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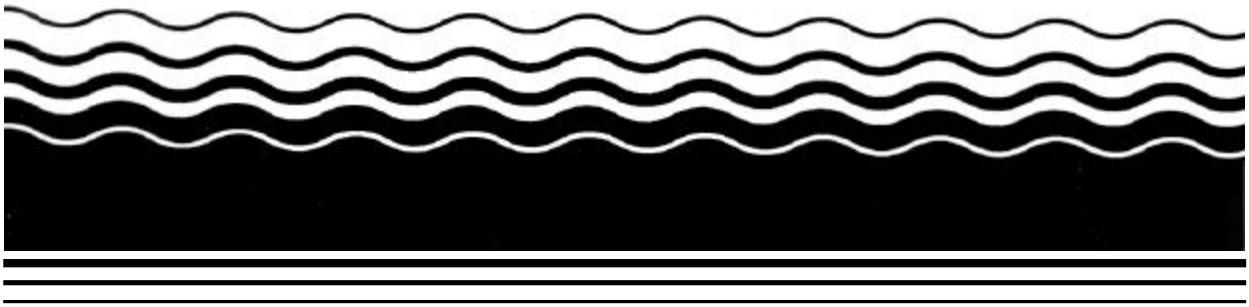
Ecological Risk Assessment Guidance for Superfund:

Process for Designing and Conducting Ecological Risk Assessments

Interim Final



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LIST OF ACRONYMS AND ABBREVIATIONS

AQUIRE:	U.S. EPA's AQUatic Information REtrieval database
ARAR:	Applicable or Relevant and Appropriate Requirements
ASTM:	American Society of Testing and Materials
BAF:	Bioaccumulation Factor
BCF:	Bioconcentration Factor
BIOSIS:	Biosciences Information Services
BTAG:	Biological Technical Assistance Group
CERCLA:	Comprehensive Environmental Response, Compensation, and Liability Act
CLP:	Contract Laboratory Program
DDT:	Dichlorodiphenyltrichloroethane
DQO:	Data Quality Objective
EC_{50}:	Effective Concentration for producing a specified effect in 50 percent of the test organisms
EEC:	Estimated Environmental Concentration
EPA:	Environmental Protection Agency
FS:	Feasibility Study
FSP:	Field Sampling Plan
FWS:	Fish and Wildlife Service
HEAST:	National Center for Environmental Assessment's Health Effects Assessment Summary Tables
HI:	Hazard Index
HQ:	Hazard Quotient
HSDB:	National Library of Medicine's Hazardous Substances Data Bank
IRIS:	EPA's Integrated Risk Information System
LC_{50}:	Concentration Lethal to 50 percent of the test organisms
Li	Liter
LOAEL:	Lowest-Observed-Adverse-Effect Level
NCP:	National Oil and Hazardous Substances Pollution Contingency Plan
NOAA:	National Oceanic and Atmospheric Administration
NOAEL:	No-Observed-Adverse-Effect Level
NRC:	National Research Council
NRDA:	Natural Resource Damage Assessment
OERR:	U.S. EPA Office of Emergency and Remedial Response
OSC:	On-Scene Coordinator
OSWER:	U.S. EPA Office of Solid Waste and Emergency Response
PA	Preliminary Assessment
PAH:	Polycyclic Aromatic Hydrocarbons
PCB:	Polychlorinated Biphenyl compound
PRP:	Potentially Responsible Party
QAPP:	Quality Assurance Project Plan
QA/QC:	Quality Assurance and Quality Control
RBP:	Rapid Bioassessment Protocol
RI:	Remedial Investigation

ROD:	Record of Decision
RPM:	Remedial Project Manager
SAP:	Sampling and Analysis Plan
SARA:	Superfund Amendments and Reauthorization Act of 1986
SI:	Site Investigation
SMDP:	Scientific/Management Decision Point
TOC:	Total Organic Carbon
WP:	Work Plan

PREFACE

This document provides guidance on the process of designing and conducting technically defensible ecological risk assessments for the Superfund Program. It is intended to promote consistency and a science-based approach within the Program and is based on the *Proposed Guidelines for Ecological Risk Assessment* (1996a) and the *Framework for Ecological Risk Assessment* (1992a) developed by the Risk Assessment Forum of the U.S. Environmental Protection Agency. When the Agency publishes its final *Guidelines for Ecological Risk Assessment*, this guidance will be reviewed and revised if necessary to ensure consistency with the Agency guidelines.

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 a site. However, it is anticipated that ecological risk assessors, as well as other individuals with input to the ecological risk assessment, will use this document.

Ecological risk assessment is an integral part of the Remedial Investigation and Feasibility Study (RI/FS) process, which is designed to support risk management decision-making for Superfund sites. The RI component of the process characterizes the nature and extent of contamination at a hazardous waste site and estimates risks to human health and the environment posed by contaminants at the site. The FS component of the process develops and evaluates remedial options. Thus, ecological risk assessment is fundamental to the RI and ecological considerations are also part of the FS process.

This document is intended to facilitate defensible site-specific ecological risk assessments. It is not intended to determine the appropriate scale or complexity of an ecological risk assessment or to direct the user in the selection of specific protocols or investigation methods. Professional judgment 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 and appropriately scaled site-specific ecological risk assessment should result.

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, non-linear process, with many parallel activities. The user should have a basic understanding of ecotoxicology and ecological risk assessment and read through this document in its entirety prior to engaging in the ecological risk assessment process. Without the basic understanding of the field and of this guidance, 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 illustrations of planning an ecological risk assessment for a hazardous waste site are provided in Appendix A. These are simplified, hypothetical examples that demonstrate and highlight specific points in the ecological risk assessment process. These examples 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 first five steps of the process, which precede a full ecological field investigation.

Excerpts from the three examples are included in the guidance document as "Example" boxes to illustrate specific points. The user is encouraged to read the three examples 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 to address specific issues.

This document supersedes the U.S. 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 for the Superfund Program. The *Environmental Evaluation Manual* contains 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

PURPOSE

This document provides guidance on how to design and conduct consistent and technically defensible ecological risk assessments for the Superfund Program. It is based on the *Proposed Guidelines for Ecological Risk Assessment* (1996a) and the *Framework for Ecological Risk Assessment* (1992a) developed by the Risk Assessment Forum of the U.S. Environmental Protection Agency (U.S. EPA or the Agency). When the Agency finalizes its (1996a) *Proposed Guidelines for Ecological Risk Assessment,* this guidance will be reviewed and revised if necessary to ensure consistency with the Agency guidelines.

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

SCOPE

This document is intended to facilitate defensible and appropriately-scaled site-specific ecological risk assessments. It is not intended to dictate the scale, complexity, protocols, data needs, or investigation methods for such assessments. Professional judgment is required to apply the process outlined in this document to ecological risk assessments at specific sites.

BACKGROUND

Superfund Program

The Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA or Superfund), as amended by the Superfund Amendments and Reauthorization Act of 1986 (SARA), authorizes the U.S. EPA to protect public health and welfare and the environment from the release or potential release of any hazardous substance, pollutant, or contaminant. U.S. EPA's Superfund Program carries out the Agency's mandate under CERCLA/SARA.

The primary regulation issued by U.S. EPA's Superfund Program is the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). The NCP calls for the identification and mitigation of environmental impacts (such as toxicity, bioaccumulation, death, reproductive impairment, growth impairment, and loss of critical habitat) at hazardous waste sites, and for the selection of remedial actions to protect the environment. In addition, numerous other federal and state laws and regulations concerning environmental protection can be designated under Superfund as "applicable" or "relevant and appropriate" requirements (ARARs) for particular sites. Compliance with these other laws and regulations generally requires an evaluation of site-related ecological effects and the measures necessary to mitigate those effects.

Risk Assessment in Superfund

An important part of the NCP is the requirement for a Remedial Investigation and Feasibility Study (RI/FS) (see Highlight I-1). The RI/FS is an analytical process designed to support risk management decision-making for Superfund sites. The RI component of the process characterizes the nature and extent of contamination at a hazardous waste site and estimates risks to human health and the environment posed by contaminants at the site. The FS component of the process develops and evaluates remedial options.

HIGHLIGHT I-1
The RI/FS Process

Risk assessment is an integral part of the 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 their distribution and concentrations. The ecological risk and human health risk assessments determine the potential for adverse effects to the environment and human health, respectively.

Although U.S. EPA has established detailed guidelines for human health risk assessment in the Superfund program (U.S. EPA, 1989a, 1991a,b), similarly detailed guidelines for site-specific ecological risk assessment do not exist for the Superfund program. *Risk Assessment Guidance for Superfund, Volume 2: Environmental Evaluation Manual* (U.S. EPA, 1989b) provides conceptual guidance in planning studies to evaluate a hazardous waste site's "environmental resources" (as used in the manual, the phrase "environmental resources" is largely synonymous with "ecological resources"). U.S. EPA also is publishing supplemental information on specific ecological risk assessment topics for Superfund in the *ECO Update* series (U.S. EPA, 1995b, 1994b,c,d,e, 1992b,c,d, 1991c,d). However, those documents do not describe an overall, step-by-step process by which an ecological risk assessment is designed and executed. The Agency's *Framework for Ecological Risk Assessment* (U.S. EPA, 1992a) provides a basic structure and a consistent approach for conducting ecological risk assessments, but is not intended to provide program-specific guidance. The *Guidelines for Ecological Risk Assessment*, currently being developed by the Agency's Risk Assessment Forum (1996a), will expand on the *Framework*, but again, will not provide program-specific guidance.

This document outlines a step-by-step ecological risk assessment process that is both specific to the Superfund Program and consistent with the more general U.S. EPA *Framework* and guidelines under development. While the Agency's *Framework* and future Agency-wide ecological risk assessment guidelines are not enforceable regulations, the concepts in those documents are appropriate to Superfund. The concepts in the published *Framework* have been incorporated into this document with minimal modification. The definitions of terms used in this ecological risk assessment guidance for Superfund (and listed in the Glossary) are consistent with the definitions in the U.S. EPA *Framework* document unless noted otherwise.

DEFINITION OF ECOLOGICAL RISK ASSESSMENT

U.S. EPA "Framework" Document

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). The *Framework* defines a stressor as any physical, chemical, or biological entity that can induce an adverse ecological response. Adverse responses can range from sublethal chronic effects in individual organisms 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, because these are the stressors subject to risk management decisions at Superfund sites.

Superfund Program

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 contaminants from 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.

THE ECOLOGICAL RISK ASSESSMENT PROCESS

U.S. EPA "Framework" Document

The *Framework* describes the basic elements of a process for scientifically evaluating the adverse effects of stressors on ecosystems and components of ecosystems. The document describes the basic process and principles to be used in ecological risk assessments conducted for the U.S. 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's (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 1983 NRC paradigm in a few ways:

- Problem formulation is incorporated into the beginning of the process to determine the focus and 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 measured in "doses") as well as chemical contamination can stress ecosystems.

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 Exhibit I-1.

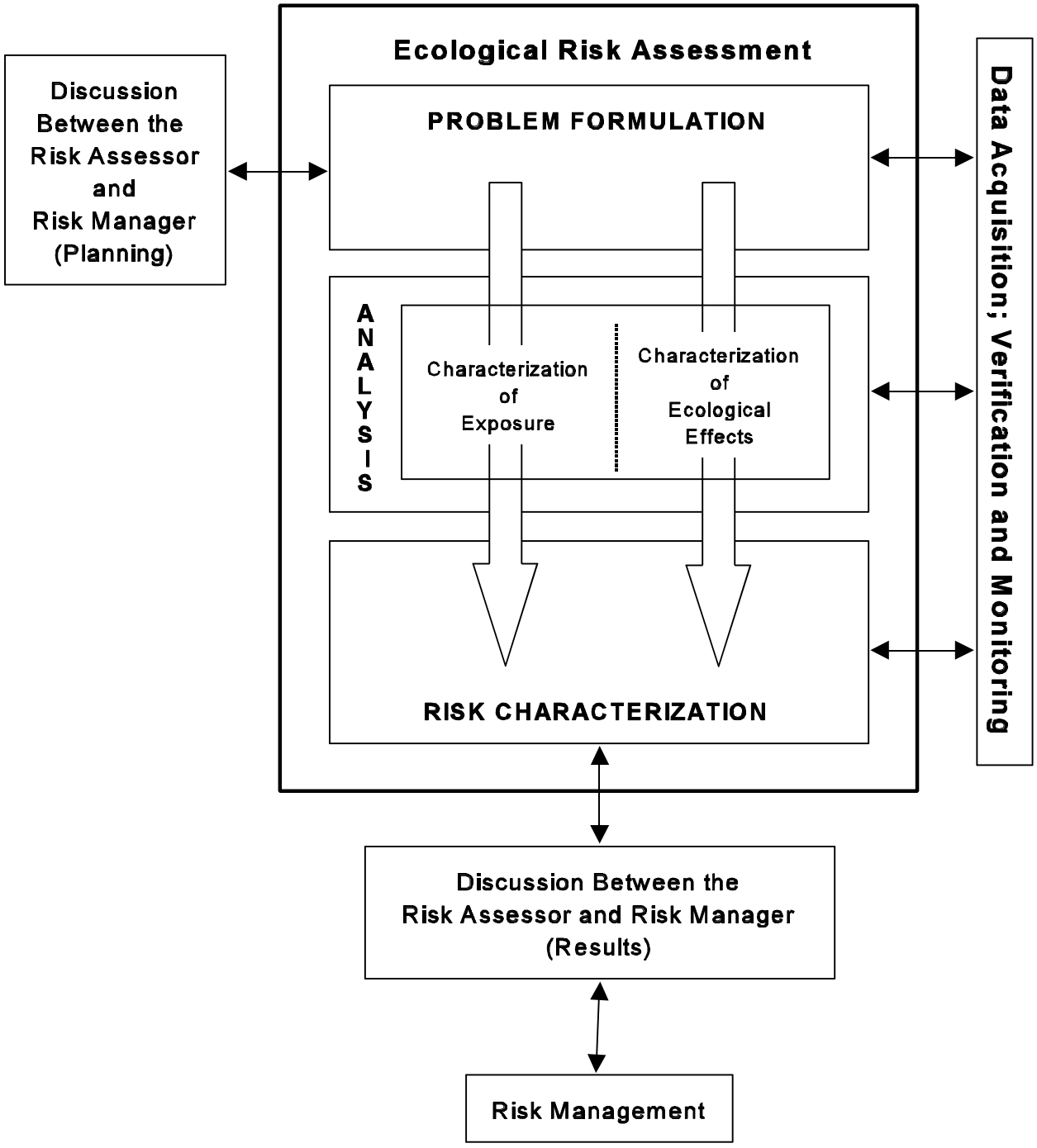
During problem formulation, the risk assessor establishes the goals, breadth, and focus of the assessment (U.S. EPA, 1992a). As indicated in the *Framework*, problem formulation is a systematic planning step that identifies the major factors to be considered and is linked to the regulatory and policy contexts of the assessment. Problem formulation includes discussions between the risk assessor and risk manager, and other involved parties, to identify the stressor characteristics, ecosystems potentially at risk, and ecological effects to be evaluated. During problem formulation, assessment and measurement endpoints for the ecological risk assessment are identified, as described below.

The Agency defines assessment endpoints as explicit expressions of the actual environmental values (e.g., ecological resources) that are to be protected (U.S. EPA, 1992a). Valuable ecological resources include those without which ecosystem function would be significantly impaired, those providing critical resources (e.g., habitat, fisheries), and those perceived as valuable by humans (e.g., endangered species and other issues addressed by legislation). Because assessment endpoints focus the risk assessment design and analysis, appropriate selection and definition of these endpoints are critical to the utility of a risk assessment.

Assessment endpoints should relate to statutory mandates (e.g., protection of the environment), but must be specific enough to guide the development of the risk assessment study design at a particular site. Useful assessment endpoints define both the valued ecological entity at the site (e.g., a species, ecological resource, or habitat type) and a characteristic(s) of the entity to protect (e.g., reproductive success, production per unit area, areal extent). Highlight I-2 provides some examples of specific assessment endpoints related to the general goal of protecting aquatic ecosystems.

A measurement endpoint is a measurable biological response to a stressor that can berelated to the valued characteristic chosen as the assessment endpoint (U.S. EPA, 1992a; although this definition may change—see U.S. EPA, 1996a). Sometimes, the assessment endpoint can be measured directly; usually, however, an assessment endpoint encompasses too many species or species that are difficult to evaluate (e.g., top-level predators). In these cases, the measurement endpoints are different from the assessment endpoint, but can be used to make inferences about risks to the assessment endpoints. For example, measures of responses in particularly sensitive species and life stages might be used to infer responses in the remaining species and life stages in a specific community. Such inferences must be clearly described to demonstrate the link between measurement and assessment endpoints. Highlight I-3 provides examples of measurement endpoints.

EXHIBIT I-1
Ecological Risk Assessment Framework (U.S. EPA, 1992a)



Measures of exposure also can be used to make inferences about risks to assessment endpoints at Superfund sites. For example, measures of water concentrations of a contaminant can be compared with concentrations known from the literature to be lethal to sensitive aquatic organisms to infer something about risks to aquatic community structure. As a consequence, for purposes of this guidance, measurement endpoints include both measures of effect and measures of exposure.

HIGHLIGHT I-2
Example Assessment Endpoints

- Sustained aquatic community structure, including species composition and relative abundance and trophic structure.
- Sufficient rates of survival, growth, and reproduction to sustain populations of carnivores typical for the area.
- Sustained fishery diversity and abundance.

A product of problem formulation is a conceptual model for the ecological risk assessment that describes how a given stressor might affect ecological components of the environment. The conceptual model also describes questions about how stressors affect the assessment endpoints, the relationships among the assessment and measurement endpoints, the data required to answer the questions, and the methods that will be used to analyze the data (U.S. EPA, 1992a).

Superfund Program

The goal of the ecological risk assessment process in the Superfund Program is to provide the risk information necessary to assist risk managers at Superfund sites (OSCs and RPMs) in making informed decisions regarding substances designated as hazardous under CERCLA (see 40 CFR 302.4). 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 identify cleanup levels that would protect those natural resources from risk. Threats to the environment include existing adverse ecological impacts and the risk of such impacts in the future. Highlight I-4 provides an overview of ecological risk assessment in the Superfund Program.

HIGHLIGHT I-3
Example Measurement Endpoints

- Communy anayss of benthic macroinvertebrates.
- Survival and growth of fish fry in response to exposure to copper.
- Community structure of fishery in proximity to the site.

Problem formulation is the most critical step of an ecological risk assessment and must precede any attempt to design a site investigation and analysis plan. To ensure that the risk manager can use the results of an ecological risk assessment to inform risk management decisions for a Superfund site, it is important that all involved parties contribute to the problem formulation phase and that the risk manager is clearly identified to all parties. These parties include the remedial project manager (RPM), who is the risk manager with ultimate responsibility for the site, the ecological risk assessment team, the Regional Superfund Biological Technical Assistance Group (BTAG), potentially responsible parties (PRPs), Natural Resource Trustees, and stakeholders in the natural resources at issue (e.g., local communities, state agencies) (U.S. EPA, 1994a, 1995b). The U.S. EPA's (1994a) *Edgewater Consensus on an EPA Strategy for Ecosystem Protection* in particular calls for the Agency to develop a "place-driven" orientation, that

HIGHLIGHT I-4
Ecological Impact and Risk Assessment

Ecological risk assessment within the Superfund Program can be a risk evaluation (potentially predictive), impact evaluation, or a combination of those approaches. The functions of the ecological risk assessment are to:

(1) Document whether actual or potential ecological risks exist at a site;

(2) Identify which contaminants present at a site pose an ecological risk; and

(3) Generate data to be used in evaluating cleanup options.

Ecological risk assessments can have their greatest influence on risk management at a site in the evaluation and selection of site remedies. The ecological risk assessment should identify contamination levels that bound a threshold for adverse effects on the assessment endpoint. The threshold values provide a yardstick for evaluating the effectiveness of remedial options and can be used to set cleanup goals if appropriate.

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 (e.g., diminished population size), although this can be difficult to demonstrate. 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 (e.g., 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 cleanup levels.

As noted above, the ecological risk assessment should provide the information needed to make risk management decisions (e.g., to select the appropriate site remedy). A management option should not be selected first, and then the risk assessment tailored to justify the option.

is, to focus on the environmental needs of specific communities and ecosystems, rather than on piecemeal program mandates. Participation in problem formulation by all involved parties helps to achieve the place-driven focus.

Issues such as restoration, mitigation, and replacement are important to the Superfund Program, but are reserved for investigations that might or might not be included in the RI phase. During the risk management process of selecting the preferred remedial option leading to the Record of Decision (ROD), issues of mitigation and restoration should be addressed. In selecting a remedy, the risk manager must also consider the degree to which the remedial alternatives reduce risk and thereby also reduce the need for restoration or mitigation.

A natural resource damage assessment (NRDA) may be conducted at a Superfund site at the discretion of Natural Resource Trustees for specific resources associated with a site. 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. The risk assessment also can provide information on what residual risks are likely for different remediation options. However, the ecological risk assessment does not constitute an NRDA. The NRDA is the sole responsibility of the Natural Resource Trustees, not of the U.S. EPA; therefore, NRDAs 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).

EXHIBIT I-4
Ecological Risk Assessment Deliverables for the Risk Manager

If the process stops at the end of Step 2:

(1) Full documentation of the screening-level assessment and SMDP not to continue the assessment.

If the process continues to Step 3:

(1) Documentation of the conceptual model, including assessment endpoints, exposure pathways, risk hypotheses, and SMDP at the end of Step 3.

(2) The approved and signed work plan and sampling and analysis plan, documenting the SMDPs at the end of Steps 4 and 5.

(3) The baseline risk assessment documentation (including documentation of the screening-level assessment used in the baseline assessment) developed in Step 7.

EXHIBIT I-2
Eight-step Ecological Risk Assessment Process for Superfund

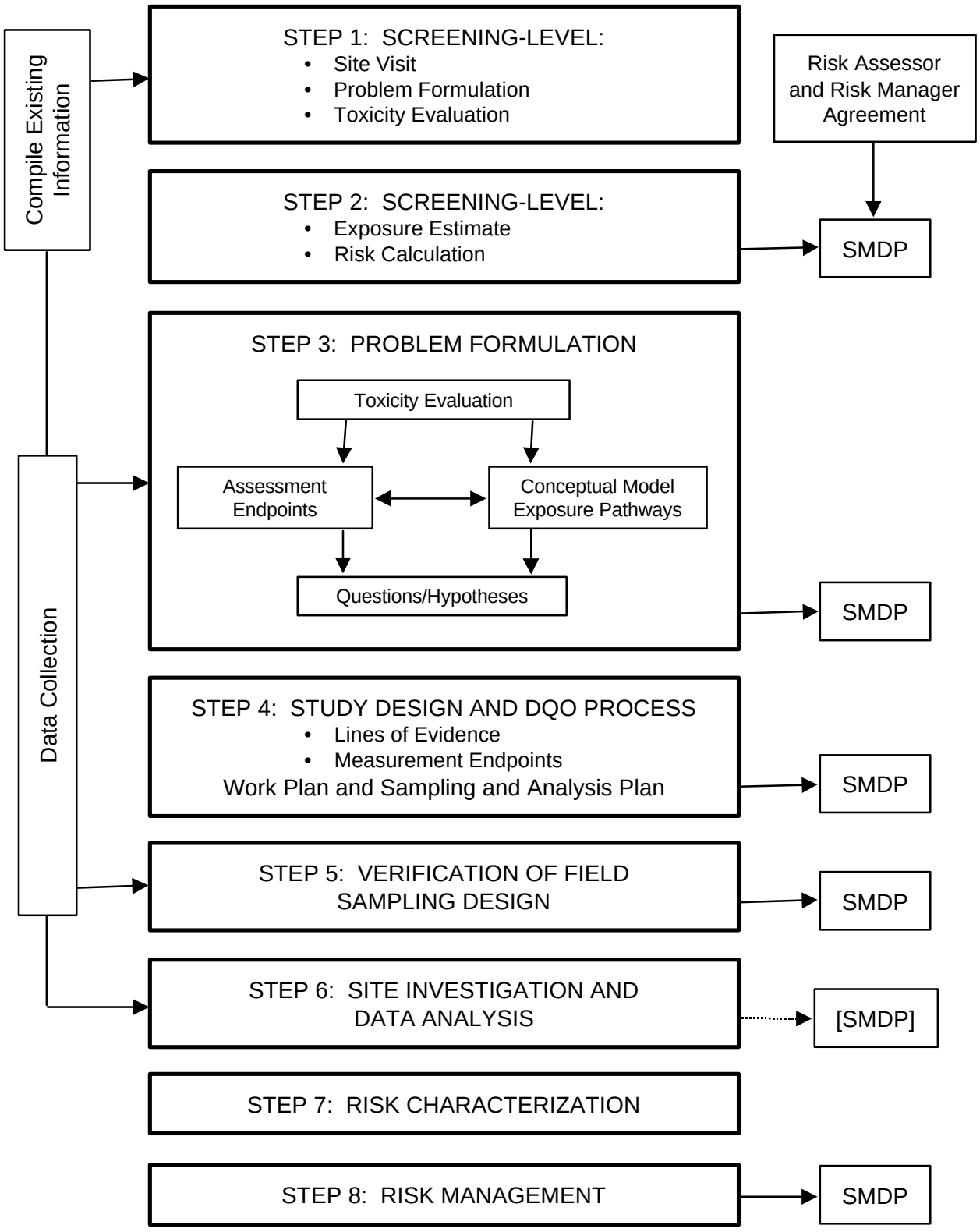


EXHIBIT I-3
Steps in the Ecological Risk Assessment Process and Corresponding Decision Points in the Superfund Process

Steps and Scientific/Management Decision Points (SMDPs):

1.	Screening-Level Problem Formulation and Ecological Effects Evaluation	
2.	Screening-Level Preliminary Exposure Estimate and Risk Calculation	SMDP (a)
3.	Baseline Risk Assessment Problem Formulation	SMDP (b)
4.	Study Design and Data Quality Objectives	SMDP (c)
5.	Field Verification of Sampling Design	SMDP (d)
6.	Site Investigation and Analysis of Exposure and Effects	[SMDP]
7.	Risk Characterization	
8.	Risk Management	SMDP (e)

Corresponding Decision Points in the Superfund Process:

(a) Decision about whether a full ecological risk assessment is necessary.

(b) Agreement among the risk assessors, risk manager, and other involved parties on the conceptual model,including assessment endpoints, exposure pathways, and questions or risk hypotheses.

(c) Agreement among the risk assessors and risk manager on the measurement endpoints, study design, and data interpretation and analysis.

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

(e) Signing the Record of Decision.

[SMDP] only if change to the sampling and analysis plan is necessary.

This Guidance Document

This ecological risk assessment guidance for Superfund is composed of eight steps (see Exhibit I-2) and several scientific/management decision points (SMDPs) (see Exhibit I-3). An SMDP requires a meeting between the risk manager and risk assessment team to evaluate and approve or redirect the work up to that point. (Consultation with the Regional BTAG is recommended for SMDPs (a) through (d) in Exhibit I-3.) The group decides whether or not the risk assessment is proceeding in a direction that is acceptable to the risk assessors and manager. The SMDPs include a discussion of the uncertainty associated with the risk assessment, that might be reduced, if necessary, with increased effort. SMDPs are significant communication points which should be passed with the consensus of all involved parties. The risk manager should expect deliverables that document specific SMDPs as outlined in Exhibit I-4. This approach is intended to minimize both the cost of and time required for the Superfund risk assessment process.

This guidance provides a technically valid approach for ecological risk assessments at hazardous waste sites, although other approaches also can be valid. The discipline of ecological risk assessment is dynamic and continually evolving; the assessments rely on data that are complex and sometimes ambiguous. Thus, if an approach other than the one described in this guidance document is used, there must be clear documentation of the process, including process design and interpretation of the results, to ensure a technically defensible assessment. Clear documentation, consistency, and objectivity in the assessment process are necessary for the Superfund Program.

An interdisciplinary team including, but not limited to, biologists, ecologists, and environmental toxicologists, is needed to design and implement a successful risk assessment and to evaluate the weight of the evidence obtained to reach conclusions about ecological risks. 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 to fill data gaps for toxicity and exposure assessments based on logic and scientific principles; and
- Interpreting the ecological significance of observed or predicted effects.

The lead risk assessor should coordinate with appropriate professionals to make many of these decisions. Specialists are needed for the more technical questions concerning the risk assessment (e.g., which model, which assumptions).

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

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 process are a streamlined version of the complete *Framework* process and are intended to allow a rapid determination by the risk assessment team and risk manager that the site poses no or negligible ecological risk, or to identify which contaminants and exposure pathways require further evaluation. Steps 3 through 7 are a more detailed version of the complete *Framework* process.

The ecological risk assessment process should be coordinated with the overall RI/FS process to the extent possible. Overall site-assessment costs are minimized when the needs of the ecological and human health risk assessments are incorporated into the chemical sampling program to determine the nature and extent of contamination during the RI. For sites at which an RI has not yet been planned or conducted, Exhibit I-5 illustrates the relationship between the eight ecological risk assessment steps and the overall Superfund process and decision points. For older sites at which an RI was conducted before an ecological risk assessment was considered, the ecological risk assessment process should build on the information already developed for the site.

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 atwhich the site is currently, the amount and types of site information available, as well as other factors. The process can be iterative, and in some iterations, certain individual steps might not be needed. In many cases, it might be appropriate and desirable to conduct several steps concurrently.

Tasks that should be accomplished in each of the eight steps in Exhibits I-2 and I-3 are described in the eight following sections. The eight sections include example boxes based on the three hypothetical Superfund sites in Appendix A as well as exhibits and highlight boxes.

EXHIBIT I-5
Ecological Assessment in the RI/FS Process