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The Role of Screening-Level Risk Assessments and Refining Contaminants of Concern in Baseline Ecological Risk Assessments

Screening-Level Ecological Risk Assessments (SLERAs)

Screening-Level Ecological Risk Assessments are conservative assessments in that they provide a high level of confidence in determining a low probability of adverse risk, and they incorporate uncertainty in a precautionary manner. It must be stressed that SLERAs are not designed nor intended to provide definitive estimates of actual risk, generate cleanup goals and, in general, are not based upon site-specific assumptions. Rather, the purpose of SLERAs is to assess the need, and if required, the level of effort necessary, to conduct a detailed or "baseline" ecological risk assessment for a particular site or facility. Therefore, refinement of contaminants of concern occurs in the baseline risk assessment rather than in the SLERA.

It is also important to note that SLERAs, like baseline ecological risk assessments, should take place with input from Regional Ecological Risk Assessors and/or the Biological Technical Assistance Group as well as in coordination with Natural Resource Trustees.

IN THIS BULLETIN

Introduction

This supplemental Ecological Risk Assessment (ERA) guidance is intended to provide further

clarification and direction regarding Screening Level Ecological Risk Assessments (SLERAs), as described in Step 1- Preliminary Problem Formulation, and Step 2 - Preliminary Risk Calculation, of the Agency's program guidance: *Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments* (U.S. EPA 1997).[1] It also provides an approach for incorporating additional components into the Problem Formulation phase of more detailed (i.e., "baseline") ecological risk assessments, particularly in Step 3.2, which discusses refining contaminants of potential concern (COPCs). The Superfund program guidance, which may be applicable to RCRA Corrective Actions, describes a process that incorporates flexibility in refining COPCs in order to focus and streamline the overall ERA process while still ensuring a consistent approach. This guidance provides more detail on how to incorporate that flexibility.

The Purpose of Screening-Level Ecological Risk Assessments

Screening-Level Ecological Risk Assessments provide a general indication of the *potential* for ecological risk (or lack thereof) and may be conducted for several purposes including: 1) to estimate the likelihood that a particular ecological risk exists, 2) to identify the need for site-specific data collection efforts, or 3) to focus site-specific ecological risk assessments where warranted.

It is important to note that this guidance adopts the presumption that all data used in the SLERA are of adequate quantity and quality, and if data deficiencies are identified, either further data collection will be undertaken or other means employed to more fully characterize exposures (e.g., fate and transport modeling). If, for example, the SLERA indicates that adverse ecological effects are possible at environmental concentrations below standard quantitation limits, a "non-detect" based on those limits cannot be used as the sole basis for a "no risk" decision. Further lines of evidence (e.g., more refined/usable data, modeling results, or other measures) are needed to fully characterize the potential for adverse effects.

This guidance also reaffirms that a screening level assessment, while abbreviated, is nonetheless a complete risk assessment. Therefore, regardless of the findings of the Scientific Management Decision Point (SMDP) occurring after Step 2 (i.e., further assessment or no further assessment required), each SLERA should include documentation supporting the risk characterization and uncertainty analysis.

If the SLERA risk characterization indicates the need for further assessment, Step 3 is begun, and decisions are made regarding additional elements of problem formulation, analysis and decision point criteria. This supplemental guidance addresses how background, frequency and magnitude of detection, and dietary considerations may be used to reduce the COPCs. The use of site-specific information, as provided for in this *ECO Update*, should be discussed with the Regional Ecological Risk Assessors and/or Biological Technical Assistance Group (BTAG) early in the Problem Formulation phase of the baseline ERA.

It is the intent of this supplemental guidance to promote consistency in the screening process, yet allow for flexibility in application and timing of the elements that can help streamline more detailed assessments. Screening-Level Ecological Risk Assessments may be completed in relatively short time frames, whereas baseline ERAs may require much longer periods for planning and implementation, particularly when attempting to address seasonal or other cyclic events. Regional Ecological Risk Assessors can use this flexible approach when introducing components into the Problem Formulation phase based on regional and site-specific needs. This will effectively reduce the COPCs carried through the baseline ERA and the time required for its completion.

The Purpose of Baseline Ecological Risk Assessments

Within the Office of Solid Waste and Emergency Response (OSWER), the Superfund and RCRA Corrective Action cleanup programs generally use baseline ecological risk assessments to: "1) identify and characterize the current and potential threats to the environment from a hazardous substance release, 2) evaluate the ecological impacts of alternative remediation strategies, and 3) establish cleanup levels in the selected remedy that will protect those natural resources at risk." (U.S. EPA 1994e, OSWER Directive # 9285.7-17). The Superfund program guidance outlines an eight-step process that meets the three OSWER objectives for the baseline ERA while further implementing the Agency's policy of writing risk assessments that provide transparency in EPA's decision making process and clarity in communication with the public regarding environmental risk (U.S. EPA 1995, Risk Characterization Policy). In addition, application of the information in this ECO Update should further ensure that, for OSWER cleanups, core assumptions and science policy are consistent and comparable across programs, well grounded in science, and fall within a "zone of reasonableness."

[1] The first three steps of the Superfund ecological risk assessment process are described in the textbox on page 3.

Standard Components of ERAs

The following text box highlights the risk assessment components common to both a SLERA and the Problem Formulation phase of a baseline ERA. In addition, the text helps to identify points in the ERA process where additional components may be considered in developing risk estimates.

Components of a SLERA

Although less detailed than a baseline ERA, screening assessments still include all of the following components:

- Screening level Problem Formulation and Ecological Effects Characterization (Step 1)
  - Identification of environmental setting and preliminary contaminants of concern
  - Determination of contaminant fate and transport pathways
  - Description of contaminant mechanisms of ecotoxicity and categories of receptors likely affected
  - Identification of complete exposure pathways and selection of generic assessment endpoints
  - Selection of screening ecotoxicity values
  - Evaluation of uncertainties
- Screening level Exposure Estimate and Risk Calculation (Step 2)
  - Determination of screening-level exposure estimate
  - Calculation of risk estimate
  - Risk characterization and evaluation of uncertainties
- Scientific Management Decision Point indicating either negligible risk or continuation to a baseline risk assessment

Components of a Baseline Ecological Risk Assessment Problem Formulation

Problem Formulation for a baseline ERA (Step 3) includes the following components:

- Refinement of the Contaminants of Potential Concern (COPCs) by examining the assumptions used in Steps 1 and 2
- Further characterization of ecological effects of contaminants
- Reviewing and refining information on contaminant fate and transport, complete exposure pathways, and ecosystems potentially at risk
- Selection of site-specific assessment endpoints
- Development of a conceptual model and associated risk questions
- Scientific Management Decision Point summarizing agreement on contaminants of concern, assessment endpoints, exposure pathways, and risk questions

Refining Contaminants of Concern

Screening is the comparison of site media concentrations with conservative toxicologically based numbers. Contaminants of concern may be refined to help streamline the overall ERA process by considering additional components early in the baseline ERA. After consultation with your Regional Ecological Risk Assessors and/or BTAG, one or more of the following components may be included in Step 3.2 of Problem Formulation. When added, it is important that the resulting Risk Characterization and Uncertainty Analysis fully address the issues listed for each component and describe the rationale underlying the selection of each component.

These components need not be implemented in the order presented in this document, nor do all the components need to be implemented. If, however, any contaminants are identified for exclusion from the baseline ERA through application of any or all of the three supplemental components described herein, it is essential to evaluate bioaccumulation, biomagnification, and bioconcentration of each such contaminant as well.

Supplemental Component 1: Background

Background concentrations of contaminants are those concentrations found in areas surrounding a site, but are unrelated to site releases. Contributions to these contaminant concentrations come from two major sources: first, natural sources (i.e., geologically derived concentrations of chemicals in the environment not influenced by human activity), and second, ambient or anthropogenic sources (i.e., concentrations present due to human activities, such as automobile use or pesticide dispersion in farming areas).

While contaminants of concern may be removed from further assessment through comparison with toxicological benchmarks, comparison with background levels generally cannot be used to remove contaminants of concern owing to the need to fully characterize site risk. Such comparisons, however, can be used effectively to focus the baseline risk assessment, if needed. An example of the application of background comparisons would be at a mining site with high levels of naturally occurring background metals due to local or nearby geological formations.

Consideration of background assumes that background contaminant levels have been properly determined. Until specific guidance on determining background levels is available, consult with your Regional Ecological Risk Assessors and/or BTAG to select an acceptable approach including minimum data requirements.

Issues to be discussed:

1. Potential toxicity of any contaminants identified as below background (particularly when toxicity benchmarks are lacking or when contaminants exceed toxicity benchmarks);
2. Potential for adverse effects caused by interactions between chemicals considered as background and those COPCs to be further investigated; and
3. Enumeration of all criteria by which contaminants are considered either background or site-related.

Supplemental Component 2: Frequency and Magnitude of Detection

Use of this component presumes that the sampling plan comports with *Guidance for Data Useability in Risk Assessment* (U.S. EPA 1992e). In particular, the sampling plan needs to characterize the full range of variability and distribution in the data and also needs to satisfactorily meet the criteria for completeness, comparability, representativeness, precision, and accuracy.

Similar to this supplemental guidance, current EPA human health risk assessment guidance discusses evaluation of COPCs based on frequency of detection and provides conditions under which compounds may be eliminated from further assessment. Owing to the typically small datasets available for ERAs, particularly screening-level assessments, compared to most human health risk assessments, a number of the conditions may not be applicable to ERAs. Nonetheless, given adequate data quality, further reduction of COPCs through application of this component may be determined acceptable following consultation with the Regional Ecological Risk Assessors and/or BTAG. Furthermore, the Project Manager's approval should be obtained before eliminating any chemicals from the risk assessment.

Issues to be discussed:

1. Influence of random and/or biased sampling on the frequency and magnitude of detected values within the distribution of data;
2. Spatial and temporal pattern of contaminants identified as low frequency and/or low magnitude;
3. Comparison of risk-based detection limits with toxicity benchmarks; and
4. Relationship of detected values to toxicity benchmarks.

Supplemental Component 3: Dietary Considerations

A number of chemicals that may be site-related function as nutrients in organisms serving as physiological electrolytes, such as calcium, iron, magnesium, sodium, and potassium. When present at concentrations that allow them to function in this manner, they typically pose little ecological risk. Conversely, nutrients such as selenium, copper, molybdenum, and boron, can transition from essential to toxic at only slightly higher concentrations.

Issues to be discussed:

1. The suite of nutrients relevant to the range of ecological receptors (wildlife vs. plants) considered at the site;
2. The potential for toxic effects resulting from site concentrations relative to the toxicological benchmarks for nutrients;
3. Whether contaminant interactions may result in a nutrient deficiency for organisms of concern; and
4. Whether the nutrient deficiency level and the toxicity benchmark are similar in magnitude.

Additional Considerations

For those COPCs identified by applying any of the components listed above, it is essential to evaluate their potential to bioaccumulate, bioconcentrate, and/or biomagnify prior to eliminating them from further consideration in the risk assessment. Compounds with a high potential to accumulate and persist in the food chain should be carried through the risk assessment.

Issues to be discussed:

1. The likelihood that contaminants identified for removal from the list of COPCs could exert adverse effects on higher trophic level organisms; and

2. A determination that bioaccumulation and/or biomagnification has been satisfactorily addressed through modeling, site-related tissue measurements, or other methods developed in consultation with the Regional Ecological Risk Assessors and/or BTAG.

The Role of Tiers and Sub-Tiers in ERA

The Superfund program guidance describes a tiered approach for conducting ERAs and further describes the potential need for additional sub-tiers or iterations of specific activities at large or complex sites. In addition to refining contaminants of concern, effective use of sub-tiering will help focus the ERA process and improve the quality of risk characterizations.

The Two-Tier Process

A two-tier process for implementing an ERA is outlined in Highlight 3-1 in the Superfund program guidance. The first tier of this process (Steps 1 and 2) is the screening-level ERA; the second tier (Steps 3 through 8) represents a baseline ERA. The two-tier process is a means by which to quickly and efficiently evaluate sites with minimal potential for ecological risk and eliminate them from further evaluation in the baseline ERA. The screening-level ERA also allows contaminants that do not pose a substantial ecological risk to be removed from the list of COPCs prior to conducting the baseline ERA.

Although a decision can be made to proceed with cleanup after any tier of the ERA process, for some sites of relatively small size or where the contamination has a sharply defined boundary, it may be preferable to cleanup the site to the screening values rather than to spend time and resources determining a less conservative cleanup number. For example, a pond receiving a discharge may contain contaminated sediments and removing these sediments (resulting in remediation to conservatively derived levels) may be less costly than the studies necessary to determine the site-specific risk based cleanup levels. Conversely, for many sites, it is preferable to move directly to a baseline ERA after the initial screening, and the guidance routinely provides for this second tier.

Sub-Tiering

A sub-tier may consist of any incremental iteration of the exposure, effects, or risk characterizations being conducted within the ERA and may occur at any point in Steps 3 through 7. It may be focused on a parameter, assumption, or assessment endpoint and may be necessitated through discovery of new information or new results from completed studies. Sub-tiering has the goal of focusing the evaluation of COPCs, so resources can be more effectively applied to the ERA process. The use of sub-tiers is primarily a function of the need to further reduce uncertainties in the baseline ERA, but incremental costs may also limit the amount or extent of additional activities.

To efficiently utilize sub-tiers, it is important to establish agreement early on the planning, execution, and documentation of the work to be performed. This is due, in part, to the time and effort needed to produce documents for the next sub-tier (e.g., conclusions of SLERA and follow-on work plan). In practice, the ecological risk assessor should provide support for effective sub-tiering by anticipating the potential sub-tiering options and facilitating agreement with the risk manager regarding criteria for acceptance of the resulting product. Anticipating results of successive risk calculations and facilitating agreements may take place at any appropriate time within the baseline ERA based on the existing information.

Example: Relationship Between Sub-Tiering and Reduction of COPCs

A screening-level ERA is to be conducted for a site with numerous COPCs. The stakeholders agree that the first evaluation will be to compare the maximum media contaminant levels to the most conservative ecotoxicity screening values, although they expect that this will result in removal of only a few COPCs from the list.

Moving from the screening phase into Problem Formulation, experience predicts that there will be COPCs with no toxicity benchmarks and other COPCs that are analyzed for, but not detected at risk-based detection limits. Therefore, the work plan for the baseline ERA states that contaminants included in the analysis of samples, but not detected, will be removed from the list of COPCs. Next, the plan states that a dietary exposure model will be used for specified and retained COPCs using conservative default assumptions, such as 100% absorption efficiency of all ingested material. The work plan further states that, for specific contaminants, an alternate lower absorption efficiency factor may be applied, if these contaminants are retained and if the lower factor is "pre-approved". This process could then continue as deemed appropriate and effective.

In this way, iterative evaluations (i.e., sub-tiering) can be done in an objective and technically sound manner, confidence may be increased in risk estimates, and bias (or perceived bias) in the risk characterization may be avoided by using input from both the risk assessor and the risk manager.

Documentation of Sub-Tiering

In terms of effectiveness of resource utilization, sub-tiering has its greatest potential benefit at the point in the ERA process before data intensive evaluations are designed. The experience and ability of the risk assessor to anticipate relevant risk questions and associated risk calculations and the ability of the site manager to organize the site documentation contribute to the most effective use of sub-tiering. What is often lacking and thereby a source of controversy, however, is the approach used to document and support the various decisions influencing work plans for each particular tier or sub-tier of the ERA. The rationale for each iteration, the questions to be answered, and intended use of the resulting information should be clearly defined and agreed upon with the Regional Ecological Risk Assessors and/or BTAG.

Analogy: Reduction of COPCs and Sieving Soil Particles

Reducing the list of COPCs within an ERA has a direct analogy to the physical separation of particles in soil particle size distribution analysis. The physical screens allow a known size particle to pass through the sieve (up to the diameter of the screen mesh size). What is not known is the absolute magnitude and size distribution of the material retained by the screen. This is precisely the rationale contained in the Superfund program guidance for the use of screening in the ecological risk assessment process. Upon the completion of a conservative screen, if no materials (contaminants) are retained by the screen, one can confidently state that there is a minimal potential for ecological risk to exist. Alternatively, if materials (contaminants) are retained by the screen, one cannot conclude that an ecological risk "actually" exists; the characteristics of the material retained by the screen are unknown, other than its size is above some specified minimum value. This is the basis for the statement in the Superfund program guidance that screening level values do not constitute technically defensible cleanup goals; those must be derived through the baseline ERA process.

Continuing to draw upon the physical analogy, the next challenge is to devise a means of sorting out desired material from extraneous material. Within the baseline ERA, we wish to focus on the contaminants that may actually pose an ecological risk (commonly referred to as the risk drivers) rather than on those COPC's that either do not actually pose an ecological risk, pose only a minimal ecological risk, or pose an ecological risk that is not related to the site and /or cannot be effectively reduced.

To sort through the "material," larger mesh sieves are used iteratively. This is done until: 1) all of the material has passed through the screen and it is concluded that the mesh size was not too large to allow wanted material to pass through, 2) it can be seen that additional iterations will not be functionally effective and a "different" approach is needed, or 3) the actual material desired is obtained. Correlating these outcomes with the SMDPs at the end of Step 2 of the Superfund program guidance document, the outcomes may be restated as follows: 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."

What corresponds to these incrementally increasing mesh sizes within the ERA process? First, it must be recognized that the same things are always occurring in the thought process. Just as the same thought process occurs in Steps 1 and 2 as occurs in Steps 3 to 7, each iteration of the ERA, whether called a tier, a sub-tier, or any other name, includes similar considerations. In each successive tier, however, more information is used and assumptions and calculations are modified appropriately. The key transition in the process is from screening, which is conducted by comparison with benchmarks, to the baseline ERA, where comparisons generally require the use of negotiated values agreed upon with Regional Ecological Risk Assessors and/or BTAGs.

Summary

This supplemental guidance clarifies the two-tier process for conducting ERAs at Superfund sites and RCRA Corrective Action facilities discussed in U.S. EPA 1997. It describes the purpose of each tier (i.e., screening-level and baseline ERAs) and highlights those components common to both. It further provides an approach for refining contaminants of concern and streamlining the ERA process. Readers are referred to the references listed below for further information.

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