999a). The descending arm is the conventional exposure–response process. The ascending arm is the translation of an effect of interest (e.g., abundance of forest butterflies and moths) into properties relevant to exposure of the next receptor (e.g., abundance and biomass of larvae during the period of nestling and fledgling development). In the example, there are three loops: air pollution to trees, trees to lepidoptera, and lepidoptera to birds. If there are branches in the causal chains, the assessment process would loop through the causes and effects in each branch until the entire conceptual model is analyzed. When all loops are completed, the final risk characterization is performed to summarize all effects. This alternative version of the ecorisk framework is more explicitly ecological and ties the assessment more directly to the conceptual model.

This framework has the incidental advantage of clarifying the nature of the "characterization of effects." This step in the US EPA framework does not in fact characterize the effects; which is rather done in the risk characterization. It defines the functional relationship between exposure and effects. Hence, an exposure state is translated into an effects state and that translation is determined by a process (the triangle in Figure 3.6) that is estimated by an exposure–response function. Such state–process–state systems are drawn from the conceptual

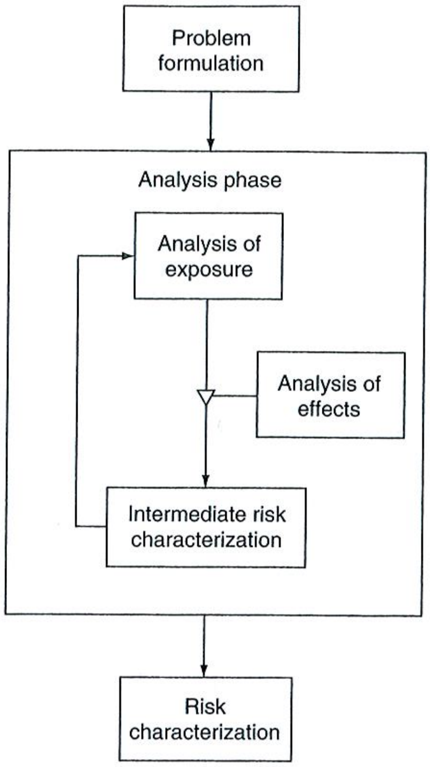

FIGURE 3.6 A framework for assessing ecological risks involving causal chains producing indirect effects. (From Suter, G.W., II, *Human and Ecological Risk Assessment*, 5, 397, 1999. With permission.)

model where they should be clearly represented (Chapter 17). Hence, this version of the ecorisk framework makes risk assessment a type of systems analysis, which has obvious potential benefits when dealing with complex systems.

3.3 EXTENDED FRAMEWORKS

Some frameworks include other types of assessments, in addition to risk assessments. These might include economic (e.g., benefit–cost; see Chapter 36), engineering feasibility, balancing of risks from contaminants at a site against risks from site remediation (Efroymson et al. 2004), environmental justice, and other assessments that contribute to decision making. An example is presented in Figure 3.7. Such frameworks have the advantage of showing the relationships among assessment activities contributing to a decision.

3.4 ITERATIVE ASSESSMENT

While a risk assessment can be performed by simply proceeding through the framework from planning to decision making, in many cases the assessments are iterated. That is, the process may be repeated one or more times until a sufficiently complete and defensible result is achieved. This may be done because more data or better models are needed to achieve sufficient confidence, the scope of the assessment must be expanded to include new issues, some issues must be analyzed in greater depth, a sequence of decisions requires a sequence of assessments, or for other reasons.

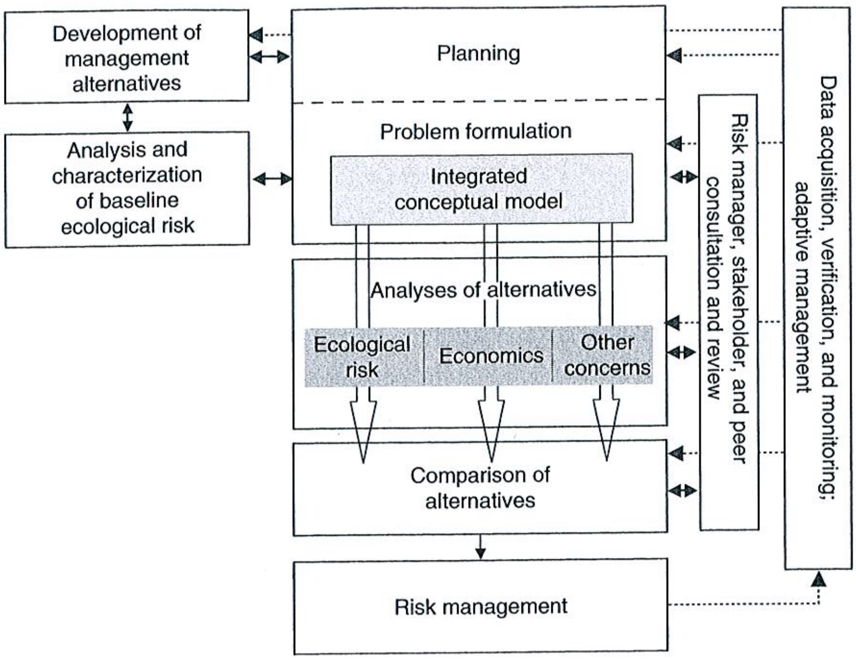

FIGURE 3.7 A framework integrating risk assessment with economic assessment. (Bruins, R.J.F. and Heberling, M.T., eds., *Integrating Ecological Risk Assessment and Economic Analysis in Watersheds: A Conceptual Approach and Three Case Studies*, EPA/600/R-03/140R, Environmental Protection Agency, Cincinnati, OH, 2004. With permission.)

One form of iterative assessment is the use of tiers of prescribed testing and measurement. The hazard assessment paradigm that preceded ecological risk assessment depended on tiering for its structure and decision logic (Figure 3.8) (Cairns et al. 1979). That is, bouts of testing and measurement were followed by simple assessments, which were followed by more testing and measurement until it was clear that a hazard did or did not exist. These tiered testing schemes were codified in the assessment methods for the regulation of pesticides and industrial chemicals (Urban and Cook 1986). Because of the potential cost-effectiveness of attempting to complete an assessment with a small and inexpensive data set before generating a more complete data set, tiered testing and assessment is still a common practice.

Recent tiered ecological risk assessment schemes are based on increasing complexity of modeling and quantitative analysis of a body of data, rather than increasing amounts of data to be analyzed. A prominent example in the United States is the aquatic and terrestrial ECOFRAM methodologies for assessing ecological risks of pesticides (ECOFRAM Aquatic Workgroup 1999; ECOFRAM Terrestrial Workgroup 1999). These methodologies define four tiers of assessment ranging from simple comparison of point estimates of exposure and effects to complex probabilistic analyses (Section 32.4). Similarly, a British framework calls for a screening assessment and two tiers of definitive assessment (UK Department of the Environment 2000). The two definitive tiers are generic quantitative risk assessments, which use standard models and assumptions, and tailored quantitative risk assessments, which use site-specific data, models, or assumptions.

Although iteration of risk assessments is often based simply on a desire for more or better information, it may also be based on a sequence of distinct types of assessments. The most common distinctions are between screening and definitive assessments and between baseline assessments and assessments of alternatives.

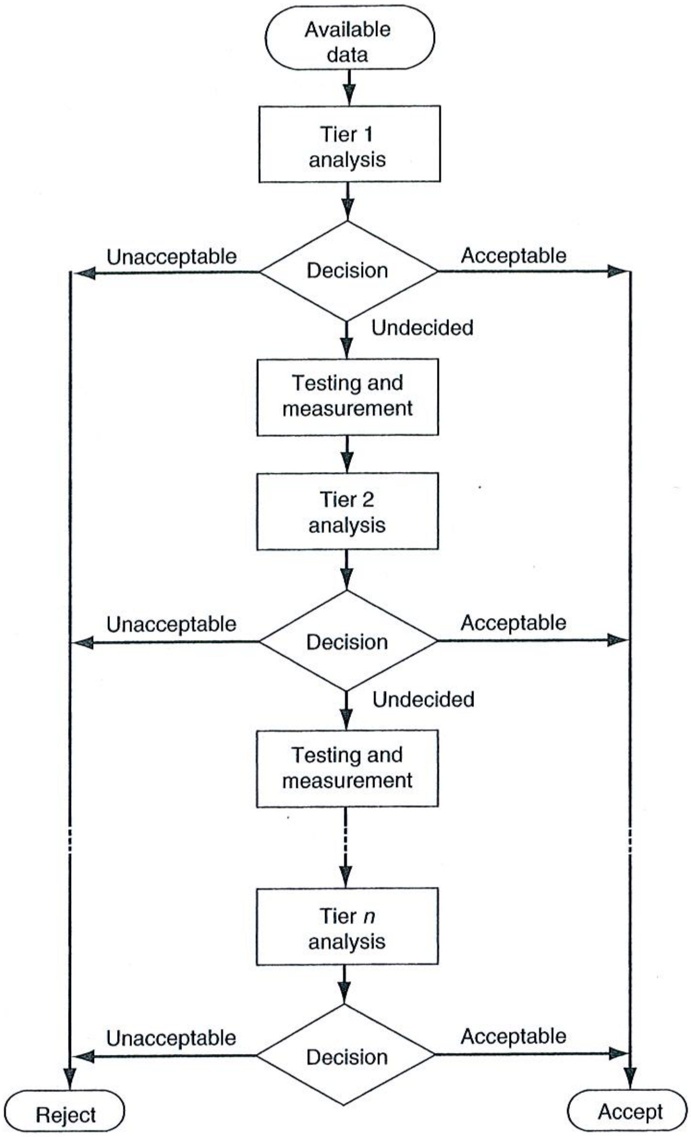

FIGURE 3.8 A framework for hazard assessment based on tiered testing and measurement.

3.4.1 Screening vs. Definitive Assessments

Screening assessments are performed to narrow the scope of subsequent assessments by distinguishing issues that can clearly be ignored from those that require testing, measurement, and more complete assessment, or those that clearly require action without further defining the risk. They are analogous to the use of a screen to separate rocks from a soil sample. Screening assessments may be performed at the beginning of an assessment program to determine the objects of subsequent assessments. Examples include the screening of contaminated sites for inclusion in the US Superfund program (EPA 1990) or the screening of existing chemicals for regulatory assessments (Royal Commission on Environmental Pollution 2003). More often, they are performed at the beginning of individual site assessments. They may use existing data to quickly identify parts of a site, classes of receptors, or agents that need not be considered further (Chapter 31). Unless all issues are screened out, the results of a screening assessment will serve as input to the problem formulation for subsequent assessments. In some cases, there will be multiple iterations of screening assessment. For example, at contaminated sites a screening assessment with existing data is commonly followed by another screening assessment based on preliminary sampling and analysis, which in turn leads to focused and intensive sampling and analysis for the definitive assessment. In rare cases, screening assessments may indicate that risks are so large and manifest, that emergency actions must be taken without further measurement or assessment. Risk characterization in screening assessment is usually limited to the quotient method with conservative assumptions and safety factors. They are discussed in detail in Chapter 31.

Definitive assessments are those that are designed to define the risks and provide the basis for management decisions. Because of preceding screening assessments, they can be highly focused on the stressors, routes of exposure, and endpoints that are critical to a decision. Thus, it is possible to intensively assess those issues using probabilistic modeling, site-specific tests, or other labor- or cost-intensive techniques, and to weigh multiple types of evidence (Chapter 32).

3.4.2 Baseline vs. Alternatives Assessments

Although risk assessment is intended to inform management decisions that choose among alternative actions, it may be appropriate to begin with an assessment that simply determines whether any action is needed. Such assessments are termed baseline risk assessments; they determine the risks associated with current conditions, if no remedial or regulatory action is taken. Hence, they are risk assessments for the no-action alternative. Baseline assessments must consider temporal trends resulting from dispersal, degradation, accumulation, and other processes, and not simply current exposure and effects. In addition to determining the need for action, baseline assessments serve to guide the development of alternatives by defining the nature and sources of significant risks and even setting target remedial levels. Subsequent comparative assessments of alternatives estimate the risks for proposed actions and compare them to each other and to the baseline risks. For example, in an ecological risk assessment for a contaminated site, the baseline assessment might consider the risks from leaving contaminated soil in place and allowing the contaminants to degrade. The subsequent alternatives assessment would consider the risks from remedial alternatives such as capping, removal and burial, or removal and incineration. If the contaminated soil is in a forest, high-quality wetland, or other vulnerable ecosystem, the ecological risks from remediation could easily exceed those from the contaminants since remediation would destroy the ecosystem (Suter et al. 2000, Chapter 9).

3.4.3 Iterative Assessment as Adaptive Management

Iterative assessment may be extended to include the management process. That is, a remedial action or restoration may be chosen and implemented based on a risk assessment of the alternative actions, recognizing that the goals may not be achieved. Hence, the management actions may be followed by monitoring of the results. If the goals are not achieved, the results of the monitoring can provide the basis for another iteration of risk assessment and another iteration of management actions. Hence, this type of iterative risk assessment may be an input to an adaptive management strategy (Section 2.8).

3.5 PROBLEM-SPECIFIC FRAMEWORKS

The EPA's ecological risk assessment framework is generic and applicable to any context; the assessment of particular classes of problems may benefit from a problem-specific framework. These frameworks show how to apply the generic ecorisk framework to a particular problem.

Examples include frameworks for the assessment of ecological risks from marine fish aquaculture (Nash et al. 2005), contaminated sites (Sprenger and Charters 1997), aircraft overflights (Efroymson and Suter 2001a,b), importation of animals (Murray 2002), nonnative fishes (Copp et al. 2005), and irrigation (Hart et al. 2005). These problem-specific frameworks show how the steps in the assessment process are performed for that problem. They include components such as lists of recommended assessment endpoints, generic conceptual models, and exposure–response models as well as pertinent examples. Although such frameworks do not require substantive changes in the generic assessment process, they may change the process or terminology to increase relevance to the problem or to more closely follow prior assessment practices.

3.6 CONCLUSIONS

The US EPA framework for ecological risk assessment was a real advance over prior risk assessment frameworks, particularly in terms of the problem formulation. However, ecological risk assessment in other nations, in specific regulatory contexts, and for specific classes of problems can benefit from modification or elaboration of that basic framework, so as to provide more relevant procedural guidance.

Advantages of using a single standard framework include familiarity and consistency, which reduce confusion and allow comparison and quality assurance of assessments. However, managers, stakeholders, and even assessors may reject the ecological risk assessment formalism if it does not appear to be applicable or if it requires too much stretching to fit their problem and context. Hence, the standard EPA framework is a preferred default for ecological risk assessment in the United States, but assessors should be willing to modify it as needed to produce a more useful and acceptable result.

Finally, problem-specific implementations of the ecological risk assessment framework should be developed for individual classes of assessments. These can provide specific guidance and useful information to facilitate state-of-the-science assessments.