Risk assessment, ecological

The term *risk assessment* is part of everyday language and the word "risk" has many and varied definitions. In this article, *risk* is defined as the (negative) outcome of an event that may or may not occur within a prescribed time frame. The two key components of risk are, therefore, the *consequence* of an event and the *likelihood* of occurrence. Risk assessments are undertaken to inform and guide a decision-making process that is subject to uncertainty. This uncertainty manifests itself in many ways, including the unknown future, imprecise knowledge of the consequences of the decision, and model incertitude. The last of these arises from the use of mathematical models to obtain estimates of "risk". They are used to describe past, present, and future conditions including predictions about events that have never occurred and for which no data is available.

There are many "genres" of risk assessment – human risk assessment, environmental risk assessment, geopolitical risk assessment, and financial risk assessment. This article is concerned with *ecological risk assessment* or ERA. ERA and environmental risk assessment are used somewhat interchangeably, although there is a clear distinction. ERA is a subset of the broader environmental risk assessment (*see* **Risk assessment, quantitative**) and it focuses specifically on the elicitation, quantification, communication, and management of risks to the *biotic* environment [1–3]. As we shall see in this article, there are well-developed paradigms and guidelines for undertaking ERAs, which have evolved over the last 25 years. As noted by Suter [4], "ecological risk assessment has become a mature practice" although he also cautions that "assessors ... [need] to ensure that ecological risk assessment becomes more useful".

The earliest formalization of risk assessment can be traced back to the 1930s and its application to the quantification of the effects on humans arising from exposure to chemicals in the workplace [5]. Around the same time, the US Food and Drug Administration (FDA) was formed and in 1938, the Food, Drug, and Cosmetics Act was passed by Congress, which provided the legal and regulatory framework for ensuring the safety of food, drugs, and cosmetics. In 1958, an amendment to the Act known as the *Delaney Clause* prohibited the approval of any food additive shown to cause cancer in humans or animals. Concern for the *ecological* effects of chemicals in the environment was ignited in 1962 when an American marine biologist, Rachel Carson, published her seminal book *Silent Spring*. The decade between 1965 and 1975 saw a flurry of intense scientific investigations into the acute and chronic effects of pollutants on aquatic organisms. While the results of these studies reduced some of the uncertainty associated with the application of arbitrary "safety" or "assessment" factors derived from human risk assessments, the increasing reliance on mathematical and statistical models introduced other difficulties associated with statistical estimation and inference.

While much of contemporary ERA is focused on the effects of toxicants and pollutants on ecological systems, the discipline is much broader and can be applied to any formal investigation of ecological hazards and stressors. A **hazard** is a situation or event that could lead to harm [6]. Ecological hazards can be natural (e.g., cyclones, earthquakes, fires) or related to human activities (e.g., destruction of a habitat). Hazards are possibilities, without probabilities. They are all those things that might happen, without saying how likely they are to happen [7]. **Stressors** are the elements of the system that precipitate an unwanted outcome (for example, low dissolved oxygen in a river is a stressor that ultimately results in the death of aquatic life) [8].

This article will outline the process for conducting a formal ERA realizing that evaluating risk has involved, and in some cases will probably continue to involve, a less-formal process. It is also important to keep in mind that assessing risk to nonhuman biota is somewhat different from assessing risks to humans, and that assessments involve varying degrees of uncertainty. When assessing risk to nonhuman biota, unless the threat is to an endangered species, the concern is usually with adverse effects at the population, community (*see* **Community, ecological**), or **ecosystem** level and not with risk to the individual. Therefore, the criterion used to

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determine adverse effects in an ERA is not whether some individuals may experience adverse effects, but whether the population, or perhaps community or ecosystem, is adversely affected. The uncertainties of an assessment are associated with our lack of knowledge regarding effects of specific stressors on specific biota or systems that are potentially at risk. It is important that uncertainties regarding effects be communicated and incorporated in the assessment process.

This article will provide references to journal articles, government documents, books, and Internet addresses as sources for additional and more detailed information on the ERA process. The information provided is based primarily on assessment guidelines published by the US **Environmental Protection Agency** (USEPA), Office of the Science Advisor [9], and Chapter 6 of Fairman *et al*. [10]. The intent is to familiarize the reader with the basic processes and nature of an ERA, but not as a guide or training in performing an ERA.

Before the Assessment Begins

There are three major groups involved with the ERA process: the risk manager, the risk assessor, and affected or interested parties [8]. Risk managers are individuals or organizations that have legal and/or regulatory authority and are responsible for making decisions regarding actions to be taken after considering the information provided by the ERA, along with legal, political, social, economical, and technical considerations. Risk managers work with the risk assessors to formulate and describe the environmental problem and communicate directly with the affected or interested parties. Risk assessors are the technical component of the ERA. They interact primarily with the risk managers and are responsible for ultimately providing evaluation, quantification, and interpretation of potential ecological risk. The affected or interested parties are the stakeholders who have identified a potential environmental problem and who will determine if the problem has been resolved. Affected or interested parties may include federal, state, tribal, and local governments, industries, environmental groups, landowners, and so on. It is critical to the success of the ERA that open and thorough communications are established among the three major groups participating in the assessment process. This communication must be initiated before the formal ERA process begins and must continue through the final decisions regarding risk and risk management. Without adequate communication between these parties, the information generated during the assessment may fail to assist the risk manager in making decisions and may result in distrust and dissension among affected or interested parties regarding these decisions.

Before we begin a discussion of the process involved in an ERA, it is important to understand the inherent, underlying uncertainties regarding risks. The ERA is intended to gather information, evaluate and quantify that information, and interpret ecological risk. It includes an explanation of the uncertainties involved in the assessment. Ecological systems are complex and it is not possible to know all the exposure routes nor all the effects on all the wild species occupying the ecosystem being evaluated. Risk assessors will rely on modeling, laboratory studies, and past field and on-site studies using representative indicator species to provide information regarding exposure and effects.

The major phases of an ERA are the problem formulation phase, analysis phase, and risk characterization phase (Figure 1) [9]. The risk assessment process begins when affected or interested parties present the risk manager with a situation that may pose an ecological risk and requires a decision regarding the potential risk and actions to avoid, reduce, or remediate that risk. Examples include a new pesticide intended for spraying on agricultural crops, and past spilling and landfill disposal of polychlorinated biphenyls (PCBs). The former example is a form of predictive ERA, while the latter is a retrospective ERA [11]. In the case of a predictive ERA, the risk manager may need to make decisions concerning ecological risks associated with the intended use of a new chemical (e.g., potential adverse effects on bird species of a new agricultural pesticide). In the case of a retrospective ERA, the risk manager may need to make a decision regarding risks associated with the past activities (e.g., potential adverse effects of PCBs on mammalian species living on or near a contaminated landfill).

Problem Formulation

The problem formulation phase marks the beginning of the formal ERA and is probably the most critical

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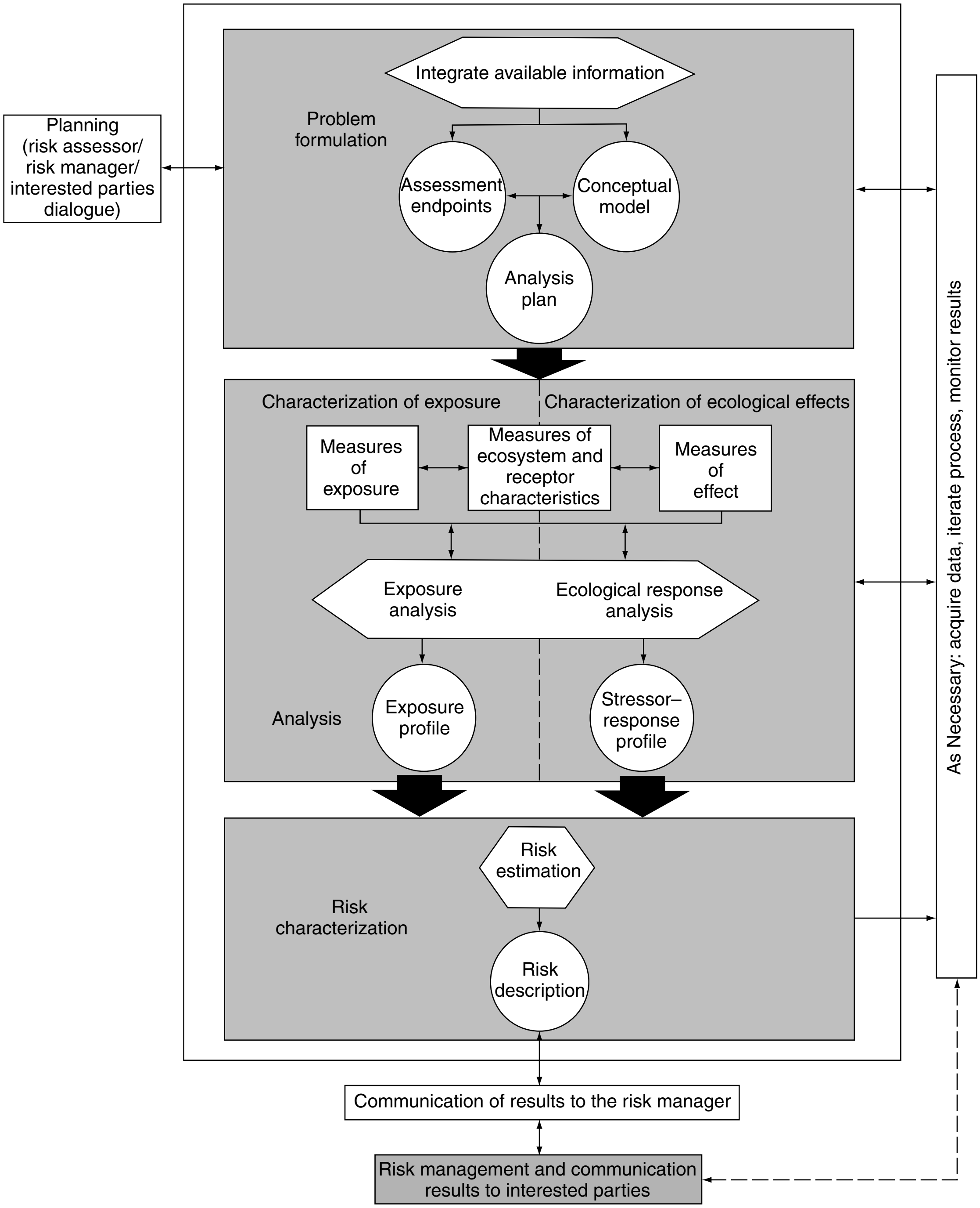

Figure 1 The framework of an ERA. Problem formulation, analysis, and risk characterization phases of the ERA are shown along with major activities within each phase. Rectangles designate inputs, hexagons indicate actions, and circles represent outputs. (Reproduced from Ref. 9, courtesy of US Environmental Protection Agency.)

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of the three phases. It is in this phase of the ERA when clear lines of communication are established between the risk manager and the risk assessor, when the goals, objectives, and endpoints of the assessment are clearly defined, and when a conceptual model is developed that will guide the assessment process.

Before we actually begin a discussion of this first phase of the ERA, it is important to realize that before it, some planning must occur. A planning dialogue has been established between the risk manager, risk assessor, and the affected or interested parties ("stakeholders"). The planning dialogue is complete when:

- agreement has been reached regarding the identity of ecological concerns and resources to be protected;
- options available to mitigate or prevent risk have been considered;
- the necessity, scope, and success criteria for the ERA have been determined; and
- available resources (time, personnel, and money) have been defined

Therefore, as the problem formulation phase begins, there has been discussion between the risk manager, risk assessor, and stakeholders regarding the concerns that have initiated the ERA, and there have been general discussions regarding possibilities for mitigating risk that may be identified by the assessment. At this point, it also is important to reemphasize that the ERA is a process that provides an orderly and systematic method to assess ecological risk. The process itself is flexible and, within the confines of the three major phases (problem formulation, assessment, and characterization), the succession of the assessment may vary depending on the factors that initiated the assessment (predictive or retrospective assessment) and the existing and available knowledge regarding various aspects of the stressors and potentially affected environment.

The problem formulation phase is initiated to produce assessment endpoints, a written description of the predicted relationships between stressors and biota (conceptual model), and an analysis plan (Figure 1). During the development of these products, there is a continued integration of existing knowledge. Available knowledge regarding the sources and nature of the stressors, characteristics of the ecosystem potentially at risk, and potential routes of exposure, along with potential adverse ecological effects, are continually addressed and evaluated during problem formulation to produce the needed products from this phase of the ERA.

The first products of the problem formulation phase that are addressed here are the assessment endpoints. Assessment endpoints are specific characterizations of the ecological value(s) that is (are) to be protected [9]. Characteristics of desirable assessment endpoints would be ecological relevance, susceptibility to potential stressors, and compatibility with the goals of the risk manager (i.e., the assessment endpoints should support the risk management decision) [12].

It is difficult to give specific examples of proper assessment endpoints without elaborating on a specific case where the stressors, ecosystem characteristics, and goals of the risk manager are known. However, the survival and reproduction of song birds, **species diversity** and **abundance** of lake fish, or production of an invertebrate food base for fish may serve as generic examples of potential assessment endpoints. These examples reflect important components of particular ecosystems that may be at risk and are to be protected; they may be sensitive to potential stressors and they may address the goals of the risk manager. In order to evaluate potential interactions (effects) between stressors and the ecological value to be protected (assessment endpoint), it will be necessary to measure potential effects. Therefore, it is desirable to select assessment endpoints that may be directly measured; for instance, the diversity and abundance of fish in a small lake. In some cases, it may be difficult to measure the chosen assessment endpoints directly, and in these cases, the risk assessor must identify measurement endpoints. For example, it may not be possible to measure survival and reproduction of all song birds in a community, but it would be possible to measure the survival and reproduction of selected song birds, such as robins (*Turdus migratorius*), blue jays (*Cyanocitta cristata*), or wood thrushes (*Hylocichla mustelina*), as representative species.

The importance of selecting appropriate assessment and measurement endpoints cannot be overstated. Clearly defined assessment endpoints will guide the direction of the risk assessment, minimize the potential for misunderstanding during later phases of the assessment, and help to reduce uncertainty. The selection of assessment endpoints serves

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as an important point of agreement between the risk manager and risk assessor and becomes a powerful tool in the assessment process [9].

A second component (product) of the problem formulation phase of an ERA is the development of a written description of the potential interactions between stressors and biota. This involves the development of a conceptual model that describes predicted relationships among stressors, pathways of exposure, and the assessment endpoints. The conceptual model includes a diagram of these interrelationships and is developed from known information about the stressors, potential pathways of exposure, and predicted effects on the assessment endpoints. Conceptual models are dynamic and their written descriptions and diagrams can change as additional information regarding the relationships between stressors and assessment endpoints is obtained. The corresponding risk hypotheses predict effects in the assessment endpoints and, along with the conceptual models, are tools that provide a means for synthesizing and communicating what is known about the stressors and their relationship to the assessment endpoints. These models also can highlight uncertainties associated with the ERA by pointing out what is *not* known about stressors, pathways of exposure, and interaction with assessment endpoints. Using the conceptual model and sources of uncertainties as a planning tool, the risk assessor may direct that additional studies be conducted to increase knowledge that will support the risk manager's ability to make appropriate decisions.

The third and final component of the problem formulation phase of an ERA is development of an analysis plan. The risk hypotheses that were developed while forming the conceptual model are examined to determine specifically how they will be evaluated during the next phase of the ERA, the analysis phase. The risk assessor specifies the methods for conducting an evaluation of the risk hypotheses based on information that is known and on what is needed. The rationale for including certain risk hypotheses and omitting others, including a consideration of the feasibility of obtaining needed information, is addressed along with uncertainties regarding the evaluation of each hypothesis. The analysis plan is a summary of the problem formulation phase of the ERA. It indicates how data will be gathered and analyzed to address selected risk hypotheses and how the resulting information relates to decisions on estimates of risk being addressed by the assessment process. The analysis plan guides the activities of the analysis phase of the ERA.

Analysis Phase

The analysis phase serves as a bridge between the problem formulation phase in which the conceptual model and associated risk hypotheses are developed, and the risk characterization phase in which ecological risk is described. During this phase of the assessment, the risk assessor evaluates studies that were conducted to address selected risk hypotheses and describes exposure and effects based on these studies. The desired products of the analysis phase are profiles that describe exposure to stressors and profiles that describe the relationships between stressors and environmental response (i.e., effects of the stressors on the assessment endpoints; Figure 1). The required information identified during the problem formulation phase is collected before beginning of the analysis phase of the ERA; therefore, the assessment process may be temporarily suspended while studies are conducted to gather the needed data.

At the beginning of the analysis phase, before developing exposure and effects (stressor–response) profiles, the risk assessor evaluates each conducted study to provide information needed for assessment of risk. This evaluation includes a determination that the objectives of the study were met and that the quality of the information collected is adequate to support the risk assessment. There may be several different methods identified during problem formulation for gathering needed information. These may include utilization of previously conducted laboratory and field studies, instigation of new laboratory and field studies, or use of information generated by models. The various methods used to gather information may differ in their ability to provide confidence in the decisions of the assessment. For instance, laboratory studies can provide a means for addressing specific questions regarding a stressor and a biotic response while controlling other environmental variables such as temperature fluctuation. However, because laboratory studies are simplifications of the true environment being assessed, the laboratory study may have omitted ecological processes important for understanding stressor interactions with the assessment

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endpoints. Similarly, various models may provide an economical method for evaluating a response to a stressor, especially in situations where the stressor may be a new chemical and where other methods for evaluation may not be available. However, these models are limited by their inherent simplification of the real environment being evaluated. Field studies also have advantages and limitations. While field studies may evaluate the relationships between stressors and assessment endpoints under realistic environmental conditions, they are often costlier, associating an observed effect with a specific stressor can be difficult and can result in increased uncertainty in the risk assessment process.

Because of the strengths and weaknesses of the various methods used in different studies, the risk assessor will often employ a tiered approach when gathering and evaluating the quality of information. For example, simple conservative models that err on the side of the environment may be evaluated initially, followed by more realistic models, laboratory studies, and field studies. The tiered approach provides a systematic and manageable approach for evaluating various studies designed to assist in assessing ecological risk. Through this process, the risk assessor can address questions regarding individual study objectives and whether each study met its intended objectives. Quality is evaluated by determining whether scientifically valid methods were employed, whether appropriate laboratory and field quality assurance and quality control protocols were followed, and whether the collected data were analyzed using appropriate statistical methods. USEPA is considering adopting the American Society of Quality Control E4 guidelines for assuring environmental data quality [9, 13] (*see* **Shewhart method**). These guidelines emphasize project planning, design of data collection, monitoring, and assessing and verification of gathered data in order to assure that study objectives are met.

Once the risk assessor completes the evaluation of studies that have generated information for the ERA, data that are determined to be useful and of sufficient quality for evaluating the risk hypotheses are selected for use in development of exposure and effect profiles. The exposure profiles describe the source of stressors, their distribution in the environment, and their pathways to and contact (or co-occurrence) with biological receptors. The conclusions of the exposure profile will be estimates of the likelihood that exposure will occur (i.e., that there will be contact between the stressor and biological receptor).

Describing the source of a stressor may appear to be a simple process. However, many stressors may have natural counterparts (e.g., naturally occurring metals), the original source of the stressor may no longer exist, or there may be several sources of the same stressor (e.g., PCBs released from electrical transformers as well as atmospheric deposition of PCBs). The risk assessor will attempt to identify the original source of the stressor, the environmental media that received the stressor, other factors that may influence the generation of the stressor, and various conditions that may influence the availability of the stressor. For example, if the common loon (*Gavia immer*) is the biological entity to be protected on a mercury-contaminated **lake**, the original source of mercury may be a factory that is no longer in operation; however, the lake sediments may still contain mercury. Atmospheric deposition and naturally occurring mercury are additional sources that need to be evaluated along with sediment characteristics and deposits and action of microbial organisms that may affect the form of mercury present (*see* **Benthic ecology**). For instance, some microbial organisms can transform one form of mercury into another, and different forms of mercury have different toxicities. Through this description, the risk assessor identifies possible sources of the stressors of concern along with their distribution in the environment.

Characterizing exposure also requires the identification of biological receptors and a description of the pathways of exposure. The conceptual models and risk hypotheses generated during problem formulation have guided the analysis phase of the ERA and have previously identified biological receptors of interest. These biological receptors are the assessment endpoints or some biological factors related to these endpoints. The pathways of exposure may be complex, and diagrams are often used in conjunction with text to describe the relationships between the stressors and the receptors. Continuing with the example of the common loon and the mercury-contaminated lake, exposure pathways can include mercury-contaminated sediment, mercury in fish, and mercury in water, all of which may contribute to the accumulation of mercury in the loon, but to varying degrees.

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The reader should be aware that although the examples and general discussion used thus far have dealt mainly with evaluation of chemical and metal stressors, physical and biological stressors also may be the focus of the ERA. Dredging or logging operations or possible introduction of a biological organism (e.g., African killer bees or wood-boring beetles in imported lumber) may also be stressors of concern.

The exposure portrait will describe the intensity of, as well as the temporal and spatial relationships between, the stressor and receptors. If there are abiotic factors that influence the bioavailability of a stressor to a biological receptor, or if the stressor and biological receptor are not spatially or temporally related, then there will be no exposure. For instance, contaminants that are tightly bound to minerals in the sediment or buried under sediments may not be available to biological receptors. Similarly, if the distribution of the stressor in the environment and the distribution of the biological receptor do not overlap, there will be no co-occurrence and, therefore, no exposure. However, co-occurrence may not always be necessary for adverse effects to be observed; for example, habitat alteration or disturbance near the foraging or breeding grounds of some bird species can adversely affect reproduction or survival.

Once the relationships between the source and distribution of the stressor, exposure pathways, and co-occurrence of the stressor and biological receptor have been described, the exposure profile is completed and the focus of the risk assessor will turn to the second product of the analysis phase of the ERA – development of an effects profile (stressor–response profile). The effects profile will summarize the effects of the stressors, evaluate how increases or decreases in the stressor result in varying levels of effects, and link the effects to the assessment endpoints.

During the problem formulation phase of the ERA, a conceptual model and analysis plan are developed. If properly developed, the results of the various studies initiated to support the ERA should assist the risk assessor in evaluating effects on the assessment endpoints resulting from exposure to the various stressors. After all, the intent of the conceptual model and analysis plan is to provide information useful in determining effects to the assessment endpoints (e.g., those environmental values that are to be protected).

In the evaluation of effects, the risk assessor conducts an ecological response analysis. The ecological response analysis describes in detail the relationships between the stressors and responses (effects) resulting from exposure to the stressors. The determination of effects is not as simple as it might initially appear. There are many potential interactions among biotic and abiotic components of an ecosystem that can affect assessment endpoints. Determining specific effects resulting from exposure to the stressors under evaluation can be quite challenging. If this challenge is properly addressed in the development of the conceptual model and analysis plan, as discussed above, study results should help to identify stressor-induced effects. For instance, the analysis plan may have included laboratory dose–response experiments (*see* **Toxicology, environmental**), the evaluation of previously published literature that determined no-observed-adverse-effects levels (*see* **Lowest-observed-adverse-effect level (LOAEL)**) in similar species, and/or experimental field studies to provide information regarding effects. If fish populations in a lake were the environmental value to be protected (i.e., the assessment endpoint), adverse effects observed from exposing several species of fish found in the lake to different concentrations of the stressor in the laboratory (dose–response experiments), along with results from exposing these same fish species to the same stressor in outdoor ponds (field experiments), should be helpful in delineating effects (*see* **Aquatic toxicology**).

The strength of an ERA will, to a great extent, lie in the ability of the risk assessment to link data on exposures and effects derived from supporting studies to provide evidence of causation. That is, the risk assessor's ability to link environmental stressors with effects in assessment endpoints helps to reduce uncertainty regarding risk and adds to confidence in the assessment outcome. The ability to establish cause–effect linkages will vary depending on the forces driving the risk assessment and whether the assessment endpoints are measured directly. For instance, establishing cause–effect linkage will be quite different for assessments driven by the potential environmental use of a new pesticide compared with assessments driven by fish kills observed in a lake with potentially toxic sediments. Criteria that have been developed for use in evaluating causation are

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helpful to the risk assessor. These include actions such as determining that the effects are regularly associated with the stressor, that the stressor always precedes the observed effects, and demonstrating that an increase in response (effects) occurs with an increase in the amount of the stressor [2].

As a final product of the analysis phase of the ERA, the risk assessor summarizes information that is known about the effects measured during the analysis. Because the determination of effects may have involved extrapolations from laboratory studies or may have been derived from the use of models, it is important that factors used for extrapolations and model parameters be fully discussed. This discussion should include justification for their use and uncertainties associated with the resulting data. The resulting effects profile will be a scientifically based assessment of measured effects related to the endpoints on which the ERA is based. The exposure and effects profiles that result from the analysis phase serve as the basis for the third and final phase to the ERA – risk characterization.

Risk Characterization

The final phase of the ERA is risk characterization. During this phase, the risk assessor estimates and describes risk to assessment endpoints based on predicted or observed effects and various lines of evidence supporting the likelihood of adverse effects (Figure 1). One of the products of the risk characterization phase is a report to the risk manager summarizing conclusions regarding risk, including a description of uncertainties, assumptions, and qualifiers used in the risk assessment.

During the problem formulation phase of the ERA, hypotheses regarding potential risks are developed and methods for testing these hypotheses are presented in an analysis plan. If those hypotheses are adequately developed and the methods for testing them are scientifically valid, then results presented in the exposure and effects profiles will allow the risk assessor to estimate risk. This illustrates the importance of the problem formulation phase of the ERA; without adequate planning and scientific forethought, the risk assessor will be challenged to estimate and describe risk to assessment endpoints during this final phase of the assessment.

The risk assessor evaluates various lines of evidence provided in the analysis phase of the ERA and also evaluates whether there is support for a conclusion of adverse effects on the assessment endpoints. The conclusions regarding risk can address spatial and temporal concerns as well as considerations for recovery. Spatial concerns address the geographic extent of the exposure and effects, whereas temporal concerns address issues such as the length of time over which exposure and/or effects occur. For example, exposure and effects may only be a concern in a small portion of the area being evaluated; however, if that small portion is a critical part of an organism's habitat, there may be significant risk. Similarly, adverse effects may be subtle and only observed after several or perhaps many years of monitoring. For example, issues regarding effects of various stressors on **global warming** exist on much longer timescale than do issues regarding effects of various stressors on reproduction in small mammalian species (*see* **Reproductive toxicology**). Taking spatial and temporal concerns into account, the risk assessor also evaluates the likelihood of recovery. Depending on the intensity of the stressors and endpoints being evaluated, natural recovery may vary from months to years, or in the case of extinction of endangered species, never (*see* **Demographic stochastic models**).

The end product of the ERA is a risk assessment report (or risk characterization report) prepared by the risk assessor for the risk manager. This report is crucial, for it communicates estimates of risks, the degree of confidence in risk estimates, the evidence supporting these estimates, and an explanation of adverse ecological effects. The risk assessment report also should include data gaps, lack of consensus, and other deficiencies in the assessment. This information must be clearly and adequately presented. The risk manager uses results of the ERA, along with economical, legal, and social factors, in making risk management decisions and communicating with stakeholders regarding these decisions. Potential decisions may include additional risk assessment (i.e., reiterations of the problem formulation or analysis phases of the ERA) or mitigation to reduce exposures or effects (and thus risk).

ERA is a process that involves a great deal of planning, forethought, and scientific methodology to arrive at estimates of risk for some valued ecological entity. The three phases of the assessment – problem formulation, analysis, and risk characterization – progressively build on one another and

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provide an organized approach to gathering pertinent information. The uniqueness and complexity of the interactions between individual ecosystems and various stressors require that the ERA process be flexible and adaptable to changing conditions and circumstances. As our knowledge increases, this process will continue to evolve, providing a useful tool for addressing important and complex issues regarding potential risk to our valued ecological resources. Additional reading on ERA may be found in Refs 11, 14–18.

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(*See also* **Ecotoxicology**; **Risk assessment, management and uncertainties**; **Systematics, numerical methods**; **Uncertainty analysis**)

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