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# PROCEDURAL GUIDELINES FOR ECOLOGICAL RISK ASSESSMENTS AT U.S. ARMY SITES VOLUME I

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The purpose of this report is to provide guidance for procedures to conduct ecological risk assessment (ERA) for use by risk assessors under contract to the U.S. Army Environmental Center (AEC) at Army National Priority sites and sites listed under the Base Realignment and Closure program. The report is designed to enhance an understanding of the requirements under the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA). Using this approach will provide AEC with cost-effective, tiered procedures with which to direct and coordinate the scientific and technical efforts of contractors involved in ERA. Employing a common framework across sites will assure the Army that requirements of state and federal regulators are satisfied. The process described in this report follows the paradigm put forward in the 1992 Environmental Protection Agency report entitled "Framework for Ecological Risk Assessment." Volume 2 contains information on more than 100 environmental models and test methods.

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## PREFACE

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# PROCEDURAL GUIDELINES FOR ECOLOGICAL RISK ASSESSMENTS AT U.S. ARMY SITES VOLUME I

## 1. INTRODUCTION

The objective of Ecological Risk Assessment (ERA) is to employ available chemical, toxicological, and ecological information to estimate the probability of undesirable ecological effects[1] and to provide a systematic means of balancing and comparing risks associated with environmental problems[2]. More specifically for the Superfund program, ERA "refers to a quantitative and/or qualitative appraisal of the actual or potential impacts of a hazardous waste site on plants and animals, other than humans and domesticated species. A risk does not exist unless: (1) the stressor has the ability to cause one or more adverse effects and (2) it co-occurs with or contacts an ecological component long enough and at sufficient intensity to elicit the identified adverse effect"[3].

The purpose of this report is to provide guidance procedures to conduct ERA for use by risk assessors under contract to the U.S. Army Environmental Center (AEC) at Army National Priority List (NPL) sites and sites listed under the Realignment and Closure (BRAC) program. This project is needed because ERA has recently been proposed to meet requirements under the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) at NPL sites. In response, the U.S. Army has begun to upgrade their ERA requirements and this effort will greatly speed up that process. The report is designed to enhance an understanding of the requirements under CERCLA. Using this approach will provide AEC with cost-effective, tiered procedures with which to direct and coordinate the scientific and technical efforts of contractors involved in ERA. Employing a common framework across sites will assure the Army that requirements of state and federal regulators are satisfied. The process described in this report follows the paradigm put forward in the 1992 Environmental Protection Agency (EPA) report entitled "*Framework for Ecological Risk Assessment*"[4]. This framework, although similar to the human health risk assessment framework, recognizes the differences between ecological and human processes. These differences include the variety of endpoints and terminology. This ERA framework, which was subjected to extensive peer-review, has been widely accepted as the proper procedure for ecological risk assessments. Currently, guidance documents are in preparation to provide procedural details for ecological risk assessments. The EPA Environmental Response Team, Edison, NJ, recently published a draft document on ERA guidance for Superfund[3]. The EPA document "provides a process for designing and conducting technically defensible ERAs within Superfund. It is not the intent of this document to determine the appropriate scale or complexity of an ERA to be conducted at a hazardous waste site. Additionally,

this document is not intended to direct the user in the selection of specific protocols or investigation methodologies". This document, for the Army, compliments the EPA Superfund report by providing more detailed procedures, thought processes, a tiered approach, sources of information, and methodologies. This report reinforces important points presented in the EPA Superfund report, such as planning and coordination steps in the Problem Formulation phase and risk characterization issues. The U.S. Army Corps of Engineers also produced a draft document entitled "*Risk Assessment Handbook, Volume II: Ecological Assessment*"[5]. It addresses the managerial oversight for ERAs performed by U.S. Army contractors.

### 1.1 Report Objectives

There is a critical need for a technical document which combines the theory of ERA with available ecological effects and exposure assessment methods to provide a guide to the scientific process of ERA. This document is a technical "road map", with examples and discussion of the thought process to lead environmental scientists through this effort. We realize that the field of ERA is in a dynamic flux and recognize that this report cannot address all of the ERA issues. Ecological risk quantification requires a multi-disciplinary approach, typically involving interaction among experts in biochemistry, biology, ecology, environmental chemistry and toxicology[6]. Ecological risk assessments, at any level of effort, have at least two phases:[2] 1) the first requires a conceptual understanding of the environmental problem; 2) the second requires quantification of spatial and temporal variances in exposure to the hazard. Success in this phase requires understanding both exposure and ecological effects.

Ecological risk assessment requires an appropriate, albeit varied, methodology to assess the variety of aquatic and terrestrial ecosystems. To effectively assess critical habitats, populations, and contaminant transfer through trophic levels, the methodology should 1) predict and isolate ecological risks from point and non-point sources; 2) distinguish changes caused by anthropogenic sources from those related to natural stresses or cycles; 3) be non-destructive (i.e., not add to the perturbation of species or the environment); 4) promote a rapid turn-around from data collection to decisions on status of the environment and remediation; and 5) protect the existing biological communities at sites within the larger ecosystem. This information should be collected in such a manner that the risk assessment can distinguish responses in organisms caused by anthropogenic stressors from those caused by natural stressors or seasonal cycles.

This document uses the framework developed by the EPA[4] as the

vehicle for conducting an ERA. The framework presents the ERA process in a technically accurate format and in a format understandable for environmental scientists. Suter[7] provides an excellent presentation of the theory of ERA and presents examples of ERA. We highly recommend developing an understanding of information presented in Suter[7]. Other publications on ERA were used to provide viewpoints and approaches for ERA. These publications were combined with the expertise of scientists experienced in research approaches to ERA through trial and error at various sites[8,3,9,10]. Those scientists are also developing new scientifically defensible technology to provide useful information for risk assessments[11].

## 1.2 History of Risk Analysis

### 1.2.1 Application of Risk to Environmental Issues

The history of the field of risk analysis is the history of the development and use of various techniques for gathering and analyzing information about potential hazards. Many different qualitative and quantitative analytic techniques have been employed, most of which are borrowed from other disciplines, including actuarial accounting, economics, biology, geology, geography, and engineering.

Risk assessment is appropriate as an analytical tool to help identify problems, set regulatory priorities, compare effectiveness of risk management options, communicate to the public, and identify research needs. Because the purpose of environmental regulations is to protect human health or the environment, risk assessment will quantitatively or qualitatively estimate needed protection levels. Risk assessment is often involved in the generation of health or environmental criteria used in the regulations. Typically, risk assessment alone will not provide, **and is not intended to result in**, a hard and fast number for regulation.

### 1.2.2 Initial Activities of Federal Agencies

Federal agencies began to use chemical risk assessment in the 1970's to estimate the cancer-causing potential of chemicals in commerce. By the mid 1970's, agencies had begun efforts to improve coordination among programs and to ensure consistent use of uniform risk assessment procedures within and across agencies of the federal government. Formal procedures for extrapolating research results to human health effects, i.e., chemical risk assessment, were adopted in the late 1970's. In 1976, the EPA established an internal working group, the Carcinogen Assessment Group (CAG), which published the first interim guidelines for assessing risks of suspected carcinogens. In 1977, the EPA, Consumer Product Safety Commission (CPSC), Food and Drug

Administration (FDA), and Occupational Safety and Health Administration (OSHA) formed the Interagency Regulatory Liaison Group (IRLG). The IRLG met as a forum for voluntary coordination and information exchange until 1980. One of its products was a "cancer policy" that attempted to present the scientific basis for determining a substance's carcinogenicity.

The efforts of agencies in the field of risk analysis were encouraged when, in 1980, the U.S. Supreme Court issued an opinion that required OSHA to perform risk assessments of toxic chemicals as a basis for regulating occupational exposures. Agencies' subsequent use of risk assessments in the development of regulations continued to be controversial, in part because authorizing legislation provided little guidance about how risks should be balanced against other factors. Thus, for example, in 1987, a federal appeals court vacated an EPA rule restricting emissions of vinyl chloride because the agency had not used risk assessment properly. Other risk assessment decisions also have been overturned by federal courts because the assessment was judged to be of insufficient technical quality.

### 1.2.3 National Academy of Science (NAS) Framework

The efforts of federal agencies to systemize risk analysis were criticized by some scientists and industrial representatives who were concerned that policy judgements were influencing scientific judgements and thus, the risk assessment process. In response, Congress requested a study by the National Academy of Sciences (NAS) of institutional arrangements to improve the agencies' use of risk assessments. This led to the landmark NAS report in 1983 entitled "*Risk Assessment in the Federal Government: Managing the Process*"[12]. This report presented the initial framework for conducting risk assessment. It discussed the need to distinguish risk assessment from risk management and recommended that uniform risk assessment guidelines be established by the federal government. Although such a uniform guide for the federal government has not yet been adopted, the Office of Science and Technology Policy (OSTP) in the Office of the President, produced a report in 1985 on chemical carcinogens and proposed a method to assess their hazards. The 1985 report described the state of the science on which decisions could be made. More recently, the National Science and Technology Council Committee on Environment and Natural Resources established a subcommittee on risk assessment to coordinate risk assessment procedures.

### 1.2.4 Cancer and Non-Cancer Guidelines

Following the 1983 NAS framework, various agencies, including the EPA have promulgated their own risk assessment guidelines for carcinogens. The EPA guidelines for cancer risk assessment were finalized in 1986 and are now in the process of being revised (in

a related report the EPA published a classification guide for carcinogens in 1986).

The risks of non-cancer effects of chemical exposure to humans also have been recognized and analyzed. As early as 1980, just before it was disbanded, the IRLG was developing guidelines for the risk assessment of effects on reproduction and human development. To date, the EPA has promulgated final guidelines for risk assessment of effects on human development and reproduction. No guidelines have yet been established for assessing risks of reproductive failure, nervous system damage, respiratory effects, or damage to the immune system.

### 1.2.5 Council, Committee, and Society Actions

Other groups are also active in risk assessment and risk management. The National Research Council (NRC) of the NAS has a permanent Committee on Risk Assessment Methodology (CRAM). They are working to consider changes in the scientific foundation of risk assessment that have occurred since the 1983 NAS report. CRAM issued their first report entitled "*Issues in Risk Assessment*"[13] in 1993. As a result of congressional discussions on the use of risk assessment in the Clean Air Act Amendments (CAAA) of 1990, Congress directed the EPA to contract with the NAS to review EPA's risk assessment methods for cancer and non-cancer health effects of exposure to hazardous air pollutants. In response, the NAS established the Committee on Risk Assessment for Hazardous Air Pollutants (CRAHAP) which completed its deliberations in 1992. A report was published in February, 1994.[14] A Commission on Risk Assessment and Management was also authorized by CAAA. The Commission will conduct meeting on various risk issues and produce a report in early 1996. In addition, professional organizations, such as the Society of Environmental Toxicology and Chemistry and the Society for Risk Analysis, were formed to bring together the various scientific disciplines interested in this field.

### 1.2.6 Ecological Risk Assessment

Ecological risk assessments were initiated by the EPA in order to develop water quality criteria required under the Clean Water Act of 1977. The first ecological risk assessments were done in the late 70's and early 80's. Ecological risk assessments initially followed the 1983 NAS framework, but in 1991 several workshops were held by the EPA and NAS to reassess the procedures for ecological risk assessment. In 1992, the EPA published a report entitled "*Framework for Ecological Risk Assessment*"[4]. This new framework, although similar to the human health risk assessment framework, recognizes the differences between ecological and human processes. These differences include terminology and the diversity incumbent in ecological assessments. Ecological risk

assessments must consider many species with various endpoints such as protection of bald eagles (*Haliaeetus leucocephalus*) or maintaining species diversity in an aquatic system, while human health is the only endpoint in health risk assessments. This ERA framework has been widely accepted as the proper procedure for ecological assessments. Currently, guidance documents are in preparation to provide procedural details for ecological risk assessments.

### 1.3 Comprehensive Environmental Response Compensation and Liability Act (CERCLA) and Ecological Risk Assessment

The Comprehensive Environmental Response Compensation and Liability Act (CERCLA), as amended by the Superfund Amendments and Reauthorization Act of 1986, requires the EPA to ensure the protection of the environment via the selection of remedial alternatives, and assessment of the degree of cleanup necessary. The CERCLA makes reference to protection of health and the environment as parts of a whole. Sections call for methods to evaluate and remedy any substance release into the environment or threats of releases which pose substantial danger to public health or the environment. The CERCLA further directs the EPA to attain a degree of cleanup which assures protection of both human health and the environment[15]. The National Oil and Hazardous Substances Pollution Control Plan (NCP) also calls for the identification and mitigation of environmental impacts at hazardous waste site. The NCP calls for the selection of remediation methods to protect organisms, populations, communities, and ecosystems. In response to these regulations the Superfund program established the remedial investigation and feasibility study (RI/FS) process. The RI/FS process characterizes the nature and extent of contamination and the resulting risks posed by the site[4].

Under the CERCLA, sites are initially evaluated for their hazard to humans or the environment by the hazard ranking system (HRS). Substances designated as hazardous under the CERCLA (40 CFR 302.4) usually are the stressor of concern. The HRS uses a health assessment along with exposure and persistence data on the chemicals to rank sites for inclusion as a Superfund site. Hazard ranking system values above 28.5 require the site to be listed on the National Priorities List (NPL). Risk assessment is used in two ways at an NPL site. First, a baseline risk assessment of health and ecological concerns is conducted to determine if the risk justifies mitigation. Second, in the remedial investigation/feasibility study (RI/FS), risk assessment is used to establish risk levels for different areas of the Superfund site.

Health and ecological risk are both critically evaluated under the CERCLA. However, depending upon site-specific

characteristics (e.g., waste site location near relatively high density human population in an urban setting versus relatively low density population in a rural location; waste site near endangered species habitats), human health and ecological risk assessments may receive different levels of effort during the RI/FS process. Regardless of the level of effort, the EPA stresses a preference toward permanence, which EPA has defined as clean-up to background levels. For example, to help establish clean-up goals under the CERCLA, applicable, relevant, and appropriate requirements (ARARs) such as the Clean Water Act, the Endangered Species Act, and other federal or state environmental statutes may be used, when available, to set these clean-up criteria.

Risk assessment can identify areas of the site that have elevated risk. These risks can be related to chemical levels necessary for remediation. An example of the use of risk assessment would be to support the Endangered Species Act. An effects (or hazard) assessment could be used to establish the chemical concentration (with uncertainty bounds) to protect a given organism. The results of the risk assessment are used with other risk management tools to determine mitigation of a site. Risk assessment is also used to evaluate alternate remedial actions.

The CERCLA directs the EPA to notify the appropriate Federal and State natural resource trustees promptly about potential dangers to natural resources. The Federal natural resource trustees include: the U.S. Fish and Wildlife Service (USFWS), the National Park Service (NPS) and the Bureau of Land Management (BLM) of the Department of Interior; the National Oceanic and Atmospheric Administration (NOAA) of the U.S. Department of Commerce; and the Forest Service of the U.S. Department of Agriculture. State agencies and Indian tribes are also designated trustees for natural resources under their jurisdiction. The trustees determine if a natural resource damage assessment (NRDA) should be conducted at a site. An ERA is a necessary step for an NRDA because it establishes the causal link between site contaminants and adverse ecological effects. When a non-CERCLA ERA is initiated, for instance under BRAC, these same agencies may be contacted to provide continuity and as a source of substantive information for the ERA.

The proposed National Contingency Plan (NCP) refers throughout to health and environment as aspects of the evaluation and remediation processes. For example, in discussing the baseline risk assessment in a Remedial Investigation (RI), the purpose is defined as to determining "whether the site poses a current or potential risk to human health and the environment in the absence of any remedial action". The exposure assessment in the RI "is conducted to identify the magnitude of actual or potential human or environmental exposures" and considers the types of adverse health or environmental effects associated with chemical

exposure. In addition, the proposed NCP states that "Superfund remedies will.. be protective of environmental organisms and ecosystems"[15].

The proposed NCP would require the lead Agency to review the remedial action every five years to ensure continued protection of the environment[15]. If, after the remedial action is completed, any hazardous substances remain on a site above levels that allow for unlimited use and unrestricted exposure for human and environmental receptors, CERCLA directs that the Superfund remedial actions meet federal and state ARARs.[15] Federal environmental statutes and regulations that may be ARARs for a particular site include: the Resource Conservation and Recovery Act (RCRA); the Federal Water Pollution Control Act; the Clean Air Act (CAA); the Toxic Substances Control Act (TSCA); the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); the Endangered Species Act of 1973; and the Clean Water Act (CWA).

### 1.4 Risk Assessment Framework

The EPA document "*A Framework for Ecological Risk Assessment*"[4] presents a concise explanation and outline of what an ERA should contain. The framework is presented in Figure 1. The authors stress the importance of preliminary discussions between the risk manager (RM) and the risk assessor (RA). These discussions should set time and funding limits and address policy issues that may affect the selection of assessment endpoints. In the Framework document, the Problem Formulation phase establishes the path the ERA will take. It includes a preliminary characterization of exposure and effects, site history, and various surveys and studies. This information is used to determine assessment and measurement endpoints. Working hypotheses are formulated on how the stressor(s) may affect ecological components.

In the Analysis phase, two interrelated activities occur: 1) characterizing exposure and 2) characterizing ecological effects. The spatial and temporal distribution of the chemicals of concern and their interaction with the ecological system are addressed. In addition, the impact of the chemicals on individuals, populations and communities is quantified. Data requirements should be part of the work plan (see below) for inclusion in the remedial investigation. As a required component of the work plan, it is necessary to address data gaps and data quality objectives[4].

The Risk Characterization phase uses input from the Analysis phase to determine the likelihood of chemical exposure resulting in adverse ecological effects. Various issues including: cause and effect, strength ("robustness") of the data, and scientific

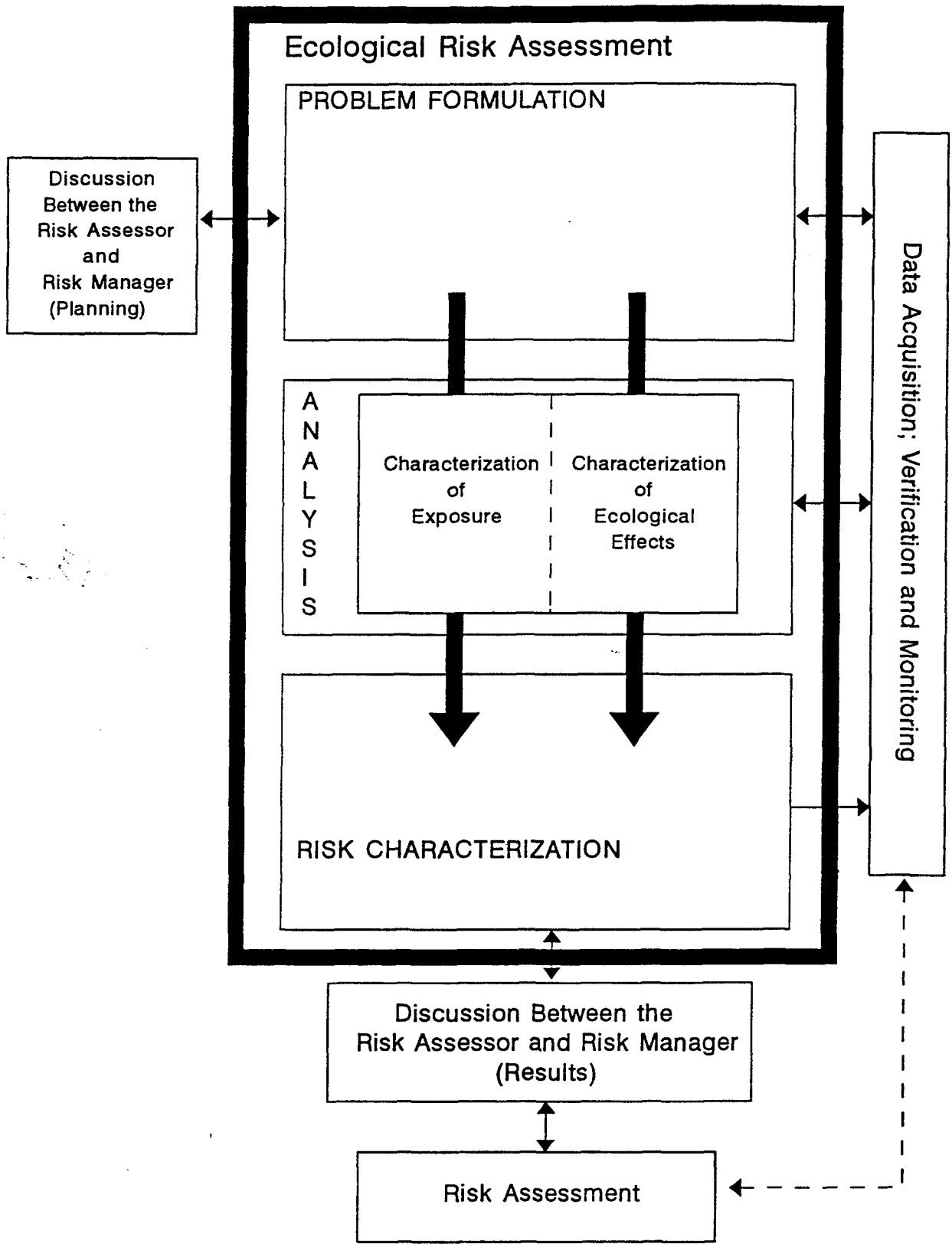


Figure 1. Framework for Ecological Risk Assessment (EPA 1992).[2]

uncertainties are used to judge the ecological significance of the risk. The results from this process are interpreted by the risk assessor in an understandable and useable format. This information should be included in the work plan for inclusion in the RI. Within the framework for ERA[4], the guidance for Superfund contains eight steps and several scientific management decision points (SMDPs) (Figure 2). The guidance stresses meetings between the primary risk managers and risk assessors to evaluate and approve or redirect the assessment up to that point. A group decision is made on whether or not the risk assessment is proceeding in a manner acceptable to the risk assessor and the managers. The guidance emphasizes the importance of SMDPs to build consensus, minimize cost, and speed up the assessment process. The first four steps are in the Problem Formulation phase of the ERA and emphasize the importance of planning and coordination at the beginning of the ERA process. These steps limit the need for repeated studies or delays. Steps 5 and 6 support the Analysis phase of ERA, with site assessments and field investigations. The final two steps are risk characterization and risk management.

### 1.5 A Tiered Approach to Ecological Risk Assessment

A tiered or phased approach has been put forward as a rational procedure by several authors[7,9]. The purpose of a tiered approach is to do the necessary and sufficient amount of work to characterize the risk to an ecological system with an acceptable degree of uncertainty. The definition of "necessary and sufficient work" should be agreed on early in the Problem Formulation phase, with agreement among the "principal responsible party" (PRP), site manager, environmental monitors, the public, and regulatory groups. Field data requirements for the ERA should be conducted in an overall RI work plan. The level of effort in the RI can act as a guide for the level of effort required for the ERA. Limiting factors such as time or funding constraints that could influence the ERA should be acknowledged early in Problem Formulation discussions with the risk manager.

The tiered-analysis process consists of three tiers, each structured similarly, with a Problem Formulation (PF) phase, Analysis phase, and Risk Characterization (RC) phase (Figure 3). Data collected in the Analysis phase of each tier is evaluated and a decision made concerning the potential for risk to occur in the RC phase, after which a decision will be made whether to proceed to testing at higher tiers. The assessment should proceed if the probability of risk is apparent, but complete characterization of risk cannot be determined due to significant data gaps. The assessment should not proceed if no risk is apparent, or if the risk is so great that action (e.g., remediation, containment, etc.) is warranted immediately.

| | | |
|---|---|---|
| 1. | Preliminary Problem Formulation and Ecological Effects Evaluation | |
| 2. | Preliminary Exposure Estimate and Risk Calculation | SMDP (a) |
| 3. | Problem Formulation: Assessment Endpoint Selection Testable Hypothesis | SMDP (b) |
| 4. | Conceptual Model Development: Conceptual Model Measurement Endpoint Selection and Study Design | SMDP (c) |
| 5. | Site Assessment to Confirm Ecological Sampling and Analysis Plan | SMDP (d) |
| 6. | Site Field Investigation | |
| 7. | Risk Characterization | |
| 8. | Risk Management | SMDP (e) |

SMDP = Scientific/Management Decision Point

(a) Early Regional decision in the Superfund Accelerated Cleanup Model (SACM) concerning priority of the site.

(b) Initial agreement on scope of the assessment and work plan.

(c) Signing approval of the work plan and sampling and analysis plan for the ecological risk assessment.

(d) Approval of any changes to the work plan or sampling and analysis plan.

(e) Signing the record of Decision

Figure 2. Steps in the ecological risk assessment process and the corresponding decision points for Superfund (EPA 1994).

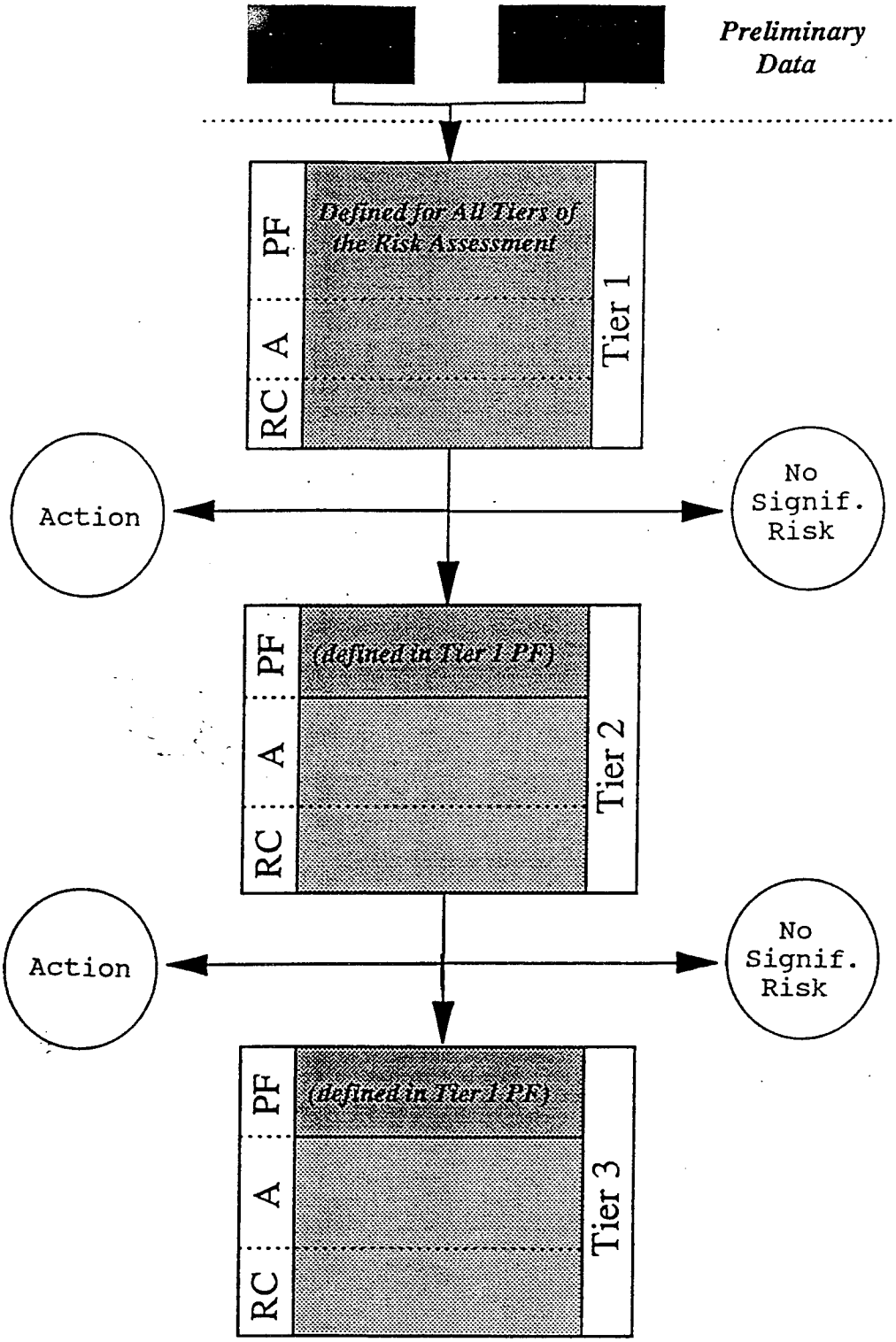


Figure 3. Generalized schematic of the tier structure in Army Risk Assessments. Abbreviations are: PF= Problem Formulation, A= Analysis, RC= Risk Characterization.

Proceeding to higher tiers in these situations would be a waste of time and money. Tiers are defined on the basis of progressive increases in the level of concern or in levels of manpower and monetary inputs in each successive tier.

Tier 1 (Figure 4) involves primarily a literature study, but adds RI results, historical site information, existing field data, literature and output from fate and effects models, and previous field surveys on the biota (including endangered and threatened species). These studies can be conducted by personnel from the installation, the USFWS, or other governmental agencies. Measurement endpoints rely on available data with underlying conservative assumptions and infer protection for assessment endpoints. These data and results may be used to develop preliminary hazard indices (risk quotients). The purpose of higher tiers (Figure 5) is to address data gaps and reduce uncertainty in the risk characterization and lessen the need for the use of conservative assumptions. This does not necessarily mean that laboratory studies are conducted in Tier 2 and field studies in Tier 3. In many cases, a laboratory study in Tier 3 will answer data gaps in the ERA with more precision than would field studies.

Tier 2 should address site-specific issues, limiting reliance on literature-cited values. This may include more models, laboratory tests, or limited field studies to address data gaps in exposure or ecological effects, and use more sophisticated analyses to develop more rigorous hazard indices to prioritize various locations at the site for potential risk. Measurement endpoints should be more complex, relying on specific laboratory or field studies that address data gaps identified in Tier 1, to better relate to assessment endpoints.

Tier 3 involves increased complexity, combining site-specific field observations with laboratory and field data to refine exposure and ecological effects characterization. Studies may include population- and ecosystem-level complexity and involve substantially longer-term investigations. The uncertainty associated with measurement endpoints is reduced, resulting in stronger data and greater confidence. At this point, the risk characterizations rely on distribution of exposure and effects results to facilitate understanding and interpretation of hazard indices at the site.

Although each tier is, in essence, an evaluation by itself, it is important that if testing proceeds to higher levels, there exists continuity in the risk assessment among tiers. Continuity is provided by establishing assessment endpoints. The measurement endpoints employed will change if the ERA progresses to higher tiers; however, the focus on assessment endpoints remains intact. For example, for an investigation of dieldrin residues in soils on a population of coyotes, one measurement endpoint in Tier 1

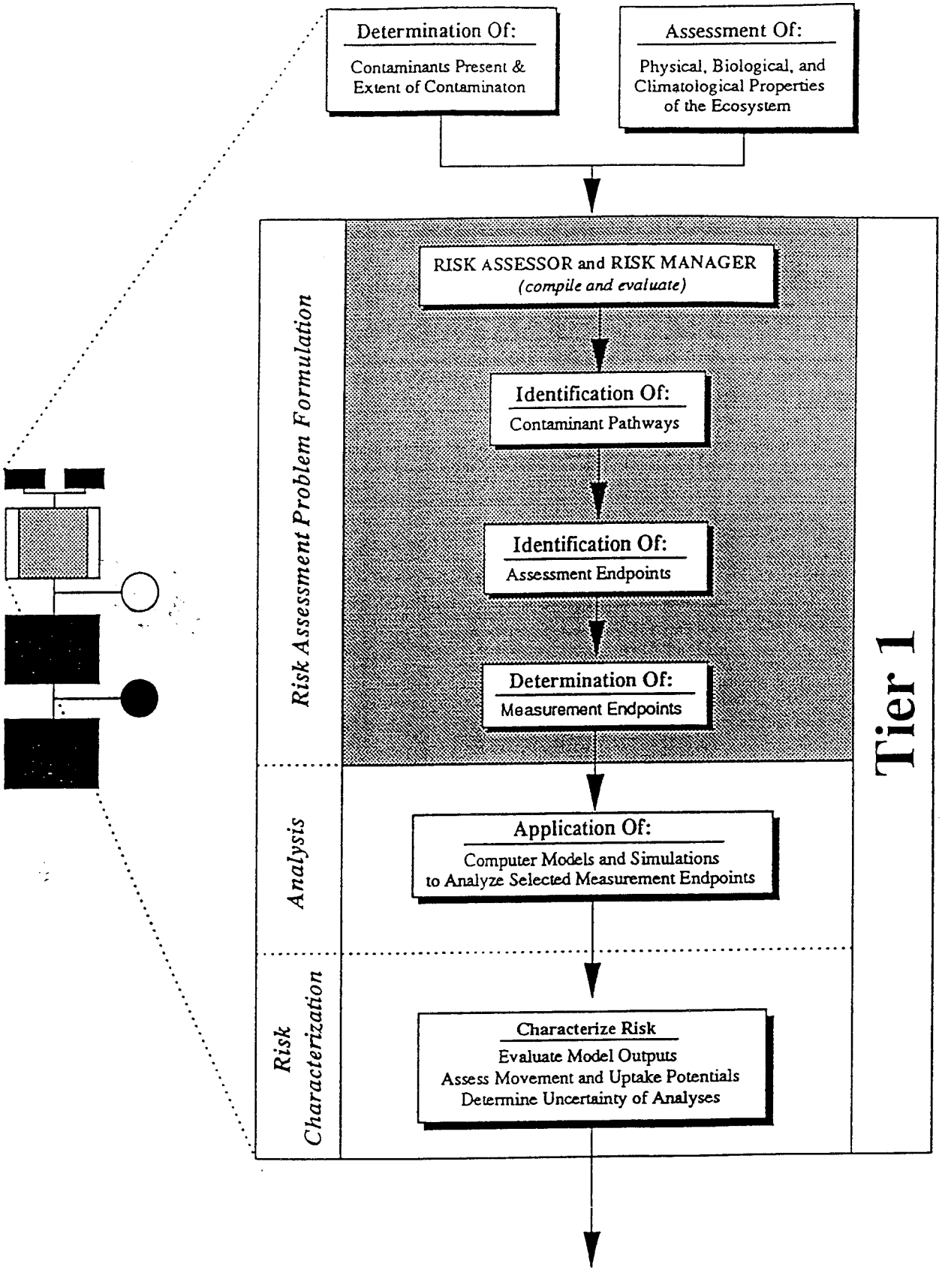


Figure 4. Tier 1 analysis.

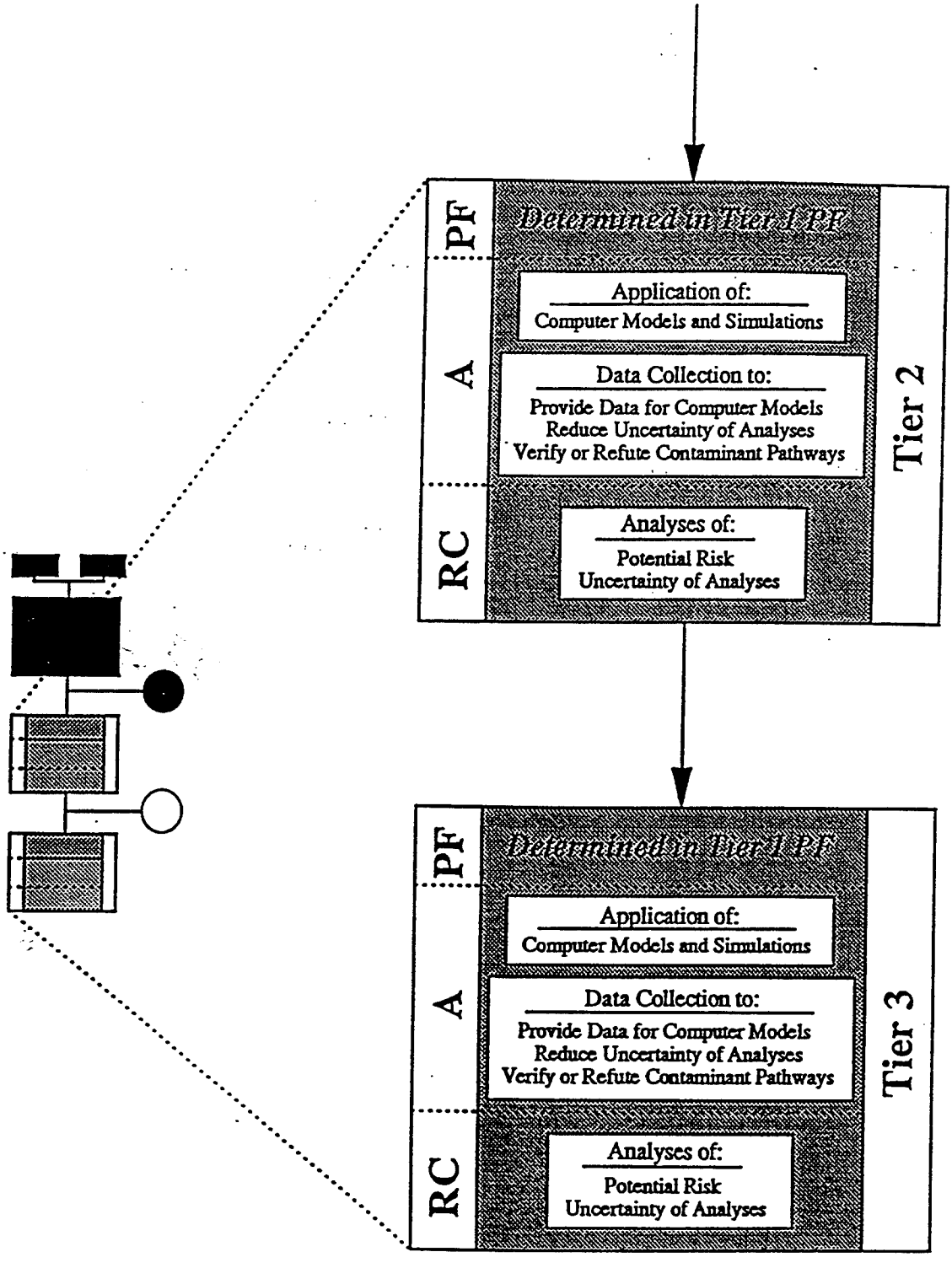


Figure 5. Tier 2 and Tier 3 analyses.

might be "dieldrin concentration in soil and in resident field mice". In Tier 2, measurement endpoints might be "analysis of coyote feeding habits on resident field mice and dieldrin concentrations in coyote tissue". In Tier 3, the procedure might involve a detailed analysis of coyote home range, time spent feeding, reproductive behavior, etc. In each tier, the measurement endpoints differ while the assessment endpoint remains the same. Further, if the assessment were stopped at Tier 1, estimates of risk would have to be conservative (e.g., broad "safety factors"). As the ERA process gathers more data on actual exposure and effects, the conservative assumptions may be relaxed.

## 2. PROBLEM FORMULATION

### 2.1 General Overview

In the Problem Formulation phase (Figure 6), policy and regulatory discussions with the risk manager establish the goals and focus of the risk assessment. The views and values of the various stakeholders concerned with the management of the site are discussed, coordinated and prioritized. In this phase, the major factors to be considered are identified for the particular assessment, and working hypotheses are developed.

The process begins by characterizing exposure and ecological effects, including evaluating the stressor characteristics, the ecosystem potentially at risk, and the ecological effects expected or observed. Assessment and measurement endpoints are then identified. A conceptual model is constructed from this information that describes how a given stressor might affect the ecological components in the environment. The model also describes the relationships among assessment and measurement endpoints, the data required, and the methodologies that will be used to analyze the data. The conceptual model serves as input to the analysis phase of the assessment[4].

Problem Formulation (PF) should clearly define the goals of the assessment (i.e., what are we trying to protect) and develop a scope that is appropriate for achieving those goals within the constraints of available resources and the overall uncertainties of the analyses. To accomplish this, the problem formulation should ensure that the assessment focuses on the stressors, ecological components, and endpoints that are most appropriate for determining whether a cause and effect relationship exists and for making ultimate management decisions. Reviewers of risk assessment case studies[16] observed that establishing cause and effect is especially critical when resources are limited by fiscal constraints. Strengths and weaknesses of the case studies seemed to originate, in large part, from decisions made during the preliminary planning stages.

Steps 1-4 presented in the EPA draft report on an ecological risk assessment process for Superfund sites (Figure 2), are addressed in the PF phase of EPA (Figure 6). After stressor characteristics, ecological effects, and ecosystem parameters have been initially reviewed (after step 2 in the EPA Superfund draft report) a scientific/management decision point (SMDP) is reached to decide whether the data warrants further study. After each of the two remaining parts of the PF phase, endpoint selection and development of the conceptual model, the EPA Superfund report[3] calls for SMDPs to formally agree to the results from these two key planning parts of PF. The use of SMDPs stresses good communication among all parties involved and

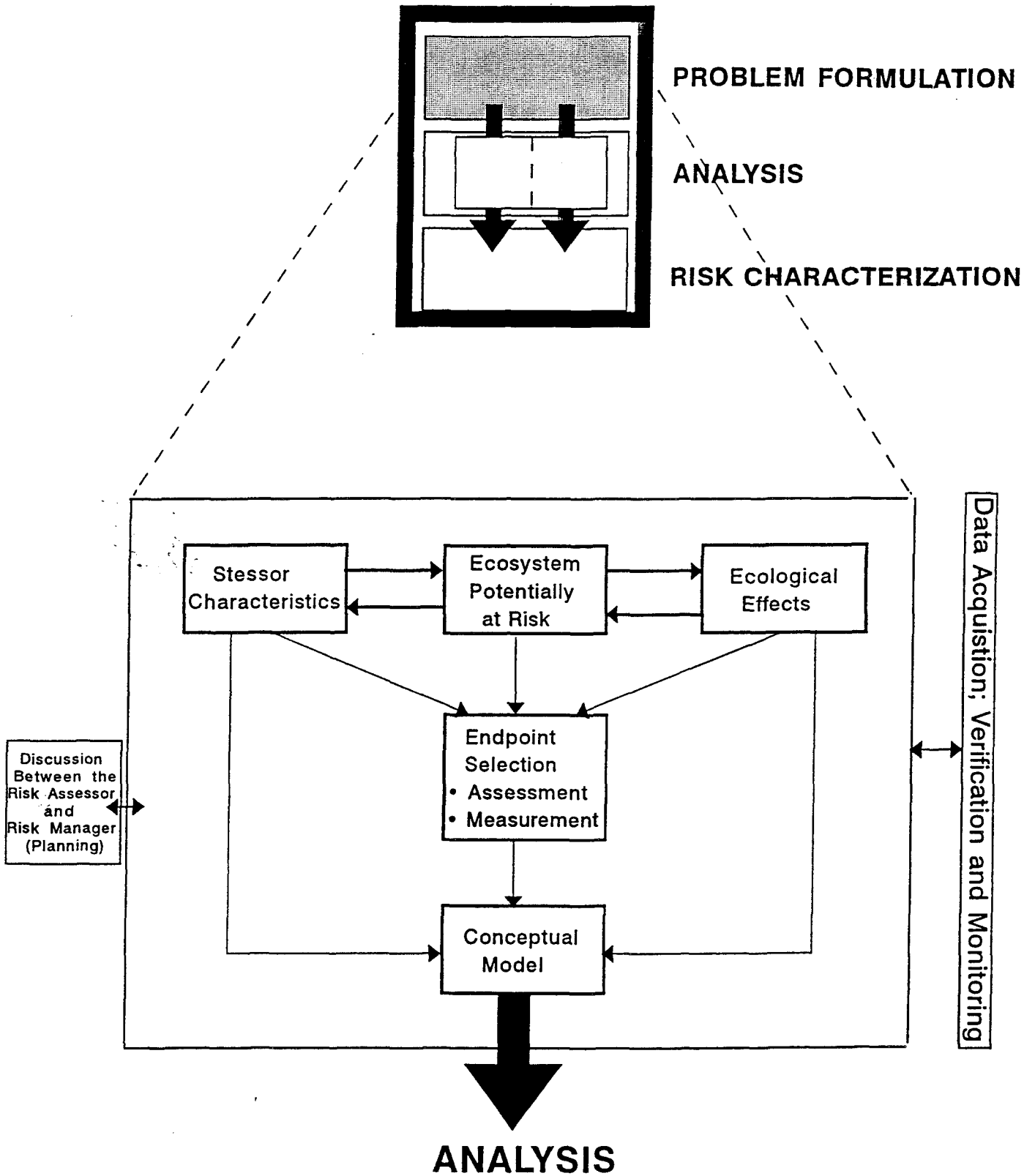


Figure 6. Problem Formulation Phase

keeps the risk assessment process focused and efficient.

## 2.2 Discussion Between Risk Assessor and Risk Manager

Establishing a two-way dialogue between the risk assessors and risk managers during the problem formulation phase is essential to achieving societal, regulatory, and scientific goals. Risk managers can ensure that the risk assessment will provide answers for questions related to protection of societal values, selection of remediation technologies, policy concerns and cost, whereas, the ecological risk assessor ensures that the assessment addresses important scientific concerns. Both perspectives are necessary to efficiently utilize resources to produce scientifically sound risk assessments that are relevant to management decisions and public concerns[4]. Establishment of SMDPs, as described above, is a good method to ensure that all policy and scientific issues are addressed.

The National Crop Loss Assessment Network (NCLAN) case study[16] was a good example of an assessment where the ultimate management issue was clear from the onset; the stressor, ecological components, and endpoints were clearly defined; and the design of the study was structured around a clear set of hypotheses amenable to scientific inquiry. This level of clarity was achieved, in part, through frequent meetings and interactions among researchers and others involved with the risk assessment/risk management process. The author and reviewers of the case study stressed the importance of this type of communication for clarifying issues and goals.

## 2.3 Stressor Characteristics

Stressors are chemical, physical or biological influences causing negative impact on the populations or ecosystems at risk. Chemical stressors include not only the contaminants of concern (COCs), but inorganic and organic chemicals inherent in the environment as well. Secondary stressors may arise as a result of primary COCs, such as increased concentrations of chlorofluorocarbons causing stratospheric ozone depletion which, in turn, results in increased exposure to ultraviolet radiation. Physical stressors are generally the abiotic environmental conditions under which the biota find themselves. These include such factors as seasonal and diurnal variance in atmospheric temperature, soil characteristics (soil type, parent material, climate, pH, organic matter content, management practices, etc.), the hydrologic regime (seasonal flooding, tidal influences, etc.) and habitat alterations (logging, construction, urbanization, etc.). Biological stressors also exist and are often important in determining survivorship of populations. Examples of biological stressors include competitor and predator species, introduced pests, such as the gypsy moth and various fungal

pathogens of tree species, or cholera epidemics in bird species. Changes in the physical/chemical environment may lead to subtle changes in competitive abilities of a species or may lead to changes in abilities to avoid predators, infestations, or disease epidemics. Therefore, biological stressors may assume larger roles in determining the maintenance of a population if the habitat has been altered chemically or physically. Stressors may also result from management practices such as harvesting of fishery or forest resources, or cultivation techniques during crop production.

Any stressor cannot be judged as such without reference to the species or community under stress. One cannot isolate the stressors from the species response, as they are interrelated. The degree to which stressors influence the survivorship of species depends on the magnitude of the stress (the intensity), the duration of the stress (how long the species is exposed, relative to its own life history characteristics), the frequency (how often a stress of a particular intensity occurs), the timing (when the stress occurs, relative to critical life history stages of the species). A complex of stress factors influence species responses; hence, creating a map of direct or indirect influences of contaminant stressors onto the "mosaic" pattern of normal stressors involves considerable thought.

The task of the RA in the PF phase is to analyze a suite of previously compiled chemical, physical and biological data. Literature data bases contain a variety of environmental toxicology data for chemicals. A partial listing of such data bases is given in Table 1. Defense Technical Information Center (DTIC), DoD research laboratories and DoD scientists may also be able to guide the RA to relevant toxicity data.

With this information, the RA then evaluates site-specific stressor characteristics in the PF phase of the Tier 1 analysis. During Tier 1, the RA identifies which chemical, physical, and biological stressors are present based on available information and estimates the nature, extent and potential interaction of these stressors. This information may be obtained from databases listed above but also from information previously collected from the site, such as record searches or Installation Assessments, reports on chemical storage, use and distribution, or from DTIC. Information on chemical properties of the contaminants should be examined in the context of biological, chemical, and physical characteristics of the ecosystem.

The manner in which contaminants interact with the physical and biological ecosystem components are predictable, within certain constraints. Interactions among site-specific soil and biotic characteristics influence contaminant distribution, fate and, importantly, allow the RA to estimate the likelihood of the contaminants remaining *in-situ* rather than moving off-site or

through the ecosystem. For example, fairly simple models (SESOIL, EXAMS; see Volume 2) may be called upon in Tier I to estimate the distribution of contaminants downstream or in soils on the site. The input data (e.g., soil moisture, pH, particle size, percent organic matter) for these types of models, if not measured directly, are available from detailed county soil surveys (Soil Conservation Service), USGS topographic maps, or state resource agencies. When more detailed and site-specific information is available, more sophisticated models may be used (CMLS, LEACHM; see Volume 2).

Table 1. Listing of databases available for information on contaminant fate and effect.

| | |
|---|---|
| **1. Chemical Information System (CIS)** | |
| AQUIRE | - Aquatic Information Retrieval |
| CERCLIS | - CERCLA Information System |
| CHRIS | - Chemical Hazard Response Information System |
| ENVIROFATE | - Environmental Fate |
| ISHOW | - Information System for Hazardous Organics in Water |
| OHMTADS | - Oil and Haz. Materials/Tech. Assist. Data System |
| PHYTOTOX | - Toxic Effects on Plants |
| **2. National Library of Medicine's Database Selection Menu** | |
| HSDB | - Hazardous Substances Data Bank |
| IRIS | - Integrated Risk Information System |
| EMICBACK | - Environmental |
| EMIC | - Environmental |
| ETICBACK | - Environmental |
| **3. Dialog Databases** | |
| Oceanic Abstracts | |
| Enviroline | |
| Pollution Abstracts | |
| Aquatic Sciences and Fisheries Abstracts | |
| Environmental Bibliography | |

Bioavailability of chemical constituents should also be considered at this point. For example, is the chemical hydrophilic or hydrophobic?; is it available in the soil water and subject to surface runoff and leaching, or is it tightly bound to soil particles and organic matter?; and how do site specific soil characteristics affect the contaminants' bioavailability?

At the end of Tier 1 PF, the risk assessor should have a good understanding of the stressor characteristics for the particular site under study. Data gaps should be addressed in Tier 2 if the assessment proceeds that far.

## 2.4 Identifying the Ecosystem Potentially at Risk

Identifying the ecosystem potentially at risk from a stressor depends in part on how the risk assessment was initiated. Once a stressor is identified, information on the spatial and temporal distribution patterns of the stressor can be helpful in identifying ecosystems potentially at risk. Similarly, if the risk assessment is initiated by observing effects, these effects can directly indicate ecosystems or ecological components of the system that may be considered in the assessment.

Ecosystem properties should be analyzed during PF. These properties include ecosystem structure (including types and abundances of different species and their trophic level relationships), ecosystem function (i.e., ecosystem energy source, pathways of energy utilization, and nutrient processing), bioavailability, and aspects of the abiotic component (see Section 2.3 above). In addition, types and chronology of historical disturbance should be determined to help predict ecological responses to stressors.

At this point, it is important to emphasize that not all aspects of ecosystem structure and function need to be analyzed in every risk assessment. The extent to which ecosystem properties are analyzed depends upon the nature of the stressors and ecosystem components, bioavailability, and the resources available. Analyses should concentrate on those ecosystem components that are determined to be at greatest risk. Knowing the stressor characteristics can help to narrow the focus of the investigation on the components of the ecosystem that are potentially most susceptible.

Once stressor characteristics and the ecosystem potentially at risk have been identified, potential pathways for contaminant(s) through the ecosystem must be identified. Contaminant pathways may be simple and straightforward or complex and highly branched. Pathways are generally defined by naturally occurring physical, chemical, and biological components of the ecosystem. As an example, consider the evapotranspiration potential,

precipitation, soil type, slope, local vegetation, and ground squirrels (*Citellus* sp.) foraging on the vegetation in a given ecosystem. In this example, the movement of an organic contaminant might be a function of the seasonal food source sought by the rodent species. In other seasons, the ground squirrels are absent or dormant; hence, they would not be subject to exposure by the same pathway.

The origin of each contaminant pathway is typically from soil or water, at the site of contamination and the end of each pathway is a component of the ecosystem where adverse effects may occur (such as threatened or endangered species, a resident small mammal population, or fish species in a downstream lake or reservoir). Several assessment endpoints (see Section 2.6 below) may exist at the end of a contaminant pathway because pathways will seldom be unidirectional or linear. Chemical pathways generally branch and proceed in multiple directions; for example, a contaminant may have the potential for moving from a contaminated site into an aquatic system, with no potential impacts (branches) en route to a pond. However, once the contaminant enters the pond, potential contaminant pathways may include uptake of the contaminant by aquatic vegetation, by aquatic organisms (e.g., mollusks, gastropods, aquatic insects), uptake by fish, or amphibians, or transport back to the terrestrial environment via birds or mammals that feed on aquatic organisms.

The number of contaminant pathways are determined by the characteristics of the contaminant and the complexity of the ecosystem. Contaminant pathways must by identified on each Army Superfund site; however, similarities in pathways will likely exist among many sites resulting from similar ecosystems. Greater definition (closer focus) of specific contaminant pathways will be a function of Tier 2 and Tier 3 chemical analyses. Ultimately, however, if a pathway is incomplete or does not exist at a particular site, no cause and effect relationship exists and there is no associated risk.

## 2.5 Ecological Effects

Ecological effects in Tier 1 of the PF phase should be derived from studies in the literature that are applicable to the stressors and ecological components of concern in the assessment, and from reports of previous studies (e.g., RI/FS) conducted at the site. Published data may come from a variety of sources including field observations (e.g., fish kills, changes in aquatic community structure), laboratory tests (e.g., single species or microcosm bioassays), and chemical structure-activity relationships. Home range, feeding area, and migratory patterns of the biota of concern at the site should be determined from USFWS, site specific sources (i.e., state fish and wildlife agencies, military installation records, etc.) or the open

literature. These data, together with spatial and temporal patterns of the COC within the site can help characterize the extent of ecological effects. Analysis of this information can help focus the assessment on specific stressors and on ecological components relevant to the site.

Caution must be taken so that the ecological effects data are properly utilized in Problem Formulation. For example, applicability of laboratory-based tests may be affected by extrapolations to various field conditions, whereas the interpretation of field observations may be influenced by site-specific factors such as natural variability or the presence of stressors other than the COCs. Ecological effects data obtained in PF can then be used to identify data gaps and to characterize ecological effects in the Analysis Phase of the assessment.

## 2.6 Endpoint Selection

Ecologically based endpoints are selected after the societal, regulatory, and biological goals have been established following review of stressor characteristics, the ecosystem potentially at risk, and the potential ecological effects. It is important that the RA and RM collaborate and agree on the endpoints selected before proceeding to the Analysis phase. An endpoint is defined as a characteristic of an ecological component (e.g., increased mortality in fish) that may be affected by exposure to the stressor[17]. Two types of endpoints, assessment and measurement, are used in the ERA to determine risk to the ecosystem.

An assessment endpoint is defined as:

> An explicit expression of the environmental value to be protected.[4]

For best use, assessment endpoints should have biological as well as societal value so that scientific information can be linked to the risk management process (e.g., policy goals). For an ERA to produce sound, acceptable results, there are five criteria necessary for choosing assessment endpoints[7,4]:

1) policy goals and societal relevance;
2) ecological relevance;
3) unambiguous operational definition;
4) accessibility to prediction and measurement; and
5) susceptibility to the hazardous agent.

When choosing assessment endpoints, two general questions must be answered: (1) what valued components of the environment are considered to be at risk; and (2) how should effects be defined? Some assessment endpoints are mandated legally or politically; however, the RA should also determine what endpoints should be

selected on technical grounds. Suter[7] suggests performing one of the following formal analyses of the relationship of components of the action being assessed and components of the receiving environment:

1. Create a matrix of exposure alternatives (e.g., soil contamination by munitions, spilling a product during shipment, etc.) and environmental receptors (fish, terrestrial plants, aquatic heterotrophic microflora, etc.) that are potentially affected. Environmental receptors are then checked off and possibly scored for the intensity and duration of the exposure and relative sensitivity to the toxic material.

2. A receptor identification exercise is valuable to identify which organism will be most exposed to a chemical. This consists of two steps: (1) performing a rapid quantitative exposure assessment to determine what media are most contaminated (note: this may be from a fate model determination), and (2) determining what communities, trophic groups, populations and life stages are most exposed to those media.

3. Indirect effects of stressors can be identified by developing models, including "event trees" showing causal linkages between site contaminants and various environmental components (Figure 7).

4. Existing data can be reviewed to determine the sensitivity of species or processes to the contaminant or to similar contaminants. These may include data from toxicity testing or from biological monitoring of prior releases.

We remind the reader that the primary objective of the Problem Formulation phase is to focus on appropriate endpoints within the risk assessment, coordinating frequently with the risk manager. Of course, the resources expended must be considered in light of the potential loss of the management resource. Often assessment endpoints cannot be directly measured. When this occurs measurement endpoints are selected that are related to assessment endpoints. Measurement endpoints are defined as:

A measurable ecological characteristic that is related to the assessment endpoint.[4]

Relating measurement to assessment endpoints is important to produce risk estimates that are scientifically sound and address policy goals. Measurement endpoints must accurately measure indicators of effects that will reflect the assessment endpoints and are often expressed as the statistical or arithmetic summaries of the observations that comprise the measurement.

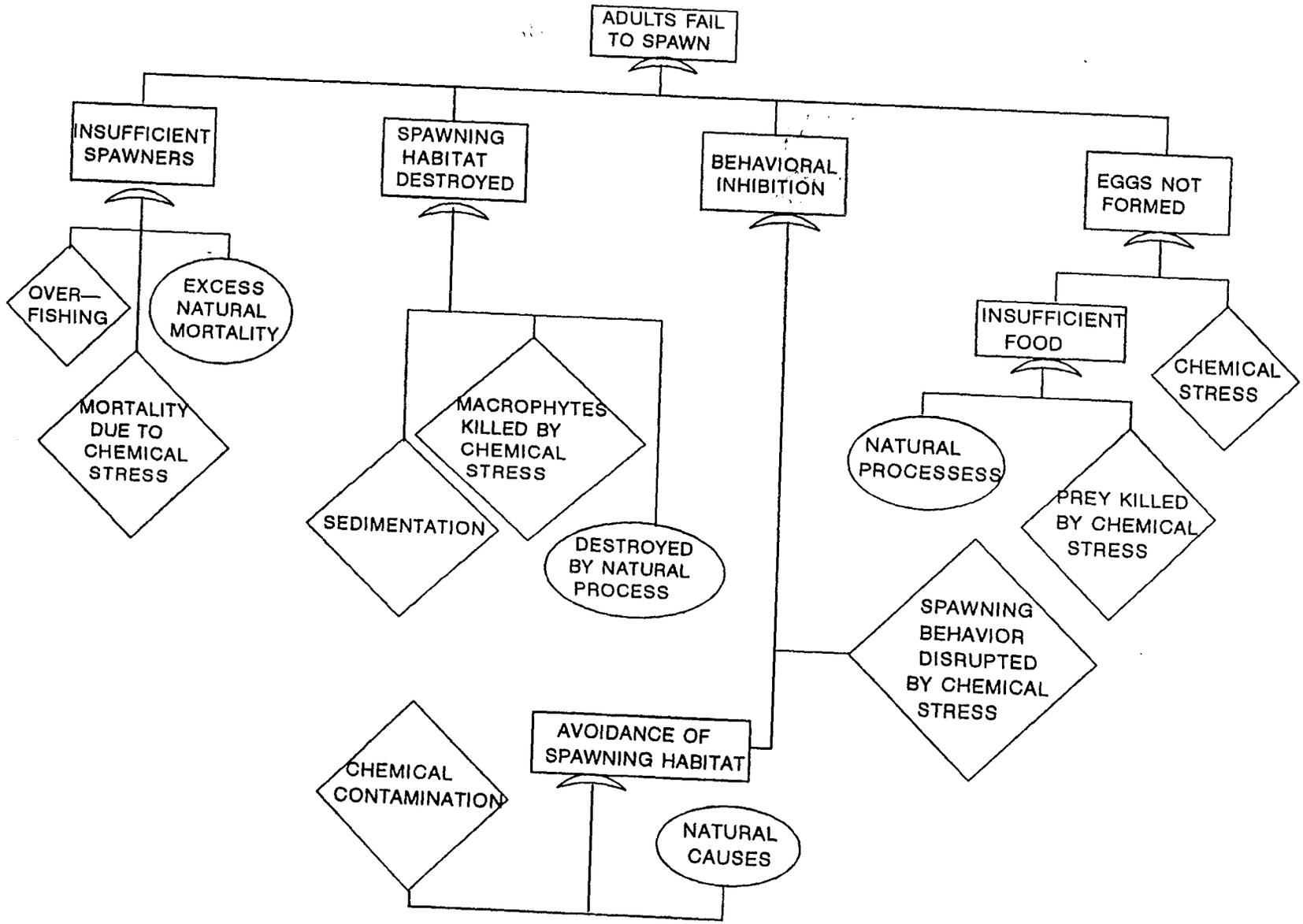


Figure 7. Event tree for failure of fish to spawn. This tree would be a branch of larger tree used to determine how toxicants might cause reductions in fish populations.[7]

Measurement endpoints may be single numbers such as $LC_{50}$'s or biomass measurements. Less common but more useful measurement endpoints are multidimensional descriptive models such as concentration-response functions. Selection of measurement endpoints must be carefully thought out prior to undertaking an ecological risk assessment. Considerations in selecting measurement endpoints are discussed in Table 2. If a tiered approach is applied, the types and number of measurement endpoints depend on the level of effort (i.e., personnel and cost) required to address data gaps in each tier (see Section B.2.). Ideally, a suite of assessment and corresponding measurement endpoints at different levels of biological organization (e.g., organism, population, community, food web) is preferred because it reduces the level of uncertainty and ensures that all relevant assessment endpoints are evaluated. However, time and monetary constraints may limit the types and quantity of measurement endpoints. Therefore, endpoints from models can sometimes be used to extrapolate across scales of time, space, and biological organization.[18] For example, measurement endpoints acquired from a sub-population (e.g., mortality, reproduction, and growth) could be used to predict effects on an assessment endpoint in a larger population (e.g., viability of a trout population in a stream). Sloof et al. (see Suter[7]) developed a simple statistical model to grossly estimate effective concentrations for ecosystem tests from a single organism-level test endpoint. Examples of assessment endpoints, indicators, and measurement endpoints are presented in Table 3.

### 2.7 The Conceptual Model

Once the stressors and potential receptors have been identified and characterized, and the assessment and measurement endpoints have been determined, a series of working hypotheses should be formulated on how the stressor(s) may affect ecological components.[4] At this point, the RA is at the stage between Problem Formulation and Analysis phases. The conceptual model (Figure 6) includes descriptions of the ecosystem potentially at risk and the relationship between measurement and assessment endpoints. Exposure scenarios should be constructed to include spatial and temporal distribution of the chemicals of concern and their interaction with the ecological system. Each scenario is defined in terms of the stressor, the type of biological system and principal ecological components, how the stressor will interact within the system, and the spatial and temporal scales.

Table 2. Considerations in selecting measurement endpoints.[4]

Relevance to an Assessment Endpoint

When an assessment endpoint cannot be directly measured, measurement endpoints are identified that are correlated with or can be used to infer or predict changes in the assessment endpoint.

Consideration of Indirect Effects

Indirect effects occur when a stressor acts on elements of the ecosystem that are required by the ecological component of concern. For example, if the assessment endpoint is the population viability of trout, measurement endpoints could evaluate possible stressor effects on trout prey species or habitat requirements.

Sensitivity and Response Time

Rapidly responding measurement endpoints may be useful in providing early warning of ecological effects, and measurement endpoints also may be selected because they are sensitive surrogates of the assessment endpoint. In many cases, measurement endpoints at lower levels of biological organization may be more sensitive that those at higher levels. However, because of compensatory mechanisms and other factors, a change in a measurement endpoint at a lower organizational level (e.g., a biochemical alteration) may not necessarily be reflected in changes at a higher level (e.g., population effects).

Signal-to-Noise Ratio

If a measurement endpoint is highly variable, the possibility of detecting stressor-related effects may be greatly reduced even if the endpoint is sensitive to the stressor.

Consistency With Assessment Endpoint Exposure Scenarios

The ecological component of the measurement endpoint should be exposed by similar routes and at similar or greater stressor levels as the ecological component of the assessment endpoint.

Diagnostic Ability

Measurement endpoints that are unique or specific responses to a stressor may be very useful in diagnosing the presence or effects of a stressor. For example, measurement of acetylcholinesterase inhibition may be useful for demonstrating responses to certain types of pesticides.

Practicality Issues

Ideal measurements endpoints are cost effective and easily measured. The availability of a large database for a measurement endpoint is desirable to facilitate comparisons and develop models.

Table 3. Examples of assessment endpoints. Possible indicators of effects on those endpoints, and possible endpoints for measurements of those indicators.[7]

| Hazard/Policy Goal | Assessment Endpoints | Indicators of Effects | Measurement Endpoints |
|---|---|---|---|
| Herbicide used for weed control in southern lakes/No acceptable loss of fisheries | Probability of >10% reduction in game fish production | Laboratory toxicity to fish | Fathead minnow $LC_{50}$ Larval bass concentration/mortality function |
| | | Laboratory toxicity to food-chain organisms | *Daphnia Magna* $LC_{50}$ *Selenastrum capricornutum* $EC_{10}$ |
| | | Field toxicity to fish | Percent mortality of caged bass |
| | | Populations in treated lakes | Catch per unit effort Size/age ratios by age class |
| Agriculture insecticide associated with bird kills/No acceptable reductions in avian populations function | Proportion of raptors killed within the region of use | Laboratory toxicity to prey | Rat $LD_{50}$ Japanese quail dietary $LC_{50}$ |
| | | Laboratory toxicity to raptors | Sparrow hawk dietary concentration/response Japanese quail dietary $LC_{50}$ |
| | | Avian field toxicity | Number of prey carcasses per hectare Number of dead moribund raptors per hectare |
| | Increase in rates of decline of declining bird populations within the region of use | Avian laboratory toxicity | Japanese quail dietary $LC_{50}$, Starling dietary $LC_{50}$ |
| | | Avian field toxicity | Number of bird carcasses per hectare by species |
| | | Trends in populations of declining birds | Rates of decline in areas of use as proportions of reference areas |

At this stage of the RA, the conceptual model should be used to predict the impact of the chemicals on individuals, populations and communities. The exposure scenario for chemical stressors usually involves consideration of sources (e.g., explosives burning ground), environmental transport (e.g., rate of movement through soil column), partitioning of the chemical among various environmental media (e.g., soil particles vs. organic matter), chemical/biological transformation or speciation processes (e.g., photolysis, biodegradation), and identification of potential routes of exposure (e.g., ingestion, plant root absorption, etc.). Exposure scenarios for non-chemical stressors such as soil compaction, or habitat alteration describe the ecological components exposed and the general temporal and spatial patterns of their co-occurrence with the stressor. For example, the exposure scenario may describe the extent and distributional pattern of compacted and disturbed soil in a field used for military training with tracked vehicles, the soil microflora, vegetation and wildlife occupying or using this field, and a comparison of the size and distribution of these populations with those in adjacent undisturbed fields[19].

The hypotheses formulated must first be "weeded out" for those considered most likely to contribute to risk. Then the risk assessor should further narrow down the choices to focus only on those hypotheses that can be addressed with available resources. These hypotheses are then evaluated in the Analysis phase. It is important that any hypotheses not originally used in the Analysis phase be re-visited when uncertainty is addressed in the Risk Characterization (RC) phase. Uncertainty considerations of model predictions in the RC phase may require that previous hypotheses explaining the assessment endpoint be reviewed. Professional judgement is needed to select the most appropriate risk hypotheses; further, it is needed to document the rationale underlying the selection process[4].

A detailed work plan should then be written describing objectives, data requirements (including assessment and measurement endpoints), experimental design, procedures and methods, quality assurance objectives, and a time schedule to estimate duration and completion dates of various phases of the assessment. Work plans will vary according to the specific needs of each assessment but should be formulated and agreed upon by all parties involved. The work plan should be included in the remedial investigation. In formulating a work plan, it is critical to address how data gaps will be handled and to explicitly state the data quality objectives[4]. The conceptual model describes the approach that will be used for the Analysis phase and the types of data and analytical tools that will be needed.

## 2.8 Evaluation of Problem Formulation

At the conclusion of PF, it is important for the risk assessors and risk managers to determine the attributes and focus of the rest of the assessment and to decide if indeed the assessment should continue. The EPA[3] has compiled a list of scientific/management decision points (Figure 2) that include factors that should be agreed upon before proceeding further with the risk assessment such as:

(1) Deciding whether or not the risk assessment should proceed further based on available information;

(2) Selecting assessment endpoints, testable hypotheses, and measurement endpoints;

(3) Agreement upon the exposure pathways;

(4) Selection of specific investigation methodology;

(5) Selection of data reduction and interpretation methods.

Agreement by all involved parties on the decisions and methodologies shown above will help to keep the risk assessment focused and save time and money.

## 3. ANALYSIS PHASE

During the Analysis phase (Figure 8), the working hypotheses developed during the PF phase link exposure assessment to ecological effects. This phase acknowledges that the abiotic and biotic characteristics of the ecosystem of concern will impact the ecological effects and the exposure profile. The various steps in this phase lead to the development of a stressor-response profile and an exposure profile. These profiles are used as the basis for risk characterization.

The most effective tool available to the ecological risk assessor is a site visit. During this visit the ecosystem is qualitatively assessed to determine potential receptors present at the site, determination of routes of exposure, and other stressors present (e.g., dredging activity, prop wash, lack of riparian habitat on the banks of a stream, etc.). Signs of direct effects may be noted during the site visit such as stressed vegetation around a seep.

On the basis of this site visit as well as existing data for the site, the risk assessor has to determine what additional data are necessary. Ecological risk assessment is commonly performed using a "weight of evidence" approach. An excellent description of this approach applied to a terrestrial ecosystem can be found in Menzie et al.[20]. They utilized predictive modeling based on measured surface water, sediment and soil concentrations of COCs, laboratory toxicity tests, field toxicity tests, and other field methods to assess potential ecological impacts.

It is important to realize that many potential hazardous waste site assessments have been designed by engineers without consultation with risk assessors. What often results is a large amount of data, none of which is of value to the risk assessor. For example, many metal water quality criteria are dependent upon site-specific water hardness, but water hardness is often not analyzed, or even thought of as important for analysis by the workplan author. Another important data quality often overlooked is the required detection limits necessary to perform risk assessment. The CLP procedure does analyze for polycyclic aromatic hydrocarbons (PAH), however CLP reporting limits are much above concentrations at which one may expect potential ecological impacts. Listed below are parameters commonly overlooked and chemicals which alternative analytical methods which provide lower detection limits may be appropriate:

* Parameters Commonly Overlooked

Hardness in surface water,
Total organic carbon in sediment and soil,
Lipid content in biological samples

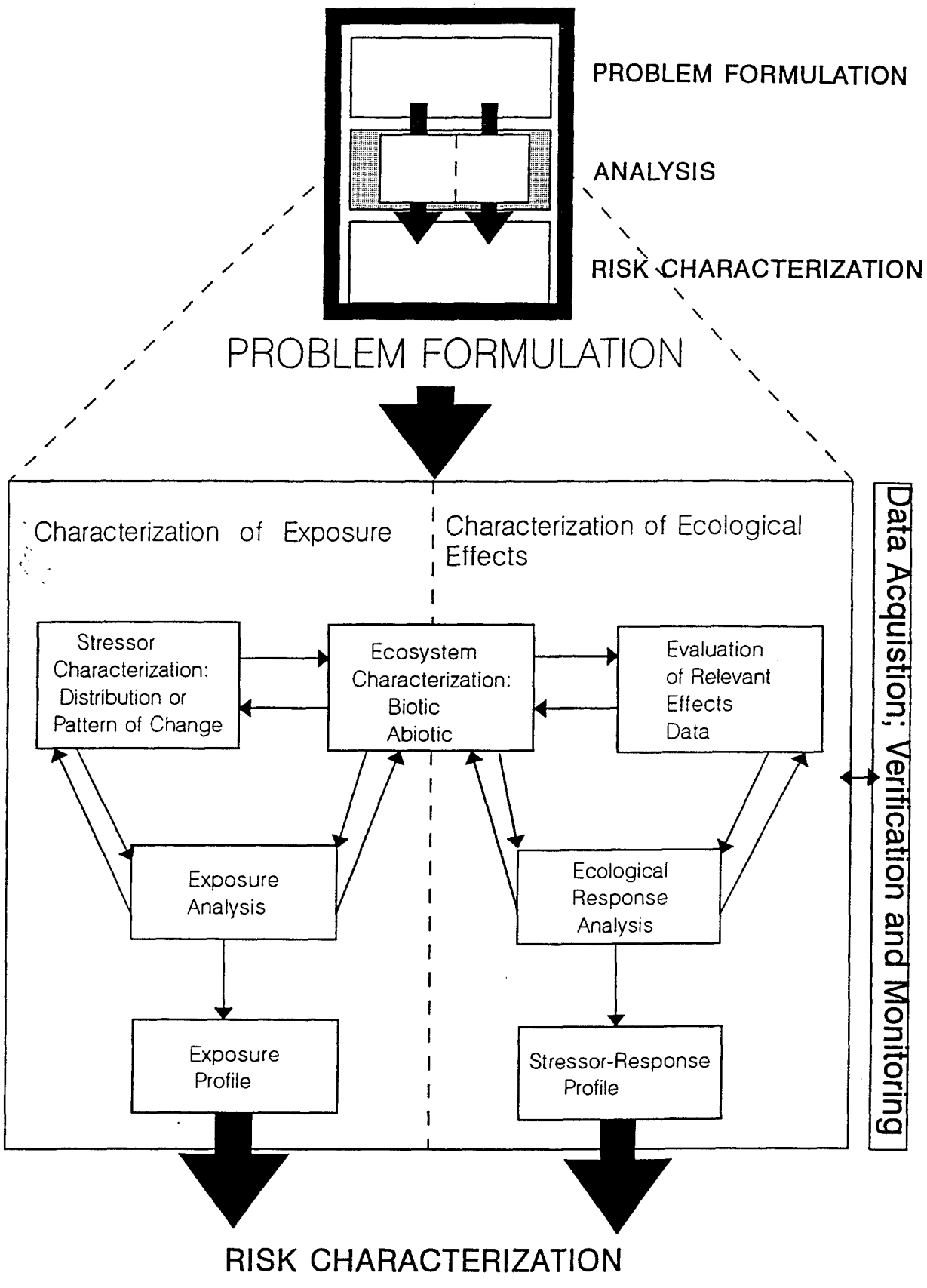


Figure 8. Analysis Phase

* Chemical Types Commonly Measured at High Reporting Limits

Polycyclic Aromatic Hydrocarbons (PAH),
Pesticides, PCBs, and some metals.

To correct this situation it is necessary to involve the risk assessment personnel early in the workplan stage. Their role should be to assure that all necessary parameters are being measured at appropriate reporting limits. Alternative analytical chemistry methods are available which allow reporting much lower detection limits than those reported using CLP standards. The risk assessment personnel should work with the analytical laboratory to determine appropriate analytical methodology. In addition, the sampling plan should be assessed to assure that proper numbers and types of samples are being taken. Biota samples will commonly be completely unsampled, and because the waste engineers tend to focus on "hot spots", by definition a biased sampling procedure, exposure will often be overestimated.

## 3.1 Exposure Characterization

### 3.1.1 Stressor Characterization

Characterization of exposure begins with determining what stressors are present at the site. Ecological risk assessment is complicated by the necessity of determining multiple stressors, often including stressors such as habitat and human actions like dredging a stream or water body.

This step determines the stressor's distribution over space and time at the study area. The primary stressor is evaluated as well as any secondary effects which have occurred due to impacts from the initial stress to the system. Background or preliminary information on the chemical-of-concern is important for the stressor characterization because such information points towards expected stressor-responses. For example, lipid-soluble organochlorine pesticides bioaccumulate fairly readily in aquatic ecosystems. Organic chemicals with low $K_{ow}$ do not accumulate readily and direct toxicity, rather than tissue uptake, is the primary concern for exposure.

Characterization of exposure begins with determining where the contaminant is on the site, where, if and how the contaminant moves from the site, and what physical/chemical characteristics lead to its bioaccumulation, degradation, transport, etc. For many chemicals, historical files provide information on quantities produced, used, stored on-site, or sprayed (pesticides, solvent cleaners). Often, chemical characteristics of the contaminant, including rates of degradation (via photolysis, hydrolysis, microbial), adsorption, solubility in water or lipid may be obtained from literature sources, on-line

chemical databases (Table 3), Material Safety Data Sheets (for industrial chemicals), and technical reports. An excellent source for environmental degradation rate is Howard et al.[21], general fate and transport data can be found in the Lewis Publishers (Chelsea, Michigan) series titled "Handbook of Environmental Fate and Exposure Data for Organic Chemicals". This series, ultimately to have seven volumes, presently consists of Large Production and Priority Pollutants (Volume I), Solvents (Volume II), Pesticides (Volume III), and Solvents 2 (Volume IV). Data provided in these volumes include basic chemical and physical properties (boiling point, melting point, molecular weight, water solubility, octanol-water partition coefficient, vapor pressure, etc.) and a description of basic fate and exposure potential including sources, important transport processes, and reported concentrations in the environment. While there are many computer databases available, the most current and reliable database encountered so far for fate and transport data is produced by the Syracuse Research Corporation, Merrill Lane, Syracuse NY 13210. They maintain several databases including BIOLOG (Biodegradation database) and CHEMFATE. CHEMFATE can be used to search for many properties and characteristics ranging from soil adsorption constants to photolysis degradation rates. The above references refer to fate and transport of organic chemicals. There are several excellent references available regarding fate and transport of metals in the environment[22,23].

The information required for a Tier 1 exposure characterization would be obtained via the documents described above. Ecological assessments may be "effects-driven" or "stressor-driven." For example, the abundance of a sediment benthic community is often used as a measure of sediment "health". If the benthic community is found to be deficient, it is commonly used as an "effects-driven" assessment. Alternatively, known dump sites, with no apparent ecological effects are an example of a "stressor-driven" assessment. This implies that the initial focus may be on understanding how the measured effects were induced ("effects-driven") or on understanding the behavior of the chemical(s) of concern ("stressor-driven"). In characterizing exposure, the RA identifies measurement endpoints along each contaminant pathway where data collection or computer simulations and models are applied to evaluate contaminant fate and consequent ecological impacts. Data collected for these measurement endpoints help reduce uncertainty by validating or refuting whether predicted contaminant movement is actually occurring. In characterizing exposure, the RA identifies measurement endpoints along each contaminant pathway where data collection or computer simulations and models are applied to evaluate contaminant fate and consequent ecological impacts. Data collected for these measurement endpoints help reduce uncertainty by validating or refuting whether predicted contaminant movement is actually occurring.

The environmental fate and potential transport of contaminants is crucial to effective risk assessment because the bioaccessibility (whether organisms come in contact with toxicants) and bioavailability (whether contact leads to uptake) are controlled by these processes. For pesticides, degradation, volatization, binding, leaching, and aging determine ultimate exposure concentrations[24]. Metals availability is controlled largely by pH and oxidation-reduction relationships in environmental media[22,25]. The chemistry and distribution of the compounds of interest must be thoroughly understood for effective risk analysis. It is crucial for the risk assessment/risk management team to understand that the bulk concentration of chemical compounds as measured in typical laboratory extraction tests (such as those provided with Contract Laboratory Program quality assurance documentation under CERCLA) do not reflect the biologically active concentrations. In practice, binding and uptake processes depend on complex environmental processes which need to be accounted for in projecting risks.

The environmental fate and transport of mercury in anoxic (oxygen depleted) environments is shown in Figure 9. Mercury has been identified as a chemical of concern in many areas of the country, primarily due to its volatilization and transport within the atmosphere. For example, within the everglades of Florida mercury has been identified as a chemical of concern for many fish, raccoons, and cougars preying on the raccoons. Obviously, there are no point sources of mercury directly in the everglades, pointing to long range transport from outside the boundaries of the everglades. The fate and transport of mercury is complex, and involves bacteria who can methylate the ion and form a highly bioaccumulative methylmercury.

Similar fate and transport figures can be produced for other metals and organic chemicals. Environmental factors will influence chemical fate and transport dependent upon the type of chemical of concern. For example, lipid-soluble (high octanol-water partition coefficient, $K_{ow}$) organochlorine pesticides bioaccumulate readily in aquatic ecosystems. Alternatively, low $K_{ow}$ chemicals do not readily bioaccumulate and direct toxicity, rather than tissue uptake, is the primary route of exposure.

Models in Tier 1 analyses serve as "screening analysis" to provide initial qualitative assessments of contaminant transport into the environment. They are designed to (1) identify each transport process controlling movement of various contaminants within and among media, (2) estimate the direction and rate of chemical movement from the site and, (3) identify areas to which contaminants have been or may be transported. Fugacity models[26,27], which calculate where a given chemical will tend to accumulate in the environment, are an example of this level of

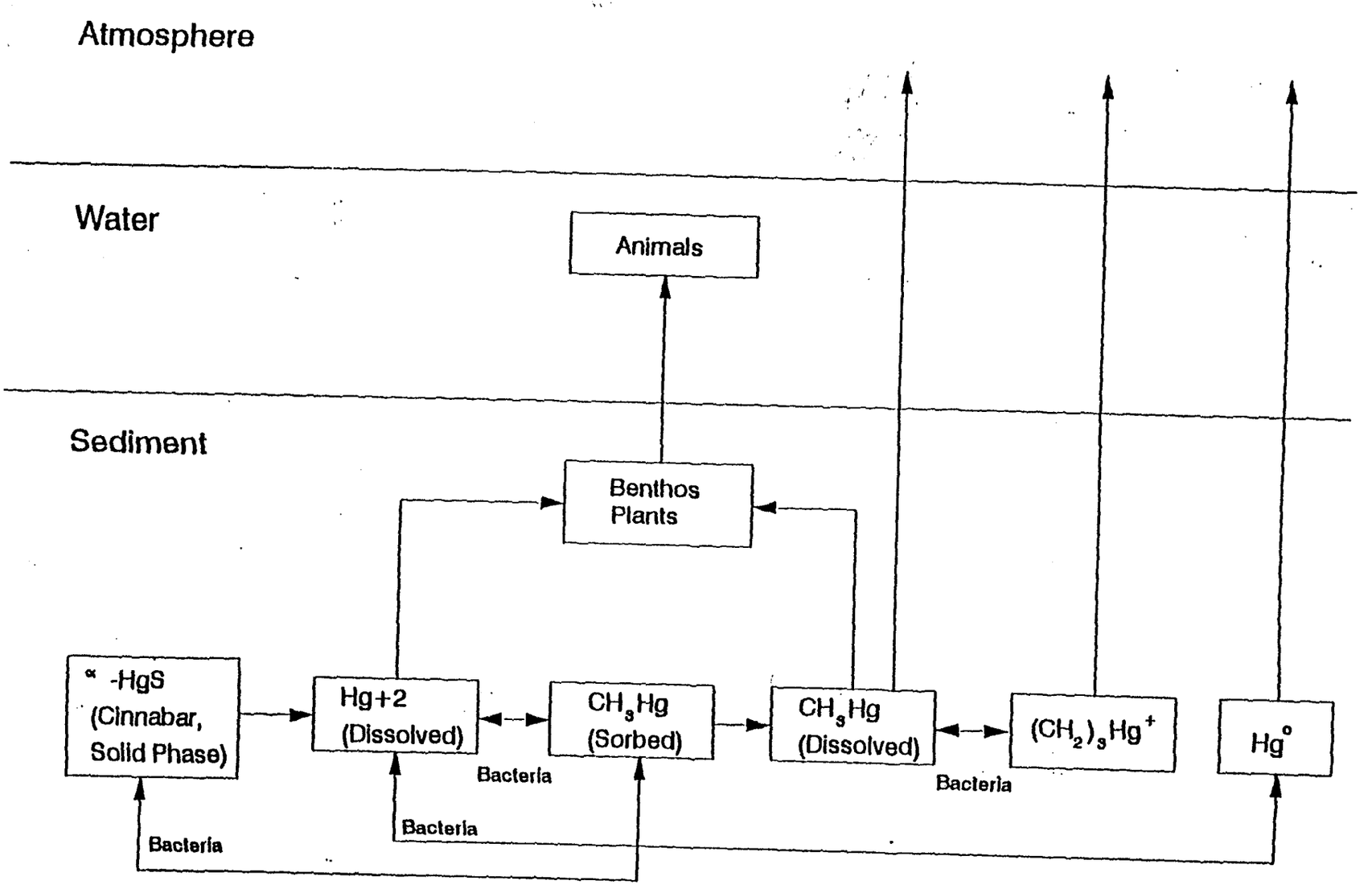


Figure 9 Environmental Fate and Transport of Mercury in Anoxic Aqueous Environments

detail. This level of modeling provides an initial organization and direction for subsequent in-depth analyses of contaminant transport. When a more in-depth analysis of environmental fate is desired, the RA should seek advice on which modeling procedure is most appropriate to the circumstances. In general, the more sophisticated models are data-, time- or resource-intensive. Table 4 is a ranking of relatively simple to complex models[28]. Criteria to consider when selecting in-depth environmental fate models are:

(1) capability of the model to account for important transport, transformation and transfer mechanisms;

(2) the fit of the model to site-specific and substance-specific parameters;

(3) data requirements of the model, in relation to the availability and reliability of site-specific data; and

(4) the form and content of the model output. That is, does the model output address relevant questions and provide data required for use as input to further analyses.

At the end of a Tier 1 study for the exposure characterization, the RA should have:

1) identified the major COCs,
2) listed physical and chemical parameters of the COCs,
3) collected environmental fate information from the literature,
4) compiled site-specific sampling data on COCs,
5) identified contaminants that may bioaccumulate,
6) identified data gaps.

As the exposure characterization progresses to tiers 2 and 3, contaminant pathways examined in Tier 1 of exposure characterization will continue to be evaluated through such options as data collection of previously unsampled measurements endpoints identified in the Tier 1 PF phase or a more intensive sampling over the same habitats to more closely characterize contaminant distribution. In Tiers 2 and 3 more intensive chemistry sampling may allow sampling of degradation products spread in a more diffuse manner throughout the site. Further data collection reduces the uncertainty of environmental fate and distribution estimates.

Monitoring data are useful for analyzing contaminant transport and fate. However, monitoring data may not allow discrimination of the contributions of contaminant loadings from point versus non-point sources. A combination of monitoring data with modeling techniques is necessary in Tiers 2 and 3 to conduct

## Table 4. Progressive Levels of Aquatic Chemical Models

| Level | Features | Data Needs | Answers |
|---|---|---|---|
| 0 | Dilution model, yields initial complete mix concentration | Effluent design flow, critical low flow in receiving water or allowable mixing radius/zone, upstream chemical concentration, effluent load or ambient standard-model solves for missing parameter | Worst case ambient concentration in the water column following mixing; additional calculations using $K_{oc}$ yields information on the expected phase distribution (particulate or dissolved) |
| 1a | Steady-state model, simple one-dimensional (1-D) segmentation, first order loss from the water column | River physiography, chemical concentration versus river mile and/or knowledge of first-order loss rates | More realistic estimate of concentration as a function of distance from the effluent, rough estimate of the chemical retained in the system |
| 1b | Steady-state model, 1-D segmentation, partitioning to solids, net settling links water to sediment | Solids loads, solids versus river mile, solids characteristics, and partitioning coefficient | Chemical distribution in particulate and dissolved phases in the water column |
| 1c | Steady-state model, 1-D segmentation, partitioning, full solids dynamics | Literature and site-specific analysis of resuspension and gross settling rates | Provides chemical levels in the sediment and the water compartments |
| 1d | Steady-state model, 1-D segmentation, partitioning, separation of abiotic and biotic solids | Information on water column abiotic-biotic solids origin and transport rates | More accuracy, better differentiation of biotic component |
| 2a | Time-variable model, 1-D segmentation, partitioning, full solids dynamics | Time variable loads and environmental conditions, better vertical solids transport rates | Response as a function of time and distance from the source(s) |
| 2b | Steady-state model, 2-D segmentation, partitioning, full solids dynamics | Hydraulic transport or routing, more spatially distributed field data | Spatially distributed (2-D) results, better representation of certain systems, a broader range of questions addressable to correspond to locations of specific interest |
| 2c | Time-variable model, 2-D segmentation, partitioning, full solids dynamics | Typically more highly resolved data (time and space) | Temporal and spatially related questions |
| 3 | More hydraulic (3-D), sorbent, chemical, or biological complexity | Additional problem-specific site data and potentially supporting research | More complex questions of source, chemical interaction, fate, transport, or effects |

analyses of contaminant fate in sites for which Tier 1 results do not allow a sufficiently accurate determination of exposure and risk.

### 3.1.2 Ecosystem Characterization

In ecosystem characterization the abiotic and biotic parameters of the system of concern are evaluated. Their impact on the distribution and bioavailability of the stressors of concern are critical parts of the exposure assessment. Migration and resource use by biota and behavioral effects of the stressors on organisms are also considered.

To fully characterize exposure and develop an exposure profile for the site, the RA must recognize the ecosystem components and functions described as important in the conceptual model formulation.

Included in the ecosystem characterization are physical characteristics of the ecosystem, including topography, geology, and hydrology, climatic patterns of the area such as precipitation, insolation, temperature, humidity, and the flora and fauna of the sites. Understanding these components and their interrelationships, in conjunction with data on the contaminant distribution, allows the RA to evaluate whether the contaminants are confined to specific areas and remain *in situ*, or whether the contaminants have the potential to move through various ecosystem components.

Barnthouse et al.[29] presented modeling approaches to link water quality to reductions in "dose" under various scenarios of ecosystem productivity. One example of a modeling approach that illustrates how ecosystem trophic status modifies the bioavailability of toxicants and decreases the subsequent dose to biota was performed by McCarthy and Bartell[30]. Their model predicts the association of a contaminant with dissolved organic material (DOM) or particulate organic material (POM) significantly lessens the bioavailability of a toxicant and, thus, the potential dose experienced by the organisms. Importantly, this paper shows the necessity of estimating the true bioavailability of a contaminant in the environment.

Seasonal or habitat variances in bioavailability can be modeled (e.g., mapped onto expected environmental chemical concentrations for species of known life history, feeding, and habitat requirements) and are a cost-effective approach to the hazard characterization of complex chemicals. For a given concentration, species may be subject to exposure for a relatively longer period of their life-span if they are smaller or less likely to move beyond the boundaries of the contaminated area (examples are earthworms, burrowing invertebrates, or small

mammals). Further, if a chemical is susceptible to being bound by organics, burrowing (or thigmotactic) benthic invertebrates (or benthos-feeding fish) may be subjected to higher exposures than would otherwise be predicted. Volume 2 includes certain models available for evaluating transport, transformation and fate of contaminants in the environment (e.g., EXAMSII, LPMM). In addition, several models estimate biotic exposure or uptake of contaminants (e.g., FGETS).

If available data indicate little potential for movement, the assessment may move in the direction of evaluating the potential for uptake by flora and fauna in the immediate vicinity of contamination. Questions might focus on whether the material is being bound within the soil by specific soil constituents or within specific soil horizons, or taken up by plants or burrowing invertebrates. These initial lines of inquiry may lead to further questions about the potential for effects on plant distribution and floral composition. Questions stemming from the hypotheses formulated in the PF phase may include: Are soil microorganisms affected to the extent that soils become infertile or soil-plant interactions disrupted? Are processes of nutrient cycling disrupted? Answers may lead to other lines of inquiry, such as the potential for movement of contaminants into animal matrices.

### 3.1.3 Exposure Analysis

Once stressor characteristics and the ecosystem potentially at risk have been identified, potential pathways for contaminant(s) through the ecosystem must be identified. The spacial and temporal distribution of the stressors and the ecological characteristics of the system of concern are combined to evaluate exposure. The concentrations of the stressor are combined with assumptions about contact or uptake by biota to determine co-occurrence with measurement endpoints. However, concentration of a contaminant does not equate to exposure. Bioavailability and the environmental fate of the chemical must also be considered. The environmental fate and potential transport of contaminants is crucial to effective risk assessment, because the bioaccessibility (whether organisms come in contact with toxicants) and bioavailability (whether contact leads to uptake) are controlled by these processes. For pesticides, degradation, volatization, binding, leaching, and aging determine ultimate exposure concentrations[24]. Metals availability is controlled largely by pH and oxidation-reduction relationships in environmental media[25]. The chemistry and distribution of the compounds of interest must be thoroughly understood for effective risk analysis. It is crucial for the risk assessment/risk management team to understand that the bulk concentration of chemical compounds as measured in typical laboratory extraction tests (such as those provided with Contract Laboratory Program

quality assurance documentation under CERCLA) do not reflect the biologically active concentrations. In practice, binding and uptake processes depend on complex environmental processes which need to be accounted for in projecting risks.

The environmental fate of a contaminant will generate pathways that may be simple and straightforward or complex and highly branched. Pathways are generally defined by naturally occurring physical, chemical, and biological components of the ecosystem. As an example, consider the evapotranspiration potential, precipitation, soil type, slope, local vegetation, and ground squirrels (*Citellus* sp.) foraging on the vegetation in a given ecosystem. In this example, the movement of an organic contaminant might be a function of the seasonal food source sought by the rodent species. In other seasons, the ground squirrels are absent or dormant; hence, they would not be subject to exposure by the same pathway.

The origin of each contaminant pathway is typically from soil or water, at the site of contamination and the end of each pathway is a component of the ecosystem where adverse effects may occur (such as threatened or endangered species, a resident small mammal population, or fish species in a downstream lake or reservoir). Several assessment endpoints may exist at the end of a contaminant pathway because pathways will seldom be unidirectional or linear. Chemical pathways generally branch and proceed in multiple directions; for example, a contaminant may have the potential for moving from a contaminated site into an aquatic system, with no potential impacts (branches) en route to a pond. However, once the contaminant enters the pond, potential contaminant pathways may include uptake of the contaminant by aquatic vegetation, by aquatic organisms (e.g., mollusks, gastropods, aquatic insects), uptake by fish, or amphibians, or transport back to the terrestrial environment via birds or mammals that feed on aquatic organisms.

The number of contaminant pathways are determined by the characteristics of the contaminant and the complexity of the ecosystem. Contaminant pathways must by identified on each Army Superfund site; however, similarities in pathways will likely exist among many sites resulting from similar ecosystems. Greater definition (closer focus) of specific contaminant pathways will be a function of Tier 2 and Tier 3 chemical analyses. Ultimately, however, if a pathway is incomplete or does not exist at a particular site, no cause and effect relationship exists and there is no associated risk.

Several models are currently used to assess the fate and distribution of toxic chemicals in ecosystems and link distribution to exposure and effects assessment. Many of these are discussed in detail in Volume 2 of this document. Most exposure models tend to be conservative because they are based on

an assumption of equilibrium, and thus overestimate exposure. Thus model validation is very important when using any predictive model. For example, if one is modeling bioconcentration of chemicals into fish at a site, the results can be compared to measured concentrations of chemicals in fish at the site to validate the model. The text that follows is meant as an introduction of modeling efforts which have been successfully used to assess chemical fate, transport and exposure.

Estimation of contaminant bioaccumulation (the net accumulation of a chemical by an organism as a result of uptake from all routes of exposure) at the site through the food web is very important to address because, in many cases, it provides a link to human health risk assessment. For example, the octanol-water partition coefficient ($K_{ow}$) may be known or estimated for organic chemicals. Typically, log $K_{ow}$ values less than 4.3[31] to 5.0[32] do not biomagnify in fish. Garten and Trabalka[33] reviewed terrestrial food-chain data and concluded that only organic chemicals with $K_{ow}$ values greater than 3.5 significantly bioaccumulate in mammals or birds. Models such as FGETS (Food and Gill Exchange of Toxic Substances) and SARAH (Surface Water Back Calculation Procedure) can be used to predict bioaccumulation potential (see Volume 2).

An example of the use of fate, transport, and exposure models were used to predict risks to humans can be found in a Newark Bay study[34]. Dredged material from Newark Bay containing dioxin was proposed for disposal at a disposal site in the New York Bight. Models were used to predict human exposure via ingestion of fish by humans (Figure 10). Accumulation factors (AF) found in Pruell et al.[35] were used to directly model transfer of dioxin from sediment to benthic organisms associated with that sediment. In order to estimate the exposure of dioxin associated with the dredged material to other aquatic organisms, it was initially partitioned to sediment interstitial water. An equilibrium fugacity model developed by Mackay[26,27] was then used to predict sediment overlying concentrations of 2,3,7,8-TCDD (Dioxin). Thomann[36,37] developed a simple aquatic food chain model using contaminant body burdens of organisms in various trophic levels, thus quantifying bioaccumulation. This same model was expanded to include interaction of aquatic biota with sediment chemicals in Thomann et al.[38]. These models were used to predict concentrations of dioxin in lobster, flounder, and bluefish in a food web. Ultimately the risk to humans ingesting these fish was calculated.

Fordham and Reagan[39] developed a food web model to evaluate potential exposure pathways for a site (Figure 11). Data collection can be complex and many assumptions on exposure and uptake are made. The model estimates acceptable concentrations

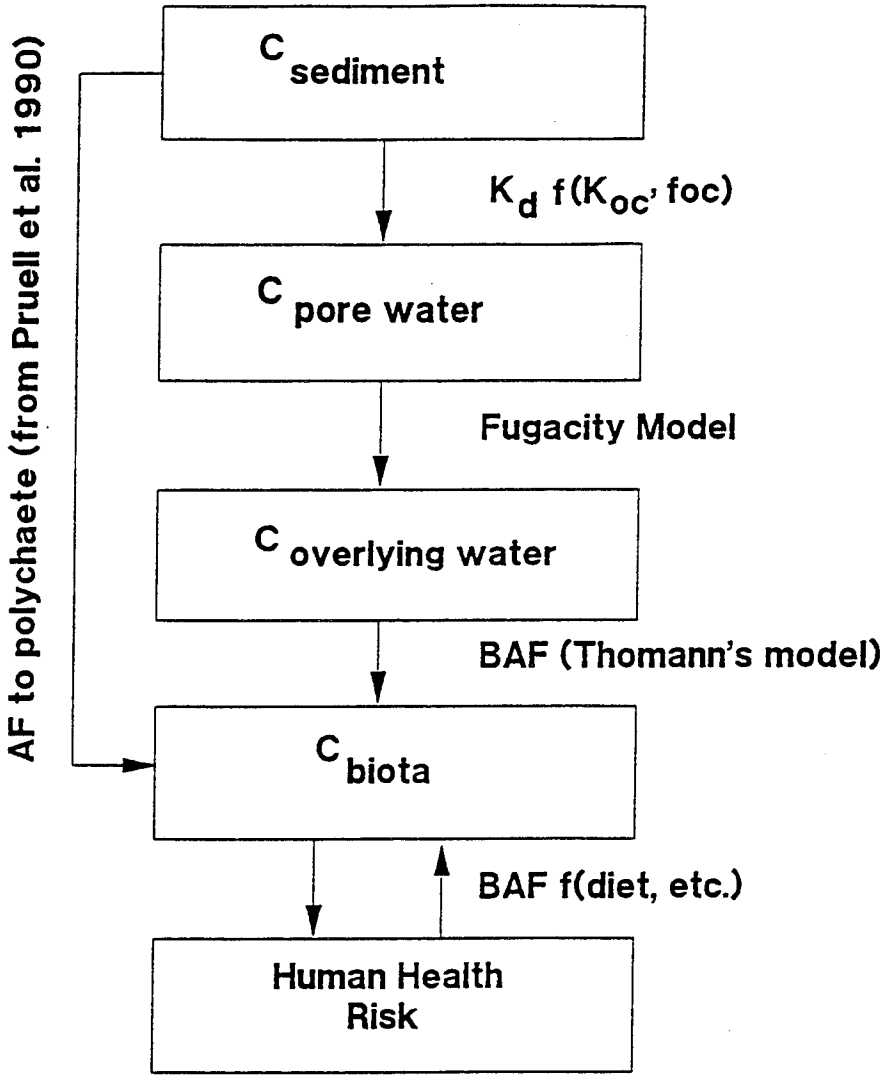


**Figure 10 Schematic presentation of the approach used to assess risk of dioxin associated with sediments.**

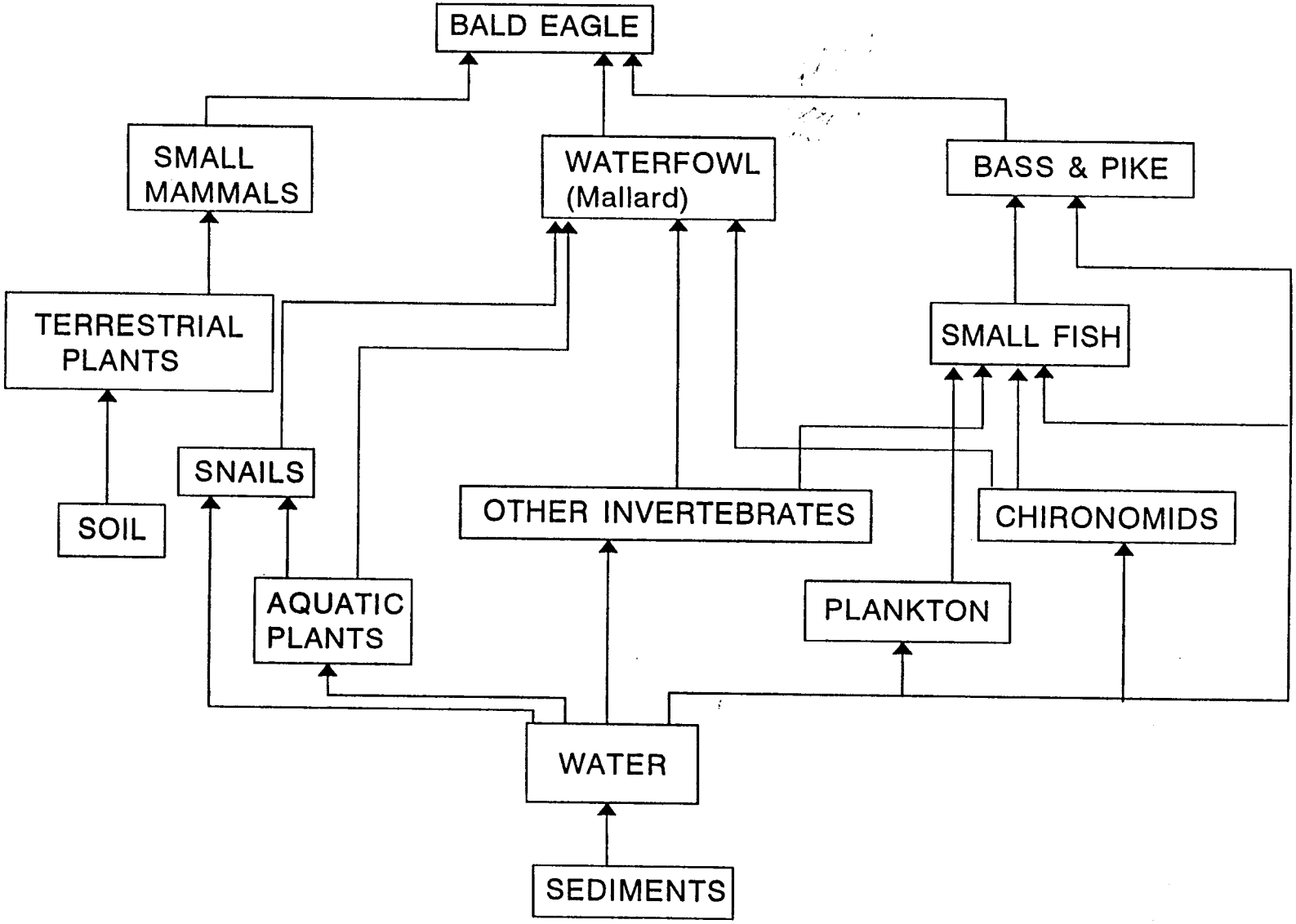


FIGURE 11. Pathways of contaminants from sediment and water to a target organism in a representative aquatic ecosystems at Rocky Mountain Arsenal.[39]

in abiotic media for each exposure pathway. Further, it develops a site-specific food web by entering data from on-site sampling as well as literature sources. Finally, the model addresses bioaccumulation in multiple food chains that terminate in a high trophic level species (e.g., bald eagle). Uncertainty and data gaps need to be stated when using this method. Data from this type of study can be utilized in ecological risk assessments when evaluating risk to populations of biota exposed to site-related contaminants via different pathways.

### 3.1.4 Exposure Profile

The exposure profile presents the concentration of the stressor and its distribution over the area of study. Exposure over time can also be addressed so that the units match those presented in the stressor-response profile. The exposure profile evaluates pathways and determines exposure or dose to measurement endpoints. The extent to which ecosystem properties are analyzed depends upon the nature of the stressors and ecosystem components, bioavailability, and the resources available. Analyses should concentrate on those ecosystem components that are determined to be at greatest risk. Knowing the stressor characteristics can help to narrow the focus of the investigation on the components of the ecosystem that are potentially most susceptible.

The exposure profile for chemical stressors usually involves consideration of sources (e.g., explosives burning ground), environmental transport (e.g., rate of movement through soil column), partitioning of the chemical among various environmental media (e.g., soil particles vs. organic matter), chemical/biological transformation or speciation processes (e.g., photolysis, biodegradation), and identification of potential routes of exposure (e.g., ingestion, plant root absorption, etc.). Exposure profiles for non-chemical stressors such as soil compaction, or habitat alteration describe the ecological components exposed and the general temporal and spatial patterns of their co-occurrence with the stressor. Shaw and Diersing[19] described the extent and distributional pattern of compacted and disturbed soil in a field used for military training with tracked vehicles, the soil microflora, vegetation and wildlife occupying or using this training field. They compared the size and distribution of these populations with those in adjacent undisturbed fields.

Statistical techniques commonly used in the exposure profile are geostatistical techniques (kriging) to determine loci of contaminant residues in soil or water and multivariate techniques (cluster analyses, canonical correlation, principal components). Perland[40] presented an effective integration of chemical fate and transport information into an exposure profile of an ecological

risk assessment. In this case, groundwater was contaminated with benzene and barium in the vicinity of valuable wetlands habitat. Surface water exposure concentrations were projected based on measured groundwater data and information regarding local precipitation, soil chemistry, contaminant binding, pH, Eh, and volatization and dilution. It was concluded in the risk characterization that potential ecological risks were not associated with groundwater contamination and site remediation proceeded as dictated by non-ecological issues.

## 3.2 Characterization of Ecological Effects

### 3.2.1 General Overview

The determination of ecological effects at a site is a critical component of the ERA because data generated in this section may drive the decision making for the rest of the assessment. Assessment endpoints guide what data or measurement endpoints are required to assess impacts. To quantify ecological effects, data can range from sublethal or behavioral effects, to lethal effects, to population shifts, to community changes, habitat loss, ecosystem structural and/or functional changes, to biomagnification of chemicals through a food web (Volume 2). Subcellular biomarkers may be useful for identifying subtle effects. Data on threatened or endangered species offer special consideration because individuals, as well as populations, must be protected[41]. Evaluating ecological effects at a particular site is made more difficult because site-specific toxicity data or specific data on a species of concern are often lacking. Ecological surveys and Geographical Information Systems (GIS) are used to support a qualitative determination of ecological health, diversity, and habitat distribution and they can help to fill such data gaps.

Potential cause and effect relationships between a contaminant and the ecological measurement endpoint must be established. Hill's criteria[4] provide a listing of the primary questions that should be addressed (Table 5). The major criteria such as strength (a high magnitude of effect associated with exposure to the stressor), consistency (the association is repeatedly observed under different circumstances) and specificity (the effect is diagnostic of a stressor) need to be recognized and considered. We caution against establishing a cause - effect relationship based on simple observations (i.e., the contaminant is present in a forest soil and the forest is in decline, therefore the decline is caused by the contaminant). Many factors such as drought, insect infestation, disease, nutrient stress, management practices, etc. may be contributing to the decline.

Table 5. Hill's Criteria for evaluating causal associations[4].

1. **Strength:** A high magnitude of effect is associated with exposure to the stressor.
2. **Consistency:** The association is repeatedly observed under different circumstances.
3. **Specificity:** The effect is diagnostic of the stressor.
4. **Temporality:** The stressor precedes the effect in time.
5. **Presence of biological gradient:** A positive correlation between the stressor and the response.
6. **A plausible mechanism of action.**
7. **Coherence:** The hypothesis does not conflict with knowledge of natural history and biology.
8. **Experimental evidence.**
9. **Analogy:** Similar stressors cause similar responses.

note: Not all of these criteria must be satisfied, but each incrementally reinforces the argument for causality. Negative evidence does not rule out a causal association but may indicate incomplete knowledge of the relationship.

At most DoD hazardous waste sites, the initial environmental effects may have occurred years ago. Cause and effect evidence of contaminant toxicity may be difficult to determine because of adaptation of the community or system. Therefore, it is important to determine as much of the natural history and biology of the site as possible and to determine whether a continuing exposure pathway exists and whether it poses a threat to the currently-existing ecosystem. The ecological system in which the contaminants or stressors are present influence the impact they have on the biota. For instance, it is well-documented that physical and chemical changes in aquatic systems affect the toxicity and distribution of chemicals. An example is the inverse correlation between toxicity of heavy metals and increasing water hardness[42] and pH[43]. Terrestrial systems can act in a similar fashion with various soil parameters such as CEC or organic matter content, enhancing the ability of a soil to adsorb chemicals[44].

Thus physical, chemical, and biological components of the ecosystem need to be considered for their impact on the bioavailability and exposure of the contaminants at the site. Furthermore, if the contamination or stress occurred years ago, the ecosystem may have had time to recover to another state. The adapted state of the system needs to be evaluated to judge habitat change, and to determine whether the changes have reduced the "value" or productivity of the site. System resilience is also important in assessing the impact of the contaminant on the biota. Resilience, defined as the capacity of the system to return to a "pre-disturbed" state, has to be defined in terms of the important effects endpoints. For example, it may be the time it takes for a bird or small mammal population to re-establish itself (years to decades) or a soil invertebrate fauna to re-establish (months to years). Resilience is most often measured in lower trophic level animals or plants, simply because of the ability of the assessor to measure their ability to recover.

Selecting appropriate reference sites is difficult but very important to accurately evaluate the ecological effects in a risk assessment. The reference habitat should be similar in all aspects but for the contamination. For example, a terrestrial location with contaminated soil should have as a reference site one that has a similar soil type with similar vegetation and wildlife habitat. It may be useful to study soil survey maps obtained from the Soil Conservation Service, consult with the National Wildlife Federation about wildlife habitats, seek categories of "reference watershed" from the EPA EMAP program, or to link gradients of chemical contamination to observed effects or measured body burdens. Lacking such data, information from regional or state parks, undisturbed areas on the site (and known to not have been subject to previous contamination) may serve for use under Tier 1.

Various data on cause and effect of the contaminant(s) at the site then need to be formatted into a contaminant/response profile. Each measurement endpoint should, in theory, have its own profile. The profile may include NOEL's and LOEL's, $LC_{50}$'s, $LD_{50}$'s, $EC_{50}$'s or other quantitative measures, as well as the percentile of the population community or system affected versus exposure dose. In practice, these data can be hard to find and difficult to generate.

An example method of profiling toxicity and exposure assessment is provided by Toxicity Reference Values (TRV) (Figure 12). The TRV method uses available toxicity data on a specific COC to generate an estimated No Observed Adverse Effects Level (NOAEL) for a species of concern at the site with safety factors or uncertainty values included in the process. Laboratory-generated TRVs for a given time period (i.e., the lowest observed effect concentration, LOEC, for a 10-day exposure) may be linked to a specific exposure duration for the population in the field. Although there are sets of limiting assumptions required for the use of TRVs, they can provide an estimate of expected toxicity for given exposure periods.

Multi-contaminated sites offer unique problems. Often, many receptors are exposed to multiple stressors simultaneously. Ecological risk is much more difficult to discern at these sites. Individual as well as synergistic effects of the stressors must be estimated to accurately determine risk. Chemical mixtures influence toxicity in two ways. First, chemical mixtures can cause a toxic effect that is qualitatively or quantitatively different from any of the individual stressors acting alone. Second, the effects of one chemical may influence the kinetics of uptake, metabolism, and excretion of other chemicals. Examples include coating of fish gills by thick mucus when exposed to excessive aqueous concentrations of zinc and damage to nephridia that may be caused by cadmium-metallothionine complexes. The metabolic kinetics of a chemical may also be affected by other chemicals that induce or inhibit enzymes, or that simply reduce the physiological capacities of an organism[7].

Direct effects of stressors on variables such as mortality or growth need to be evaluated at higher levels of organization (population, community, or system) than the organismal (individual or species) level alone. These variables will typically be harder to measure, but usually will provide more pertinent information on the ecological effects caused by the stressors. A population shift, in and of itself however, does not imply a negative impact on the community. The relevance of

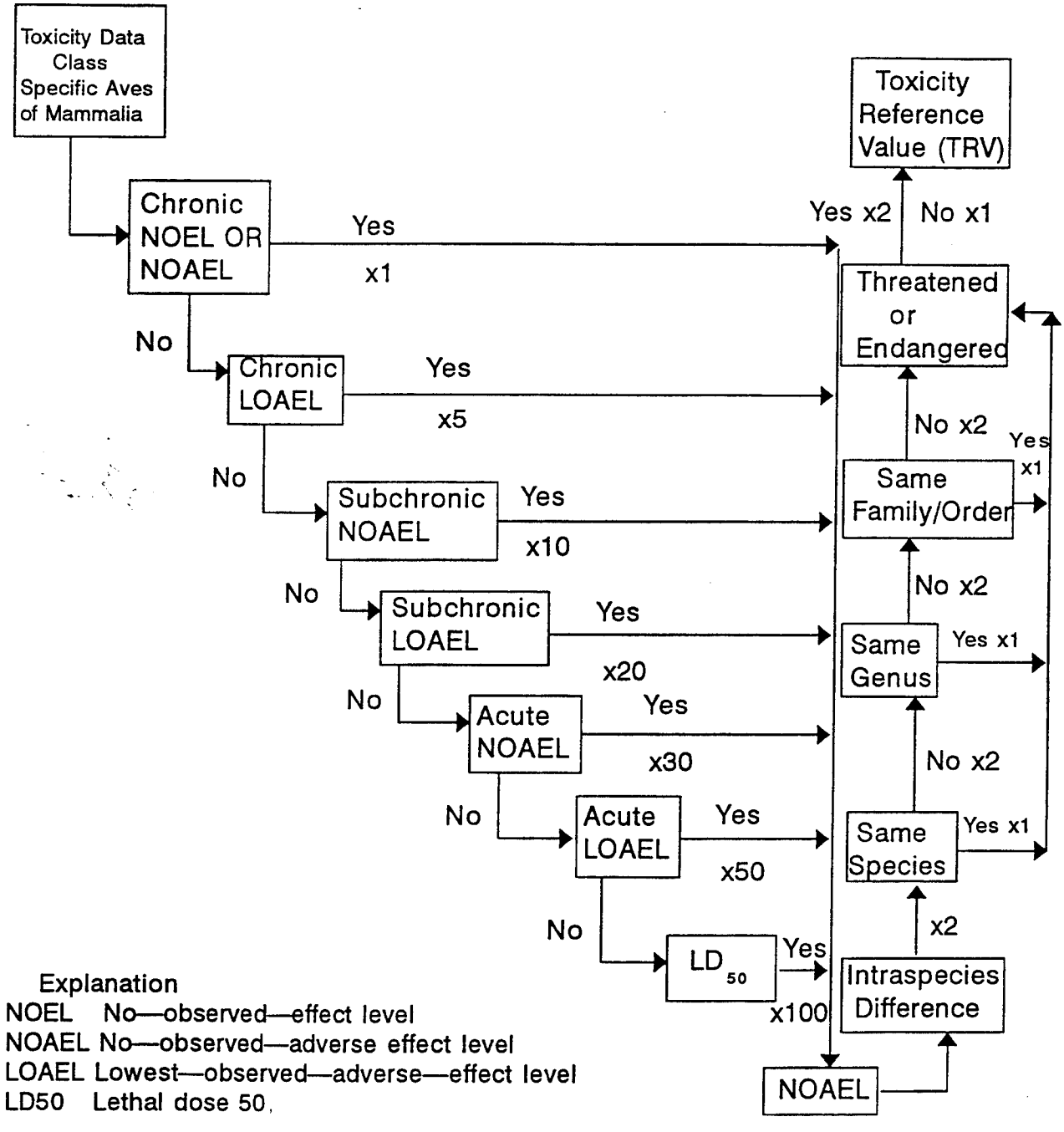


Figure 12. Methodology to derive toxicity reference values (TRV's) from class—specific toxicity data.

effects at the population level to the stressors of concern must then be determined.

Indirect effects must also must be considered and include impacts on habitat, effects on biota in the food web, changes in reproductive capacity, etc. The interaction of all indirect effects to each other and to direct effects should be obtained in order to accurately characterize risk. The simplest assumption is that indirect effects are additive, but more complex interactions are possible. The best understood of the nonadditive effects are thresholds[7]. For instance, populations of a certain species will not be supported once habitat area drops below a certain size; anoxia occurs once the organic input into a water body rises above a certain level, and extinction occurs when mortality rates rise above a certain level in a population. Identification and quantification of such thresholds is a critical component of cumulative affects assessment. Synergistic and antagonistic relationships are more difficult to delineate. Mixtures of chemicals may have more or less than additive effects. In the case of the California condor (*Gymnogyps californianus*), habitat degradation and toxic exposures had a joint effect (extinction in the wild) that was greater than would have been expected from simply adding the losses that either would have caused acting alone[7].

In ecological effects analyses, information collected on measurement endpoints must relate to appropriate assessment endpoints. Extrapolations may include those between species, between responses, from laboratory to field, or from field to field. For example, the responses of organisms (earthworms, plants, small mammals) exposed to soils in the laboratory could be extrapolated to similar populations in the field[45]. An example of a field-to-field extrapolation is provided by La Point et al.[46], in which the diversity of soil invertebrates in ten heavy-metal contaminated sites were compared. The more heavily contaminated sites had fewer insects, leading to the determination that management practices were influencing insect distribution. Assessment endpoints may also be predicted by analysis of indirect effects such as relating removal of long-leaf pine to reduced populations of the red-cockaded woodpecker, or by analysis of higher organizational levels, e.g., relating reduced individual fecundity to reduced population size. These extrapolations require professional judgment. The thought process must be clearly and carefully described to avoid confusion. Conservative assumptions are often used during Tiers 1 and 2. If and when the risk assessment proceeds beyond Tier 2, the data and information gathered to this point reduces uncertainty and fills data gaps to enable the risk assessor to use less conservative assumptions in Tier 3. The assumptions should be clearly stated so a reviewer or risk manager is aware of them. These assumptions should be restated in the Risk

Characterization phase so that reviewers are, once again, aware of the thought process.

3.2.2 Method of Characterizing Ecological Effects

* Tier 1

Methods used in Tier 1 should focus on available information, estimation methods, and literature searches. Available information includes past site reports, surveys or assessments, on-site record searches and Installation Assessments. Much of this information would be gathered under the RI. Wildlife and habitat information may be available from the installation, National Biological Survey, U.S. Fish and Wildlife Service, the State Natural Resources Dept, or other local resources (Table 6). Regional Biological and Technical Assistance Group (BTAG) of U.S. EPA (Table 7) and the U.S. Army BTAG (Table 8) should be able to provide further sources of contacts, information and technical assistance.

Critical focus needs to be placed on threatened or endangered species at the installation. A threatened or endangered species may dominate the concerns of ecological effects and drive the decision on risk characterization. The reason for this is because individuals of threatened or endangered species must be protected as assessment endpoints instead of general populations, communities or ecological systems.

At the end of a Tier 1 study for ecological effects of contaminants at the site, the risk assessor should have:

(1) the available toxicity data on the chemicals of concern (COC);

(2) any available ecological information and information on biological incidents e.g., fish kills, dead birds;

(3) identified threatened or endangered species at the site and estimated their homerange or migrational pattern;

(4) identified any contaminants that may bioaccumulate;

(5) identified habitat areas of concern and areas known to be adversely affected by contaminants; and

(6) identified data gaps.

This information is summarized in a contaminant/response profile for the COC. At this stage and level of effort, the degree of uncertainty may be high and data gaps will occur, but the risk

**Table 6. Sources of Site Information**

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|---|
| U.S. EPA Environmental Research Laboratories |
| U.S. Department of Agriculture<br>(e.g., Southern Forest Experiment Station, New Orleans, LA) |
| U.S. Soil Conservation Service<br>(e.g., County soil surveys, Natural resources inventories) |
| U.S. Fish and Wildlife Service |
| National Oceanic and Atmospheric Administration |
| State Parks and Wildlife Departments |
| Agricultural Experiment Stations (within University systems) |
| Sierra Club (e.g., Naturalist's guides) |

**Table 7. U.S. EPA Regional BTAG Coordinators/Contacts**

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**Table 7. U.S. EPA Regional BTAG Coordinators/Contacts (cont'd.).**

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**Table 8. U.S. Army BTAG Coordinators/Contacts.**

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**U.S. Army Waterways Experiment Station (USAWES)**

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US Army Waterways Experiment Station
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3909 Halls Ferry Road
Vicksburg, MS 39180

assessor must use professional judgement to summarize this information with appropriate uncertainty included.

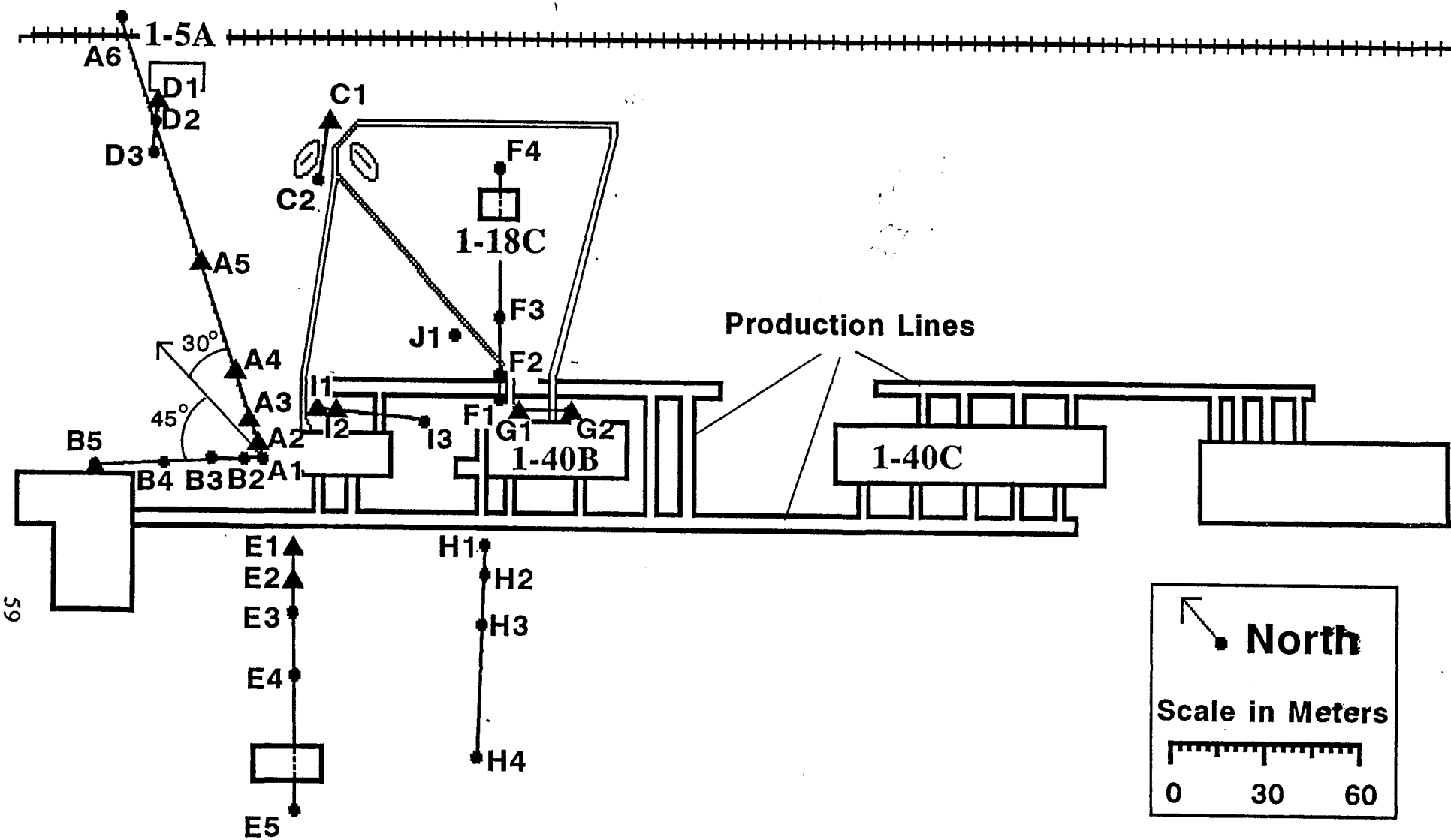
* Tier 2

The purpose of Tier 2 is to build on information gathered in Tier 1 by addressing data gaps to reduce uncertainty. Ecological effects data need to focus on the main COCs and reduce uncertainty when addressing their impacts on threatened or endangered species, habitat, or important populations. Measurement endpoints used in Tier 1 may become more complex or sophisticated in Tier 2. An example would be the use of literature toxicity data in Tier 1 verses specific laboratory toxicity studies in Tier 2.

Pathways where COCs could biomagnify in the food web to affect threatened or endangered species are addressed in this tier. Simple estimation methods of contaminant biomagnification for Tier 1 need to be upgraded in Tier 2 to reduce uncertainty or to fill data gaps. An example of a simplified approach to measuring biomagnification is a food-chain laboratory microcosm[47], in which lower trophic level organisms are exposed to contaminated water or sediments and subsequently fed to top predators to develop estimates of biomagnification. Estimation methods based on $K_{ow}$ values and other physical and chemical parameters of the COCs should provide a technically sound estimate of the ability of the COCs to biomagnify. If the COC has been estimated by models or by use of $K_{ow}$ values to biomagnify in the food web, then field or laboratory tissue studies will provide confirmation of model estimates.

Laboratory toxicity studies using site specific soil or sediment may also serve to reduce uncertainty and data gaps identified in Tier 1. Soil or sediment tests for sites contaminated with multiple COCs provide useful specific data on toxicity of mixtures of COCs. The results from laboratory toxicity studies, used as Tier 2 measurement endpoints, should provide information to better define areas at the site where the soil, water or sediment are toxic or nontoxic. An example of how toxicity testing can help delineate between toxic and non-toxic areas at a site was a study of soils conducted at Joliet Army Ammunition Plant, Joliet, IL.

In the Joliet study, six sites were identified by a remedial investigation as potentially having high concentrations of explosives and heavy metals[48]. Soil sampling was performed along transects through areas suspected of having high contamination at each site. Subsequent toxicity testing and chemical analyses identified the two most toxic sites, defined the shape and extent of the toxic areas within each site (Figures 13 and 14) and




# Area L7 Group 1
# Transects and sampling locations

Figure 13. Joliet Army Ammunition Plant Group 1 load, assemble, and pack area showing transects and locations with non-toxic ● or toxic ▲ response to at least one toxicity test.[45]

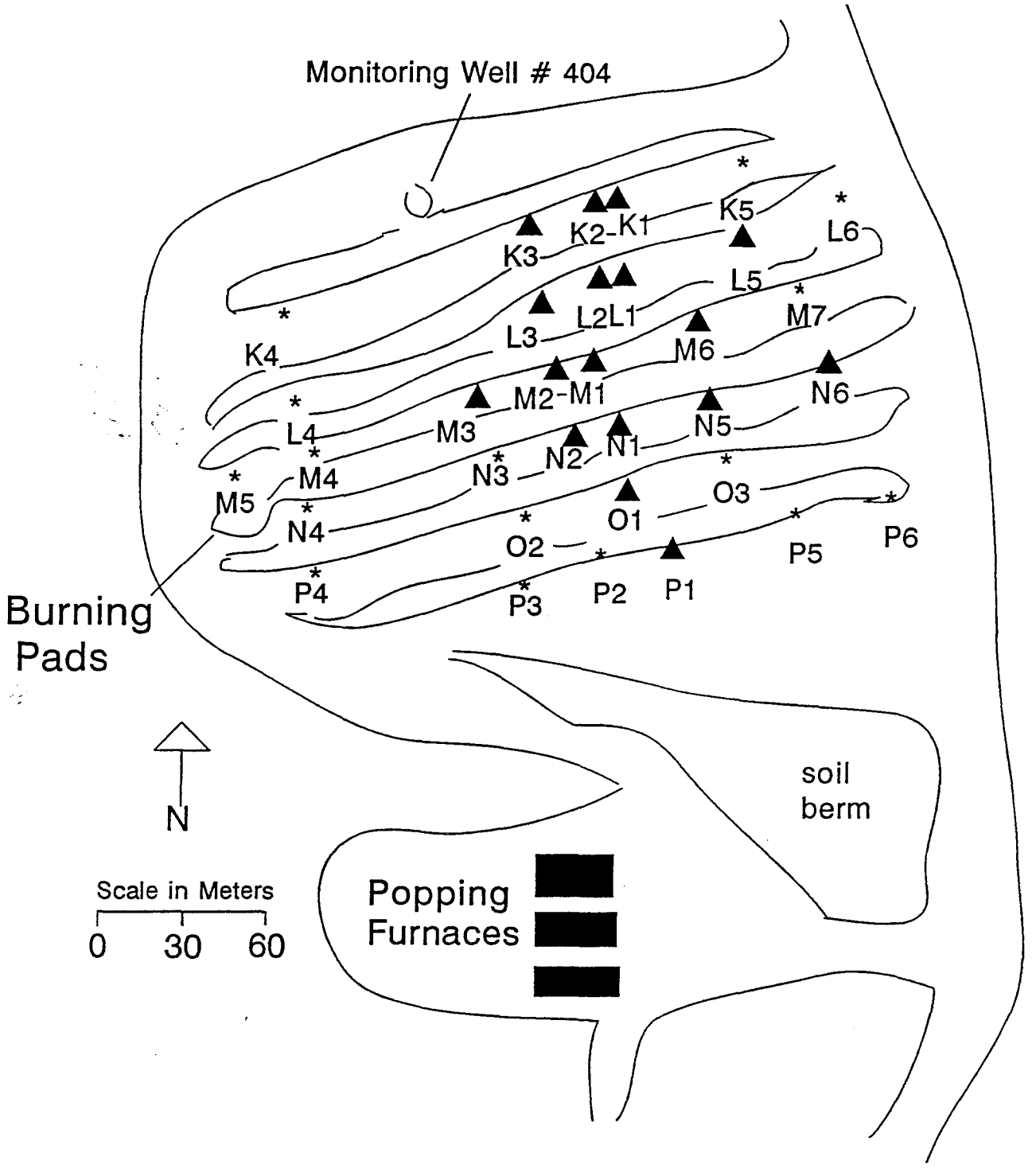



Figure 14. Joliet Army Ammunition Plant Area L2 explosive burning ground showing transects and soil sampling locations with **non-toxic** • or toxic * response to at least one toxicity test.[45]

against concentration values of explosives. TNT was determined to have the greatest $R^2$ (coefficient of determination) value of the eight compounds detected. Lowest observed effects concentrations (LOEC) of TNT were then extrapolated from these data.

In the preceding study, relatively inexpensive, short term (≤14-day) toxicity tests provided information to risk managers that will save time and money in the long run. For instance, remediation can be concentrated on the two sites that pose the greatest ecological risk. Within sites, risk managers can use these results, together with results from studies of other components of the ecosystem, to decide on the extent and type of remediation. Managers may also use these results to decide if further, more extensive testing is necessary in areas where soil concentrations are on the borderline of causing toxic effects. Furthermore, this study incorporated a series of bioassays to investigate effects at different levels of biological organization. This approach is more effective than using bioassays at the same organizational level because response to a stressor may vary among organisms at different levels of organization.

It is important to note that ANOVA results, LOEC's, and $R^2$ values in this study are site-specific and highly dependent upon soil characteristics and concentrations of other soil contaminants. As cited previously, toxicity of many chemicals, and soil explosives in particular are highly dependant on pH, organic matter, CEC and other characteristics of the site soil. Therefore, soil characteristics should be considered before extrapolating toxicity data between sites and between studies.

The Joliet case study is example of the use of toxicity testing established gradients of concentrations of explosives in site soils[45]. Plant (two species), earthworm, and Microtox™ bioassays were used to assess soil toxicity. Highly toxic, moderately toxic, or not significantly toxic soils were determined based on statistical significance compared to control soils. These categories were used to define the shape of toxic areas at each site. Soil samples with significant toxicity, according to at least one test, and representative samples displaying no toxicity, were analyzed for explosives at each site. The explosives, trinitrotoluene (TNT), cyclotrimethylenetrinitramine (RDX), and their degradation products were identified via HPLC analyses. End points of toxicity tests were then regressed to assess risk in Tier 2 of an ERA. An extensive compilation of ecological effects methods is presented in Volume 2. The reader is referred to Volume 2 for measurement endpoints to support specific goals of the ERA.

Field studies conducted in Tier 2 will be focused to address data gaps identified in Tier 1 and the overall assessment endpoints for the ERA. Ecological assessment may be necessary if the installation or other agencies do not have the information on biota present at the site. GIS can be used to identify habitat and land use patterns at the installation. Biotic surveys can determine species diversity, predominant populations, and identify population shifts.

Results from the Tier 2 ecological effects studies will further support cause and effect relationships between the COCs and the biota, community or ecological system. Uncertainty will have been reduced and most data gaps addressed. Various measurement endpoints will be "mapped" onto site locations to generate contaminant response profiles of species tested at the sites. These will, as in Tier 1, be related to the assessment endpoint(s) identified in the initial phase of the ERA.

* Tier 3

Tier 3 should involve larger levels of effort reflecting increased levels of concern to reduce uncertainty and address ecological effects data gaps in the ERA. Investigations in Tier 3 are not meant to deal with the highly toxic or hazardous areas within a site. The highly toxic sites could, and should, be identified in Tier 1 as areas where significant ecological effects occur and significant risk is probable. In Tier 1 or 2, these areas would be recommended for remediation. In Tier 3, there is no need to analyze the specific toxicity of contaminants or conduct more in-depth ecological studies on the highly toxic sites, if it is clear from Tiers 1 and 2 that they will be remediated. Tier 3 should focus on the "gray" areas, where it is still uncertain if significant ecological effects occur.
By the end of the Tier 2 investigation, sites should have been identified that are clearly affected by COCs, as well as sites where no effects occur following COC exposure. Further laboratory and field toxicity tests may be required to establish NOEL concentrations. These refined measurement endpoints are designed to reduce uncertainty and address data gaps not covered in Tiers 1 and 2. In Tier 3, collecting field data to determine tissue concentration in wildlife should be conducted to confirm the presence and extent of bioaccumulation, bioconcentration, and/or biomagnification that was suspected from results of Tier 2 studies. Additionally, if chronic physiological effects are suspected, they should be performed in Tier 3, particularly if evidence for such effects is obtained in previous tiers.
However, these types of studies are often time consuming and expensive. Work should proceed only if all parties agree that the studies are essential to adequately complete the risk assessment and enough funds and resources are available to do quality experimentation.

A study by McBee et al.[49] is a good example of focused field research appropriate for a Tier 3 study to examine subtle, chronic ecological effects. In this study, the existence of environmental mutagenesis was determined by examining standard metaphase chromosome preparations from resident small mammals (*Peromyscus leucopus, Sigmodon hispidus*) trapped over a two-year period at a site polluted with petrochemical waste products, heavy metals, and PCBs. Significant differences in levels of chromosomal aberrations were found between animals collected at the contaminated site and those captured at two uncontaminated sites, even though acute toxicity was not apparent. Levels of chromosomal aberrations were not significantly different between the control sites. Potential longer-term, chronic effects suggested by the cytogenetic analyses, however, clearly indicated responses relevant to site assessments evaluating adverse ecological effects, and reinforced the importance of reference sites when correlative analyses are considered in the assessment of biological effects in the field.

Food web sampling is more complex but offers more complete information on contaminant pathways through the food web. Fordham and Reagan[39] (Figure 11) developed a food web model to evaluate potential exposure pathways for a site. The model estimates acceptable concentrations in abiotic media for each exposure pathway. Further, it develops a site-specific food web by entering data from on-site sampling as well as literature sources. Finally, the model addresses bioaccumulation in multiple food chains that terminate in a high trophic level species (e.g., bald eagle). Data from this type of study can be utilized in ecological risk assessments when evaluating risk to populations of biota exposed to site-related contaminants via different pathways.

When conducting any field study, various problems must be anticipated. The data collected will be more variable than laboratory studies. Analytical detection limits for tissue, soil, or water need to be known before data are collected. Detection limits in tissue need to be low enough so a no effect level can be related back to soil or water concentrations. Estimates from Tier 2 should be used to provide a guide for setting detection limits in Tier 3.

Co-locating tissue samples with soil or water samples at the site of collection may be necessary to accurately assess the toxicity of the COCs. The spatial relationship of data points collected during a field survey will be important for relating tissue concentration to exposure[15]. Maps have been used extensively to study and display spatial patterns. Many cartographic and GIS techniques are available for displaying spatially varying quantitative data. For example, if the variable of interest (e.g., distribution of TNT) is spatially continuous, it can be

conceptualized as a surface in three dimensions. The surface can be displayed as contour lines, isopleths, or as perspective plots. Alternatively, if the variable is discontinuous, the magnitude of an observation at a point can be represented by a symbol size or color. Synopses of these methods with references are found in Volume 2 of this publication.

Additional data needed to assess wildlife impacts include: home range, feeding area, and migratory patterns of the biota of concern at the site. This information can be provided by USFWS, site specific sources (i.e., state fish and wildlife department, military installation records, etc.) or the open literature. Identification of critical habitat to species of concern should be conducted. These data, together with spatial and temporal patterns of the COCs within the site help characterize the extent of ecological effects. Contaminant effects on local habitats, if extensive enough, can be related to cumulative impact on the watershed in which the site or sites are contained. These data may be used later to mitigate impacts through the additional critical habitat areas to the site. Mitigation options need to be viewed in light of minimizing further damage or risk to the resource. For example, if a habitat has been shown to be critical for a top avian predator (e.g., old-growth tree snags for osprey), it would not be suitable to suggest grading and incinerating of the vegetation from the site, unless similar habitat were set aside elsewhere as a mitigation option. Additional laboratory studies may focus on establishing no effect levels for the COCs. These studies should include tissue analyses so toxicity responses can be related to COC concentrations in tissues. These data are valuable for determining no effect levels of COCs in soils, water, or sediment. Other Tier 3 studies may be driven by regulatory or local concerns that may arise only after previous studies have been performed.

### 3.2.3 Linking Exposure and Stressor-Response Profiles

During the final stages of the Analysis phase, ecological effects and exposure are characterized concurrently. Data on fate and effects are objectively evaluated for their utility in ascribing cause and effect of the stressor. The degree to which organisms are adversely affected beyond those due to "normal" physical or biological stressors must be quantified. To this end, collected data are often subject to statistical methods to describe the inherent mean tendency and distribution of the population parameters (behavior, growth, reproduction, mortality, etc.). Among the statistical techniques commonly applied to such situations are geostatistical techniques (kriging) to determine loci of contaminant residues in soil or water, multivariate techniques (cluster analyses, canonical correlation, principal components) and univariate approaches to measure the organismal or population responses (e.g., differences in mean body burden of

chemical in an exposed set of organisms; differences in reproductive success of exposed small mammals).

The paths by which contaminants move from the point of origin through the biota and ecosystem may be simple and straightforward or complex and highly branched. Contaminant pathways will generally be defined by naturally-occurring physical, chemical, and biological components of the ecosystem (e.g., soil, vegetation growing on those soils, and microtine rodents foraging on the vegetation). The necessity of moving to Tier 2 or 3 under an ERA will largely depend on the complexity of the pathways, as determined by stressor-response and ecological analysis portion of the Analysis Phase.

On typical CERCLA sites, most contaminant pathways branch and proceed in multiple directions; for example, contaminants may have the potential for moving from the point of contamination into an aquatic system, with no potential impacts (branches) en route. An example of such a scenario is provided by groundwater movement of soluble nitrogenous compounds or pesticides, emerging via seepage into a stream or pond. Once the contaminant enters the water body, potential contaminant pathways may include uptake of the contaminant by aquatic vegetation, aquatic organisms (e.g., mollusks, gastropods, aquatic insects), fish or amphibians, or transport of the contaminant to birds or mammals feeding on aquatic organisms. Within each tier, contaminant pathways must by identified on each Superfund site. However, similarities in pathways will likely exist among many sites because of similarities of habitats and organisms in similar ecosystems (e.g., grasslands, deciduous forest, bottomland hardwood, etc.). It should be re-emphasized that the number of contaminant pathways are determined by the characteristics of the contaminant and the complexity of the ecosystem. Under situations of high complexity and/or diversity, when the magnitude, frequency or duration of the stressor varies in unpredictable ways, the estimates of ecological response(s) and exposure scenarios may require effort and cost beyond Tier 1.

A summary of the Analysis phase is provided by a stressor-response profile. In developing such, the RA identifies measurement endpoints along each contaminant pathway where data collection or computer simulations and models are applied to evaluate contaminant fate or assess potential impacts. This can be conducted early in Tiers 1 or 2. Data collected for these measurement endpoints will help validate or refute whether predicted movement or effects on assessment endpoints are actually occurring. As testing progresses to higher tier levels, these same contaminant pathways will continue to be evaluated through such options as data collection at previously unsampled measurements endpoints identified in the Tier 1 PF phase, or by more intensive data collection at previously sampled measurement endpoints to reduce the uncertainty of analyses. The Tier 1 or

Tier 2 identification of contaminant pathways (and modeling efforts) thus unify the investigative efforts of the ecological risk assessment through all levels of the tier structure.

Under Tier 1, the RA analyzes a suite of previously-compiled data and evaluates site-specific characteristics collected in the PF phase of the analysis (Figure 3). The RA might consider which contaminants were present and estimate the extent of contamination. Under Tier 1, information on chemical/physical properties of the contaminants would be examined in the context of tabled or otherwise compiled physical, biological, chemical and climatological characteristics of the ecosystem. How the contaminants interact with the physical and biological components of the ecosystem will be predictable, within certain constraints. In any case, using reports, maps and some preliminary sample collections would allow the RA to estimate the likelihood of the contaminants remaining *in situ* or moving off-site or through the ecosystem. In the final components of the Analysis phase, information should have been collected to link contaminant exposure to biotic response of critical species and/or habitats. The linkage is made by measuring the response in toxicity, biomagnification, reduction in population density, or other critical measurement endpoints to exposure. Hence, model development is critical at this juncture to understand how the COCs are accumulated by the biota and what a given tissue concentration means to the organisms[18]. In Tier 1, the models used may be as in Thomann[36] or relating concentrations in the soil to toxicity and species presence (as in Apparent Effects Threshold[50]). Under Tiers 2 and 3, model predictions are approximated empirically using on-site or laboratory exposures of naive organisms to measure uptake and consequent effects.

It should be stressed that in Tier 1 analyses, highly conservative risk measures should be developed from the assessments. As more information is collated under Tier 2 and 3 investigations, the need for "application factors" of safety should diminish. This means that, as effects are measured directly or via the use of surrogate organisms exposed on-site, the need for wide confidence limits around the estimates of effect lessens. The measures of risk become more direct.

### 3.2.4 Examples of Linking Biotic Responses and Exposure

Three examples linking exposure to biotic response are provided to describe situations in which exposure is related to biotic effects. The first involves birds subject to agricultural pesticides used on crops in the midwest. The second is an example of mammals located on a terrestrial grassland site. The third example describes assessment in an aquatic system.

* **Avian example integrating exposure and stressor-response profile.**

Birds are often used in evaluating wildlife exposure to, and trophic transport of, environmental contaminants[11]. Birds have a high metabolic rate and, therefore, consume large amounts of food relative to their body weight. This may lead to elevated bioaccumulation or biomagnification, even with contaminants less persistent in the environment. The avian respiratory system, characterized by lungs with air sacs, is highly efficient, moving large amounts of air through the lungs. This physiological characteristic may yield avian species highly susceptible to exposure and accumulation of particulate or vaporized air-borne contaminants. Additionally, many species of birds prey heavily on larval or adult insects during the breeding season[8]. Most of these insects spend all or a portion of their life cycle on or in soil or thatch where they are highly likely to come in contact with environmental contaminants. Other bird species prey upon flying adult insects as they emerge from aquatic and benthic larval forms, and are thus exposed to contaminants in water and sediments. Birds are often numerous in natural and disturbed habitats and can provide an adequate sample size to satisfy quantitative analyses.

Procedures for sampling exposure and response to contaminants in birds can be designed for each level of effort and costs relative to Tier 1, 2, or 3 studies as defined in this document.

A Tier 1 effort may involve avian censusing techniques to determine relative frequency and abundance of bird species on the study area. Habitat use and activity data collected during the census, graphically displayed, will quickly identify which species are most likely to be exposed to the contaminant(s) of concern. Once susceptible species are identified, efforts to assess exposure may be concentrated on these species. In certain situations, susceptible species may have been extirpated from the site.

At the Tier 2 level, the RA can attempt to answer more complex questions. In such cases, reference sites are necessary to determine reference (e.g., "control") estimates of contaminant uptake. Contaminant levels may be determined by collecting individuals and conducting residue analyses. A limited sampling of food items of targeted species may provide insight into the nature of exposure route. If the species included for study are cavity nesting birds, nest boxes can be erected on the study site to increase that species' presence and activity level on the site and increase access for sampling[51]. In some cases, one species may naturally nest in abundance on the study site, providing adequate sampling opportunity.

Sampling across several environmental matrices, such as soil, water, invertebrates, and adult and nestling birds can quantify contaminant availability to the species under investigation at different trophic levels. Monitoring contaminant intake in nestling birds quantifies exposure; then, measuring endpoints such as enzyme response (i.e., cholinesterase in the case of organophosphorus or carbamate insecticides), immune system response, growth and survival, quantifies effects at the measured exposure levels.

Tier 3 levels of funding and personnel would allow thorough assessment of exposure and effects along several food chains, each of which having a different bird species as the top predator. Exposure duration may play a significant role in the degree of effects observed in higher trophic levels. This is particularly true for the more environmentally persistent contaminants. Therefore, selecting a food chain with a long-lived, resident, predacious bird (e.g., bald eagle; Figure 9) at the top would likely provide an assessment of the worst case exposure scenario.

Certain birds of prey such as barn owls (*Tyto* sp.), screech owls (*Otus asio*) and barred owls (*Strix varia*) utilize nest boxes, thus providing easy access to nestlings. By selecting several top predators, each representing a different food chain, adequate data can be gathered to predict risk to a broader array of species. European starlings (*Sturnus vulgaris*), tree swallows (*Iridopocne bicolor*), and barn owls, for example, represent diverse food chains that would provide exposure and effects data applicable to numerous other species.

In a Tier 3 study, long term monitoring of adult birds using tarsus banding or radio telemetry provides valuable data on survival and demographics relative to exposure and accumulation of environmental contaminants. In some cases, multiple captures and non-lethal sampling of blood or fecal urates over extended periods of time provide temporal patterns of exposure. For example, repeated blood samples from an individual bird provides insight into exposure to certain heavy metals or to exposure to anticholinergic compounds. The more information determinable in diverse food chains about routes of exposure, bioaccumulation, biomagnification, and organism response to exposure, the more accurately the RA can predict risk for various avian species.

* **Example of integrating exposure and stressor-response profile for small mammals on a hazardous waste site.**

Initially, maps of the site provide estimates of "hot spots," on which small mammal distributions are mapped. Species lists of mammals and birds were collected from local resource managers. In situations in which small mammals are known to be abundant on a site, the collection and study of small mammals provides an

excellent "model" with which to relate exposure characterization and ecological effects. For example, deer mice (*Peromyscus* sp.) or cotton rats (*Sigmodon hispidus*) are often widely distributed over terrestrial sites, are easily live-captured, and respond to contaminants[49,52,53]. Small mammals have relatively small home ranges, ensuring that they are exposed to on-site contaminants. Depending on the local species, rodents, shrews (Insectivora) and mustelids (e.g., badgers) represent different trophic levels, feeding on a variety of food sources, from grasses and seeds to meat. Hence, using such local populations, observed individual or population responses can be readily attributed to contaminants at a particular site.

Under Tier 1, the estimates of effect would stem from, initially, estimates of contaminant concentration in the soil and developing a quotient of soil concentration to body burden. In addition, published information on effects of given concentrations for other small mammals (e.g., laboratory mice) would provide estimates of expected effects for given body burdens. However, variance in the diversity and concentration of contaminants at hazardous waste sites and in "reference" sites may make it desirable to empirically determine exposure using individual mammals with a known, uncontaminated history. This procedure moves to efforts and cost related to Tiers 2 and 3.

Under Tiers 2 or 3, the use of clean, "sentinel" animals introduced onto the site(s) allow quantification of contaminant accumulation and any consequent biological effects. The use of such organisms also experimentally controls for differences in intra-specific variability. Finally, linking the use of biomarkers to population dynamics in introduced organisms allows a conservative estimate of how successful remediation efforts are to minimize biological effects subsequent to site clean-up. If sufficient justification for exposure is determined and justification for closely assessing exposure the organisms experience "removed" some distance from the highly hazardous areas.

Tier 3 calls for measuring endpoints of controlled-exposure small mammals. Such endpoints include monitoring metabolic enzyme activity, such as hepatic microsomal ethoxyresorufin-O-deethylase[54], immunological endpoints[53] and reproduction[55]. Such biomarkers of exposure may be linked to population presence and abundance, the final measure of continued population survival at a site.

* **Impacts of multiple contaminants**

An example of a study that sought to determine the ecological effects and potential risk of multiple contaminants to multiple receptors was the Commencement Bay study[56]. This study investigated the extent of sediment contamination and adverse biological effects in a heavily industrialized area at the southern end of the main basin of Puget Sound. The tide flats area comprises seven waterways and associated shoreline with water depths less than 60 feet. Chemicals of concern included eight metals and 18 organic compounds. Exposure was evaluated by measuring concentrations of chemicals in sediments. A model was used to predict natural recovery. Effects were evaluated by determining benthic abundance, occurrence of liver abnormalities in fish, and various measures of sediment toxicity.

Risks to the fish and invertebrates in Commencement Bay were characterized by comparing conditions at contaminated sites to benchmark or reference locations, applying apparent effects threshold (AET) values for chemical concentrations in sediments. An AET was defined as the concentration in sediments above which statistically significant biological effects (relative to reference sediments) would always be expected. This study included several notable examples for a successful ERA: 1) multiple chemical measurements and biological endpoints were used; 2) the combination of field-collected sediment bioassays and AET's helped to differentiate between effects associated with different contaminants; and 3) by expressing all chemical and biological measures as elevations relative to a reference site, comparisons among these measures and demonstrations of concordance were straightforward.

The Commencement Bay ERA has certain limitations, including: 1) the ecological assessment was neither predictive nor probabilistic, although not originally conceived as a risk assessment; 2) the empirical significance of some endpoints was not explained, particularly with respect to individual site characteristics; 3) the definition of AET as the highest concentration at which no effect is observed (rather than the lowest concentration at which any effect is observed) is the least protective of possible definitions for effects thresholds. This method assumes a consistently increasing biological response at increasing concentrations of chemical. Unmeasured chemicals, physical conditions, species interactions, and other community-level processes may alter the dose-response relationship.

The Commencement Bay study was a multi-year, multimillion dollar effort to explain the ecological effects of many stressors on biota within an ecosystem. Other case studies offer smaller-scale, less expensive, but equally effective methods to examine individual and synergistic effects caused by multiple stressors[16].

# 4. RISK CHARACTERIZATION

## 4.1 General Overview

Risk characterization is the critical process in an ERA. In the risk characterization, information on exposure, exposure-effects relationships, and defined or presumed target populations (whether from direct sampling efforts or from estimates derived from reports and literature) is integrated to attribute the likelihood, severity, and characteristics of adverse effects to environmental stressors present at the site (Figure 15). It is these parameters which determine the ecological significance of risk, and therefore the appropriate level of risk management response.

It is important to understand that "risk" is an integrative concept, not a single, directly measurable value. Risk is estimated by calculation from information on exposure and contaminant fate. However, risk assessment findings and conclusions may be verified and confirmed by measurement. Direct measures of impact and effect may be important in developing the weight of evidence which supports the attribution of risk to different sources of stress.

The framework document[4], outlined in Section 1, emphasizes the possible interaction of alternate sources of stress and the necessity to identify contaminant-related effects in this context. Draft guidance[3] provides a conceptual foundation for implementing this evaluation. The various components of a weight-of-evidence evaluation should be developed in advance of conducting the analyses, and the relative importance of each should be determined *a priori*. This procedure helps prevent biased conclusions by employing previously agreed-upon input information in deriving risk estimates. In many cases it will be up to the risk manager to understand the administrative record for project plan approvals and act accordingly, because experience has shown that when preconceived notions of risk are not supported by site-specific evidence, risk assessors may come to disagreement or indeed attempt to stretch the assessment process by undertaking further, unplanned and possibly unnecessary studies.

Risk calculations must always be related to assessment endpoint(s) via measurement endpoints. It is this relationship that supports the utility of risk assessment for risk management. It is crucial that assessment and measurement endpoints be understood in the context of the range of ecological stressors present at a site, and that the ERA be conducted to effectively attribute effects (if any) to site-related contaminants. Ecological risk assessment is one of a number of sources of information that must be considered in evaluating the possible

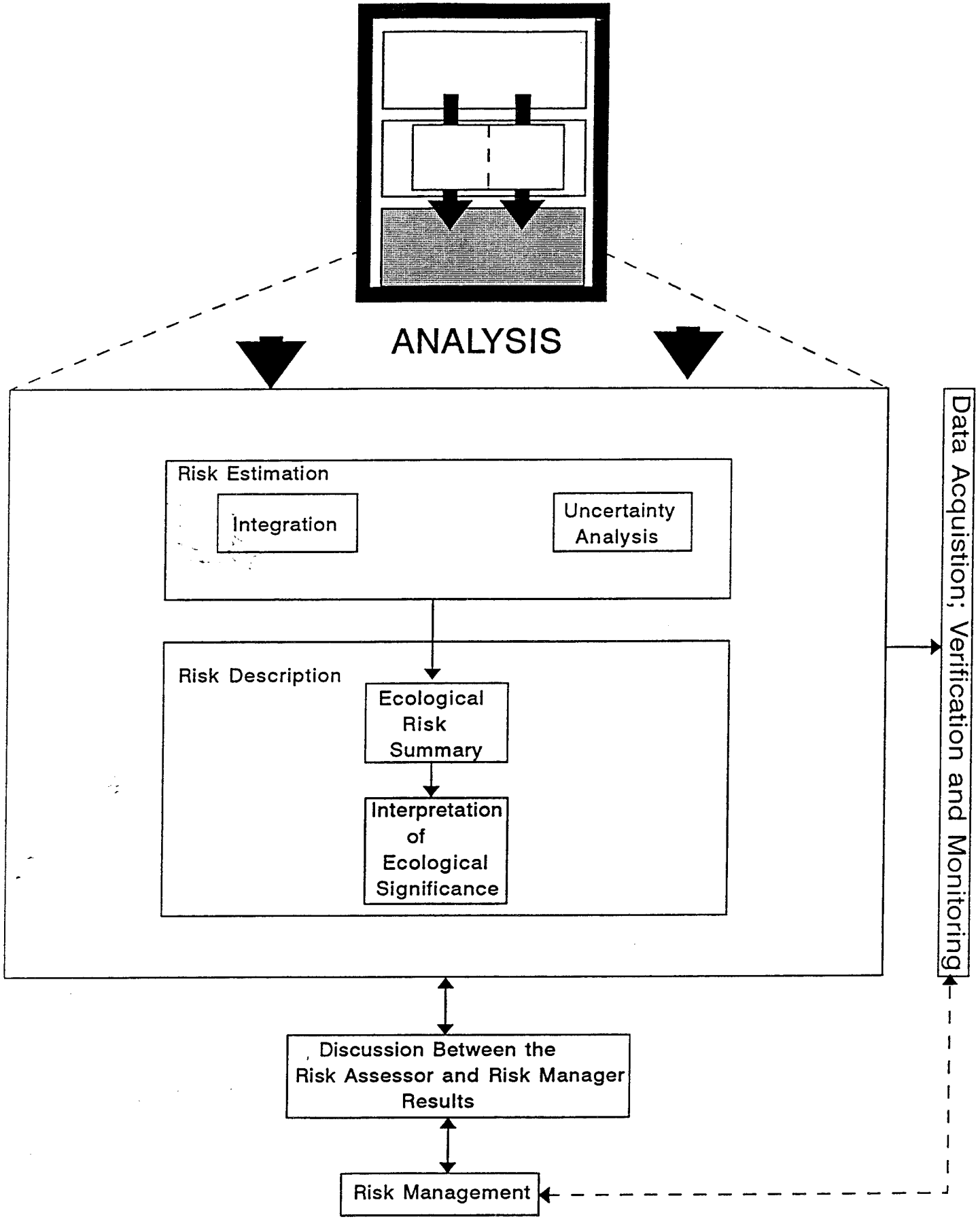



Figure 15. Risk Characterization Phase

remediation of a contaminated site. For ecological assessment to play a proper role in this process, ecological risk characterization must be as accurate and scientifically sound as possible[57] in keeping with the objectives of the assessment. These objectives are identified during the problem formulation phase. Risk assessment objectives in the tiered approach are related to specific decision points which can be useful in determining possible need for further data gathering, evaluation effort, or management actions. Decision points are fundamental to successful implementation of a tiered ERA[3].

## 4.2 Decision Points

The tiered approach to ecological assessment provides an effective framework for risk estimation. The key to successful implementation of the phased approach at the risk characterization stage is the *a priori* provision of decision points for the risk assessment. Review Draft Guidance[3] identifies a series of administrative decision points relating to the review and approval of certain documents. In practice, the risk assessment/risk management team needs to identify technical decision points at which the possible requirements for further investigation, uncertainty evaluation, or risk management consideration are characterized. It is important that such decision points be built in to project planning, to avoid the truncation of the process by time and effort constraints which fail to account realistically for the needs of the assessment process.

Action-oriented decision points will vary with site conditions and assessment objectives, and thus cannot be detailed generically. However, certain categories of decision points can be identified based on habitats present and the overall role of risk assessment in the site management and weight-of-evidence evaluation processes. This section provides brief examples of decision points appropriate for different habitats and levels of assessment. For any particular site, the risk assessment/risk management team should develop in advance detailed decision points on which to base technical progress.

Terrestrial Habitats. Tier 1 investigations in terrestrial habitats will identify areas of heavily contaminated soils. Tier 2 and 3 investigations will focus on the margins of the heavily contaminated zones, and quantify risks associated with contaminant transport and chronic exposure.
Presence of elevated concentrations of organic toxicants or metals relative to "reference" conditions is a primary decision threshold determining the need for further investigation. The need for quantitative assessment beyond Tier 1 can be ascertained by simple, point estimate of exposure vs. known effects concentrations. In general, simple point estimates of risk are

most valuable as indicators of need for further evaluation, and not for defining risk management. Decisions to move to Tier 3 level of investigation should be based on the nature of contamination (bioaccumulative organic compounds, for example) and the complexity of site conditions. For example, presence of endangered or threatened species in areas of elevated contamination suggest the need for advanced analyses.

Risk management decisions in terrestrial habitats should incorporate realistic estimates of exposure based on bioaccessibility and bioavailability of toxicants (Section 3.1). Hypothetical risks based on highly conservative assumptions should not, in general, define active remediation.

Three categories of biota are often the focus for decision making in terrestrial habitats. Vegetation is often not demonstrably impacted (except by herbicide discharge) unless contaminant concentrations are very high. However, vegetation can be a key exposure route through uptake to the consumer food web. Soil fauna, because of local nature of exposure and intimate contact with the primary medium, may provide excellent decision points, and some promising techniques for assessing contaminant effects on soil fauna communities are being developed[58]. Vertebrate organisms are often exposed primarily through the food web. Probabilistic risk estimates based on all exposure routes (see discussion of Conceptual Models in Section 2) provide the decision making thresholds for these receptors.

Aquatic Habitats. Tier 1 investigations in aquatic habitats may focus on point estimates of exposure compared with effects levels such as the available EPA Ambient Water Quality Criteria. Such comparisons should not be made simplistically, however. The published criteria for some metals are weighted relative to water hardness, and this should be accounted for in making decisions on this basis. In addition, the criteria may be modified on a site specific basis to account for resident species (with a recalculation based on supporting toxicity data) or based on site specific toxicological testing. The latter should be considered Tier 2 and 3 studies, respectively, with the decision to undertake such investigations dependent on the level of risk inferred from simple point estimates.

Beyond criteria comparisons, aquatic food web models and probabilistic exposure estimates should be applied when Tier 2 and 3 studies are warranted by potential contaminant-related effects. Effects may be verified by community structure measurements of water column and benthic biota, and perhaps direct toxicity testing. These techniques have the disadvantage, however, of integrating all sources of impact and exposure. They should only be employed when the potential site risks are

sufficient to support the level of technical effort necessary to apportion impacts.

Monitoring and Assessment Validation. In all habitats and under all risk management scenarios, post-assessment monitoring or assessment validation data collection may be important. In general, monitoring is useful in situations where residual contamination will be present after the remedial alternative is implemented. The decision to undertake post-cleanup monitoring is best based on: 1) the relative uncertainty of the risk assessment (more uncertain assessments, especially those based on single point estimates, may need a greater investment in monitoring); and 2) projected exposure reductions associated with the remediation. Properly designed monitoring programs serve simultaneously to assure the efficacy of the cleanup and to validate the risk assessment and its application, i.e., determine the accuracy of the original estimate of risk[59].

The most elaborate and expensive monitoring and validation programs will be used where Tier 1 and 2 assessments have been employed to support cleanup decisions. Tier 3 assessments will generally include intensive field investigations to validate risk assessment parameters. The low uncertainty associated with this greater investigation effort may be reflected in reduced monitoring requirements.

## 4.3 Risk Estimation

The fundamental tools of risk estimation are the simple hazard quotient and probabilistic risk estimates. Each has its uses, and each supports certain decision points for a particular site.

### 4.3.1 Hazard Quotient

The simple hazard quotient is a tool primarily useful in the Tier 1 and some Tier 2 levels of investigation. Simple hazard quotients are point estimates relating presumed exposure concentrations to known or extrapolated effects levels of toxicants. Conceptually, the hazard quotient is represented as:

$$HQ = \frac{EEC}{TEC}$$

where EEC is the expected exposure point concentration and TEC is the appropriate toxicological endpoint concentration. As a basis for risk assessment, separate hazard quotients are calculated for each contaminant/receptor pair. It may be possible to derive hazard indices by combining hazard quotients for different compounds for a single receptor taxon. Such indices are generally constructed by simple addition, and the result is very poorly supported by existing toxicological data. Assessment uncertainty is greatly increased by combining hazard quotients. Where necessary, such combinations should only be made of compounds likely to have similar modes of action. For example, some organochlorine pesticides which each act to suppress brain enzyme activity, or some metals which each act to damage kidney cells might be combined for risk assessment. It would be inappropriate and ineffective to construct a hazard index which combined hazard quotients of, for example, trichloroethane, PCB Arochlor 1248, and arsenic. Each of these compounds has a different mode of action, and their effect in combination is not additive or even directly related, particularly at the chronic dose level usually observed in relation to hazardous sites.

Uncertainties surrounding point estimates arise from extrapolation of the available toxicity data bases and inference regarding exposures. Because the hazard quotient is a point estimate only, the estimate itself must account for uncertainty in application to the field situation. As illustrated in Figure 12, the process of extrapolating toxicity data for point estimates sometimes incorporates divisors which compensate for possible uncertainties but which could lead to inflated and unrealistic hazard estimates. Similarly, inflated exposure assumptions could be employed to compensate for presumed uncertainty. Despite these drawbacks, the quotient method is a useful and appropriate tool for Tier 1 and certain Tier 2 investigations. The risk assessor must, however, be vigilant in deriving realistic, site-specific quotients rather than simply applying generic, overly conservative values[60].

$LD_{50}$ estimates, ambient water quality criteria, and reproductive effects thresholds are examples of single number effect and exposure profiles. The $LD_{50}$ is that level of exposure dose that is lethal to 50% of the population exposed. The ratio, or quotient, of the exposure value to the effect value provides the relative estimate of risk. Under any tier, the quotient method may be employed to estimate the possibility of an adverse effect from single sources[61]. In general, ratios of EEC to TEC greater than 1.0 are considered to indicate a potential risk. Because the quotient method yields only a point estimate, effects probabilities cannot be easily specified. To account for this, safety factors are sometimes considered in interpreting findings. For example, Menzie et al.[20] interpreted HQs between 1 and 10 as having "some small potential" for adverse effects, HQs between 10

and 100 as having "significant potential", and HQs greater than 100 as indicating "expected" adverse effects. However, it is important to note that no statistical analysis supports this interpretation, and indeed none is possible within the context of a single site investigation.

For more quantitative assessment, lower ($F_L$) and upper ($F_U$) safety factor(s) may be included in the basic HQ equation so that if the ratio is less than the lower-bound factor ($EEC/TEC<F_L$), the release is considered potentially "safe". If the quotients exceed some upper-bound factor(s) ($EEC/TEC>F_U$), exposure concentrations are considered "unsafe". Quotients between $F_L$ and $F_U$ indicate uncertainty about safety and imply the need for further assessment. In many cases, such boundary limits cannot be specified, and a single factor (F) is used (i.e., if EEC/TEC<F, the release is considered safe; otherwise, it is not). The quotient is deterministic, in that it establishes a number without an associated variance.

A practical example of a Tier 1 application of the Quotient Method is an evaluation of DDT residues at a Superfund site. Because DDT is known to accumulate in earthworms, and because American robins feed almost exclusively on earthworms in the spring, the robin would be a good population on which to base a bird safety assessment using the Quotient Method. Assume we determined from the literature the DDT 6-month $LC_{50}$ for robins is 5 ppm and a conservative upper allowable exposure level for the site ($F_U$) was established at 50% of the $LC_{50}$. If the mean residue level in earthworms on site was 3.7 ppm, the quotient equation would be EEC (3.7 ppm)/TEC (5 ppm) = 0.74 > $F_U$ (0.5). Therefore, the site contamination level is greater than the acceptable safety criteria. In this case, the decision is made to remediate the site and no further study on the site is required. If, however, there are not adequate data in the literature regarding the TEC, there is tremendous uncertainty about what level of exposure may be considered safe, or there are numerous species for which risk estimation is needed, the Quotient Method may still be applicable but would be elevated to a Tier 2 or 3 effort.

One example of the use of Quotient method in Tier 2 of a RA was conducted by Charters, *et al.*[62] at a PCB and lead contaminated wetland. They evaluated three pathways of exposure and established measurement and assessment endpoints for each. The measurement endpoints were toxicity values or body contaminant burdens; assessment endpoints were population maintenance (continuance of viable populations). Exposure estimates incorporated field and laboratory measurements and information derived from available scientific literature. In keeping with the objectives of a Tier 2 level of effort, risk estimates were focused on sensitive receptors and suggested the need for further

action (quantitative Tier 3 site evaluation and remedial actions).

Another effective application of the simple quotient method in a Tier 2 assessment is described in Boucher[63]. In this case, protective criteria for representative receptor organisms were derived based on extrapolated toxic hazards and site-specific exposure levels. Exposure concentrations were verified with field data, and point estimates were incorporated in a weight-of-evidence evaluation of cleanup alternatives. Some of the uncertainties inherent in the point estimate approach were accounted for by the use of site-specific measurement data on concentrations in environmental media and biotic tissues. Others were accounted for by employing realistic, technically sound estimates for toxicity and exposure parameters.

### 4.3.2 Probabilistic Risk Estimates

Probabilistic risk estimates provide a technically sound basis for evaluating possible contaminant hazards in the "gray zone" beyond heavily contaminated areas and for cases where remedial activities would be costly and highly destructive. Probabilistic approaches allow much more precise quantitation of risks and the nature and location of contaminants driving risks. In general, probabilistic estimates are most useful in Tier 2 and 3 investigations, where the level of site complexity and decision making importance warrant more accurate and precise risk evaluation.

Probabilistic approaches require more investment of resources in the assessment, but provide a substantial return on this investment by more clearly and effectively guiding risk management engineering. Probabilistic risk estimates are based on ranges of input values manipulated mathematically to yield an ecologically realistic picture of potential site related exposure and exposure related effects. Statistical distributions of input data are derived from available scientific information, and risk quantitation is calculated for various combinations of these distributions. Risk quantitation by this approach avoids the highly conservative uncertainty divisors which are often applied to assure the protective nature of risk estimates based on single point estimates. Probabilistic assessment also offers the risk manager objective specification of the level of protection provided by cleanup scenarios which may require understanding of the trade offs inherent in environmental destruction associated with active remediation vs. the benefit of contaminant removal or exposure reduction.

A detailed description of a comprehensive approach to probabilistic risk estimation is provided in Bartell et al.[1]. The fundamental components of a probabilistic assessment are:

- identify contaminants of primary concern;
- develop statistical distributions of concentration-dependent effects of contaminants on representative receptor organisms;
- develop statistical distributions of site-specific exposure of receptor organisms to contaminants;
- combine effects and exposure distributions to yield probabilistic estimates of effect.

Because the distributions account for data-driven uncertainties, elaborate and conservative uncertainty factors are not applied. The distributional nature of the estimates allows the risk assessor to provide the risk manager with clear statements of risk probability. Thus, for example, should risk management objectives include "protecting 95% of species present in a body of water from adverse effects of cadmium", the distributions of exposure and toxicological effect allow the risk assessor to determine, in light of site specific bioaccessibility and bioavailability, realistic and protective concentration objectives.

Analysis of distributions of exposure and effects, rather than using single values, makes probabilistic risk estimates possible. Risk is quantified by an expression of the overlap between the two distributions, with greater overlap indicating greater risk (Figure 16). Figure 16 presents a simplistic view of the overlap between exposure and effect, relating to risk. In reality, exposure varies temporally and spatially. The heuristic model presented in Figure 16 can be expanded in other dimensions (time and space), with an integration of the multi-dimensional curves, to arrive at a more realistic estimate of the risk. We are unaware of such an approach being taken to date. One method which has been applied to multidimensional risk evaluation is fuzzy modeling[64]. Such an approach could be used to fully incorporate spatial and temporal considerations in risk quantitation.

An example of this method, Analysis of Extrapolation Error (AEE), is described in Suter[7]. The AEE approach uses the variability in and relationship between responses of particular species to a range of contaminants to predict effects of unstudied contaminant-receptor pairs. For example, the distribution of effects of varying concentrations of various contaminants may be known for fish species A and B, while the contaminant of interest may only be known for species A. Relative sensitivity to other contaminants predict, with quantifiable uncertainty, the response of species B to the untested contaminant of interest. When data are available to support AEE, the approach has substantial value.

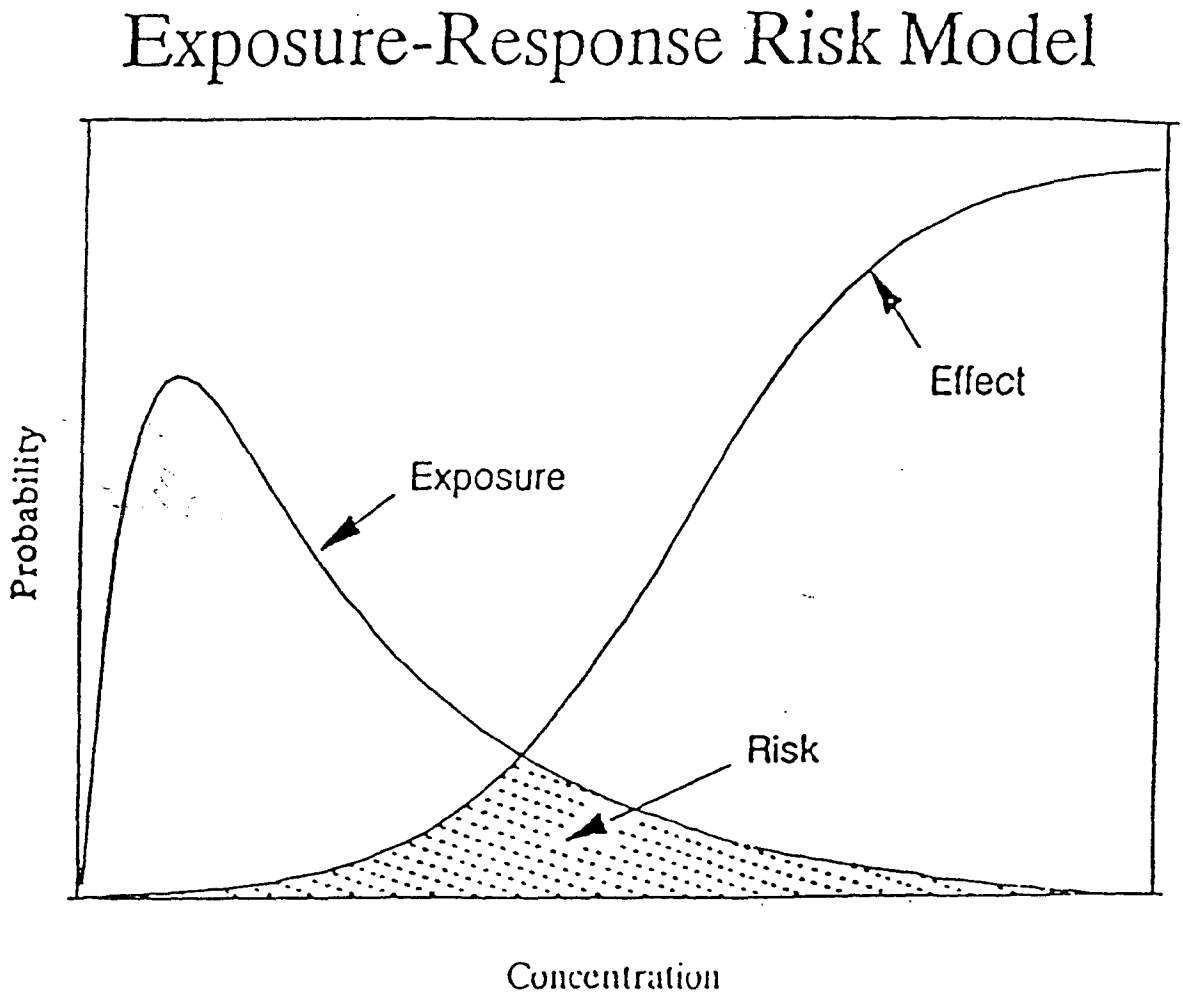



Figure 16. Exposure-Response Risk Model.

As Suter[7] states:

> The main advantage of the AEE method is that it clearly distinguishes, quantifies, and displays both the extrapolations that must be made from the toxicity data and relate it to the assessment endpoints and the uncertainties associated with the process of extrapolation. In contrast, the quotient method with factors treats uncertainties and correlations as equivalent and does not systematically account for either one.

However, AEE only addresses the response component of risk. The exposure component must often be measured or modeled directly in Tier 2 and 3 assessments, accounting as necessary for contaminant bioaccessibility and bioavailability (Section 3).

Probabilistic approaches to risk assessment have been applied for investigations at hazardous waste sites. For example, Cardwell et al.[65] employed effects and exposure distributions to estimate risk probabilities associated with metals contamination of river ecosystems (Figure 17). In this approach it is relatively simple to visualize the proportion of species in the community potentially at risk of chronic or acute contaminant effects. In this case, test species (measurement endpoints) were assumed to represent the balanced, indigenous community in the rivers (assessment endpoints). Because the presentation is essentially a cumulative probability density function (CPDF) of the toxicity data obtained, it is critically important that the assumption of representativeness is realized to the greatest extent possible. If the species and endpoints used in the presentation are not representative of the community potentially at risk, the CPDFs generated will not accurately reflect potential risks in the environment. For example, if the CPDF is constructed from data for *Daphnia* and *Hyalella*, two invertebrate species, but is used as a reference for fish, the results may be far too uncertain to use. The concept of balance is also critically important when using this form of presentation. If the data upon which the CPDF is based are not balanced with respect to numbers and types of test species and endpoints (e.g., 20 *Daphnia* values and only 2 for fathead minnow values), the resulting CPDF will be biased toward the one test species and again, comparisons will be very uncertain. If CPDFs are constructed from data which accurately represent the composition and balance of the community potentially at risk, the technique presented by Cardwell et al.[65] can contribute a valuable additional layer to the presentation of uncertainty.

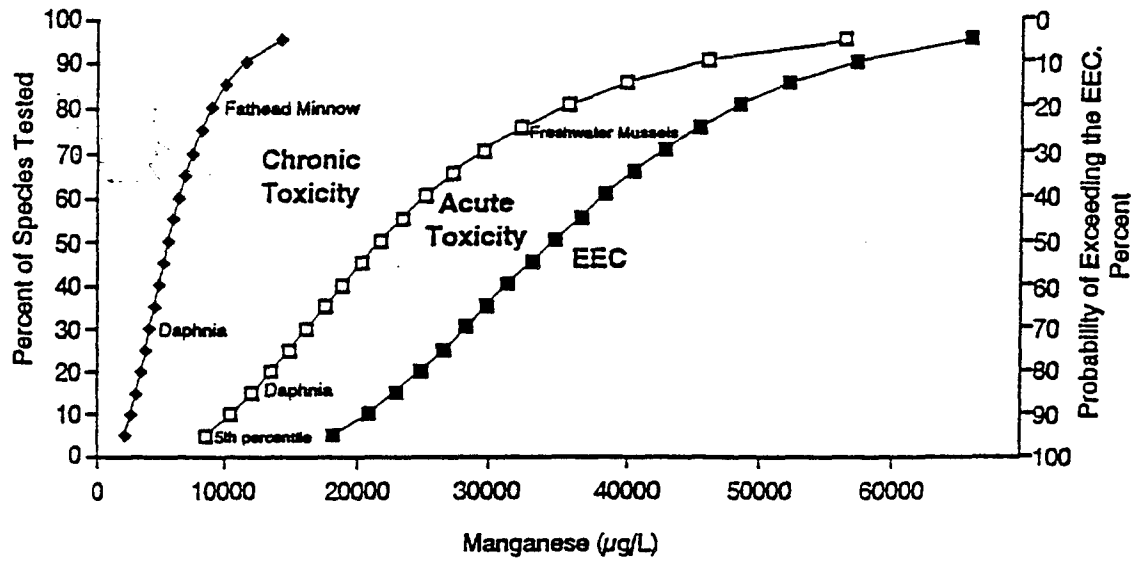



Figure 17. Comparison of Expected Environmental Concentrations of dissolved manganese with concentrations causing acute and chronic toxicity (from Cardwell et al. 1993).

## 4.4 Simulation and Exposure Modeling

Simulation and exposure modeling may be useful in any investigation tier. For Tier 1, simple exposure models incorporating estimated bioaccumulation factors and initial engineering investigation data on the nature and extent of contamination in environmental media can be used to "screen" sites or areas for further investigation. For Tiers 2 and 3, modeling, usually with integral probabilistic components, is often crucial to the overall weight of evidence evaluation.

It is desirable in risk characterization to obtain probabilistic estimates of risk for a species or group of species. Simulation models can provide such estimates by integrating exposure and stressor-response profiles. These profiles may include information on the frequency, timing, and duration of the exposure in addition to the variables which characterize the stressor-response.

There are two basic types of simulation models used in ecological risk assessments: 1) single-species population models and 2) multi-species models. Single species population models are used to predict direct effects on single populations, using measurement endpoints at the individual organism level. Multi-species models include various components of the ecosystem, such as food-web relationships (i.e., predator-prey, competition), plant succession, etc. Multi-species models evaluate both direct and indirect effects. An example of an indirect effect predicted through modeling is the potential for a change in avian behavior that would tip the balance of interspecific competition for nest sites or behavior that reduces some aspect of parental care. The influence such responses may have on population status may be either very obvious or subtle and only substantiated by empirical results or complex models. When the population response is less complex, such as reduced fledgling success in a bird species, it may be advantageous to use simpler, single-species population models to predict the probability of a given response level. When selecting a model, it is important to thoroughly consider the appropriateness of the model for the particular application.

Information needed to develop an estimation of risk may come from field studies, existing literature, or a combination of the two. In some cases risk estimation need not require a full-scale field study conducted over several years or seasons. As stated in the examples under the Analysis phase, above, the risk characterization may proceed using key sentinel species, with known life-history requirements (feeding, reproduction, habitat). Use of such surrogate species, which may be free-ranging wild individuals or individuals introduced to the site, may be far less costly than full-scale field surveys. When naturally occurring individuals or introduced individuals are exposed on the site for a defined time, the body burdens,

biochemical responses, and/or alterations in behavior may be correlated to distributions of the contaminants. Such an assessment would provide the variety of measures (measurement endpoints) and allow estimates of variance within each set. In this manner, site-specific probabilities could be associated with each of the expected adverse effects.

The Rocky Mountain Arsenal Environmental Risk Assessment is used as a case history example in "A Review of Ecological Assessment Case Studies from a Risk Assessment Perspective"[16]. This case study presents an example of a food chain-based model developed to predict effects on animal species on the site. The model is developed and tested using data from Tier 3 level field studies of exposure and effects in sentinel species.

For probabilistic estimates of risk, there are a wide variety of available models useful in any of the tiers (Volume 2, Appendix A). Several models focus on how the environment modifies the contaminant bioavailability (e.g., FGETS model, Volume 2). Modeling approaches presently exist to link water quality to reductions in "dose" under various scenarios of ecosystem productivity[29]. One example of a modeling approach that illustrates how ecosystem trophic status modifies the bioavailability of toxicants and decreases the subsequent dose to biota was performed by McCarthy and Bartell[66]. Their model predicts the association of a contaminant with dissolved organic material (DOM) or particulate organic material (POM), which significantly lessens the bioavailability of a toxicant, and thus, the potential dose experienced by the organisms. Importantly, this paper shows the necessity of estimating the true bioavailability of a contaminant in the environment.

Model projections which include seasonal or habitat variances in bioavailability (e.g., mapped onto expected environmental chemical concentrations for species of known life history, feeding, and habitat requirements) are a cost-effective approach to the hazard characterization of complex chemicals. For a given concentration, species may be subject to exposure for a relatively longer period of their life-span if they are smaller or less likely to move beyond the boundaries of the contaminated area (examples are earthworms, burrowing invertebrates, or small mammals). Further, if a chemical is susceptible to being bound by organics, burrowing (or thigmotactic) benthic invertebrates (or benthos-feeding fish) may be subjected to higher exposures than would otherwise be predicted. Volume 2 includes certain models available for evaluating transport, transformation and fate of contaminants in the environment (e.g., EXAMSII, LPMM). In addition, several models estimate biotic exposure or uptake of contaminants (e.g., FGETS).

Environmental and ecological monitoring data may be evaluated

using a Geographical Information System (GIS) as part of a Tier 3 effort to gain a higher level of understanding of potential contaminant-associated problems and approaches to effective risk management. Coupling modeling and GIS is particularly effective when geographic distributions of contaminants and the integration of these contaminants and wildlife activities on the study site are important parts of the risk analysis and characterization. For example, animal home-range analyses can be incorporated to GIS software and home-range use can be correlated with geographic distributions of contaminants to estimate potential for exposure. From this information, risk management alternatives can be evaluated on a "what if" basis by having remediation engineers identify contaminant parcels most amenable to control. The risk assessment benefit of such projected risk management efforts can then be evaluated directly through the GIS. Such an approach is being explored for remediation at Rocky Mountain Arsenal[67]. In this case, the site-wide risk reduction associated with local "hotspot" removal is clearly demonstrated by linking exposure models to GIS for immediate evaluation of the benefits of various remediation scenarios. This is illustrated in Figure 18 which contains "risk surfaces" for burrowing owls exposed to dieldrin via diet at Rocky Mountain Arsenal. The upper surface is prior to remediation and clearly shows the dieldrin "hot spot" (HQ=434). The bottom surface is a post-remediation projection with no HQ greater than 1.0.

Using GIS in the risk assessment process is also a highly effective way to produce graphics and visual aids to demonstrate and explain (to military and regulatory personnel, and to the public) the critical environmental relationships that influence ecological risk.

### 4.5 Uncertainty Analysis

Risk estimation infers a degree of uncertainty. The estimation is derived from comparison of organism exposure to organism response to the stressor(s) under investigation. The stressor-response profiles used in this process may involve a single value response such as an $LD_{50}$, or a suite of responses such as immune system function responses combined with contaminant blood levels. The degree of uncertainty around the estimate is related to the precision of the stressor-response profiles used. When the response evaluated is death, or death of 50% of the population ($LD_{50}$), the uncertainty of an adverse effect will be greater than if the response level of concern is a measured level of sublethal immune system response. The more conservative response variables are more likely to err on the safety side of the equation, and result in lower uncertainty of the negative effects under consideration. Within each tier, there will be assumptions and uncertainties involved in characterizing the ecological risk. By the very nature of the lower effort and cost at the lower tiers,

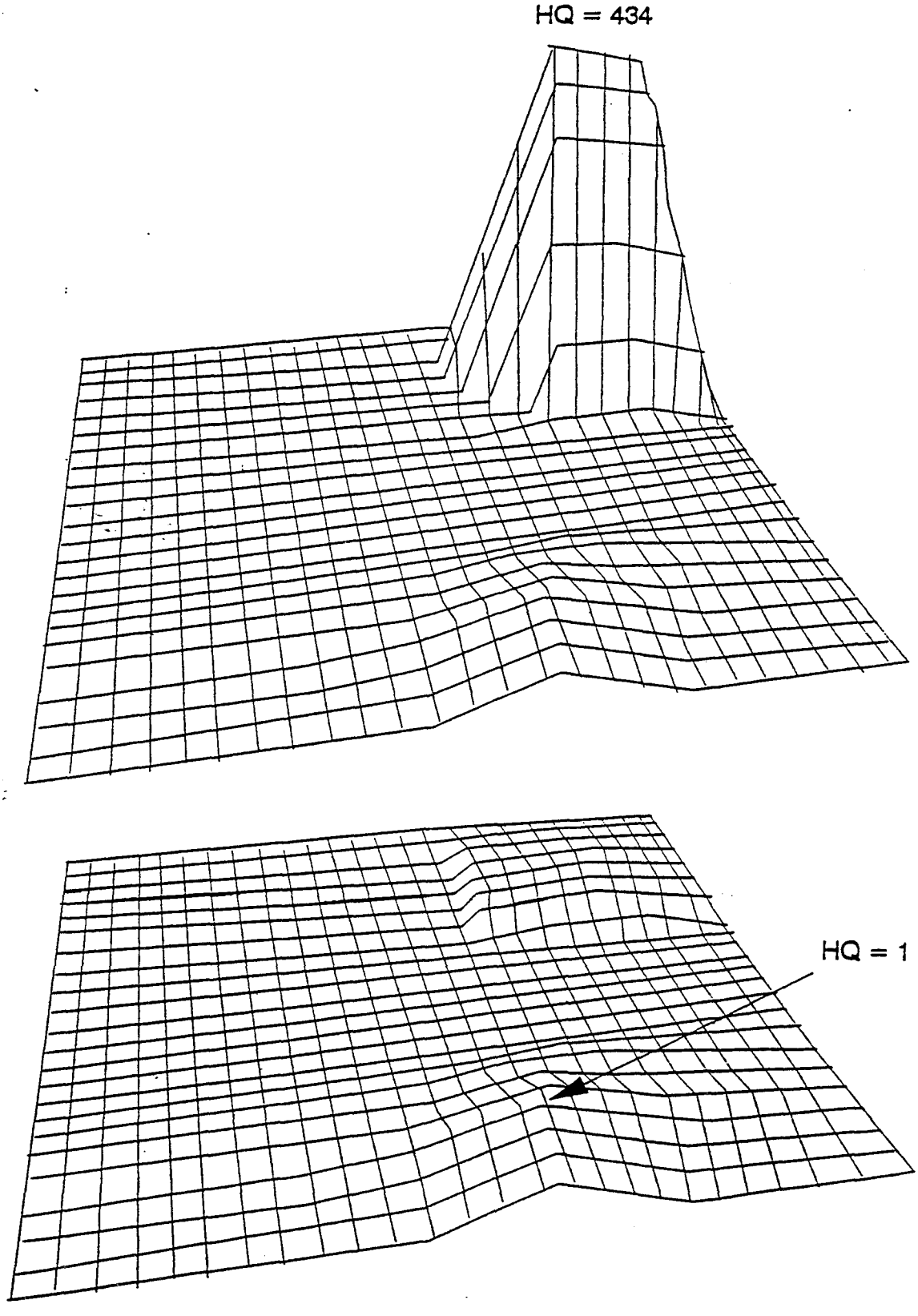



Figure 18. GIS-based "risk surfaces" for dieldrin at Rocky Mountain Arsenal.

risk characterization will have larger uncertainties. The benefit of more focused effort in the higher tiers becomes primarily one of incorporating more site-specific information, thus reducing the need for simplifying assumptions, and therefore reducing the level of associated uncertainty.

Uncertainty analysis is thus an important part of the Risk Characterization phase and occurs as a function of questions and variances from all phases of an ERA. The objective of uncertainty analysis is to identify and quantify, to the highest degree possible, the cumulative uncertainty surrounding the estimates of risk. Products of the uncertainty analysis are an evaluation of the effects of uncertainties on the overall assessment and on the risk management process. For example, if risk assessment uncertainty is high, and conservative assumptions were used to suggest a major cleanup effort, additional investigation to reduce uncertainly might be warranted. However, if conservative or realistic risk estimates yield an objective, credible risk management program, the level of uncertainty is clearly appropriate to the assessment goals.

Sources and effects of uncertainty overlap throughout the risk assessment. The reader can find in-depth discussions of the subject in the references listed in the Risk Assessment Framework[68,69,70]. Some major sources of uncertainty include:

1) formulation of the conceptual model: are the correct working hypotheses established?

2) incomplete information and data: if the correct data are not collected, little can be said of the exposure or response.

3) natural variability: variance in spatial, temporal distributions of the COC, biotic and abiotic stressors, and population at risk.

4) procedural or design error: unless data quality assurance plan is formulated, it is likely that errors and greater uncertainty will increase from incorrect or inappropriate analyses.

### 4.5.1 Conceptual Model Formulation

Flaws in the conceptual model may be the most pervasive source of uncertainty, and the most difficult to identify, quantify or reduce. The conceptual model, which is the product of the problem formulation phase, provides the basis for the analysis phase and the development of the exposure and stressor-response profiles. If incorrect assumptions are made during the

conceptual model development regarding the potential effects of a stressor, the influence of environmental variables, the interaction of wildlife species with the stressor, or the sensitivity of organisms to the stressor, the final risk assessment will be flawed. Once the conceptual model is correctly developed during the course of the ERA, care should be taken not to incorporate factors that erroneously increase uncertainty, lead to incorrect conclusions, or limit management decisions. Awareness and avoidance of factors that unduly increase uncertainty are critical at all phases of the assessment.

### 4.5.2 Incomplete Information and Data

The risk assessor will invariably encounter situations where information or data are incomplete. In some cases the assessment may be halted until further information is obtained or further study completed to fill in data gaps. However, there will be cases when the resources, technology, or fundamental ecological knowledge needed to close such gaps are not available. In these cases, the risk assessor must rely on professional judgement and cautious use of assumptions. When judgement and assumptions are inserted into the assessment, they must be clearly identified as such throughout the various phases of the assessment, and thoroughly explained and evaluated during the Risk Characterization phase.

### 4.5.3 Natural Variability

Natural variability (stochasticity) is an ever-present condition that influences the distribution, availability and influence of stressors in the environment. It equally biases our perception and interpretation of these factors. Variability inherent in the physical environment (moisture, nutrients, organic material, temperature, etc.) causes variability in biological components of the environment (animal health, size, sensitivity, exposure level, etc.). Although the uncertainty caused by variability may be complex, it can be acknowledged and described, but not reduced[70]. When sufficient databases exist, stochasticity can be quantitatively estimated and analyzed via such methods as Monte Carlo simulation and statistical uncertainty analyses[71,72].

### 4.5.4 Procedural and Design Error

Errors in measurement and sampling can be reduced through adherence to a good quality control program or Good Laboratory Practices Guidelines. Raw data review and data entry verification procedures are invaluable in reducing the introduction of human errors. Errors in study design are best avoided by assuring a strong peer review of protocols. Errors and uncertainty in the development of simulation models can be

addressed through sensitivity analysis and field verification or model validation.

## 4.6 Risk Description: Ecological Risk Summary and Interpretation of the Significance.

The EPA Framework[4] describes two elements of ecological risk description: 1) a summary of the risk estimation results to describe the confidence level in the risk estimates; and 2) interpretation of ecological significance, identified in the Framework Document as the magnitude of the risks relative to the assessment endpoints. This approach has been carried into the Review Draft Superfund Guidance[3] as a weight-of-evidence foundation for ecological risk assessment. A weight-of-evidence approach incorporates the judgement of how variable are estimates of contaminant distribution, exposure and biotic uptake potential, and the probability of adverse effects of residual contamination and possible remedial activities.

### 4.6.1 Ecological Risk Summary

The ecological risk summary succinctly reports results of the risk estimation phase and discusses the uncertainty of previous phases of the assessment. This involves an overview of measured endpoints (or estimates) of exposure and response at the individual or population level, bioaccumulation potential, integration of single or distributional exposure and stressor-response profiles, and/or model predictions. This overview must also include a discussion of the uncertainty inherent in each phase of the assessment. Whenever possible, the conclusion of the risk estimation should be expressed as a quantitative expression (there is a 30% probability of 25% mortality in American robins). Another example consists of a study on the effects of molybdenum mine tailings on marine fish and invertebrates[16]. The scientists calculated the risk to aquatic organisms by developing a probability of exceeding a water quality criterion level for copper (over a 55 year period) and -conservatively- assuming 100% mortality if organisms were exposed to concentrations higher than the criterion. Hence, the probability of greater-than-criterion levels for copper in water and sediments becomes the probability of effect. The conservatism of this approach could be made less, with greater accuracy, if more data were collected from the field or laboratory exposures were developed using native organisms. However, the example does provide a case where the effects are cast in probabilistic terms.

However, ecological risk assessments completed to date usually express the risk estimation in qualitative format with terms such as "high likelihood", "moderate", "low likelihood" of a given negative impact (e.g., avian mortality). Uncertainty also will

be expressed in quantitative or qualitative terms. In the discussion of uncertainty, it is important to include evaluation of the relative contributions of the uncertainties from different aspects of the assessment to the final estimate of risk.

### 4.6.2 Weight of Evidence and Ecological Significance

Weight of evidence for projecting risks and impacts is a conceptual approach which dictates that all sources of information be considered in making risk management decisions. Because the weight of evidence links the risk assessment to the risk management process, it is imperative that the risk assessor provide clear characterization of uncertainty in each component of the weight of evidence and the meaning of each component for ecological impacts.

The evaluation of the ecological significance of risk is a process at the very edge of the capability of ecological science. Biological populations are very dynamic and population measures and models are relatively simple compared to the underlying ecological complexity. Yet it is at the population level that ecological significance must be evaluated (except for endangered or threatened species, which are often evaluated at the individual level). Suter[7] provides an example of an approach to quantifying population level effects of toxicological risks. Yet this exercise cannot be validated, and is only tested by additional modeling[73].

An instructive example of the difficulty of projecting the significance of risk estimates is provided in Barnthouse et al.[74]. While this paper discusses the impacts and importance of power plant withdrawals on finfish communities, the principles developed apply to contaminated site assessments. Barnthouse et al. evaluated more than ten year's worth of effort to extrapolate the effects of cooling water withdrawal on fish populations in the Hudson River. Such withdrawals are inevitably associated with the loss of individuals. At issue was the relative ecological importance of such losses. In practice, despite highly certain estimates of the loss rates, estimates of importance at the population and ecosystem levels were so uncertain as to be useless.

Whenever possible, the assessment should clearly distinguish between impacts to individuals, or even portions of populations, and those impacts that affect whole populations. For example, Hinckley and Porter[75] demonstrated at a midwestern NPL site some individual impacts to white-footed mice from lead. However, impacts to the population as a whole were minimal. In contrast, although many fewer red-tailed hawks were impacted, a much greater proportion of their population was involved.

Thus, the current state of ecological science is not conducive to elucidating "ecological significance" of estimated risks. The most productive approach for most sites, in keeping with the conclusions of Barnthouse et al.[74], is to document for risk managers the potential impacts of contamination and remediation and make site specific decisions on risk reduction. It may be appropriate at large, complex sites to undertake attempts to quantify ecological significance as a component of Tier 3 evaluation, but such efforts should be tempered by sound risk management judgement.

Weight of evidence in an ERA is supported by the quality and sufficiency of data. Quality assurance programs are paramount in any ERA and provide confidence in precision, reproducibility, etc. Sufficiency of the data is addressed relative to the effort involved. Tier 1 information provides primarily corroborative information, such as lists of known chemicals (and, hence, toxicity and physico-chemical characteristics), suspected distribution on the site, and limited data on direct measures of exposure and effects. Models applied at this tier may require several default assumptions for parameters.

In Tiers 2 and 3, the information on exposure and ecological effects provide a higher degree of correlation between the stressor and consequent effects. For example, a better resolution of contaminant effects of metals in a wetland on waterfowl may be obtained for migratory avian species when the timing and distribution of the migratory species is matched to times when their food base (burrowing insects) lead to exposure to the contaminant. To discern how much of the exposure stems from on-site, relative to exposure elsewhere takes time and effort not available under Tier 1. Ultimately, to reduce uncertainty in analyses, one must understand the situation in greater detail. Hence, it may be necessary to conduct follow-on studies to corroborate initial judgement calls.

When a population responds to a contaminant, its response may range from biochemical or physiological responses at the cellular level to behavioral changes or (ultimately) death and the reduction of population numbers. The significance of the responses need to be addressed in an ERA relative to the ecological context. Organismal responses (physiological, behavioral) may be transient enough, relative to the exposure duration or life history characteristics of the species, that they have little or no influence on the assessment endpoint. However, it may be that such "lower level" responses provide sufficient questions as to sub-lethal effects that another problem formulation may be called for. As an example, such a situation might exist within a site with multiple contaminant point sources, such as certain hazardous waste sites with a history of uncontrolled dumping of multiple, complex wastes. The

tiered assessment may focus on chemicals known to have been dumped at the site; however, some animals may be exposed to an unknown or unrecognized source. Biomarkers of exposure (cf., cytochrome P450 induction, porphyrin profiles; Volume 2, Appendix B) would indicate that exposure has occurred and that the potential for adverse affects on the population may warrant further investigation of the nature and extent of risk.

The interpretation of ecological effects also needs to take into account the spatial and temporal nature of the stressor and population exposed. Risk stemming from a wide area of diffuse contamination will be more difficult to summarize than areas with defined "hot spots" of contamination. Further, if the area and duration of exposure are long enough relative to the generation time of the species, then one may expect sublethal toxicity be expressed. For certain species, a small area of contamination may lead to local population extermination if the stress is high. This might occur if a species requires a very specific habitat (e.g., wood ducks in wetlands). Should the habitat be altered even a little, the effect on the species could be catastrophic.

In addition to local, catastrophic effects, stressor responses identified throughout the risk assessment process may have ecological significance of a broader, more diffuse nature. For example, it may be determined that the response of nestling birds to a contaminant consumed in their food is 25% mortality. However, a follow-on evaluation of nestling fledgling rates and post-fledgling survival indicates there is an increase in overall fledgling and survival. For these results, the explanation is that nestling survival is density-dependent and the loss of an average of one nestling per nest resulted in more parental attention and more food for the remaining nestlings. Thus remaining nestlings were of greater body weight at fledgling and this equated to greater overall post-fledgling survival compared to non-dosed nestlings. In a case such as this, we may conclude that while there was a significant effect to individuals, the effect on population was positive, not negative. Therefore, there was little or no ecological significance.

The interpretation of ecological significance places risk estimates in the context of the types and extent of anticipated effects. Interpretation of these factors relies heavily on professional judgement. The significance of effects may be evaluated in context of several variables:

1) the nature and magnitude of effects,
2) the spatial and temporal patterns of effects,
3) the duration of effects, and
4) the potential for the system or species to recover from the effects.

All the above factors help to place expected risks into broader

ecological perspectives. Interpretation of significance may take into consideration other ecological components not specifically addressed in the risk assessment. For example, the risk assessment may have addressed reduction in a population of breeding voles (a species of small mouse-like mammals) thought to be due to a stressor. The reduction in vole numbers may not be discernable following the reproductive season, when autumn vole populations are no different on the impact site than on reference sites. The significance of the toxic effect to the vole population may prove to be small. However, as part of the interpretation of the significance of the spring decline in adult voles, the risk manager may make the connection with a separate report that northern harrier production in the area has declined and question whether this is related to the decreased availability of voles, the harrier's staple diet.

A final strength of the tiered approach to risk assessment is related to resolving the question "how does one go about measuring when clean is clean enough?" The tiered approach provides some guidance: for example, if surrogate organisms are used as part of a Tier 3 evaluation of exposure (i.e., nest boxes), this assessment process could be left intact, or repeated, as an on-site biomonitoring assessment following mitigation. If mitigation truly reduced bioavailability, the exposure in the surrogate species should measurably decline. If biochemical markers of exposure indicate no exposure, then the contaminant (even if at detectable levels in soil) is not being taken up by the organisms. Hence, a measure of the success of clean up efforts becomes available.

The summary decisions and projections of risk within the Risk Description phase concludes the risk assessment process and provides the basis for communication between the risk assessor and the risk manager, ultimately responsible for making the appropriate regulatory decisions.

## 4.7 Risk Management

Environmental cleanup actions have technical and social foundations. At many sites, various stakeholders and stakeholder groups have divergent interests and concerns. Remedial activities are truly effective when stakeholder interests are satisfied. For example, the site assessment team might agree that low, but elevated, concentrations of a particular contaminant could remain in place without adverse effects. Owners of adjacent properties, concerned about real estate values, might be more concerned about *de minimis* residual contamination. Or the risk management team might determine that destructive remediation of a wetland is warranted by contaminant levels, while local recreational boaters might desire simple monitoring.

Clearly, there is a trade off in risk management, between destructive remediation (all currently available technologies destroy the habitat in place) and residual contamination. While it is desirable to make decisions on a "risk averse" basis, it is not always clear what is "riskier": site remediation or site contamination. Risk assessment uncertainty (described below) plays a crucial role in this decision threshold, because the risk of remedy associated with site cleanup is highly certain, and must be balanced against the weight of evidence for contaminant-related risks.

The trade off between risks due to existing contaminants and those due to remediation was illustrated at a midwestern site by Hinckley and Porter[75]. These authors demonstrated that removal of lead from a wetland entailed its destruction, while only providing minimal reduction in hazard quotients for mice and raptors.

Once the decision has been made to undertake site cleanup, the nature and extent of remedial activities must be determined. With the exception of highly contaminated "hotspots", these definitions are best supported by Tier 2 and 3 evaluations with decision criteria developed in advance.

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