STEP 1: SCREENING-LEVEL PROBLEM FORMULATION AND ECOLOGICAL EFFECTS EVALUATION

OVERVIEW

The screening-level problem formulation and ecological effects evaluation is part of the initial ecological risk screening assessment. For this initial step, it is likely that site-specific information for determining the nature and extent of contamination and for characterizing ecological receptors at the site is limited. 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

Step 1 is the screening-level problem formulation process and ecological effects evaluation (Highlight 1-1 defines screening-level risk assessments). Consultation with the BTAG is recommended at this stage. How to brief the BTAG on the setting, history, and ecology of a site is described in *ECO Update Volume 1, Number 5* (U.S. EPA, 1992d). Section 1.2 describes the screening-level problem formulation, and Section 1.3 describes the screening-level ecological effects evaluation. Section 1.4 summarizes this step.

1.2 SCREENING-LEVEL PROBLEM FORMULATION

For the screening-level problem formulation, the risk assessor develops a conceptual model for the site that addresses five issues:

(1) Environmental setting and contaminants known or suspected to exist at the site (Section 1.2.1);

(2) Contaminant fate and transport mechanisms that might exist at the site (Section 1.2.2);

(3) The mechanisms of ecotoxicity associated with contaminants and likely categories of receptors that could be affected (Section 1.2.3);

(4) What complete exposure pathways might exist at the site (a complete exposure pathway is one in which the chemical can be traced or expected to travel from the source to a receptor that can be affected by the chemical) (Section 1.2.4); and

(5) Selection of endpoints to screen for ecological risk (Section 1.2.5).

HIGHLIGHT 1-1
Screening-level Risk Assessments

Screening-level risk assessments are simplified risk assessments that can be conducted with limited data by assuming values for parameters for which data are lacking. At the screening level, it is important to minimize the chances of concluding that there is no risk when in fact a risk exists. Thus, for exposure and toxicity parameters for which site-specific information is lacking, assumed values should consistently be biased in the direction of overestimating risk. This ensures that sites that might pose an ecological risk are studied further. Without this bias, a screening evaluation could not provide a defensible conclusion that negligible ecological risk exists or that certain contaminants and exposure pathways can be eliminated from consideration.

1.2.1 Environmental Setting and Contaminants at the Site

To begin the screening-level problem formulation, there must be at least a rudimentary knowledge of the potential environmental setting and chemical contamination at the site. The first step is to compile information from the site history and from reports related to the site, including the Preliminary Assessment (PA) or Site Investigation (SI). The second step is to use the environmental checklist presented in *Representative Sampling Guidance Document, Volume 3: Ecological* (U.S. EPA, 1997; see Appendix B) to begin characterizing the site for problem formulation. Key questions addressed by the checklist include:

- What are the on- and off-site land uses (e.g., industrial, residential, or undeveloped; current and future)?
- What type of facility existed or exists at the site?
- What are the suspected contaminants at the site?
- What is the environmental setting, including natural areas (e.g., upland forest, on-site stream, nearby wildlife refuge) as well as disturbed/man-made areas (e.g., waste lagoons)?
- Which habitats present on site are potentially contaminated or otherwise disturbed?
- Has contamination migrated from source areas and resulted in "off-site" impacts or the threat of impacts in addition to on-site threats or impacts?

These questions should be answered using the site reports, maps (e.g, U.S. Geological Survey, National Wetlands Inventory), available aerial photographs, communication with appropriate agencies (e.g., U.S. Fish and Wildlife Service, National Oceanic and Atmospheric Administration, State Natural Heritage Programs), and a site visit. Activities that should be conducted during the site visit include:

- Note the layout and topography of the site;
- Note and describe any water bodies and wetlands;
- Identify and map evidence indicating contamination or potential contamination (e.g., areas of no vegetation, runoff gullies to surface waters);
- Describe existing aquatic, terrestrial, and wetland ecological habitat types (e.g., forest, old field), and estimate the area covered by those habitats;
- Note any potentially sensitive environments (see Section 1.2.3 for examples of sensitive environments);
- Describe and, if possible, map soil and water types, land uses, and the dominant vegetation species present; and
- Record any observations of animal species or sign of a species.

Mapping can be useful in establishing a "picture" of the site to assist in problem formulation. The completed checklist (U.S. EPA, 1997) will provide information regarding habitats and species potentially or actually present on site, potential contaminant migration pathways, exposure pathways, and the potential for non-chemical stresses at the site.

After finishing the checklist, it might be possible to determine that present or future ecological impacts are negligible because complete exposure pathways do not exist and could not exist in the future. Many Superfund sites are located in highly industrialized areas where there could be few if any ecological receptors or where site-related impacts might be indistinguishable from non-site-related impacts (see Highlight 1-2). For such sites, remediation to reduce ecological risks might not be needed. However, all sites should be evaluated by qualified personnel to determine whether this conclusion is appropriate.

Other Superfund sites are located in less disturbed areas with protected or sensitive environments that could be at risk of adverse effects from contaminants from the site. State and federal laws (e.g., the Clean Water Act, the Endangered Species Act) designate certain types of environments as requiring protection. Other types of habitats unique to certain areas also could need special consideration in the risk assessment (see Section 1.2.3).

1.2.2 Contaminant Fate and Transport

During problem formulation, pathways for migration of a contaminant (e.g., windblown dust, surface water runoff, erosion) should be identified. These pathways can exhibit a decreasing gradient of contamination with increasing distance from a site. There are exceptions, however, because physical and chemical characteristics of the media also influence contaminant distribution (e.g., the pattern of sediment deposition in streams varies depending on stream flow and bottom characteristics). For the screening-level risk assessment, the highest contaminant concentrations measured on the site should be documented for each medium.

HIGHLIGHT 1-2
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 impacts related to contaminants from a particular site and impacts related to non-contaminant stressors or to contaminants from other sites. However, even in these cases, it could be appropriate to take some remedial actions based on ecological risks. These actions might be limited to source removal or might be more extensive. An ecological risk assessment can assist the risk manager in determining what action, if any, is appropriate.

1.2.3 Ecotoxicity and Potential Receptors

Understanding the toxic mechanism of a contaminant helps to evaluate the importance of potential exposure pathways (see Section 1.2.4) and to focus the selection of assessment endpoints (see Section 1.2.5). Some contaminants, for example, 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 certain insect groups (e.g., by interfering with hormones needed for metamorphosis), plants (e.g., herbicides), or other groups of organisms. For substances that affect, for example, reproduction of mammals at much lower environmental exposure levels than they affect other groups of organisms, the screening-level risk assessment can initially focus on exposure pathways and risks to mammals. Example 1-1 illustrates this point using the PCB site example provided in Appendix A. A review of some of the more recent ecological risk and toxicity assessment literature can help identify likely effects of the more common contaminants at Superfund sites.

An experienced biologist or ecologist can determine what plants, animals, and habitats exist or can be expected to exist in the area of the Superfund site. Exhibit 1-1, adapted from the Superfund Hazard Ranking System, is a partial list of types of sensitive environments that could require protection or special consideration. Information obtained for the environmental checklist (Section 1.2.1), existing information and maps, and aerial photographs should be used to identify the presence of sensitive environments on or near a site that might be threatened by contaminants from the site.

EXAMPLE 1-1
Ecotoxicity PCB Site

Some PCBs are reproductive toxins in mammals (Ringer et al., 1972; Aulerich et al., 1985; Wren et al., 1991; Kamrin and Ringer, 1996). When ingested, they induce (i.e., increase concentrations and activity of) enzymes in the liver, which might affect the metabolism of some steroid hormones (Rice and O'Keefe, 1995). Whatever the mechanism of action, several physiological functions that are controlled by steroid hormones can be altered by the exposure of mammals to certain PCBs, and reproduction appears to be the most sensitive endpoint for PCB toxicity in mammals (Rice and O'Keefe, 1995). Given this information, the screening ecological risk assessment should include potential exposure pathways for mammals to PCBs that are reproductive toxins (see Example 1-2).

1.2.4 Complete Exposure Pathways

Evaluating potential exposure pathways is one of the primary tasks of the screening-level ecological characterization of the site. For an exposure pathway to be complete, a contaminant must be able to travel from the source to ecological receptors and to be taken up by the receptors via one or more exposure routes. (Highlight 1-3 defines exposure pathway and exposure route.) Identifying complete exposure pathways prior to a quantitative evaluation of toxicity allows the assessment to focus on only those contaminants that can reach ecological receptors.

Different exposure routes are important for different groups of organisms. For terrestrial animals, three basic exposure routes need to be evaluated: inhalation, ingestion, and dermal absorption. For terrestrial plants, root absorption of contaminants in soils and leaf absorption of contaminantsevaporating from the soil or deposited on the leaves are of concern at Superfund sites. For aquatic animals, direct contact (of water or sediment with the gills or integument) and ingestion of food (and sometimes sediments) should be considered. For aquatic plants, direct contact with water, and sometimes with air or sediments, is of primary concern.

HIGHLIGHT 1-3
Exposure Pathway and Exposure Route

Exposure Pathway: The pathway by which a contaminant travels from a source (e.g., drums, contaminated soils) to receptors. A pathway can involve multiple media (e.g., soil runoff to surface waters and sedimentation, or volatilization to the atmosphere).

Exposure Route: A point of contact/entry of a contaminant from the environment into an organism (e.g., inhalation, ingestion, dermal absorption).

The most likely exposure pathways and exposure routes also are related to the physical and chemical properties of the contaminant (e.g., whether or not the contaminant is bound to a matrix, such as organic carbon). Of the basic exposure routes identified above, more information generally is available to quantify exposure levels for ingestion by terrestrial animals and for direct contact with water or sediments by aquatic organisms than for other exposure routes and receptors. Although other

exposure routes can be important, more assumptions are needed to estimate exposure levels for those routes, and the results are less certain. Professional judgment is needed to determine if evaluating those routes sufficiently improves a risk assessment to warrant the effort.

If an exposure pathway is not complete for a specific contaminant (i.e., ecological receptors cannot be exposed to the contaminant), that exposure pathway does not need to be evaluated further. For example, suppose a contaminant that impairs reproduction in mammals occurs only in soils that are well below the root zone of plants that occur or are expected to occur on a site. Herbivorous mammals would not be exposed to the contaminant through their diets because plants would not be contaminated. Assuming that most soil macroinvertebrates available for ingestion live in the root zone, insectivorous mammals also would be unlikely to be exposed. In this case, a complete exposure pathway for this contaminant for ground-dwelling mammals would 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 from the soil to ground water that discharges to surface water, thereby posing a risk to the aquatic environment or to terrestrial mammals that drink the water or consume aquatic prey. Example 1-2 illustrates the process of identifying complete exposure pathways based on the hypothetical PCB site described in Appendix A.

1.2.5 Assessment and Measurement Endpoints

For the screening-level ecological risk assessment, assessment endpoints are any adverse effects on ecological receptors, where receptors are plant and animal populations and communities, habitats, and sensitive environments. Adverse effects on populations can be inferred from measures related to impaired reproduction, growth, and survival. Adverse effects on communities can be inferred from changes in community structure or function. Adverse effects on habitats can be inferred from changes in composition and characteristics that reduce the habitats' ability to support plant and animal populations and communities.

Many of the screening ecotoxicity values now available or likely to be available in the future for the Superfund program (see Section 1.3) are based on generic assessment endpoints (e.g., protection of aquatic communities from changes in structure or function) and are assumed to be widely applicable to sites around the United States.

EXHIBIT 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)
Federally-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
Wetlands[b]

[a] The categories are listed in groups from those assigned higher factor values to those assigned lower factor values in the Hazard Ranking System (HRS) for listing hazardous waste sites on the National Priorities List (U.S. EPA, 1990b). See *Federal Register*, Vol. 55, pp. 51624 and 51648 for additional information regarding definitions.

[b] Under the HRS, wetlands are rated on the basis of size. See *Federal Register*, Vol. 55, pp. 51625 and 51662 for additional information.

EXAMPLE 1-2
Complete Exposure Pathways for Mammals PCB Site

Three possible exposure pathways for mammals were evaluated at the PCB Site: inhalation, ingestion through the food chain, and incidental soil/sediment ingestion.

Inhalation. PCBs are not highly volatile, so the inhalation of PCB vapors by mammals would be an essentially incomplete exposure pathway. Inhalation of PCBs adsorbed to soil particles might need consideration in areas with exposed soils, but this site is well vegetated.

Ingestion through the food chain. PCBs tend to bioaccumulate and biomagnify in food chains. PCBs in soils are not taken up by most plants, but are accumulated by soil macroinvertebrates. Thus, in areas without significant soil deposition on the surfaces of plants, mammalian herbivores would not be exposed to PCBs in most of their diet. In contrast, mammalian insectivores, such as shrews, could be exposed to PCBs in most of their diet. For PCBs, the ingestion route for mammals would be essentially incomplete for herbivores but complete for insectivores. For the PCB site, therefore, the ingestion exposure route for a mammalian insectivore (e.g., shrew) would be a complete exposure pathway that should be evaluated.

Incidental soil/sediment ingestion. Mammals can ingest some quantity of soils or sediments incidentally, as they groom their fur or consume plants or animals from the soil. Burrowing mammals are likely to ingest greater quantities of soils during grooming than non-burrowing mammals, and mammals that consume plant roots or soil-dwelling macroinvertebrates are likely to ingest greater quantities of soils attached to the surface of their foods than mammals that consume other foods. The intake of PCBs from incidental ingestion of PCB-contaminated soils is difficult to estimate, but for insectivores that forage at ground level, it is likely to be far less than the intake of PCBs in the diet. For herbivores, the incidental intake of PCBs in soils might be higher than the intake of PCBs in their diet, but still less than the intake of PCBs by mammals feeding on soil macroinvertebrates. Thus, the exposure pathway for ground-dwelling mammalian insectivores remains the exposure pathway that should be evaluated.

1.3 SCREENING-LEVEL ECOLOGICAL EFFECTS EVALUATION

The next step in the screening-level risk assessment is the preliminary ecological effects evaluation and the establishment of contaminant exposure levels that represent conservative thresholds for adverse ecological effects. In this guidance, those conservative thresholds are called screening ecotoxicity values. Physical stresses unrelated to contaminants at the site are not the focus of the risk assessment (see Highlight 1-4), although they can be considered later when evaluating effects of remedial alternatives.

A literature search for studies that quantify toxicity (i.e., exposure-response) is necessary to evaluate the likelihood of toxic effects in different groups of organisms. Appendix C provides a basic introduction to conducting 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 routes being evaluated and the dose or environmental concentration that causes a specified adverse effect.

For each complete exposure pathway, route, and contaminant, a screening ecotoxicity value should be developed.[1] The U.S. EPA Office of Emergency and Remedial Response has developed screening ecotoxicity values [called ecotox threshold values (U.S. EPA, 1996c)]. The values are for surface waters and sediments, and are based on direct exposures routes only; bioaccumulation and biomagnification in food chains have not been accounted for. The following subsections describe preferred data (Section 1.3.1), dose conversions (Section 1.3.2), and analyzing uncertainty in the values (Section 1.3.3).

1.3.1 Preferred Toxicity Data

Screening ecotoxicity values should represent a no-observed-adverse-effect-level(NOAEL)forlong-term (chronic) exposures to a contaminant. Ecological effects of most concern are those that can impact populations (or higher levels of biological organization). Those include adverse effects on development, reproduction, and survivorship. Community-level effects also can be of concern, but toxicity data on community-level endpoints are limited and might be difficult to extrapolate from one community to another.

HIGHLIGHT 1-4
Non-Chemical Stressors

Ecosystems can be stressed by physical, as well as by chemical, alterations of their environment. For this reason, EPA's (1992a) *Framework for Ecological Risk Assessment* addresses "stressor-response" evaluation to include all types of stress instead of "dose-response" or "exposure-response" evaluation, which implies that the stressor must be a toxic substance.

For Superfund sites, however, the baseline risk assessment addresses risks from hazardous substances released to the environment, not risks from physical alterations of the environment, unless caused indirectly by a hazardous substances (e.g., loss of vegetation from a chemical release leading to serious erosion). This guidance document, therefore, focuses on exposure-response evaluations for toxic substances. Physical destruction of habitat that might be associated with a particular remedy is considered in the Feasibility Study.

When reviewing the literature, one should be aware of the limitations of published information in characterizing actual or probable hazards at a specific site. U.S. EPA discourages reliance on secondary references because study details relevant for determining the applicability of findings to a given site usually are not reported in secondary sources. Only primary literature that has been carefully reviewed by an ecotoxicologist should be used to support a decision. Several considerations and data preferences are summarized in Highlight 1-5 and described more fully below.

NOAELS and LOAELS. For each contaminant for which a complete exposure pathway/route exists, 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 mortality) in a potential receptor species. This value is called a lowest-observed-adverse-

[1] It is possible to conduct a screening risk assessment with limited information and conservative assumptions. If site-specific information is too limited, however, the risk assessment is almost certain to move into Steps 3 through 7, which require field-collected data. The more complete the initial information, the better the decision that can be made at this preliminary stage.

effect-level or LOAEL. For those contaminants with documented adverse effects, one also should identify the highest exposure level that is a NOAEL. A NOAEL is more appropriate than a LOAEL to use as an screening ecotoxicity value to ensure that risk is not underestimated (see Highlight 1-6). However, NOAELs currently are not available for many groups of organisms and many chemicals. When a LOAEL value, but not a NOAEL value, is available from the literature, a standard practice is to multiply the LOAEL by 0.1 and to use the product as the screening ecotoxicity value. Support for this practice comes from a data review indicating that 96 percent of chemicals included in the review had LOAEL/NOAEL ratios of five or less, and that all were ten or less (Dourson and Stara, 1983).

Exposure duration. Data from studies of chronic exposure are preferable to data from medium-term (subchronic), short-term (acute), or single-exposure studies because exposures at Superfund remedial sites usually are long-term. Literature reviews by McNamara (1976) and Weil and McCollister (1963) indicate that [2] chronic NOAELs can be lower than subchronic (90-day duration for rats) NOAELs by up to a factor of ten[2].

HIGHLIGHT 1-5
Data Hierarchy for Deriving Screening Ecotoxicity Values

To develop a chronic NOAEL for a screening ecotoxicity value from existing literature, the following data hierarchy minimizes extrapolations and uncertainties in the value:

- A NOAEL is preferred to a LOAEL, which is preferred to an LC_{50} or an EC_{50}.
- Long-term (chronic) studies are preferred to medium-term (subchronic) studies, which are preferred to short-term (acute) studies.
- If exposure at the site is by ingestion, dietary studies are preferred to gavage studies, which are preferred to non-ingestion routes of exposure. Similarly, if exposure at the site is dermal, dermal studies are preferred to studies using other exposure routes.

Exposure route. The exposure route and medium used in the toxicity study should be comparable to the exposure route in the risk assessment. For example, data from studies where exposure is by gavage generally are not preferred for estimating dietary concentrations that could produce adverse effects, because the rate at which the substance is absorbed from the gastrointestinal tract usually is greater following gavage than following dietary administration. Similarly, intravenous injection of a substance results in "instantaneous absorption" and does not allow the substance to first pass through the liver, as it would following dietary exposure. If it is necessary to attempt to extrapolate toxicity test results from one route of exposure to another, the extrapolation should be performed or reviewed by a toxicologist experienced in route-to-route extrapolations for the class of animals at issue.

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[2] The literature reviews of McNamara (1976) and Weil and McCollister (1963) included both rodent and non-rodent species. The duration of the subchronic exposure usually was 90 days, but ranged from 30 to 210 days. A wide variety of endpoints and criteria for adverse effects were included in these reviews. Despite this variation in the original studies, their findings provide a general indication of the ratio between subchronic to chronic NOAELs for effects other than cancer and reproductive effects. For some chemicals, chronic dosing resulted in increased chemical tolerance. For over 50 percent of the compounds tested, the chronic NOAEL was less than the 90-day NOAEL by a factor of 2 or less. However, in a few cases, the chronic NOAEL was up to a factor of 10 less than the subchronic NOAEL (U.S. EPA, 1993e).

Field versus laboratory. Most toxicity studies evaluate effects of a single contaminant on a single species under controlled laboratory conditions. Results from these studies might not be directly applicable to the field, where organisms typically are exposed to more than one contaminant in environmental situations that are not comparable to a laboratory setting and where genetic composition of the population can be more heterogeneous than that of organisms bred for laboratory use. In addition, the bioavailability of a contaminant might be different at a site than in a laboratory toxicity test. In a field situation, organisms also will be subject to other environmental variables, such as unusual weather conditions, infectious diseases, and food shortages. These variables can have either positive or negative effects on the organism's response to a toxic contaminant that only a site-specific field study would be able to evaluate. Moreover, single-species toxicity tests seldom provide information regarding toxicant-related changes in community interactions (e.g., behavioral changes in prey species that make them more susceptible to predation).

1.3.2 Dose Conversions

For some data reported in the literature, conversions are necessary to allow the data to be used for species other than those tested or for measures of exposure other than those reported. Many doses in laboratory studies are reported in terms of concentration in the diet (e.g., mg contaminant/kg diet or ppm in the diet). Dietary concentrations can be converted to dose (e.g., mg contaminant/kg body weight/day) for comparison with estimated contaminant intake levels in the receptor species.

When converting doses, it is important to identify whether weights are measured as wet or dry weights. Usually, body weights are reported on a wet-weight, not dry-weight basis. Concentration of the contaminant in the diet might be reported on a wet- or dry-weight basis.

HIGHLIGHT 1-6
NOAEL Preferred to LOAEL

Because the NOAEL and LOAEL are estimated by hypothesis testing (i.e., by comparing the response level of a test group to the response level of a control group for a statistically significant difference), the actual proportion of the test animals showing the adverse response at an identified LOAEL depends on sample size, variability of the response, and the dose interval. LOAELs, and even NOAELs, can represent a 30 percent or higher effect level for the minimum sample sizes recommended for standard test protocols. For this reason, U.S. EPA recommends that the more conservative NOAELs, instead of LOAELs, are used to determine a screening exposure level that is unlikely to adversely impact populations. If dose-response data are available, a site-specific low-effect level may be determined.

Ingestion rates and body weights for a test species often are reported in a toxicity study or can be obtained from other literature sources (e.g., U.S. EPA, 1993a,b). For extrapolations between animal species with different metabolic rates as well as dietary composition, consult U.S. EPA 1992e and 1996b.

1.3.3 Uncertainty Assessment

Professional judgment is needed to determine the uncertainty associated with information taken from the literature and any extrapolations used in developing a screening ecotoxicity value. The risk assessor

should be consistently conservative in selecting literature values and describe the limitations of using those values in the context of a particular site. Consideration of the study design, endpoints, and other factors are important in determining the utility of toxicity data in the screening-level risk assessment. All of those factors should be addressed in a brief evaluation of uncertainties prior to the screening-level risk calculation.

1.4 SUMMARY

At the conclusion of the screening-level problem formulation and ecological effects evaluation, the following information should have been compiled:

- Environmental setting and contaminants known or suspected to exist at the site and the maximum concentrations present (for each medium);

- Contaminant fate and transport mechanisms that might exist at the site;
  The mechanisms of ecotoxicity associated with contaminants and likely categories of receptors that could be affected;

- The complete exposure pathways that might exist at the site from contaminant sources to receptors that could be affected; and

- Screening ecotoxicity values equivalent to chronic NOAELs based on conservative assumptions.

For the screening-level 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 and will be used to establish the screening ecotoxicity values. Those values will be used with estimated exposure levels to screen for ecological risks, as described in Step 2.

STEP 2: SCREENING-LEVEL EXPOSURE ESTIMATE AND RISK CALCULATION

OVERVIEW

The screening-level exposure estimate and risk calculation comprise the second step in the ecological risk screening for a site. Risk is estimated by comparing maximum documented exposure concentrations with the ecotoxicity screening values from Step 1. At the conclusion of Step 2, the risk manager and risk assessment team will decide that either the screening-level ecological risk assessment is adequate to determine that ecological threats are negligible, or the process should continue to a more detailed ecological risk assessment (Steps 3 through 7). If the process continues, the screening-level assessment serves to identify exposure pathways and preliminary contaminants of concern for the baseline risk assessment by eliminating those contaminants and exposure pathways that pose negligible risks.

2.1 INTRODUCTION

This step includes estimating exposure levels and screening for ecological risks as the last two phases of the screening-level ecological risk assessment. The process concludes with a SMDP at which it is determined that: (1) ecological threats are negligible; (2) the ecological risk assessment should continue to determine whether a risk exists; or (3) there is a potential for adverse ecological effects, and a more detailed ecological risk assessment, incorporating more site-specific information, is needed.

Section 2.2 describes the screening-level exposure assessment, focusing on the complete exposure pathways identified in Step 1. Section 2.3 describes the risk calculation process, including estimating a hazard quotient, documenting the uncertainties in the quotient, and summarizing the overall confidence in the screening-level ecological risk assessment. Section 2.4 describes the SMDP that concludes Step 2.

2.2 SCREENING-LEVEL EXPOSURE ESTIMATES

To estimate exposures for the screening-level ecological risk calculation, on-site contaminant levels and general information on the types of biological receptors that might be exposed should be known from Step 1. Only complete exposure pathways should be evaluated. For these, the highest measured or estimated on-site contaminant concentration for each environmental medium should be used to estimate exposures. This should ensure that potential ecological threats are not missed.

2.2.1 Exposure Parameters

For parameters needed to estimate exposures for which sound site-specific information is lacking or difficult to develop, conservative assumptions should be used at this screening level. Examples of conservative assumptions are listed below and described in the following paragraphs:

- Area-use factor 100 percent (factor related to home range and population density; see Highlight2-1);
- Bioavailability 100 percent;
- Life stage most sensitive life stage;
- Body weight and food ingestion rate minimum body weight to maximum ingestion rate; and
- Dietary composition 100 percent of diet consists of the most contaminated dietary component.

HIGHLIGHT 2-1
Area-use Factor

An animal's area-use factor can be defined as the ratio of the area of contamination (or the site area under investigation) to the area used by the animal, e.g., its home range, breeding range, or feeding/foraging range. To ensure that ecological risks are not underestimated, the highest density and smallest area used by each animal should be assumed. This allows the maximum number of animals to be exposed to site contaminants and makes it more likely that "hot spots" (i.e., areas of unusually high contamination levels) will be significant proportions of an individual animal's home range.

Area-use factor. For the screening level exposure estimate for terrestrial animals, assume that the home range of one or more animals is entirely within the contaminated area, and thus the animals are exposed 100 percent of the time. This is a conservative assumption and, as an assumption, is only applicable to the screening-level phase of the risk assessment. Species- and site-specific home range information would be needed later, in Step 6, to estimate more accurately the percentage of time an animal would use a contaminated area. Also evaluate the possibility that some species might actually focus their activities in contaminated areas of the site. For example, if contamination has reduced emergent vegetation in a pond, the pond might be more heavily used for feeding by waterfowl than uncontaminated ponds with little open water.

Bioavailability. For the screening-level exposure estimate, in the absence of site-specific information, assume that the bioavailability of contaminants at the site is 100 percent. For example, at the screening-level, lead would be assumed to be 100 percent bioavailable to mammals. While some literature indicates that mammals absorb approximately 10 percent of ingested lead, absorption efficiency can be higher, up to about 60 percent, because dietary factors such as fasting, and calcium and phosphate content of the diet, can affect the absorption rate (Kenzaburo, 1986). Because few species have been tested for bioavailability, and because Steps 3 through 6 provide an opportunity for this issue to be addressed specifically, the most conservative assumption is appropriate for this step.

Life stage. For the screening-level assessment, assume that the most sensitive life stages are present. If an early life stage is the most sensitive, the population should be assumed to include or to be in that life stage. For vertebrate populations, it is likely that most of the population is not in the most sensitive life stage most of the time. However, for many invertebrate species, the entire population can be at an early stage of development during certain seasons.

Body weight and food ingestion rates. Estimates of body weight and food ingestion rates of the receptor animals also should be made conservatively to maximize the dose (intake of contaminants) on a body-weight basis and to avoid understating risk, although uncertainties in these factors are far less than the uncertainties associated with the environmental contaminant concentrations. U.S. EPA's *Wildlife Exposure Factors Handbook* (U.S. EPA, 1993a,b) is a good source or reference to sources of this information.

Bioaccumulation. Bioaccumulation values obtained from a literature search can be used to estimate contaminant accumulation and food-chain transfer at a Superfund site at the screening stage. Because many environmental factors influence the degree of bioaccumulation, sometimes by several orders of magnitude, the most conservative (i.e., highest) bioaccumulation factor (BAF) reported in the literature should be used in the absence of site-specific information.

Dietary composition. 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 example, if some foods (e.g., insects) are likely to be more contaminated than other foods (e.g., seeds and fruits) typical in the diet of a receptor species, assume that the receptor species feeds exclusively on the more contaminated type of food. Again, EPA's *Wildlife Exposure Factors Handbook* (U.S. EPA, 1993a,b) is a good source or reference to sources of this information.

2.2.2 Uncertainty Assessment

Professional judgment is needed to determine the uncertainty associated with information taken from the literature and any extrapolations used in developing a parameter to estimate exposures. All assumptions used to estimate exposures should be stated, including some description of the degree of bias possible in each. Where literature values are used, an indication of the range of values that could be considered appropriate also should be indicated.

2.3 SCREENING-LEVEL RISK CALCULATION

A quantitative screening-level risk can be estimated using the exposure estimates developed according to Section 2.2 and the screening ecotoxicity values developed according to Section 1.3. For the screening-level risk calculation, the hazard quotient approach, which compares point estimates of screening ecotoxicity values and exposure values, is adequate to estimate risk. As described in Section 1.3, a screening ecotoxicity value should be equivalent to a documented and/or best conservatively estimated chronic NOAEL. Thus, for each contaminant and environmental medium, the hazard quotient can be expressed as the ratio of a potential exposure level to the NOAEL:
where:

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

HQ = hazard quotient;

Dose = estimated contaminant intake at the site (e.g., mg contaminant/kg body weight per day);

EEC = estimated environmental concentration at the site (e.g., mg contaminant/L water, mg contaminant/kg soil, mg contaminant/kg food); and

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

An HQ less than one (unity) indicates that the contaminant alone is unlikely to cause adverse ecological effects. If multiple contaminants of potential ecological concern exist at the site, it might be appropriate to sum the HQs for receptors that could be simultaneously exposed to the contaminants that produce effects by the same toxic mechanism (U.S. EPA, 1986a). The sum of the HQs is called a hazard index (HI); (see Highlight 2-2). An HI less than one indicates that the group of contaminants is unlikely to cause adverse ecological effects. An HQ or HI less than one does not indicate the absence of ecological risk; rather, it 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 more certain pass/fail decision point.

HIGHLIGHT 2-2
Hazard Index (HI) Calculation

For contaminants that produce adverse effects by the same toxic mechanism:

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

where:

EEC_i = estimated environmental concentration for the i^{th} contaminant; and

NOAELi = NOAEL for the i^{th} contaminant (expressed either as a dose or environmental concentration).

The EEC and the NOAEL are expressed in the same units and represent the same exposure period (e.g., chronic). Dose could be substituted for EEC throughout provided the NOAEL is expressed as a dose.

The screening-level risk calculation is a conservative estimate to ensure that potential ecological threats are not 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. If the potential for ecological impacts exists, this calculation can be used to eliminate the negligible-risk combinations of contaminants and exposure pathways from further consideration.

If the screening-level risk assessment indicates that adverse ecological effects are possible at environmental concentrations below standard quantitation limits, a "non detect" based on those limits cannot be used to support a "no risk" decision. Instead, the risk assessment team and risk manager should request appropriate detection limits or agree to continue to Steps 3 through 7, where exposure concentrations will be estimated from other information (e.g., fate-and-transport modeling, assumed or 0 estimated values for non-detects).

2.4 SCIENTIFIC/MANAGEMENT DECISION POINT (SMDP)

At the end of Step 2, the lead risk assessor communicates the results of the preliminary ecological risk assessment to the risk manager. The risk manager needs to decide whether the information available is adequate to make a risk management decision and might require technical advice from the ecological risk assessment team to reach a decision. There are only three possible decisions at this point:

(1) There is adequate information to conclude that ecological risks are negligible and therefore no need for remediation on the basis of ecological risk;

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

(3) The information indicates a potential for adverse ecological effects, and a more thorough assessment is warranted.

Note that the SMDP made at the end of the screening-level risk calculation will not set a preliminary cleanup goal. Screening ecotoxicity values are derived to avoid underestimating risk. Requiring a cleanup based solely on those values would not be technically defensible.

The risk manager should document both the decision and the basis for it. If the risk characterization supports the first decision (i.e., negligible risk), the ecological risk assessment process ends here with appropriate documentation to support the decision. The documentation should include all analyses and references used in the assessment, including a discussion of the uncertainties associated with the HQ and HI estimates.

For assessments that proceed to Step 3, the screening-level analysis in Step 2 can indicate and justify which contaminants and exposure pathways can be eliminated from further assessment because they are unlikely to pose a substantive risk. (If new contaminants are discovered or contaminants are found at higher concentrations later in the site investigation, those contaminants might need to be added to the ecological risk assessment at that time.)

U.S. EPA must be confident that the SMDP made after completion of this calculation will protect the ecological components of the environment. The decision to continue beyond the screening-level risk calculation does not indicate whether remediation is necessary at the site. That decision will be made in Step 8 of the process.

2.5 SUMMARY

At the conclusion of the exposure estimate and screening-level risk calculation step, the following information should have been compiled:

(1) Exposure estimates based on conservative assumptions and maximum concentrations present; and

(2) Hazard quotients (or hazard indices) indicating which, if any, contaminants and exposure pathways might pose ecological threats.

Based on the results of the screening-level ecological risk calculation, the risk manager and lead risk assessor will determine whether or not contaminants from the site pose an ecological threat. If there are sufficient data to determine that ecological threats are negligible, the ecological risk assessment will be complete at this step with a finding of negligible ecological risk. If the data indicate that there is (or might be) a risk of adverse ecological effects, the ecological risk assessment process will continue.

Conservative assumptions have been used for each step of the screening-level ecological risk assessment. Therefore, requiring a cleanup based solely on this information would not be technically defensible. To end the assessment at this stage, the conclusion of negligible ecological risk must be adequately documented and technically defensible. A lack of information on the toxicity of a contaminant or on complete exposure pathways will result in a decision to continue with the ecological risk assessment process (Steps 3 through 7) not a decision to delay the ecological risk assessment until a later date when more information might be available.

STEP 3: BASELINE RISK ASSESSMENT PROBLEM FORMULATION

OVERVIEW

Step 3 of the eight-step process initiates the problem-formulation phase of the baseline ecological risk assessment. Step 3 refines the screening-level problem formulation and, with input from stakeholders and other involved parties, expands on the ecological issues that are of concern at the particular site. In the screening-level assessment, conservative assumptions were used where site-specific information was lacking. In Step 3, the results of the screening assessment and additional site-specific information are used to determine the scope and goals of the baseline ecological risk assessment. Steps 3 through 7 are required only for sites for which the screening-level assessment indicated a need for further ecological risk evaluation.

Problem formulation at Step 3 includes several activities:

- Refining preliminary contaminants of ecological concern;
- Further characterizing ecological effects of contaminants;
- Reviewing and refining information on contaminant fate and transport, complete exposure pathways, and ecosystems potentially at risk;
- Selecting assessment endpoints; and
- Developing a conceptual model with working hypotheses or questions that the site investigation will address.

At the conclusion of Step 3, there is a SMDP, which consists of agreement on four items: the assessment endpoints, the exposure pathways, the risk questions, and conceptual model integrating these components. The products of Step 3 are used to select measurement endpoints and to develop the ecological risk assessment work plan (WP) and sampling and analysis plan (SAP) for the site in Step 4. Steps 3 and 4 are, effectively, the data quality objective (DQO) process for the baseline ecological risk assessment.

3.1 THE PROBLEM-FORMULATION PROCESS

In Step 3, problem formulation establishes the goals, breadth, and focus of the baseline ecological risk assessment. It also establishes the assessment endpoints, or specific ecological values to be protected (U.S. EPA, 1992a). Through Step 3, the questions and issues that need to be addressed in the baseline ecological risk assessment are defined based on potentially complete exposure pathways and ecological effects. A conceptual model of the site is developed that includes questions about the assessment endpoints and the relationship between exposure and effects. Step 3 culminates in an SMDP, which is agreement between the risk manager and risk assessor on the assessment endpoints, exposure pathways, and questions as portrayed in the conceptual model of the site.

The conceptual model, which is completed in Step 4, also will describe the approach, types of data, and analytical tools to be used for the analysis phase of the ecological risk assessment (Step 6). Those components of the conceptual model are formally described in the ecological risk WP and SAP in Step 4 of this eight-step process. If there is not agreement among the risk manager, lead risk assessor, and the other professionals involved with the ecological risk assessment on the initial conceptual model developed in Step 3, the final conceptual model and field study design developed in Step 4 might not resolve the issues that must be considered to manage risks effectively.

The complexity of questions developed during problem formulation does not depend on the size of a site or the magnitude of its contamination. Large areas of contamination can provoke simple questions and, conversely, small sites with numerous contaminants can require a complex series of questions and assessment endpoints. There is no rule that can be applied to gauge the effort needed for an ecological risk assessment based on site size or number of contaminants; each site should be evaluated individually.

At the beginning of Step 3, some basic information should exist for the site. At a minimum, information should be available from the site history, PA, SI, and Steps 1 and 2 of this eight-step process. For large or complex sites, information might be available from 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. Repeating the selection of assessment endpoints and/or the questions and hypotheses concerning those endpoints 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 intentional tiering (or phasing) of ecological site investigations at large or complex sites (see Highlight 3-1). The process of problem formulation at complex sites is the same as at more simple sites, but the number, complexity, and/or level of resolution of the questions and hypotheses can be greater at complex sites.

While problem formulation is conceptually simple, in practice it can be a complex and interactive process. Defining the ecological problems to be addressed during the baseline risk assessment involves identifying toxic mechanisms of the contaminants, characterizing potential receptors, and estimating exposure and potential ecological effects. Problem formulation also constitutes the DQO process for the baseline ecological risk assessment (U.S. EPA, 1993c,d).

The remainder of this section describes six activities to be conducted prior to the SMDP for this step: refining preliminary contaminants of ecological concern (Section 3.2); a literature search on the potential ecological effects of the contaminants (Section 3.3); qualitative evaluation of complete exposure pathways and ecosystems potentially at risk (Section 3.4); selecting assessment endpoints (Section 3.5); and developing the conceptual model and establishing risk questions (Section 3.6).

3.2 REFINEMENT OF PRELIMINARY CONTAMINANTS OF CONCERN

The results of the screening-level risk assessment (Steps 1 and 2) should have indicated which contaminants found at the site can be eliminated from further consideration and which should be evaluated further. It is important to realize that contaminants that might pose an ecological risk can be different from those that might pose a human health risk because of differing exposure pathways, sensitivities, and responses to contaminants.

The initial list of contaminants investigated in Steps 1 and 2 included all contaminants identified or suspected to be at the site. During Steps 1 and 2, it is likely that several of the contaminants found at the site were eliminated from further assessment because the risk screen indicated that they posed a negligible ecological risk. Because of the conservative assumptions used during the risk screen, some of the contaminants retained for Step 3 might also pose negligible risk. At this stage, the risk assessor should review the assumptions used (e.g., 100 percent bioavailability) against values reported in the literature (e.g., only up to 60 percent for a particular contaminant), and consider how the HQs would change if more realistic conservative assumptions were used instead (see Section 3.4.1). For those contaminants for which the HQs drop to near or below unity, the lead risk assessor and risk manager should discuss and agree on which can be eliminated from further consideration at this time. The reasons for dropping any contaminants from consideration at this step must be documented in the baseline risk assessment.

HIGHLIGHT 3-1
Tiering an Ecological Risk Assessment

Most ecological risk assessments at Superfund sites are at least a two-tier process. 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. The baseline risk assessment may serve as the second tier. Additional tiers could be needed in the baseline risk assessment for large or complex sites where there is a need to sequentially test interdependent hypotheses developed during problem formulation (i.e., evaluating the results of one field assessment before designing a subsequent field study).

While tiering can be an effective way to manage site investigations, multiple sampling phases typically require some resampling of matrices sampled during earlier tiers and increased field-mobilization costs. Thus, in some cases, a multi-tiered ecological risk assessment might cost more than a two-tiered assessment. The benefits of tiering should be weighed against the costs.

Sometimes, new information becomes available that indicates the initial assumptions that screened some contaminants out in Step 2 are no longer valid (e.g., site contaminant levels are higher than originally reported). In this case, contaminants can be placed back on the list of contaminants to be investigated with that justification.

Note that a contaminant should not be eliminated from the list of contaminants to be investigated only because toxicity information is lacking; instead, limited or missing toxicity information must be addressed using best professional judgment and discussed as an uncertainty.

3.3 LITERATURE SEARCH ON KNOWN ECOLOGICAL EFFECTS

The literature search conducted in Step 1 for the screening-level risk assessment might need to be expanded to obtain the information needed for the more detailed problem formulation phase of the baseline ecological risk assessment. The literature search should identify NOAELs, LOAELs, exposure-response functions, and the mechanisms of toxic responses for contaminants for which those data were not collected in Step 1. Appendix C presents a discussion of some of the factors important in conducting a literature search. Several U.S. EPA publications (e.g., U.S. EPA, 1995a,e,g,h) provide a window to original toxicity literature for contaminants often found at Superfund sites. For all retained contaminants, it is important to obtain and review the primary literature.

3.4 CONTAMINANT FATE AND TRANSPORT, ECOSYSTEMS POTENTIALLY AT RISK, AND COMPLETE EXPOSURE PATHWAYS

A preliminary identification of contaminant fate and transport, ecosystems potentially at risk, and complete exposure pathways was conducted in the screening ecological risk assessment. In Step 3, the exposure pathways and the ecosystems associated with the assessment endpoints that were retained by the screening risk assessment are evaluated in more detail. This effort typically involves compiling additional information on:

(1) The environmental fate and transport of the contaminants;

(2) The ecological setting and general flora and fauna of the site (including habitat, potential receptors, etc.); and

(3) The magnitude and extent of contamination, including its spatial and temporal variability relative to the assessment endpoints.

For individual contaminants, it is frequently possible to reduce the number of exposure pathways that need to be evaluated to one or a few "critical exposure pathways" which (1) reflect maximum exposures of receptors within the ecosystem, or (2) constitute exposure pathways to ecological receptors sensitive to the contaminant. The critical exposure pathways influence the selection of assessment endpoints for a particular site. If multiple critical exposure pathways exist, they each should be evaluated, because it is often difficult to predict which pathways could be responsible for the greatest ecological risk.

3.4.1 Contaminant 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 might lead to significant ecological effects (see Highlight 3-2). Chemically, contaminants can undergo several processes in the environment:

- Degradation,[3]
- Complexation,
- Ionization,
- Precipitation, and/or
- Adsorption.

HIGHLIGHT 3-2
Environmental Fate and Exposure

If a contaminant in an aquatic ecosystem is highly lipophilic (i.e., essentially insoluble in water), it is likely to partition primarily into sediments and not into the water column. Factors such as sediment particle size and organic carbon influence contaminant partitioning; therefore, these attributes should be characterized when sampling sediments. Similar considerations regarding partitioning should be applied to contaminants in soils.

Physically, contaminants might move through the environment by one or more means:

- Volatilization,
- Erosion,
- Deposition (contaminant sinks),
- Weathering of parent material with subsequent transport, and/or
- Water transport:
    - in solution,
    - as suspended material in the water, and
    - bulk transport of solid material.

Several biological processes also affect contaminant fate and transport in the environment:

- Bioaccumulation,
- Biodegradation,
- Biological transformation,[4]
- Food chain transfers, and/or
- Excretion.

[3] The product might be more or less toxic than the parent compound.

[4] The product might be more or less toxic than the parent compound.

Additional information should be gathered on past as well as current mechanisms of contaminant release from source areas at the site. The mechanisms of release along with the chemical and physical form of a contaminant can affect its fate, transport, and potential for reaching ecological receptors.

A contaminant flow diagram (or exposure pathway diagram) comprises a large part of the conceptual model, as illustrated in Section 3.6. A contaminant flow diagram originates at the primary contaminant source(s) and identifies primary release mechanisms and contaminant transport pathways. The release and movement of the contaminants can create secondary sources (e.g., contaminated sediments in a river; see Example 3-1), and even tertiary sources.

The above information is used to evaluate where the contaminants are likely to partition in the environment, and the bioavailability of the contaminant (historically, currently, or in the future). As indicated in Section 3.2, it might be possible for the risk assessment team and the risk manager to use this information to replace some of the conservative assumptions used in the screening-level risk assessment and to eliminate additional chemicals from further evaluation at this point. Any such negotiations must be documented in the baseline risk assessment.

3.4.2 Ecosystems Potentially at Risk

The ecosystems or habitats potentially at risk depend on the ecological setting of a site. An initial source of information on the ecological setting of a site is the data collected during the preliminary site visit and characterization (Step 1), including the site ecological checklist (Appendix B). The site description should provide answers to several questions including:

- What habitats (e.g., maple-beech hardwood forest, early-successional fields) are present?
- What types of water bodies are present, if any?
- Do any other habitats listed in Exhibit 1-1 exist on or adjacent to the site?

While adequately documented information should 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 at the site are not overlooked; hence, a site visit might be needed to supplement the one conducted during the screening risk assessment. If a habitat actually present on the site is omitted during the problem formulation phase, this step might need to be repeated later when the habitat is found, resulting in delays and additional costs for the risk assessment.

EXAMPLE 3-1
Exposure Pathway Model DDT Site

An abandoned pesticide production facility had released DDT to soils through poor handling practices during its operation. Due to erosion of contaminated soils, DDT migrated to stream sediments. The contaminated sediments represent a secondary source that might 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, which are considered a valuable component of the local ecosystem. This example illustrates how contaminant transport is traced from a primary source to a secondary source and from there through a food chain to an exposure point that can affect an assessment endpoint.

Available information on ecological effects of contaminants (see Section 3.3) can help focus the assessment on specific ecological resources that should be evaluated more thoroughly, because some groups of organisms can be more sensitive than others to a particular contaminant. For example, a species or group of species could be physiologically sensitive to a particular contaminant (e.g., the contaminant might interfere with its vascular system); or, the species might not be able to metabolize and detoxify the particular contaminant(s) (e.g., honey bees and grass shrimp cannot effectively biodegrade PAHs, whereas fish generally can). Alternatively, an already-stressed population (e.g., due to habitat degradation) could 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 could feed primarily on one prey type that is a primary receptor of the contaminant. Some species might preferentially feed in a habitat where the contaminant tends to accumulate. On the other hand, a species might change its behavior to avoid contaminated areas. Both sensitivity to toxic effects of a contaminant and behaviors that affect exposure levels can influence risks for particular groups of organisms.

3.4.3 Complete Exposure Pathways

The potentially complete exposure pathways identified in Steps 1 and 2 are described in more detail in Step 3 on the basis of the refined contaminant fate and transport evaluations (Section 3.4.1) and evaluation of potential ecological receptors (Section 3.4.2).

Some of the potentially complete exposure pathways identified in Steps 1 and 2 might be ruled out from further consideration at this time. Sometimes, additional exposure pathways might be identified, particularly those originating from secondary sources. Any data gaps that result in questions about whether an exposure pathway is complete should be identified, and the type of data needed to answer those questions should be described to assist in developing the WP and SAP in Step 4.

During Step 3, the potential for food-chain exposures deserves particular attention. Some contaminants are effectively transferred through food chains, while others are not. To illustrate this point, copper and DDT are compared in Example 3-2.

3.5 SELECTION OF ASSESSMENT ENDPOINTS

As noted in the introduction to this guidance, an assessment endpoint is "an explicit expression of the environmental value that is to be protected" (U.S. EPA, 1992a). In human health risk assessment, only one species is evaluated, and cancer and noncancer effects are the usual assessment endpoints. Ecological risk assessment, on the other hand, involves multiple species that are likely to be exposed to differing degrees and to respond differently to the same contaminant. Nonetheless, it is not practical or possible to directly evaluate risks to all of the individual components of the ecosystem at a site. Instead, assessment endpoints focus the risk assessment on particular components of the ecosystem that could be adversely affected by contaminants from the site.

EXAMPLE 3-2
Potential for Food Chain Transfer Copper and DDT Sites

Copper can be toxic in aquatic ecosystems and to terrestrial plants. However, it is an essential nutrient for both plants and animals, and organisms can regulate internal copper concentrations within limits. For this reason, copper tends not to accumulate in most organisms or to 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. (Copper is known to accumulate by several orders of magnitude in phytoplankton and in filter-feeding mollusks, however, and thus can pose a threat to organisms that feed on those components of aquatic ecosystems; U.S. EPA, 1985a.) In contrast, DDT, a contaminant that accumulates in fatty tissues, can biomagnify in many different types of food chains. Upper-trophic-level species (such as predatory birds), therefore, are likely to be exposed to higher levels of DDT through their prey than are lower-trophic-level species in the ecosystem.

The selection of assessment endpoints includes discussion between the lead risk assessor and the risk manager concerning management policy goals and ecological values. The lead risk assessor and risk manager should seek input from the regional BTAG, PRPs, and other stakeholders associated with a site when identifying assessment endpoints for a site. Stakeholder input at this stage will help ensure that the risk manager can readily defend the assessment endpoints when making decisions for the site. *ECO Update Volume 3, Number 1*, briefly summarizes the process of selecting assessment endpoints (U.S. EPA, 1995b).

Individual assessment endpoints usually encompass a group of species or populations with some common characteristics, such as a specific exposure route or contaminant sensitivity. Sometimes, individual assessment endpoints are limited to one species (e.g., a species known to be particularly sensitive to a site contaminant). Assessment endpoints can also encompass the typical structure and function of biological communities or ecosystems associated with a site.

Assessment endpoints for the baseline ecological risk assessment must be selected based on the ecosystems, communities, and/or species potentially present at the site. The selection of assessment endpoints depends on:

(1) The contaminants present and their concentrations;
(2) Mechanisms of toxicity of the contaminants to different groups of organisms;
(3) Ecologically relevant receptor groups that are potentially sensitive or highly exposed to the contaminant and attributes of their natural history; and
(4) Potentially complete exposure pathways.

Thus, the process of selecting assessment endpoints can be intertwined with other phases of problem formulation. The risk assessment team must think through the contaminant mechanism(s) of ecotoxicity to determine what receptors will or could be at risk. This understanding must include how the adverse effects of the contaminants might be expressed (e.g., eggshell thinning in birds), as well as how the chemical and physical form of the contaminants influence bioavailability and the type and magnitude of adverse response (e.g., inorganic versus organic mercury).

The risk assessment team also should determine if the contaminants can adversely affect organisms in direct contact with the contaminated media (e.g., direct exposure to water, sediment, soil) or if the contaminants accumulate in food chains, resulting in adverse effects in organisms that are not directly exposed or are minimally exposed to the original contaminated media (indirect exposure). The team should decide if the risk assessment should focus on toxicity resulting from direct or indirect exposures, or if both must be evaluated.

Broad assessment endpoints (e.g., protecting aquatic communities) are generally of less value in problem formulation than specific assessment endpoints (e.g., maintaining aquatic community composition and structure downstream of a site similar to that upstream of the site). Specific assessment endpoints define the ecological value in sufficient detail to identify the measures needed to answer specific questions or to test specific hypotheses. Example 3-3 provides three examples of assessment endpoint selection based on the hypothetical sites in Appendix A.

The formal identification of assessment endpoints is part of the SMDP for this step. 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. Once assessment endpoints have been selected, testable hypotheses and measurement endpoints can be developed to determine whether or not a potential threat to the assessment endpoints exists. Testable hypotheses and measurement endpoints cannot be developed without agreement on the assessment endpoints among the risk manager, risk assessors, and other involved professionals.

EXAMPLE 3-3
Assessment Endpoint Selection DDT, Copper, and PCB Sites

DDT Site

An assessment endpoint such as "protection of the ecosystem from the effects of DDT" would give 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 in a specific group of birds. This assessment endpoint provides the foundation for identifying appropriate measures of effect and exposure and ultimately the design of the site investigation. It is not necessary that a specific species of bird be identified on site. It is necessary that the exposure pathway exists and that the presence of a piscivorous bird could be expected.

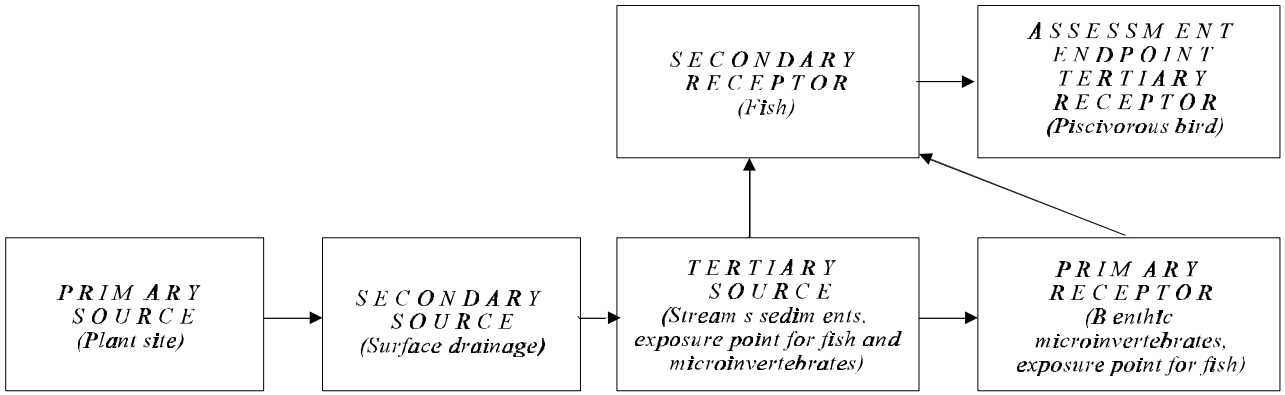
Copper Site

Copper can be acutely or chronically toxic to organisms in an aquatic community through direct exposure of the organisms to copper in the water and sediments. Threats of copper toxicity to higher-trophic-level organisms are unlikely to exceed threats to organisms at the base of the food chain, because copper is an essential nutrient which is effectively regulated by most organisms if the exposure is below immediately toxic levels. Aquatic plants (particularly phytoplankton) and mollusks, however, are poor at regulating copper and might be sensitive receptors or effective in transferring copper to the next trophic level. In addition, fish fry can be very sensitive to copper in water. Based on these receptors and the potential for both acute and chronic toxicity, an appropriate general assessment endpoint for the system could be the maintenance of aquatic community composition. An operational definition of the assessment endpoint for this site would be pond fish and invertebrate community composition similar to that of other ponds of similar size and characteristics in the area.

PCB Site

The primary ecological threat of PCBs in ecosystems is not through direct exposure and acute toxicity. Instead, PCBs bioaccumulate in food chains and can diminish reproductive success in some vertebrate species. PCBs have been implicated as a cause of reduced reproductive success of piscivorous birds (e.g., cormorants, terns) in the Great Lakes (Kubiak et al., 1989; Fox et al., 1991) and of mink along several waterways (Aulerich and Ringer, 1977; Foley et al., 1988). Therefore, reduced reproductive success in high-trophic-level species exposed via their diet is a more appropriate assessment endpoint than either toxicity to organisms via direct exposure to PCBs in water, sediments, or soils, or reproductive impairment in lower-trophic-level species.

EXAMPLE 3-5
Conceptual Model Diagram DDT
Site



3.6 THE CONCEPTUAL MODEL AND RISK QUESTIONS

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. In the conceptual model, the possible exposure pathways are depicted in an exposure pathway diagram and must be linked directly to the assessment endpoints identified in Section 3.5. Developing the conceptual model and risk questions are described in Sections 3.6.1 and 3.6.2, respectively. Selection of measurement endpoints, completing the conceptual model, is described in Step 4.

3.6.1 Conceptual Model

Based on the information obtained from Steps 1 and 2, knowledge of the contaminants present, the exposure pathway diagram, and the assessment endpoints, an integrated conceptual model is developed (see Example 3-4). The conceptual model includes a contaminant fate-and-transport diagram that traces the contaminants' movement from sources through the ecosystem to receptors that include the assessment endpoints (see Example 3-5). Contaminant exposure pathways that do not lead to a species or group of species associated with the proposed assessment endpoint indicate that either:

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

(2) There are missing components or data necessary to demonstrate a complete exposure pathway.

If case (1) is true, the proposed assessment endpoint should be reevaluated to determine if it is an appropriate endpoint for the site. If case (2) is true, then additional field data could 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.

As indicated in Section 3.5, appropriate assessment endpoints differ from site to site, and can be at one or more levels of biological organization. At any particular site, the appropriate assessment endpoints might involve local populations of a particular species, 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. The conceptual model can use assumptions that generally represent a group of organisms or ecosystem components.

The intent of the conceptual model is not to describe a particular species or site exactly as much as it is to be systematic, representative, and conservative where information is lacking (with assumptions biased to be more likely to overestimate than to underestimate risk). For example, it is not necessary or even recommended to develop new test protocols to use species that exist a site to test the toxicity of site media (See Step 4). Species used in standardized laboratory toxicity tests (e.g., fathead minnows, *Hyallela* amphipods) usually are adequate surrogates for species in their general taxa and habitat at the site.

EXAMPLE 3-4
Description of the Conceptual Model DDT Site

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. Eggshell thinning was selected as the measure of effect. During the literature review of the ecological effects of DDT, toxicity studies were found that reported reduced reproductive success (i.e., number of young fledged) in birds that experienced eggshell thinning of 20 percent or more (Anderson and Hickey, 1972; Dilworth et al., 1972). Based on those data, the lead risk assessor and risk manager agreed that eggshell thinning of 20 percent or more would be considered an adverse effect for piscivorous birds.

Chronic DDT exposure can also reduce some animals' ability to escape predation. Thus, DDT can indirectly increase the mortality rate of these organisms by making them more susceptible to predators (Cooke, 1971; Krebs et al., 1974). That effect of DDT on prey also can 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.

3.6.2 Risk Questions

Ecological risk questions for the baseline risk assessment at Superfund sites are basically questions about the relationships among assessment endpoints and their predicted responses when exposed tocontaminants. The risk questions should be based on the assessment endpoints and provide a basis for developing the study design (Step 4) and for evaluating the results of the site investigation in the analysis phase (Step 6) and during risk characterization (Step 7).

The most basic question applicable to virtually all Superfund sites is whether site-related contaminants are causing or have the potential to cause adverse effects on the assessment endpoint(s). To use the baseline ecological risk assessment in the FS to evaluate remedial alternatives, it is helpful if the specific contaminant(s) responsible can be identified. Thus refined, the question becomes "does (or could) chemical X cause adverse effects on the assessment endpoint?" In general, there are four lines of evidence that can be used to answer this question:

(1) Comparing estimated or measured exposure levels to chemical X with levels that are known from the literature to be toxic to receptors associated with the assessment endpoints;
(2) Comparing laboratory bioassays with media from the site and bioassays with media from a reference site;
(3) Comparing *in situ* toxicity tests at the site with *in situ* toxicity tests in a reference body of water; and
(4) Comparing observed effects in the receptors associated with the site with similar receptors at a reference site.

These lines of evidence are considered further in Step 4, as measurement endpoints are selected to complete the conceptual model and the site-specific study is designed.

3.7 SCIENTIFIC/MANAGEMENT DECISION POINT (SMDP)

At the conclusion of Step 3, there is a SMDP. The SMDP consists of agreement on four items: contaminants of concern, assessment endpoints, exposure pathways, and risk questions. Those items can be summarized with the assistance of the diagram of the conceptual model. Without agreement between the risk manager, risk assessors, and other involved professionals on the conceptual model to this point, measurement endpoints cannot be selected, and a site study cannot be developed effectively. Example 3-5 shows the conceptual model for the DDT site example in Appendix A.

HIGHLIGHT 3-3
Definitions:
Null and Test Hypotheses

Null hypothesis: Usually a hypothesis of no differences between two populations formulated for the express purpose of being rejected.

Test (or alternative) hypothesis: An operational statement of the investigator's research hypothesis.

When appropriate, formal hypothesis testing is preferred to make explicit what error rates are acceptable and what magnitude of effect is considered biologically important. However, it might not be practical for many assessment endpoints or be the only acceptable way to state questions about those endpoints. See Example 4-1 in the next chapter.

3.8 SUMMARY

By combining information on: (1) the potential contaminants present; (2) the ecotoxicity of the contaminants; (3) environmental fate and transport; (4) the ecological setting; and (5) complete exposure pathways, 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 based on: (1) exposure pathways to sensitive species' populations or communities; and (2) exposure levels associated with predominant fate and transport mechanisms at a site.

Based on that information, the risk assessors and risk manager agree on assessment endpoints and specific questions or testable hypotheses that, together with the rest of the conceptual model, form the basis for the site investigation. At this stage, site-specific information on exposure pathways and/or the presence of specific species is likely to be incomplete. By using the conceptual model developed thus far, measurement endpoints can be selected, and a plan for filling information gaps can be developed and written into the ecological WP and SAP as described in Step 4.

STEP 4: STUDY DESIGN AND DATA QUALITY OBJECTIVE PROCESS

OVERVIEW

The site conceptual model begun in Step 3, which includes assessment endpoints, exposure pathways, and risk questions or hypotheses, is completed in Step 4 with the development of measurement endpoints. The conceptual model then is used to develop the study design and data quality objectives. The products of Step 4 are the ecological risk assessment WP and SAP, which describe the details of the site investigation as well as the data analysis methods and data quality objectives (DQOs). As part of the DQO process, the SAP specifies acceptable levels of decision errors that will be used as the basis for establishing the quantity and quality of data needed to support ecological risk management decisions.

The lead risk assessor and the risk manager should agree that the WP and SAP describe a study that will provide the risk manager with the information needed to fulfill the requirements of the baseline risk assessment and 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 will have 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 once the WP and SAP are finalized.

Step 4 of the ecological risk assessment establishes the measurement endpoints (Section 4.1), completing the conceptual model begun in Step 3. Step 4 also establishes the study design (Section 4.2) and data quality objectives based on statistical considerations (Section 4.3) for the site assessment that will accompany site-specific studies for the remedial investigation. The site conceptual model is used to identify which points or assumptions in the risk assessment include the greatest degree of conservatism or uncertainty. The field sampling then can be designed to address the risk model parameters that have important effects on the risk estimates (e.g., bioavailability and toxicity of contaminants in the field, contaminant concentrations at exposure points).

The products of Step 4 are the WP and SAP for the ecological component of the field investigations (Section 4.4). Involvement of the BTAG in the preparation, review, and approval of WPs and SAPs can help ensure that the ecological risk assessment is well focused, performed efficiently, and technically correct. The WP and SAP should specify the site conceptual model developed in Step 3, and the measurement endpoints developed in the beginning of Step 4. The WP describes:

- Assessment endpoints;

- Exposure pathways;
- Questions and testable hypotheses;
- Measurement endpoints and their relation to assessment endpoints; and
- Uncertainties and assumptions.

The SAP should describe:

- Data needs;
- Scientifically valid and sufficient study design and data analysis procedures;
- Study methodology and protocols, including sampling techniques;
- Data reduction and interpretation techniques, including statistical analyses; and
- Quality assurance procedures and quality control techniques.

The SAP must include the data reduction and interpretation techniques, because it is necessary to known how the data will be interpreted to specify the number of samples needed. Prior to formal agreement on the WP and SAP, the proposed field sampling plan is verified in Step 5.

4.1 ESTABLISHING MEASUREMENT ENDPOINTS

As indicated in the Introduction, a measurement endpoint is defined as "a measurable ecological characteristic that is related to the valued characteristic chosen as the assessment endpoint" and is a measure of biological effects (e.g., mortality, reproduction, growth) (U.S. EPA, 1992a; although this definition may change—see U.S. EPA 1996a). Measurement endpoints are frequently numerical expressions of observations (e.g., toxicity test results, community diversity measures) that can be compared statistically to a control or reference site to detect adverse responses to a site contaminant. As used in this guidance, measurement endpoints can include measures of exposure (e.g., contaminant concentrations in water) as well as measures of effect. The relationship between measurement and assessment endpoints must be clearly described within the conceptual model and must be based on scientific evidence. This is critical because the assessment and measurement endpoints usually are different endpoints (see the Introduction and Highlight 4-1)

Typically, the number of measurement endpoints that are potentially appropriate for any given assessment endpoint and circumstance is limited. The most appropriate measurement endpoints for an assessment endpoint depend on several considerations, a primary one being how many and which lines of evidence are needed to

HIGHLIGHT 4-1
Importance of Distinguishing Measurement from Assessment Endpoints

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 could be mistaken as the basis for a remedial decision, when the actual basis for the decision is the protection of the aquatic community as a whole (including higher-trophic-level game fish that depend on lower trophic levels in the community), as indicated by a few sensitive invertebrate and algal species.

support risk-management decisions at the site (see Section 3.6.2). Given the potential ramifications of site actions, the site risk manager might want to use more than one line of evidence to identify site-specific thresholds for effects. The risk manager and risk assessors must consider the utility of each type of data given the cost of collecting those data and the likely sensitivity of the risk estimates to the data.

There are some situations in which it might only be necessary or possible to compare estimated or measured contaminant exposure levels at a site to ecotoxicity values derived from the literature. For example, for contaminants in surface waters for which there are state water-quality standards, exceedance of the standards indicates that remediation to reduce contaminant concentrations in surface waters to below these levels could be needed whether impacts are occurring or not. For assessment endpoints for which impacts are difficult to demonstrate in the field (e.g., because of high natural variability), and toxicity tests are not possible (e.g., food-chain accumulation is involved), comparing environmental concentrations with a well-supported ecotoxicity value might have to suffice.

A bioassay using contaminated media from the site can suffice if the risk manager and risk assessor agree that laboratory tests with surrogate species will be taken as indicative of likely effects on the assessment endpoint. For sites with complex mixtures of contaminants without robust ecotoxicity values and high natural variability in potential measures for the assessment endpoint, either laboratory or *in situ* toxicity testing might be the best technique for evaluating risks to the assessment endpoint. For inorganic substances in soils or sediments, bioassays often are needed to determine the degree to which a contaminant is bioavailable at a particular site. Laboratory toxicity tests can indicate the potential for adverse impacts in the field, while *in situ* toxicity testing with resident organisms can provide evidence of actual impacts occurring in the field.

Sometimes more than one line of evidence is needed to reasonably demonstrate that contaminants from a site are likely to cause adverse effects on the assessment endpoint. For example, total recoverable copper in a surface water body to which a water quality standard did not apply could exceed aquatic ecotoxicity values, but not cause adverse effects because the copper is only partially bioavailable or because the ecotoxicity value is too conservative for the particular ecosystem. Additional evidence from bioassays or community surveys could help resolve whether the copper is actually causing adverse effects (See Example 4-1). Alternatively, if stream community surveys indicate impairment of community structure downstream of a site, comparing contaminant concentrations with aquatic toxicity values can help identify which contaminants are most likely to be causing the effect. When some lines of evidence conflict with others, professional judgment is needed to determine which data should be considered more reliable or relevant to the questions.

Once there is agreement on which lines of evidence are required to answer questions concerning the assessment endpoint, the measurement endpoints by which the questions or test hypotheses will be examined can be selected.

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 toxic mechanisms might be evaluated. For example, if a contaminant primarily causes damage to vertebrate kidneys, the use of daphnids (which do not have kidneys) would be inappropriate.

EXAMPLE 4-1
Lines of Evidence Copper Site

Primary question: Are ambient copper levels in sediments causing adverse effects in benthic organisms in the pond?

Possible lines of evidence phrased as test hypotheses:

(1) Mortality in early life stages of benthic aquatic insects in contact with sediments from the site significantly exceeds mortality in the same kinds of organisms in contact with sediments from a reference site (e.g., $p \leq 0.1$).

(2) Mortality in *in situ* toxicity tests in sediments at the pond significantly exceeds mortality in *in situ* toxicity tests in sediments at a reference pond (e.g., $p \leq 0.1$).

(3) There are significantly fewer numbers of benthic aquatic insect species present per m^2 of sediment at the pond near the seep than at the opposite side of the pond (e.g., $p \leq 0.1$).

Statistical and biological significance: Differences in the incidence of adverse effects between groups of organisms exposed to contaminants from the site and groups not exposed might be statistically significant, but not biologically important, depending on the endpoint and the power of the statistical test. Natural systems can sustain some level of perturbation without changing in structure or function. The risk assessor needs to evaluate what level of effect will be considered biologically important. Given the limited power of small sample sizes to detect an effect, the risk assessor might decide that any difference that is statistically detectable at a p level of 0.1 or less is important biologically.

Potential measurement endpoints in toxicity tests or in field studies should be evaluated according to how well they can answer questions about the assessment endpoint or support or refute the hypotheses developed for the conceptual model. Statistical considerations, including sample size and statistical power described in Section 4.3, also must be considered in selecting the measurement endpoints. The following subsections describe additional considerations for selecting measurement endpoints, including species/community/habitat (Section 4.1.1), relationship to the contaminant(s) of concern (Section 4.1.2), and mechanisms of ecotoxicity (Section 4.1.3).

4.1.1 Species/Community/Habitat Considerations

The function of a measurement endpoint is to represent an 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 be inclusive of risks to all of the species, populations, or groups included in the assessment endpoint that are not directly measured. In other words, the measurement endpoint should be representative of the assessment endpoint for the site and not lead to an underestimate of risk to the assessment endpoint. Example 4-2 illustrates this point for the DDT site in Appendix A.

In selecting a measurement endpoint, the species and life stage, population, or community chosen should be the one(s) most susceptible to the contaminant for the assessment endpoint in question. For species and populations, this selection is based on a review of the species: (1) life history; (2) habitat utilization; (3) behavioral characteristics; and (4) physiological parameters. Selection of measurement endpoints also should be based on which routes of exposure are likely. For communities, careful evaluation of the contaminant fate and transport in the environment is essential.

4.1.2 Relationship of the Measurement Endpoints to the Contaminant of Concern

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

HIGHLIGHT 4-2
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 defined terms.

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 (Klemm et al., 1990; Nebeker et al., 1984; Pascoe et al., 1989). To assess the effects of exposure of benthic communities to metal-contaminated sediment, *C. riparius* might be the better species to use as a test organism for many aquatic systems to ensure that risks are not underestimated. In general, the most sensitive of the measurement endpoints appropriate for inferring risks to the assessment endpoint should be used. If all else is equal, however, species that are commonly used in the laboratory are preferred over non-standard laboratory species to improve test precision.

Some species have been identified as being particularly sensitive to certain contaminants. For example, numerous studies have demonstrated that mink are among the most sensitive of the tested mammalian species to the toxic effects of PCBs (U.S. EPA, 1995a). Species that rely on quick reactions or behavioral responses to avoid predators can be particularly sensitive to contaminants affecting the central nervous system, such as mercury. Thus, the sensitivity of the measurement endpoint relative to the assessment endpoint should be considered for each contaminant of concern.

4.1.3 Mechanisms of Ecoxicity

A contaminant can exert adverse ecological effects in many ways. First, a contaminant might affect an organism after exposure for a short period of time (acute) or after exposure over an extended period of time (chronic). Second, the effect of a contaminant could 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 lifespan or reproductive success. For example, if a contaminant reduces the reaction speed of a prey species, the prey can become more susceptible to

predation. Third, a contaminant might act directly or indirectly on an organism. Direct effects include lethal or sublethal effects of the chemical on the organism. Indirect effects occur when the contaminant damages the food, habitat, predator-prey relationships, or competition of the organism in its community.

Mechanisms of ecotoxicity and exposure pathways have already been considered during problem formulation and identification of the assessment endpoints. However, toxicity issues are revisited when selecting appropriate measurement endpoints to ensure that they measure the assessment endpoint's toxic response of concern.

4.2 STUDY DESIGN

In Section 4.1, one or more lines of evidence that could be used to answer questions or to test hypotheses concerning the assessment endpoint(s) were identified. This section provides recommendations on how to design a field study for: bioaccumulation and field tissue residue studies (Section 4.2.1); population/community evaluations (Section 4.2.2); and toxicity testing (Section 4.2.3). A thorough understanding of the strengths and limitations of these types of field studies is necessary to properly design any investigation.

Typically, no one line of evidence can stand on its own. Analytic chemistry on co-located samples and other lines of evidence are needed to support a conclusion. When population/community evaluations are coupled with toxicity testing and media chemistry, the procedure often is referred to as a triad approach (Chapman et al., 1992; Long and Chapman, 1985). This method has proven effective in defining the area affected by contaminants in sediments of several large bays and estuaries.

The development of exposure-response relationships is critical for evaluating risk management options; thus, for all three types of studies, sampling is applied to a contamination gradient when possible as well as compared to reference data. Reference data are baseline values or characteristics that should represent the site in the absence of contaminants released from the site. Reference data might be data collected from the site before contamination occurred or new data collected from a reference site.

The reference site can be the least impacted (or unimpacted) area of the Superfund site or a nearby site that is ecologically similar, but not affected by the site's contaminants. For additional information on selecting and using reference information in Superfund ecological risk assessments, see *ECO Update Volume 2, Number 1* (U.S. EPA, 1994e).

The following subsections present a starting point for selecting an appropriate study design for the different types of biological sampling that might apply to the site investigation.

EXAMPLE 4-2
Selecting Measurement Endpoints DDT Site

As described in Example 3-1, one of the assessment endpoints selected for the DDT site is the protection of piscivorous birds from egg-shell thinning due to DDT exposure. 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. In this illustration, the kingfishers are used as the most highly exposed of the piscivorous birds potentially present. Thus, one can conclude that, if the risk assessment shows no threat of eggshell thinning to the kingfisher, there should be minimal or no threat to other piscivorous birds that might utilize the site. Thus, eggshell thinning in belted kingfishers is an appropriate measurement endpoint for this site.

4.2.1 Bioaccumulation and Field Tissue Residue Studies

Bioaccumulation and field tissue residue studies typically are conducted at sites where contaminants are likely to accumulate in food chains. The studies help to evaluate contaminant exposure levels associated with measures of effect for assessment endpoint species.

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. As indicated in Section 2.2.1, the most conservative BAF values identified in the literature generally are used to estimate bioaccumulation in Step 2 of the screening-level risk assessment. Where the potential for overestimating bioaccumulation by using conservative literature values to represent the site is substantial, additional evaluation of the literature for values more likely to apply to the site or a site-specific tissue residue study might be advisable.

A tissue residue study generally is conducted on organisms that are in the exposure pathway (i.e., food chain) associated with the assessment endpoint. Data seldom are available to link tissue residue levels in the sampled organisms to adverse effects in those organisms. Literature toxicity studies usually associate effects with an administered dose (or data that can be converted to an administered dose), not a tissue residue level. 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 thatspecies,particularly in situations in which several media and trophic levels are in the exposure pathway.

The concentration of a contaminant in the primary prey/food also should be linked to an exposure concentration from a contaminated medium (e.g., soil, sediment, water), because it is the medium, not the food chain, that will be remediated. Thus, contaminant concentrations must be measured in environmental media at the same locations at which the organisms are collected along contaminant gradients and at reference locations. Co-located samples of the contaminated medium and organisms are needed 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 gradient of contaminant concentrations. In addition, tissue residues from sessile organisms (e.g., rooted plants, clams) are easier to attribute to specific contaminated areas than are tissue residues from mobile organisms (e.g., large fish). Example 4-3 illustrates these concepts using the DDT site example in Appendix A

EXAMPLE 4-3
Tissue Residue Studies DDT Site

In the DDT site example, 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 the relationship between the DDT levels in the sediments and the levels in the forage fish 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. Using the DDT concentrations measured in fish that correspond to a LOAEL and NOAEL for adverse effects in birds and the relationship between the DDT levels in the sediments and in the forage fish, the corresponding sediment contamination levels can be estimated. Those sediment DDT concentrations can then be used to estimate a cleanup level that would reduce threats of eggshell thinning to piscivorous birds.

Although it might 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 are likely to constitute a large portion of the diet of the species of concern (e.g., new growth on maple trees, rather than cattails, as a food source for deer) 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 can be critical, and failure to plan accordingly can 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. The recommendations of Phillips (1977, 1978) include 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; and
(4) Of reasonable size to give adequate tissue for analysis (e.g., 10 grams for organic analysis and 0.5 gram for metal analysis for many laboratories (Roy F. Weston, Inc.,1994).

Additional considerations for some situations would be that the species is:

(5) Sufficiently long-lived to allow for sampling more than one age class; and

(6) Easy to sample and hardy enough to survive in the laboratory (allowing for the organisms to eliminate contaminants from their gastrointestinal tract 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, 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 measure bioavailability directly; (2) to provide site-specific estimates of exposure to higher-trophic-level organisms; and (3) to relate tissue residue levels to concentrations in environmental media (e.g., in soil, sediment, or water). Sometimes these studies also can be used to link tissue residue levels with observed effects in the organisms sampled. However, in a "pure" accumulation study, 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 or not a population in the field is affected by accumulation of a contaminant, it is important to try. Exposure that results in adverse responses might alter the animal's feeding rates or efficiency, diet, degree of activity, or metabolic rate, and thereby influence the animal's daily intake or accumulation of the contaminant and the estimated BAF. For example, if the rate of bioaccumulation of a contaminant in an organism decreases with increasing environmental concentrations (e.g., its toxic effects reduce food consumption rates), using a BAF determined at low environmental concentrations to estimate bioaccumulation at high environmental concentrations would overestimate risk. Conversely, if bioaccumulation increased with increasing environmental concentrations (e.g., its toxic effects impair the organisms' ability to excrete the contaminant), using a BAF determined at low environmental concentrations would underestimate risks at higher environmental concentrations.

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 be more appropriate to analyze prey species that do not metabolize 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 cannot be drawn about ecological risks posed by contaminants at the site. The home range, particularly the foraging areas within 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 can be 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 animals with small home and

foraging ranges and limited movement patterns. Examples of organisms with small home ranges 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.

Population size. 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 organisms actually collected should be not only of the same species, but also of similar age or size to reduce data variability when BAFs are being evaluated. 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 best to have individual animals large enough for chemical analysis, without having to pool (combine) individuals prior to chemical analysis. However, composite samples will be needed if individuals from the species selected cannot yield sufficient tissue for the required analytical methods. Linking contaminant levels in organisms to concentrations in environmental media is easier if composites are made up of members of the same species, sex, size, and age, and therefore exhibit similar accumulation characteristics. When deciding whether or not to pool samples, it is important to consider what impact the loss of information on variability of contaminant levels along these dimensions will have on data interpretation. The size, age, and sex of the species collected should be representative of the range of prey consumed by the species of concern.

Summary. Although it can 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 because the ranking depends on the study objectives. 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. Further information on factors that can influence bioaccumulation is available from the literature (e.g., Phillips, 1977, 1978; U.S. EPA, 1995d).

4.2.2 Population/Community Evaluations

Population/community evaluations, or biological field surveys, are potentially useful for both contaminants that are toxic to organisms through direct exposure to the contaminated medium and contaminants that bioaccumulate 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 typically are not predictive. The release of the contaminant must already have occurred and exerted an effect in order for the population/community evaluation to be. an effective tool for a risk assessment.

Population and community surveys evaluate the current status of an ecosystem, often using several measures of population or community structure (e.g., standing biomass, species richness) or function (e.g., feeding group analysis). The most commonly used measures include number of species and abundance of organisms in an ecosystem, although some species are difficult to evaluate. It is difficult to detect changes in top predator populations affected by bioaccumulation of substances in their food chain due to the mobility of top predators. Some species, most notably insects, can develop a tolerance to contaminants (particularly pesticides); in these cases, a population/community survey would be ineffective for evaluating existing impacts. While population/community evaluations can be useful, the risk assessors should consider the level of effort required as well as the difficulty in accounting for natural variability.

A variety of population/community evaluations have been used at Superfund sites. Benthic macroinvertebrate surveys are the most commonly conducted population/community evaluations. There are methods manuals (e.g., U.S. EPA 1989c, 1990a) and publications that describe the technical procedures for conducting these studies. In certain instances, fish community evaluations have proven useful at Superfund sites. However, these investigations typically are more labor-intensive and costly than a comparable macroinvertebrate study. In addition, fish generally are not sensitive measures of the effects of sediment contamination, because they usually are more mobile than benthic macroinvertebrates. Terrestrial plant community evaluations have been used to a limited extent at Superfund sites. For those surveys, it is important to include information about historical land use and physical habitat disruption in the uncertainty analysis.

Additional information on designing field studies and on field study methods can be found in *ECO Update Volume 2, Number 3* (U.S. EPA, 1994d).

Although population- and community-level studies can be valuable, several factors can confound the interpretation of the results. For example, many fish and small mammal populations normally cycle in relation to population density, food availability, and other factors. Vole populations have been known to reach thousands of individuals per acre and then to decline to as low as tens of individuals per acre the following years without an identifiable external stressor (Geller, 1979). 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 different, "natural" factors. Populations located relatively close to each other can be affected independently: one might 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 another; for example, a paved highway can be as effective a barrier as a river, and populations on either side can fluctuate independently. Failure to evaluate such issues can result in erroneous conclusions. The level of effort required to resolve some of these issues can make population/community evaluations impractical in some circumstances.

4.2.3 Toxicity Testing

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. As indicated earlier, the

species tested and the responses measured must be compatible with the mechanism of toxicity. 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); toxicity tests using contaminated media from the site would not be appropriate for evaluating this type of ecological threat.

There are numerous U.S. 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, particularly laboratory tests, the risk assessor must evaluate what a particular toxicity test measures and, just as importantly, 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?

(7) What endpoints should be measured?

There are 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, but one must consider the original purpose of the test.

New toxicity tests are being developed continually and can be of value in designing a Superfund 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.

In situ toxicity tests involve placing organisms in locations that might be affected by site contaminants and in reference locations. Non-native species should not be used, because of the risk of their release into the environment in which they could adversely affect (e.g., prey on or outcompete) resident species. *In situ* tests might provide more realistic evidence of existing adverse effects than laboratory toxicity tests; however, the investigator has little control over many environmental parameters and the experimental organisms can be lost to adverse weather or other events (e.g., human interference) at the site or reference location.

For additional information on using toxicity tests in ecological risk assessments, see *ECO Update Volume 2, Numbers 1* and *2* (U.S. EPA, 1994b,c).

4.3 DATA QUALITY OBJECTIVES AND STATISTICAL CONSIDERATIONS

The SAP indicates the number and location of samples to be taken, the number of replicates for each sampling location, and the method for determining sampling locations. In specifying those parameters, the investigator needs to consider, among other things, the DQOs and statistical methods that will be used to analyze the data.

4.3.1 Data Quality Objectives

The DQO process represents a series of planning steps that can be employed throughout the development of the WP and SAP to ensure that the type, quantity, and quality of environmental data to be collected during the ecological investigation are adequate to support the intended application. Problem formulation in Steps 3 and 4 is essentially the DQO process. By employing problem formulation and the DQO process, the investigator is able to define data requirements and error levels that are acceptable for the investigation prior to the collection of data. This approach helps ensure that results are appropriate and defensible for decision making. The specific goals of the general DQO process are to:

- Clarify the study objective and define the most appropriate types of data to collect;
- Determine the most appropriate field conditions under which to collect the data; and
- Specify acceptable levels of decision errors that will be used as the basis for establishing the quantity and quality of data needed to support risk management decisions.

As the discussion of Steps 3 and 4 indicates, those goals are subsumed in the problem formulation phase of an ecological risk assessment. Several U.S. EPA publications provide detailed descriptions of the DQO process (U.S. EPA, 1993c,d,f, 1994f). Because many of the steps of the DQO process are already covered during problem formulation, the DQO process should be reviewed by the investigator and applied as needed.

4.3.2 Statistical Considerations

Sampling locations can be selected "randomly" to characterize an area or non-randomly, as along a contaminant concentration gradient. The way in which sampling locations are selected determines which statistical tests, if any, are appropriate for evaluating test hypotheses.

If a toxicity test is to be used to identify contaminant concentrations in the environment associated with a threshold for adverse effects, the statistical power of the test is important. The threshold for effects is assumed to be between the NOAEL and LOAEL of a toxicity test (see Section 7.3.1). For toxicity tests that use a small number of test and control organisms or for which the toxic response is highly variable, the increase in response rate of the test animals compared with controls often must be relatively high (e.g., 30 to 50 percent increase) for the response to be considered a LOAEL (i.e., statistically increased level of an adverse response compared with control levels). If a NOAEL-to-LOAEL range that might represent a 20 to 50 percent increase in adverse effect is unacceptable (e.g., a population is unlikely to sustain itself with an additional 40 percent mortality), then the power of the study design must be increased, usually by increasing sample size, but sometimes by taking full advantage of all available information to improve the power of the design (e.g., stratified sampling, special tests for trends, etc.). A limitation on the use of toxicity values from the literature is that often, the investigator does not discuss the statistical power of the study design, and hence does not indicate the minimum statistically detectable effect level. Appendix D describes additional statistical considerations, including a description of Type I and Type II error, statistical power, statistical models, and power efficiency.

In evaluating the results of statistical analyses, one should remember that a statistically significant difference relative to a control or reference population does not necessarily imply a biologically important or ecologically significant difference (see Example 4-1).

4.4 CONTENTS OF WORK PLAN AND SAMPLING AND ANALYSIS PLAN

The WP and SAP for the ecological investigation should be developed as part of the initial RI sampling event if possible. If not, the WP and SAP can be developed as an additional phase of the site investigation. In either case, the format of the WP and SAP should be similar to that described by U.S. EPA (1988a, 1989b). Accordingly, those documents should be consulted when developing the ecological investigation WP and SAP.

The WP and SAP are typically written as separate documents. In that case, the WP can be submitted for the risk manager's review so that any concerns with the approach can be resolved prior to the development of the SAP. For some smaller sites, it might be more practical to combine the two documents, in which case, the investigators should discuss the overall objectives and approach with the risk manager to ensure that all parties agree.

The WP and SAP are briefly described in Sections 4.4.1 and 4.4.2, respectively. A plan for testing the SAP before the site WP and SAP are signed and the investigation begins is described in Section 4.4.3.

4.4.1 Work Plan

The purpose of the WP is to document the decisions and evaluations made during problem formulation and to identify additional investigative tasks needed to complete the evaluation of risks to ecological resources. As presented in U.S. EPA (1988a), the WP generally includes the following:

- A general overview and background of the site including the site's physical setting, ecology, and previous uses;
- A summary and analysis of previous site investigations and conclusions;
- A site conceptual model, including an identification of the potential exposure pathways selected for analysis, the assessment endpoints and questions or testable hypotheses, and the measurement endpoints selected for analysis;
- The identification of additional site investigations needed to conduct the ecological risk assessment; and
- A description of assumptions used and the major sources of uncertainty in the site conceptual model and existing information.

The general scope of the additional sampling activities also is presented in the WP. A detailed description of the additional sampling activities is presented in the SAP along with an anticipated schedule of the site activities.

4.4.2 Sampling and Analysis Plan

The SAP typically consists of two components: a field sampling plan (FSP) and a quality assurance project plan (QAPP). The FSP provides guidance for all field work by providing a detailed description of the sampling and data-gathering procedures to be used for the project. The QAPP provides a description of the steps required to achieve the objectives dictated by the intended use of the data.

Field sampling plan. The FSP provides a detailed description of the samples needed to meet the objectives and scope of the investigation outlined in the WP. The FSP for the ecological assessment should be detailed enough that a sampling team unfamiliar with the site would be able to gather all the samples and/or required field data based on the guidelines presented in the document. The FSP for the ecological investigation should include a description of the following elements:

- Sampling type and objectives;
- Sampling location, timing, and frequency;
- Sample designation;

- Sampling equipment and procedures; and
- Sample handling and analysis.

A detailed description of those elements for chemical analyses is provided in Appendix B of U.S. EPA (1988a). Similar specifications should be developed for the biological sampling.

Quality assurance project plan. The objective of the QAPP is to provide a description of the policy, organization, functional activities, and quality control protocols necessary for achieving the study objectives. Highlight 4-3 presents the elements typically contained in a QAPP.

U.S. EPA has prepared guidance on the contents of a QAPP (U.S. EPA, 1987a, 1988a, 1989a). Formal quality assurance and quality control (QA/QC) procedures exist for some types of ecological assessments, for example, for laboratory toxicity tests on aquatic species. For standardized laboratory tests, there are formal QA/QC procedures that specify (1) sampling and handling of hazardous wastes; (2) sources and culturing of test organisms; (3) use of reference toxicants, controls, and exposure replicates; (4) instrument calibration; (5) record keeping; and (6) data evaluation. For other types of ecological assessments, however, QA/QC procedures are less well defined (e.g., for biosurveys of vegetation, terrestrial vertebrates). BTAG members can provide input on appropriate QA/QC procedures based on their experience with Superfund sites.

4.4.3 Field Verification of Sampling Plan and Contingency Plans

For biological sampling, uncontrolled variables can influence the availability of species to be sampled, the efficiency of different types of sampling techniques, and the level of effort required to achieve the sample sizes specified in the SAP. As a consequence, the risk assessor should develop a plan to test the sampling design before the WP and SAP are signed and the site investigationbegins. Otherwise, field sampling during the site investigation could fail to meet the DQOs specified in the SAP, and the study could fail to meet its objectives. Step 5 provides a description of the field verification of the sampling design.

HIGHLIGHT 4-3
Elements of a QAPP

(1) Project description
(2) Designation of QA/QC responsibilities
(3) Statistical tests and data quality objectives
(4) Sample collection and chain of custody
(5) Sample analysis
(6) System controls and preventive maintenance
(7) Record keeping
(8) Audits
(9) Corrective actions
(10) Quality control reports

To the extent that potential field problems can be anticipated, contingency plans also should be specified in the SAP. An example of a contingency plan is provided in Steps 5 and 6 (Examples 5-2 and 6-1).

4.5 SCIENTIFIC/MANAGEMENT DECISION POINT (SMDP)

The completion of the ecological risk assessment WP and SAP should coincide with an SMDP. Within this SMDP, the ecological risk assessor and the ecological risk manager agree on: (1) selection of measurement endpoints; (2) selection of the site investigation methods; and (3) selection of data reduction and interpretation techniques. The WP or SAP also should specify how inferences will be drawn from the measurement to the assessment endpoints.

4.6 SUMMARY

At the conclusion of Step 4, there will be an agreement on the contents of the WP and SAP. As noted earlier, these plans can be parts of a larger WP and SAP that are developed to meet other remedial investigation needs, or they can 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 WP and/or the SAP 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, datainterpretation methods, and statistical analyses that will be used.