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ECOLOGICAL RISK ASSESSMENT GUIDANCE FOR SUPERFUND:

PROCESS FOR DESIGNING AND CONDUCTING ECOLOGICAL RISK ASSESSMENTS

U.S. Environmental Protection Agency
Environmental Response Team
Edison, NJ

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Ecological Risk

9629

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Environmental Protection Agency (EPA). 1992. *Framework for Ecological Risk Assessment*. Washington, DC: Risk Assessment Forum: EPA/630/R-92/001.

APPENDIX D: REPRESENTATIVE SAMPLING GUIDANCE DOCUMENT, VOLUME 3: ECOLOGICAL

Environmental Protection Agency (EPA). 1994. *Representative Sampling Guidance Document, Volume 3: Ecological*. Washington, DC: Office of Emergency and Remedial Response.

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PREFACE

This document is a Program-specific process guidance document, which was produced to promote consistent and technically defensible ecological risk assessments within the Superfund Program. It is based upon the *Framework for Ecological Risk Assessment* developed by **EPA's Risk Assessment Forum**. This document describes a process for **designing and conducting** technically defensible ecological risk assessments **within Superfund**.

It is not the intent of this document to determine the appropriate scale or complexity of an ecological risk assessment 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. Professional judgement is essential in designing and determining the data needs for any ecological risk assessment. However, when the process outlined in this document is followed, a technically defensible, appropriately scaled, and site-specific ecological risk assessment should result.

This document is directed to the site managers (i.e., On-Scene Coordinators [OSCs] and Remedial Project Managers [RPMs]) who are legally responsible for the management of the site. However, it is anticipated that the ecological risk assessors, as well as all other individuals with input to the ecological risk assessment, will use this document.

Ecological risk assessment is an interdisciplinary field drawing upon environmental toxicology, ecology, and environmental chemistry, as well as other areas of science and mathematics. It is important that users of this document understand that ecological risk assessment is a complex and non-linear process **with many parallel activities**. The user should read through the document in its entirety, as well as have a basic understanding of ecotoxicology and ecological risk assessment, prior to evaluating the details of the ecological risk assessment process. Without this basic understanding, the reader might not recognize the relationships among different components of the risk assessment process.

To assist the user **in interpreting this guidance document**, three site illustrations are provided **in Appendix A**. These are simplified site examples which demonstrate and highlight specific points in the ecological risk assessment process. These illustrations are incomplete and not intended to present a thorough discussion of the ecological or ecotoxicological issues that would exist at an actual site. **Instead, they are intended to illustrate the five steps of the process that precede a full ecological field investigation. Excerpts from the three illustrations are included in the guidance document as "Example Boxes" to illustrate specific points.** The user is encouraged to read the **three** illustrations in Appendix A in addition to the **Example Boxes** within the guidance document itself.

Ecological risk assessment is a dynamic field, and this document represents a process framework into which changes in ecological risk assessment approaches can readily be incorporated. Four appendices are included with this document; additional appendices may be developed for this document to address specific issues.

This document supersedes EPA's (1989b) *Risk Assessment Guidance for Superfund, Volume 2: Environmental Evaluation Manual* as guidance on how to design and conduct an ecological risk assessment in the Superfund Program. The *Environmental Evaluation Manual*, however, does contain useful information on the statutory and regulatory basis of ecological assessment, basic ecological concepts, and other background information that is not repeated in this document.

INTRODUCTION: ECOLOGICAL RISK ASSESSMENT FOR SUPERFUND

This document is a Program-specific process guidance document, which was produced to promote consistent and technically defensible ecological risk assessments within the Superfund Program. It is based upon the ***Framework for Ecological Risk Assessment*** developed by **EPA's Risk Assessment** Forum. This document provides a process for **designing and conducting** technically defensible ecological risk assessments **within Superfund**.

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This document is directed to the site managers (i.e., OSCs and RPMs) who are legally responsible for the management of the site. However, it is anticipated that the ecological risk assessors, as well as all other individuals with input to the ecological risk assessment, will use this document.

The Comprehensive Environmental Response, Compensation and Liability Act of 1980 (CERCLA), as amended by the Superfund Amendments and Reauthorization Act of 1986 (SARA), **authorizes** the United States Environmental Protection Agency (EPA or the Agency) to protect **public health and welfare and** the environment from the release or potential release of **any hazardous substance, pollutant, or** contaminant. The National Oil and Hazardous Substances Pollution Contingency Plan (NCP) calls for the identification and mitigation of the environmental **impacts (such as toxicity, bioaccumulation, death, reproductive impairment, growth impairment, and loss of critical habitat) of hazardous waste sites,** and for the selection of remedial actions to **protect organisms, populations, communities, and ecosystems.** In addition, numerous **other** Federal and State laws and regulations concerning environmental protection are potentially Applicable or Relevant and Appropriate Requirements (ARARs). Compliance with these laws and regulations requires an evaluation of site-related ecological effects and the measures necessary to mitigate these effects.

In response to CERCLA, the Superfund Program established **the remedial investigation and feasibility study (RI/FS)** process (see Figure 1) [to be developed].[1] The RI/FS process characterizes the nature and extent **of contamination and the resulting** risks posed by hazardous waste site. **The RI/FRS also develops and evaluates**

[1] A graphic is being developed that will show the relationship of the process described in this document to the larger Superfund process.

remedial options. Because the RI/FS is an analytical process designed to support risk management decision-making for Superfund sites, risk assessment is an integral part of the RI/FS.

HIGHLIGHT BOX 1
The RI/FS Process

Risk assessment is an integral part of the Remedial Investigation and Feasibility Study (RI/FS). The three parts of the RI are: (1) characterization of the nature and extent of contamination; (2) ecological risk assessment; and (3) human health risk assessment. The investigation of the nature and extent of contamination determines the chemicals present on site, as well as the distribution and concentrations of the chemicals. The ecological risk and human health risk assessments determine the potential for adverse effects to the environment and human health, respectively.

Purpose and Context of This Guidance Document

The purpose of this guidance document is to describe an acceptable process for designing and conducting ecological risk assessments under the Superfund Program. EPA has established guidelines for human health risk assessment for the Superfund program (U.S. EPA, 1989a, 1991a,b); however, widely applicable protocols for formal, site-specific ecological risk assessment do not exist in Superfund or Agency-wide. *Risk Assessment Guidance for Superfund, Volume 2: Environmental Evaluation Manual* (U.S. EPA, 1989b) provided conceptual guidance in planning studies to evaluate a site's "environmental resources," where "environmental resources" is largely synonymous with "ecological resources." EPA also is publishing supplemental information on specific topics in ecological risk assessment for Superfund in the ECO Update series (U.S. EPA, 1992b,c, 1991c,d). However, these documents do not describe an overall, step-by-step process by which an ecological risk assessment is designed and executed. Recently, EPA's Risk Assessment Forum established an Agency-wide *Framework for Ecological Risk Assessment* (U.S. EPA, 1992a). The *Framework* provides a basic structure and a consistent approach for conducting and evaluating ecological risk assessments independent of specific EPA programs. This guidance document describes an accepted process for conducting an ecological risk assessment within the Superfund Program that is consistent with the general EPA *Framework*. While the Agency's *Framework* has no regulatory role, the concepts are appropriate to Superfund and have been incorporated with minimal modification. The definitions used in this document (and listed in the Glossary) are consistent with the definitions in the EPA *Framework* document.

Definition of Ecological Risk Assessment

Ecological risk assessment is defined in the *Framework* as a process that evaluates the likelihood that adverse ecological effects are occurring or may occur as a result of exposure to one or more stressors (U.S. EPA, 1992a). As defined by EPA (1992a), a stressor is any physical, chemical, or biological entity that can induce an adverse ecological response. Adverse responses can range from sublethal chronic effects in an

individual organism to a loss of ecosystem function. Although stressors can be biological (e.g., introduced species), only chemical or physical stressors will be addressed in this document, as these are the stressors likely to be encountered on Superfund sites.

The phrase "ecological risk assessment," as used specifically for the Superfund Program in this document, refers to a qualitative and/or quantitative 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 a sufficient intensity to elicit the identified adverse effect.

Framework for Ecological Risk Assessment

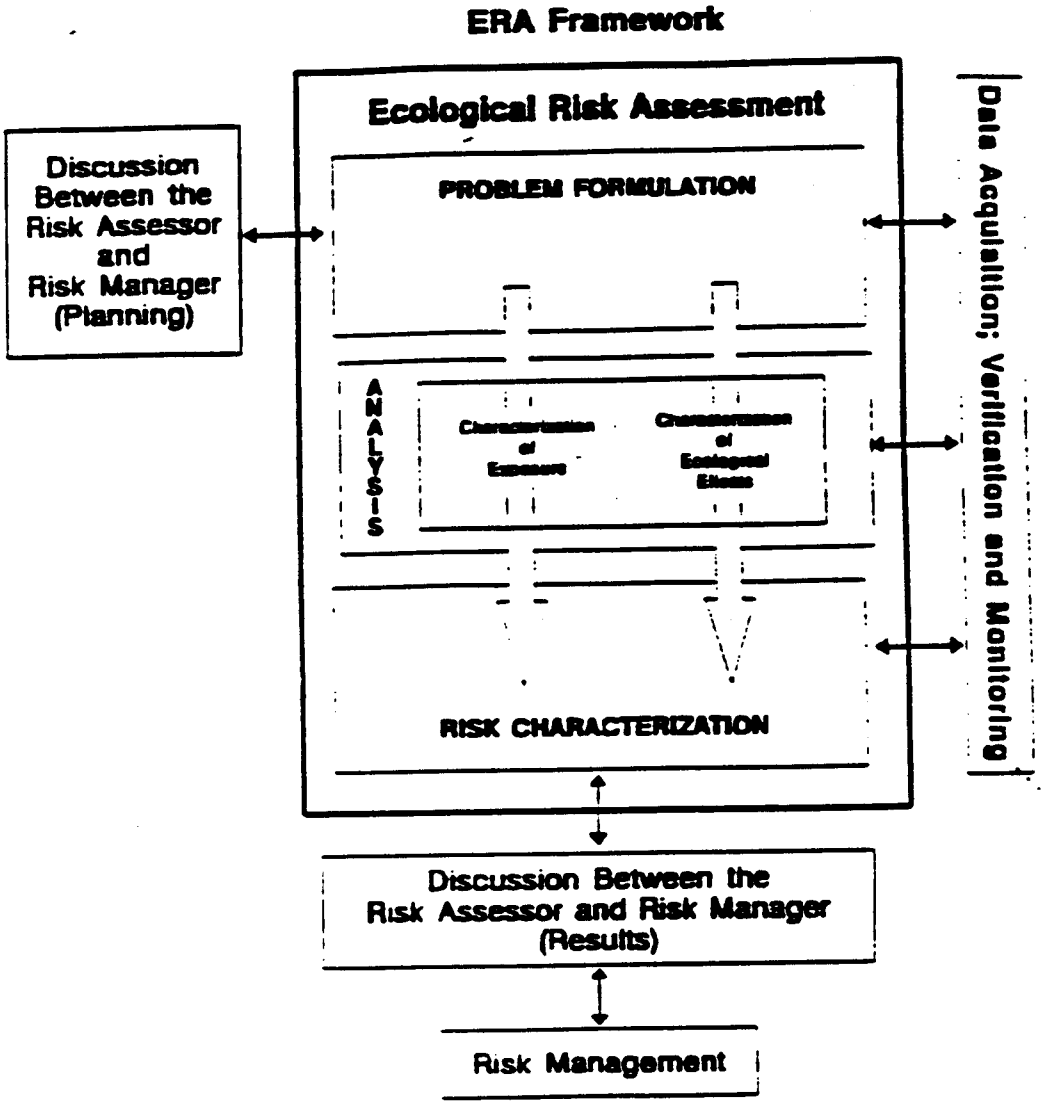
The *Framework* describes the basic elements of a process for scientifically evaluating the adverse effects of stressors on the environment. The document describes the basic structure and principles to be used in ecological risk assessments conducted for EPA, provides operational definitions for terms used in ecological risk assessments, and outlines basic principles around which Program-specific guidelines for ecological risk assessment should be organized.

The *Framework* is similar to the National Research Council (NRC) paradigm for human health risk assessments (NRC, 1983) and the more recent NRC ecological risk paradigm (NRC, 1993). The 1983 NRC paradigm consists of four fundamental phases: hazard identification, dose-response assessment, exposure assessment, and risk characterization. The *Framework* differs from the NRC paradigm in a few ways:

- Problem formulation is added to the beginning of the process to determine the scope of the assessment;
- Hazard identification and dose-response assessment are combined in an ecological effects assessment phase; and
- The phrase "dose-response" is replaced by "stressor-response" to emphasize the possibility that physical changes (which are not usually measured in "doses") can stress ecosystems as well as chemical contamination.

Moreover, the *Framework* emphasizes the parallel nature of the ecological effects and exposure assessments by joining the two assessments in an analysis phase between problem formulation and risk characterization, as shown in Figure 2.

Figure 2


ERA Framework
Ecological Risk Assessment
Discussion Between the Risk Assessor and Risk Manager (Planning)
PROBLEM FORMULATION
ANALYSIS
RISK CHARACTERIZATION
Data Acquisition; Verification and Monitoring
Discussion Between the Risk Assessor and Risk Manager (Results)
Risk Management

During problem formulation, the risk assessor establishes the goals, breadth, and focus of the assessment (U.S. EPA, 1992a). As indicated in EPA's *Framework*, it is a systematic planning step that identifies the major factors to be considered. Problem formulation includes a discussion between the lead risk assessor and lead risk manager, and identifies the stressor characteristics, ecosystems potentially at risk, and ecological effects to be evaluated. During problem formulation, assessment and measurement endpoints are identified:

> *Assessment endpoints are explicit expressions of the actual environmental values that are to be protected. Measurement endpoints are measurable responses to a stressor that are related to the valued characteristics chosen as the assessment endpoints (Suter, 1990)* (U.S. EPA, 1992a).

Assessment endpoints are the focus of the risk characterization: they link the measurement endpoints to the risk management process (e.g., policy goals). The outcome of problem formulation is a conceptual model that describes how a given stressor might affect ecological components of the environment. The conceptual model also describes the relationships among the assessment and measurement endpoints, the data required, and the methodologies that will be used to analyze the data (U.S. EPA, 1992a). (For a full description of these concepts, consult the *Framework*, which is included as Appendix C.)

Ecological Risk Assessments for Superfund

In the Superfund Program, substances designated as hazardous under CERCLA (see 40 CFR 302.4) usually are the stressors of concern. The goal of the Superfund ecological risk assessment process is to provide risk information necessary to assist risk managers at Superfund sites (i.e., On-Scene Coordinators [OSCs] and Remedial Project Managers [RPMs]) in making informed decisions. The specific objectives of the process, as stated in OSWER Directive 9285.7-17, are: (1) to identify and characterize the current and potential threats to the environment from a hazardous substance release; and (2) to establish clean-up levels that will protect those natural resources at risk.

Issues such as restoration, mitigation, and replacement are important to the Program, but are reserved for investigations that may or may not be included in the RI phase. During the management decision process of selecting the preferred remedial option leading to the Record of Decision (ROD), issues of mitigation and restoration should be addressed, although they are not necessarily issues within the baseline ecological risk assessment. However, in selecting a remedy, consideration should be given to how various remedial alternatives will reduce risk and thereby also reduce the need for restoration or mitigation.

A natural resource damage assessment (NRDA) may be conducted at any Superfund site at the discretion of the Natural Resource Trustees. An ecological risk assessment is a necessary step for an NRDA, because it establishes the causal link between site contaminants and specific adverse ecological effects necessary for an NRDA.

HIGHLIGHT BOX 2
Ecological Impact and Risk Assessment

The ecological risk assessment within the Superfund Program may take several forms. It may be a risk evaluation (potentially predictive), impact evaluation, or a combination of these approaches. In this respect, a Superfund ecological risk assessment often is more truly a field ecological epidemiological investigation than a true risk assessment. The functions of the ecological risk assessment are to:

(1) document whether actual or potential ecological risk exists at a site;

(2) screen the contaminants present at a site for those that might pose an ecological risk, thereby focusing further efforts; and

(3) generate data to be used in evaluating clean-up options.

Ecological risk assessments can have their greatest influence on site management in the evaluation and selection of site remedies. The ecological risk assessment should generate target clean-up goals, provide a "yard stick" for the evaluation of the effectiveness of remedy options, and have other uses in risk management.

To justify a site action based upon ecological concerns, the ecological risk assessment must establish that an actual or potential ecological threat exists at a site. The potential for (i.e., risk of) impacts can be the threat of impacts from a future release or redistribution of contaminants, which could be avoided by taking actions on "hot spots" or source areas. "Risk" also can be viewed as the likelihood that current impacts are occurring, although they are difficult to demonstrate (e.g., diminished population size). For example, it may not be practical or technically possible to document existing ecological impacts, either due to limited technique resolution, the localized nature of the actual impact, or limitations resulting from the biological or ecological constraints of the field measurements (i.e., measurement endpoints, exposure point evaluation). Actually demonstrating existing impacts confirms that a "risk" exists. Evaluating a gradient of existing impacts along a gradient of contamination can provide an stressor-response assessment that helps to identify clean-up levels.

As noted above, the ecological risk assessment should provide the information needed to make risk management decisions (i.e., to select the appropriate site remedy). The ecological risk assessment, however, should not be used to justify a particular management option.

It also can provide information on what residual risks may exist assuming different remediation options. However, the ecological risk assessment does not constitute a complete NRDA. The portion of the NRDA beyond the risk assessment is the sole responsibility of the Natural Resource Trustees, not of EPA; therefore, natural resource damage assessment will not be addressed in this guidance. **For additional information**

on the role of Natural Resource Trustees in the Superfund process. see *ECO Update Volume 1, Number 3* (U.S. EPA 1992c).

This ecological risk assessment guidance for Superfund is composed of eight steps (see Figures 3 and 4) and several scientific/management decision points (SMDPs). An SMDP requires a meeting between primary risk managers and risk assessors to evaluate and approve or redirect the work up to that point. The group decides whether or not the risk assessment is proceeding in a direction that is acceptable to the risk assessor and the managers. The SMDPs include a discussion of the uncertainty associated with the risk assessment, which can be reduced, if necessary, with increased effort. SMDPs are significant communication points which should be passed with the consensus of all involved parties. This approach is intended to minimize costs and speed up the Superfund risk assessment process.

This guidance does not provide the only technically valid approach for ecological risk assessments at hazardous waste sites. The discipline of ecological risk assessment is dynamic and continually evolving; the assessments rely on data that are complex and sometimes ambiguous. However, if an approach other than the one described in this document is used, there must be clear documentation of the process, including process design and interpretation of the results, to ensure an equivalent and technically defensible assessment. Clear documentation, consistency, and objectivity in assessment processes are necessary for the Superfund Program.

This guidance document does not eliminate the need for scientific expertise and professional judgment. An interdisciplinary team (including, but not limited to, biologists, ecologists, and environmental toxicologists) is needed to design and conduct a successful risk assessment. Some of the many points at which the Superfund ecological risk assessment process requires professional judgment include:

- Determining the level of effort needed to assess ecological risk at a particular site;
- Determining the relevance of available data to the risk assessment;
- Designing a conceptual model of the ecological threats at a site and measures to assess those threats;
- Selecting methods and models to be used in the various components of the risk assessment;
- Developing assumptions for toxicity and exposure assessments based on logic and scientific principles to fill data gaps; and
- Interpreting the ecological significance of observed or predicted effects.

FIGURE 3
Steps in the Ecological Risk Assessment Process and Corresponding Decision Points in the Superfund Process

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.

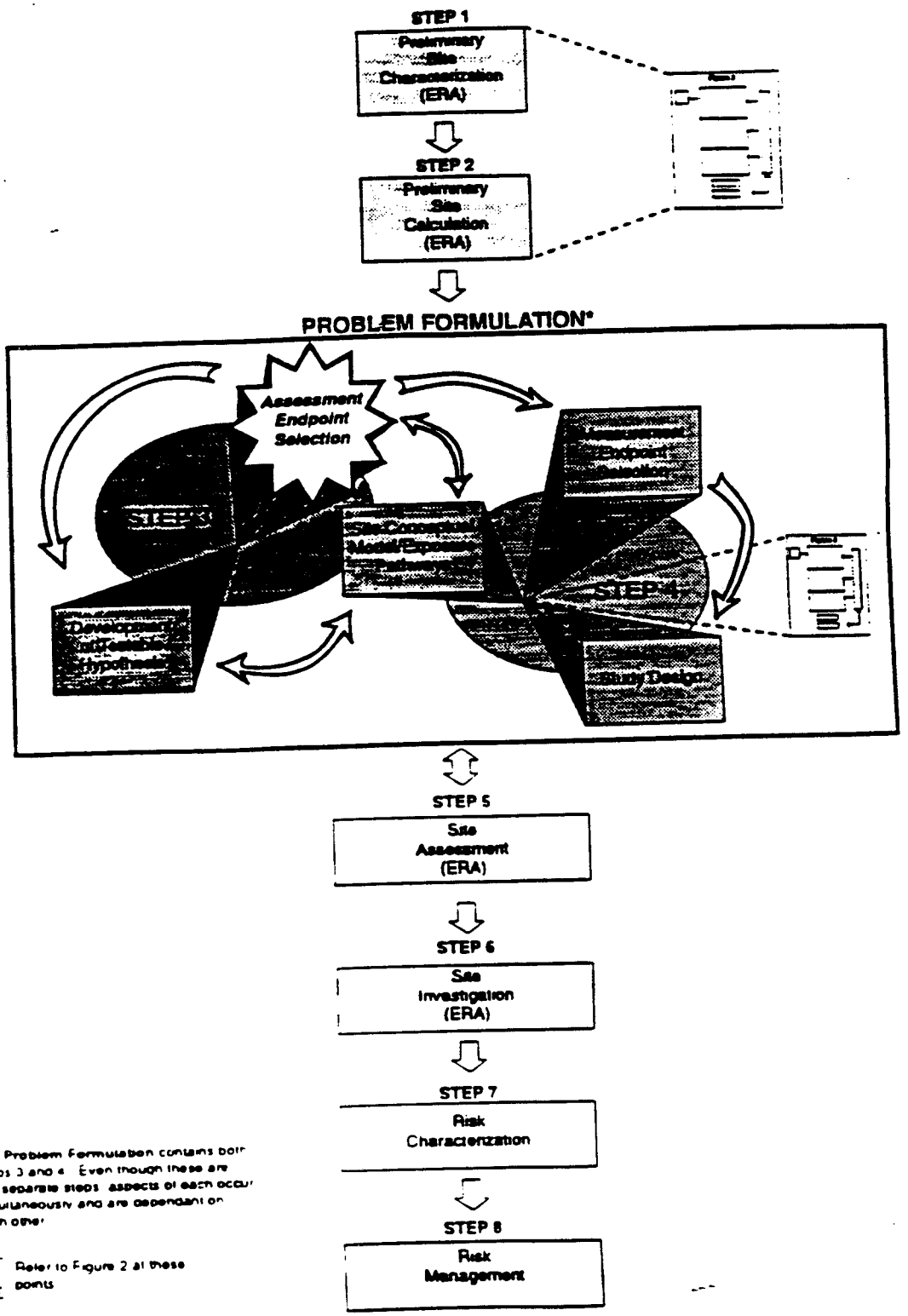
(c) Signing approval of the work plan and sampling and analysis plan for the ecological risk assessment.

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

(e) Signing the Record of Decision.

FIGURE 4

Site Screening Risk Assessment



* The Problem Formulation contains both Steps 3 and 4. Even though these are two separate steps, aspects of each occur simultaneously and are dependant on each other.

Refer to Figure 2 at these points

The lead risk assessor should coordinate with appropriate professional to make many of these decisions. Specialists are needed for the more technical questions concerning the risk assessment (e.g., which model, which assumptions). Since technical judgments or interpretations of data can differ, a decision-making approach that resolves differences in professional judgment is necessary.

After the risk assessment is complete, the risk manager may require additional professional assistance in interpreting the implications of the baseline ecological risk assessment and selecting a remedial option. This guidance document focuses on the *risk assessment* process in Superfund, and does not address all of the issues that a *risk manager* may need to consider.

Relationship of the Eight-step Ecological Risk Assessment Process to the RI/FS Process

[Note to Reviewers: There will be additional discussion relating the eight-step process to the RI/FS process, referring to the figures in preparation.]

The risk assessment process must be structured to ensure that site management decisions can be made without the need for repeated studies or delays. The first two steps in the assessment are a streamlined version of the complete *Framework* process and are intended to allow a rapid determination by the risk assessor and risk manager that the site poses no or negligible ecological risk. Steps 3 through 8 are a more detailed version of the complete *Framework* process and reflect efforts to determine a proposed site-specific clean-up goal that is protective of the environment. Within the RI/FS process, the SMDPs for steps 3 and 4 should co-occur with the finalization of the Work Plan (WP) and the Sampling and Analysis Plan (SAP) under which the ecological risk assessment will be conducted.

These SMDPs also represent opportunities to coordinate all three components of an RI/FS (see Highlight Box 1-1), thus ensuring that needs of the ecological and human health risk assessments are incorporated into the chemical sampling program to determine the extent and degree of contamination. The ecological WP and SAP described in Steps 3 and 4 cover any additional chemical or biological sampling and field studies that may be needed for the ecological risk assessment. WP and SAP approval can be viewed as an agreement between the lead ecological risk assessor and the lead risk manager that the designed risk assessment will provide the information required to make site management decisions.

Tasks that should be accomplished in each of the eight steps in Figures 2 and 3 are presented in the chapters that follow. It is important to realize that this eight-step approach is not a simple linear or sequential process. The order of actions taken will depend upon the stage of the RI/FS at which the site is currently, the amount and types of site information available, as well as other factors. The process may be repetitive or iterative; individual steps may not be relevant and thus not needed. In some cases, it may be appropriate and desirable to conduct several steps concurrently.

It should be remembered that the establishment of exposure-response relationships (through the use of a gradient of exposure or other means) is critical to any risk assessment.

CHAPTER 1
STEP 1: PRELIMINARY PROBLEM FORMULATION AND ECOLOGICAL EFFECTS EVALUATION

CHAPTER OVERVIEW

The preliminary problem formulation and ecological effects evaluation is part of the initial ecological risk screening assessment. In this step of the eight-step process, it is assumed that limited information is available for site characterization, as well as for determining the extent and nature of contamination. This step includes all the functions of problem formulation (more fully described in Steps 3 and 4), and ecological effects analysis, but on a screening level. The results of this step will be used in conjunction with exposure estimates in the preliminary risk calculation in Step 2.

1.1 INTRODUCTION

This chapter explains **the preliminary problem formulation process and describes what data are necessary to screen for ecological effects at the site.** Section 1.2 describes problem formulation, focusing on four issues:

1. **Environmental setting**, and contaminants known or suspected to exist at the site.
2. Contaminant fate and transport mechanisms that may exist at the site.
3. The toxic mechanism associated with each contaminant and categories of receptors likely to be affected.
4. The complete exposure pathways that may exist at the site. (A complete exposure

HIGHLIGHT BOX 1
Screening Evaluations

Screening-level risk assessments are simplified assessments that can be conducted with limited data by assuming values for parameters for which data are lacking. For Superfund sites, it is important to minimize the chance of type II error (the likelihood that the actual risk is greater than that predicted). To ensure that sites that might pose an ecological risk are studied further, where site-specific data are lacking, assumed values should consistently be biased in the direction of overestimating risk. Without this bias, a screening evaluation could not provide a defensible conclusion that no ecological risk exists.

route is one in which the chemical can be traced from the source to the receptor being evaluated.)

Section 1.3 describes the preliminary ecological exposure-response evaluation and the establishment of contaminant exposure levels that represent a conservative threshold for adverse ecological effects.

1.2 PRELIMINARY PROBLEM FORMULATION

Environmental Setting and Contaminants at the Site

To begin the **preliminary problem formulation**, there must be at least a rudimentary knowledge of the potential **environmental setting and** chemical contamination at the site. This information can be compiled from reports related to the site, including the Preliminary Assessment (PA) or Site Investigation (SI), conducted by the State, EPA, or by another interested party, **and the site history**. The environmental checklist presented in *Representative Sampling Guidance Document, Volume 3: Ecological* (U.S. EPA 1994; see Appendix D) is a good source of the basic information needed to begin characterizing the site for problem formulation.

HIGHLIGHT BOX 2
Industrial or Urban Settings

Many hazardous waste sites exist in currently or historically industrialized or urbanized areas. In these instances, it can be difficult to distinguish between site-related and non-site related impacts or threats. However, even in these cases, it is often appropriate to take some actions based upon ecological risks. These actions might be limited to source removal or might be more extensive. Thus, even in these settings, an ecological risk assessment can assist the risk manager in determining what action, if any, is appropriate.

Many Superfund sites are located in highly industrialized areas where site-related environmental threats may appear to be low **or indistinguishable from non-site related impacts**, or where site remediation may result in limited improvement of the overall environmental quality of the area. However, all sites should be evaluated by qualified personnel to determine whether this conclusion is appropriate. Information collected using the environmental checklist **(U.S. EPA, 1994; see Appendix D)** can help determine the level of effort needed to assess ecological risk at a particular site. Key questions addressed by the checklist, which will help determine whether further work is needed in Step 1, include:

- What are the on- and off-site land uses (e.g., industrial, residential, or undeveloped)?
- **What is the environmental setting**, including natural areas (e.g., upland forest, onsite stream, nearby wildlife refuge) as well as disturbed/man-made areas (e.g., waste lagoons)?

- Whether or not habitats present on site are potentially contaminated or otherwise disturbed.

- Whether or not contamination has migrated from source areas and resulted in "off-site" impacts or the threat of impacts, in addition to on-site threats.

The completed checklist will provide information regarding habitats and species potentially or actually present on site, potential contaminant migration pathways, exposure routes, and the potential for physical environmental disturbances at the site. After completing the checklist, it may be possible to determine that no significant ecological impacts are occurring or could occur because there are no complete exposure routes possible, or because there is little or negligible potential for any complete exposure route to be completed in the future.

Site Visit

If additional site data are needed to confirm and document the presence or absence of complete exposure routes, this information should be collected during a preliminary site visit. During this site visit, the area of the site contamination should be estimated (this estimate will be used in the development of an area use factor calculation in Step 4), and the layout and topography of the site should be noted. Existing ecological habitat types (e.g., forest, old field, wetland) should be described, and the area covered by these habitats should be estimated. Any observations of animal species or signs of a species should be recorded. The dominant vegetation species present and soil and water types should also be described. The possibility that the area might be used by any endangered or threatened species also should be considered, and any habitat suitable for such species on-site or near the site should be noted.

Visual observations, existing information and maps, and aerial photographs should be used to identify the presence of sensitive habitats on-site or habitats off-site that may be potentially threatened by a contaminant(s) from the site. State and Federal laws (e.g., the Clean Water Act, the Endangered Species Act) designate certain types of environments that require special consideration or protection. In addition to habitats that meet specific State or Federal criteria, other types of habitat unique to certain areas may require special attention in the assessment. Table 1-1 lists types of habitats that may require special consideration.

Contaminant Fate and Transport

Pathways or routes for migration of a contaminant off site (e.g., windblown dust, surface water runoff, erosion, and drainage ditches), should be described. Along these pathways, a decreasing gradient of contamination may exist with increasing distance from a site, although there are exceptions, because physical and chemical characteristics of the media sampled also influence contaminant distribution (e.g., the pattern of contaminated sediment deposition in streams varies depending on flow and bottom characteristics). For the preliminary site assessment (which is a very conservative

TABLE 1-1:
LIST OF SENSITIVE ENVIRONMENTS IN THE HAZARD RANKING SYSTEM.[a]

Critical habitat for Federal designated endangered or threatened species
Marine Sanctuary
National Park
Designated Federal Wilderness Area
Areas identified under the Coastal Zone Management Act
Sensitive areas identified under the National Estuary Program or Near Coastal Waters Program
Critical areas identified under the Clean Lakes Program
National Monument
National Seashore Recreational Area
National Lakeshore Recreational Area

Habitat known to be used by Federal designated or proposed endangered or threatened species
National Preserve
National or State Wildlife Refuge
Unit of Coastal Barrier Resources System
Coastal Barrier (undeveloped)
Federal land designated for protection of natural ecosystems
Administratively Proposed Federal Wilderness Area
Spawning areas critical for the maintenance of fish/shellfish species within river, lake, or coastal tidal waters
Migratory pathways and feeding areas critical for maintenance of anadromous fish species within river reaches or areas in lakes or coastal tidal waters in which the fish spend extended periods of time
Terrestrial areas utilized for breeding by large or dense aggregations of animals
National river reach designated as Recreational

Habitat known to be used by state designated endangered or threatened species
Habitat known to be used by species under review as to its Federal endangered or threatened status
Coastal Barrier (partially developed)
Federal designated Scenic or Wild River

State land designated for wildlife or game management
State designated Scenic or Wild River
State designated Natural Areas
Particular areas, relatively small in size, important to maintenance of unique biotic communities

State designated areas for protection or maintenance of aquatic life

[a] The categories are listed in groups from those assigned higher factor values to those assigned lower factor values in the HRS. See *Federal Register*, Vol. 55, p. 51624 for additional information regarding definitions.

assessment), the highest levels determined or predicted on the site should be documented on a medium-by-medium basis. The preliminary risk calculation in Step 2 should help to determine whether or not to continue to a more definitive, site-specific ecological risk assessment. The preliminary risk calculation should not be used to determine a "site-specific clean-up" level.

Ecotoxicity and Potential Receptors

Understanding the toxic mechanism of a contaminant is necessary to evaluate potential exposure routes. Some contaminants, for example, may affect primarily vertebrate animals by interfering with organ systems not found in invertebrates or plants (e.g., distal tubules of vertebrate kidneys, vertebrate hormone systems). Other substances might affect primarily arthropods (e.g., insecticides), plants (e.g., herbicides) or other groups of organisms. For substances that affect, for example, the reproduction of mammals at much lower exposure levels than they affect other vertebrates, invertebrates, or plants, the screening ecological risk assessment can initially focus on mammals. To demonstrate this point, an example of the toxicity of an organic compound (PCBs) is provided in Example Box 1-1.

Complete Exposure Pathways

The evaluation of potential exposure routes is one of the primary tasks of the preliminary ecological characterization of the site. It is important to identify complete exposure pathways prior to evaluation of toxicity to focus the assessment only on those contaminants that can reach ecological receptors. For terrestrial animals, there are three basic exposure routes that need to be evaluated: inhalation, ingestion, and dermal absorption. **For terrestrial plants, root absorption is a common exposure route at hazardous waste sites. For animals in aquatic environments, direct contact of water with the gills/dermis and ingestion of food (and possibly sediments) are primary routes of exposure. For aquatic plants, direct contact with water and possibly sediments are primary exposure routes.**

The most likely routes of exposure are also related to the physical **and chemical** properties of the contaminant (e.g., **whether or not** the contaminant is bound to another matrix, such as organic carbon). **Of basic exposure routes identified above, more information**

EXAMPLE BOX 1-1
PCB Site: Ecotoxicity

Some **PCBs are reproductive** toxins in **mammals that, when ingested, act through the induction of enzyme systems in the liver.** The enzymes are not specific for PCBs and will also enhance the degradation of steroid hormones. The reduction in circulating steroid hormones impairs the ability of mammals to reproduce. Other effects, such as liver changes, are also evident at high exposures. Given this information, the screening ecological risk assessment should include potential exposure pathways for mammals to PCBs (see Example Box 1-2).

generally is available to quantify exposure levels for ingestion by terrestrial animals, and for direct contact with water by aquatic organisms, than for other exposure routes. Although other routes can be important and should be evaluated as determined by professional judgment, more assumptions are needed to estimate exposure levels for those routes, and the results are less certain.

If receptors that can be adversely affected by a contaminant cannot be exposed to the contaminant, the exposure pathway does not need to be evaluated. For example, suppose a contaminant that impairs reproduction in mammals exists on a site only below a depth of four feet and is therefore not taken up by plants. In this case, a complete exposure route for surface-dwelling mammals does not exist, and the contaminant would not pose a significant risk to this group of organisms. Secondary questions might include whether the contaminant is leaching, or whether the contaminant would be carried to ground water that discharges to surface water, thereby posing a risk to the aquatic environment or to terrestrial mammals that drink the water. Whether there are indigenous, deep-burrowing mammals that could be exposed to the buried contamination must also be considered.

1.3 PRELIMINARY ECOLOGICAL EFFECTS EVALUATION

The next step in the preliminary risk assessment is the evaluation of the ecological effects associated with the chemicals documented or anticipated at the site and development of a toxicity profile and screening ecotoxicity value for those chemicals.[2] A literature search of studies that evaluate the toxicity (target tissue and dose-response) and toxic mechanisms of chemicals is necessary to evaluate the likelihood of toxic effects. Appendix B gives a basic introduction to a literature search, but an expert should be consulted to minimize time and costs. The toxicity profile should describe the toxic mechanisms of action for the exposure route being evaluated and the dose or environmental concentration that causes a specified adverse effect.

For each complete exposure route, a screening-level ecotoxicity value, or benchmark, should be developed. The EPA Office of Emergency and Remedial Response is currently developing preliminary ecological risk calculation numbers specifically for this risk assessment guidance, but until those numbers are available, ecotoxicity benchmarks should be developed from other sources, as described below.

For each complete exposure route, the literature should be reviewed for the lowest exposure level (e.g., concentration in water or in the diet, ingested dose) shown to produce adverse effects (e.g., reduced growth, impaired reproduction, increased

[2] It is possible to conduct a screening risk assessment with limited information and conservative assumptions. If site-specific information is too limited, however, the Scientific/Management Decision is almost certain to move the risk assessment into Steps 3 through 8, which may require field-collected data. The more complete the initial information, the better the decision that can be made at this preliminary stage, or at any stage.

EXAMPLE BOX 1-2
PCB Site: Complete Exposure Pathways

PCBs are not highly volatile, so the inhalation of PCBs by animals would be an essentially incomplete exposure pathway. PCBs in soils generally are not taken up by most plants, but are accumulated by soil macroinvertebrates. Thus, herbivores would not be exposed to PCBs in most of their diet; whereas insectivores, such as shrews, could be exposed to accumulated PCBs in most of their diet. For PCBs, the ingestion route would be essentially incomplete for herbivores but complete for insectivores. The relative significance of dermal exposure of mammals to PCBs is uncertain; grooming would most likely result in ingestion of the contaminant prior to actual dermal contact. The dermal route is very difficult to document as a complete pathway, and the uncertainty in exposure estimates would be very high. This evaluation indicates that the ingestion exposure route needs evaluation and that an insectivore would be appropriate receptor to evaluate for this route. PCBs also tend to bioaccumulate and biomagnify, particularly in aquatic ecosystems. If an aquatic ecosystem were on or near the site, the potential for PCBs to accumulate in aquatic food chains also should be evaluated.

mortality) in a potential receptor species (i.e., a lowest-observed-adverse-effect-level or LOAEL). In addition, the highest exposure level at which no adverse effects have been demonstrated (no-observed-adverse-effect-level or NOAEL) should be identified. A NOAEL is more appropriate than a LOAEL for the initial screening assessment to ensure that risk is not underestimated. However, NOAELs are not currently available for many wildlife species or many chemicals. In some cases, toxicity data from a related species can be used to estimate a NOAEL for a receptor species. When a NOAEL value is not available but a LOAEL is obtained from the literature, the standard practice is to multiply the LOAEL by 0.1 to estimate the NOAEL.

Professional judgment must be employed at this stage to determine the uncertainty associated with information taken from the literature and any extrapolations used in developing a screening-level ecotoxicity benchmark. Consideration of the study design, endpoints, as well as other factors are important in determining the utility of toxicity data in the ecological risk assessment. Use of toxicity data for a species different from the receptor species should be noted. All of these factors should be addressed in the uncertainty analysis prior to the preliminary risk calculation.

Studies which report NOAELs and/or LOAELs must be reviewed critically to ensure that the study is scientifically sound and appropriate for risk assessment. The exposure route and dose used in the study should be comparable to the route and concentration in the risk assessment. Data obtained in studies where exposure is by injection or gavage may not be appropriate for estimating the dietary concentrations that

could produce adverse effects. Data from long-term exposure studies are preferable to data from single-exposure studies, especially if site exposure is long-term.

When reviewing the literature, one should be aware of the limitations of published information in characterizing actual or probable hazards at a specific site. Most toxicological studies evaluate effects of a single contaminant on a single species under controlled laboratory conditions. Results from these studies may not be applicable to the field, where organisms typically are exposed to a mixture of contaminants in situations that are not comparable to a laboratory study. In a field situation, organisms will also be subject to other environmental stressors, such as unusual weather conditions, infectious diseases, and food shortages. These "natural" stressors can have either positive or negative effects on the organism's response to a toxic contaminant that only a site-specific field study will be able to evaluate. Single-species tests seldom provide information regarding toxicant-related changes in community interactions (e.g., behavioral changes in prey species which make them more susceptible to predation). Reliance on secondary references is discouraged, because the possibilities for stressor interactions are unlikely to be apparent in the secondary source. Any literature study that is used to support any decision must be reviewed.

For some data reported in the literature, conversions may be necessary to allow them to be used for species different than those tested. A significant body of literature exists concerning species-to-species extrapolations (e.g., see studies in Suter, 1993). Many doses from laboratory studies are reported in terms of concentration in the diet (e.g., mg contaminant/kg diet). Diet concentration should be converted to dose (e.g., mg contaminant/kg body weight per day), so that dose is not under- or overestimated when it is applied to an organism consuming different amounts of food per body weight.

Average ingestion rate and body weight for a species often are reported in relevant studies or may be obtained from other literature sources (e.g., U.S. EPA, 1993a,b) to be used in this general conversion:

$$\textit{Dose (mg/kg-day)} = \textit{Diet (mg/kg)} \times \textit{Ingestion Rate (kg/day)} \times 1/\textit{Bodyweight (kg)}$$

Food and water ingestion rates also can be estimated for species for which measured values are not available on the basis of allometric equations and body weight (see U.S. EPA, 1993a).

The ecotoxicity screening value (or benchmark) obtained as described above will influence data quality objectives (in particular, the implications of detection and quantitation limits). If adverse ecological effects are expected at environmental concentrations below Contract Laboratory Program (CLP) quantitation limits, a "no detect" based on those limits cannot be utilized to support a "no risk" decision. In these cases, either exposure concentrations will need to be estimated from other information or the risk assessor and risk manager will need to consider requesting lower detection limits.

1.4 SUMMARY

At the conclusion of the preliminary problem formulation, the following information should be compiled:

1. Environmental setting and contaminants known or suspected to exist at the site, and the maximum concentrations present (by media).

2. Contaminant fate and transport mechanisms that may exist at the site.

3. The ecotoxicity associated with contaminants and likely categories of receptors that could be affected.

4. The complete exposure pathways that may exist at the site from contaminant sources to receptors that could be affected.

For the screening ecological risk assessment, assessment endpoints will include any likely adverse ecological effects on receptors for which exposure pathways are complete, as determined from the information listed above. Measurement endpoints will be based on the available literature regarding mechanisms of toxicity, as described more thoroughly in the next chapter. In addition, through the exposure-response evaluation, exposure at or above levels at which adverse ecological effects might be expected should have been established for the contaminants and exposure pathways of concern. This information will be used with estimated exposure levels in the preliminary risk calculation, as described in Step 2.

CHAPTER 2
STEP 2: PRELIMINARY EXPOSURE ESTIMATE AND RISK CALCULATION

CHAPTER OVERVIEW

The exposure estimate and preliminary risk calculation comprise the second step in the ecological risk screening for a site. **Risk is estimated by comparing maximum likely exposure levels with the screening-level ecotoxicity values from Step 1.** At the conclusion of this step, it will be decided that either: (1) the site preliminary screening is adequate to determine that there is little or no ecological threat; or (2) the ecological risk assessment should continue.

2.1 INTRODUCTION

The preliminary risk calculation can be performed using the **screening-level ecotoxicity values derived in Step 1 and the exposure levels estimated in this Step.** The risk calculation (Section 2.3) consists of comparing the exposure estimate (Section 2.2) to the screening ecotoxicity value (Section 1.3) using the hazard quotient method. The preliminary risk calculation should include:

- A description of the complete exposure route(s) or lack thereof;
- The result of the hazard quotient calculation;
- A discussion of the uncertainty of the hazard quotient; and
- A summary of the overall confidence in the assessment.

For the purposes of the preliminary risk calculation, the Agency will consistently use conservative assumptions. It is important to note that the Scientific/Management Decision made at the end of the preliminary risk calculation will not set a clean-up goal. Instead, one of the following will be decided:

1. The ecological risk assessment should be continued to develop a site-specific clean-up goal, or to reduce uncertainty in the evaluation of no risk; or

2. The preliminary screening is adequate to determine that little or no ecological risk exists.

The Agency must be confident that the Scientific/Management Decision made after the completion of this calculation will protect the ecological components of the

environment. The decision to continue beyond the preliminary risk calculation does not indicate whether risk reduction is necessary at the site. That decision will be made in Step 8 of the process. Again, the Agency emphasizes that the results of the preliminary risk screening in this step are not to be used to define clean-up goals. Their use as such will not be supported by the Agency because they would likely result in excessive cleanups (i.e., cleanups to environmental concentrations below what is necessary to protect ecological receptors).

2.2 PRELIMINARY EXPOSURE ESTIMATE

To estimate exposures for the preliminary ecological risk calculation, contaminant levels on-site and general information on the types of biological receptors present or anticipated on-site should be known. Only complete exposure pathways should be evaluated. For these, the highest measured or estimated on-site contaminant concentration, on a medium-by-medium basis, should be used to calculate exposures to ensure that potential ecological threats will not be missed.

Some of the conservative assumptions used in the preliminary exposure estimate (in the absence of sound site-specific information) are described below. Specifically these assumptions are:

- Area use factor, 100 percent (related to home range; see Highlight Box 2-1);
- Bioavailability, 100 percent;
- Sensitive life stage, use of most sensitive life stage; and
- Body weight, minimum body weight to maximum ingestion rate.

For the preliminary exposure estimate, the home range is considered to be encompassed entirely by the highly contaminated areas of the site. This is a conservative assumption and is applicable only to the preliminary, or screening, phase of the risk assessment. Site-specific home range information is needed later, in Step 4, to more accurately estimate the percent of time a receptor would utilize a contaminated area (i.e., the area use factor). As indicated in Highlight Box 2-1, the home range is the area in which an animal spends most of its time and obtains its food. If an animal's home range is smaller than the contaminated area of the site, the animal would obtain 100 percent of its food and water from contaminated areas. Additional factors that influence the duration and extent of exposure (e.g., whether an animal is migratory, whether it has a home range larger than the site, and how its time spent away from the site) will be considered in Steps 3 and 4 if the conservative assumptions in Step 2 indicate a risk.

For the preliminary exposure estimate, the bioavailability of contaminants at the site is assumed to be 100 percent. This is another conservative assumption; it probably would not be used in the conceptual model in Step 3 or the final risk calculation in Step 7. For example, in the preliminary exposure estimate, lead (Pb) would be assumed to be 100 percent bioavailable. While some literature indicates that mammals absorb approximately 10 percent of ingested lead, absorption efficiency can be much higher, up

to about 60 percent, because dietary factors such as fasting, as well as calcium and phosphate content of the diet, can affect the absorption rate (Friberg et al., 1986). Because few species have been tested for bioavailability, and because Steps 3 through 8 provide an opportunity for this issue to be specifically addressed, the most conservative assumption is appropriate at this step.

The most sensitive life stage also should be assumed for the preliminary risk calculation. If an early life stage is the most sensitive, the population should be assumed to be in this particular life stage. While this a not a standard case, it is a potential scenario (e.g., during a macroinvertebrate hatch).

Estimates of body weight and food ingestion rates also should be made conservatively to avoid understanding risk, although uncertainties in these factors are far less than the uncertainties associated with the environmental contaminant concentrations. The composition of the diet of potential receptors should be estimated conservatively to maximize exposure. For species that feed on more than one type of food, the screening-level assumption should be that the diet is composed entirely of whichever type of food is most contaminated. For instances where surrogates are used for the diet of a receptor, the diet should be selected to ensure a complete exposure pathway and to maximize the dose estimated for the receptor.

HIGHLIGHT BOX 2-1
AREA USE FACTOR

An animal's area use factor (AUF) can be defined as the ratio of its home range, breeding range, or feeding/foraging range to the area of contamination or the site area under investigation. To ensure that ecological risks are not underestimated, AUFs should be selected to maximize the estimated exposure to the contaminated area. While this assumption may not seem realistic in many situations, it can be plausible for some. For example, in an area contaminated by DDT, exposed fiddler crabs can be slow to react to predators. The predators, rewarded by high success rates capturing crabs in the contaminated area compared with elsewhere, might concentrate their foraging efforts in that area.

2.3 PRELIMINARY RISK CALCULATION

A quantitative screening risk value can be calculated using exposure estimates developed according to Section 2.2 and the screening ecotoxicity values developed according to Section 1.3. Although several approaches can be used to estimate risk, for the preliminary risk calculation, the hazard quotient method comparing single effect and exposure values is adequate.

The hazard quotient method compares the estimated exposure levels to the measured or predicted threshold value for effects (e.g., NOAEL for acute or chronic toxicity) (U.S. EPA, 1989b). As described in Step 1 (Section 1.3), for the screening

ecological risk assessment, the ecotoxicity threshold value should be based on the documented and/or best conservatively estimated NOAEL.

A hazard quotient is expressed as the ratio of a potential exposure level to the ecotoxicity screening value:

$$HQ = \frac{Dose}{NOAEL} \quad or \quad HQ = \frac{EEC}{NOAEL}$$

where:

HQ = hazard quotient;

Dose = **estimated contaminant intake (e.g., mg/kg-day);**

EEC = **estimated environmental concentration (e.g., mg/L water): and**

NOAEL = **no-observed-adverse-effects-level (in units that match the dose or EEC).**

A hazard quotient greater than 1 is interpreted as a level at which adverse ecological effects are likely to occur. A hazard quotient less than 1 does not indicate a lack of risk, but should be interpreted based on the severity of the effect reported and the magnitude of the calculated quotient. As certainty in the exposure concentrations and the NOAEL increase, there is greater confidence in the predictive value of the hazard quotient model, and unity (HQ = 1) becomes a pass/fail decision point. If multiple contaminants of ecological concern exist at the site, it may be appropriate to sum the HQs for contaminants with the same ecological effect endpoint and/or the same mechanism of toxic effect (see Highlight Box 2-2). When it is appropriate to sum the HQs, the HQ summation should not exceed 1.

The preliminary risk calculation is a conservative estimate to ensure that

HIGHLIGHT BOX 2-2
Hazard Index Calculation

$$\text{Hazard Index} = EEC_1/NOAEL_1 + EEC_2/NOAEL_2 + \ldots + EEC_i/NOAEL_i \ldots$$

where:

EEC_i = expected environmental concentration for the ith contaminant;

$NOAEL_i$ = NOAEL for the ith contaminant (expressed either as a dose or environmental concentration); and

EEC and the NOAEL are expressed in the same units and represent the same exposure period (e.g., chronic, acute).

potential ecological threats will not be overlooked. The calculation is used to document a decision **about whether or not** there is a negligible potential for ecological impacts, based on the information available at this stage.

2.4 SCIENTIFIC/MANAGEMENT DECISION POINT (SMDP)

The last issue in Step 2 is the SMDP, where the risk assessor communicates the results of the preliminary ecological risk assessment to the risk manager. The risk manager needs to decide if the information available is adequate to make a risk management decision. The only possible conclusion at this point is either:

1. There is adequate information to determine that little or no risk of adverse ecological effects, and therefore little or no need for remediation; or

2. The information is not adequate to make a decision at this point, and the ecological risk assessment process will continue to Step 3.

This decision is definitive, and the risk manager should document both the decision and the basis for it.

2.5 SUMMARY

The result of the preliminary ecological risk calculation step will determine if there is adequate information available **regarding** the site and **its** contaminants to complete the ecological risk assessment at this step. The lead risk manager and lead risk assessor will determine if there is little or no ecological threat related to the site. If this is the case, the ecological risk assessment will be complete at this step. If not, the ecological risk assessment will continue to refine the problem formulation in Step 3.

The intent of this step is not to derive a "reasonable" exposure; Steps 3 through 8 are the guidance for developing a "reasonable" exposure and for developing a site-specific clean-up goal based on the exposure. The uncertainty inherent in the preliminary risk assessment step is biased conservatively both in the area use factors and in the site-specific contamination.[5] [OR] **Conservative assumptions have been used for each step of the preliminary ecological risk assessment.**[5] Therefore, requiring a cleanup based solely on this information would not be technically defensible. The preliminary risk calculation must be able to adequately document a decision that there is a negligible or no ecological risk, and that the preliminary risk calculation is an adequate ecological risk assessment. A lack of information on the toxicity of a chemical or on a complete exposure routes will result in decision to continue with the ecological risk assessment process (Steps 3 through 8) -- not a decision to delay the ecological risk assessment until a later date when more information will be available.

[5]Note to reviewers: We are considering two different introductions to this paragraph.

CHAPTER 3
Step 3: PROBLEM FORMULATION: Assessment Endpoint Selection and Testable Hypotheses

CHAPTER OVERVIEW

Step 3 of the eight-step ecological risk assessment process begins to refine the preliminary problem formulation, expanding on the ecological issues that are of concern for the ecological risk assessment. In Step 3, the assessment endpoints are selected and the questions or hypotheses that the site investigation will answer are developed. Problem formulation will continue in Step 4 with the development of the conceptual model. Once the assessment endpoints and testable hypotheses are established in Step 3, measurement endpoints can be determined and a site investigation can be designed to meet the site needs in Step 4.

The products of problem formulation (Steps 3 and 4) are used to develop the site work plan. The work plan specifies the assessment endpoints and the questions to be answered by site investigations. It also defines the objectives of the site ecological investigation.

3.1 THE PROBLEM FORMULATION PROCESS

Step 3 encompasses the scoping and initial development of the ecological risk assessment work plan, which is finalized at the end of the development of the conceptual model (Step 4). Through Step 3, critical questions and issues that need to be addressed in the ecological risk assessment are defined based on exposure pathways and ecological effects.

Evaluating exposure and toxicity can be complex: environmental fate and transport of multiple contaminants, and toxicity to multiple species, must be evaluated. Fortunately, for individual contaminants, it is frequently possible to identify one or more "critical pathways" of exposure, which is anticipated to: (1) reflect maximum exposures of receptors within the ecosystem; or (2) constitute exposure pathways to particularly sensitive ecological receptors (i.e., "critical species"). This helps to focus the risk assessment and to identify the critical assessment endpoints for the local ecosystem. However, if multiple exposure pathways exist, they should be evaluated because it usually is not possible to predict which pathway may be responsible for the greatest ecological risk. The assessment endpoints and the set of questions (testable hypotheses) developed during Step 3, together with the products of the site conceptual model, are the bases for the site ecological assessment work plan (WP) and the sampling and analysis plan (SAP).

This stage of problem formulation is critical because it defines the issues that need to be addressed in the site investigation (Step 6).

At the conclusion of Step 3, there is a scientific/management decision point (SMDP) at which there should be agreement on the selected assessment endpoints and the testable hypotheses. If the basis of the questions or the selection of the assessment points is not understood and agreed upon by the risk manager, risk assessor, and the other professionals involved with the ecological risk assessment, then the study developed from the conceptual model may not resolve the issues that must be considered to effectively manage risks.

In this stage of problem formulation, some basic information should exist for the site. At a minimum, information should be available from the site history, preliminary assessment, site inspection, and Steps 1 and 2 of this eight-step process. For large or complex sites, extensive information may be available from historical data or earlier site investigations. It is important to be as complete as possible early in the process so that Steps 3 through 8 need not be repeated. Repetition of Step 3 (selection of assessment endpoints and/or the testable hypotheses) is appropriate only if new information indicating new threats becomes available. The SMDP process should prevent having to return to the problem formulation step because of changing opinions on the questions being asked. Repetition of Step 3 should not be confused with the tiering of ecological site investigations at large or complex sites (see Highlight Box 3-1). The process of problem formulation at complex sites does not change, but the number, complexity, and/or level of resolution of the testable hypotheses can change.

The complexity of the questions developed during problem formulation is independent of site size or the magnitude of site contamination. Large areas of contamination may provoke simple questions; conversely, small sites with numerous contaminants may require a complex series of questions and assessment points. There is no rule that can be applied to gauge the effort needed for an ecological risk assessment based upon site size or number of contaminants: each site should be evaluated independently.

While problem formulation is conceptually simple, in practice it is generally a complex and interactive process. Defining the problems involves identifying toxic mechanisms of the contaminants, identifying potential receptors, and characterizing exposure and the potential ecological effects. The remainder of this Chapter describes five activities to be conducted during Step 3 prior to the SMDP for Step 3: (1) a literature search; (2) identification of contaminants of potential ecological concern; (3) selection of assessment endpoints; (4) exposure characterization; and (5) hazard characterization.

HIGHLIGHT BOX 3-1
Tiering an Ecological Risk Assessment

The tiering of a site-specific ecological risk assessment is independent of the goals of the ecological risk assessment. Tiering is a cost management mechanism for the site investigation. Reasons for tiering an ecological risk assessment may include the size and complexity of the site or the need to sequentially test interdependent hypotheses developed during problem formulation.

Steps 1 and 2 of this guidance serve as a first, or screening, tier prior to expending a larger effort for a detailed, site-specific ecological risk assessment.

However, it must be understood that, while tiering may be an effective means of managing the site investigations, the necessity of multiple sampling events will require some resampling of matrices sampled during earlier tiers and increased field mobilization costs. Thus, in some cases, a tiered ecological risk assessment may cost more than a non-tiered ecological risk assessment. The benefits of tiering should be weighed against the costs.

3.2 LITERATURE SEARCH

It will be necessary to conduct a literature search to obtain much of the information needed for problem formulation. The literature search conducted for the preliminary risk calculation (Step 1) should be expanded to obtain the needed information for the detailed problem formulation. If only preliminary risk screening numbers were applied the preliminary risk calculation, then a literature search for NOAELs, LOAELs, and the mechanisms of toxic responses should be completed. A discussion of some of the factors important in conducting an appropriate literature search is presented in Appendix B.

3.3 IDENTIFICATION OF CONTAMINANTS OF POTENTIAL ECOLOGICAL CONCERN

During problem formulation, a set of contaminants to be investigated needs to be defined. The initial list of contaminants to be investigated includes those contaminants identified at the site. A contaminant should not be eliminated from the list of contaminants to be investigated only because toxicological information is lacking. During the preliminary risk assessment (Steps 1 and 2), some of the contaminants found at the site may have been eliminated from further assessment because they were not believed to pose any ecological risk. However, if new information becomes available that indicates that the initial assumptions used in the preliminary risk assessment are no longer valid

(e.g., site contaminant levels are higher than originally reported, joint action toxicity was not considered in the preliminary risk characterization, etc.), contaminants can be placed back on the list of contaminants to be investigated.

It may not be necessary to evaluate all contaminants of concern with the same rigor. Evaluation of the fate, transport, and ecotoxicity of the contaminants may determine which one(s) will be of greatest importance in the ecological risk assessment. If greater emphasis is placed on specific contaminants, the justification for this approach must be discussed and the potential to underestimate risk described.

3.4 SELECTION OF ASSESSMENT ENDPOINTS

EXAMPLE BOX 3-1
DDT SITE: Assessment Endpoint Selection

An assessment endpoint such as "protection of the ecosystem from the effects of DDT" gives little direction to the risk assessment. However, "protection of piscivorous birds from eggshell thinning due to DDT exposure" directs the risk assessment toward the food-chain transfer of DDT that results in eggshell thinning. This assessment endpoint provides the foundation for the identification of appropriate measurement endpoints and ultimately the design of the site investigation for the site.

It is not necessary that a specific piscivorous species of bird be identified on site. It is necessary that the exposure pathway to a piscivorous bird exists and that the presence of a piscivorous bird could be expected.

As noted in the introduction, an assessment endpoint is "an explicit expression of the environmental value that is to be protected" (U.S. EPA 1992a). Assessment endpoints for the baseline ecological risk assessment must be selected based on the ecosystems, communities, and/or species that are of particular concern at the site. Broad assessment endpoints are generally of less value in problem formulation than specific assessment endpoints.

The formal identification of assessment endpoints is part of the SMDP for Step 3. Regardless of the level of effort to be expended on the subsequent phases of the risk assessment, the assessment endpoints identified are critical elements in the design of the ecological risk assessment and must be agreed upon as the focus of the risk assessment.

The process of selecting the assessment endpoints may, however, be iterative and interactive with other phases of problem formulation and with the development of the conceptual model. The selection of assessment endpoints and testable hypotheses during problem formulation depends on:

1. The contaminants present and their concentrations:

2. Mechanisms of toxicity to different groups of organisms;

3. Potential species present; and

4. Potential complete exposure pathways.

When selecting assessment endpoints, there is an important distinction between human risk assessment and ecological risk assessment. In a human health risk assessment, the only species evaluated is the human, and cancer and noncancer systemic effects are common assessment endpoints. Ecological risk assessment, on the other hand, involves multiple species that are likely to be exposed at different levels and may respond differently to the same contaminant. Therefore, knowledge of: (1) the fate and transport of the contaminant within the ecosystems at the site; (2) the specific mechanisms of toxicity of the contaminant in different groups of organisms; and (3) the presence of sensitive receptors at or near the site is important in the selection of appropriate assessment endpoints.

Once assessment endpoints have been selected, testable hypotheses can be developed to determine whether or not a potential threat to these endpoints exists.

The assessment endpoints are refined in Step 4, and the hypotheses are tested during the site investigation phases (Steps 5 and 6) of the ecological risk assessment. It is important that the problems be clearly and correctly identified, since inappropriate or inadequate problem formulation may lead to unsound management decisions or to conclusions that do not address site needs, thereby resulting in lost time and wasted resources.

3.5 EXPOSURE CHARACTERIZATION

The objective of exposure characterization is to gather information from which to determine the pathways and media through which ecological receptors may be exposed to site contaminants. This effort typically involves compiling additional information on:

1. The ecological setting of the site (including habitat, potential receptors, etc.);

2. The inventory of contaminants that are or may be present at the site;

3. The extent and magnitude of the contaminant concentrations present, along with the spatial and temporal variability of those concentrations; and

4. The environmental fate and transport of the contaminants.

3.5.1 ECOLOGICAL SETTING OF THE SITE

The ecological setting of the site defines the contaminant transport pathways and the environmental fate of the contaminants. The ecological setting also defines the habitat and species that may be exposed and potential food chain pathway(s) to those species.

An initial source of information on the ecological setting of the site is the data collected during the preliminary site visit and characterization (Step 1), including the site ecological checklist (Appendix D). At a minimum, the site description should provide answers to the following questions:

- What habitats (e.g., maple-beech hardwood forest, early successional fields) are present?
- What types of water bodies are present, if any?
- Do critical habitats for threatened or endangered species exist at the site or in the immediate area of the site?
- Do any other habitats listed in Table 1 exist on or adjacent to the site?

While all available information must be used, it is not critical that complete site setting information be collected during this phase of the risk assessment. However, it is important that habitats that do exist at the site not be overlooked; hence, a site visit is needed. If a critical habitat that is actually present on the site is omitted during the problem formulation phase, this phase will need to be repeated, resulting in delays and additional costs.

3.5.2 INVENTORY OF CONTAMINANTS

Based upon the results of the preliminary risk calculation and other information, a list of contaminants requiring further ecological risk evaluation is developed. For each contaminant on the list, the chemical fate, transport, and ecotoxicity must be known. In some cases, groups of contaminants may be viewed collectively, based upon similar chemical or toxicological properties. However, as noted earlier, it is not appropriate to eliminate a contaminant from the list based solely upon a lack of information; rather, such a lack of information must be discussed as an uncertainty. In practice, the list of contaminants that ultimately will "drive" the ecological risk assessment is likely to be small, even at large or complex sites. A thorough assessment of all contaminants retained on the list of contaminants for the site is necessary to ensure that an important ecological threat is not overlooked.

It is important to realize that, even at the same site, contaminants that may pose an ecological risk can be different from those that may pose a human health risk because of differing exposure pathways, sensitivities, and responses to contaminants.

3.5.3 EXTENT AND MAGNITUDE OF CONTAMINATION

Information on the concentrations as well as the spatial and temporal distribution of the contamination must be gathered during the remedial investigation for both the human and ecological exposure assessments. However, the analytical detection limits necessary for the human and ecological exposure assessments may be different. The amount of data available for the evaluation of the extent of contamination will vary with the site history and the phase within the Superfund process the site is in. It is necessary to be able to evaluate how and why the data were collected (i.e., the sampling design) in order to evaluate how the data can be properly used. If the available data were biased for worst-case or site-ranking needs or for other purposes, they may not be appropriate for accurate evaluation of actual site exposure.

3.5.4 ENVIRONMENTAL FATE AND TRANSPORT

Information on how the contaminants will or could be transported or transformed in the environment physically, chemically, and biologically is used to identify the exposure pathways that may lead to significant ecological effects.

HIGHLIGHT BOX 3-2
Environmental Fate and Exposure

If a contaminant is highly lipophilic (i.e., very water insoluble), it is likely to partition primarily into sediments and not the water column. Sampling sediments for grain-size distribution and total organic carbon, which can influence contaminant partitioning, may be important in evaluating ecological exposure.

Physically, contaminants may move through the environment by:

- Volatilization;
- Wind erosion;
- Deposition (contaminant sinks);
- Weathering of parent material with subsequent transport; and
- Water transport:
  - in solution,
  - as suspended material in the water, and
  - bulk transport of solid material (e.g., sediments).

Chemically, contaminants may undergo:

- Degradation[1];

[1] The product may be more toxic or less toxic than the parent compound.

- Complexation:
- Ionization:
- Precipitation: and/or
- Adsorption.

Biologically, contaminants may:

- Bioaccumulate:
- Biodegrade:
- Be transferred within the food web:
- Be transformed[1]:
- Be excreted: or
- Be sequestered.

Additional information should be gathered on past as well as current mechanisms of contaminant release from source areas at the site. The mechanism and the chemical and/or physical form of contaminant release can have an important effect on the fate, transport, and potential for ecological exposure.

The above information is used to evaluate: (1) where the contaminants are likely to be partitioned in the environment; and (2) the bioavailability of the contaminant (historically, currently, or in the future).

3.6 HAZARD CHARACTERIZATION/ECOTOXICOLOGIC EFFECTS

The risk assessor must "think through" the risk assessment to determine what receptors will or could be at risk. To accomplish this, the risk assessor must understand the ecotoxicologic effects of contaminants at the site. This understanding must include how the adverse effects of the contaminants may be expressed, as well as how the chemical and physical forms of the contaminants influence the type and magnitude of adverse response. It is necessary to know if the contaminants are direct toxins, adversely affecting the organisms in contact with the contaminated media (e.g., water, sediment, soil), or if the contaminants accumulates in food chains, resulting in adverse effects in organisms that are not directly exposed or are minimally exposed to the original contaminated media. Given limited resources, it may be necessary to make decisions about the scope of the risk assessment. For example, should the focus of the risk assessment be toxicity resulting from direct exposure to contaminated media, or food chain accumulation, or both?

Ecological impacts of a contaminant on an ecosystem can be direct or indirect, immediate or delayed, permanent or reversible. Available information on ecological effects of stressors (e.g., laboratory toxicity test results, ecological observations made during the scoping visit [Step 1]) can be used to help focus the assessment on specific stressors or on ecological resources that should be more thoroughly evaluated. For example, some groups of organisms can be more sensitive (more susceptible) than others

to a particular contaminant for several reasons. First, a species or group of species may be physiologically sensitive to a particular contaminants. For example, the contaminant may interfere with the organisms' hormone systems. Or, the species may not have a metabolic system that can detoxify the particular contaminant(s) (e.g., honey bees and grass shrimp cannot effectively biodegrade PAHs, whereas fish generally can do so). Second, an already stressed species or population (e.g., threatened or endangered species) may be particularly sensitive to any added stresses.

Variation in sensitivity should not be confused with variation in exposure, which can result from behavioral and dietary differences among species. For example, predators can be exposed to higher levels of contaminants that biomagnify in food chains than herbivores. A specialist predator may feed primarily on one prey type that is a primary receptor of the contaminant. Some species may preferentially feed in a habitat where the contaminant tends to accumulate. On the other hand, a species may change its behavior to avoid contaminated media.

3.7 SCIENTIFIC/MANAGEMENT DECISION POINT (SMDP)

At the conclusion of Step 3, there is a SMDP. The SMDP consists of agreement on two items: the assessment endpoints and testable hypotheses. Measurement endpoints cannot be developed without this agreement on the assessment endpoints among the risk manager, risk assessor, and other involved professionals. In addition, without the agreement upon the testable hypotheses, a site study cannot be developed.

3.8 SUMMARY

By combining a knowledge of: (1) the contaminants present; (2) the ecological setting; (3) environmental fate and transport; (4) the life history of potential receptor species; and (5) the ecotoxicity of the contaminants, an evaluation is made of what aspects of the ecosystem at the site could be at risk and what the adverse ecological response could be. "Critical exposure pathways" are identified within habitats for each ecological receptor under consideration. The critical exposure pathways may be based on: (1) an exposure pathway to sensitive species populations, or communities; (2) predominant fate and transport mechanisms at a site; and/or (3) specific aspects of the ecotoxicity of the contaminants.

Problem formulation summarizes the existing information on (1) the ecosystem present at the site, (2) the contaminants, and (3) the ecotoxicity of the contaminants. It incorporates the concepts of exposure assessment and hazard evaluation to identify ecological problems or issues. This results in the identification of assessment endpoints and specific questions or testable hypotheses that, together with the conceptual model, form the basis for the site investigation. It is not critical that complete site-specific information is available on site exposure pathways and/or the presence of specific species at the site for this step of the ecological risk assessment process. Through the development of the conceptual model and site sampling and analysis plan, a plan for filling information gaps will be developed and tested.

EXAMPLE BOX 3-3
Assessment Endpoint Selection

Copper Site

Copper can be acutely or chronically toxic to the organisms in an aquatic community through direct exposure to the water and sediments. Food chain bioaccumulation threats from copper are unlikely to exceed these direct exposure threats. This is because copper is an essential element and is effectively regulated by organisms if the exposure is below toxic levels. An appropriate assessment endpoint for an aquatic system may be the integrity of the stream community.

PCB Site

The primary ecological threat of PCBs in ecosystems is not through the direct exposure and acute toxicity. Therefore, assessing toxicity due to direct exposure would not be an appropriate assessment endpoint. PCBs bioaccumulate in animals and can affect reproductive success in some species, so an appropriate assessment endpoint may be reproductive impairment to selected species exposed through the food chain.

CHAPTER 4
STEP 4: PROBLEM FORMULATION:
Site Conceptual Model, Measurement Endpoint Selection, and Study Design

CHAPTER OVERVIEW

The development of the site conceptual model **that began in Step 3 continues in Step 4. In Step 3, assessment endpoints were selected and testable hypotheses developed for the conceptual model.** The goals of Step 4 are to **fully describe complete** exposure pathways, select measurement endpoints, and establish the study design **and data needs** for the ecological risk assessment, **thereby completing the conceptual model.** The study design defines the scope of the investigation, investigation methodologies, and data interpretation. **Establishment of the study design initiates the analysis phase of the framework.**

The products of Step 4 are **used to develop** both the ecological risk assessment work plan (WP) and the sampling and analysis plan (SAP). The WP and SAP describe the details of the site investigation as well as methods of data analysis. **The lead risk assessor and the lead risk manager should agree that the WP and SAP describe a study that will provide the risk manager with the information needed to incorporate ecological considerations** into the site remedial process. Once this step is completed, **most of the professional judgment needed for the ecological risk assessment should have already been incorporated into the design and details of the WP and SAP.** This does not limit the need for qualified professionals in the implementation of the investigation, data acquisition, or data interpretation. However, there should be no fundamental changes in goals or approach to the ecological risk assessment.

4.1 THE CONCEPTUAL MODEL

The site conceptual model establishes the complete exposure pathways that will be evaluated in the ecological risk assessment and the relationship of the measurement endpoints to the assessment endpoints. The possible exposure pathways are directly linked to the selection of assessment endpoints in Step 3 and measurement endpoints in Step 4.

One of the functions of the site conceptual model is to trace contaminant(s) through an ecosystem, including various food chains, thereby allowing the risk assessor to evaluate: (1) potential threats to chosen assessment endpoints; and (2) the appropriateness of potential measurement endpoints.

At the completion of Step 4 and the conceptual model, the ecological risk assessment work plan and the sampling and analysis plan also should be complete. The WP and SAP should specify:

- Assessment endpoints;
- Testable hypotheses;
- Site conceptual model;
- Measurement endpoints;
- Data needs;
- Study methodology and protocols;
- Study design, uncertainties, and assumptions;
- Data quality objectives;
- Data analysis procedures; and
- Data interpretation.

The site conceptual model can be used to identify the points or assumptions in the risk assessment that include the greatest degree of uncertainty. The field sampling then can be designed to reduce the major sources of uncertainty. Typical sources of uncertainty are the bioavailability and toxicity of contaminants in the field, and contaminant concentrations at exposure points.

EXAMPLE BOX 4-1
DDT Site: Ecotoxicity

Data from the literature suggest that DDT can have a bioaccumulation factor in water as high as six orders of magnitude (10^6); however, in many systems, the actual accumulation of DDT from the environment is substantially lower than 10^6. Many factors influence the actual accumulation of DDT in the environment. There is considerable debate over the parameters of any proposed theoretical accumulation model; therefore, it is advisable to conduct a field accumulation study to determine site-specific bioaccumulation.

The site conceptual model identifies the critical exposure pathways and the ecotoxicological threats posed to specific trophic levels or other ecosystem components. It is not possible to specify what components of an ecosystem should be protected or at what level of biological organization assessment endpoints should be specified at all Superfund sites. At any given Superfund site, the appropriate assessment endpoints may involve individual endangered species, local populations of a particular species,

EXAMPLE BOX 4-2
DDT Site: Description of the Conceptual Model

One of the assessment endpoints selected for the DDT site (Appendix A) is the protection of piscivorous birds. The site conceptual model includes the release of DDT from the spill areas to the adjacent stream, followed by food chain accumulation of DDT from the sediments and water through the lower trophic levels to forage fish in the stream. The forage fish are the exposure point for piscivorous birds. The measurement endpoint selected was eggshell thinning. During the literature review of the ecological effects of DDT, a toxicity study was found that reported reduced reproductive success (i.e., number of young fledged) in birds that experienced eggshell thinning of 20 percent or more. The risk assessor and risk manager agreed that eggshell thinning of 20 percent or more would be considered an adverse effect in the piscivorous birds. The belted kingfisher was selected as a piscivorous bird with the smallest home range that could utilize the area of the site, thereby maximizing the calculated dose to a receptor. Because the kingfisher was selected as the piscivorous bird species likely to be most exposed, it can be assumed that if the risk assessment for the kingfisher indicates that there is no threat of eggshell thinning in the kingfisher (the measurement endpoint), there should be minimal or no threat to other piscivorous birds that may utilize the site.

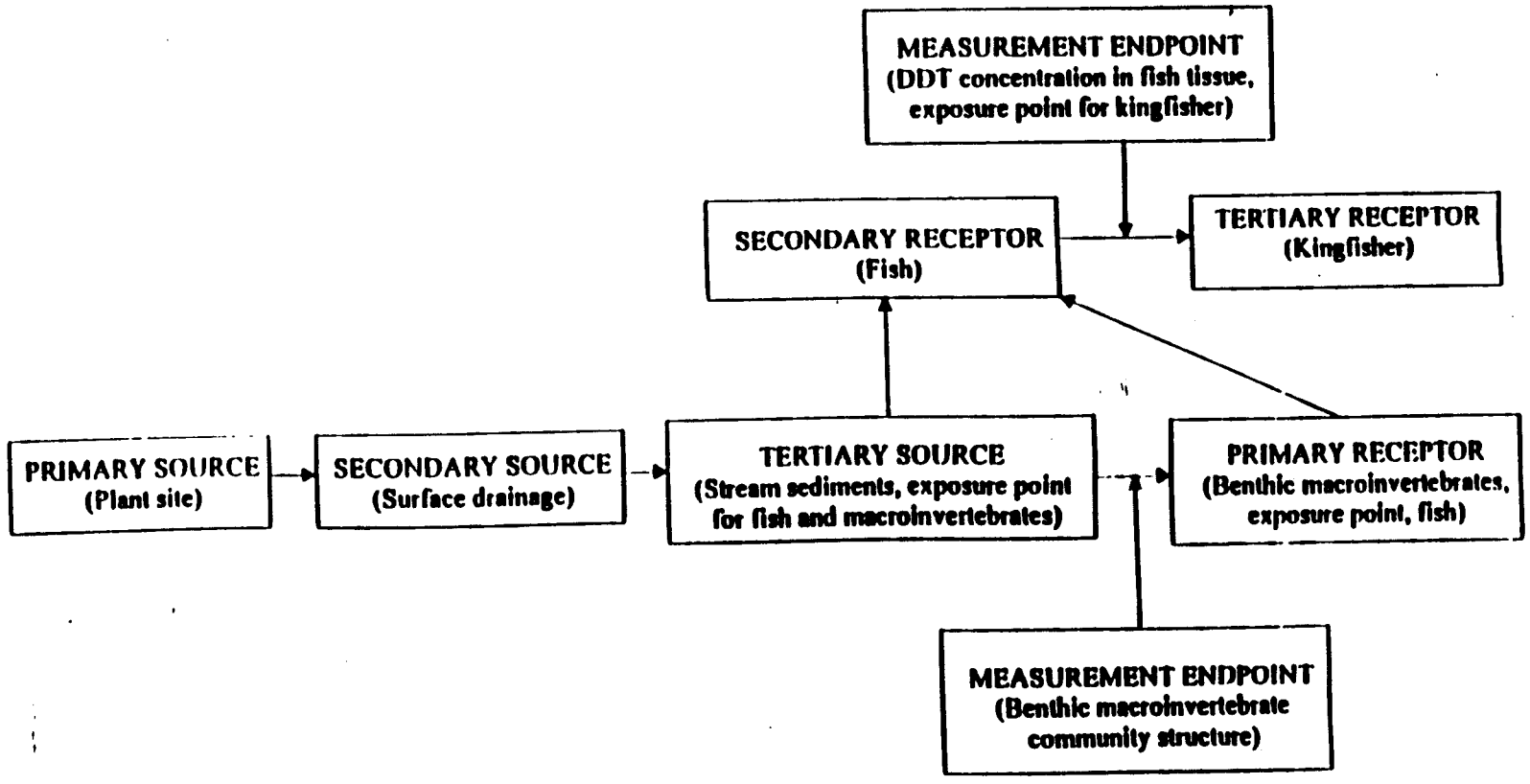
community level integrity, and/or habitat preservation. The site conceptual model must encompass the level of **biological organization appropriate for the assessment endpoints** for the site. A model that accomplishes this objective may use assumptions or model parameters that **may or may not be biologically "accurate" for that particular site, but which are representative of a group of organisms or ecosystem components encompassed by the assessment endpoint.** The intent of the model is not to be biologically "accurate" as much as it is to be systematic, representative, and conservative **(with uncertainties tending to be one-directional) to ensure** that the **assessment endpoints** at the site will be adequately protected.

The existence of contaminant source areas, or "hot spots", frequently requires a risk assessor to use assumptions that might not be biologically accurate. However, conservative assumptions should ensure that the risk posed by these areas is identified in the ecological risk assessment.

4.2 DEVELOPMENT OF EXPOSURE PATHWAY MODEL

Based on the information obtained from **Steps 1 and 2 of the ecological risk assessment process**, knowledge of the contaminants present, and the results of **Step 3**, a model is developed of the contaminants' fate and transport through the ecosystem to **receptors that reflect the** assessment endpoints (see **Example Box 4-3**).

EXAMPLE BOX 4-3
DDT Site: Conceptual Model



Conceptually, the contaminant flow diagram (or exposure pathways) originates at the primary contaminant source(s) and identifies primary release mechanisms and contaminant transport routes. The release and movement of the contaminants can create secondary sources (e.g., contaminated sediments in a river; see Example Box 4-4). These source/release couplets continue through the ecosystem, leading to the receptors associated with the assessment endpoints for the site. For well-defined assessment endpoints, the flow diagram will follow a logical sequence of steps. A source/release couplet that does not lead to a species or group of species associated with the proposed assessment endpoint indicates that either:

(1) There is an incomplete exposure pathway to the proposed assessment endpoint; or

(2) There are missing source/release couplets necessary to complete the pathway.

If case (1) is true, the selected assessment endpoint should be reevaluated to determine if it is an appropriate endpoint. If it is an appropriate endpoint, then there are no ecological risks from that exposure pathway. If case (2) is true, then additional effort may be needed to evaluate contaminant fate and transport at the site. Failure to identify a complete exposure pathway that does exist at the site can result in incorrect conclusions or in extra time and effort being expended on a supplementary investigation to the ecological risk assessment.

EXAMPLE BOX 4-4
DDT Site: Exposure Pathway Model

An abandoned pesticide production facility released DDT to soils through poor handling practices. Due to erosion of contaminated soils, DDT migrated to stream sediments. The contaminated sediments may affect benthic organisms through direct contact or ingestion. Benthic organisms that have accumulated DDT can be consumed by fish, and fish that have accumulated DDT can be consumed by piscivorous birds. This example illustrates how the contaminant transport is traced from the primary source to a secondary source and from there through a food chain to an exposure point that can affect the assessment endpoint.

Once the exposure pathways have been identified, the next step is to identify what measures can be used to infer effects on the assessment endpoint, as described in the next section.

4.3 DEVELOPMENT OF MEASUREMENT ENDPOINTS

Measurement endpoints are defined as "a measurable ecological characteristic that is related to the valued characteristic chosen as the assessment endpoint" (U.S. EPA, 1992a). Measurement endpoints are frequently numerical expressions of observations (e.g., toxicity test results, community diversity measures) that may be compared statistically to detect adverse responses to a site contaminant. The relationship between measurement and assessment endpoints must be clearly described within the conceptual model and based on scientific evidence or judgment. This is critical because it is not unusual for assessment and measurement endpoints to differ because the assessment endpoint cannot be measured directly or has poor resolution (i.e., low signal-to-noise ratio).

If a measurement endpoint is mistaken for an assessment endpoint, the misperception can arise that Superfund is basing a remediation on an arbitrary or esoteric justification. For example, protection of a few invertebrate and algal species may be mistaken as the basis for a remedial decision, when the actual decision basis is the protection of the aquatic community as a whole, as indicated by a few sensitive invertebrate and algal species.

Each measurement endpoint should represent the same exposure pathway and toxic mechanism of action as the assessment endpoint it represents. Otherwise, irrelevant exposure pathways or inappropriate toxic mechanisms may be evaluated.

The measurement endpoints selected may be directly assessed in the site investigation (Step 6), or evaluated in Step 7 using data collected in Step 6. There are typically limited numbers of measurement endpoints that are potentially appropriate for any given circumstance. Measurement endpoints should not be confused with the measurement of exposure point concentrations. For example in Example Box 4-5, the measurement endpoint (eggshell thinning) is not actually measured, it is the exposure point (i.e., the DDT concentration in forage fish) that is measured in the field investigation. Examples of typical measurement endpoints include mortality, growth, or reproduction in toxicity tests; individual abundance; number of species; and presence or absence of indicator taxa in field surveys of existing impacts.

The most appropriate measurement endpoint(s) for an assessment endpoint depends on the exposure pathway as well as the ecotoxicity of the contaminant. Measurement endpoints in field studies or toxicity tests should be evaluated according their ability to attribute the measurement endpoint response to the contaminant(s) being studied. In other words, can causal links be made between site contaminants and the measurement endpoint response? In addition, statistical considerations, such as sample size, must be considered in selecting the measurement endpoints.

EXAMPLE BOX 4-5
DDT Site: Maintaining Exposure Pathways in Measurement Endpoint Selection

In the DDT site example, it was noted that breeding mallard ducks also occurred at the site. Because the measurement endpoint included eggshell thinning, it was suggested that the eggs be collected from the duck nests and that eggshell thickness be measured to directly evaluate impacts of DDT on water birds at the site. While the direct measurement of eggshell thickness seems acceptable conceptually, the complete exposure pathway to piscivorous birds, which includes multiple trophic levels and the opportunity for DDT to biomagnify in a food chain, is lost. Mallards do not feed on fish, instead they consume invertebrates and plant materials. Although the invertebrates are likely to accumulate DDT from the sediments, fish that feed on the invertebrates are likely to accumulate even higher concentrations of DDT. Thus, mallards are likely to be exposed to lower concentrations of DDT in their diet than are piscivorous birds, and therefore may not exhibit eggshell thinning at environmental concentrations of DDT that would cause eggshell thinning in piscivorous birds. Thus, if the eggshells of mallards did not exhibit thinning, no conclusions could be drawn about risks of eggshell thinning in piscivorous birds.

4.3.1 SPECIES/COMMUNITY/HABITAT CONSIDERATIONS

The function of a measurement endpoint is to represent the assessment endpoint for the site. The measurement endpoint must allow clear inferences about potential changes in the assessment endpoint. Whenever assessment and measurement endpoints are not the same (which usually is the case), measurement endpoints should be selected to include risks to the populations, species, or groups included in the assessment endpoint that cannot be directly measured. In other words, the measurement endpoint should be representative of the site but not lead to an underestimate of the risk to the assessment endpoint.

Assessment endpoints can be limited to one species (e.g., maintaining the population of a threatened or endangered species, or of a species known to be particularly sensitive to a site contaminant). Assessment endpoints more frequently encompass a group of species or populations with some common characteristics, such as a specific exposure route or contaminant sensitivity. Assessment endpoints also can encompass the integrity or maintenance of an entire community or ecosystem. In selecting a measurement endpoint, the species and life stage, population, or community chosen should be the one(s) most affected by the contaminant for the assessment endpoint in question. For species and populations, this selection is based on a review of the species' life history, habitat utilization, behavioral characteristics, or physiological

parameters. For communities, careful evaluation of the contaminant fate and transport in the environment is essential.

4.3.2 Relationship of the Measurement Endpoint to the Contaminant of Concern

Additional criteria to consider when selecting measurement endpoints are inherent properties (such as the physiology or behavior characteristics of the species) or life history parameters that make a species most useful in evaluating the effects of site-specific contaminants.

Some species have been identified as being particularly sensitive to certain contaminants. For example mink have been identified as sensitive to PCB exposure for physiological reasons. Species that rely on quick reactions or behavioral responses to avoid predators may be particularly sensitive to contaminants affecting the central nervous system, such as mercury.

For example, *Chironomus tentans* (a species of midge that is used as a standard sediment toxicity testing species in the larval stage) is considered more tolerant of metals contamination than is *C. riparius*, a similar species. To assess the effects of exposure of benthic communities to metal-contaminated sediment, *C. riparius* may be the better species to use as a toxicity test organism, to provide a more conservative estimate of ecological risk.

EXAMPLE BOX 4-6
DDT Site: Indirect Effects

One effect of chronic DDT exposure on some organisms is to reduce their ability to escape predation. Thus, DDT indirectly increases the mortality rate of these organisms by making them more susceptible to predators (Cooke 1971, Krebs et al., 1974). This effect of DDT on prey organisms can also have an indirect consequence for the predators. If predators are more likely to capture the more contaminated prey, the predators could be exposed to DDT at levels higher than represented in the average prey population.

4.3.3 Mechanisms of Ecotoxicity

When selecting a measurement endpoint, the mechanism of toxicity of the contaminants should be reviewed. This is to ensure that the measurement endpoint is in fact measuring the same toxicity response that is of concern to the assessment endpoint.

A contaminant may exert an adverse ecological effect through many means. First, a contaminant might affect an organism immediately (acutely) or over an extended

HIGHLIGHT BOX 4-1
Terminology and Definitions

In the field of ecotoxicology there historically have been multiple definitions for some terms, including definitions for direct effects, indirect effects, acute effects, chronic effects, acute tests, and chronic tests. This multiplicity of definitions has resulted in misunderstandings and inaccurate communication of study designs. Definitions of these and other terms, as they are used in this document, are provided in the glossary. When consulting other reference materials, the user should evaluate how the authors are defining terms.

period of time (chronically). Second, the effect of a contaminant may be lethal (killing the organism) or sublethal (causing adverse effects other than death, such as reduced growth, behavioral changes, etc.). Sublethal effects can reduce an organism's life span or reproductive success. For example, if a contaminant impairs vision in a visual predator, the predator may not be able to hunt well enough to survive or provide for its offspring. Third, a contaminant may act directly or indirectly on an organism. Direct effects include lethal or sublethal effects by the chemical on the organism. Indirect effects occur when the contaminant damages the food or habitat of the organism.

Some contaminants are effectively transferred through food chains, while other contaminants are not. To illustrate this point, copper and DDT are compared in Example Box 4-7.

EXAMPLE BOX 4-7
Copper and DDT Sites

Copper can be toxic in aquatic systems or to terrestrial plants. However, it is an essential nutrient, and concentrations within an organism are normally regulated. For this reason, copper tends not to accumulate in organisms or biomagnify in food chains, and thus tends not to reach levels high enough to cause adverse responses through food chain transfer to upper-trophic-level organisms. In contrast, DDT, a contaminant that accumulates in fatty tissues, can biomagnify in many food chains. Upper-trophic-level species (such as predatory birds) are therefore likely to be exposed to higher levels of DDT through their prey than are lower-trophic-level species in the ecosystem.

Mechanisms of ecotoxicity and exposure pathways have already been considered during problem formulation and identification of the assessment endpoints. However, toxicity issues are revisited throughout the development of the site conceptual model in order to determine the proper exposure pathway(s) and to select appropriate measurement endpoints.

4.3.4 FIELD STUDY METHODOLOGY CONSIDERATIONS

There are a limited number of fundamental approaches currently available for conducting site-specific field investigations on ecological effects. These fundamental approaches are: (1) bioaccumulation and field tissue residue studies; (2) population/community evaluations; and (3) toxicity testing. A thorough understanding of the strengths and limitations of each approach is necessary to properly design any investigation. None of the methods can be successful without supportive information. In all cases, the development of an exposure-response relationship is important for evaluating cleanup options; thus, selected methods are typically applied to a contamination gradient. The following subsections present a starting point for selecting an appropriate approach to a site ecological investigation.

4.3.4.1 Bioaccumulation and Field Tissue Residue Studies

Usually, the species upon which an assessment endpoint is based cannot or should not be collected and analyzed for contaminant levels. Not only are there limited data relating tissue residue levels to adverse effects, but collection of many individuals could result in more harm to the local population than the contaminants might cause. Instead, levels of contamination in the food of species of concern should be estimated or measured.

The degree to which a contaminant is transferred through a food chain can be evaluated in several ways. The most common type of study reported in the literature is a contaminant bioaccumulation (uptake) study. Bioaccumulation values obtained from a literature search can be used to evaluate contaminant accumulation and food chain transfer at a Superfund site. Because many environmental factors influence the degree of bioaccumulation, sometimes by several orders of magnitude, the most conservative (i.e., highest) bioaccumulation factor reported in the literature should be used in the absence of site-specific information (as described in the discussion of the preliminary risk calculation in Step 2, Chapter 2). As stated previously, the selection of consistently conservative assumptions should result in the uncertainties in the ecological risk assessment being in one direction (i.e., the actual risk should be less than that calculated). To reduce the uncertainty associated with using a literature value to represent the site, a site-specific tissue residue study must be conducted.

A tissue residue study generally is conducted on organisms that are in the exposure pathway (i.e., food chain) associated with the assessment endpoint. Contaminant concentrations are measured in environmental media at the same locations at which the organisms are collected. Data seldom are available to link tissue residue levels to adverse effects on the contaminated organisms or on the consumers of those organisms. Instead, toxicity studies usually associate effects with the administered dose (or data that can be converted to an administered dose). Thus, the purpose of a field tissue residue study usually is to measure contaminant concentrations in foods consumed by the species associated with the assessment endpoint. This measurement minimizes the uncertainty associated with estimating a dose (or intake) to that species,

particularly in situations in which several media and trophic levels are in the exposure pathway.

EXAMPLE BOX 4-8
DDT Site: Tissue Residue Studies

In **the DDT site example (Appendix A)**, a forage fish **(e.g., creek chub)** will be collected at several locations with known DDT concentrations in sediments. The forage fish will be analyzed for body burdens of DDT, and a relationship between the sediment DDT levels and the forage fish DDT levels will be established. The forage fish DDT concentrations can be used to evaluate the **DDT** threat to **piscivorous birds** feeding on the forage fish at each location. **Where** potential threats exist from a concentration **measured** in forage fish, **the corresponding sediment contamination levels can be determined. These sediment DDT levels then can be used to derive a cleanup level that would reduce threats of eggshell thinning to piscivorous birds.**

The concentration of a contaminant(s) in the primary prey/food item also must be linked to an exposure concentration from a contaminated medium **(i.e., soil, sediment, water)**, because it is the medium, **not the food chain**, that will be remediated. Co-located samples of the **contaminated** medium **must** be collected **in the same area as the tissue samples representing exposure points** to establish a correlation between the **tissue residue levels and contamination levels in** the medium under evaluation. These studies are most effective if conducted over a range of contaminant concentrations ("**i.e., using a** gradient approach"). **In addition, tissue residues from sessile organisms (e.g., rooted plants, clams) are easier to attribute to specific contaminated areas than tissue residues from mobile organisms (e.g., fish).**

Although it may seem obvious, it is important to confirm that the organisms examined for tissue residue levels are in the exposure pathways of concern established by the conceptual model. Food items targeted for collection should be those that constitute a large portion of the diet of the species of concern (e.g., new growth on maple trees as a food source for deer, rather than cattail tubers) and/or represent pathways of maximum exposure. If not, erroneous conclusions or study delays and added costs can result. Because **specific organisms often can only be captured in one season,** the timing of the study may be critical, and its failure may result in serious site management difficulties.

There are numerous factors that must be considered when selecting a species **in which to measure contaminant residue levels. Several investigators have discussed** the "ideal" characteristics of **the species to be collected and analyzed.** Philips (1977, 1978) and Butler (1971) recommend that the species selected should be:

1. Able to accumulate the chemical of concern without being adversely affected by the levels encountered at the site;

2. Sedentary (small home range) in order to be representative of the area of collection;

3. Abundant in the study area;

4. Sufficiently long-lived to allow for sampling more than one age class;

5. Of reasonable size to give adequate tissue for analysis (10 grams for organic analysis, 0.5 gram for metal analysis); and

6. Easy to sample and hardy enough to survive in the laboratory (allowing for the organisms to eliminate some contaminants from their bodies prior to analysis, if desired, and allowing for laboratory studies on the uptake of the contaminant).

It is usually not possible or necessary to find an organism that fulfills all of the above requirements. The selection of an organism for tissue analysis should balance these characteristics with the hypotheses being tested (from problem formulation), knowledge of the contaminants fate and transport, and the practicality of using the particular species. In the following sections, several of the factors mentioned above are described in greater detail.

Ability to Accumulate the Contaminant

The objectives of a tissue residue study are (1) to provide site-specific estimates of exposure to higher-trophic-level organisms, and (2) to relate tissue residue levels to concentrations in environmental media (i.e., in soil, sediment, or water). Ideally, the species selected for collection and tissue analysis should be ones that can accumulate a contaminant(s) without being adversely affected by the levels encountered in the environment. While it is difficult to evaluate whether a population is affected by accumulation of a contaminant, it is important to determine the level of exposure. Exposure that results in adverse responses may alter the animal's feeding rates or efficiency, diet, degree of activity, or metabolic rate. Each of these factors can influence the animal's daily intake or accumulation of the contaminant. For example, a contaminant that causes nausea at low doses may result in less food being eaten.

Consideration of the physiology and biochemistry of the species selected for residue analysis also is important. Some species can metabolize certain organic contaminant(s) (e.g., fish can metabolize PAHs). If several different types of prey are consumed by a species of concern, it would not be appropriate to analyze a prey species that can biodegrade the contaminant if other prey species cannot biodegrade the contaminant.

Home Range

When selecting species for residue analyses, one should be confident that the contaminant levels found in the organism depend on the contaminant levels in the environmental media under evaluation. Otherwise, valid conclusions about ecological risks posed by contaminants at the site cannot be drawn. The home range and movement patterns of a species are important in making this determination. Organisms do not utilize the environment uniformly. For species that have large home ranges or are migratory, it is frequently difficult to evaluate potential exposure to contaminants at the site. Attribution of contaminant levels in an organism to contaminant levels in the surrounding environment is easiest for species with small home ranges and limited movement patterns. Examples include young-of-the-year fish, burrowing crustacea (such as fiddler crabs or some crayfish), and small mammals.

Species also should be selected for residue analysis to maximize the overlap between the area of contamination and the species' home range or feeding range. This provides a conservative evaluation of potential exposure levels. The possibility that a species' preferred foraging areas within a home range overlap the areas of maximum contamination also should be considered.

Size of Species Population

A species selected for tissue residue analysis should be sufficiently abundant at the site that adequate numbers (and sizes) of individuals can be collected to support the tissue mass requirements for chemical analysis and to achieve the sample size needed for statistical comparisons. The animals actually collected should be not only of the same species, but also of similar age or size. The practicality of using a particular species is evaluated in Step 5.

Size/Composites

When selecting species in which to measure tissue residue levels, it is optimum to have animals large enough for individual analysis, without having to pool individuals. However, composite samples may be used if individuals from the species selected cannot yield sufficient tissue for the required analytical methods. If composites are used, they should be made up of members of the same species, sex, size, and age. There are some instances in which the study design may dictate composites, such as when collecting organisms that represent the food supply of a species under evaluation.

Summary

Although it may be difficult to meet all of the suggested criteria for selecting a species for tissue residue studies, an attempt should be made to meet as many criteria as possible. No formula is available for ranking the factors in order of importance within a particular site investigation. However, a key criterion is that the organism be sedentary or have a limited home range. It is difficult to connect site contamination to organisms

that migrate over great distances or that have extremely large home ranges. When a wide-ranging species is used, the uncertainty associated with site-specific exposure estimate becomes extremely large. Animals that have limited movement, at least within the confines of the site area, are better suited for evaluation of contaminant uptake.

The preceding subsections introduce only some of the factors that can influence contaminant bioaccumulation. Further information is available from the literature (e.g., Phillips, 1977, 1978).

4.3.4.2 Population/Community Evaluations

Population/community evaluations, or field surveys, are potentially useful measurement endpoints for both a contaminant that is toxic through direct exposure to the contaminated medium and for one that bioaccumulates in food chains. In either case, careful consideration must be given to the mechanism of contaminant effects. Since population/community evaluations are "impact" evaluations, they are not predictive. The release of the contaminant must have already occurred and exerted an effect in order for the population/community evaluation to be an effective tool.

When population/community evaluations are coupled with toxicity testing and media chemistry, the procedure is referred to as the triad approach (Chapman et al., 1992; Long and Chapman 1985). This method has been effective in defining the area affected by contaminants in sediments of several large bays and estuaries.

Population and community surveys evaluate the current status of an ecosystem, often using several measures of population or community structure (e.g., population standing biomass crop, species diversity). The most commonly used measures include number of species and abundance of organisms in an ecosystem. These studies are useful for evaluating the impact of a contaminants already released into the environment. However, these evaluations would not reflect changes in top predator populations affected by bioaccumulated substances at concentrations that may not affect species lower in the food chain. In addition, some populations, most notably insects, can develop a tolerance to contaminants (particularly pesticides); in these cases, a population/community survey may be an ineffective tool for the evaluation of existing impacts. While population/community evaluations can be of great use, it is necessary to consider the level of effort needed to conduct them. Several types of population/community evaluations (benthic macroinvertebrate surveys, fish community evaluations, and terrestrial plant community evaluations) are identified below.

Benthic macroinvertebrate surveys are the most commonly conducted population/community evaluations. There are numerous method manuals (e.g., U.S. EPA 1989c) and publications that describe the technical procedures for conducting these studies.

In certain instances, fish community evaluations have proved to be useful at Superfund sites. However, these investigations typically are more labor-intensive and

costly than a comparable macroinvertebrate study. **In addition, they generally are not sensitive measures of the effects of contamination.**

Terrestrial plant community evaluations have been used to a limited extent at Superfund sites. In these cases, it is important to include information about historical land use and physical habitat disruption in the uncertainty analysis.

Population- and community-level studies can be valuable, but **several factors can confound the results. For example, many fish and small mammal** populations normally peak and crash in relation to population density, food availability, and other factors. Vole populations have been known to reach thousands of individuals per acre and then decline to as low as several individuals per acre the following years without an **identifiable** external stressor **(e.g., low food supply)**. It is important that the "noise of the system" be evaluated so that the impacts attributed to chemical contamination at the site **are not actually the result of a different,** "natural" factor. Populations located relatively close to each other can be affected independently: one may undergo a crash while another is peaking. Physical characteristics of a site can isolate populations **so that one population level is not a good indicator of the other; for example,** a paved highway may be as effective a "natural" barrier as a river, **and populations on either side may fluctuate independently.** Failure to evaluate these issues may result in erroneous conclusions. The level of effort required to resolve some of these issues may make population/community evaluations impractical in some circumstances.

4.3.4.3 Toxicity Testing/Direct Toxins

The bioavailability and toxicity of site contaminants can be tested directly with toxicity tests. As with other **methods,** it is critical that the **media tested are in** exposure pathways **relevant to the assessment endpoint.** If the site conceptual model involves exposure **of benthic invertebrates** to contaminated sediments, then a solid-phase toxicity test using contaminated sediments (as opposed to a water-column exposure **test**) and an infaunal species would be appropriate. In addition, **the species tested and the responses measured must be compatible** with the mechanism of toxicity. **For example, if a contaminant primarily causes damage to vertebrate kidneys,** the use of daphnids (which do not have kidneys) would be inappropriate. Some common site contaminants are not **toxic to most organisms at the same environmental concentrations that threaten top predators because the contaminant biomagnifies in food chains (e.g., PCBs);** in these cases, toxicity tests are not an appropriate means of evaluating their ecological threat.

There are numerous EPA methods manuals and ASTM guides and procedures for conducting toxicity tests **(see references in the Bibliography).** While documented methods exist for a wide variety of toxicity tests, it is critical to evaluate what a particular toxicity test measures and, just as important, what it does not measure. Questions to consider when selecting an appropriate toxicity test include:

1. What is the **mechanism of toxicity** of the contaminant(s)?

2. What contaminated media are being evaluated (water, soil, sediment)?

3. What toxicity test species are available to test the media being evaluated?

4. What life stage of the species should be tested?

5. What should the duration of the toxicity test be?

6. Should the test organisms be fed during the test?

There is a limited number of toxicity tests that are readily available for testing environmental media. Many of the aquatic toxicity tests were developed for the regulation of aqueous discharges to surface waters. These tests are useful tools, but consideration of the purpose of the test is necessary.

New toxicity tests are continually being developed, and they can be of value in designing a site ecological risk assessment. However, when non-standard tests are used, complete documentation of the specific test procedures is necessary to support use of the data.

4.5 SCIENTIFIC/MANAGEMENT DECISION POINT (SMDP)

The completion and approval of the ecological risk assessment work plan and sampling and analysis plan should coincide with an SMDP. Within this SMDP are: (1) agreement about the exposure pathways; (2) selection of measurement endpoints; (3) selection of specific investigation methodology; and (4) selection of data reduction and interpretation methods. The work plan or sampling and analysis plan also should specify how inferences will be drawn from the measurement to the assessment endpoints.

4.6 SUMMARY

At the conclusion of the problem formulation and conceptual model phase of the ecological risk assessment, there will be an approved work plan and sampling and analysis plan. These plans may be part of a larger work plan and sampling and analysis plan that are developed to meet other remedial investigation needs, or they may be separate documents. When possible, any field sampling efforts for the ecological risk assessment should overlap with other site data collection efforts to reduce sampling costs and to prevent redundant sampling.

The conceptual model should describe the ecological concerns and provide a clear outline of the study design for addressing the ecological issues. The work plan and/or the sampling and analysis plan should specify the methods by which the collected data will be analyzed. The plan(s) should include all food chain exposure model parameters, data reduction techniques, data interpretation methods, and statistical analyses.

CHAPTER 5
STEP 5: SITE ASSESSMENT FOR SAMPLING FEASIBILITY

CHAPTER OVERVIEW

The function of the site assessment step is to verify that the study design for the risk assessment as specified in the workplan and sampling and analysis plan is appropriate and implementable at the site. During the site assessment, the testable hypotheses, exposure pathway models, measurement endpoints, and study design are evaluated for their appropriateness and implementability. The assessment endpoint, however, should not be under evaluation in this step as the appropriateness of the assessment endpoint should have been resolved earlier in the process. If the assessment endpoint is changed at this step, the process must return to Step 3, because the entire process leading to the actual site investigation (Step 6, the next step) assumes the selection of the correct assessment endpoints.

Most of the information necessary for this step should have been gathered during earlier steps, including the ecological checklist, although some new information may need to be collected.

5.1 PURPOSE OF THE SITE ASSESSMENT

The primary purpose of this step is to ensure that the samples specified by the sampling and analysis plan can actually be collected. A species that will be associated with a measurement endpoint and/or exposure point concentration will have been observed at the preliminary site characterization or noted during previous site visits. During this step, previously obtained information will need to be verified and the feasibility of sampling will need to be checked by a site visit. Preliminary sampling will determine if the species is present and -- equally important -- collectable using the sampling and analysis plan.

This site assessment also allows for final confirmation of the habitats that exist on or near the site. Habitat maps are verified a final time, and interpretations of aerial photographs are checked. Final assessments of the qualifications of habitats and species for protection under State and Federal laws are conducted.

Final decisions on reference areas also should be made in this step. The reference area should be as similar as is practical to the part of the site being investigated. Parameters to be evaluated for similarity include, but are not limited to: habitat, species potentially present, soil and sediment characteristics, and water quality

parameters. If several on-site habitats are being investigated, then several reference areas may be required. Reference areas should be as free of site-related contaminants as practical and should not contain additional contamination that may affect the risk assessment.

5.2 DETERMINING SAMPLING FEASIBILITY

When sampling biota, it is difficult to predict what level of effort will be necessary to obtain an adequate number of individuals of the required size. Population swings are not uncommon and may be attributable to "natural" factors, such as density effects, drought, and flooding. The site investigation should be conducted as soon as possible after the site assessment, and during the same growing season, to limit the complicating effect of those uncontrollable variables. For example, evaluation of current population density may indicate to the investigator that 400 trap-nights instead of 50 are necessary to collect the required number of small mammals in the specified time.

Sampling methods for abiotic media should also be tested. There is a wide variety of sampling devices and methods, and it is important to use the most appropriate. For example:

- When sampling a stream's surface water, if the stream is only three inches deep, collecting the water directly into 32-ounce bottles would not be practical.
- When analyzing filterable materials, the high algae content of a pond may make it almost impossible to filter water through a 0.45μm filter.
- Sampling the substrate in a stream may be desirable, but if the substrate is bedrock covered by a film of particulates, it may not be feasible.
- While extent-of-contamination sampling may be conducted in phases if difficulties arise within the RI/FS, abiotic (exposure media) and biotic samples must be collected simultaneously because the interactions (both temporal and spatial) between the matrix to be remediated and the biota are crucial to the development of a field dose-response relationship.

A dose-response relationship between contamination and biota response is a key component of establishing causality. A failure in the collection of one sample, or the collection of temporally uncoordinated samples, can significantly affect the interpretation of the data.

These and other problems associated with the practical implementation of sampling must be resolved prior to the full site investigation (Step 7). Assessing the feasibility of the sampling plan before the site investigation begins saves costs in the

long term because it minimizes the chances of failing to meet data quality objectives during the site investigation.

Sampling locations need to be checked to make sure that they are appropriately described and placed within the context of the sampling plan. Directions for a sediment sample "to be taken 5 feet from the north side of stream A," could cause confusion if the stream is only 4 feet wide, or if the sampler doesn't know if the sample should be taken in the stream, or 5 feet away from the edge of the stream. All samples should be checked against the intended use of the data to be obtained.

Contaminant migration pathways may have changed, either due to natural causes (e.g., storms) or during site remediation activities (e.g., erosion channels may have been filled or dug up to prevent further migration of contaminants). Channels of small or large streams, brooks, or rivers may have moved; sites may have been flooded. All of the assumptions of the migration and exposure pathways need to be verified prior to the site investigation. If a contaminant gradient is necessary for the sampling design, it is important to verify that the gradient exists and that the range of contaminant concentrations is appropriate. A range of contamination that causes no impacts at the highest concentration measured has as little value as a gradient that kills everything at the lowest concentration measured; in either case, the gradient would not provide useful exposure-response information. The gradient determination will require chemical sampling, but a screening-level evaluation may be adequate.

All pathways for the migration of contaminants off-site should be evaluated, such as windblown dust, surface water runoff, erosion, and drainage ditches. Along these pathways, a gradient of decreasing contamination with increasing distance from the site may exist. Site-specific ecological evaluations and risk assessments can be more useful to risk managers if gradients of contamination can be located and evaluated.

Example Boxes 5-1 and 5-2 describe the site sampling feasibility assessment step for the copper and DDT sites illustrated in Appendix A.

Note that the scope of the site assessment differed for the two sites. For the DDT site, a modification to the study design was necessary. For both sites, the issues were resolved and a sign-off was obtained at the site assessment SMDP.

Exposure pathways must be verified. Any change in measurement endpoints will require that exposure pathways to the new measurement endpoint be checked. The new measurement endpoint must fit into the established conceptual model. Changes to measurement endpoints may require revision of the conceptual model and agreement to the changes at the SMDP following this step. The agreed-upon conceptual model should be modified and approved by the same basic group of individuals who developed it.

EXAMPLE BOX 5-1
Copper Site: Assessing Sampling Feasibility

Copper was released from a seep area of a landfill adjacent to a small pond; the release and resulting elevated copper levels in the pond are of concern. The problem formulation and conceptual model stated that the assessment endpoint was the maintenance of a typical pond community for the area, including the benthic invertebrates and fish. Toxicity testing was selected to evaluate the potential toxicity of copper to aquatic organisms. Three toxicity tests were selected: a 10-day solid-phase sediment toxicity test (with the amphipod *Hyalella azteca*), and two water column tests (i.e., the 7-day growth test with the green alga *Selenastrum capricornutum* and the fathead minnow 7-day larval growth test). The study design specified that sediment and water for the toxicity tests would be collected at the leachate seeps known to be at the pond edge, and at three additional equidistant locations transecting the pond (including the point of maximum pond depth). The pond contains water year-round; however, the seep flow depends on rainfall. Therefore, it is only necessary to verify that the leachate seep will be active at the time of sampling.

5.3 SCIENTIFIC/MANAGEMENT DECISION POINT (SMDP)

The SMDP for the site assessment is relevant only if alterations to the work plan or the sampling and analysis plan are necessary for the implementation of the site investigation. In the worst cases, changes in the measurement endpoints may be necessary, with corresponding changes to the testable hypotheses and sampling design. Any new measurement endpoints must be evaluated according to their utility for inferring changes in the assessment endpoints and their compatibility with the site-conceptual model (from Steps 3 and 4). Loss of the relationship between measurement endpoints and the assessment endpoints, the testable hypothesis, and the site conceptual model will result in a failure to meet study objectives.

Depending on the site circumstances and the magnitude of the alterations in the sampling and analysis plan, the SMDP may be a verbal agreement, or it may require a formal, written agreement to the modifications. At a minimum, the changes to the proposed investigation must be made in consultation with the risk manager and the risk assessors. The risk manager must understand what changes have been made and why, and must ensure that the risk management decisions can be made from the information that the new study design can provide. The risk assessors must be involved to ensure that the assessment endpoints and testable hypotheses are still being addressed.

Despite one's best efforts to conducting a sound site assessment, unexpected circumstances may still make it necessary for changes of the sampling design to be

EXAMPLE BOX 5-2
DDT Site: Assessing Sampling Feasibility

For the stream DDT site, the assessment endpoint was protection of piscivorous birds from adverse reproductive effects. The conceptual model included the exposure pathway of sediment to forage fish to the kingfisher. The measurement endpoint selected was tissue residue levels in creek chub, which could be associated with contaminant levels in sediments. Existing information on the stream contamination indicates that a gradient of contamination exists and that five specific sampling locations should be sufficient to characterize the gradient to the point where concentrations are unlikely to have adverse effects. The study design specified that 10 creek chub of the same size and sex be collected at each location. Each chub should be approximately 20 grams, so that minimum sample mass requirements could be met without relying on the use of composite samples for analysis. In addition, QA/QC protocol requires that 10 more fish be collected at one of the locations.

In this example, a site assessment is necessary to verify that a sufficient number of creek chub of the specified size are present to meet the sampling requirements. Stream conditions must be evaluated to determine what fish sampling technique will work at the targeted locations. A field assessment was conducted, and several fish collection techniques were used in order to determine which was the most effective for the site. Collected creek chub and other fish were examined to determine the size range available and whether the sex of the individuals could be identified.

The site assessment indicated that the creek chub may not be present in sufficient numbers to provide the necessary biomass for chemical analyses. Based upon these findings, a contingency plan was agreed to, which stated that both the creek chub and the longnosed dace (*Rhinichthys cataractae*) would be collected: If the creek chub were collected at all locations in sufficient numbers, then these samples would be analyzed and the dace would be released. If sufficient creek chub could not be collected but sufficient longnosed dace could, the longnosed dace would be analyzed and the creek chub released. If neither species could be collected at all locations in sufficient numbers, then a mix of the two species would be used; however, for any given site only one species would be used to make the sample. In addition, at one location, which preferably had high DDT levels in the sediment, sufficient numbers (20 grams) of both species would be collected to allow comparison (and calibration) of the accumulation between the two species.

adopted in the field during the site investigation stage. In these instances, a verbal approval of the changes is necessary.

5.4 SUMMARY

The site assessment step verifies that the selected assessment endpoints, testable hypotheses, exposure pathway model, measurement endpoints, exposure pathways, and study design from Steps 3 and 4 are appropriate and implementable at the site. By conducting a site assessment prior to the full site investigation, well-considered alterations can be made to the study design and/or implementation, if necessary. These changes will ensure that the ecological risk assessment meets the study objectives.

CHAPTER 6
STEP 6: SITE INVESTIGATION

CHAPTER OVERVIEW

The site investigation includes all of the field sampling and surveys that are conducted as part of the ecological risk assessment. The site investigation should be straightforward, following the work plan and sampling and analysis plan developed and tested in Steps 3 through 5.

The site investigation step of the ecological risk assessment should be straightforward. In Steps 3, 4, and 5, all issues related to the study design, data quality objectives, mechanisms for data reduction and interpretation as well as sample collection, should have been identified and resolved. The work plan should include the selected assessment endpoints, the testable hypotheses, and the site conceptual model. The sampling and analysis plan should include the data quality objectives and specify the necessary number, volume, and types of samples to be collected and the sampling techniques to be used. The sampling and analysis plan also should include the data reduction and interpretation techniques, since it is necessary to known how the data will be interpreted in order to specify the number of samples needed. The feasibility of the sampling design was tested in Step 5. Therefore, the sampling effort should be a direct implementation of the previously designed study.

In instances where unexpected conditions arise in the field that make the collection of specified samples impractical or impossible, the ecological risk assessment process should return to a site assessment mode (Step 5). Field efforts should not necessarily be halted, but decisions to change sampling procedure or design must be agreed to by the site manager and risk assessor or project-delegated equivalents.

Field modifications to study designs are not uncommon in field investigations. However, with a precise conceptual model accompanied by a study design that has specified data analyses, informed modifications to the sampling plan can be made to maintain compliance with the objectives of the study. In addition, contingency plans can be incorporated into the study design in anticipation of situations during the site investigation that may require modification.

EXAMPLE BOX 6-1
DDT Site: Fish Sampling Contingency Plan

At the DDT site where creek chub are to be collected for DDT tissue residue analyses, a contingency plan for the site investigation was developed. An alternate species, the longnosed dace, was specified in the expectation that, at one location or all locations, the creek chub may be absent at the time of the site investigation (see Example Box 5-2). These contingencies are prudent even when the site assessment indicates that the samples are obtainable.

CHAPTER 7
STEP 7: RISK CALCULATION

CHAPTER OVERVIEW

In risk calculation, the information on exposure and effects are integrated into a statement about risk to the assessment endpoints established during problem formulation. A weight-of-evidence approach is used to interpret the implications of different studies or tests for the assessment endpoints. In a well-designed study, data analysis should be straightforward because the procedures were established in the sampling and analysis plan. The risk characterization section of the baseline ecological risk assessment should include a presentation of the risk results and associated uncertainties.

As stated in the Preface, it is not within the scope of this document to provide a detailed guidance on the selection and utilization of the risk model parameters. The risk assessor and the risk manager must develop and agree upon the model, its assumptions, uncertainties, and interpretation in Steps 3 and 4. This is the function of the SMDPs within Steps 3 and 4. Unless the site investigation discovers new information, the risk assessment should move smoothly through the analysis phase, answering the questions from the testable hypotheses.

Through **Steps 3 and 4** of the ecological risk assessment, testable hypotheses were developed and studies were designed to investigate them. Within the study design, it was necessary to determine the level of test resolution and **statistical** power **desired** in order to determine the number of samples needed to adequately answer the stated questions. Data quality objectives were **specified; for example**, chemical detection limits were established for potentially-contaminated media, and the sample size grid for delineating the extent of contamination was **specified (U.S. EPA 1987b, c, 1990a).**

In a well-designed study, the data analyses **should be** routine, since the procedures were specified within the sampling and analysis plan. While it may be appropriate to investigate a data set for trends, outliers, or other statistical indicators, these investigations should be secondary to the specified data interpretations. Unless a specified data interpretation process is stated in the sampling and analysis plan **and followed during the risk calculation, biased, multiple, or inconsequential conclusions may be obtained.**

The calculations described in the preliminary risk calculation may be used directly in this step of the ecological risk assessment. At this step, however, site-specific data are used to replace many of the assumed parameter values for the preliminary risk calculation, thereby reducing the uncertainty in the risk calculations.

For some biological tests (e.g., toxicity tests, benthic macroinvertebrate studies), all or some of the data interpretation process may be outlined in existing documents, such as in toxicity testing manuals. However, in most cases, it will be necessary to provide details on how the data are to be interpreted for a site. While these data interpretation methods were described in the sampling and analysis plans, they should be presented in the risk calculation section of the baseline risk assessment report. For example, if the triad approach was used to evaluate contaminated sediments, the risk calculation section should describe how the three types of studies (i.e., toxicity test, benthic invertebrate survey, and sediment chemistry) are integrated to draw conclusions from the sediment triad.

For many Superfund ecological risk assessments, a weight-of-evidence approach will be used. This frequently will require that different types of data be evaluated together. These types of data may include toxicity test results, assessments of existing impacts on-site, or "true" risk calculations comparing estimated exposure doses with toxicity values from the literature. Balancing and interpreting the different types of data can be a major task. As indicated above, the strength of evidence provided by different types of tests and the precedence that one type of study may have over another should already have been determined during Steps 3 and 4. This will ensure that data interpretation is objective and not designed (i.e., biased) to support a preconceived answer.

Some presentations of risk information are more informative than others. Where full exposure-response functions were not available or developed, the quotient method of comparing an estimated exposure concentration to a threshold for response can be used, as in Step 2. Whenever possible, however, presentation of full exposure-response functions provides the risk manager with more information on which to base site decisions. This guidance has recommended the use of on-site contamination gradients to demonstrate on-site exposure-response functions. Where such data have been collected, they should be presented in the risk calculation section. The results of *in situ* toxicity testing or community survey data can be mapped along with analytic chemistry data to provide a clear picture of the relationship between areas of contamination and effects.

The risk calculation section should describe how inferences are made from the measurement endpoints to the assessment endpoints established in problem formulation. In addition, the causal evidence linking ecological effects with site-related contamination or physical alterations should be discussed. The uncertainties inherent in the final risk estimates also need to be described and quantified to the extent possible.

CHAPTER 8
STEP 8: RISK MANAGEMENT

CHAPTER OVERVIEW

Risk management at a Superfund site is the responsibility of the site risk manager, who must balance risk reductions associated with cleanup of contaminants with potential impacts of the remedial actions themselves. In Step 7, the risk assessor identified an ecological cleanup goal as a range between contamination levels identified as posing no ecological risk and the lowest contamination levels identified as likely to produce adverse ecological effects. In Step 8, the risk manager evaluates several factors in deciding whether or not to clean up to within that range.

Risk management is a distinctly different process from risk assessment (NRC, 1983; U.S. EPA, 1984). The risk assessment establishes that a risk is present and defines a range or magnitude of the risk. Risk management then evaluates the criteria for selection of the preferred remedy and, using information from the risk assessment and the listing of remedial options (e.g., in the feasibility study (FS)), ultimately allows the selection of a preferred remedy.[1]

Risk management decisions are the responsibility of the site manager (the risk manager), not the risk assessor. The risk manager must be involved in the risk assessment, as knowledge of the risk management options may frame the risk assessment. The risk manager must understand the risk assessment, including its uncertainties, and the level of resolution within the assessment. For example, a risk assessment based on mortality studies and impacts to a stream community should be given more weight than one based on a study of chronic response endpoints in a sensitive species and modeled food chain accumulation. In the first case, the study may document that impacts have occurred and identify the boundary of these impacts, whereas the second study may suggest that a potential for adverse response in the environment exists. The risk management decision in both cases may be to take an action; however, in the case of the impact study, not taking an action may require a greater justification.

The NCP describes criteria for removal actions in Section 300.415. Section 300.415(b)(2) lists the factors that "shall be considered in determining the appropriate removal action" as "(i) Actual or potential exposure to nearby human populations,

[1] The current criteria for the selection of a preferred remedy are likely to change with Superfund reauthorization; therefore, they are not listed here.

animals, or the food chain from hazardous substances or pollutants or contaminants; (ii) Actual or potential contamination of drinking water supplies or sensitive ecosystems; [and] (iii) Other situations or factors that may pose threats to public health or welfare or the environment."

NCP Section 300.430 (remedial investigation/feasibility study and selection of remedy states, "The purpose of the remedy selection process is to eliminate, reduce, or control risks to human health and the environment."

In addition, Section 300.430 of the NCP states that "...the lead agency shall conduct a site-specific baseline risk assessment to characterize the current and potential threats to human health and the environment that may be posed by contaminants migrating to ground water or surface water, releasing into air, leaching through soil, remaining in the soil, and bioaccumulating in the food chain. The results of the baseline risk assessment will help establish acceptable exposure levels for use in developing remedial alternatives in the feasibility study..." and "Alternatives shall be developed that protect human health and the environment by recycling waste or eliminating, reducing, and/or controlling risks posed through each pathway by a site."

The feasibility study uses the risk assessment in conjunction with the remedy selection criteria to achieve the goals stated above. However, ecological risk management must also take into account that ecological impacts may result from the implementation of the selected remedial option. Recognizing that the remedy can have a direct impact on the assessment endpoints is an important aspect of ecological risk management. Therefore, ecological risk management may require balancing between the residual risk (i.e., impact) posed by site contaminants after implementation of the selected remedy, and the impact of the selected remedy on the environment independent of the contaminant effect. The selection of the most appropriate ecologically based remedy however, may increase the residual liability at the site. Consideration of the environmental effects of the remedy itself may result in a decision to allow higher contaminant levels (for which responsible parties are liable) to remain on-site.

The selection of a remedial alternative may require tradeoffs between long-term risk and short-term impacts. The ecological risks posed by the "no action" alternative are the risks estimated by the baseline ecological risk assessment. For all other remedial options, there may be some ecological impact associated with the remedy. This impact might be anything from a short-term loss of the present habitat and community, to complete and permanent loss of the habitat and community. In the instances where ecological impacts will result from the remedy (e.g., dredging a wetland), the risk manager will need to compare the impacts of the remedy to the threats posed by the site contamination when selecting the appropriate site remedy.

The ecological risk assessment should set the limits or boundaries on potential risk at the site. The lower boundary of risk would be based on consistent-conservative assumptions and NOAEL values. The upper boundary would be based on observed impacts or predictions that ecological impacts could be occurring. This upper boundary

would be developed using consistent assumptions, site-specific data, LOAEL values, or an impact evaluation. The boundaries of potential risk under baseline conditions can be compared with the evaluation of the impact of the remedial options in the feasibility study to justify the preferred remedy. The preferred remedy should provide overall protection to the environment within the context of long- and short-term risks.

As indicated above, the selected remedial option may not remove all risk posed by in-place site contaminants. Thus, if residual levels of contaminants presumed to pose an ecological risk are left in place, there needs to be clear justification for the selected remedy. The risk manager should have a thorough understanding of the ecological risk assessment, including the uncertainties associated with the assumptions used. An understanding of potential adverse effects posed by residual levels of site contaminants and the statistical uncertainties associated with the risk assessment is critical in evaluating the overall protectiveness of any remedy.

The risk management decision should lead to an action that will result in residual contaminant levels that are above the risk assessment NOAELs and below the LOAELs. The cleanup goal need not be below the level at which the ecological risk assessment estimates that no risk exists, since remediation to this level would be excessive. Similarly, the target cleanup goal should not be above the level at which the risk assessment estimates that adverse ecological effects will reoccur. However, there may be specific instances in which the management decision is to clean up to contaminant levels outside this range if adequate justification for such a decision is provided.

GLOSSARY

This glossary includes definitions from several sources. A superscript number next to a word identifies the reference from which the definition was adapted (listed at the end of the Glossary).

Abiotic.[1] Characterized by absence of life; includes such factors as temperature. pH. humidity, and other physical and chemical influences.

Absorption Efficiency. A measure of the rate at which an organism absorbs a substance across exchange boundaries (e.g., gastrointestinal tract).

Absorbed Dose.[2] The amount of a substance penetrating the exchange boundaries of an organism after contact. Absorbed dose is calculated from the intake and the absorption efficiency.

Accumulation Rate (factor).[3] The ratio of the concentration of a contaminant in an organism to the concentration in the ambient environment at steady state.

Accuracy.[4] The degree to which a measurement reflects the true value of a variable.

Acute.[5] Having a sudden onset, lasting a short time. Of a stimulus, severe enough to induce a response rapidly. Can be used to define either the exposure or the response to an exposure (effect). The duration of an acute aquatic toxicity test is generally 4 days or less and mortality is the response usually measured.

Acute Response. The response (effect) of an organisms which has a rapid onset.. A rapid onset response commonly measured is mortality in toxicity tests.

Acute Tests. A toxicity test of short duration. typically 4 days or less, and usually of short duration relative to the lifespan of the test organism.

Administered Dose.[2] The mass of a substance given to an organism and in contact with an exchange boundary (i.e., gastrointestinal tract) per unit body weight per unit time (e.g., mg/kg-day)

Adsorption.[14] The surface retention of solid. liquid. or gas molecules, atoms, or ions by a solid. or liquid. as opposed to absorption. the penetration of substances into the bulk of the solid or liquid.

Area Use Factor. The ratio of an organism's home range, breeding range, or feeding/ foraging rage to the area of contamination or the site area under investigation.

Assessment Endpoint.[6] An explicit expression of the environmental value that is to be protected.

Benthic Community.[7] The community of organisms dwelling at the bottom of a river, lake, or ocean.

Bioaccumulation.[5] General term describing a process by which chemicals are taken up by an organism either directly from exposure to a contaminated medium or by consumption of food containing the chemical.

Bioassay.[5] Test used to evaluate the relative potency of a chemical by comparing its effect on living organisms with the effect of a standard preparation on the same type of organism. Bioassay and toxicity tests are not the same - see toxicity test.

Bioassessment. A general term referring to environmental evaluations involving living organisms. May include bioassays, community analyses, etc.

Bioavailability.[4] The degree to which a material in environmental media is assimilable by an organism.

Bioconcentration.[5] A process by which there is a net accumulation of a chemical directly from an exposure medium into an organism.

Biodegrade.[15] Decompose into more elementary compounds by the action of microorganisms such as bacteria.

Biomagnification.[5] Result of the process of bioaccumulation by which tissue concentrations of chemicals increase as the chemical passes up through two or more trophic levels. The term implies an efficient transfer of the chemical from food to consumer.

Biomarker.[3] General molecular change that is taken as an indicator of pollution/stress. May be general or specific.

Biomonitoring.[5] Use of living organisms as "sensors" in environmental quality surveillance to detect changes in environmental conditions which may threaten the environment.

Body Burden. The concentration of a material which accumulates in the biological tissues of an exposed organism.

Breeding Range. The area utilized by an organism during the reproductive phase of its life cycle and during the time that young are reared.

Bulk Sediment.[8] Field collected sediments used to conduct toxicity tests; may contain multiple contaminants and/or unknown concentrations of contaminants.

Characterization of Ecological Effects.[6] A portion of the analysis phase of ecological risk assessment that evaluates the ability of a stressor to cause adverse effects under a particular set of circumstances.

Characterization of Exposure.[6] A portion of the analysis phase of ecological risk assessment that evaluates the interaction of the stressor with one or more ecological components. Exposure can be expressed as co-occurrence, or contact depending on the stressor and ecological component involved.

Chemicals of Potential Concern.[2] Chemicals that are potentially site-related and whose data are of sufficient quality for use in the qualitative risk assessment.

Chronic.[5] Involving a stimulus that is lingering or continues for a long time; often signifies periods from several weeks to years, depending on the reproductive life cycle of the species. Can be used to define either the exposure or the response to an exposure (effect). Chronic exposures typically induce a biological response of relatively slow progress and long duration.

Chronic Response. The response (effect) of an organism to a chemical which is not immediately or directly lethal to the organism.

Chronic Tests.[9] A toxicity test used to study the effects of continuous, long-term exposure of a chemical or other potentially toxic material on an organism.

Common Laboratory Contaminants.[2] Certain organic chemicals (considered by EPA to be acetone, 2-butanone, methylene chloride, toluene, and phthalate esters) that are commonly used in the laboratory and thus may be introduced into a sample from laboratory cross-contamination.

Community.[6] An assemblage of populations of different species within a specified location and time.

Complexation.[14] Formation of a group of ^X< compounds in which a part of the molecular bonding is of the coordinate type.

Concentration.[5] Quantifiable amount of a chemical in environmental media.

Concentration Response Curve.[5] A curve describing the relationship between exposure concentration and percent of the test population responding.

Conceptual Model.[6] Describes a series of working hypotheses of how the stressor might affect ecological components. Describes ecosystem potentially at risk, ant the relationships between measurement and assessment endpoints and exposure scenarios.

Contaminant of (Ecological) Concern. A material detected at a hazardous waste site which has the potential to adversely affect ecological receptors due to its concentration, distribution, and/or mode of toxicity.

Control.[5] A treatment in a toxicity test that duplicates all the conditions of the exposure treatments but contains no test material. The control is used to determine the absence of toxicity of basic test conditions (e.g. health of test organisms, quality of dilution water).

Correlation.[10] An estimate of the degree to which two sets of variables vary simultaneously, with no distinction between dependent and independent variables.

Critical Exposure Pathway. The exposure pathway which either maximizes the dose or is the primary pathway of exposure to an identified receptor of concern.

Degradation.[14] Conversion of an organic compound to one containing a smaller number of carbon atoms.

Deposition.[14] The lying, placing, or throwing down of any material.

Depuration.[5] A process that results in elimination of toxic material from an organism.

Depuration Rate. The rate at which a material is depurated from an organism.

Dietary Accumulation.[9] The net accumulation of a substance by an organism as a result of ingestion in the diet.

Direct Effect (toxin).[6] An effect where the stressor itself acts directly on the ecological component of interest, not through other components of the ecosystem.

Dose.[11] A measure of integral exposure. Examples include (1) the amount of a chemical ingested, (2) the amount of a chemical taken up, (3) the product of ambient exposure concentration and the duration of exposure.

Dose-Response Curve.[5] Similar to concentration response curve except that the dose (i.e. the quantity) of the chemical administered to the organism is known. The curve is plotted as Dose versus Response.

Duplicate.[8] A sample taken from and representative of the same population as another sample. Both samples are carried through steps of sampling, storage, and analysis in an identical manner.

Ecological Component.[6] Any part of an ecosystem, including individuals, populations, communities, and the ecosystem itself.

Ecological Risk Assessment.[6] The process that evaluates the likelihood that adverse ecological effects may occur or are occurring as a result of exposure to one or more stressors.

Ecosystem.[6] The biotic community and abiotic environment within a specified location and time.

Ecotoxicity.[11] The study of toxic effects on nonhuman organisms, populations, or communities.

Estimated or Expected Environmental Concentration.[5] The concentration of a material estimated as being likely to occur in environmental media to which organisms are exposed.

Exposure.[6] Co-occurrence of or contact between a stressor and an ecological component. The contact reaction between a chemical and a biological system, or organism.

Exposure Assessment.[2] The determination or estimation (qualitative or quantitative) of the magnitude, frequency, duration, and route of exposure.

Exposure Pathway.[2] The course a chemical or physical agent takes from a source to an exposed organism. Each exposure pathway includes a source or release from a source, an exposure point, and an exposure route. If the exposure point differs from the source, transport/exposure media (i.e., air, water) are also included.

Exposure Pathway Model. A model in which potential pathways of exposure are identified for the selected receptor species.

Exposure Point.[2] A location of potential contact between an organism and a chemical or physical agent.

Exposure Point Concentration. The concentration of a contaminant occurring at an exposure point.

Exposure Profile.[6] The product of characterization of exposure in the analysis phase of ecological risk assessment. The exposure profile summarizes the magnitude and spatial and temporal patterns of exposure for the scenarios described in the conceptual model.

Exposure Route.[2] The way a chemical or physical agent comes in contact with an organism (i.e., by ingestion, inhalation, or dermal contact).

Exposure Scenario.[6] A set of assumptions concerning how an exposure may take place, including assumptions about the exposure setting, stressor characteristics, and activities that may lead to exposure.

False Negative. The conclusion that an event is false when in fact it is true.

False Positive. The conclusion that an event is true when in fact it is false.

Fate.[5] Disposition of a material in various environmental compartments (e.g. soil or sediment, water, air, biota) as a result of transport, transformation, and degradation.

Food Chain Transfer. A process by which materials accumulate in the tissues of lower trophic level organisms and are passed on to higher trophic level organisms by dietary intake.

Forage (feeding) Area. The area utilized by an organism for hunting or food gathering food.

Habitat.[1] Place where a plant or animal lives, often characterized by a dominant plant form or physical characteristic.

Hazard. Likelihood that a chemical will cause an injury or adverse effect under specified conditions.

Hazard Identification.[2] The process of determining whether exposure to an agent can cause an increase in the incidence of a particular adverse effect, and whether an adverse effect is likely to occur.

Hazard Quotient.[2] The ratio of a single substance exposure level to a toxicity value selected for the risk assessment (i.e., LOAEL or NOAEL).

Home Range.[12] The area to which an animal confines its activities.

Hydrophilic.[12] A characteristic of charged molecules in which they tend to interact with water molecules.

Hydrophobic.[12] With regard to a molecule or side group, tending to dissolve readily in organic solvents, but not in water, resisting wetting, not containing polar groups or sub-groups.

Hypothesis.[12] A proposition set forth as an explanation for a specified phenomenon or group of phenomena.

Indirect Effect.[6] An effect where the stressor acts on supporting components of the ecosystem, which in turn have an effect on the ecological component of interest.

Ingestion Rate. The rate at which an organism consumes food, water, or other materials (i.e., soil, sediment). Ingestion rate is usually expressed in terms of unit of mass or volume per unit of time (i.e., kg/day, L/day).

Ionization.[14] The process by which a neutral atom loses or gains electrons, thereby acquiring a net change and becoming an ion.

Lethal.[5] Causing death by direct action.

Lipid.[13] One of a variety of organic substances that are insoluble in polar solvents, such as water, but that dissolve readily in non-polar organic solvents. Includes fats, oils, waxes, steroids, phospholipids, and carotenes.

Lowest Observable Adverse Effect Level.[5] The lowest concentration of a material used in a toxicity test that has a statistically significant adverse effect on the exposed population of test organisms as compared with the controls. Same as LOEL (lowest observed effects level).

Matrix.[14] The analyte as considered in terms of its being an assemblage of constituents, each with its own properties.

Measurement Endpoint.[6] A measurable ecological characteristic that is related to the valued characteristic chosen as the assessment endpoint. Measurement endpoints are often expressed as the statistical or arithmetic summaries of the observations that make up the measurement.

Media.[15] Specific environments - air, water, soil - which are the subject of regulatory concern and activities.

Median Effective Concentration (EC50).[5] The concentration of a material to which test organisms are exposed that is estimated to be effective in producing some sublethal response in 50 percent of the test population. The EC50 is usually expressed as a time dependent value (e.g., 24-hour EC50). The sublethal response elicited from the test organisms as a result of exposure must be clearly defined.

Median Lethal Concentration (LC50).[5] A statistically or graphically estimated concentration that is expected to be lethal to 50 percent of a group of organisms under specified conditions.

Metric.[16] A measurement of one of various components of community structure (e.g., species richness, % similarity).

Mortality. Death

No Observed Adverse Effect Level (NOAEL).[5] The highest level of a stressor evaluated in a test that causes no statistically significant difference in effect as compared with the controls. Same as NOEL (no observed effect level).

Nonparametric.[17] Statistical methods which make no assumptions regarding the distribution of the data.

Parameter.[18] Constants applied to a model which are obtained by theoretical calculation or measurements taken at another time and/or place, and are assumed to be appropriate for the place and time being studied.

Parametric.[14] Statistical methods used when the distribution of the data is known.

Population.[6] An aggregate of individuals of a species within a specified location in space and time.

Power.[10] Sensitivity of a statistical test.

Precipitation.[14] The process of producing a separable solid phase within a liquid medium.

Precision.[19] A measure of closeness of agreement among individual measurements.

Reference.[11] A relatively unpolluted site used for comparison to polluted sites in environmental monitoring studies, often incorrectly referred to as a control.

Regression Analysis.[10] Simultaneous analysis of two variables which are functionally related, with the X variable classified as the independent variable, and the Y variable classified as the dependent variable (i.e, the change in Y is dependent on the change in X).

Replicate. Duplicate analyses of an individual sample. Replicate analyses are used for quality control.

Representative.[18] Analytical results which correspond with actual environmental quality or the condition experienced by the contaminant receptor.

Risk.[5] The expected frequency or probability of undesirable effects resulting from exposure to known or expected stressors.

Risk Characterization.[6] A phase of ecological risk assessment that integrates the results of the exposure and ecological effects analyses to evaluate the likelihood of adverse ecological effects associated with exposure to the stressor. The ecological significance of the adverse effects is discussed, including consideration of the types and magnitudes of the effects, their spatial and temporal patterns, and the likelihood of recovery.

Sample.[14] Representative fraction of a material tested or analyzed; a selection or collection from a larger collection.

Scientific/Management Decision Point (SMDP). A point during the risk assessment process when the risk assessor communicates results of the assessment at that stage to a manager. At this point the manager determines whether the information is sufficient to arrive at a decision regarding management strategies and/or the need for additional information to characterize risk.

Sediment.[20] Particulate material lying below water.

Sensitive Life Stage. The life stage (i.e., juvenile, adult, etc.) which exhibits the highest degree of sensitivity (i.e., effects are evident at a lower exposure concentration) to a contaminant in toxicity tests.

Species.[13] A group of organisms that actually or potentially interbreed and are reproductively isolated from all other such groups; a taxonomic grouping of morphologically similar individuals; the category below genus.

Statistic.[10] A computed or estimated statistical quantity such as the mean, the standard deviation, or the correlation coefficient.

Stressor.[6] Any physical, chemical, or biological entity that can induce an adverse response.

Sublethal.[5] Below the concentration that directly causes death. Exposure to sublethal concentrations of material may produce less obvious effects on behavior, biochemical and/or physiological functions, and histology of organisms.

Threshold Concentration.[5] A concentration above which some effect (or response) will be produced and below which it will not.

Toxicity Assessment. Review of literature regarding the toxicity of any given material to an appropriate receptor.

Toxicity Curve.[5] The curve obtained by plotting the median survival times of a population of test organisms against concentration on a logarithmic scale.

Toxicity Test.[5] The means by which the toxicity of a chemical or other test material is determined. A toxicity test is used to measure the degree of response produced by exposure to a specific level of stimulus (or concentration of chemical).

Toxicity Value.[2] A numerical expression of a substance's dose-response relationship that is used in risk assessments.

Toxin. A poisonous substance.

Trophic Level.[6] A functional classification of taxa within a community that is based on feeding relationships (e.g., aquatic and terrestrial plants make up the first trophic level, and herbivores make up the second).

Type I Error.[10] Rejection of a true null hypothesis.

Type II Error.[10] Acceptance of a false null hypothesis.

Uptake.[5] A process by which materials are transferred into or onto an organism.

Uncertainty.[11] Imperfect knowledge concerning the present or future state of the system under consideration; a component of risk resulting from imperfect knowledge of the degree of hazard or of its spatial and temporal distribution.

Volatilization.[14] The conversion of a chemical substance from a liquid or solid state to a gaseous vapor state.

Xenobiotic.[6] A chemical or other stressor that does not occur naturally in the environment. Xenobiotics occur as a result of anthropogenic activities such as the application of pesticides and the discharge of industrial chemicals to air, land, or water.

Endnotes

[1] Krebs 1978, [2] U.S. EPA 1989, [3] Calow 1993, [4] Freedman 1989, [5] Rand and Petrocelli 1985, [6] U.S. EPA 1992a, [7] Ricklefs 1990, [8] U.S. EPA 1992b, [9] ASTM 1993a, [10] Sokal and Rohlf 1981, [11] Suter 1993, [12] Wallace et al. 1981, [13] Curtis 1983, [14] Parker 1994, [15] Sullivan 1993, [16] U.S. EPA 1990, [17] Zar 1984, [18] Keith 1988, [19] Gilbert 1987, [20] ASTM 1993b.

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APPENDIX A

ILLUSTRATION ECOLOGICAL RISK ASSESSMENTS

APPENDIX A

ILLUSTRATION 1: COPPER SITE

STEP 1: PRELIMINARY PROBLEM FORMULATION AND ECOLOGICAL EFFECTS EVALUATION

Site History. This is a former municipal landfill located in an upland area of the mid-Atlantic plain. Residential, commercial, and industrial refuse were disposed of at this site from 1961 to 1980. Large amounts of copper wire were also disposed of at this site over several years. Currently, minimal cover has been placed over the fill and planted with grasses. Terrestrial ecosystems in the vicinity of the landfill include upland forest, successional fields, agricultural land, and residential and commercial areas. The surface of the landfill has deteriorated in several locations. Leachate seeps have been noted on the slope of the landfill, and several seeps discharge to a five-acre pond down-gradient of the site.

Preliminary Site Visit. A preliminary site visit was conducted, and the ecological checklist completed for the site. The checklist indicated the following: the pond has an organic substrate, and emergent vegetation including cattail and *Phragmites* occurs along the shore near the leachate seeps; the pond reaches a depth of five feet toward the middle. Several species of sunfish, fathead minnows, and carp were observed in the pond. A diverse benthic macroinvertebrate community also has been noted in the pond. The pond appears to function as a valuable habitat for fish and other wildlife using this area. Preliminary sampling indicated elevated copper levels in the seep as well as elevated base cations, total organic carbon (TOC), and depressed pH levels (pH 5.7).

Preliminary Problem Formulation. Copper is leaching from the landfill into the pond from a seep area. EPA's ambient water quality criteria document for copper (U.S. EPA, 1984) indicates that it can cause toxic effects in both aquatic plants and aquatic invertebrates at relatively low water concentrations. Thus, the ability of the pond to support macroinvertebrate and fish communities and the wildlife that feed on them may be threatened. Terrestrial ecosystems do not need to be evaluated because the overland flow of the seeps is limited to short gullies, a few inches wide. Thus, the area of concern has been identified as the five-acre pond and the associated leachate seeps. Copper in surface water and sediments of the pond may be of ecological concern.

Preliminary Ecological Effects Evaluation. Copper, the site contaminant of ecological concern, is toxic to both aquatic plants and animals. Therefore, aquatic toxicity-based data will be used to screen for ecological risk in the preliminary risk calculation. The screening toxicity value selected for water-column exposure is the EPA chronic ambient water quality criterion (12 μg/l). The toxicity screening value for copper in sediments was identified as [value to be determined] mg/kg.

STEP 2: PRELIMINARY EXPOSURE ESTIMATE AND RISK CALCULATION

Preliminary Exposure Estimate. Preliminary sampling data indicate that the leachate contains 53 μg/l copper as well as elevated base cations, TOC, and depressed pH (pH 5.7). Sediment concentrations range from 300 mg/kg to below detection (2 mg/kg), decreasing with distance from the leachate seeps.

Preliminary Risk Calculation. The copper concentration in the seep water (53 μg/l) substantially exceeds the chronic water quality criterion for copper (12 μg/l). The maximum sediment copper concentration of 300 mg/kg exceeds the toxicity screening value for copper in sediments ([value to be determined] mg/kg). Therefore, the screening-level hazard quotients for both sediment and water exceed 1. The decision at the SMDP is to continue the ecological risk assessment.

Similar screening for the levels of base cations generated hazard quotients below 1 in the seep water; TOC and pH are not regulated under CERCLA. Sediment concentrations of chemicals other than copper generated hazard quotients of less than 1 at the maximum concentration found.

STEP 3: PROBLEM FORMULATION: Assessment Endpoints and Testable Hypotheses

Based on the preliminary problem formulation, copper is known to be of ecological concern at the site.

Ecotoxicity Literature Review. A review of the literature on the ecotoxicity of copper to aquatic biota was conducted and revealed the following information: Young aquatic organisms are more sensitive to copper than adults (Demayo *et al.*, 1982; Kaplan and Yoh, 1961; Hubschman, 1965). Fish are less sensitive to copper as body weight increases (Demayo *et al.*, 1982). Although the exact mechanism of toxicity to fish is unknown, a loss of osmotic control has been noted in several studies (Demayo *et al.* 1982; Cheng and Sullivan, 1977). Several studies using fathead minnows determined an LC_{50} of 460 μg/l to 6-month-old juveniles, and an LC_{50} of 490 μg/l to 6-week-old fry. A copper concentration in water of 37 μg/l has been shown to cause a significant reduction in fish egg production (Pickering *et al.*, 1977). Studies have also been conducted with adult *Hyalella azteca*, (an amphipod) exposed to copper in sediments. One of these studies indicated an LC_{50} of 1,078 mg/kg in the sediment (Cairns *et al.*, 1984), however a no-observed-adverse-effect level (NOAEL) for copper in sediments was not identified for an early life stage of a benthic invertebrate.

A literature review of the ecotoxicity of copper to aquatic plants, both algae and vascular plants, also was conducted. Although the toxic mechanism of copper to plants is not known, toxic effects of exposure to high copper levels include inhibition of photosynthesis and growth (U.S. EPA, 1984), inhibition of cell separation after cell division (Hatch, 1978), and inhibition of iron uptake. Several studies conducted using

Selenastrum capricornutum indicated that 300 μg/l kill algae after 7 days, and a value of 90 μg/l causes complete growth inhibition after 7 days (Bartlett *et al.*, 1974).

The literature indicates that copper does not biomagnify in food chains and does not bioaccumulate in animals because it is a biologically regulated essential element. The toxicity of copper in water is influenced by water hardness, alkalinity, and pH.

Assessment Endpoints and Testable Hypotheses. The refined assessment endpoint is maintenance of the pond ecosystem, with no loss of species or community alteration due to copper toxicity. The testable hypothesis is that the maximum concentrations of copper present in the sediments and water are toxic to aquatic plants or animals. A further question is at what copper concentration in sediments do detectable adverse effects occur?

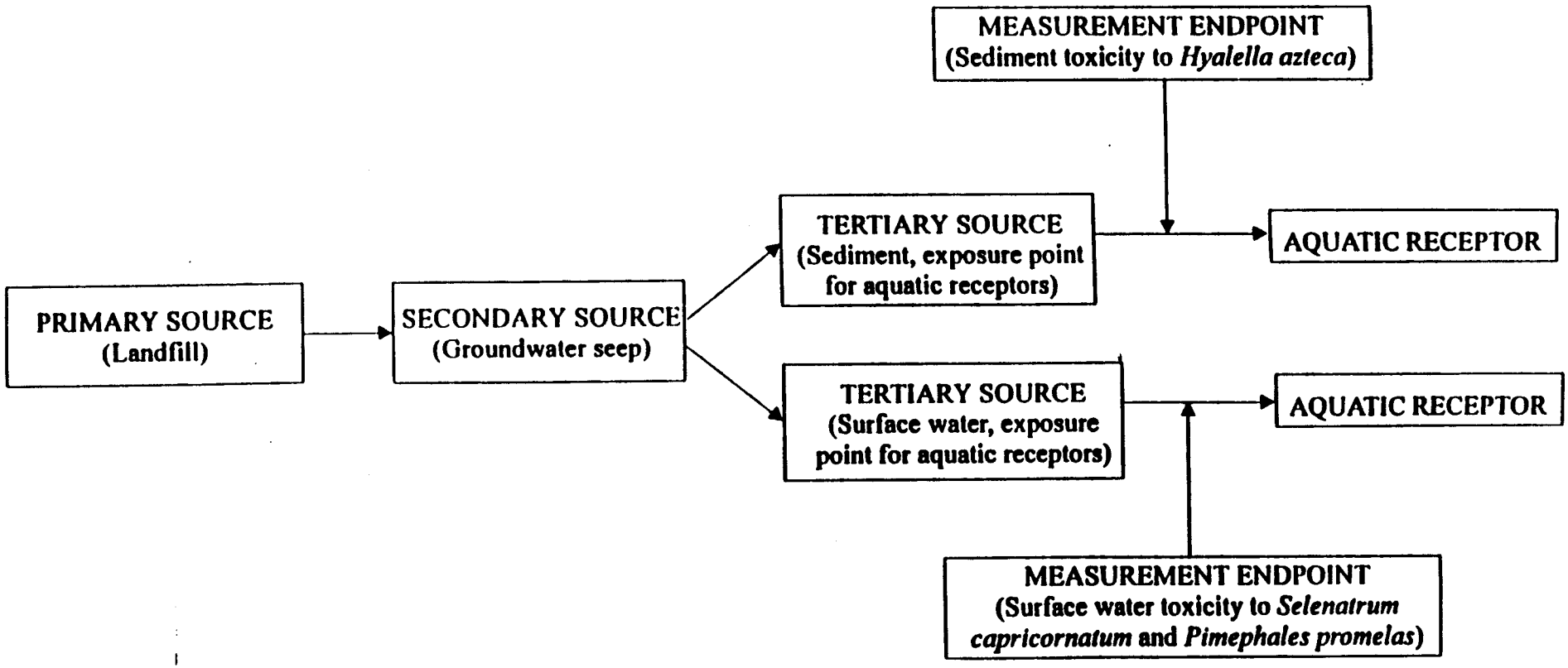
STEP 4: PROBLEM FORMULATION: Conceptual Model, Measurement Endpoints, and Study Design

Conceptual Model and Exposure Pathways. A conceptual model was prepared to determine the environmental pathways that could result in impacts of copper to indigenous biota (see Figure A-1). Direct exposure to copper in the pond water and sediments could cause acute or chronic toxicity in early life stages of fish and/or benthic invertebrates, and in aquatic plants. The exposure pathways that will be evaluated will be direct contact with contaminated sediments and water.

Measurement Endpoints. Since the identified assessment endpoint is community health, the possibility of directly measuring the condition of the pond communities was evaluated. Consultation with experts on benthic macroinvertebrates suggested that standard measures of the pond benthic invertebrate community would likely be an insensitive measure of existing effects, as well as being labor intensive. Measuring the fish community also would be unsuitable, due to the limited size of the pond and low diversity of fish species anticipated. Since copper does not bioaccumulate or biomagnify in aquatic systems, direct toxicity testing was selected as an appropriate measurement endpoint. Because early life stages are the most sensitive to the toxic effects of copper, chronic toxicity would be measured on early life stages. Toxicity was defined as a statistically significant decrease in survival or juvenile growth rates in a population exposed to water or sediments as compared with a population exposed to water or sediments from the reference sites.

One toxicity test selected was a 10-day (i.e., chronic) solid-phase sediment toxicity test using an early life stage of *Hyalella azteca* (an amphipod). The measurement endpoints for the test are mortality rates and growth rates (measured as length and weight increases). Two water-column toxicity tests were selected: a 7-day test using the alga *Selenastrum capricornutum* (growth test) and a 7-day larval fish test using *Pimephales promelas* (mortality and growth endpoints). The *H. azteca* and *P. promelas* toxicity tests will be used to determine the effects of copper on early life stages of invertebrates and

FIGURE A-1
Conceptual Model For the Copper Site



fish in sediment and the water column, respectively. The test on *S. capricornutum* will be used to determine the phytotoxicity of copper in the water column.

Study Design. To answer the questions stated in the problem formulation step, the water column tests will be run on 100% seep water, 100% pond water near the seep, and 100% reference site water as well as the laboratory control. EPA test protocols will be followed. Five sediment samples will be collected from the pond bottom at intervals along the observed concentration gradient, starting at a copper concentration of 300 mg/kg at the leachate seeps down to approximately 5 mg/kg near the other end of the pond. All sediment samples will be split so that copper concentrations can be measured in sediments from each sampling location. A reference sediment will be collected and a laboratory control will be run. Test organisms will not be fed during the test; sediments will be sieved to remove native organisms and debris. Laboratory procedures will follow established protocols and will be documented and reviewed prior to initiation of the test. For the water-column test, statistical comparisons will be made between responses to each of the two pond samples and the reference site, as well as the laboratory control. Statistical comparisons also will be made of responses to sediments taken from each sampling location and responses to the reference sediment sample.

The study design specified that sediment for the toxicity tests would be collected from leachate seeps known to be at the pond edge and four additional locations transecting the pond at equidistant locations, but including the point of maximum pond depth.

Because leachate seeps can be intermittent (depending on rainfall), the study design specified that a pre-sampling visit would be required to confirm that the seep was flowing and could be sampled. The sampling and analysis plan specified the collection of co-located sediment and water samples from the seep and the pond.

At the work plan and SAP finalization stage, the SMDPs were agreed upon for the site conceptual model and the study design.

STEP 5: SITE ASSESSMENT FOR SAMPLING FEASIBILITY

A site assessment was conducted two days prior to the scheduled initiation of the site investigation to confirm that the seep was active. It was determined that the seep was active and that the site investigation could be initiated.

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APPENDIX A

ILLUSTRATION 2: STREAM DDT SITE

STEP 1: PRELIMINARY PROBLEM FORMULATION AND ECOLOGICAL EFFECTS EVALUATION

Site History. This is the site of a former chemical production facility located adjacent to a stream. The facility manufactured and packaged dichlorodiphenyltrichloroethane (DDT). Due to poor storage practices, several DDT spills have occurred.

Preliminary Site Visit. As part of the preliminary site characterization, a preliminary site visit was conducted and the ecological checklist was completed. Information gathered indicates that surface water drainage from the site flows through several drainage swales toward a small unnamed creek. This creek is a second order stream containing riffle-run areas and small pools. The stream substrate is composed of sand and gravel in the pools **with some small depositional areas in backwater areas,** and primarily cobble in the riffles.

Preliminary Problem Formulation. Previous sampling efforts have indicated the presence of DDT and its metabolites in stream sediments at a concentration of 230 mg/kg. A variety of wildlife, especially piscivorous birds, utilize this area for feeding. Many species of minnow have been noted in this stream. **DDT is well known for its tendency to bioaccumulate and biomagnify in food chains, and available evidence indicates that it can cause reproductive failure in birds due to eggshell thinning.**

The area of concern has been identified as a several-mile length of the stream with DDT contaminated sediments. The **assessment endpoint is adverse effects on reproduction of high trophic level wildlife, particularly piscivorous birds.**

Preliminary Ecological Effects Evaluation. Because DDT is well studied, a dietary concentration above which eggshell thinning might occur was identified in existing EPA documents on the ecotoxicity of DDT. Moreover, a no-observed-adverse-effect-level (NOAEL) for the ingestion route for birds also was identified.

STEP 2: PRELIMINARY EXPOSURE ESTIMATE AND RISK CALCULATION

Preliminary Exposure Estimate. For the preliminary exposure estimate, maximum concentrations of DDT identified in the sediments were used. To estimate the concentration of DDT in forage fish, the maximum concentration in sediments was multiplied by the highest DDT bioaccumulation factor relating forage fish tissue concentrations to sediment concentrations reported in the literature. Moreover, it was assumed that the birds obtain 100 percent of their diet from the contaminated area.

Preliminary Risk Calculation. The predicted concentrations of DDT in forage fish were compared with the dietary NOAEL for DDT in birds. This risk screen indicated that DDT concentrations measured at this site might be high enough to cause adverse reproductive effects in birds. Thus, transfer of DDT from the sediments to the stream and biota are of concern at this site.

STEP 3: PROBLEM FORMULATION: Assessment Endpoints and Testable Hypotheses

Based on the preliminary problem formulation, potential bioaccumulation of DDT in aquatic food chains and effects of DDT on reproduction in piscivorous birds is one known concern. During refinement of the problem, the potential for additional ecological effects of DDT was examined.

Ecotoxicity Literature Review. In freshwater systems, DDT can have direct effects on animals, particularly insects. A literature review of the aquatic toxicity of DDT was conducted, and a NOAEL identified for aquatic insects. Aquatic plants are not affected by DDT. Additional quantitative information on effects of DDT on birds was reviewed, particularly to identify that level of eggshell thinning likely to reduce reproductive success. A number of studies have correlated measured DDT residues in eggs of birds to increased eggshell thinning and egg loss due to breakage. Eggshell thinning of more than 20 percent appears to result in decreased nesting success due to eggshell breakage (Anderson and Hickey, 1972; Dilworth *et al.*, 1972). Information was not available for any piscivorous species of bird. Lincer (1975) conducted a laboratory feeding study using American kestrel. Females fed a diet of 6 mg/kg DDE[1] (1.1 mg/kg-day) produced eggs with shells which were 25.5 percent thinner than archived eggshells collected prior to widespread use of DDT. Based on this information, a LOAEL of 1.1 mg/kgBW-day was selected to evaluate the effects of DDT on piscivorous birds.

Assessment Endpoints and Testable Hypotheses. Based on knowledge of the fate and transport of DDT in aquatic systems, as well as the ecotoxicity of DDT to aquatic organisms and birds, two assessment endpoints were identified: (1) maintenance of a stream community not affected by the contaminant, and (2) protection of piscivorous birds from eggshell thinning that would result in reduced reproductive success. The

[1]DDE is a degradation product of DDT; typically, field measures of DDT are reported as the sum of the concentrations of DDT, DDE, and DDD (another degradation product).

testable hypotheses identified were: (1) has the stream community been affected by the DDT, and (2) does food chain accumulation and transfer of DDT take place so that eggshell thinning to a degree of 20 percent or more could occur in piscivorous birds utilizing the area?

STEP 4: PROBLEM FORMULATION: Conceptual Model, Measurement Endpoints, and Study Design

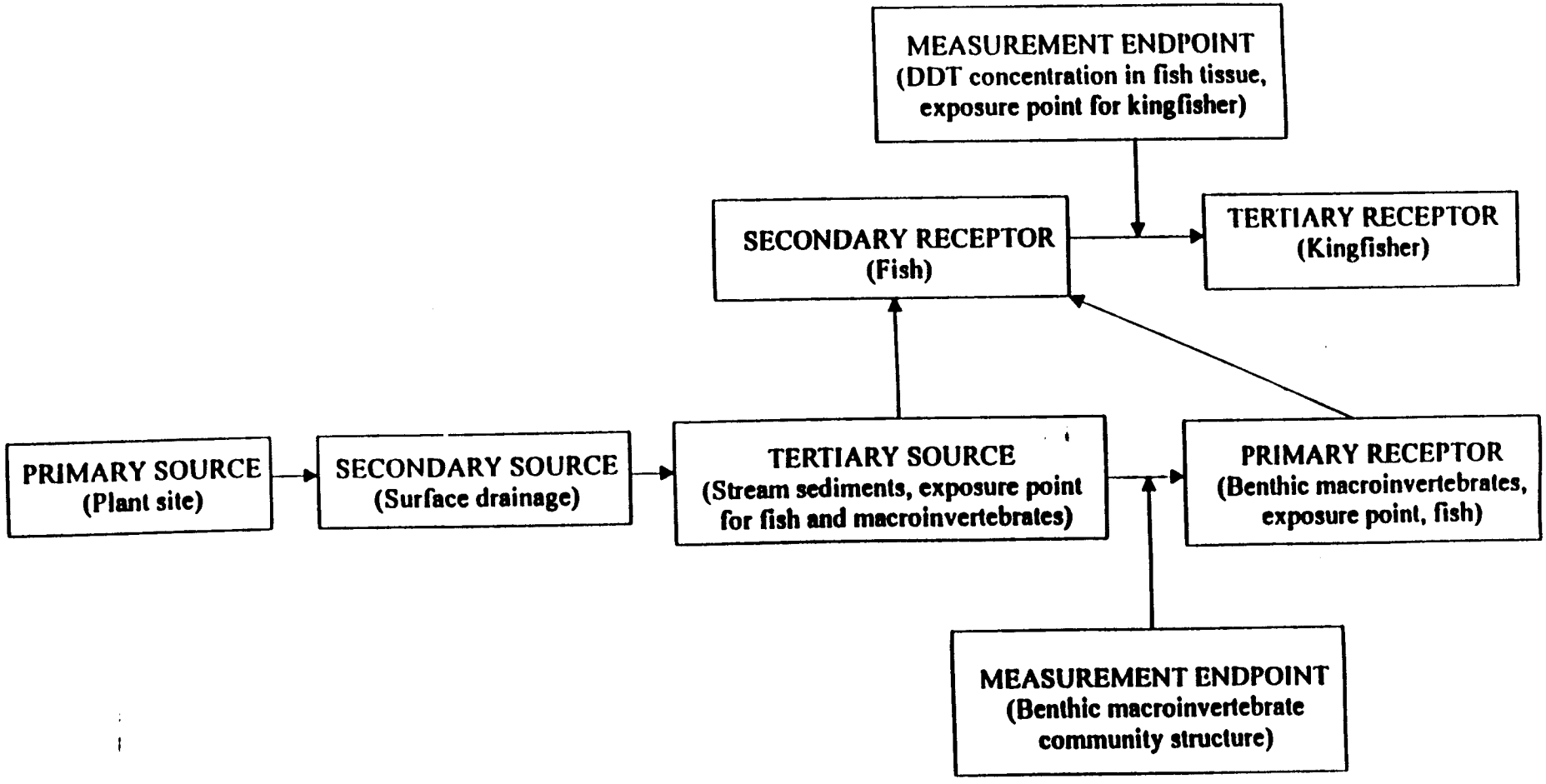
Conceptual Model and Exposure Pathways. A conceptual model evaluated the environmental pathways for DDT that could result in ecological impacts. DDT buried in the sediments can be released to the water column during resuspension and redistribution of the sediments. Some diffusion of DDT to the water column from the sediment surface also will occur. The benthic community would be an initial receptor for the DDT in sediments. Fish that feed on benthic organisms could be exposed to DDT both in the water column and in their food. Piscivorous birds would be exposed to the DDT that has accumulated in the fish.

Measurement Endpoints. For the assessment endpoint of protecting piscivorous birds from eggshell thinning (see Step 3), the conceptual model indicated that DDT in sediments could reach piscivorous birds through forage fish (Figure A-2). Belted kingfishers are known to feed in the stream. They also have the smallest home range of the piscivorous birds in the area, which means that more kingfishers can forage entirely from the contaminated stream area than can other species of piscivorous birds. Eggshell thinning in the belted kingfisher therefore was selected as the measurement endpoint.

Existing information on the distribution of DDT in the stream indicates that a general gradient of DDT concentrations exists in the sediments, and five locations could be identified that corresponded to a range of DDT concentrations in sediments. Based on information available on fish communities in streams similar to the one in the site area, creek chub (*Semotilus atromaculatus*) were selected to measure exposure levels for kingfishers. Creek chub feed on benthic invertebrates, which are in direct contact with the contaminated sediments. Creek chub also can reach a size of 10 inches, allowing for analysis of individual fish, and they have limited within-season movement.

The conceptual model also specified that the Hazard Quotient (HQ) method would be used to evaluate the effects of DDT on the kingfisher in the risk calculation phase (Step 7). To determine the HQ, a calculated dose is divided by a LOAEL or NOAEL. To estimate the DDT dose to the kingfisher, the DDT concentrations in the chub will be multiplied by the fish ingestion rate for kingfishers and divided by the body weight of kingfishers. This dose will be adjusted by the "area use factor." The area use factor corresponds to what proportion of the diet of a kingfisher would consist of fish from the contaminated area, and it is a function of the home range size of kingfishers relative to the area of contamination. The adjusted dose will be compared to the LOAEL found in the literature (i.e., 1.1 mg/kgBW-day identified above). A HQ of greater than 1 implies that there may be impacts due to site contamination, and an HQ

FIGURE A-2
Conceptual Model for the Stream DDT Site



of less than 1 implies no impacts due to site contaminants (see text for a description of the limitations of hazard quotients).

For the assessment endpoint of stream community health, the selected measurement endpoints were several metrics describing the abundance and trophic structure of the stream benthic macroinvertebrate community.

Study Design. The study design for measuring DDT residue levels in creek chub specifies that 10 creek chub of the same size and sex will be collected at each location. Each creek chub should be approximately 20 grams, so that individuals can be analyzed. In addition, at one location, QA/QC requirements dictate that an additional 10 fish are collected. In this example, a site assessment is necessary to verify that sufficient numbers of creek chub of the specified size are present to meet the tissue sampling requirements. In addition, stream conditions must be evaluated to determine what fish sampling techniques will work at the targeted locations.

The study design and methods for benthic macroinvertebrate collection followed the Rapid Bioassessment Protocol (RBP) manual for level three evaluation (U.S. EPA, 1989). Benthic macroinvertebrate samples were co-located with sampling for fish tissue residue levels so that one set of co-located water and sediment samples for analytic chemistry could serve for comparison with both tissue analyses.

STEP 5: SITE ASSESSMENT FOR SAMPLING FEASIBILITY

A field assessment was conducted and several minnow collection techniques were used to determine which technique was the most effective for the site. Collected minnows were examined to determine the size range available and to determine if individuals could be sexed.

The site assessment included a seine netting of the areas targeted for fish collection. The results of this sampling indicated that the creek chub may not be present in sufficient numbers to provide the necessary biomass for chemical analyses. Based on these findings, a contingency plan was agreed to; this stated that both the creek chub and the longnosed dace (*Rhinichthys cataractae*) would be collected. If the creek chub were collected at all locations in sufficient numbers, then these samples would be analyzed and the dace would be released. If sufficient creek chub could not be collected but sufficient longnosed dace could, the longnosed dace would be analyzed and the creek chub released. If neither species could be collected at all locations in sufficient numbers, then a mix of the two species would be used; however, for any given site only one species would be used to make the sample. In addition, at one location, preferably one with high DDTr levels in the sediment, sufficient numbers (20 grams) of both species would be collected to allow comparison (and calibration) of the accumulation between the two species. If necessary to meet the study needs, mixed sexes would be used and pooling of similarly sized individuals would be done for the creek chub. Pooling is necessary for the dace. Samples would be collected by electro-shocking. Field notes would be taken for

all samples (including number of fish per sample pool, sex, weight, length, presence of parasites or deformities, etc.).

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APPENDIX A

ILLUSTRATION 3: TERRESTRIAL PCB SITE

STEP 1: PRELIMINARY PROBLEM FORMULATION AND ECOLOGICAL EFFECTS ANALYSIS

Site History. This is a former waste oil recycling facility located in a remote area. Oils contaminated with polychlorinated biphenyl compounds (PCBs) were disposed of in a lagoon. The lagoon was not lined, and the soil was composed mostly of sand. Oils contaminated with PCBs migrated through the soil and contaminated a wide area adjacent to the site.

Preliminary Site Visit. A preliminary site visit was conducted and the ecological checklist completed. Most of the habitat is upland forest, old field, and successional terrestrial areas. Biological surveys at this site have noted a variety of small mammal signs. In addition, red-tailed hawks were observed.

Preliminary Problem Formulation. The area of concern has been identified as the 10-acre area surrounding the site. Some PCBs are reproductive toxins in mammals that, when ingested, induce (i.e., increase concentrations and activity of) enzyme systems in the liver. The enzymes are not specific for PCBs and will also enhance the degradation of steroid hormones. The reduction in circulating steroid hormones impairs the ability of vertebrates to reproduce. Other effects, such as liver pathology, are also evident at high exposures. PCBs are not highly volatile, so inhalation of PCBs by animals would not be an important exposure pathway. PCBs in soils generally are not taken up by most plants, but are accumulated by soil macroinvertebrates. Thus, herbivores, such as voles and rabbits, would not be exposed to PCBs in most of their diets; whereas insectivores, such as shrews, or omnivores, such as deer mice, could be exposed to accumulated PCBs in their diets. PCBs also are known to biomagnify in terrestrial food chains. Thus, this evaluation indicates that the ingestion exposure route needs evaluation and that shrews and/or voles would be appropriate mammalian receptors to evaluate for this route. Potential reproductive effects on predators that feed on shrews or voles also would be important to evaluate. The literature indicated that exposure to PCBs through the food chain could cause chronic toxicity to predatory birds.

Preliminary Ecological Effects Evaluation. No-observed-adverse-effect levels (NOAELs) for the effects of PCBs and other contaminants at the site on mammals and other biota were identified in the literature.

STEP 2: PRELIMINARY EXPOSURE ESTIMATE AND RISK CALCULATION

Preliminary Exposure Estimate. For the preliminary risk calculation, the highest PCB and other contaminant levels measured onsite were used to estimate exposures.

Preliminary Risk Calculation. The potential contaminants of concern were screened based on NOAELs for exposure routes appropriate to each contaminant. Based on this preliminary screening, PCBs were confirmed to be the contaminants of concern to small mammals based on the levels measured at this site.

STEP 3: PROBLEM FORMULATION: Assessment Endpoints and Testable Hypotheses

Refining the problem formulation includes further evaluation of contaminant fate and transport, ecotoxicity of contaminants of concern (i.e., acute, chronic, or food chain transferable), important exposure pathways, effects to sensitive life stages, identification of lowest-observed-adverse-effect levels (LOAELs), and development of testable hypotheses.

Ecotoxicity Literature Review. A literature review revealed the following information: Limited information was available on the effects of PCBs to red-tailed hawks. A study on American kestrel indicated that consumption of 33 mg/kg-day PCBs resulted in a significant decrease in sperm concentration in male kestrels (Bird *et al.*, 1983). Implications of this decrease on reproductive success in kestrels was not evaluated in this study, but studies on other bird species indicate that it could increase the incidence of infertile eggs and therefore reduce the number of young fledglings per pair. The Great Lakes International Joint Commission recommends 0.1 mg/kg total PCBs as a prey tissue level that will protect predatory birds and mammals (International Joint Commission 1988). (This number is used as an illustration and not to suggest that this particular level is appropriate.)

Assessment Endpoint and Testable Hypotheses. The assessment endpoint selected was the protection of predatory birds from reproductive impairment caused by PCBs. The testable hypothesis is that concentrations of PCBs in the prey exceed levels known to impair reproduction in predatory birds.

STEP 4: PROBLEM FORMULATION: Conceptual Model, Measurement Endpoints, and Study Design

Conceptual Model and Exposure Pathways. As determined in Step 3, the assessment endpoint was the protection of predatory birds from adverse reproductive effects from PCBs that had accumulated in their prey. A conceptual model was prepared to determine the exposure pathways by which predatory birds could be exposed to PCBs originating in the soil at the site (see Figure A-3). Red-tailed hawks were observed at the site. The prey of red-tails include voles, deer mice, and various insects. While voles may be prevalent at the site, they are not part of the exposure pathway for predators because they are herbivorous and PCBs do not accumulate in plants (see Step 1). Deer mice (*Peromyscus maniculatus*), on the other hand, also are abundant at the site and, being omnivorous, are likely to be exposed to PCBs that have accumulated in the insect component of their diet.

Measurement Endpoints. Given the assessment endpoint and exposure pathways established in the conceptual model, impairment of reproduction in the red-tailed hawk was selected as the measurement endpoint. To test the hypothesis that PCB levels in prey of the red-tailed hawk exceed levels that might impair their reproduction, PCB levels will be measured in deer mice taken from the site (deer mice are assumed to accumulate the highest levels of PCBs of any of the red-tailed hawk's prey).

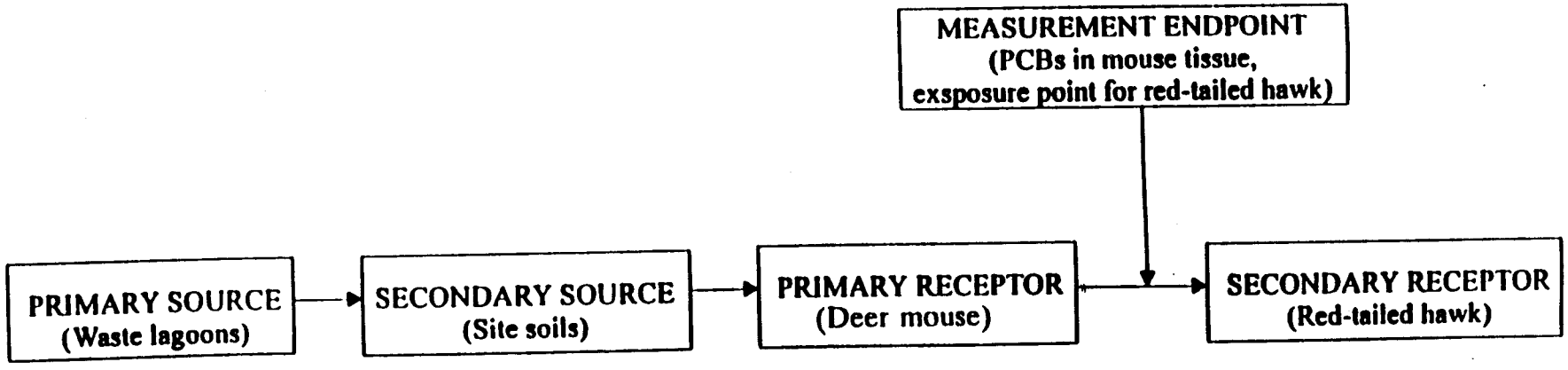
The conceptual model specifies that the Hazard Quotient (HQ) method will be used to evaluate the effects of PCBs on the red-tailed hawk in the risk calculation phase (Step 7). To determine the HQ, a calculated dose is divided by a LOAEL or NOAEL. To estimate the dose to the red-tailed hawk, the PCB concentrations in deer mice will be multiplied by the quantity of deer mice that could be ingested by a red-tailed hawk each day and divided by the body weight of the hawk. This dose will be adjusted by a factor that corresponds to the proportion of the diet of a red-tailed hawk that would come from the contaminated area. This "area use factor" is a function of the home range size of the hawks relative to the area of contamination. The dose will be compared to the LOAEL found in the literature (in this case, the 33 mg/kg-day as stated above). A HQ of greater than 1 implies that there may be impacts due to site contamination, and an HQ of less than 1 implies no impacts due to site contaminants.

Study Design. The available measures of PCB concentrations in soil at the site indicated a gradient of decreasing PCB concentration with increasing distance from the unlined lagoon. Three locations along this gradient were selected to measure PCB concentrations in prey. The study design specifies that eight deer mice of the same size and sex will be collected at each location. Each mouse should be approximately 20 grams so that contaminant levels can be measured in individual mice. With eight measures from individual mice, it is possible to estimate a mean contaminant concentration in deer mice and an upper confidence limit of the mean for the location. In addition, QA/QC requirements dictate that an additional eight deer mice should be collected at one location. In this example, a site assessment was necessary in order to verify that sufficient numbers of deer mice of the specified size are present to meet the sampling requirements. In addition, habitat conditions must be evaluated to determine what trapping techniques will work at the targeted locations.

STEP 5: SITE ASSESSMENT FOR SAMPLING DESIGN

A field assessment using several trapping techniques was conducted to determine (1) which technique was most effective for capturing deer mice at the site and (2) if the technique would yield sufficient numbers of mice over 20 grams to meet the specified sampling design. On the evening of the first day of the sampling feasibility assessment, two survey lines of 10 live traps were set for deer mice in typical old field habitat in the area believed to contain the desired concentration gradient for the study design. At the beginning of the second day, the traps were retrieved. Two deer mice over 20 grams were captured in each of the survey lines. These results indicate that collection of deer

FIGURE A-3
Conceptual Model for the Terrestrial PCB Site



mice with this number and spacing of live traps should be adequate to meet study objectives.

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APPENDIX B

SUPPLEMENTAL GUIDANCE ON LITERATURE SEARCH

SUPPLEMENTAL GUIDANCE ON LITERATURE SEARCH

A literature search is conducted to obtain information on contaminants of concern, their potential ecological effects, and species of concern. A literature search may be conducted to determine which chemicals are selected as contaminants of concern. This appendix is separated into 2 sections; Section I describes the information necessary for the literature review portion of an ecological risk assessment. Subtopics include exposure profile requirements, bioavailability or bioconcentration factors for various compounds, life history information for the species of concern or the surrogate species, and an ecological effects profile.

Section II lists techniques and resources useful for conducting a focused literature search. Subtopics include a discussion on the selection of key words on which to base a search, and the various databases and scientific abstracts available. Examples of literature reviews, journal articles, and government documents are provided as additional sources of pertinent information. Threatened and endangered species are discussed separately due to the unique literature bases and information sources available for these species.

Prior to conducting a literature search, it is important to determine specific information necessary to the risk assessment. The questions raised in Section I of this chapter must be thoroughly reviewed, the information necessary to complete the assessment must be determined, and the purpose of the assessment must be clearly defined. Once these questions are addressed, the actual literature search may begin. This will assist in focusing the search to reduce the amount of time necessary to conduct the search.

SECTION I

Specific Information

It is important to decide the information necessary for the risk assessment. For example, if the purpose of the assessment is to determine the effects of soil lead concentrations on terrestrial vertebrates, then literature information on the effects of dissolved lead to fish may not be appropriate. In addition, the type of contaminant, the chemical form and the species of concern can often focus the literature search. For example, the toxicity of organometallic compounds is quite different from the comparable inorganic form. Different isomers of organic compounds may also have different toxicological effects.

Studies which report toxic levels should be reviewed critically to ensure that the study was scientifically sound. For example, such items as field exposure routes, endpoints and the use of accepted scientific techniques should be determined. The exposure route used in the study should also be comparable to the route in the risk assessment. Data obtained in studies where exposure is by injection or gavage are not comparable to dietary exposure studies. Therefore, an uncertainty factor may be incorporated into the risk design, or the

study should be eliminated from further review based on an incompatibility with the risk assessment. Data from long-term exposure studies are preferable to data from single exposure toxicity studies.

To use some data reported in the literature, conversions may be necessary to allow data to be used for species different than those tested. Many doses from laboratory studies are reported in terms of mg contaminant/kg diet. This dose should be converted to mg contaminant/kg bodyweight/day, so that dose is not under- or overestimated when it is applied to a different species. Average ingestion rate and bodyweight for a species are often reported in the study, or should be obtained from other literature sources to make this conversion (mg/kg diet X ingestion rate (kg/day) X 1/bodyweight (kg)).

Exposure Profile

Once contaminants of concern are selected, a general overview of chemical properties is needed. The environmental fate of contaminants will influence potential routes of exposure of biota. Many chemicals undergo degradation (e.g., hydrolysis, photolysis, microbial) after release into the environment. Degradation can affect toxicity, persistence, and fate and transport of compounds.

Development of an exposure profile requires information regarding inherent properties of chemicals which may affect fate and transport or bioavailability. Contaminants of concern should be selected based on the contaminant levels present on-site, media where the contaminants are located, and the potential for adverse ecological effects associated with a particular contaminant.

Bioavailability

Factors which influence bioavailability should be determined, as they will affect exposure of biota. Some factors which affect bioavailability of contaminants from soil and sediment include: organic matter, pH, and grain size. The aerobic state of the sediments is important because this may affect the chemical form of the contaminants. These physical properties of the media determine the chemical form of the contaminant and may result in a chemical form which is more or less toxic than the original chemical. Contaminants may be adsorbed to organic matter which will also affect the availability of the contaminant to biota.

Environmental factors which influence the bioavailability of a chemical from water to biota should also be determined, if appropriate. Such factors as pH, hardness, or aerobic state will determine both the chemical form and the uptake of contaminants by biota. Other environmental factors may influence physiological process. For example, as ambient temperatures rise, metabolism increases and the rate of uptake increases.

If the literature search reveals information on the bioavailability of a chemical, then the appropriate bioaccumulation/bioconcentration factors for the contaminants of concern should be determined. If not readily available in the literature, these values may be calculated based on studies where media information and body burden are provided. Caution must be used in these calculations to determine the accuracy of these calculations.

Whether a contaminant bioaccumulates, or is associated with acute or chronic toxicity will influence the selection of assessment methods. Therefore, some information on the activity of the chemicals is necessary in the literature review.

Life History

Because it is impossible to model an entire ecosystem, the selection of the species of concern and the modeled species is a detailed process. This process is more fully described in Section XX. To determine which species to test, or which species are of concern, the habitat present on-site should be evaluated to determine the potential species which will utilize the site. Once the species of concern are selected, life history information for these species should be collected. Activities or feeding habits of a species may increase or decrease potential exposure to a contaminant (e.g. grooming activities of small mammals, egestion of bone and hide by owls). Other important parameters to incorporate into the risk assessment are ingestion rates, composition of the diet, average bodyweight, home range size, and seasonal activities such as migration.

Ecological Effects Profile

Once contaminants of concern are selected, a general overview of toxicity and toxic mechanisms are needed. Again, much of this information will be based on the information and decisions **made during problem formulation.**

The distinction between the species of concern and the surrogate species must be decided. For this review, the species of concern is the actual site animal that may be at risk due to life history activities on the site. The surrogate species is the animal used to evaluate risk. These species may or may not be the same. If the species are different, they should be biologically similar, within the constraints of the study and the amount of information available.

Toxicity information must be obtained for incorporation into the risk assessment. For each exposure route, levels shown to be toxic to receptor species should be located. A low observed adverse effect level (LOAEL) for receptor species should be obtained. Unfortunately, LOAELs are not available for wildlife species and a variety of chemicals. If used with caution, toxicity data from a closely related species can be used to estimate a

LOAEL for a receptor species. Sometimes the only toxicity data available is an LD_{50} value. A commonly used conversion factor is a factor of 10 to convert an LD_{50} to an LOAEL.

SECTION II

Literature Review

Section II describes information resources that may be examined for information necessary in the ecological risk assessment. A logical and focused literature search will reduce the time spent searching for pertinent information.

The first step in a literature search is to develop a list of key words. Specific examples are provided on the selection of key words. The next step is to review databases, either on-line or CD-ROM based information systems. These systems may be searched based on a number of parameters.

Abstracts which contain up-to-date listings of current, published information and are useful information sources. Most abstracts are indexed by author or subject. Several literature reviews are available which list toxicological or life history information. Toxicity information may be located in the literature cited section of previously published documents. Often, the same type of information as found in the published article may be found.

The original article in which the data is cited must be obtained before the data is cited in a risk assessment. Once the original article is received, it must be critically reviewed to determine if the information is useful for the risk assessment.

Moore (1980) provides further insights on conducting a literature search. Such topics as techniques to limit a search, selection of key words and the location of dissertations are discussed. This information is specifically related to wildlife information and is useful in all aspects of an ecological risk assessment.

Key words

As described in Section I, it is useful to prepare a list of specific information necessary for use in a risk assessment. Once this list is developed, a series of key words may be developed.

Card catalogs, abstracts and other reference materials are often indexed on key words. Therefore, key words used to locate information need to be very specific. The words used may be the contaminant of concern, the biological species of concern, specific toxicity information, or other associated words. In addition, related subjects may be used as key words. However, it may be necessary to exclude peripheral aspects of the subject in order

to narrow the search. For example, if the literature is the effects of lead on moles, then both lead and moles may be used as key words. If information is required on a specific animal, key words may be the scientific name (i.e. class or genus) or an accepted common name. The determination of the function of the data will assist with the determination of the key words on which to search.

If someone else will conduct a literature search, it is important that the key words, and data objectives, are understood by the person conducting the search. Once key words are established, then a variety of media may be reviewed to obtain the necessary information.

Databases

Databases are usually on-line or CD-ROM based information systems. These systems may be searched based on a number of parameters. Prior to searching a database, the database that will most likely yield the type of information required for the assessment should be determined. For example, ACQUIRE (Aquatic Toxicity Information Retrieval Database) provides information specifically on the toxicity of chemicals to aquatic plants and animals. IRIS (Integrated Risk Information System) provides information on health risks and regulatory information (such as oral and chronic inhalation doses) for a variety of chemicals. Other databases may include HSDB (Hazardous Substances Database), HEAST (Health effects Assessment Summary Tables), and BIOSIS (Biosciences Information Services).

Several states have Fish and Wildlife History Databases or Academy of Science databases. These sources often provide useful life history information. State databases are good references to locate information on endemic organisms or geographically distinct habitats.

Databases may yield a large amount of information in a short period of time. However, if the key words do not accurately describe the needed information, database searches will provide a large amount of information that is not relevant to the assessment. Access fees and on-line fees may apply, therefore, the selection of relevant key words and an organized approach to the search will reduce the time and expense of this method of data acquisition.

Abstracts

Abstracts contain up-to-date listings of current, published information. Most abstracts are indexed by author or subject. Authors and key words may be cross referenced to determine acceptable publications. Abstracts also include a copy of the abstract from the journal or book. A review of this information is a relatively quick way to determine if an

article is applicable to the risk assessment. As with databases, it is important to determine which abstracts are appropriate to the information necessary for a risk assessment.

These documents are very useful because they may be indexed by authors. If an author is known to conduct a specific type of research, their name may be referenced in the abstract for other articles on similar subjects. If an abstract is determined to be pertinent, the original article must be retrieved for the details concerning the study and the exact calculations for any data. Common abstracts include Biological Abstracts, Chemical Abstracts, and Applied Ecology Abstracts.

Abstracts usually must be manually searched. This can be a very time consuming step in a literature review. The use of relevant key words will also reduce the amount of time searching abstracts.

Literature Review Publications

Several literature reviews are available which list toxicological or life history information. For example, the USFWS has published several contaminant specific documents which list toxicological data on terrestrial, aquatic and avian studies (e.g. Eisler, 1988). The US Environmental Protection Agency publishes Ambient Water Quality Criteria (1980) documents which list all the data used to calculate these values. Other documents publish toxicological data in which the authors further evaluate the information (e.g. Long and Morgan, 1990). The *Wildlife Exposure Factors Handbook* (U.S. EPA 1993a,b) provides pertinent information on exposure factors (e.g., body weights, food ingestion rates, dietary composition, home range size) for 34 selected wildlife species.

Literature reviews provide an extensive amount of information. However, the review must be specific to the information necessary in the risk assessment. When using these types of documents, it is important to use the values as described in the document to prevent invalid study conclusions. Therefore, the original article should be obtained to validate the conclusions in the literature review.

References Cited in Previous Studies

Toxicity information may be located in the literature cited section of previously published documents. Often, the same type of information as found in the published article may be found. In addition, this may be a source of additional authors who work on parallel studies. This type of literature tends to require an intensive level of effort; and may not be very effective. However, this is probably most common approach used in literature searches. If this approach is selected, the best place to start is a review article. Many journals do not list the entire citation for an article, therefore, this may not be a useful technique. Also, it

may be difficult to retrieve literature cited because it may be found in obscure journals. foreign journals that need translation or in dissertations.

The use of this technique can be the most time consuming of the literature search methods. However, this is probably the most common means for locating information.

Journal Articles; Books; Government Documents

There are a variety of journals, books and government documents that contain information useful to risk assessments.

Once an article is retrieved, the complete citation should be noted for future reference. In addition, the original article must be obtained prior to citation in a risk assessment. Once the original article is received, it must be critically reviewed to determine if the information is useful for the risk assessment.

Threatened and Endangered Species

Threatened or endangered species are concerns of both federal and state governments. When conducting an ecological risk assessment, it is often necessary to determine the effects of site contaminants to Federal Threatened or Endangered Species. In addition, special status state listed species may also be the focus of the assessment. The US Fish and Wildlife Service or State Natural Heritage programs should be contacted to determined if these species are present on or near the site.

Once the presence of an endangered species is confirmed, information on this species as well as on surrogate species should be located in the literature search. This information can be used in the determination of site decisions and impacts. There are specific programs that deal with these issues and there maybe much more information on these species than on similar species. However, threatened species may not be the most appropriate species to model.

APPENDIX C

FRAMEWORK FOR ECOLOGICAL RISK ASSESSMENT

U.S. Environmental Protection Agency
Risk Assessment Forum
Washington, DC

February 1992

(EPA/630/R-92/001)

APPENDIX D

REPRESENTATIVE SAMPLING GUIDANCE DOCUMENT
VOLUME 3: ECOLOGICAL

U.S. Environmental Protection Agency
Office of Emergency and Remedial Response
Washington, DC

DRAFT

(DO NOT CITE OR QUOTE)

SUPERFUND PROGRAM

CHECKLIST FOR ECOLOGICAL ASSESSMENT/SAMPLING

DRAFT

26 JANUARY 1993

Environmental Response Branch
Emergency Response Division

Office of Emergency and Remedial Response
Office of Solid Waste and Emergency Response

INTRODUCTION

The following checklist provides guidance in making observations for an ecological assessment. It is not intended to be used for limited actions (e.g.: removals of a few drums), nor for purely industrial settings with no discharges. The checklist is a screening tool for preliminary site evaluation, and may also be useful in planning more extensive site investigations in the future. Therefore, please complete it in as much detail as time allows. The results of the checklist will serve as a starting point for the collection of appropriate ecological data to be used in developing an Action Memorandum. The preparers of this checklist recognize that certain questions are not universally applicable and that site-specific conditions will influence interpretation. Therefore, please provide a site synopsis to facilitate final review of the checklist.

Draft Copy

Date_____

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Checklist for Ecological Assessment/Sampling

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Date_____

I. SITE DESCRIPTION

1. Site Name: _____

   Location: _____

   _____

   Country:_____ City:_____ State:_____

2. Latitude: _____ Longitude: _____

3. What is the approximate area of the site? _____

4. Is this the first site visit? ☐ yes ☐ no If no, attach trip report of previous site visit(s) if available.

   Date(s) of previous site visit(s):_____

5. Please attach USGS topographic map(s) of the site to the checklist, if available.

6. Are aerial or other site photographs available? ☐ yes ☐ no If yes, please attach any available photo(s) to the site map at the conclusion of this section.

7. The land use on the site is:

____% Urban

____% Rural

____% Residential

____% Industrial(☐ light ☐ heavy)

____% Agricultural

*(Crops:*_____*)*

____% Recreational

(Describe; note if it is a park, etc.)

_____

_____

____% Undisturbed

____% Other

The area surrounding the site is:
_____ mile radius

____% Urban

____% Rural

____% Residential

____% Industrial (☐ light ☐ heavy)

____% Agricultural

*(Crops:*_____*)*

____% Recreational

(Describe; note if it is a park, etc.)

_____

_____

____% Undisturbed

____% Other

8. Has any movement of soil taken place at the site? ☐ yes ☐ no. If yes, please identify the most likely cause of this disturbance:

____ Agricultural Use ____ Heavy Equipment ____ Mining

____ Natural Events ____ Erosion ____ Other

Please describe:

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Date_____

9. Do any potentially sensitive environmental areas exist adjacent to or in proximity to the site, e.g., Federal and State parks, National and State monuments, wetlands, prairie potholes, etc.? *Remember, flood plains and wetlands are not always obvious; do not answer "no" without confirming information.*

9a. Please provide the source(s) of information used to identify these sensitive areas, and indicate their general location on the site map.

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Date_____

10. What type of facility is located at the site?

☐ chemical ☐ manufacturing ☐ mixing ☐ waste disposal

☐ other (specify)_____

11. What are the suspected contaminants of concern at the site? If known, what are the maximum concentration levels?

12. Check any potential routes of off-site migration of contaminants observed at the site:

☐ swales ☐ depressions ☐ drainage ditches

☐ runoff ☐ windblown particulates ☐ vehicular traffic

☐ other (specify)_____

13. If known, what is the approximate depth to the water table?_____

14. Is the direction of surface runoff apparent from site observations? ☐ yes ☐ no If yes, to which of the following does the surface runoff discharge? Indicate all that apply.

☐ surface water ☐ groundwater ☐ sewer ☐ collection impoundment

15. Is there a navigable waterbody or tributary to a navigable waterbody? --☐ yes ☐ no

16. Is there a waterbody anywhere on or in the vicinity of the site? If yes, also complete Section III: Aquatic Habitat Checklist -- Non-Flowing Systems and/or Section IV: Aquatic Habitat Checklist -- Flowing Systems.

☐ yes (approx. distance_____) ☐ no

17. Is there evidence of flooding? ☐ yes ☐ no. *Wetlands and flood plains are not always obvious; do not answer "no" without confirming information.* If yes, complete Section V: Wetland Habitat Checklist.

18. If a field guide was used to aid any of the identifications, please provide a reference. Also, estimate the time spent identifying fauna. [Use the back of this page if additional space for text is needed.]

19. Are any threatened and/or endangered species (plant or animal) known to inhabit the area of the site? ☐ yes ☐ no *If yes, it is required to verify this information with the U.S. Fish and Wildlife Service.* If species' identity is known please list them below.

20. Weather conditions at the time this checklist was prepared.

DATE:_____

_____ Temperature (°C/°F)

_____ Normal daily high temperature

_____ Wind (Direction/Speed)

_____ Precipitation (rain, snow)

_____ Cloud cover

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Date_____

IA. SUMMARY OF OBSERVATIONS AND SITE SETTING

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Date_____

Completed by_____ Affiliation_____

Additional Preparers_____

OSC_____

Date_____

II. TERRESTRIAL HABITAT CHECKLIST

IIA. WOODED

1. Are there any wooded areas at the site? ☐ yes ☐ no. If no, go to Section B: Shrub/Scrub.

2. What percentage or area of the site is wooded? (____% ____ acres). Indicate the wooded area on the site map attached to a copy of to this checklist. Please identify what information was used to determine the wooded area of the site.

3. What is the dominant type of vegetation in the wooded area? (Circle one: Evergreen Deciduous Mixed) Provide a photograph, if available.

   Dominant plant, if known:_____

4. What is the predominant size of the trees at the site? Use diameter at breast height.

   ☐ 0-6 in. ☐ 6-12 in. ☐ > 12 in.

5. Specify type of understory present, if known. Provide a photograph, if available.

IIB. SHRUB/SCRUB

1. Is shrub/scrub vegetation present at the site? ☐ yes ☐ no If no, go to Section C: Open Field.

2. What percentage of the site is covered by scrub/shrub vegetation? (____% ____ acres). Indicate the areas of shrub/scrub on the site map. Please identify what information was used to determine this area.

3. What is the dominant type of scrub/shrub vegetation, if known? Provide a photograph if available.

4. What is the approximate average height of the scrub/shrub vegetation?

   ☐ 0-2 ft. ☐ 2-5 ft. ☐ > 5 ft.

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Date_____

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Date_____

5. Based on site observations, how dense is the scrub/shrub vegetation?

☐ dense ☐ patchy ☐ sparse

IIC. OPEN FIELD

1. Are there open (bare, barren) field areas present at the site? ☐ yes ☐ no If yes, please indicate the type below:

☐ prairie/plains ☐ savannah ☐ old field ☐ other (specify)_____

2. What percentage of the site is open field? (_____% _____ acres). Indicate the open fields on the site map.

3. What is/are the dominant plant(s)? Provide a photograph, if available.

4. What is the approximate average height of the dominant plant?_____

5. Describe the vegetation cover: ☐ dense ☐ sparse ☐ patchy

IID. MISCELLANEOUS

1. Are other types of terrestrial habitats present at the site other than woods, scrub/shrub, and open field? ☐ yes ☐ no If yes, identify and describe them below.

2. Describe the terrestrial miscellaneous habitat(s) and identify these area(s) on the site map.

3. What observations, if any, were made at the site regarding the presence and/or absence of insects, fish, birds, mammals, etc.?

4. Review the questions in Section I to determine if any additional habitat checklists should be completed for this site.

Date

III. AQUATIC HABITAT CHECKLIST – NON-FLOWING SYSTEMS

Note: Aquatic systems are often associated with wetland habitats. Please refer to Section V, Wetland Habitat Checklist.

1. What type of open-water, non-flowing system is present at the site?

   ☐ Natural (pond, lake)
   ☐ Man-made (lagoon, reservoir, canal, impoundment)

2. If known, what is the name(s) of the waterbody(ies) on or adjacent to the site?

   _____

3. If a waterbody is present, what are the known uses of it (e.g.: recreation, navigation, etc.)?

4. What is the approximate size of the waterbody(s)? _____ acre(s).

5. Is any aquatic vegetation present? ☐ yes ☐ no If yes, please identify the type of vegetation present (if known).

   ☐ emergent ☐ submergent ☐ floating

6. If known, what is the depth of the water? _____

7. What is the general composition of the substrate? Check all that apply.

   ☐ Bedrock ☐ Sand (coarse) ☐ Muck (fine/black)
   ☐ Boulder (>10 in.) ☐ Silt (fine) ☐ Debris
   ☐ Cobble (2.5-10 in.) ☐ Marl (shells) ☐ Detritus
   ☐ Gravel (0.1-2.5 in.) ☐ Clay (slick) ☐ Concrete
   ☐ Other (specify)_____

8. What is the source of water in the waterbody?

   ☐ River/stream/creek ☐ Groundwater ☐ Other (specify)_____
   ☐ Industrial discharge ☐ Surface runoff

Date_____

9. Is there a discharge from the site to the waterbody? ☐ yes ☐ no If yes, please describe this discharge and its path.

10. Is there a discharge from the waterbody? ☐ yes ☐ no If yes, and the information is available, identify from the list below the environment into which the waterbody discharges.

☐ River/stream/creek	☐ on-site	☐ off-site	Distance_____
☐ Groundwater	☐ on-site	☐ off-site	
☐ Wetland	☐ on-site	☐ off-site	Distance_____
☐ Impoundment	☐ on-site	☐ off-site	

11. Identify any field measurements and observations of water quality that were made. For those parameters for which data were collected provide the measurement and the units of measure below.

_____ Area

_____ Depth (average)

_____ Temperature (depth of the water at which the reading was taken ____)

_____ pH

_____ Dissolved oxygen

_____ Salinity

_____ Turbidity (clear, slightly turbid, turbid, opaque) (Secchi disk depth ____)

_____ Other (specify)

12. Describe observed color and area of coloration.

13. Mark the open-water, non-flowing system on the site map which will be attached to this checklist.

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Date_____

14. What observations, if any, were made at the waterbody regarding the presence and/or absence of benthic macroinvertebrates, fish, birds, mammals, etc.?

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Date_____

IV. AQUATIC HABITAT CHECKLIST -- FLOWING SYSTEMS

Note: Aquatic systems are often associated with wetland habitats. Please refer to Section V, Wetland Habitat Checklist.

1. What type(s) of flowing water system(s) is (are) present at the site?

- ☐ River
- ☐ Dry wash
- ☐ Man-Made (ditch, etc.)
- ☐ Stream
- ☐ Arroyo
- ☐ Intermittent Stream
- ☐ Other (specify)_____
- ☐ Creek
- ☐ Brook
- ☐ Channeling

2. If known, what is the name of the waterbody?_____

3. For natural systems, are there any indicators of physical alteration (e.g., channeling, debris, etc.)?
☐ yes ☐ no If yes, please describe indicators that were observed.

4. What is the general composition of the substrate? Check all that apply.

- ☐ Bedrock
- ☐ Boulder (>10 in.)
- ☐ Cobble (2.5-10 in.)
- ☐ Gravel (0.1-2.5 in.)
- ☐ Other (specify)_____
- ☐ Sand (coarse)
- ☐ Silt (fine)
- ☐ Marl (shells)
- ☐ Clay (slick)
- ☐ Muck (fine/black)
- ☐ Debris
- ☐ Detritus
- ☐ Concrete

5. What is the condition of the bank (e.g., height, slope, extent of vegetative cover)?

6. Is the system influenced by tides? ☐ yes ☐ no What information was used to make this determination?

Date_____

7. Is the flow intermittent? ☐ yes ☐ no If yes, please note the information that was used in making this determination.

8. Is there a discharge from the site to the waterbody? ☐ yes ☐ no If yes, please describe the discharge and its path.

9. Is there a discharge from the waterbody? ☐ yes ☐ no If yes, and the information is available, please identify what the waterbody discharges to and whether the discharge is on site or off site.

10. Identify any field measurements and observations of water quality that were made. For those parameters for which data were collected provide the measurement and the units of measure in the appropriate space below:

____ Width (ft.)

____ Depth (ft.)

____ Velocity (specify units:_____)

____ Temperature (depth of the water at which the reading was taken_____)

____ pH

____ Dissolved oxygen

____ Salinity

____ Turbidity (clear, slightly turbid, turbid, opaque) (Secchi disk depth _____)

____ Other (specify)_____

Draft Copy

Date_____

11. Describe observed color and area of coloration.

12. Is any aquatic vegetation present? ☐ yes ☐ no. If yes, please identify the type of vegetation present if known.

☐ emergent ☐ submergent ☐ floating

13. Mark the flowing water system on the attached site map.

14. What observations were made at the waterbody regarding the presence and/or absence of benthic macroinvertebrates, fish, birds, mammals, etc.?

Draft Copy

Date_____

V. WETLAND HABITAT CHECKLIST

1. Based on observations and/or available information, are designated or known wetlands definitely present at the site? ☐ yes ☐ no

   Please note the sources of observations and information used (e.g., USGS Topographic Maps, National Wetland Inventory, Federal or State Agency, etc.) to make this determination.

2. Based on the location of the site (e.g., along a waterbody, in a floodplain, etc.) and site conditions (e.g., standing water; dark, wet soils; mud cracks; debris line; water marks), are wetland habitats suspected? ☐ yes ☐ no If yes, proceed with the remainder of the wetland habitat identification checklist.

3. What type(s) of vegetation are present in the wetland?

   ☐ Submergent ☐ Emergent
   ☐ Scrub/Shrub ☐ Wooded

   ☐ Other (specify)_____

4. Provide a general description of the vegetation present in and around the wetland (height, color, etc.). Provide a photograph of the known or suspected wetlands, if available.

5. Is standing water present? ☐ yes ☐ no If yes, is this water: ☐ Fresh ☐ Brackish
   What is the approximate area of the water (sq. ft.)?_____
   Please complete questions 4, 11, 12 in Checklist III - Aquatic Habitat -- Non-Flowing Systems.

6. Is there evidence of flooding at the site? What observations were noted?

   ☐ Buttressing ☐ Water marks ☐ Mud cracks

   ☐ Debris line ☐ Other (describe below)

Data Copy

Date_____

7. If known, what is the source of the water in the wetland?

☐ Stream/River/Creek/Lake/Pond ☐ Groundwater

☐ Flooding ☐ Surface Runoff

8. Is there a discharge from the site to a known or suspected wetland? ☐ yes ☐ no If yes, please describe.

9. Is there a discharge from the wetland? ☐ yes ☐ no If yes, to what waterbody is discharge released?

☐ Surface stream/River ☐ Groundwater ☐ Lake/Pond ☐ Marine

10. If a soil sample was collected, describe the appearance of the soil in the wetland area. Circle or write in the best response.

Color (blue/gray, brown, black, mottled) _____

Water content (dry, wet, saturated/unsaturated) _____

11. Mark the observed wetland area(s) on the attached site map.

Date_____

EXPLANATION OF TERMS USED IN THIS CHECKLIST

Arroyo	Dry gulch, brook, or creek. A deep gully cut by an intermittent brook or stream.
Benthic	Pertaining to the bottom of a waterbody.
Detritus	Loose fragments or particles formed by the disintegration of rocks.
Marl	A mixture of clays, carbonates of calcium and magnesium and remnants of shells.
Riparian	Of, or on the bank of a natural course of water.
Secchi (disk)	Basic measure of turbidity, visibility or transparency of water.
Submergent Vegetation	Hidden, obscure vegetation which is inundated with water.
Swales	Low tracts of land which are often moist or marshy.

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Date_____