AN ASSESSMENT OF THE RISK ASSESSMENT PARADIGM FOR ECOLOGICAL RISK ASSESSMENT

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Summary

This document reviews the strengths and limitations of the paradigm for ecological risk assessment and its implementation. The review is derived from discussions with government and professional organizations, recent literature, and attendance at various relevant symposia, workshops, and other meetings. The prevailing paradigm for ecological risk assessment is reflected in the U.S. Environmental Protection Agency's (1992) *Framework for Ecological Risk Assessment* (Figure 1). The National Research Council (1993) published a similar paradigm.

The USEPA (1992) paradigm for ecological risk assessment expands upon the NRC's (1983) four-step paradigm presented in *Risk Assessment in the Federal Government: Managing the Process*. One of the earliest adaptations of the 1983 paradigm for use in ecological risk assessment is presented in Barnthouse and Suter (1986) and their work provided a starting point for the development of the *Framework*. Consisting of Problem Formulation, Analysis, and Risk Characterization components, the *Framework* illustrates the importance of communication between risk assessors and risk managers and the role of monitoring and other data collection efforts.

Strengths

Perhaps the *Framework's* greatest strength is that it is sufficiently flexible to apply to a broad range of environmental problems. In particular, the *Framework* attempts to broaden the conceptual approach beyond a perceived narrow view of risk assessment as the evaluation of a chemical's effect on a few species. The *Framework* has gained wide acceptance as the basis for developing ecological risk assessment methods and organizing risk assessments within many federal and state agencies. Most people surveyed by us found that the *Framework* provided an acceptable conceptual structure for developing more detailed guidance or for organizing ecological risk assessments.

An important characteristic and potential strength of the *Framework* is its introduction of the term "Problem Formulation" in place of "Hazard Identification" to characterize the nature of initial activities that should occur as part of the risk assessment process. Problem Formulation is the most critical step in ecological risk assessment because it provides direction for the analysis and should take into account the ecological, societal, and political issues related to the questions being addressed. Ecological problems can range from simpler analyses involving a single chemical and a limited number of species to more complex issues such as watershed-level assessments of multiple physical, chemical, or biological stressors. Ecological stressors may include an overabundance of essential nutrients (e.g., nitrogen loading), chemical contaminants, physical alterations (e.g., temperature, water levels, soil type), radionuclides, habitat loss or modification, oxygen consuming substances, introduced species, and genetically-engineered organisms. Ecological receptors affected by one or more of these stressors could include individual organisms,

species, communities, habitats, and ecosystems. The diversity of potential stressors and receptors indicates the care that must be taken at the Problem Formulation stage and its importance for structuring the assessment.

The Problem Formulation stage is also important because it attempts to integrate the perspectives of stakeholders, risk managers, and risk assessors. People do not have a common value system or knowledge base with respect to ecological or environmental issues. Communication among stakeholders, risk managers, and risk assessors at the Problem Formulation stage - as well as during the assessment - is, therefore, important for formulating the questions, identifying differences in perspective, and resolving issues.

The development of the *Framework* and the discussions related to its implementation have fostered the use of a common language for discussing the ecological risk assessment process. In addition, the *Framework* has helped define what is meant by an ecological risk assessment. This has been especially useful inasmuch as a diversity of terms and approaches have arisen to serve various environmental programs.

Limitations

The major limitations related to the paradigm regard knowing how and when to use it. The USEPA, other federal agencies, states, industry, and professional organizations are currently grappling with the development of guidance or approaches for conducting assessments. Much of the discussion in forums related to guidance development centers on fundamental components of the analyses, indicating that we are still at a basic level in understanding how to conduct ecological risk assessment. Further, while there is a growing recognition that the ecological risk assessment process should include ongoing communication among stakeholders, risk managers, and risk assessors, there is little guidance on how this should occur. The importance of communication with stakeholders is not identified within the prevailing *Framework* paradigm.

Risk assessments are tools and as such are better suited for some environmental problems than others. In most cases, risk assessments are used to help answer questions related to decisions. The choice to use risk assessment to answer the questions or help with the decisions will depend on the ecological issues and on other factors that may affect the decision. In this same vein, the complexity of the risk assessment should be appropriate to the question or decision and the level of uncertainty that can be accepted. To this end, a number of groups have identified the need for tiered or phased approaches for conducting assessments leading from simpler to more complex analysis. Finally, there may be cases where risk assessment or any other technical assessment can not meet expectations within an acceptable level of uncertainty due to limits in our understanding of environmental processes and predictive abilities. In such cases, risk assessment may still have value in identifying the extent of uncertainty and gaps in knowledge. However, it would be inappropriate to think that risk assessment has provided a clear "answer".

Recommendations

This review makes the following recommendations:

1. The USEPA's *Framework* should be accepted as the paradigm for most ecological risk assessments. However, the *Framework* could be augmented to: a) reflect the importance of communication among stakeholders, risk managers, and risk assessors throughout the process, and b) identify the iterative nature of risk assessments. The report presents a modified framework to address these issues (Figure 10).

2. Guidance should be developed for implementing components of the *Framework* through a series of case studies. This should be undertaken as a collaborative effort involving stakeholders, risk managers, and risk assessors. Guidance is especially needed in the following areas:

   Problem Formulation: This critical step establishes the direction and scope of the ecological risk assessment. The process by which this is done involves identifying the actual environmental value(s) to be protected (Assessment Endpoints) and selecting ways in which these can be measured and evaluated (Measurement Endpoints). The selection and articulation of Assessment Endpoints is the key starting place for the assessment. However, there is very little guidance on how this process should occur and who should be involved. Because of the fundamental importance of this step to the overall assessment, this process should be given the highest priority for guidance development. The selection and articulation of Assessment Endpoints is a focus of communication between stakeholders, managers, and assessors, and, therefore, guidance should be developed through a process that involves representatives from all of these groups.

Weight-of-Evidence Approach: Many ecological risk assessments involve the conduct of a "weight-of-evidence approach". However, there is no consensus on the definition of weight-of-evidence" or how such an approach should be applied. Often the approach reflects an individual's professional judgement and the conclusions reached may not be transparent to others. A definition should be established for use in ecological risk assessment. Further, an effort should be undertaken to examine the professional judgements that underpin weight-of-evidence approaches and how they can be made more explicit. Finally, guidance for conducting quantitative and qualitative weight-of-evidence approaches should be developed. The 1995 report prepared by the Massachusetts Weight-of-Evidence Workgroup (contact Nancy Bettinger at Massachusetts Department of Environmental Protection) is an effort to address this need.

Tiered or Phased Approaches: There is general agreement that risk assessments are best conducted using tiered or phased approaches. There is a need to establish how these should be structured and linked to management decisions. Because tiered assessments are imbedded within management strategies, guidance development should include both risk assessors and risk managers. Related to the implementation of a tiered strategy is addressing the uncertainties inherent in the various levels of analyses. There are many sources of uncertainty in ecological risk assessment. These should be presented and discussed as part of the assessment. Methods for quantifying these uncertainties should be identified and evaluated. The uncertainty in the analysis should be addressed in a manner appropriate for the parties involved in the decision. For example, one goal of uncertainty analysis could be to insure that the decision is "protective" within a reasonable level of uncertainty.

Risk Characterization: Many of the groups surveyed by us identified this component as an area where guidance was needed. Available methods are considered to be limited and often overly simplistic. In some cases, risk characterization is interpreted simply as a restatement of test results. Risk characterization can be viewed as the final stage of a weight-of-evidence approach that relates the analysis results to the Assessment Endpoints. In screening level assessments, simple methods might be employed if these are adequate to answer questions with an acceptable level of protection. In more complex situations, it may be necessary to employ more sophisticated risk characterization tools. Guidance is needed both on when to use tools of varying complexity as well as which tools are most appropriate for a given problem. Ultimately the risk characterization should synthesize and provide information that can be understood and applied to risk management decisions. Identifying and characterizing the uncertainties in the analyses are important aspects of characterizing risks. These are often overlooked or excluded. Guidance is needed on how best to characterize and discuss uncertainty as part of risk characterization.

Communication: Ecological issues can pose communication difficulties among stakeholders, risk managers, and risk assessors. These individuals do not share common language systems and may not share common value systems. These differences are often not recognized and this can lead to problems throughout the assessment process. A better understanding of these differences is needed in order to learn how the groups can communicate more effectively. Discussions concerning the development of Assessment Endpoints is a useful place for exploring the nature of these differences and identifying methods for bridging gaps in understanding among the groups. This could be accomplished by working through a number of case studies.

3. Stakeholders should have greater involvement in the ecological risk assessment process. However, guidance is needed on how and when to involve stakeholders. For example, there may be many small or well-defined assessments that are part of established regulatory programs where it may not be practical to involve stakeholders in each and every case. Stakeholder involvement should be considered when generic guidance and guidelines are being developed for broad application. Stakeholder involvement should also be considered for larger local or regional assessments where the interests of stakeholders could be affected by the decision(s). The need for stakeholder involvement at early stages within an ecological risk assessment is more important than for human health risk assessment because of greater diversity of values the public places on natural resources. Ultimately, it is the risk manager's responsibility to determine how to consider and incorporate the interests of stakeholders. This too is an area where guidance is needed.

4. Scientists, policy makers, and the public should be educated on the ecological risk assessment process, its strengths and limitations, and how and when it can be used as a tool to help answer questions or make decisions.

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1.0 Introduction

Ecological risk assessment has received increased attention over the past several years. While the process of ecological risk assessment has been applied for decades, if not centuries, to help make decisions regarding resource management or pollution control, it is only within the last few years that a concerted effort has been made to define the characteristics of such assessments and to establish a common language for discussing approaches and results.

Because ecological risk assessment has been practiced for some time in the absence of a universally or nationally accepted framework or language, there exists a diversity of approaches and terms. Groups working on specific problems such as pesticide registrations, acid rain, or siting of future facilities have developed strategies and terms for assessing risks that are internally understood but which may not relate specifically to those used by other groups. There has also been a "lumpers and splitters" debate concerning what is and what is not an ecological risk assessment.

Because the process of arriving at a common approach and language for ecological risk assessment is relatively new, there has been substantial discussion concerning the structure of these assessments as well as semantics. There has also been apprehension among some ecologists that ecological risk assessment is simply becoming a retrofitted human health risk assessment applied to other species. In particular, there is concern that simplification of the process (i.e., to make it look like the more familiar human health risk paradigm) could result in an oversimplification of ecological problems in an effort to make them fit.

A paradigm is "a philosophical and theoretical framework of a scientific school or discipline." As such, it differs from a specific protocol or guidance. Rather, it provides a general conceptual framework for organizing problems and approaches. The National Research Council (NRC) proposed a four-step paradigm in a 1983 report, *Risk Assessment in the Federal Government: Managing the Process*. This conceptual model included hazard identification, dose-response assessment, exposure assessment, and risk characterization. The U.S. Environmental Protection Agency (USEPA) and other agencies readily accepted this paradigm for the conduct of human health risk assessments. To a limited degree, the paradigm or similar paradigms were applied to certain ecological risk assessments, most notably those related to ocean disposal of sewage sludge (Bierman et al., 1985; Nocito et al, 1989) and investigations of hazardous waste sites (Suter, 1993; Maughan, 1993). One of the earliest adaptations of the 1983 paradigm for use in ecological risk assessment is presented in Barnthouse and Suter (1986) and their work provided a starting point for the development of the *Framework*.

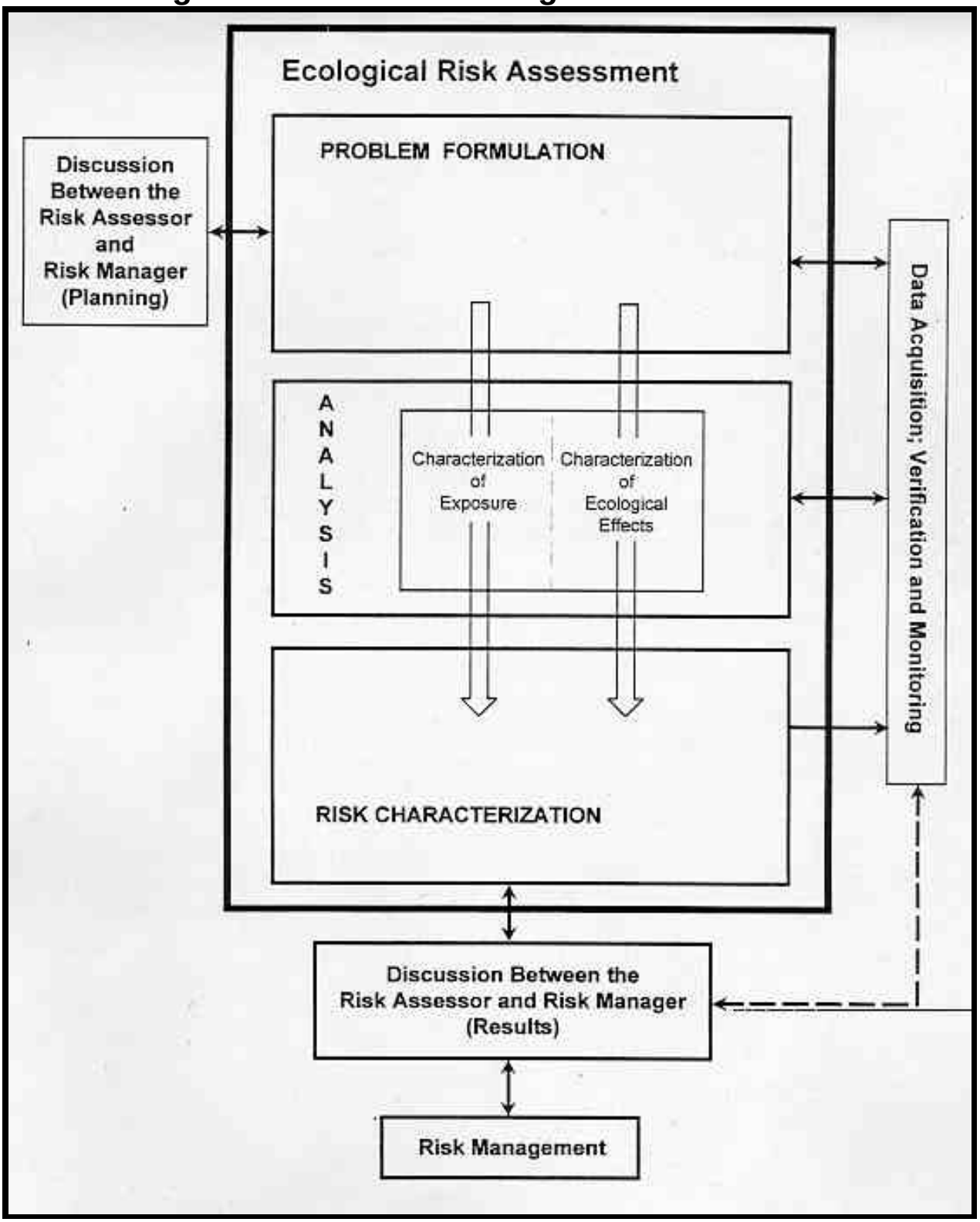
Considerable attention has been given to the development of ecological risk assessment paradigms or frameworks over the past five years. Major efforts have been undertaken by the USEPA in its 1992 *Framework for Ecological Risk*

Assessment and by the NRC in its 1993 *Issues in Risk Assessment*. While these efforts resulted in paradigms that resemble those proposed in 1983 and adopted for use in human health risk assessment, they differ in several respects. The USEPA's framework for ecological risk assessment is illustrated in Figure 1 and consists of Problem Formulation, Analysis, and Risk Characterization components. The most apparent differences between the *Framework* and the 1983 NRC risk assessment paradigm are: 1) the introduction of the term "Problem Formulation" in place of "Hazard Identification" to characterize the nature of up-front activities, and 2) the incorporation of Exposure and Effects assessments into the Analysis component. The integration of exposure and effects characterizations or assessments indicates that these are closely related within the overall analyses. However, they are still identified as distinct conceptual components that are brought together into a characterization of risks. Maintaining a conceptual view of exposure and effects as distinct but inter-related aspects of an analysis is consistent with the NRC's 1983 "four-step" paradigm. USEPA (1992) describes the kinds of information that would be developed for characterizing exposure and for characterizing effects. The USEPA's framework also identifies key areas where communication should take place and the role of data acquisition, verification, and monitoring.

The NRC (1993) reviewed the appropriateness of the 1983 paradigm for application to ecological problems and reached similar conclusions to those of USEPA and proposed a similar paradigm to that reflected in the *Framework* in Figure 1. Although the NRC paradigm retains the term "Hazard Identification", this component is functionally consistent with "Problem Formulation." The USEPA's 1992 *Framework* has come into more common usage than the NRC (1993) paradigm and is considered the prevailing conceptual approach for ecological risk assessment in the United States.

This report examines the utility of the "four-step" risk assessment paradigm for conducting ecological risk assessments as it has been implemented thus far; the USEPA's 1992 *Framework* is considered as the model for the paradigm. Specifically, the report reviews how various agencies and organizations have used the paradigm to guide ecological risk assessment activities, and identifies strengths and limitations. Section 2 of the report examines how key federal agencies, selected state agencies, and professional societies have utilized risk assessment paradigms for ecological risk assessment and identifies some of the strengths and limitations of current approaches as perceived by these groups. Section 3 provides recommendations based on discussions with these groups, experience, and insights from recent colloquia, workshops, and seminars.

Figure 1. USEPA Ecological Framework



2.0 Utilization of Paradigms for Ecological Risk Assessment

To evaluate the usefulness of the ecological risk assessment paradigm, we conducted a survey of the approaches used by various federal and state agencies and several professional organizations and of the application of these approaches.

Federal agencies contacted include:

- USEPA
  - Regional Biological Technical Assistance Groups (BTAGs)
  - Office of Solid Waste
  - Office of Pesticides Program
  - Office of Pollution Prevention and Toxics
  - Office of Water
- National Oceanic and Atmospheric Administration (NOAA)
- Department of Defense
  - Army
  - Navy
  - Air Force
- US Department of Agriculture
  - Animal and Plant Health Inspection Service
  - Forest Service
- Department of Energy
- Regional Ecosystems Office (Interagency)

We also reviewed the methods developed by the Massachusetts Department of Environmental Protection and the California Environmental Protection Agency and the efforts of several professional societies, including American Society for Testing and Materials (ASTM), Ecological Society of America, Society of Environmental Toxicology and Chemistry (SETAC), and Water Environment Federation.

In this section, we discuss the approach used by each agency in conducting or reviewing ecological risk assessments, including methodologies or guidance which have been developed or adopted by each agency. We also summarize staff experience in implementing these approaches.

2.1 USEPA Biological Technical Assistance Groups (BTAGs)

Biological Technical Assistance Groups (BTAGs) have been established in the ten USEPA Regions to provide support on ecological issues related to investigations and clean-up of Superfund sites. BTAG members typically include regional scientists from USEPA as well as from other federal agencies such as U.S. Fish and Wildlife and the National Oceanic and Atmospheric Administration (NOAA).

We contacted several of the Regional BTAG coordinators to discuss their experiences in applying the ecological paradigm to hazardous waste sites over the past few years. BTAG members also discussed the application of the paradigm by USEPA contractors and the utility of the paradigm for risk communication and risk management.

2.1.1 Approach to Risk Assessment by BTAGs

All of the BTAG coordinators contacted indicated that they are using the *Ecological Framework for Ecological Risk Assessment* (USEPA, 1992) to review and critique ecological risk assessments. However, BTAG members also indicated that program-level guidance was also necessary to conduct and evaluate ecological risk assessments for hazardous waste sites. To meet these needs, regional BTAG members reference a variety of ecological guidance documents as part of their technical reviews. For example, BTAG members in Region 2 currently use the draft *Ecological Risk Assessment Guidance for Superfund* (USEPA, 1994). BTAG members in Region 9 use California's *Guidance for Ecological Risk Assessment at Hazardous Waste Sites and Permitted Facilities* (CA EPA, 1994) but do not currently use the draft Superfund guidance. Both guidance documents have formats which parallel the USEPA *Framework*, but are tailored to specific programs.

2.1.2 Application of the Framework by BTAGs

The BTAG members that were contacted felt that the USEPA *Framework* document provides a sound foundation to prepare and conduct ecological risk assessments. Many also indicated that they have observed a trend toward more consistent, standardized ecological risk assessments by Superfund contractors since the introduction of the USEPA *Framework*. However, they also stated that contractors do not often fully implement the framework. Examples cited by BTAG members include lack of site conceptual models, incomplete risk characterization and components of the framework either removed or added to facilitate an assessment. Some BTAG members also stated that some of the concepts and definitions within the *Framework* document are poorly understood by Superfund risk assessment contractors and others. For example, some risk assessments reviewed by BTAG members imply that the Assessment Endpoint[1] is as general as "protection of the ecological system," instead of a specific,

[1] Assessment Endpoints are explicit expressions of the actual environmental value to be protected (USEPA, 1992).

ecologically significant endpoint. Other BTAG members indicated that terms such as "stressor"[2] were not well-defined. Some of the BTAG members indicated that the definitions and components within the framework could be better defined using case study examples.

Several USEPA Regions also use the draft *Ecological Risk Assessment Guidance for Superfund* document. Those BTAG members using the draft guidance indicated that it provides useful program-level guidance to evaluate hazardous waste sites. A discussion of the draft guidance is provided in Section 2.2.

2.2 USEPA Office of Solid Waste

2.2.1 Approach to Risk Assessment by Office of Solid Waste

Prior to the introduction of the most recent draft Superfund guidance for ecological risk assessments, the framework for Superfund ecological assessment (Figure 2) was very similar in structure to the USEPA *Framework*. This framework included a "Problem Formulation", "Exposure Assessment", "Ecological Effects Assessment", "Risk Characterization" and several risk management components. This framework evolved from the 1983 NRC paradigm with two significant modifications. First, it displays the ecological risk assessment as an iterative process. Second, it stresses the relationship between risk management and risk assessment.

In September 1994, the USEPA Environmental Response Team released a review draft of *Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments*. This guidance document is loosely based upon the USEPA *Framework*, and is intended to be a program-specific process tool for site managers and risk assessors. The document provides three site illustrations to demonstrate and highlight specific points in the ecological risk assessment process. In addition, the document provides "example boxes" throughout its sections.

The document outlines an eight-step approach (Figure 3) with corresponding risk management decision points in the Superfund process. The steps include:

1. Preliminary Problem Formulation and Ecological Effects Evaluation
2. Preliminary Exposure Estimate and Risk Calculation
3. Problem Formulation: Assessment Endpoint Selection; Development of Testable Hypothesis

[2] A stressor is any physical, chemical, or biological entity that can induce an adverse response (USEPA, 1992).

Ecological Assessment of Superfund Sites: Overview

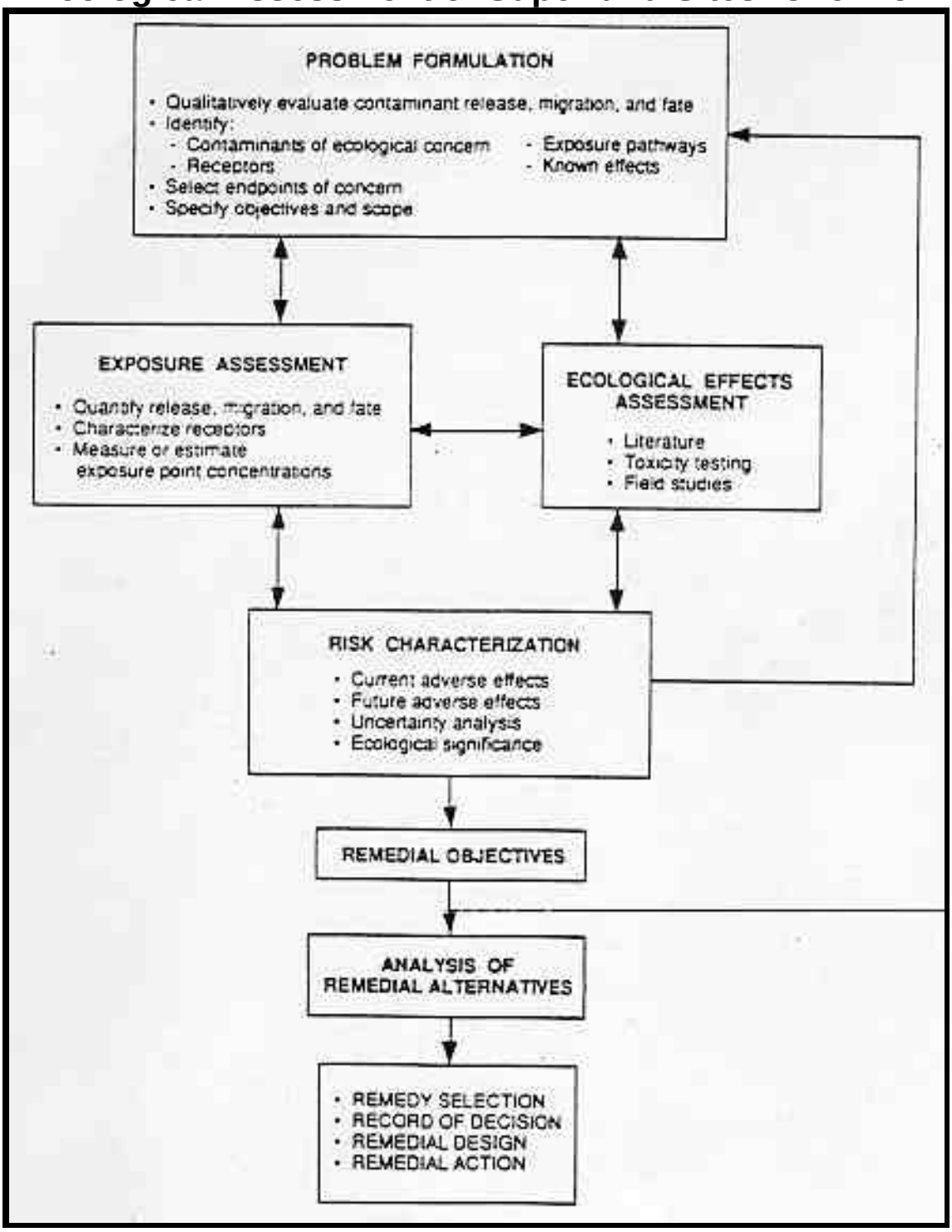


Figure 2. USEPA 1991 Superfund Ecological Risk Assessment Overview.

Site Screening Risk Assessment

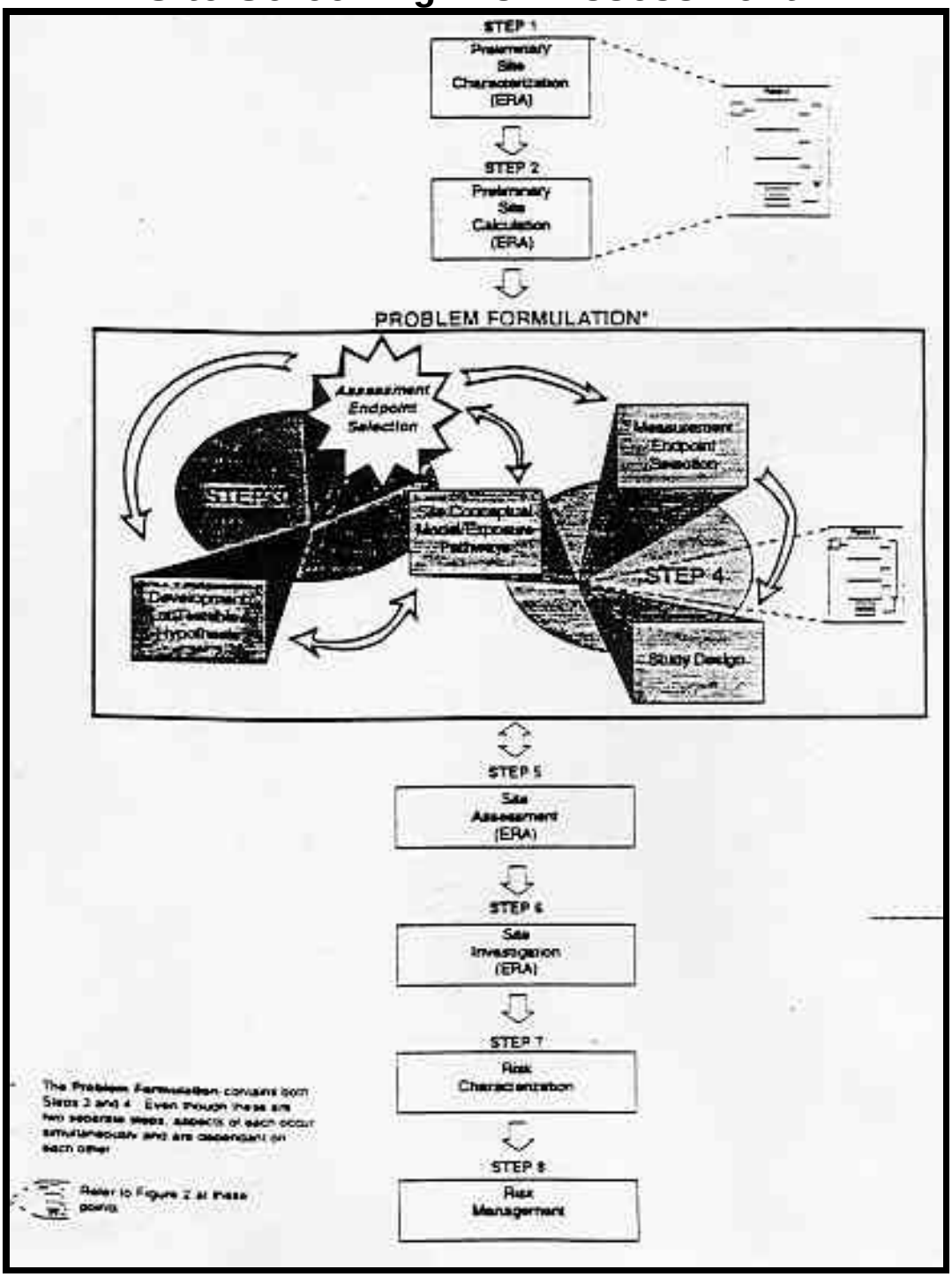


Figure 3. USEPA 1994 Superfund Ecological Risk Assessment Steps.

4. Conceptual Model Development: Site Conceptual Model; Exposure Pathways; Measurement Endpoint Selection and Study Design
5. Site Assessment to Confirm Ecological Sampling and Analysis Plan
6. Site Field Investigation
7. Risk Characterization
8. Risk Management

Steps 1 and 2 consist of a preliminary ecological risk assessment intended to provide early risk management decisions concerning the priority of the site (i.e., if the site poses no or negligible risk). Steps 3 through 8 represent a modified version of the USEPA *Framework* process and include efforts to determine a proposed site-specific clean-up goal that is protective of the environment. The Superfund guidance organizes "Hazard Characterization/Ecotoxicological Effects" and "Exposure Characterization" as part of its "Problem Formulation", while within the USEPA *Framework*, these steps constitute the "Analysis" of a risk assessment, which occur after the "Problem Formulation" has been established.

The draft guidance document also indicates that the steps are not intended to necessarily be linear or sequential. The order of these steps will depend upon the stage of the Remedial Investigation and Feasibility Study (RI/FS), the amount and type of information currently available, and other factors.

2.2.2 Application of the Draft Superfund Guidance

The draft *Ecological Risk Assessment Guidance for Superfund* is currently used within several of the USEPA regions. As with the USEPA *Framework*, the Superfund guidance has been successfully applied to a variety of hazardous waste sites. Some of the USEPA regions have not adapted the Superfund guidance due to its draft status.

Some regional BTAG members currently using the Superfund guidance indicated concern over Steps 1 and 2 of the guidance (preliminary risk assessment). They felt individuals could misinterpret these steps as requiring a "risk assessment before the risk assessment" instead of a process for prioritizing no-risk or low-risk sites.

2.3 USEPA Office of Pesticides Program

The Office of Pesticides Program (OPP) performs approximately 900 risk assessments per year on new and existing pesticides. These assessments vary in complexity depending upon the nature of the chemical and use. For example, simple screening level risk assessments are typically conducted to evaluate the new use of an existing pesticide, while a highly specialized risk assessment may be required to evaluate the cancellation of a pesticide.

2.3.1 Approach to Risk Assessment by Office of Pesticides Program

The Office of Pesticides Program uses the USEPA *Framework* to develop their ecological risk assessments. In addition, OPP uses the *Standard Evaluation Procedure for Ecological Risk Assessment* (1986), which provides program-level standard procedures to determine the risks of pesticides to non-target species. The *Framework* and the *Standard Evaluation Procedure* documents are used in tandem to establish a consistent methodology for conducting the assessments.

2.3.2 Application of the USEPA Framework

The USEPA *Framework* has been successfully applied within the OPP to a wide variety of pesticide risk assessments. The scope and depth of each risk assessment is driven by the nature of the pesticide. Screening level risk assessments are conducted using limited toxicity and exposure information, and a standard set of receptors and exposure assumptions. Some of the guidance required for this level of assessment is obtained from the *Standard Evaluation Procedure* document. More in-depth ecological assessments may entail a weight-of-evidence approach and incorporate information such as product history and field observations. Weight-of-evidence is the process by which multiple measurement endpoints, which may include field, laboratory and/or predictive information, are related to an assessment endpoint to evaluate whether significant risk of harm is posed to the environment.

For new pesticide registration, the OPP may conduct iterative ecological assessments. Such assessments typically begin with initial conservative assumptions. The registrant may then submit additional information if the preliminary risk assessment results indicate potential impacts or risks. Overall, the *Framework* document has proven to be flexible in handling a number of different types of risk assessments with varied amounts of toxicological and exposure information.

2.4 USEPA Office of Pollution Prevention and Toxics

The Office of Pollution Prevention and Toxics (OPPT) is responsible for conducting ecological risk assessments on any new chemicals that are not covered by other statutes. In addition, OPPT evaluates existing chemicals on the Toxic Substances Control Act (TSCA) Chemical Substances Inventory List.

2.4.1 Approach to Risk Assessment by the Office of Pollution Prevention and Toxics

OPPT conducts ecological risk assessments using an approach that is consistent with the USEPA *Framework*. The format and sections of their ecological risk assessment reports follow the same outline presented within the first and second order diagrams of the framework document. Their reports differ from the *Framework* only in some terminology (e.g., "Hazard Assessment" is used by OPPT instead of "Characterization of Ecological Effects").

2.4.2 Application of the USEPA Framework

Ecological risk assessments conducted by OPPT evaluate effects of single chemical stressors. For new chemicals, the ecological risk assessments are sometimes restricted in scope because most applicants do not provide ecological toxicity information. In addition, OPPT typically has limited exposure information and must select receptors based on most likely exposure pathways.

Additional toxicological, fate and transport, and life-cycle information are usually available to OPPT for use in evaluating existing chemicals. In such cases, OPPT conducts a screening-level risk assessment to evaluate whether a risk exists under conservative assumptions. If so, a more detailed risk assessment may follow. OPPT has found the *Framework* to be flexible in evaluating both new and existing chemicals with a wide range of available data.

Currently, the Office of Pollution Prevention andToxics is focusing attention on improving its risk characterization and risk communication. Risk characterization currently includes the use of the quotient method and a weight-of-evidence approach. Risk communication occurs with USEPA risk managers and also with submitter. The risk assessment process can be halted during any stage by the withdrawal of the new chemical by thesubmitter.

2.5 USEPA Office of Water

The Office of Water and the Risk AssessmentFoum are sponsoring the development of a series of five case studies to evaluate how the*Framework* could be applied and further developed for a variety of watershed assessments. We talked with Office of Water personnel to discuss their on-going efforts in developing this modified framework and their experiences to date. This is a multi-agency effort that includes federal, state and local professional participation.

2.5.1 Approach to Risk Assessment by the Office of Water

Office of Water has found the *Framework* to be flexible and to provide the basic principles needed to conduct ecological risk assessment. However, the Office has experimented with changing the sequence of some of the components of the

Framework, and has placed a greater emphasis on the relationship of the risk assessment to risk management. For example, the Office of Water focuses on the selection of assessment endpoints as the interpretation of management goals and develops conceptual models at multiple levels. The conceptual model is used to illustrate the relationships among stressors, receptors, and the endpoints being evaluated. The conceptual models are used to guide data acquisition and analysis.

2.5.2 Application of the Office of Water Methodology

The ecological risk assessment case studies being developed involve a wide variety of physical and chemical stressors including nutrients, hydrology, and land use and are conducted using only available data sources. The case studies also evaluate risks over a wide range of ecological organization including individuals, communities, habitats, landscapes, ecosystems, or some combination of these. Locations of these case studies include Snake River,Middleplatte, Waquoit Bay, Big Darby Creek, and Clinch River. Stressors for these sites included:

Location	Description of stressors
Snake River	nutrients, sediment, water flow
Middleplatte	hydrology (imbalance in water table)
Waquoit Bay	nutrients
Big Darby Creek	point and non-point sources, sedimentation
Clinch River	toxics, sedimentation, and habitat alteration

Because of the complex nature of the stressors and ecological components in these case studies, more communication with risk managers and other interested parties was required within the risk assessment process. The Office of Water has found that such communication was important not only at the beginning and end of the process but at certain critical steps such as the selection of Assessment Endpoints. Depending upon the size and complexity of the watershed, a variety of public and constituency group meetings were held. Opening up the risk assessment process at this stage was especially important to ensure that Assessment Endpoints captured the watershed issues important to interested parties (i.e., managers, regulated community, and the local community).

2.6 National Oceanic and Atmospheric Administration (NOAA)

NOAA provides technical support to USEPA in the development and review of aquatic ecological risk assessments in navigable water bodies. In addition, NOAA is involved with risk management decisions by providing technical support in the determination of target clean-up levels, remedies and mitigation.

2.6.1 Approach to Risk Assessment by NOAA

Currently, NOAA uses both the USEPA *Framework* and the draft Superfund guidance in reviewing risk assessments. NOAA conducts preliminary screening for waste sites of concern consistent with Superfund guidance; however, NOAA's work in support of EPA's risk assessment process is generally for sites warranting complete analysis.

2.6.2 Application of the Framework and Superfund Guidance by NOAA

NOAA staff indicated that both the *Framework* and draft Superfund guidance are providing good direction for the risk assessment process. They also stated that they would like to see more emphasis placed on the "Problem Formulation", including the site conceptual model. They also indicated that they would like to see more in-depth guidance on the characterization and integration of ecological effects and exposure assessment.

2.7 Department of Defense

The Navy, Army and Air Force conduct ecological risk assessments for their respective facilities under the Resource Conservation and Recovery Act (RCRA) and Superfund. These assessments are typically conducted by defense contractors, reviewed and modified as necessary, and then submitted to USEPA.

2.7.1 Approach to Risk Assessment by Department of Defense

The Army has developed the guidance document *Procedural Guidelines for Ecological Risk Assessment* (1994) to evaluate hazardous waste sites. This guidance document was developed from the USEPA *Framework* and the draft Superfund guidance documents, but has been tailored for use at Army sites. The Navy and Air Force are also considering implementing these guidelines to evaluate ecological risks at their sites. In addition, the Army Corps of Engineers is in the process of developing their own separate guidance.

2.7.2 Application of the Paradigms by Department of Defense

The Navy has several regional divisions which evaluate sites within their respective jurisdiction. Each division is responsible for developing risk assessments, and therefore, each conducts risk assessments in slightly different ways. In general, however, the Navy works cooperatively with regulatory agencies to develop the Problem Formulation and establish the Assessment Endpoints. They also work up-front on developing an agreement with regulatory agencies on selecting receptors and a plan for analysis (e.g., field sampling). The Army and Air Force conduct ecological risk assessments in a similar fashion.

2.8 US Department of Agriculture (USDA): Animal and Plant Health Inspection Service (APHIS)

Risk assessments on biological stressors (i.e., non-indigenous biota) are conducted by the Animal and Plant Health Inspection Service (APHIS). Other types of risk assessments conducted by the USDA (e.g., risks associated with chemical-associated pest or vegetation management programs), are addressed by the US Forest Service Environmental Impact Statement process (see Section 2.9)

2.8.1 Approach to Risk Assessment by APHIS

APHIS has developed the *Generic Non-Indigenous Pest Risk Assessment Process* (1993) to estimate pest risk associated with the introduction of non-indigenous organisms. The approach described in the "generic" process is an adaptation of the 1993 NRC paradigm as well as the USEPA*Framework* (Figure 4). It has been tailored specifically for assessing biological stressors such as animal disease, insects, nematodes, exotic fish and gypsy moths. The generic process is also being used by NOAA in assessing aquatic nuisance species and by USEPA for non-indigenous pest species.

The generic process was developed to evaluate the risk of non-indigenous biota associated with a specific commodity or pathway. The generic process is intended to provide a useful framework to allow information to be organized into a format that is understandable and useful to managers and decision makers. Three steps are outlined in the generic process: initiation, risk assessment and risk management. The "initiation" stage involves the initial identification of a high-risk pathway that may result in the introduction of an exotic organism. This stage is analogous to a screening level risk assessment to determine whether sufficient risk is present to trigger a more in-depth analysis. The "risk assessment" stage involves: a) collection of pathway data; b) creating a list of non-indigenous organisms of concern; c) conducting individual pest risk assessments; d) assembling the risk data associated with the commodity; and e) providing recommendations.

2.8.2 Application of the APHIS Process

The APHIS generic process has recently been used in assessing risks from organisms found through the importation of Chilean logs (USDA, 1993). The analysis was carried out by a six-member scientific team who assembled and evaluated available information on forests in Chile, the U.S., and the pests that could be transported. The team followed a methodology which is based on collective professional judgement to determine the Pest Risk Potential (PRP) of each major pest. The analysis relies on knowledge of the pest's and host's biologies, distributions, and the mechanisms that could bring them into contact.

The process was designed to be flexible and dynamic enough to accommodate a variety of approaches depending upon the available resources and accessibility of the biological information. The methodology is designed to accommodate a full

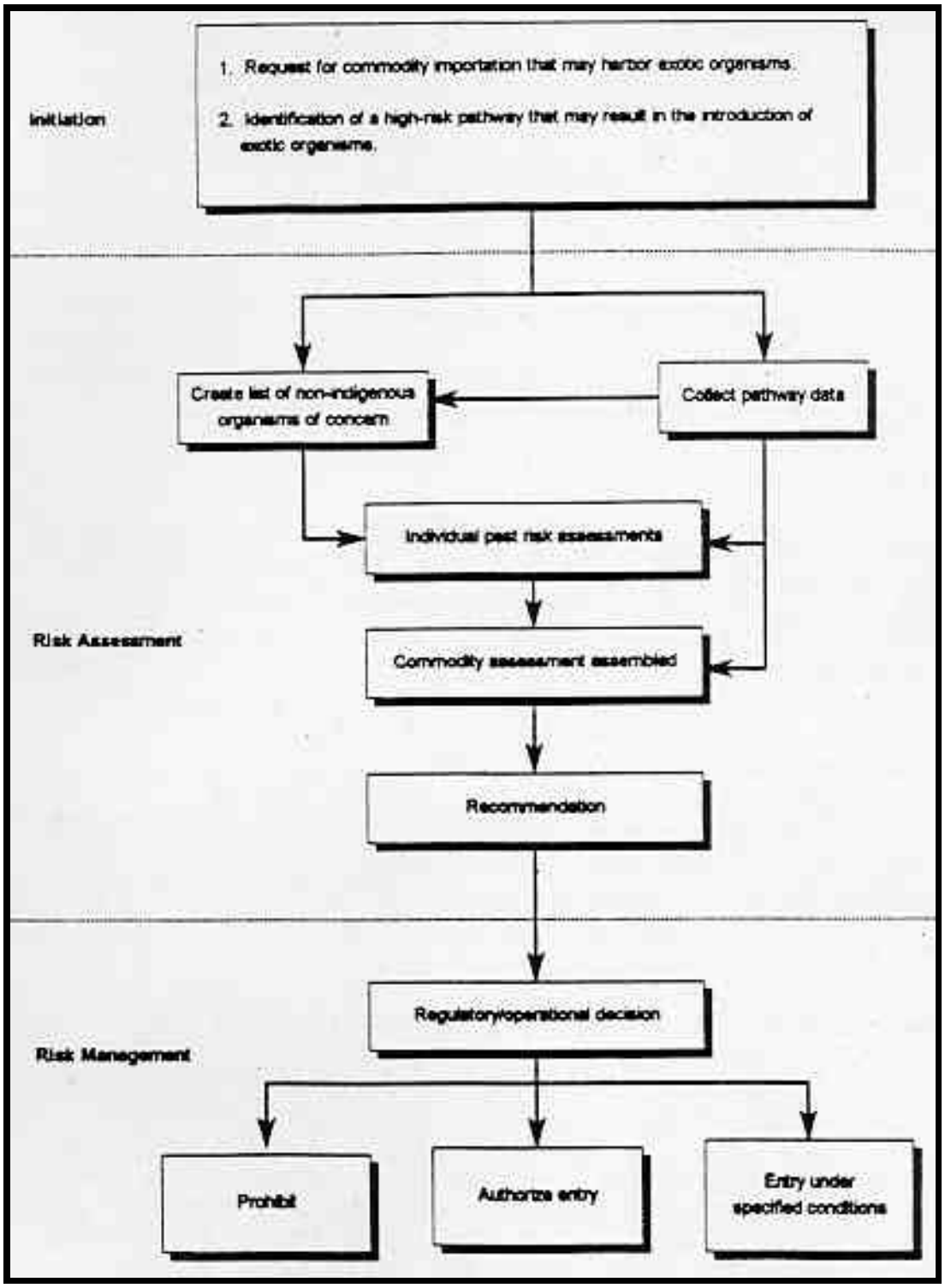


Figure 4. USDA Generic Non-Indigenous Pest Risk Assessment Process.

range of the types of risk assessments required by APHIS. These assessments may range from a simple, screening level assessment to an extensive, research intensive study.

2.9 US Department of Agriculture - US Forest Service

The US Forest Service (USFS), while long familiar with conducting human health and process safety risk assessments, until now has not addressed environmental responses to vegetation or pest management programs. However, the USFS is beginning to address ecological risks as part of Environmental Impact Statements (EIS).

2.9.1 Approach to Risk Assessment by USFS

In the limited number of vegetation management and/or pesticide risk assessments that have been conducted, USFS contractors follow the USEPA *Framework*. USFS personnel have also consulted *Setting Priorities Getting Results: A New Direction for EPA* (National Academy of Public Administration, 1994) when reviewing ecological risk assessments.

2.9.2 Application of Paradigm

The USFS does not conduct its own risk assessments, but rather functions in a reviewing capacity. To date, less than five ecological risk assessments have been completed by USFS contractors. The first final draft ecological risk assessment, conducted as part of an EIS, addressed the risks associated with diflubenzuron applications for controlling gypsy moths. This assessment followed USEPA's *Framework* closely.

2.10 United States Department of Energy (DOE)

Many of the nearly 100 DOE facilities in 31 states and territories are undergoing restoration and are required to consider ecological health and the disposition of ecological resources. Accordingly, DOE has produced a document that proposes a policy framework and an implementation plan for using ecological risk assessment to support environmental management decisions at DOE facilities.

2.10.1 Approach to Risk Assessment by DOE

The *Policy Framework and Implementation Plan for using Ecological Risk Assessment at DOE Facilities* (1993) proposes that DOE adopt the USEPA *Framework* as its primary process to provide technical information on past, present, and future risks to ecological resources across DOE complexes. The document proposes that ecological risk assessments be conducted proactively and holistically at DOE sites. This means that ecological risk assessments should be conducted before management decisions have been made concerning engineered

solutions for environmental restoration, waste management, and so on. The holistic approach calls for ecological risk assessments to be based on ecological entities of interest (e.g., habitat boundaries) rather than on regulatory entities such as operable units or facilities.

DOE proposes a four-phase program of activities:

> Phase I: DOE Headquarters (DOE-HQ) is responsible for conducting a complex-wide, macro-level assessment of ecological resources and stressors on the resources. This assessment provides DOE-HQ with the information necessary to develop site-specific guidance and policies.
>
> Phase II and Phase III: Program and field offices are responsible for conducting "umbrella" risk assessments. Umbrella risk assessments are conducted for the major combinations of ecological resources and stressors. Rather than focusing on discrete risks posed by individual stressors, umbrella risk assessments address cumulative risks to ecological resources posed by separate, multiple stressors.
>
> Phase III: Program and field offices are responsible for conducting targeted risk assessments for habitats, species, or areas defined during Phase II.
>
> Phase IV: This step includes all risk management activities, and calls for the integration of DOE-HQ, field and program office activities.

In practice, individual DOE facilities start with the Policy Framework document and develop site-specific ecological risk assessment guidance for each waste area group (WAG) at each site. In the case of Oak Ridge, guidance is applicable for the entire Oak Ridge site rather than being developed for each WAG.

2.10.2 Application of DOE Paradigm

A number of DOE sites have developed their own site-specific guidance. These sites include Oak Ridge National Laboratory, Idaho National Engineering Laboratory, Hanford Reservation, and Los Alamos.

2.11 Regional Ecosystem Office (Interagency)

The Regional Ecosystem Office is an interagency office created as a result of the Record of Decision for Federal land management within the range of the northern spotted owl. The interagency office consists of members of the Forest Service, Bureau of Land Management, Fish and Wildlife Service, National Marine Fisheries Service, Bureau of Indian Affairs, National Park Service, Army Corps of Engineers, and the USEPA. One of the Regional Ecosystem Office's initial responsibilities was to develop an interagency watershed analysis process to implement an Aquatic Conservation Strategy. Results of watershed analyses

completed using the interagency process are used to establish the watershed context for the subsequent design and evaluation of proposed land management activities.

2.11.1 Approach to Watershed Analysis by Regional Ecosystems Office

The interagency approach presented in the *Ecosystem Analysis at the Watershed Scale* (1995) is similar conceptually to the USEPA *Framework* (Figure 5).

The process includes six steps:

1. Characterize the Watershed
2. Identify Issues and Key Questions
3. Describe Current Conditions
4. Describe Reference Conditions
5. Synthesize and Interpret Results
6. Develop Recommendations

Step 1 of the process places the watershed in context within the river basin, provinces or a broader geographic area and analyzes and describes the dominant physical, biological and human features, characteristics, and uses of the watershed. Step 2 identifies uses and values associated with the watershed and focuses the analysis on key elements of the ecosystem that are most relevant to the management questions, human values and/or resource conditions within the watershed. Step 3 documents the current range and condition of ecosystem elements. Steps 1, 2 and 3 are similar to the Problem Formulation stage in the USEPA *Framework*. Steps 1 and 3 are similar to characterization of ecological components while Step 2 is analagous to identifying measurement and assessment endpoints.

Step 4 documents how conditions from Step 3 have changed over time due to human influence and natural disturbances. This step is similar to the Analysis stage of the USEPA *Framework*.

Step 5 compares existing, historical and reference conditions of specific ecosystem elements to explain significant differences or similarities. This step is similar to Risk Characterization.

Step 6 identifies those management activities that could move the system toward reference conditions or management objectives. This step is similar to risk communication which occurs after the completion of a risk assessment.

2.11.2 Application of Watershed Approach

As of this writing, this six step process is being implemented by the Forest Service and Bureau of Land Management to conduct all watershed analyses for federal lands in Oregon, Washington, and California that are within the range of the northern spotted owl.

Suggested Format for
Watershed Analysis Report

Executive Summary

I. **Step 1: Characterization of the Watershed** (Place it in context and highlight dominant features/processes.)

II. **Step 2: Identify Issues and Key Questions** (Specify Issues and Key Questions to focus the analysis.)

III. **Step 3: Describe Current Conditions** (Focus on ecological elements relevant to the issues.)

IV. **Step 4: Describe Reference Conditions** (Within the constraints of geology, climate, and topography.)

V. **Step 5: Interpretation** (Explain the changes in ecosystem conditions and their probable causes, including the management objectives for the watershed.)

VI. **Step 6: Recommendations** (Recommend activities for restoration, monitoring, protection of sensitive areas and resources, and management.)

Appendices
A - Glossary
B - References
C - Maps

Figure 5. Regional Ecosystems Office Six Step Process.

2.12 State Example: Massachusetts Department of Environmental Protection (MADEP)

The Massachusetts Contingency Plan (MCP), first enacted in 1987, contained language addressing ecological risks as part of the site investigation process. These state regulations were amended to include a methodology for assessing ecological risks in 1993 and 1995.

2.12.1 Approach to Ecological Risk Assessment by MADEP

The MCP currently details a two step ecological risk characterization process that includes a Stage I Environmental Screening and Stage II Environmental Risk Characterization. The Stage I lists criteria to determine whether there is current or potential future exposure of ecological receptors, whether there is readily apparent harm, and whether the current or potential future exposure is potentially significant. Criteria for whether there is current or potential future exposure of ecological receptors include: visible evidence of oil or hazardous material in soil, water, or sediment; records of impacts such as fish kills or stressed vegetation; analytical data indicating the presence of oil or hazardous material in wetlands, surface water or sediment; and oil or hazardous material in soil within two feet of the ground surface.

The final step of the Stage I screening is to evaluate whether the identified ecological exposures that do not constitute readily apparent harm are "potentially significant". This step of the process applies screening criteria to evaluate whether these exposures are potentially significant. These criteria include: state surface water quality standards and federal Ambient Water Quality Criteria; concentrations reported in the scientific literature to be associated, or potentially associated, with toxic effects; and other site-specific criteria identified by the Massachusetts Department of Environmental Protection (DEP).

If the current or future exposure is potentially significant according to Stage I criteria, then a Stage II Environmental Risk Characterization is performed. The Stage II Environmental Risk Characterization follows a process similar to the USEPA's *Framework* and Superfund guidance including Problem Formulation, Analysis, and Risk Characterization. Exposure assessment and effects assessment occur in the “Analysis” stage of the process.

2.12.2 Application of the MCP Environmental Risk Characterization

Massachusetts has approximately two years experience with including the environmental risk characterization process as part of site investigation. Most site investigations in the state are conducted under the supervision of Licensed Site Professionals registered by the state, rather than by DEP employees. In practice, many sites are screened out of the ecological risk assessment process in the Stage I screening.

The DEP continues to run a workgroup to advise them how ecological risk assessment should be applied within the state. There are a number of issues that still need clarification. Thus, while the paradigm appears appropriate, guidance is needed on how to implement it.

2.13 State Example: California Environmental Protection Agency, Department of Toxic Substances Control (DTSC)

The Department of Toxic Substances Control is responsible for managing California's hazardous waste program to protect public health and the environment. The Human and Ecological Risk Section within the Office of Scientific Affairs provides scientific assistance in the areas of toxicology, risk and environmental assessment, and guidance to the regional offices within DTSC.

2.13.1 Approach to Ecological Risk Assessment by DTSC

The Human and Ecological Risk Section of DTSC has recently developed the *Guidance for Ecological Risk Assessment at Hazardous Waste Sites and Permitted Facilities* draft document (1994). The purpose of the guidance is to provide a suggested framework and conceptual model for the approach to, and the organization of ecological risk assessment for DTSC regulated sites.

The draft guidance describes a tiered assessment approach to evaluating hazardous waste sites. Initially, a Scoping Assessment is conducted, which consists of a site characterization, biological characterization, and pathway assessment (Figure 6). Based on the results of the Scoping Assessment, a Phase I predictive ecological risk assessment and Phase II Predictive Assessment Validation (Figure 7) may be conducted. The Phase I and Phase II Predictive Assessment frameworks focus upon use of ARARs, established criteria, and the calculation of Hazard Quotients. A Phase III mitigation/impact assessment is conducted based on the results of the predictive assessments. In Phase III, more detailed field or laboratory studies may be conducted to determine whether there are measurable ecological effects at the site.

2.13.2 Application of the DTSC Guidance

The DTSC guidance is currently used by the Region 9 BTAG as part of their evaluation of ecological risk assessments for Superfund sites. At this writing, the guidance document is still under review.

2.14 Professional Society: Ecological Society of America

According to staff members, the Ecological Society of America is not currently involved in ecological risk assessments. The Society has not reviewed or used any ecological risk paradigms or frameworks.

Initial Scoping Assessment

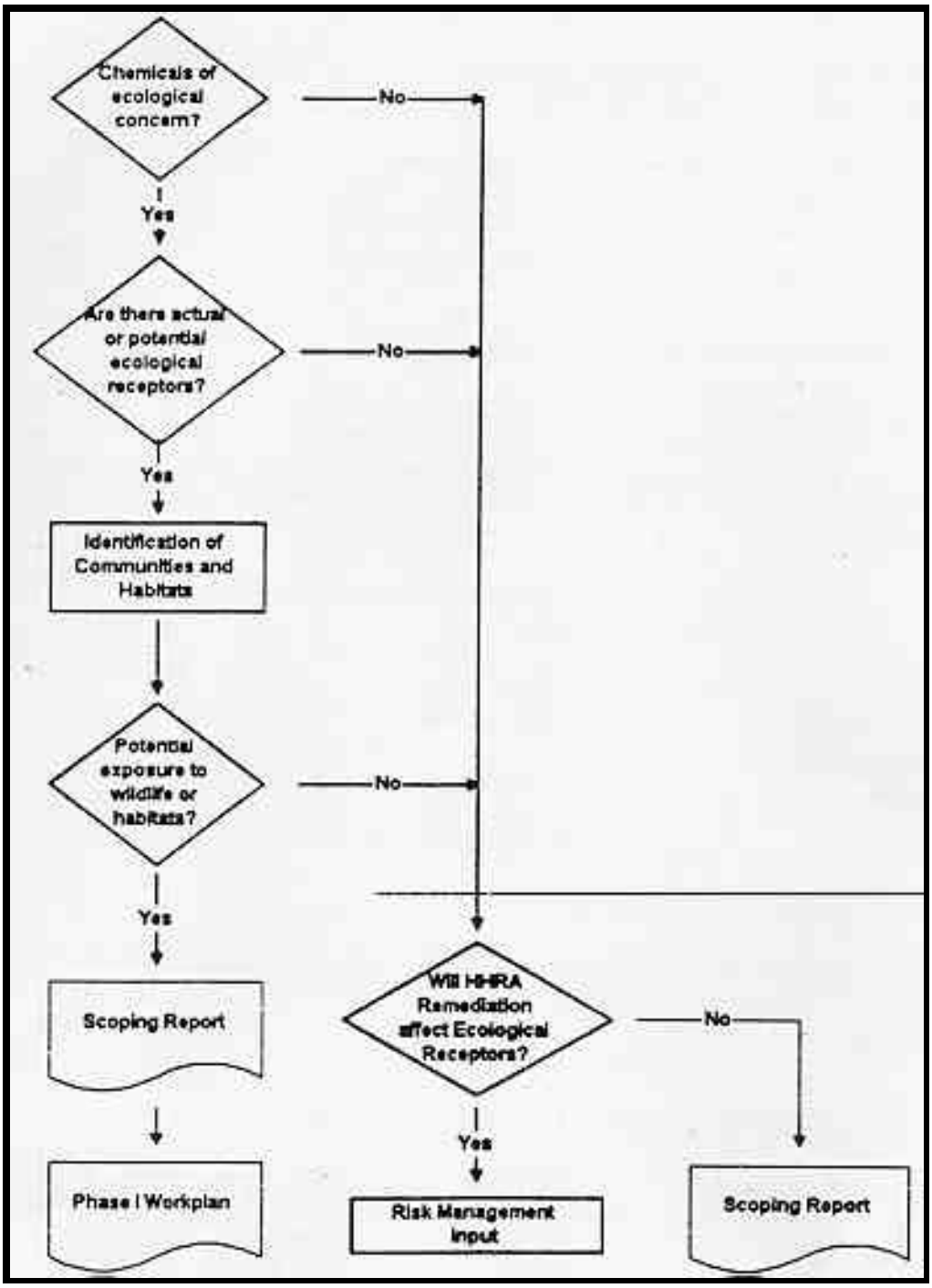


Figure 6. CA EPA Initial Scoping Assessment Overview.

Phase I Predictive Assessment
Phase II Predictive Assessment Validation

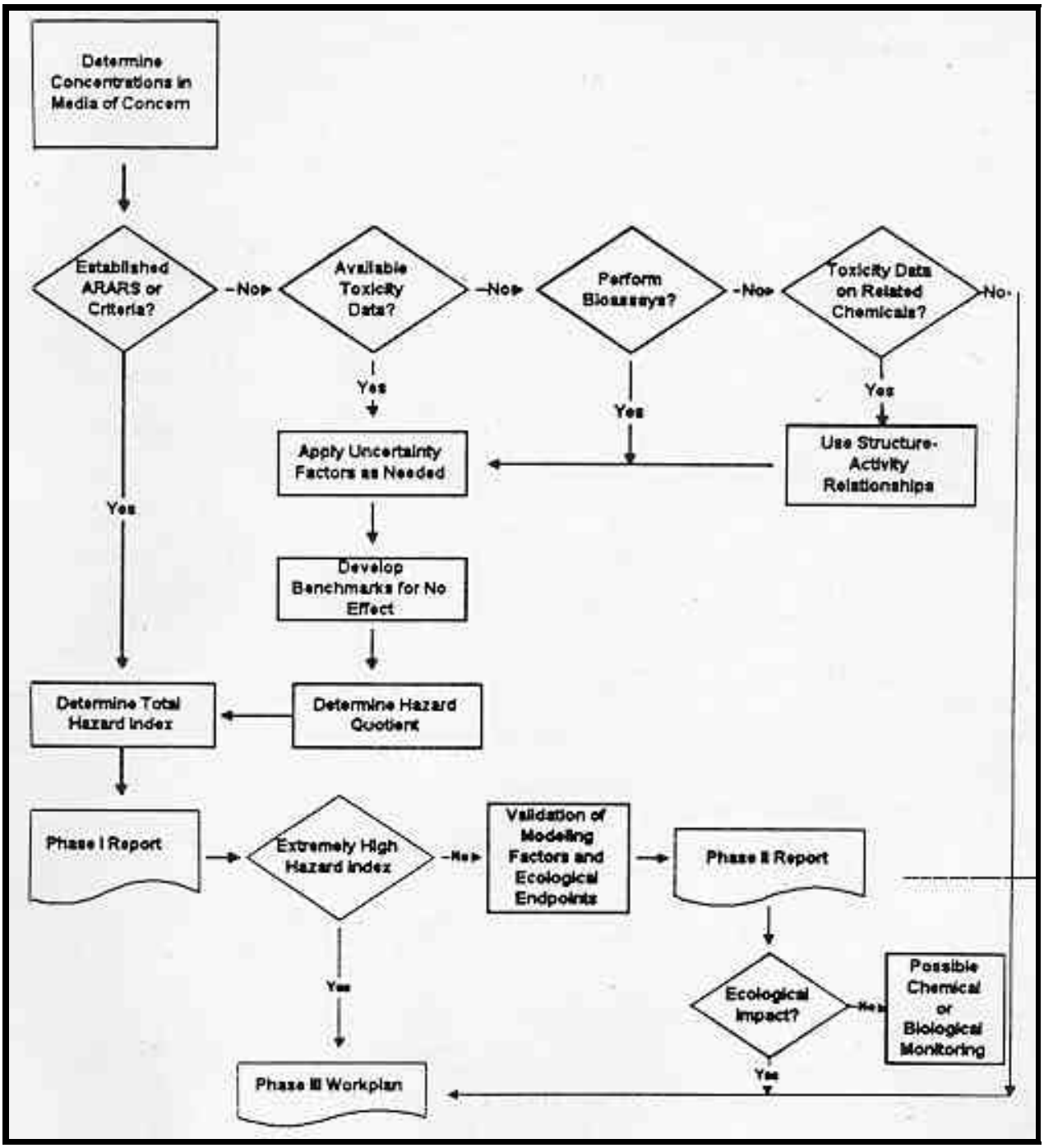


Figure 7. CA EPA Phase 1 and Phase II Predictive Assessment Overview.

2.15 Professional Society: Society of Environmental Toxicology and Chemistry (SETAC)

SETAC does not officially endorse or select any specific ecological paradigm or framework. However, the influence of the USEPA *Framework* can often be seen through SETAC symposia and paper development. In addition, their planning sessions have incorporated the *Framework* document as their starting point. In the future, SETAC will be holding several workshops which will address some important *Framework* issues. These include uncertainty in ecological risk assessments; best assessment/management practices; and risk manager/risk assessor communication.

2.16 Professional Society: Water Environment Federation (WEF)

The research arm of WEF - the Water Environment Research Foundation - has sponsored a two-year project culminating in a *Methodology for Aquatic Ecological Risk Assessment* (AERA) (Parkhurst *et al.*, 1994) for use by members of the regulated (WEF members) or regulatory communities. This project involved a peer-reviewed workshop that included representative of industries, municipalities, universities, national laboratories, state regulatory agencies, and the EPA who were asked to review, evaluate, and comment on the draft protocols.

2.16.1 Approach to Risk Assessment by WEF

The WEF has proposed a three-tiered approach to ecological risk assessment: Tier 1 (screening level), Tier 2 (quantification of risks identified as potentially significant in Tier 1, using existing data) and Tier 3 (risk quantification using new site-specific data). Each Tier progressively builds on the information of the previous tiers.

The AERA methodology was designed to meet the following objectives:

It is applicable to toxic chemicals in surface waters;

It should be consistent with EPA's *Risk Assessment Paradigm* and *Framework for Ecological Risk Assessment*;

It should be consistent with the US EPA's *Technical Support Document for Water Quality-Based Toxics Control*;

It should explicitly address uncertainty; and

It should be used to evaluate clean-up and remediation costs in the context of ecological risk assessment.

In general, the methodology proposed by WEF follows the conceptual approach proposed in the USEPA paradigm. The authors relied on existing ecological risk assessment methods as the basis for the Tier 1 methodology. However, the paradigm has been modified or amplified at several points to enhance its effectiveness as a tool, and procedures in Tiers 2 and 3 are primarily original and were developed by the investigators.

Tier 1 AERA is the most ecologically protective, conservative step in the risk assessment process. The methods used in Tier 1 are designed to eliminate those chemicals that pose no risk, allowing risk assessors to focus exclusively on chemicals with the greatest potential risk in subsequent tiers. Tier 1 involves developing a conceptual model for the site and includes a description of the ecosystem potentially at risk, working hypotheses regarding how chemicals may affect the ecosystem, a plan for hypotheses testing, and a quantitative assessment of risk for each chemical, without addressing uncertainty.

Tier 2 AERA involves preparing a more reliable estimate of the risks from chemicals identified in Tier 1. Tier 2 does not necessarily call for obtaining more data, but rather relies on existing data while incorporating an uncertainty analysis. For example, probabilistic analyses of environmental exposure concentrations (EEC) are addressed in Tier 2. The probability distribution of EECs is compared with the probability distributions for ecological risk criteria to estimate risks. Robust methods for deriving probability distributions are presented, including detailed guidance on how to handle below-detection-level toxicity values. Risk characterization is at the species and community-level, the latter being the percent of species affected by acute or chronic toxicity of chemicals, singly or in combination.

The results of Tier 2 will indicate that many of the contaminants of concern either pose a non-significant risk or pose a risk that is significant within some desired level of reliability. There may also be additional contaminants for which a reliable remediation decision cannot be made based on Tier 2 data, primarily due to the level of uncertainty in the risk estimates. These contaminants are taken through Tier 3, which follows the same basic methodology as Tier 2, but calls for additional data collection to focus on key parameters with the highest uncertainty. More detailed modeling and analysis may be called for, as well as a greater reliance on measured, site-specific data.

2.16.2 Application of WEF Paradigm

The WEF paradigm has been applied to several case studies, including the Clear Creek/Central City Superfund site in Colorado and the municipal wastewater treatment plant effluents on the Trinity River near the Dallas-Fort Worth (Texas) Metroplex. It is unknown whether there have been regulatory applications of the methodology. The case studies rely on data collected by other agencies or consultants. The studies were conducted to evaluate the proposed methodology.

3.0 Conclusions

In this report we have examined the following questions based on an evaluation of the experience of agencies and organizations that perform ecological risk assessments:

1. Is the "four-step" risk assessment paradigm useful for conducting ecological risk assessments?

2. What are the strengths and limitations associated with applying the paradigm to ecological problems?

Because the prevailing paradigm for ecological risk assessment is the USEPA's *Framework*, we have used this as a basis for evaluating the usefulness of the existing paradigm. Strengths and limitations are judged relative to this particular paradigm.

Our conclusions and recommendations are based on the survey presented in Section 2 as well as on recent colloquia and workshops and many other discussions with agencies, groups, and individuals. With regard to the questions posed in this report the following conclusions were reached:

- The prevailing paradigm - the USEPA *Framework* - is becoming widely used as a conceptual framework for ecological risk assessment and appears to be flexible enough to handle a wide variety of applications. To some extent, agencies and groups are modifying their existing approaches to be consistent with the terminology and structure of the *Framework*. This is described further in Section 3.1.

- Various agencies and groups, including offices within USEPA, use the *Framework* as a starting point and modify it to suit their particular applications. These modifications often include detail related to phasing assessments, communications between risk assessors and risk managers, and the relationship between assessment and management decisions.

- Because a number of guidance documents were written prior to the establishment of the *Framework*, there can be conflicts between using the "off-the-shelf-guidance" and the general approach suggested by the *Framework*. Practitioners may need guidance on how to resolve historical approaches with the current ecological risk assessment philosophy. The case study reports prepared by EPA (USEPA, 1993) provide insight into how older methodologies relate to the framework. In addition, the guideline being developed by EPA provides several examples drawn from other applications. These documents are a useful starting place for relating various assessment approaches to the framework for ecological risk assessment.

- While the conceptual approach presented in the *Framework* is widely accepted, there is considerable uncertainty regarding the interpretation of the approach, how it should be applied in particular situations, and the mechanics of implementation. Many people identified a need for additional guidance to translate the broad concepts enunciated in the *Framework* into guidance for practical use. This is described further in Section 3.2.

3.1 Usefulness of the Existing Paradigm for Ecological Risk Assessment

In this section, we review the usefulness of the existing paradigm or "four-step" process. Within this report, the "existing" paradigm refers to both the USEPA *Ecological Framework*, and the similar 1993 "four-step" paradigm developed by NRC. While most of the regulatory agencies we contacted implement the *Framework* for ecological assessment, the NRC "four-step" process also reflects an important part of the existing paradigm.

Based on conversations held with various regulatory agencies (Section 2.0) and a review of published ecological assessment case studies, the existing paradigm appears to provide a flexible format for planning and conducting ecological risk assessment. It has been successfully applied to a wide variety of environmental problems for a broad range of chemical, physical, and biological stressors, different levels of biological organization, and a variety of spatial scales. In addition, the existing paradigm has been implemented within or appears appropriate for many regulatory programs.

Examples of the successful application of the *Framework* for non-chemical stressors include *Risk Assessment for the Release of Recombinant Rhizobia at a Small-Scale Agricultural Field Site* and *Effects of Physical Disturbance on Water Quality Status and Water Quality Improvement Function of Urban Wetlands* as presented as part of the Risk Assessment Forum's review of ecological assessment case studies (USEPA, 1994). Additionally, the Office of Water is applying the *Framework* to case studies which involve a variety of physical stressors, including habitat loss and urban encroachment. In addition, the USDA generic process (Section 2.8) used to evaluate risks due to non-indigenous organisms, is based on the NRC paradigm and the *Framework*. Most of the regulatory staff conducting assessments on non-chemical stressors indicated that the *Framework* is well-suited for such evaluations.

The *Framework* has also successfully been applied at different levels of biological organization, including the individual, population, community, and ecosystem levels. Examples of ecological assessments conducted at the individual and population level include those conducted by Office of Pollution Prevention and Toxics, Office of Pesticides Program, and Office of Solid Waste. Many of the assessments presented as part of the Risk Assessment Forum's review of case studies were conducted on the community and ecosystem level including *Risk Characterization Methods Used in Determining the Effects of Synthetic*

Pyrethriods, Assessing Ecological Risk at Rocky Mountain Arsenal, and *The Role of Monitoring in Ecological Risk Assessment*: *An EMAP Example*.

Spatial scales which have been assessed using the *Framework* include those on local, regional and national levels. Some agencies conduct assessments on a variety of levels. For example, Office of Pesticides Program may conduct risk assessments using the *Framework* on a local or national scale, depending upon function of the assessment (e.g., pesticide registration versus cancellation) and the nature and application of the chemical. The Regional Ecosystems Office and the Office of Water are each currently conducting watershed level assessments using methodologies similar to the *Framework*.

The *Framework* has also proven to be flexible in handling assessments of varying complexity. A number of regulatory agencies contacted indicated that they were using the *Framework* to develop both screening level and in-depth risk assessments. Examples of detailed assessments include the dioxin case study reviewed by the Risk Assessment Forum (USEPA, 1994) and acarbofuran case study conducted by the Office of Pesticides Program (USEPA, 1993).

The NRC has also conducted a review of case studies and their applicability to the existing paradigm (NRC, 1993). They found that most of the case studies reviewed fit reasonably well, although they indicated that the case studies involving chemical stressors provided the most obvious fit. In addition, they found substantial variation in the emphasis placed on the individual components. One weakness observed in all of the case studies was inadequate risk characterization including the treatment of uncertainty.

The usefulness of the existing paradigm is reflected in the fact that a wide variety of federal and state agencies, Environment Canada, and professional groups have adopted the *Framework* as a starting point for their own conceptual approaches.

3.2 The Need for Guidance

In general, practitioners find the existing paradigm acceptable and flexible. There does not appear to be a major issue with its use as a conceptual framework for organizing ideas and approaches. It has been used to help various agencies, offices, and groups develop their own risk assessment approaches.

Our survey revealed a desire among practitioners and organizations for <u>guidance</u> on the ecological risk assessment process beyond that currently provided by the *Framework*. Although some guidance already exists within particular USEPA offices and other agencies, the following issues were frequently identified for guidance development:

1. Problem Formulation
   - the selection and articulation of Assessment Endpoints;
   - linkage of Measurement Endpoints with Assessment Endpoints;
   - the identification and characterization of stressors, especially where

multiple stressors were present;

2. Communication and the Risk Assessor/Risk Manager Interface
   - the role of stakeholders in the process;
   - the interface between risk assessment and risk management;
   - communication on ecological matters and risks;

3. Risk Characterization
   - conduct of weight-of-evidence approaches;
   - risk characterization methods;
   - methods for treating or handling uncertainties;

The USEPA's Risk Assessment Forum has been working toward the development of USEPA's agency-wide ecological risk assessment guideline. At a recent colloquium on developing a USEPA guideline, The Risk Assessment Forum indicated that the guideline will expand upon the process described in the USEPA report *Framework for Ecological Risk Assessment* (USEPA, 1995). The guideline will be designed to provide principles and approaches and are not intended as "textbooks or cookbooks." A number of the issues identified above are subjects to be considered within the guideline. The process of developing a draft agency-wide guideline is currently underway. An initial draft of the guideline was peer reviewed in December 1995.

Many of the issues identified above were raised at the colloquium. Two issues that appear to fall outside of the main emphasis of USEPA guideline development but which have generated much discussion are: 1) the roles of stakeholders, and 2) the risk assessor/risk manager interface. For example, Richard Kimerle speaking on behalf of the American Industrial Health Council (ACIH), highlighted the value of early involvement of and partnerships between industry and government agencies. ACIH also provided a suggested framework change for use in guideline development (Figure 8). The key features of the diagram are the iterative process and tiers that may be required to reformulate the problem and the interactive nature of the risk assessor and risk manager throughout this process. In another example, Environment Canada has used the USEPA's Framework as a starting point but has modified it to emphasize continuous iterations and the inclusion of stakeholders in the process (Figure 9). Moore and Biddinger (1995) have outlined a number of critical issues related to the interaction between risk assessors and risk managers during problem formulation.

Many people who were contacted during our survey identified the value of good case studies to illustrate the ecological risk assessment process. Participants at the EPA Colloquium generally expressed the opinion that case studies would help illustrate approaches in the guideline and would indicate the flexible nature of risk assessment.

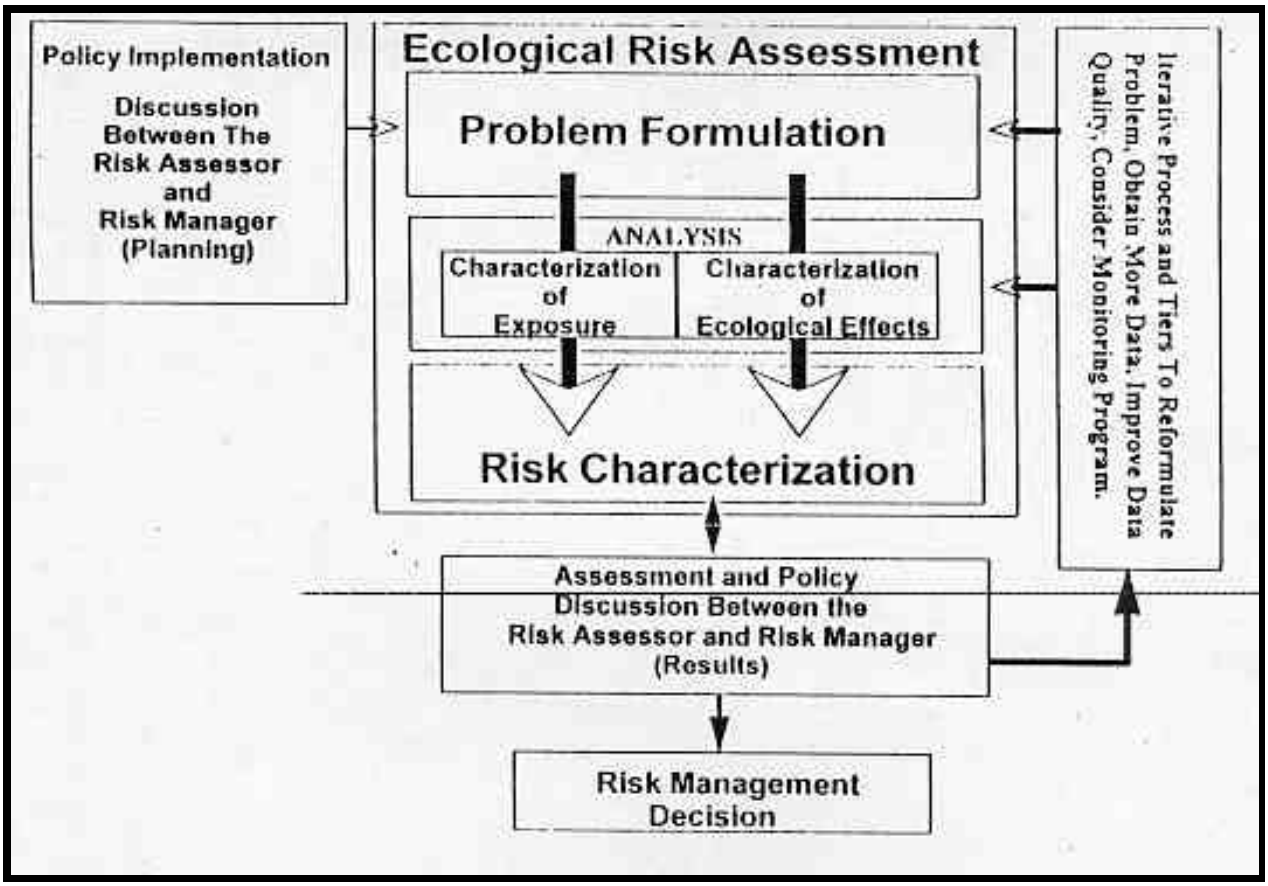


Figure 8. AIHC Suggested Framework.

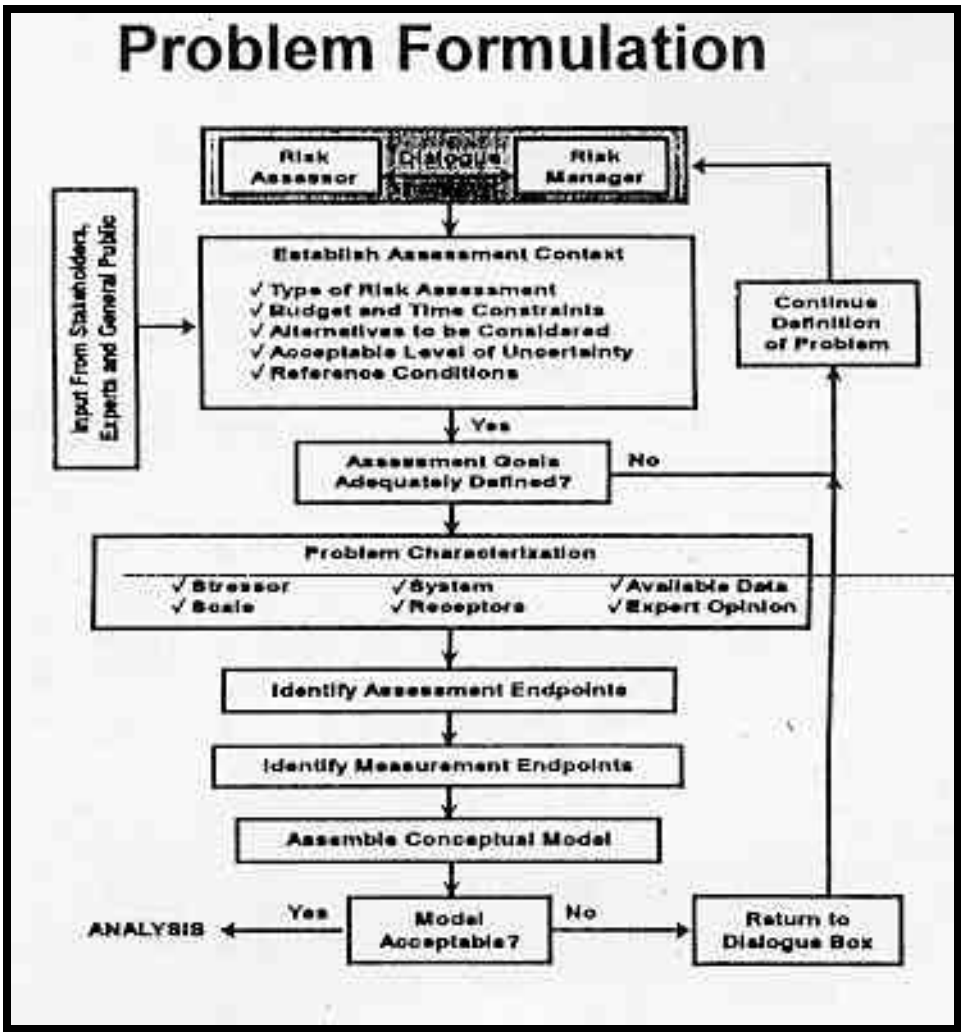


Figure 9. Expanded Problem Formulation Developed by Environment Canada.

Two aspects of the risk assessment process received considerable discussion regarding the need for guidance: Problem Formulation and Communication. These are highlighted below because they appear to be particularly important for the conduct of ecological risk assessments.

3.2.1 The Importance of the Problem Formulation Phase

While the general framework or paradigm appears adequate and appropriate for ecological risk assessments, there are specific aspects of the paradigm that differ greatly from the original paradigm proposed by the NRC in 1983. The most significant difference concerns the Problem Formulation stage. Because it is so important for the implementation of a successful ecological risk assessment, we discuss it in some detail here. Many of the concerns regarding the need for guidance relate to different aspects of the Problem Formulation component. Problem Formulation is the first phase of ecological risk assessment and establishes the goals, breadth, and focus of the assessment; it is a systematic planning step that identifies the major factors to be considered in a particular assessment, and is linked to the regulatory and policy context of the assessment (USEPA, 1992). The Problem Formulation or Hazard Identification phase of Ecological Risk Assessment is perhaps the most important step of the process. In a review of ecological assessment case studies, USEPA (1993) notes that:

> *The case studies illustrate the importance of clearly defining the goals of the assessment and of developing a scope that is appropriate for achieving those goals within the constraints of available resources and the overall uncertainties of the analyses. Reviewers of the case studies generally indicated that a good assessment is one that provides the information needed to address the hypothesis, question, or management decision at a level appropriate to the decision...The strengths and weaknesses of the case studies seem to originate, in large part, from decisions made during the preliminary stages.*

The NRC (1993) noted that the "Hazard Identification" term used in 1983 Red Book report should be expanded for ecological risk assessment to include the identification of policy considerations or regulatory mandates that influence the scope and objectives of the assessment. Again, this underscores the importance of the initial planning phase.

Suter (1993) discusses the activities that occur during the "Hazard Definition" (a.k.a. Problem Formulation) stage of the analysis and emphasizes the process of integrating the process of choosing endpoints, describing the environment, and identifying sources. He notes that although these activities are often performed independently, they should be coordinated so that the Assessment Endpoints are appropriate to the environment, the scope of the environment is appropriate to the size of the source term, etc. Suter focuses on the process of selecting Assessment Endpoints and this emphasis has been carried into the USEPA's *Framework*.

The importance of the Problem Formulation phase is reflected in more recent guidance documents. The *Ecological Risk Guidance for Superfund* (USEPA, 1994 draft) identifies a Preliminary Problem Formulation step as part of site screening and a Problem Formulation step for more complete analyses. The process involves the development of a Conceptual Model for a site and is used to develop a site work plan which specifies the Assessment Endpoints and questions to be answered by site investigations. It further defines the objectives of the site ecological investigation.

3.2.2 Communication

While human health and ecological risk assessments share common conceptual frameworks, they differ in important ways. One of the most important differences is the process of formulating the questions the assessments are intended to address. Questions set the direction for the technical aspects of both human health and ecological risk analyses. An assessment that does not begin with a clear question may never meet the expectations of the risk manger or stakeholders involved in or affected by the decision. This underscores the importance of communication throughout the process.

Human health risk assessments and associated risk management decisions are strongly anthropocentric. There is no question about which species we are interested in, namely ourselves - Homo sapiens - and it is generally clear that we care about a broad range of effects that may affect our health, most notably cancer and systemic health effects. There is no comparable starting point in ecological risk assessment.

It can not be assumed that stakeholders, risk managers, and risk assessors share a common view of what is important to address. People do not have a common value system or knowledge base with respect to ecological or environmental issues. Some may identify the need to maintain biological diversity, some may be drawn toward protection of "charismatic megafauna", others may relate to overall aesthetic quality, while still others may be concerned with the functioning of systems. Against these issues are balanced a host of economic and social concerns regarding land use and access as well as maintenance of commercial and recreational resources. Amidst this divergence of perspectives, special care and attention must be given to developing the questions to be addressed by an ecological risk assessment.

A common misconception is that the ecologist or environmental scientist (risk assessor) is the one who knows what is important to address in an ecological risk assessment and should, therefore, formulate the questions. Where this occurs, the risk assessor assumes the roles of risk assessor, risk manager, and stakeholder, bringing to the problem formulation their own personal set of values. While the scientists involved in ecological risk assessment may be knowledgeable about the structure and function of ecosystems and the factors needed to support species, they can not be expected to represent or appreciate the broad range of

opinion and views held by stakeholders and risk managers. "What is important?" is not solely an ecological question. It is also a question of "What is important to people?" If the assessment is disconnected from what stakeholders and risk managers consider important or if the importance of the assessment can not be established in a meaningful way, then the analysis is likely to fail in providing information useful for decision making.

Over the past few years, the need for up-front communication among stakeholders, risk managers, and risk assessors has been increasingly stressed as a critical component in the conduct of ecological risk assessment. Defining the questions to be addressed has come to be viewed more and more as a collaborative effort. EPA's 1992 Framework for Ecological Risk Assessment identified the need for discussions between the risk assessor and risk manager as part of the planning stages in the initial "Problem Formulation" phase of the assessment. The inclusion of this interaction between the risk manager and the assessor -- as an illustrated box in the framework diagram -- resulted from substantial discussion. The Framework document states that, "At the initiation of the risk assessment, the risk manager can help ensure that the risk assessment will ultimately provide information that is relevant to making decisions on the issues under consideration, while the risk assessor can ensure that the risk assessment addresses all relevant ecological concerns." The framework document does not explicitly mention stakeholders. Including stakeholders within the framework has been suggested by various groups.

The importance of stakeholder and risk manager involvement during the planning of an assessment was raised in a number of forums over the past year. For example, at the May 3, 1995 Colloquium on Developing an EPA Ecological Risk Assessment Guidance, individuals representing such diverse organizations as the Risk Science Institute, the American Industrial Health Council, the Environmental Defense Fund, the State of California, Environment Canada, consulting companies, academics, and industry groups stressed the value of communication with stakeholders on the development of guidelines. They also identified the need for this type of communication as an element for incorporation into the guidance. During an EPA workshop "Communicating with the Public on Ecological Issues," participants discussed the need for "up front" discussions among scientists, managers, and the public as part of the communication process that leads to definition of the questions. This process was referred to as the "box before the box," with reference to the Problem Formulation stage of EPA's Framework for Ecological Risk Assessment.

Because we do not share common value systems and because ecological issues are multi-dimensional, it should be apparent that a "one size fits all" approach in defining the questions for ecological risk assessment is unlikely to work. Instead, we need to extend and modify current approaches to foster communication among all parties prior to and as part of the Problem Formulation stage of an assessment. This suggests that some "customizing" of the assessment will occur in response to the dynamics of the process and that more time may be needed to arrive at an understanding of what is important.

Initial communication among all parties does not mean that each assessment must "start from scratch." There is much experience and knowledge that can be brought to these discussions which can help shape the questions. The scientist/risk assessor can play a key role in this regard in two important ways: 1) as an informed listener, and 2) as a source of information on ecological processes, perhaps with experience in other similar situations.

At initial stages, the scientist should listen carefully to the issues and concerns of others in order to identify where information would be helpful in improving understanding and in formulating the question. The scientist should also be open minded and recognize that what is important to other people may not overlap squarely with what the scientist believes is important ecologically. Most importantly, the scientist should reflect on how the issues and concerns articulated by others can be carried into the Problem Formulation stage of the analysis and where information would be helpful in focusing the questions. Finally, the scientist should listen for what is missed in these opening discussions that may be ecologically important but not obvious to others.

As communications proceed, the scientist/risk assessor can serve as a resource, providing ecological information or experience from other sites. The information may improve others' understanding of the problem; experience from similar situations can help provide direction.

The questions carried into the assessment should reflect a combination of societal values and important ecological concerns. These should lead to the development of Assessment Endpoints: explicit expressions of the actual environmental values to be protected which are the ultimate focus in ecological risk characterization. While it is desirable to achieve a common understanding of the problem and agreement upon the questions and Assessment Endpoints, this is not always possible. People do not necessarily share common interests or values concerning particular environmental issues. In such cases, the risk manager will need to exercise judgement on how the assessment should proceed. An inability to reach consensus does not negate the importance of the process.

While the importance of initial communication is becoming recognized, our experience and understanding of the process is limited. There may be lessons that can be drawn from the work carried out on risk communication in the human health field. One of the greatest challenges will be in developing a better understanding of people's value systems regarding ecological issues. Another challenge will be educating scientists/risk assessors regarding how to communicate effectively with others about these issues and to broaden their frames of reference concerning what is important.

4.0 Recommendations

Recommendations

This review makes the following recommendations:

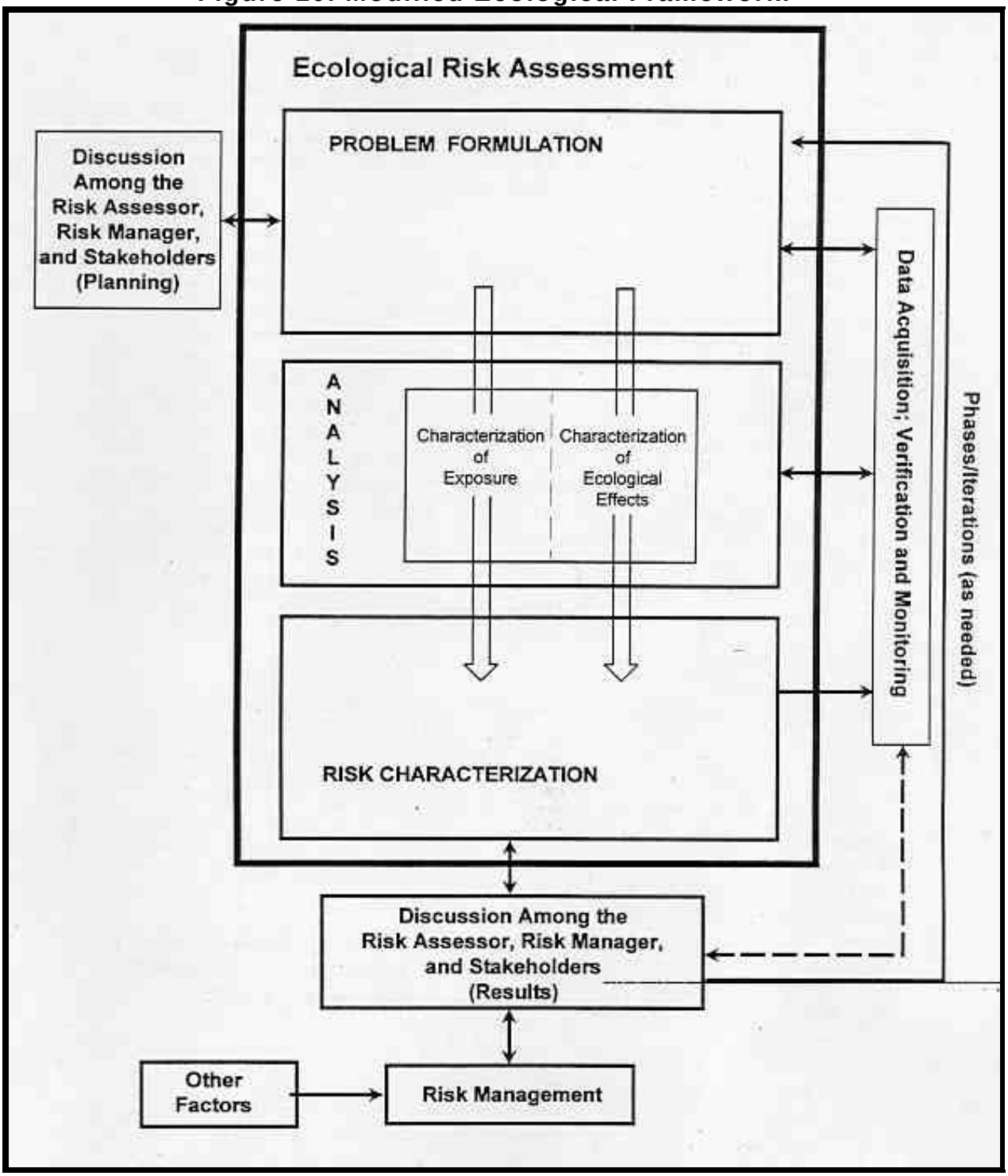
1. The USEPA's *Framework* should be accepted as the paradigm for most ecological risk assessments. However, the *Framework* could be augmented to: a) reflect the importance of communication among stakeholders, risk managers, and risk assessors throughout the process, and b) identify the iterative nature of risk assessments. The report presents a modified framework to address these issues (Figure 10).

2. Guidance should be developed for implementing components of the *Framework* through a series of case studies. This should be undertaken as a collaborative effort involving stakeholders, risk managers, and risk assessors. Guidance is especially needed in the following areas:

   Problem Formulation: This critical step establishes the direction and scope of the ecological risk assessment. The process by which this is done involves identifying the actual environmental value(s) to be protected (Assessment Endpoints) and selecting ways in which these can be measured and evaluated (Measurement Endpoints). The selection and articulation of Assessment Endpoints is the key starting place for the assessment. However, there is very little guidance on how this process should occur and who should be involved. Because of the fundamental importance of this step to the overall assessment, this process should be given the highest priority for guidance development. The selection and articulation of Assessment Endpoints is a focus of communication between stakeholders, managers, and assessors, and, therefore, guidance should be developed through a process that involves representatives from all of these groups.

   Weight-of-Evidence Approach: Many ecological risk assessments involve the conduct of a "weight-of-evidence approach". However, there is no consensus on the definition of weight-of-evidence" or how such an approach should be applied. Often the approach reflects an individual's professional judgement and the conclusions reached may not be transparent to others. A definition should be established for use in ecological risk assessment. Further, an effort should be undertaken to examine the professional judgements that underpin weight-of-evidence approaches and how they can be made more explicit. Finally, guidance for conducting quantitative and qualitative weight-of-evidence approaches should be developed. The 1995 report prepared by the Massachusetts Weight-of-Evidence Workgroup (contact Nancy Bettinger at Massachusetts Department of Environmental Protection) is an effort to address this need.

Figure 10. Modified Ecological Framework.



Tiered or Phased Approaches: There is general agreement that risk assessments are best conducted using tiered or phased approaches. There is a need to establish how these should be structured and linked to management decisions. Because tiered assessments are imbedded within management strategies, guidance development should include both risk assessors and risk managers. Related to the implementation of a tiered strategy is addressing the uncertainties inherent in the various levels of analyses. There are many sources of uncertainty in ecological risk assessment. These should be presented and discussed as part of the assessment. Methods for quantifying these uncertainties should be identified and evaluated. The uncertainty in the analysis should be addressed in a manner appropriate for the parties involved in the decision. For example, one goal of uncertainty analysis could be to insure that the decision is "protective" within a reasonable level of uncertainty.

> *Risk Characterization:* Many of the groups surveyed by us identified this component as an area where guidance was needed. Available methods are considered to be limited and often overly simplistic. In some cases, risk characterization is interpreted simply as a restatement of test results. Risk characterization can be viewed as the final stage of a weight-of-evidence approach that relates the analysis results to the Assessment Endpoints. In screening level assessments, simple methods might be employed if these are adequate to answer questions with an acceptable level of protection. In more complex situations, it may be necessary to employ more sophisticated risk characterization tools. Guidance is needed both on when to use tools of varying complexity as well as which tools are most appropriate for a given problem. Ultimately the risk characterization should synthesize and provide information that can be understood and applied to risk management decisions. Identifying and characterizing the uncertainties in the analyses are important aspects of characterizing risks. These are often overlooked or excluded. Guidance is needed on how best to characterize and discuss uncertainty as part of risk characterization.

Communication: Ecological issues can pose communication difficulties among stakeholders, risk managers, and risk assessors. These individuals do not share common language systems and may not share common value systems. These differences are often not recognized and this can lead to problems throughout the assessment process. A better understanding of these differences is needed in order to learn how the groups can communicate more effectively. Discussions concerning the development of Assessment Endpoints is a useful place for exploring the nature of these differences and identifying methods for bridging gaps in understanding among the groups. This could be accomplished by working through a number of case studies.

3. Stakeholders should have greater involvement in the ecological risk assessment process. However, guidance is needed on how and when to

involve stakeholders. For example, there may be many small or well-defined assessments that are part of established regulatory programs where it may not be practical to involve stakeholders in each and every case. Stakeholder involvement should be considered when generic guidance and guidelines are being developed for broad application. Stakeholder involvement should also be considered for larger local or regional assessments where the interests of stakeholders could be affected by the decision(s). The need for stakeholder involvement at early stages within an ecological risk assessment is more important than for human health risk assessment because of greater diversity of values the public places on natural resources. Ultimately, it is the risk manager's responsibility to determine how to consider and incorporate the interests of stakeholders. This too is an area where guidance is needed.

4. Scientists, policy makers, and the public should be educated on the ecological risk assessment process, its strengths and limitations, and how and when it can be used as a tool to help answer questions or make decisions.

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