STEP 5: FIELD VERIFICATION OF SAMPLING DESIGN

OVERVIEW

Before the WP and SAP are signed, it is important to verify that the field sampling plan they specify is appropriate and implementable at the site. If this has not already been done, it should be done now. During field verification of the sampling design, the testable hypotheses, exposure pathway models, and measurement endpoints are evaluated for their appropriateness and implementability. The assessment endpoint(s), however, should not be under evaluation in this step; the appropriateness of the assessment endpoint should have been resolved in Step 3. If an assessment endpoint is changed at this step, the risk assessor must return to Step 3, because the entire process leading to the actual site investigation in Step 6 assumes the selection of appropriate assessment endpoints.

5.1 PURPOSE

The primary purpose of field verification of the sampling plan is to ensure that the samples specified by the SAP actually can be collected. A species that will be associated with a measurement endpoint and/or exposure point concentration should have been observed at the preliminary site characterization or noted during previous site visits. During this step, previously obtained information should be verified and the feasibility of sampling will need to be checked by a site visit. Preliminary sampling will determine if the targeted species is present and—equally important—collectable in sufficient numbers or total biomass to meet data quality objectives. This preliminary field assessment also allows for final confirmation of the habitats that exist on or near the site. Habitat maps are verified a final time, and interpretations of aerial photographs can be checked.

Final decisions on reference areas also should be made in this step. The reference areas should be chosen to be as similar as possible to the site in all aspects except contamination. Parameters to be evaluated for similarity include, but are not limited to: slope, habitat, species potentially present, soil and sediment characteristics, and for surface waters, flow rates, substrate type, water depth, temperature, turbidity, oxygen levels, water hardness, pH, and other standard water quality parameters. If several on-site habitats or habitat variables are being investigated, then several reference areas could be required. Reference areas should be as free of site-related contaminants above background levels as practical.

5.2 DETERMINING SAMPLING FEASIBILITY

When sampling biota, it is difficult to predict what level of effort will be necessary to obtain an adequate number of individuals of the required size. Some preliminary field measurements often can help determine adequate sampling efforts to attain the sample sizes specified in the SAP for statistical analyses. The WP and SAP should be signed and the site investigation should be implemented immediately after verification of the sampling design to limit effects of uncontrolled field variables. For example, evaluation of current small mammal population density might indicate to the investigator that 400 trap-nights instead of 50 are necessary to collect the required number of small mammals. If there is a time lag between the field sampling verification and the actual site investigation, it could be necessary to reverify the field sampling to determine if conditions have changed.

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

- When sampling a stream's surface water, if the stream is only three inches deep, collecting the water directly into 32-ounce bottles would not be practical.

- Sampling the substrate in a stream might be desirable, but if the substrate is bedrock, it might not be feasible or the intent of the sampling design.

An exposure-response relationship between contamination and biological effects is a key component of establishing causality during the analysis phase of the baseline risk assessment (Step 6). If extent-of-contamination sampling is conducted in phases, abiotic exposure media and biotic samples must be collected simultaneously because the interactions (both temporal and spatial) between the matrix to be remediated and the biota are crucial to the development of a field exposure-response relationship. Failure to collect one sample properly or to coordinate samples temporally can significantly impact the interpretation of the data.

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

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

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

These and other problems associated with the practical implementation of sampling should be resolved prior to finalizing the SAP to the extent practicable. Assessing the feasibility of the sampling plan before the site investigation begins saves costs in the long term because it minimizes the chances of failing to meet DQOs during the site investigation.

Examples 5-1 and 5-2 describe the field verification of the sampling plan for the hypothetical copper and DDT sites illustrated in Appendix A. Note that the scope of the field verification differs for the copper and DDT sites. For the DDT site, a modification to the study design was necessary. For both sites, the issues were resolved and a sign-off was obtained at the SMDP for this step.

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

5.3 SCIENTIFIC/MANAGEMENT DECISION POINT (SMDP)

The SMDP for the field verification of the sampling design is the signing of the finalized WP and SAP. Any changes to the investigation proposed in Step 4 must be made with agreement from the risk manager and risk assessment team. The risk manager must understand what changes have been made and why, and must ensure that the risk management decisions can be made from the information that the new study design can provide. The risk assessors must be involved to ensure that the assessment endpoints and testablehypotheses are still being addressed.In the worst cases, changes in the measurement endpoints could be necessary, with corresponding changes to the risk hypotheses and sampling design. Any new measurement endpoints must be evaluated according to their utility for inferring changes in the assessmentendpoints and their compatibility with the site conceptual model (from Steps 3 and 4). Loss of the relationship between measurement endpoints and the assessment endpoints, the risk questions or testable hypothesis, and the site conceptual model will result in a failure to meet study objectives.

EXAMPLE 5-1
Field Verification of Sampling Design – Copper Site

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

Despite one's best efforts to conduct a sound site assessment, unexpected circumstances might still make it necessary for the sampling plan to be changed in the field. Any changes should be agreed to and documented by the lead risk assessor in consultation with the risk manager.
Once the finalized WP and SAP are approved and signed, Step 6 should begin.

5.4 SUMMARY

In summary, field verification of the sampling plan is very important to ensuring that the DQOs of the site investigation can be met. This step verifies that the selected assessment endpoints, testable hypotheses, exposure pathway model, measurement endpoints, and study design from Steps 3 and 4 are appropriate and implementable at the site. By verifying the field sampling plan prior to conducting the full site investigation, well-considered alterations can be made to the study design and/or implementation if necessary. These changes will ensure that the ecological risk assessment meets the study objectives.

If changing conditions force changes to the sampling plan in the field (e.g., selection of a different reference site), the changes should be agreed to and documented by the lead risk assessor in consultation with the risk manager.

EXAMPLE 5-2
Field Verification of Sampling Design–DDT Site

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

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

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

STEP 6: SITE INVESTIGATION AND ANALYSIS PHASE

OVERVIEW

Information collected during the site investigation is used to characterize exposures and ecological effects. The site investigation includes all of the field sampling and surveys that are conducted as part of the ecological risk assessment. The site investigation and analysis of exposure and effects should be straightforward, following the WP and SAP developed in Step 4 and tested in Step 5.

Exposure characterization relies heavily on data from the site investigation and can involve fate-and-transport modeling. Much of the information for characterizing potential ecological effects was gathered from the literature review during problem formulation, but the site investigation might provide evidence of existing ecological impacts and additional exposure-response information.

6.1 INTRODUCTION

The site investigation (Section 6.2) and analysis phase (Section 6.3) of the ecological risk assessment should be straightforward. In Step 4, all issues related to the study design, sample collection, DQOs, and procedures for data reduction and interpretation should have been identified and resolved. However, as described in Step 5, there are circumstances that can arise during a site investigation that could require modifications to the original study design. If any unforeseen events do require a change to the WP or SAP, all changes must be agreed upon at the SMDP (Section 6.4). The results of Step 6 are used to characterize ecological risks in Step 7.

6.2 SITE INVESTIGATION

The WP for the site investigation is based on the site conceptual model and should specify the assessment endpoints, risk questions, and testable hypotheses. The SAP for the site investigation should specify the relationship between measurement and assessment endpoints, the necessary number, volume, and types of samples to be collected, and the sampling techniques to be used. The SAP also should specify the data reduction and interpretation techniques and the DQOs. The feasibility of the sampling design was tested in Step 5. Therefore, the site investigation should be a direct implementation of the previously designed study.

During the site investigation, it is important to adhere to the DQOs and to any requirements for co-located sampling. Failure to collect one sample properly or to coordinate samples temporally can significantly affect interpretation of the data. Changing field conditions (Section 6.2.1) and new information on the nature and extent of contamination (Section 6.2.2) can require a change in the SAP.

6.2.1 Changing Field Conditions

In instances where unexpected conditions arise in the field that make the collection of specified samples impractical or not ideal, the ecological risk assessor should reevaluate the feasibility of the sampling design as described in Step 5. Field efforts should not necessarily be halted, but decisions to change sampling procedures or design must be agreed to by the risk manager and lead risk assessor or project-delegated equivalents.

Field modifications to study designs are not uncommon during field investigations. When the WP and SAP provide a precise conceptual model and study design with specified data analyses, informed modifications to the SAP can be made to comply with the objectives of the study. As indicated in Step 4, contingency plans can be included in the original SAP in anticipation of situations that might arise during the site investigation (see Example 6-1). Any modifications, and the reasons for the modifications, must be documented in the baseline risk assessment.

EXAMPLE 6-1
Fish Sampling Contingency Plan – DDT Site

At the DDT site where creek chub are to be collected for DDT tissue residue analyses, a contingency plan for the site investigation was developed. An alternate species, the longnosed dace, was specified with the expectation that, at one or all locations, the creek chub might be absent at the time of the site investigation. Such contingency plans are prudent even when the verification of the field sampling design described in Step 5 indicates that the samples are obtainable.

6.2.2 Unexpected Nature or Extent of Contamination

It is not uncommon for an initial sampling phase of the RI to reveal that contamination at levels of concern extend beyond areas initially established for characterizing contamination and ecological effects at the site or that contaminant gradients are much steeper than anticipated. If this contingency changes the opportunity for evaluating biological effects along a contamination gradient, the ecological risk assessors and risk manager need to determine whether additional sampling (e.g., further downstream from the site) is needed.

Thus, it is important for the ecological risk assessors to track information on the nature and extent of contamination as RI sampling is conducted. On occasion, new contaminants are identified during an RI. In this case, the risk assessors and site manager will need to return to Step 1 to screen the new contaminants for ecological risk.

Immediate analysis of the data for each type of sampling and communication between the risk assessors and risk managers can help ensure that the site investigation is adequate to achieve the study goals and objectives when field modifications are necessary. If a change to the WP or SAP is needed, the lead risk assessor and risk manager must agree on all changes (the SMDP in Section 6.4).

6.3 ANALYSIS OF ECOLOGICAL EXPOSURES AND EFFECTS

The analysis phase of the ecological risk assessment consists of the technical evaluation of data on existing and potential exposures (Section 6.3.1) and ecological effects (Section 6.3.2) at the site. The analysis is based on the information collected during Steps 1 through 5 and often includes additional assumptions or models to interpret the data in the context of the site conceptual model. As illustrated in Exhibit 6-1, analysis of exposure and effects is performed interactively, with the analysis of one informing the analysis of the other. This step follows the data interpretation and analysis methods specified in the WP and SAP, and therefore should be a straightforward process.

In the analysis phase, the site-specific data obtained during the site investigation replace many of the assumptions that were made for the screening-level analysis in Steps 1 and 2. For the exposure and ecological effects characterizations, the uncertainties associated with the field measurements and with assumptions where site-specific data are not available must be documented.

6.3.1 Characterizing Exposures

Exposure can be expressed as the co-occurrence or contact of the stressor with the ecological components, both in time and space (U.S. EPA, 1992a). Thus, both the stressor and the ecosystem must be characterized on similar temporal and spatial scales. The result of the exposure analysis is an exposure profile that quantifies the magnitude and spatial and temporal patterns of exposure as they relate to the assessment endpoints and risk questions developed during problem formulation. The exposure profile and a description of associated uncertainties and assumptions serve as input to the risk characterization in Step 7.

Stressor characterization involves determining the stressor's distribution and pattern of change. The analytic approach for characterizing ecological exposures should have been established in the WP and SAP on the basis of the site conceptual model. For chemical stressorsat Superfund sites, usually a combination of fate-and-transport modeling and sampling data from the site are used to predict the current and likely future nature and extent of contamination at a site.

HIGHLIGHT 6-1
Uncertainty in Exposure Models

The accuracy of an exposure model depends on the accuracy of the input parameter values and the validity of the model's structure (i.e., the degree to which it represents the actual relationships among parameters at the site). Field measurements can be used to calibrate model outputs or intermediate calculations. Such field measurements should be specified in the WP and SAP. For example, studies of tissue residue levels often are used to calibrate exposure and food-chain models.

When characterizing exposures, the ecological context of the site established during problemformulation is analyzed further, both to understand potential effects of the ecosystem on fate and transport of chemicals in the environment and to evaluate site-specific characteristics of species or communities of concern. Any site-specific information that can be used

to replace assumptions based on information from the literature or from other sites is incorporated into the description of the ecological components of the site. Remaining assumptions and uncertainties in the exposure model (Highlight 6-1) should be documented.

6.3.2 Characterizing Ecological Effects

At this point, all evidence for existing and potential adverse effects on the assessment endpoints is analyzed. The information from the literature review on ecological effects is integrated with any evidence of existing impacts based on the site investigation (e.g., toxicity testing). The methods for analyzing site-specific data should have been specified in the WP and SAP, and thus should be straightforward. Both exposure-response information and evidence that site contaminants are causing or can cause adverse effects are evaluated.

Exposure-response analysis. The exposure-response analysis for a Superfund site describes the relationship between the magnitude, frequency, or duration of a contaminant stressor in an experimental or observational setting and the magnitude of response. In this phase of the analysis, measurement endpoints are related to the assessment endpoints using the logical structure provided by the conceptual model. Any extrapolations that are required to relate measurement to assessment endpoints (e.g., between species, between response levels, from laboratory to field) are explained. Finally, an exposure-response relationship is described to the extent possible (e.g., by a regression equation), including the confidence limits (quantitative or qualitative) associated with the relationship.

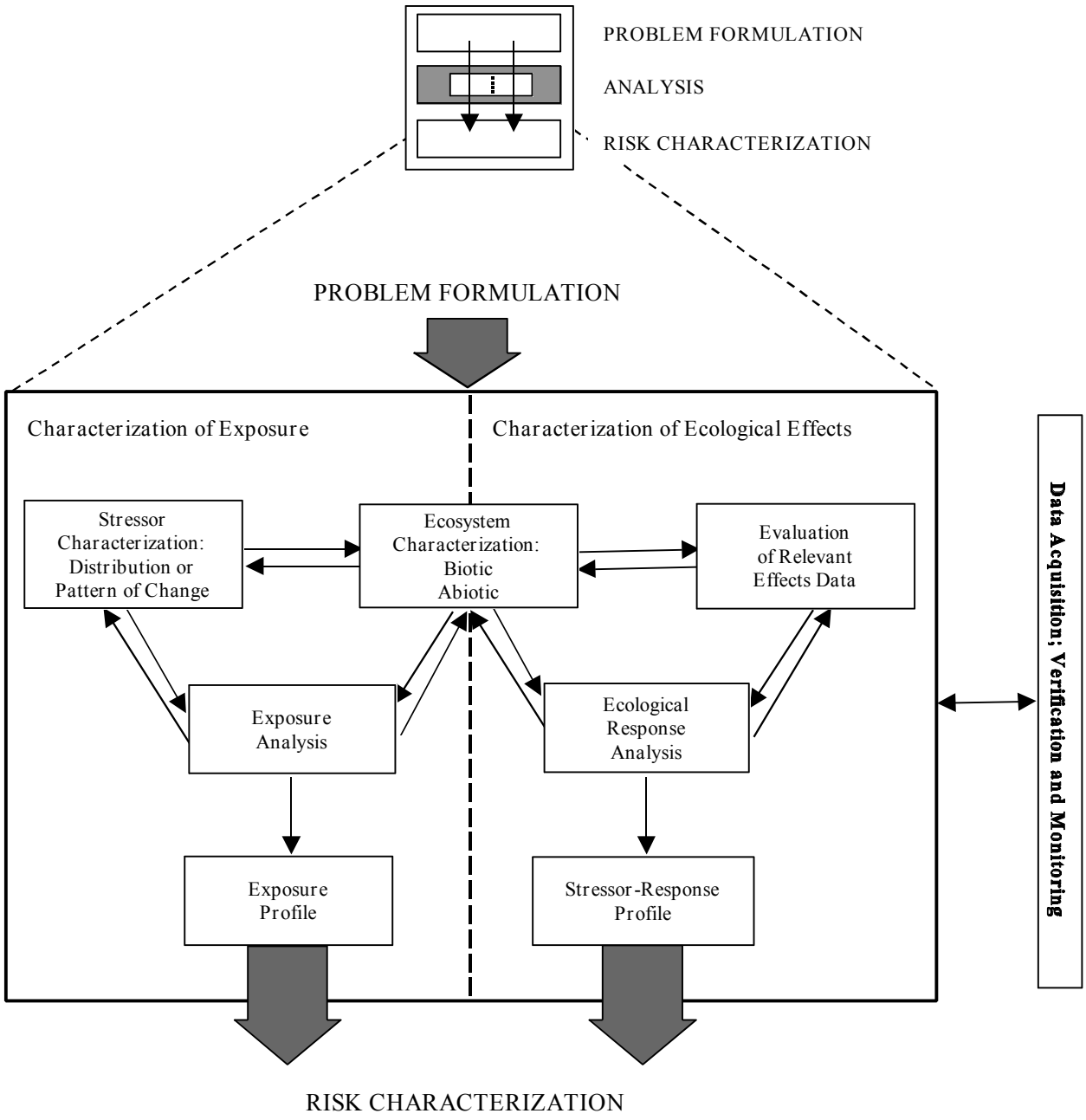
Under some circumstances, site-specific exposure-response information can be obtained by evaluating existing ecological impacts along a contamination gradient at the site. Statistical techniques to identify or describe the relationship between exposure and response from the field data should have been specified in the WP and SAP. The potential for confounding stressors that might correlate with the contamination gradient should be documented (e.g., decreasing water temperature downstream of a site; reduced soil erosion further from a site).

An exposure-response analysis is of particular importance to risk managers who must balance human health and ecological concerns against the feasibility and effectiveness of remedial options. An exposure-response function can help a risk manager to specify the trade-off between the degree of cleanup and likely benefits of the cleanup and to balance ecological and financial costs and benefits of different remedial options, as discussed in Step 8.

When exposure-response data are not available or cannot be developed, a threshold for adverse effects can be developed instead, as in Step 2. For the baseline risk assessment, however, site-specific information should be used instead of conservative assumptions whenever possible.

Evidence of causality. At Superfund sites, evidence of causality is key to the risk assessment. Thus, it is important to evaluate the strength of the causal association between site-related contaminants and effects on the measurement and assessment endpoints. Demonstrating a

EXHIBIT 6-1
Analysis Phase (U.S. EPA, 1992a)



correlation between a contaminant gradient and ecological impacts at a site is a key component of establishing causality, but other evidence can be used in the absence of such a demonstration. Moreover, an exposure-response correlation at a site is not sufficient to demonstrate causality, but requires one or more types of supporting evidence and analysis of potential confounding factors. Hill's (1965) criteria for evaluating causal associations are outlined in the Framework (U.S. EPA, 1992a).

6.4 SCIENTIFIC/MANAGEMENT DECISION POINT (SMDP)

An SMDP during the site investigation and analysis phase is needed only if alterations to the WP or SAP become necessary. In the worst case, changes in measurement endpoints could be required, with corresponding changes to the testable hypotheses and sampling design. Any new measurement endpoints must be evaluated according to their utility for inferring changes in the assessment endpoints and their compatibility with the site conceptual model; otherwise, the study could fail to meet its objectives.

Proposed changes to the SAP must be made in consultation with the risk manager and the risk assessors. The risk manager must understand what changes have been made and why, and must ensure that the risk management decisions can be made from the information that the new study design can provide. The risk assessors must be involved to ensure that the assessment endpoints and study questions or testable hypotheses are still being addressed.

6.5 SUMMARY

The site investigation step of the ecological risk assessment should be a straightforward implementation of the study designed in Step 4 and verified in Step 5. In instances where unexpected conditions arise in the field that indicate a need to change the study design, the ecological risk assessors should reevaluate the feasibility or adequacy of the sampling design. Any proposed changes to the WP or SAP must be agreed upon by both the risk assessment team and the risk manager and must be documented in the baseline risk assessment.

The analysis phase of the ecological risk assessment consists of the technical evaluation of data on existing and potential exposures and ecological effects and is based on the information collected during Steps 1 through 5 and the site investigation in Step 6. Analyses of exposure and effects are performed interactively, and follow the data interpretation and analysis methods specified in the WP and SAP. Site-specific data obtained during Step 6 replace many of the assumptions that were made for the screening-level analysis in Steps 1 and 2. Evidence of an exposure-response relationship between contamination and ecological responses at a site helps to establish causality. The results of Step 6 are used to characterize ecological risks in Step 7.

STEP 7: RISK CHARACTERIZATION

OVERVIEW

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

7.1 INTRODUCTION

Risk characterization is the final phase of the risk assessment process and includes two major components: risk estimation and risk description (U.S. EPA, 1992a; Exhibit 7-1). Risk estimation (Section 7.2) consists of integrating the exposure profiles with the exposure-effects information and summarizing the associated uncertainties. The risk description (Section 7.3) provides information important for interpreting the risk results and, in the Superfund Program, identifies a threshold for adverse effects on the assessment endpoints (Section 7.4).

It is U.S. EPA policy that risk characterization should be consistent with the values of "transparency, clarity, consistency, and reasonableness" (U.S. EPA, 1995f). "Well-balanced risk characterizations present risk conclusions and information regarding the strengths and limitations of the assessment for other risk assessors, EPA decision-makers, and the public" (U.S. EPA, 1995f). Thus, when preparing the risk characterization, the risk assessment team should make sure that the documentation of risks is easy to follow and understand, with all assumptions, defaults, uncertainties, professional judgments, and any other inputs to the risk estimate clearly identified and easy to find.

7.2 RISK ESTIMATION

Documentation of the risk estimates should describe how inferences are made from the measurement endpoints to the assessment endpoints established in problem formulation. As stated earlier, it is not the purpose of this document to provide a detailed guidance on the selection and utilization of risk models. The risk assessment team should have developed and the risk manager should have agreed upon the conceptual model used to characterize risk, its assumptions, uncertainties, and interpretation in Steps 3 through 5. This agreement is specified in The site WP and SAP and is the purpose of the SMDPs in Steps 3 through 5.

Unless the site investigation during Step 6 discovers unexpected information, the risk assessment should move smoothly through the risk characterization phase, because the data interpretation procedures were specified in the WP and SAP. While it might be informative to investigate a data set for trends, outliers, or other statistical indicators, these investigations should be secondary to the data interpretations specified in the SAP. Analysis of the data beyond the purposes for which it was collected might be informative, but could lead to biased, conflicting, or superfluous conclusions. Those outcomes can divert or confound the risk characterization process.

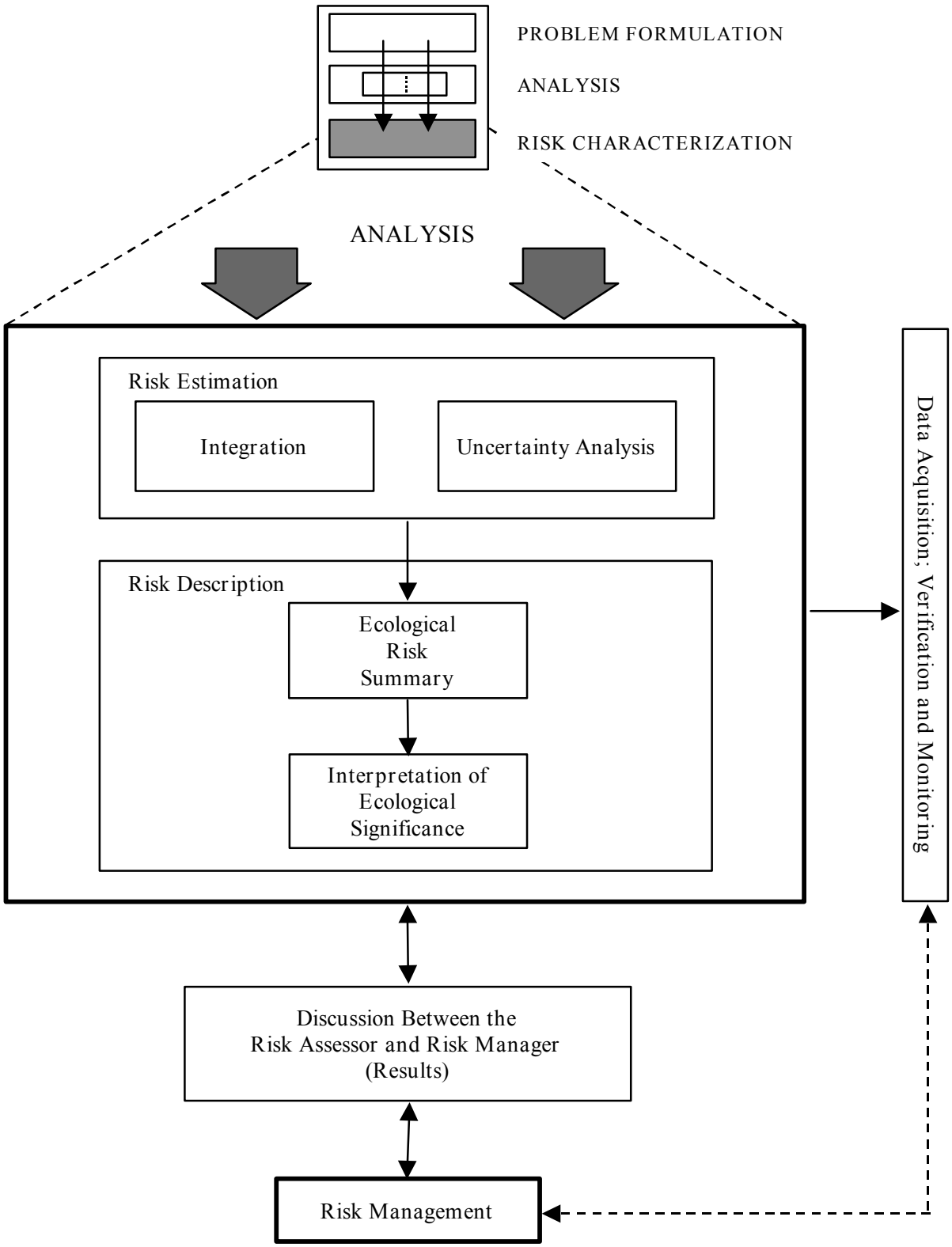
For ecological risk assessments that entail more than one type of study (or line of evidence), a strength-of-evidence approach is used to integrate different types of data to support a conclusion. The data might include toxicity test results, assessments of existing impacts at a site, or risk calculations comparing exposures estimated for the site with toxicity values from the literature. Balancing and interpreting the different types of data can be a major task and require professional judgment. As indicated above, the strength of evidence provided by different types of tests and the precedence that one type of study might have over another should already have been established during Step 4. Taking this approach will ensure that data interpretation is objective and not biased to support a preconceived answer. Additional strength-of-evidence considerations at this stage include the degree to which DQOs were met and whether confounding factors became evident during the site investigation and analysis phase.

For some biological tests (e.g., toxicity tests, benthic macroinvertebrate studies), all or some of the data interpretation process is outlined in existing documents, such as in toxicity testing manuals. However, in most cases, the SAP must provide the details on how the data are to be interpreted for a site. The data interpretation methods also should be presented in the risk characterization documentation. For example, if the triad approach was used to evaluate contaminated sediments, the risk estimation section should describe how the three types of studies (i.e., toxicity test, benthic invertebrate survey, and sediment chemistry) are integrated to draw conclusions about risk.

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

In addition to developing point estimates of exposure concentrations, as for the hazard quotient approach, it might be possible to develop a distribution of exposure levels based on the potential variability in various exposure parameters (see Section 7.3.2). Probabilities of exceeding a threshold for adverse effects might then be estimated. Again, the risk assessment team and risk manager should have already agreed to what analyses will be used to characterize risks.

EXHIBIT 7-1
Risk Characterization (U.S. EPA, 1992a)



7.3 RISK DESCRIPTION

A key to risk description for Superfund sites is documentation of environmental contamination levels that bound the threshold for adverse effects on the assessment endpoints (Section 7.3.1). The risk description can also provide information to help the risk manager judge the likelihood and ecological significance of the estimated risks (Sections 7.3.2 and 7.3.3, respectively).

7.3.1 Threshold for Effects on Assessment Endpoints

Key outputs of the risk characterization step are contaminant concentrations in each environmental medium that bound the threshold for estimated adverse ecological effects given the uncertainty inherent in the data and models used. The lower bound of the threshold would be based on consistent conservative assumptions and NOAEL toxicity values. The upper bound would be based on observed impacts or predictions that ecological impacts could occur. This upper bound would be developed using consistent assumptions, site-specific data, LOAEL toxicity values, or an impact evaluation.

The approach to estimating environmental contaminant concentrations that represent thresholds for adverse ecological effects should have been specified in the study design (Step 4). When higher-trophic-level organisms are associated with assessment endpoints, the study design should have described how monitoring data and contaminant-transfer models would be used to back-calculate an environmental concentration representing a threshold for effect. If the site investigation demonstrated a gradient of ecological effects along a contamination gradient, the risk assessment team can identify and document the levels of contamination below which no further improvements in the assessment endpoints are discernable or expected. If departures from the original analysis plan are necessary based on information obtained during the site investigation or data analysis phase, the reasons for change should be documented.

When assessment endpoints include populations of animals that can travel moderate distances, different ways of presenting a threshold for adverse effects are possible. Various combinations of level of contamination and areal extent of contamination relative to the foraging range of the animals can result in similar contaminant intake levels by the animals. In that case, a point of departure for identifying a threshold for effect would be to identify that level of contamination, which if uniformly distributed both at the site and beyond, would not pose a threat. The assumption of uniform contamination has been used to back-calculate water-quality criteria to protect piscivorous wildlife in the Great Lakes (U.S. EPA, 1995a). Again, use of this approach should have been specified in the study design.

7.3.2 Likelihood of Risk

In addition to identifying one or more thresholds for effects, the risk assessment team might develop estimates of the probability that exposure levels would exceed the ecotoxicity thresholds given the distribution of values likely for various exposure parameters (e.g., home range size, population density). A distributional analysis might be used to estimate the range of likely exposure levels associated with a given exposure model based on ranges for the input variables.

7.3.3 Additional Risk Information

In addition to developing numerical estimates of existing impacts, risks, and thresholds for effect, the risk assessor should put the estimates in context with a description of their extent, magnitude, and potential ecological significance. Additional ecological risk descriptors are listed below:

- The location and areal extent of existing contamination above a threshold for adverse effects;
- The degree to which the threshold for contamination is exceeded or is likely to be exceeded in the future, particularly if exposure-response functions are available; and
- The expected half-life (qualitative or quantitative) of contaminants in the environment (e.g., sediments, food chain) and the potential for naturalrecovery once the sources of contamination are removed.

To interpret the information in light of remedial options, the risk manager might need to solicit input from specific experts.

At this stage, it is important for the risk assessors to consider carefully several principles of risk communication, as described in U.S. EPA's (1996a) Proposed Guidelines for Ecological Risk Assessment.

7.4 UNCERTAINTY ANALYSIS

There are several sources of uncertainties associated with Superfund ecological risk estimates. One is the initial selection of substances of concern based on the sampling data and available toxicity information. Other sources of uncertainty include estimates of toxicity to ecological receptors at the site based on limited data from the laboratory (usually on other species), from other ecosystems, or from the site over a limited period of time. Additional uncertainties result from the exposure assessment, as a consequence of the uncertainty in chemical monitoring data and models used to estimate exposure concentrations or doses. Finally, further uncertainties are included in risk estimates when simultaneous exposures to multiple substances occur.

Uncertainty should be distinguished from variability, which arises from true heterogeneity or variation in characteristics of the environment and receptors. Uncertainty, on the other hand, represents lack of knowledge about certain factors which can sometimes be reduced by additional study.

This section briefly notes several categories of uncertainty (Section 7.4.1) and techniques for tracking uncertainty through a risk assessment (Section 7.4.2). Additional guidance on discussing uncertainty and variability in risk characterization is provided in U.S. EPA's (1992f) Guidance on Risk Characterization for Risk Managers and Risk Assessors

7.4.1 Categories of Uncertainty

There are three basic categories of uncertainties that apply to Superfund site risk assessments: (1) conceptual model uncertainties; (2) natural variation and parameter error; and (3) model error. Each of these is described below.

There will be uncertainties associated with the conceptual model used as the basis to investigate the site. The initial characterization of the ecological problems at a Superfund site, likely exposure pathways, chemicals of concern, and exposed ecological components, requires professional judgments and assumptions. To the extent possible, the risk assessment team should describe what judgments and assumptions were included in the conceptual model that formed the basis of the WP and SAP.

Parameter values (e.g., water concentrations, tissue residue levels, food ingestion rates) usually can be characterized as a distribution of values, described by central tendencies, ranges, and percentiles, among other descriptors. When evaluating uncertainty in parameter values, it is important to distinguish uncertainty from variability. Ecosystems include highly variable abiotic (e.g., weather, soils) and biotic (e.g., population density) components. If all instances of a parameter (e.g., all members of a population) could be sampled, the "true" parameter value distribution could be described. In practical terms, however, only a fraction of the instances (e.g., a few of the members of the population) can be sampled, leaving uncertainty concerning the true parameter value distribution. The risk assessor should provide either quantitative or qualitative descriptions of uncertainties in parameter value distributions.

Finally, there is uncertainty associated with how well a model (e.g., fate and transport model) approximates true relationships between site-specific environmental conditions. Models available at present tend to be fairly simple and at best, only partially validated with field tests. As a consequence, it is important to identify key model assumptions and their potential impacts on the risk estimates.

7.4.2 Tracking Uncertainties

In general, there are two approaches to tracking uncertainties through a risk assessment: (1) using various point estimates of exposure and response to develop one or more point estimates of risk; and (2) conducting a distributional analysis to predict a distribution of risks based on a distribution of exposure levels and exposure-response information. Whether one or the other or both approaches are taken should have been agreed to during Step 4, and the specific type of analyses to be conducted should have been specified in the SAP.

7.5 SUMMARY

Risk characterization integrates the results of the exposure profile and exposure-response analyses, and is the final phase of the risk assessment process. It consists of risk estimation and risk description, which together provide information to help judge the ecological significance of risk estimates in the absence of remedial activities. The risk description also identifies a threshold for effects on the assessment endpoint as a range between contamination levels identified as posing no ecological risk and the lowest contamination levels identified as likely to produce adverse ecological effects. To ensure that the risk characterization is transparent, clear, and reasonable, information regarding the strengths and limitations of the assessment must be identified and described.

STEP 8: RISK MANAGEMENT

OVERVIEW

Risk management at a Superfund site is ultimately the responsibility of the site risk manager, who must balance risk reductions associated with cleanup of contaminants with potential impacts of the remedial actions themselves. The risk manager considers inputs from the risk assessors, BTAGs, stakeholders, and other involved parties. In Step 7, the risk assessment team identified a threshold for effects on the assessment endpoint as a range between contamination levels identified as posing no ecological risk and the lowest contamination levels identified as likely to produce adverse ecological effects. In Step 8, the risk manager evaluates several factors in deciding whether or not to clean up to within that range.

8.1 INTRODUCTION

Risk management is a distinctly different process from risk assessment (NRC, 1983, 1994; U.S. EPA, 1984a, 1995f). The risk assessment establishes whether a risk is present and defines a range or magnitude of the risk. In risk management, the results of the risk assessment are integrated with other considerations to make and justify risk management decisions. Additional risk management considerations can include the implications of existing background levels of contamination, available technologies, tradeoffs between human and ecological concerns, costs of alternative actions, and remedy selection. For further information on management of ecological risks Agency-wide, see U.S. EPA 1994h. Some Superfund-specific considerations are described below.

8.2 ECOLOGICAL RISK MANAGEMENT IN SUPERFUND

According to section 300.40 of the NCP, the purpose of the remedy selection process is to eliminate, reduce, or control risks to human health and the environment. The NCP indicates further that the results of the baseline risk assessment will help to establish acceptable exposure levels for use in developing remedial alternatives during the FS. Based on the criteria for selecting the preferred remedy and, using information from the human health and ecological risk assessments and the evaluation of remedial options in the FS, the risk manager then selects a preferred remedy.

The risk manager must consider several types of information in addition to the baseline ecological risk assessment when evaluating remedial options (Section 8.2.1). Of particular concern for ecological risk management at Superfund sites is the potential for remedial actions themselves to cause adverse ecological impacts (Section 8.2.2). There also exists the opportunity to monitor ecological components at the site to gauge the effectiveness (or impacts) of the selected remedy (Section 8.2.3).

8.2.1 Other Risk Management Considerations

The baseline ecological risk assessment is not the only set of information that the risk manager must consider when evaluating remedial options during the FS phase of the Superfund process. The NCP (40 CFR 300.430(f)(1)(i)) specifies that each remedial alternative should be evaluated according to nine criteria. Two are considered threshold criteria, and take precedence over the others:

(1) Overall protection of human health and the environment; and

(2) Compliance with applicable or relevant and appropriate requirements (ARARs) (unless waiver applicable).

As described in Section 8.2.2 below, a particularly important consideration for the first criterion are the ecological impacts of the remedial options.

Five of the nine criteria are considered primary balancing criteria to be considered after the threshold criteria:

(3) Long-term effectiveness and permanence;

(4) Reduction of toxicity, mobility, or volume of hazardous wastes through the use of treatment;

(5) Short-term effectiveness;

(6) Implementability; and

(7) Cost.

Finally, two additional criteria are referred to as modifying criteria that must be considered:

(8)State acceptance, and

(9)Community acceptance.

Effective risk communication is particularly important to help ensure that a remedial option that best satisfies the other criteria can be implemented at a site. U.S. EPA's (1996a) Proposed Guidelines for Ecological Risk Assessment provides an overview of this topic and identifies some of the relevant literature.

Additional factors that the site risk manager takes into consideration include existing background levels (see U.S. EPA, 1994g); current and likely future land uses (see U.S. EPA, 1995c); current and likely future resource uses in the area; and local, regional, and national ecological significance of the site. Consideration of the ecological impacts of remedial options and residual risks associated with leaving contaminants in place are very important considerations, as described in the next section.

8.2.2 Ecological Impacts of Remedial Options

Management of ecological risks must take into account the potential for impacts to the ecological assessment endpoints from implementation of various remedial options. The risk manager must balance: (1) residual risks posed by site contaminants before and after implementation of the selected remedy with (2) the potential impacts of the selected remedy on the environment independent of contaminant effects. The selection of a remedial alternative could require tradeoffs between long-term and short-term risk.

The ecological risks posed by the "no action" alternative are the risks estimated by the baseline ecological risk assessment. In addition, each remedial option is likely to have its own ecological impact. This impact could be anything from a short-term loss to complete and permanent loss of the present habitat and ecological communities. In instances where substantial ecological impacts will result from the remedy (e.g., dredging a wetland), the risk manager will need to consider ways to mitigate the impacts of the remedy and compare the mitigated impacts to the threats posed by the site contamination.

During the FS, the boundaries of potential risk under the no-action alternative (i.e., baseline conditions) can be compared with the evaluation of potential impacts of the remedial options to help justify the preferred remedy. As indicated above, the preferred remedy should minimize the risk of long-term impacts that could result from the remedy and any residual contamination. When the selected remedial option leaves some site contaminants presumed to pose an ecological risk in place, the justification for the selected remedy must be clearly documented.

In short, consideration of the environmental effects of the remedy itself might result in a decision to allow contaminants to remain on site at levels higher than the threshold for effects on the assessment endpoint. Thus, selection of the most appropriate ecologically based remedy can result in residual contamination that presents some risk.

8.2.3 Monitoring

Ecological risk assessment is a relatively new field with limited data available to validate its predictions. At sites where remedial actions are taken to reduce ecological impacts and risks, the results of the remediation efforts should be compared with the predictions made during the ecological risk assessment.

While it often is difficult to demonstrate the effectiveness of remedial actions in reducing human health risks, it often is possible to demonstrate the effectiveness of remediations to reduce ecological risks, particularly if a several-year monitoring program is established. The site conceptual model provides the conceptual basis for monitoring options, and the site investigation should have indicated which options might be most practical for the site. Monitoring also is important to assess the effectiveness of a no-action alternative. For example, monitoring sediment contamination and benthic communities at intervals following removal of a contaminant source allows one to test predictions of the potential for the ecosystem to recover naturally over time.

8.3 SCIENTIFIC/MANAGEMENT DECISION POINT (SMDP)

The risk management decision is finalized in the Record of Decision (ROD). The decision should minimize the risk of long-term impacts that could result from the remedy and any residual contamination. When the selected remedy leaves residual contamination at levels higher than the upper-bound estimate of the threshold for adverse effects on the assessment endpoint, the risk manager should justify the decision (e.g., describe how a more complete physical remedy could jeopardize an ecological community more than the residual contamination).

8.4 SUMMARY

Risk-management decisions are the responsibility of the risk manager (the site manager), not the risk assessor. The risk manager should have been involved in planning the risk assessment; knowing the options available for reducing risks, the risk manager can help to frame questions during the problem-formulation phase of the risk assessment.

The risk manager must understand the risk assessment, including its uncertainties, assumptions, and level of resolution. With an understanding of potential adverse effects posed by residual levels of site contaminants and posed by the remedial actions themselves, the risk manager can balance the ecological costs and benefits of the available remedial options. Understanding the uncertainties associated with the risk assessment also is critical to evaluating the overall protectiveness of any remedy.

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GLOSSARY

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

Abiotic.[1] Characterized by absence of life; abiotic materials include non-living environmental media (e.g., water, soils, sediments); abiotic characteristics include such factors as light, temperature, pH, humidity, and other physical and chemical influences.

Absorption Efficiency. A measure of the proportion of a substance that a living organism absorbs across exchange boundaries (e.g., gastrointestinal tract).

Absorbed Dose.[2] The amount of a substance penetrating the exchange boundaries of an organism after contact. Absorbed dose for the inhalation and ingestion routes of exposure is calculated from the intake and the absorption efficiency. Absorbed dose for dermal contact depends on the surface area exposed and absorption efficiency.

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

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

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

Acute Tests. A toxicity test of short duration, typically 4 days or less (i.e., of short duration relative to the lifespan of the test organism).

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

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

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

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

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

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

Bioccumulation Factor (BAF).[3] The ratio of the concentration of a contaminant in an organism to the concentration in the ambient environment at steady state, where the organism can take in the contaminant through ingestion with its food as well as through direct contact.

Bioassay.[5] Test used to evaluate the relative potency of a chemical by comparing its effect on living organisms with the effect of a standard preparation on the same type of organism. Bioassay and toxicity tests are not the same—see toxicity test. Bioassays often are run on a series of dilutions of whole effluents.

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

Bioavailability.[4] The degree to which a material in environmental media can be assimilated by an organism.

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

Biodegrade.[15] Decompose into more elementary compounds by the action of living organisms, usually referring to microorganisms such as bacteria.

Biomagnification.[5] Result of the process of bioaccumulation and biotransfer by which tissue concentrations of chemicals in organisms at one trophic level exceed tissue concentrations in organisms at the next lower trophic level in a food chain.

Biomarker.[21] Biochemical, physiological, and histological changes in organisms that can be used to estimate either exposure to chemicals or the effects of exposure to chemicals.

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

Body Burden. The concentration or total amount of a substance in a living organism; implies accumulation of a substance above background levels in exposed organisms.

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

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

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

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

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

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

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

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

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

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

Concentration. The relative amount of a substance in an environmental medium, expressed by relative mass (e.g., mg/kg), volume (ml/L), or number of units (e.g., parts per million).

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

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

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

Control.[5] A treatment in a toxicity test that duplicates all the conditions of the exposure treatments but contains no test material. The control is used to determine the response rate expected in the test organisms in the absence of the test material.

Coordinate Bond.[14] A chemical bond between two atoms in which a shared pair of electrons forms the bond and the pair of electrons has been supplied by one of the two atoms. Also known as a coordinate valence.

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

Critical Exposure Pathway. An exposure pathway which either provides the highest exposure levels or is the primary pathway of exposure to an identified receptor of concern.

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

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

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

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

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

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

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

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

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

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

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

Ecosystem.[6] The biotic community and abiotic environment within a specified location and time, including the chemical, physical, and biological relationships among the biotic and abiotic components.

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

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

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

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

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

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

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

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

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

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

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

False Negative. The conclusion that an event (e.g., response to a chemical) is negative when it is in fact positive (see Appendix D).

False Positive. The conclusion that an event is positive when it is in fact negative (see Appendix D).

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

Food-Chain Transfer. A process by which substances in the tissues of lower-trophic-level organisms are transferred to the higher-trophic-level organisms that feed on them.

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

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

Hazard. The likelihood that a substance will cause an injury or adverse effect under specified conditions.

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

Hazard Index.[3] The sum of more than one hazard quotient for multiple substances and/or multiple exposure pathways. The HI is calculated separately for chronic, subchronic, and shorter-duration exposures.

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

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

Hydrophilic.[22] Denoting the property of attracting or associating with water molecules; characteristic of polar or charged molecules.

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

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

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

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

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

Lethal.[5] Causing death by direct action.

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

Lowest-Observable-Adverse-Effect Level (LOAEL). The lowest level of a stressor evaluated in a toxicity test or biological field survey that has a statistically significant adverse effect on the exposed organisms compared with unexposed organisms in a control or reference site.

Matrix.[14] The substance in which an analyte is embedded or contained; the properties of a matrix depend on its constituents and form.

Measurement Endpoint.[6] A measurable ecological characteristic that is related to the valued characteristic chosen as the assessment endpoint. Measurement endpoints often are expressed as the statistical or arithmetic summaries of the observations that make up the measurement. As used in this guidance document, measurement endpoints can include measures of effect and measures of exposure, which is a departure from U.S. EPA's (1992a) definition which includes only measures of effect.

Media.[15] Specific environmental compartments—air, water, soil—which are the subject of regulatory concern and activities.

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

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

Metric.[16] Relating to measurement; a type of measurement—for example a measurement of one of various components of community structure (e.g., species richness, % similarity).

Mortality. Death rate or proportion of deaths in a population.

No-Observed-Adverse-Effect Level (NOAEL).[5] The highest level of a stressor evaluated in a toxicity test or biological field survey that causes no statistically significant difference in effect compared with the controls or a reference site.

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

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

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

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

Power.[10] The power of a statistical test indicates the probability of rejecting the null hypothesis when it should be rejected (i.e., the null hypothesis is false). Can be considered the sensitivity of a statistical test. (See also Appendix D.)

Precipitation.[14] In analytic chemistry, the process of producing a separable solid phase within a liquid medium.

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

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

Regression Analysis.[10] Analysis of the functional relationship between two variables; the independent variable is described on the X axis and the dependent variable is described on the Y axis (i.e. the change in Y is a function of a change in X).

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

Representative Samples.[18] Serving as a typical or characteristic sample; should provide analytical results that correspond with actual environmental quality or the condition experienced by the contaminant receptor.

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

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

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

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

Sediment.[20] Particulate material lying below water.

Sensitivity. In relation to toxic substances, organisms that are more sensitive exhibit adverse (toxic) effects at lower exposure levels than organisms that are less sensitive.

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

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

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

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

Sublethal.[5] Below the concentration that directly causes death. Exposure to sublethal concentrations of a substance can produce less obvious effects on behavior, biochemical and/or physiological functions, and the structure of cells and tissues in organisms.

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

Toxic Mechanism of Action.[23] The mechanism by which chemicals produce their toxic effects, i.e., the mechanism by which a chemical alters normal cellular biochemistry and physiology. Mechanisms can include; interference with normal receptor-ligand interactions, interference with membranae functions, interference with cellular energy production, and binding to biomolecules.

Toxicity Assessment. Review of literature, results in toxicity tests, and data from field surveys regarding the toxicity of any given material to an appropriate receptor.

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

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

Toxicant. A poisonous substance.

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

Type I Error.[10] Rejection of a true null hypothesis (see also Appendix D).

Type II Error.[10] Acceptance of a false null hypothesis (see also Appendix D).

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

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

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

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

ENDNOTES

[1] Krebs 1978, [2] U.S. EPA 1989, [3] Calow 1993, [4] Freedman 1989, [5] Rand and Petrocelli 1985, [6] U.S. EPA 1992a, [7] Ricklefs 1990, [8] U.S. EPA 1992b, [9] ASTM 1993a, [10] Sokal and Rohlf 1981, [11] Suter 1993, [12] Wallace et al. 1981, [13] Curtis 1983, [14] Parker 1994, [15] Sullivan 1993, [16] U.S. EPA 1990, [17] Zar 1984, [18] Keith 1988, [19] Gilbert 1987, [20] ASTM 1993b, [21] Huggett et al. 1992, [22] Stedman 1995, [23] Amdur et al. 1991.

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