Considerations for Developing Problem Formulations for Ecological Risk Assessments Conducted at Contaminated Sites under CERCLA

A Discussion Paper

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List of Acronyms

BERA	-	baseline ecological risk assessment
COPC	-	chemical of potential concern
CERCLA	-	Comprehensive Environmental Response, Compensation, and Liability Act
DQO	-	data quality objectives
DELT	-	deformities, fin erosion, lesions, and tumors
ERA	-	ecological risk assessment
HHRA	-	human health risk assessments
K_{ow}	-	octanol-water partition coefficients
K_{oc}	-	organic carbon partition coefficients
RI/FS	-	remedial investigation and feasibility study
SMDP	-	Scientific Management Decision Point
SERA	-	screening-level ecological risk assessment
SQGs	-	sediment quality guidelines
TECs	-	threshold effect concentrations

Chapter 1 Introduction

1.0 Background

This document was prepared to support the design and implementation of ecological risk assessments (ERA) of contaminated sites that are conducted as part of a remedial investigation and feasibility study (RI/FS) under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). More specifically, this document describes some key elements of the problem formulation process (i.e., which defines the questions that need to be addressed during the ERA) and outlines some of the options that can be pursued to adequately assess risks to ecological receptors at such sites. This chapter of the document provides an overview of the RI/FS process and describes the purpose of the report.

1.1 Remedial Investigation and Feasability Study

In the United States, remediation of contaminated sites is performed primarily under the provisions of CERCLA (Suter *et al.* 2000). The regulations that govern implementation of the act are contained within the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), which necessitate protection of both human health and the environment. The regulations call for conducting an RI/FS at contaminated sites to determine the need for remediation and for choosing a remedial alternative. More specifically, the remedial investigation serves as the mechanism for collecting data to:

- Characterize site conditions;
- Determine the nature of the waste;
- Assess risk to human health and the environment; and,
- Conduct treatability testing to evaluate the potential performance and cost of the treatment technologies that are being considered.

By comparison, the feasability study represents the principal mechanism for developing, screening, and evaluating alternative remedial actions. In general, a phased approach is used to conduct the RI/FS, with the phases including: i) scoping; ii) site characterization; iii) development and screening of alternatives; iv) treatability investigations; and, v) detailed analysis (www.epa.gov/superfund/whatissf/sfprocess/rifs.htm).

1.1.1 Characterization of the Nature and Extent of Contamination

As indicated above, one of the main purposes of the RI is to gather sufficient information on the site to define the nature and extent of chemical contamination (i.e., in water, sediment, soil, and biota) and to support human health (HHRA) and/or ecological (ERA) risk assessments. In general, a phased approach is used to evaluate the nature and extent of chemical contamination at a site. In the first phase of the RI, historical data and information are used to develop a preliminary list of chemicals of potential concern (COPCs) and determine the analytical protocols needed to evaluate the nature and extent of contamination. A Phase I sampling program is then designed to provide the data needed to determine the types of contaminants that occur in environmental media and their geographic distribution within the site. These data also support the design of the Phase II sampling program and the human health and ecological risk assessments.

The second phase of the remedial investigation typically involves the design of a focused sampling program for further characterizing the site. More specifically, the Phase II sampling program provides a basis for identifying sources of COPCs, further evaluating the nature and extent of contamination (including concentration gradients in environmental media and in reference areas), and evaluating impacts on selected receptors at the site. The data collected during the Phase II RI also support the HHRA and the ERA. Accordingly, it is essential to ensure that nature and extent study is designed to provide all of the information needed to conduct the risk assessments and to delineate the scope of remedial activities.

1.1.2 Ecological Risk Assessment

In response to concerns regarding environmental contamination, an ecological risk assessment is typically conducted at contaminated sites that are addressed under CERCLA. Such an ERA must be conducted in accordance with the *Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessment* (USEPA 1997). The United States Environmental Protection Agency (USEPA) guidance document describes an eight-step process for conducting an ERA, including:

Step 1: Screening-Level Preliminary Problem Formulation and Ecological Effects Evaluation;

Step 2: Screening-Level Preliminary Exposure Estimate and Risk Calculation Scientific Management Decision Point (SMDP);

Step 3: Baseline Risk Assessment Problem Formulation SMDP;

Step 4: Study Design and Data Quality Objectives SMDP;

Step 5: Field Verification of Sampling Design SMDP;

Step 6: Site Investigation and Analysis of Exposure and Effects SMDP;

Step 7: Risk Characterization; and,

Step 8: Risk Management SMDP.

In accordance with the USEPA guidance, the objectives of such an ERA are:

- To estimate the risks posed to ecological receptors by environmental contamination at the contaminated site; and,
- To provide the information needed by risk managers to make decisions regarding the need for remedial actions, including the establishment of clean-up goals for the site.

1.2 Purpose of this Report

This document was prepared to support the design and implementation of ecological risk assessments conducted at contaminated sites that are addressed under CERCLA. More specifically, this document is designed to support the problem formulation process for screening-level and baseline ERAs (i.e., SERAs and BERAs, respectiviely) by identifying candidate assessment endpoints, risk questions, and measurement endpoints that should be considered for application at contaminated sites. Importantly, consideration of the options identified in this document will help establish the goals, scope, and focus of the ERAs that are conducted at such sites, inform study designs (as defined in the sampling and analysis plans), and support the data quality objectives process (i.e., by establishing the measurement endpoints that will be used in the assessment).

Chapter 2 Considerations for Developing Problem Formulations for Ecological Risk Assessments

2.0 Introduction

The process of defining the questions that will be addressed during an ERA is termed *problem formulation*. Problem formulation is a systematic planning process that identifies the factors to be addressed in an ERA and consists of five major activities (USEPA 1997), including:

- Refinement of the preliminary list of COPCs at the site;
- Further characterization of the potential ecological effects of the COPCs at the site;
- Review and refinement of the information on the fate and transport of the COPCs on potential exposure pathways, and on the receptors potentially at risk;
- Selection of assessment and measurement endpoints; and,
- Development of a conceptual model with testable hypotheses (or risk questions) that the site investigation will address.

At the conclusion of the problem formulation, there is a scientific/management decision point, which consists of agreement on four items: the assessment endpoints, the exposure pathways, the risk questions, and the conceptual model that integrates these components (USEPA 1997).

Information developed during the problem formulation process is intended to provide a basis for evaluating the applicability of the risk questions/testable hypotheses, exposure pathway models, and measurement endpoints that have been proposed for the BERA. In this way, the problem formulation document contributes to the development of the sampling design. The problem formulation process is also intended to define how the information collected during the site investigation will be used to characterize exposures, ecological effects, and ecological risks, including associated uncertainties.

- Definition of the scope of the site;
- Identification of COPCs;
- Evaluation of the environmental fate and effects of the COPCs;
- Identification of key exposure pathways;
- Identification of receptors potentially at risk;
- Development of the conceptual site model;
- Selection of assessment endpoints;
- Articulation of risk questions and/or testable hypotheses;
- Identification of measurement endpoints; and,
- Development of a plan for analyzing risk and evaluating uncertainty.

Each of these steps in the problem formulation process is discussed briefly in the following sections of this chapter.

2.1 Definition of the Geographic Scope of the Site

For the purposes of assessing risks to ecological receptors, it is necessary to define the scope of the study area. According to Suter *et al.* (2000), the spatial extent of a site can be established based on one or more of the following criteria:

- The areas in which wastes have been deposited;
- The areas believed to be contaminated;
- The area owned or controlled by the responsible party;
- The extent of transport processes; and,
- Buffer zones.

Much of the information needed to define the boundaries of the site can be obtained from historical data and site records. However, site inspections should also be conducted to identify COPC sources, obtain other evidence of contamination, and evaluate likely transport processes. While such information can prove to be invaluable, sampling and analysis are usually needed to establish the actual extent of contamination (Suter *et al.* 2000). In some cases, it may be necessary to extend the boundaries of the site as new information becomes available.

2.2 Identification of Chemicals of Potential Concern

A BERA that is conducted as part of an overall RI/FS is intended to evaluate the risks posed to ecological receptors associated with exposure to environmental contamination at the site. In addition, a BERA is intended to provide risk managers with the information required to make decisions regarding the need for remedial actions. The problem formulation process provides a basis for systematically planning the various elements of the BERA and communicating this strategy to all stakeholders.

There are a number of natural and anthropogenic sources of toxic and bioaccumulative substances at contaminated sites. Natural sources of such substances can include weathering and erosion of terrestrial soils, bacterial decomposition of vegetation and animal matter, and long-range transport of substances originating from forest fires or other natural combustion sources. Anthropogenic sources of COPCs can include industrial wastewater discharges, municipal wastewater treatment plant discharges, stormwater discharges, surface water recharge by contaminated groundwater, non-point source discharges, spills associated with production and transport activities, and deposition of substances that have been released into the atmosphere.

The identification of chemicals of potential concern (COPCs) represents an essential element of the problem formulation process (USEPA 1998).

When used together, the information on historic and current uses of the site, on regional land use patterns, on the characteristics of effluent and stormwater discharges in the vicinity of the site provides a basis for identifying the preliminary COPCs at a site. However, further refinement of this list requires data on the physical/chemical properties of each of those substances. More specifically, information should be compiled on the octanol-water partition coefficients (K_{ow}), organic carbon partition coefficients (K_{oc}), and solubilities of the preliminary COPCs. Substances with moderate to high log K_{ow} or log K_{oc} values (i.e., > 3.5) and/or those that are sparingly soluble in water are the most likely to accumulate in sediments. The preliminary COPCs that have a high potential for accumulating in sediments should be identified as the sediment-associated COPCs at the site.

In addition to information on the sources and fate of chemical substances, historical sediment chemistry data provide a basis for identifying sediment-associated COPCs. However, evaluating the relevance and quality of historic data before using it in this application is important. For example, historical data sets may include only a limited suite of chemical analytes, which restricts their use for identifying COPCs. In addition, the applicability of the sediment chemistry data may be further restricted by high analytical detection limits and/or poor recoveries of target analytes from sediments. Furthermore, spatial coverage of the study area may not include the areas that are most likely to have contaminated sediments. Due to these potential limitations, historical data sets should be used with caution for eliminating substances from the list of COPCs for a site. However, substances that have been measured in sediments at concentrations in excess of threshold effect concentrations (TECs) or similar sediment quality guidelines (SQGs) should be identified as COPCs.

2.3 Evaluation of the Environmental Fate and Effects of the Chemicals of Potential Concern

A stressor is any physical, chemical, or biological entity that has the potential to cause a change in the ecological condition of the environment (USEPA 2000). Accurate identification of the stressor or stressors that are causing or substantially contributing to

biological impairments in aquatic and terrestrial ecosystems is important because it provides a basis for developing strategies that are likely to improve the quality of aquatic resources (USEPA 2000). In this way, limited human and financial resources can be directed at the challenges that are most likely to maintain or restore beneficial uses.

Many physical (e.g., water temperature, salinity, dissolved oxygen, erosion and sedimentation, habitat degradation, and pH) and biological (e.g., introduced species, recreational and commercial fishing, disease) factors also have the potential to adversely affect aquatic and terrestrial organisms utilizing habitats in the vicinity of contaminated sites. However, quantification of the effects of these factors on key ecological receptors is outside the scope of a BERA. For this reason, it is important to develop a strategy for addressing this apparent limitation of the BERA process. Typically this involves assessing risks to ecological receptors in the study areas relative to the comparable risks to those receptors in reference areas. In this way, it is possible to estimate the incremental risks (i.e., or additional risks, which is often referred to as Δ risk) posed by COPCs above that posed by physical and biological stressors in the systems. In addition, any unaccounted effects of such factors on the measurement endpoints can be addressed in the associated uncertainty analysis. Accordingly, identification and selection of reference sites represents a key element of the overall ERA process.

2.4 Identification of Key Exposure Pathways

Ecological risk assessment describes the process in which the risks associated with exposure of ecological receptors to contaminated environmental media (i.e., water, sediment, soil, or biological tissues) are estimated. Evaluation of the risks posed by COPCs at a contaminated site requires a detailed understanding of the pathways through which ecological receptors are exposed to these substances. In turn, the identification of key exposure pathways requires an understanding of the sources and releases of environmental contaminants and the environmental fate of these substances.

There are a number of sources of toxic and bioaccumulative substances at contaminated sites. Natural sources of such substances include weathering and erosion of terrestrial soils, bacterial decomposition of vegetation and animal matter, and long-range transport of substances originating from forest fires or other natural combustion sources. Anthropogenic sources of environmental contaminants in the estuary include industrial wastewater discharges, municipal wastewater treatment plant discharges, surface water recharge by contaminated groundwater, non-point source discharges, and deposition of substances that have been released into the atmosphere.

Upon release into aquatic ecosystems, COPCs partition into environmental media (i.e., water, sediment, soils, and/or biota) in accordance with their physical and chemical properties and the characteristics of the receiving water body. As a result of such partitioning, COPCs can occur at elevated levels in surface water, bottom sediments, soils and/or the tissues of aquatic or terrestrial organisms. To facilitate the development of conceptual models that link stressors to receptors, the COPCs can be classified into three groups based on their fate and effects in the aquatic and terrestrial ecosystems, including bioaccumulative substances, toxic substances that partition into soils and sediments, and toxic substances that partition into water (including the surface microlayer).

Once released to the environment, there are three pathways through which ecological receptors can be exposed to COPCs. These routes of exposure include direct contact with contaminated environmental media, ingestion of contaminated environmental media, and inhalation of contaminated air. All three of these exposure routes need to be considered in the problem formulation process.

2.5 Identification of Receptors Potentially at Risk

A critical element of the problem formulation process is the identification of the receptors at risk within the study area. USEPA guidance is available to help identify receptors at risk (USEPA 1989; 1992; 1997). The guidance states that receptors at risk include: (1) resident

species or communities exposed to the highest chemical concentrations in environmental media; (2) species or functional groups that are essential to, or indicative of, the normal functioning of the affected habitat; and, (3) federal or state threatened or endangered species.

At contaminated sites, the ecological receptors potentially at risk include the plants and animals that utilize the aquatic, wetland, and terrestrial habitats within the watershed that have been contaminated by historic releases of COPCs. These groups of organisms include microbiota, aquatic and terrestrial plants, aquatic and terrestrial invertebrates, fish, reptiles, amphibians, birds, and mammals. All of the receptor groups should be evaluated to determine if potentially complete exposure pathways exist at the site.

2.6 Development of the Conceptual Site Model

In accordance with USEPA guidance, the problem formulation for a BERA is intended to provide three main products, including: assessment endpoints, conceptual models, and a risk analysis plan (USEPA 1997; 1998). Development of the conceptual model represents a particularly important component of the problem formulation process because it enhances the level of understanding regarding the relationships between human activities and ecological receptors at the site under consideration. Specifically, the conceptual model describes key relationships between stressors and assessment endpoints. In so doing, the conceptual model provides a framework for predicting effects on ecological receptors and a template for generating risk questions and testable hypotheses (USEPA 1997; 1998). The conceptual model also provides a means of highlighting what is known and what is not known about a site. In this way, the conceptual model provides a basis for identifying data gaps and designing monitoring programs to acquire the information necessary to complete the assessment.

Conceptual models consist of two main elements, including: a set of hypotheses that describe predicted relationships between stressors, exposures, and assessment endpoint responses (along with a rationale for their selection); and, diagrams that illustrate the relationships

presented in the risk hypotheses. Accordingly, development of the conceptual model depends on information on sources and releases of COPCs, the fate and transport of these substances, the pathways by which ecological receptors are exposed to the COPCs, and the potential effects of these substances on the ecological receptors that occur at the site. In turn, this information is used to develop a series of hypotheses that provide predictions regarding how ecological receptors will be exposed to and respond to the COPCs.

2.7 Selection of Assessment Endpoints

In the environment, a variety of plant and animal species can be exposed to COPCs (these species are referred to as receptors potentially at risk). Each of these receptors can be exposed to a chemical through different exposure routes and have the potential to exhibit different types and severities of effects. While information on the effects of each chemical on each component of the ecosystem would provide comprehensive information for evaluating ecological risks, it is neither practical nor feasible to directly evaluate risks to all of the individual components of the ecosystem that could be adversely affected by environmental contamination at a site (USEPA 1997). For this reason, risk assessment activities typically focus on the receptors that represent valued ecosystem components (e.g., sportfish species) and on the receptors that support valued ecosystem functions (e.g., carbon processing by the microbial community, which is needed to support healthy fish populations). Of particular interest are those receptors that are most likely to be adversely affected by the presence of environmental contaminants at the site (USEPA 1998).

An assessment endpoint is an 'explicit expression of the environmental value that is to be protected' (USEPA 1997). The selection of assessment endpoints is an essential element of the overall ERA process because it provides a means of focusing assessment activities on the key environmental values (e.g., reproduction of sediment-probing birds) that could be adversely affected by exposure to environmental contaminants.

As part of the preliminary problem formulation, a number of candidate assessment endpoints should be considered for use in the BERA, including:

- Activity of the microbial community;
- Survival and growth of aquatic and terrestrial plants;
- Survival and growth, and reproduction of aquatic invertebrates;
- Survival and growth, and reproduction of terrestrial invertebrates;
- Survival, growth and reproduction of fish;
- Survival, growth and reproduction of amphibians;
- Survival, growth and reproduction of reptiles;
- Survival, growth and reproduction birds; and,
- Survival, growth and reproduction of mammals.

Assessment endpoints must be selected based on the ecosystems, communities, and species that occur, have historically occurred, or could potentially occur at the site (USEPA 1997). The following factors need to be considered during the selection of assessment endpoints (USEPA 1997):

- The COPCs that occur in environmental media and their concentrations;
- The mechanisms of toxicity of the COPCs to various groups of organisms;
- The ecologically-relevant receptor groups that are potentially sensitive to or highly exposed to the contaminant, based upon their natural history attributes; and,
- The presence of potentially complete exposure pathways.

Thus, the fate, transport, and mechanisms of ecotoxicity for each contaminant or group of contaminants must be considered to determine which receptors are likely to be most at risk. This information must include an understanding of how the adverse effects of the contaminant

could be expressed (e.g., eggshell thinning in birds) and how the form of the chemical in the environment could influence its bioavailability and toxicity.

2.8 Articulation of Risk Questions and/or Testable Hypotheses

Selection of assessment endpoints represents an essential element of the overall problem formulation process. While such assessment endpoints are essential for defining the environmental values that need to be protected at the Anniston PCB Site, it is difficult or impossible to measure the effects on all of the members of a receptor group that are associated with exposure to COPCs at the site. For this reason, it is necessary to articulate specific risk questions (i.e., testable hypotheses) that can be answered through the collection of focused data and information at the site. A list of candidate assessment endpoints and associated risk questions that could be applied at contaminated sites addressed under CERCLA includes:

1. ***Survival and Growth of Aquatic and Terrestrial Plants***
    - Are the levels of contaminants in surface water, whole sediments and/or soils from the site greater than benchmarks for the survival, growth, or reproduction of aquatic or terrestrial plants?
    - Is the survival, growth, or reproduction of aquatic and/or terrestrial plants exposed to surface water, sediments, or soil from the site significantly lower than that for aquatic and/or terrestrial plants exposed to media from reference sites?

2. ***Survival, Growth, and Reproduction of Aquatic Invertebrates***
    - Are the levels of contaminants in surface water and/or whole sediments from the site greater than benchmarks for the survival, growth, or reproduction of aquatic invertebrates?

- Is the survival, growth or reproduction of aquatic invertebrates exposed to whole sediments from the site significantly lower than that in reference sediments?
- Is the structure of aquatic invertebrate communities at the site outside the normal range (i.e., 95th percentile) for aquatic invertebrate communities in reference areas?

3. Survival, Growth, and Reproduction of Terrestrial Invertebrates

- Are the levels of contaminants in soil from the site greater than benchmarks for the survival, growth, or reproduction of terrestrial invertebrates?
- Is the survival, growth or reproduction of terrestrial invertebrates exposed to soils from the site significantly lower than that in reference soils?
- Is the structure of terrestrial invertebrate communities in the site soils outside the normal range (i.e., 95th percentile) for terrestrial invertebrate communities in reference areas?

4. Survival, Growth and Reproduction of Fish

- Are the levels of contaminants in surface water and/or whole sediments from the site greater than benchmarks for the survival, growth, or reproduction of fish?
- Is the survival, growth or reproduction of fish exposed to surface water or sediments from the site significantly lower than that for reference media?
- Is the frequency of deformities, fin erosion, lesions and tumors (DELT) abnormalities significantly higher in fish from the site than in fish from reference areas?
- Are the levels of contaminants in fish tissues from the site greater than critical tissue values for the survival, growth, or reproduction of fish?

5. Survival, Growth and Reproduction of Amphibians

- Are the levels of contaminants in surface water, whole sediments and/or soil from the site greater than benchmarks for the survival, growth, or reproduction of amphibians?
- Is the survival, growth or reproduction of amphibians exposed to surface water, whole sediments and/or soils from the site significantly lower than that for reference media?
- Is the frequency of abnormalities significantly higher in amphibians from the site than in amphibians from reference areas?
- Is the sex ratio of amphibians significantly different between the site and reference areas?

6. Survival, Growth and Reproduction of Reptiles

- Are the levels of contaminants in surface water, whole sediments and/or soil from the site greater than benchmarks for the survival, growth, or reproduction of reptiles?
- Is the frequency of abnormalities significantly higher in reptiles from the site than in reptiles from reference areas?

7. Survival, Growth and Reproduction Birds

- Does the daily dose of contaminants received by birds from consumption of the tissues of prey species and from other media at the site exceed the toxicity reference values (TRVs) for survival, growth or reproduction of birds? If yes, what are the probabilities of effects of differing magnitude for survival and/or reproduction of sediment-probing birds?
- Are the concentrations of contaminants in bird eggs from the site greater than benchmarks for the survival, growth, or reproduction of birds?
- Is the reproduction of birds utilizing the habitats in the vicinity of the site significantly impaired compared to that measured for reference areas?

8. Survival, Growth and Reproduction of Mammals

- Does the daily dose of contaminants received by mammals from consumption of the tissues of prey species and from other media at the site exceed the toxicity reference values (TRVs) for survival, growth or reproduction of mammals? If yes, what are the probabilities of effects of differing magnitude for survival and/or reproduction of sediment-probing birds?
- Are the concentrations of contaminants in mammal tissues from the site greater than benchmarks for the survival, growth, or reproduction of mammals?

2.9 Identification of Measurement Endpoints

A measurement endpoint is defined as 'a measurable ecological characteristic that is related to the valued characteristic that is selected as the assessment endpoint' and it is a measure of biological effects (e.g., mortality, reproduction, growth; USEPA 1997). Measurement endpoints are frequently numerical expressions of observations (e.g., toxicity test results, community diversity measures) that can be compared to similar observations at a control and/or reference site. Such statistical comparisons provide a basis for evaluating the effects that are associated with exposure to a contaminant or group of contaminants at the site under consideration. Measurement endpoints can include measures of exposure (e.g., contaminant concentrations in water or sediments) or measures of effects (e.g., survival or growth of amphipods in 10-d toxicity tests). The relationship between an assessment endpoint, a risk question, and a measurement endpoint must be clearly described within the conceptual model and must be based on scientific evidence (USEPA 1997).

After identifying receptors potentially at risk and selecting assessment endpoints, it is helpful to describe the linkages that are likely to exist between exposure media (i.e., stressors) and receptors at the site. The results of this process provide a basis for identifying focal species for each group of receptors and each group of chemical substances. In turn, this information

is used to identify measurement endpoints that can be used to evaluate the status of each assessment endpoint. As it would not be practical nor possible to incorporate all of the possible measurement endpoints into an RI, it is necessary to identify the measurement endpoints that would provide the most useful information for evaluating the ecological risks associated with exposure to environmental contaminants in the study area. To illustrate this process, a number of candidate measurement endpoints that relate to the candidate assessment endpoints and risk questions that were identified previously are presented below:

1. ***Survival and Growth of Aquatic and Terrestrial Plants***

   Risk Question:

   Are the levels of contaminants in surface water, whole sediments and/or soils from the site greater than benchmarks for the survival, growth, or reproduction of aquatic or terrestrial plants?

   Candidate Measurement Endpoint: COPC concentrations in surface water, whole sediments and soils, and associated physical/chemical measurements.

   Risk Question:

   Is the survival, growth, or reproduction of aquatic and/or terrestrial plants exposed to surface water, sediments, or soil from the site significantly lower than that for aquatic and/or terrestrial plants exposed to media from reference sites?

   Candidate Measurement Endpoint: Survival, growth, and/or reproduction of aquatic and/or terrestrial plants in laboratory toxicity tests.

2. ***Survival, Growth, and Reproduction of Aquatic Invertebrates***

   Risk Question:

   Are the levels of contaminants in surface water and/or whole sediments from the site greater than benchmarks for the survival, growth, or reproduction of aquatic invertebrates?

Candidate Measurement Endpoint: COPC concentrations in surface water and/or whole sediments, and associated physical/chemical measurements.

Risk Question:

Is the survival, growth or reproduction of aquatic invertebrates exposed to whole sediments from the site significantly lower than that in reference sediments?

Candidate Measurement Endpoint: Survival, growth, and/or reproduction of aquatic invertebrates in laboratory toxicity tests.

Risk Question:

Is the structure of aquatic invertebrate communities at the site outside the normal range (i.e., 95th percentile) for aquatic invertebrate communities in reference areas?

Candidate Measurement Endpoint: Standardized measures of benthic invertebrate community structure for riffles, runs and depositional areas within the site and for similar habitat types in reference areas.

3. Survival, Growth, and Reproduction of Terrestrial Invertebrates

Risk Question:

Are the levels of contaminants in soil from the site greater than benchmarks for the survival, growth, or reproduction of terrestrial invertebrates?

Candidate Measurement Endpoint: COPC concentrations in soils and associated physical/chemical measurements.

Risk Question:

Is the survival, growth or reproduction of terrestrial invertebrates exposed to soils from the site significantly lower than that in reference soils?

Candidate Measurement Endpoint: Survival, growth, and/or reproduction of terrestrial invertebrates in laboratory toxicity tests.

Risk Question:

Is the structure of terrestrial invertebrate communities at the site outside the normal range (i.e., 95th percentile) for terrestrial invertebrate communities in reference areas?

Candidate Measurement Endpoint: Standardized measures of terrestrial invertebrate community structure for various habitat types within the Site and reference areas.

4. Survival, Growth and Reproduction of Fish

Risk Question:

Are the levels of contaminants in surface water and/or whole sediments from the site greater than benchmarks for the survival, growth, or reproduction of fish?

Candidate Measurement Endpoint: COPC concentrations in surface water and/or whole sediments, and associated physical/chemical measurements.

Risk Question:

Is the survival, growth or reproduction of fish exposed to surface water or sediments from the site significantly lower than that for reference media?

Candidate Measurement Endpoint: Survival, growth, and/or reproduction of fish in laboratory toxicity tests.

Risk Question:

Is the frequency of DELT abnormalities significantly higher in fish from the site than in fish from reference areas?

Candidate Measurement Endpoint: Frequency of DELT in fish within the site and reference areas.

Risk Question:

Are the levels of contaminants in fish tissues from the site greater than critical tissue values for the survival, growth, or reproduction of fish?

Candidate Measurement Endpoint: COPC concentrations in the tissues (whole body and liver) of fish from the site and reference areas, and associated variables (e.g., percent lipids, fish species, fish length, weight, age).

5. Survival, Growth and Reproduction of Amphibians

Risk Question:

Are the levels of contaminants in surface water, whole sediments and/or soil from the site greater than benchmarks for the survival, growth, or reproduction of amphibians?

Candidate Measurement Endpoint: COPC concentrations in water, whole sediments and soil, and associated physical/chemical measurements.

Risk Question:

Is the survival, growth or reproduction of amphibians exposed to surface water, whole sediments and/or soils from the site significantly lower than that for reference media?

Candidate Measurement Endpoint: Survival, growth, and/or reproduction of amphibians in laboratory toxicity tests.

Risk Question:

Is the frequency of abnormalities in amphibians from the site significantly higher than that in amphibians from reference areas?

Candidate Measurement Endpoint: Frequency of abnormalities in amphibians collected within the site and in those collected from reference areas (i.e., biological surveys).

Candidate Measurement Endpoint: Fetal and embryonic toxicity in amphibians (African clawed toad) as measured using standard laboratory toxicity tests (e.g., FETAX).

Risk Question:

Is the sex ratio of amphibians significantly different between the site and reference areas?

Candidate Measurement Endpoint: Sex ratio of adult amphibians collected within the site and of those collected at reference sites (i.e., biological surveys).

6. *Survival, Growth and Reproduction of Reptiles*

Risk Question:

Are the levels of contaminants in surface water, whole sediments and/or soil from the site greater than benchmarks for the survival, growth, or reproduction of reptiles?

Candidate Measurement Endpoint: COPC concentrations in water, whole sediments, and soil, and associated physical/chemical measurements.

Risk Question:

Is the frequency of abnormalities in reptiles from the site significantly higher than that in reptiles from reference areas?

Candidate Measurement Endpoint: Frequency of physical abnormalities in reptiles collected from the site and in those collected from reference areas (i.e., biological surveys).

7. *Survival, Growth and Reproduction Birds*

Risk Question:

Does the daily dose of contaminants received by birds from consumption of the tissues of prey species and from other media at the site exceed the toxicity reference values (TRVs) for survival, growth or reproduction of birds? If yes, what are the probabilities of effects of differing magnitude for survival and/or reproduction of sediment-probing birds?

Candidate Measurement Endpoint: Concentrations of COPCs in the tissues of prey species (i.e., whole body tissue residues) and associated measurements (e.g., prey size).

Risk Question:

Are the concentrations of contaminants in bird eggs from the site greater than benchmarks for the survival, growth, or reproduction of birds?

Candidate Measurement Endpoint: Concentrations of COPCs in the eggs of selected bird species and associated information (e.g., species, location; i.e., targeted biological surveys).

Risk Question:

Is the reproduction of birds utilizing the habitats in the vicinity of the site significantly impaired compared to that measured for birds in reference areas?

Candidate Measurement Endpoint: Concentrations of COPCs in the eggs of selected bird species (and/or other measures of exposure) and measures of reproductive success (e.g., hatching and fledging success).

8. Survival, Growth and Reproduction of Mammals

Risk Question:

Does the daily dose of contaminants received by mammals from consumption of the tissues of prey species and from other media at the site exceed the toxicity reference values (TRVs) for survival, growth or reproduction of mammals? If yes, what are the probabilities of effects of differing magnitude for survival and/or reproduction of sediment-probing birds?

Candidate Measurement Endpoint: Concentrations of COPCs in the tissues of prey species (i.e., whole body tissue residues) and associated measurements (e.g., prey size).

Risk Question:

Are the concentrations of contaminants in mammal tissues from the site greater than benchmarks for the survival, growth, or reproduction of mammals?

Candidate Measurement Endpoint: Concentrations of COPCs in the tissues of selected mammalian species and associated information (e.g., species, location; i.e., targeted biological surveys).

2.10 Development of a Plan for Analyzing Risk and Evaluating Uncertainty

The development of a risk analysis plan represents the final stage of the problem formulation process. During risk analysis planning, risk questions and testable hypotheses are developed and evaluated to determine how they will be assessed using available and new data (USEPA 1997). The risk analysis plan includes four components, including descriptions of the assessment design, the data requirements, the measurements that will be made, and the methods for conducting the analysis phase of the risk assessment (USEPA 1997). Outstanding data gaps and uncertainties associated with the risk assessment are also identified during risk analysis planning. Importantly, the risk analysis plan should also describe how the data collected to support the ERA will be used to define preliminary remediation goals for the site.

Chapter 3 Overview of the Data Quality Objectives Process

3.0 Introduction

For large, complex sites that are addressed under CERCLA, it is useful to have a formal process to ensure that the information provided by the ecological risk assessment will provide the information needed for decision making. To accomplish this goal, input from the risk manager is sought during problem formulation to obtain answers to questions such as: What are the protection goals for the site? What is the appropriate spatial and temporal scale? How should risk be expressed to best facilitate decision making? Should possible clean up goals be derived for receptors at risk?

To facilitate the necessary interaction between risk managers and risk assessors, the USEPA has developed a process call the data quality objectives (DQO) process (see Suter *et al.* 2000 for a summary). The steps in the DQO process are (as presented by Suter *et al.* 2000):

- **State the Problem.** Clearly specify the problem to be solved by the remediation process. If a contaminant of concern is persistent and bioaccumulative (e.g., PCBs), it could cause effects to exposed predators. The ecological assessment endpoint entity in this case could be the locally exposed sub-population of piscivorous mammals.
- **Identify the Decision.** State the decision that must be made to address the problem. For example, will floodplain soil need to be removed to protect small mammals from exposure to PCBs?
- **Identify Inputs to the Decision.** Identify the information required to make the decision and the data and analyses required to provide that information. Data needs could include data on foraging range and diet of the receptor of interest, and concentrations in dietary items. Analyses to be conducted could include probabilistic exposure and risk analyses.

- **Define the Study Boundaries.** Specify the spatial area, time period and site-use scenarios. The study boundaries should conform to the area for which decisions are to be made. For large complex sites, it may be useful to divide the site into "operable units". The study boundaries define the area for which information is collected. For example, fish tissue samples should be collected within the study boundaries because these inputs are required for exposure modeling with piscivorous birds or mammals.
- **Develop Decision Rules.** Define the criteria under which a remedial action will or will not take place. For example, no action may be required if there is less than a 20% probability of an effect of magnitude 10% or greater. Removing, isolating or degrading contaminants may be required, however, if there is greater than a 50% probability of an effect of magnitude 20% or greater.
- **Specify Acceptable Limits of Decision Error.** Define the error rates that are acceptable to decision makers. Such error rates are analogous to error rates from hypothesis testing. For example, an error rate of 10% may be considered acceptable for falsely concluding that reproductive fecundity is reduced by 20% or more. The corresponding error rate for falsely concluding that reproductive fecundity is reduced by 20% or more might be 25%.
- **Optimize the Design.** Given the expected variances in the study results, design the most efficient program that will provide an acceptable error rate for each decision rule. For sampling programs (e.g., collection of fish tissues for inputs to exposure models), power analyses may be used to determine sample sizes for different areas, contaminants and prey sizes.

The DQO process can be difficult to apply exactly as outlined above because, for example, risk managers may be reluctant or unable to specify decision rules and acceptable limits of decision error in a quantitative fashion. Also, in ecological risk assessment, other lines of evidence are sometimes used in a weight of evidence assessment. These other lines of evidence may be qualitative (e.g., species has been observed to be abundant in contaminated areas) but can influence risk characterization and eventual decision making. These and other issues, however, do not negate the utility of the DQO process for ecological risk assessment.

Chapter 4 References

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