Fact Sheet #19 – Technical Support Memorandum 4: Step 4 Baseline Ecological Risk Assessment

This memorandum supplements the Department of Environmental Quality (DEQ) Voluntary Remediation Program (VRP) Fact Sheet #19, *Ecological Risk Assessment - Steps 3 and 4 Screening and Baseline Ecological Risk Assessment.* VRP Fact Sheet #8 (*Site Characterization),* VRP Fact Sheet #28 (*Data Quality Objectives [DQOs]*), and VRP Fact Sheet #14 (*Ecological Risk Assessment - Steps 1 and 2 Ecological Exclusion and Scoping Assessments*) should be referred to in order to develop an adequate, complete data set for use in the "baseline" Ecological Risk Assessment. This memorandum should be used for VRP sites that screen through the Step 3 Ecological Risk Assessment. The DEQ VRP risk assessment process is shown on Figure 1 of Fact Sheet #19.

Step 4. Baseline Ecological Risk Assessment Instructions

The procedures to guide volunteers through a VRP Step 4 baseline Ecological Risk Assessment (ERA) are described below. The baseline ERA should be completed by a biologist, ecologist, toxicologist, or other qualified environmental professional who is familiar with baseline ERAs. In general, DEQ expects the equations presented herein will be used when performing risk assessment calculations. Volunteers may, however, propose other means of calculating ecological risk and these will be considered by DEQ on an individual, case by case basis. Volunteers are encouraged to consult and collaborate with the DEQ frequently while conducting the Step 4 ERA.

The Step 4 ERA consists of the updated problem formulation, characterization of effects, characterization of exposure, and characterization of risk. Discussion and planning of the ERA is described within this memorandum. Because ERAs are site-specific, methods and procedures used by the volunteer that are not explained in this memorandum should be discussed and approved by the DEQ prior to submitting the final ERA report.

INTRODUCTION

The purpose of the VRP Step 4 baseline ERA is to estimate site- and receptor-specific ecological risks to determine if adverse effects are occurring as a result of exposure to site-related constituents of potential ecological concern (COPECs) carried forward from VRP Step 3. Information gathered during ecological risk assessment Steps 1, 2, and/or 3 should be used to focus the effort required during Step 4. However, additional effort may be required during Step 4 to provide information that has not been evaluated in previous steps. Figure 1 of Fact Sheet #19 presents an overview of the VRP ecological risk assessment process and highlights how each of the steps lead towards fulfillment of the VRP risk assessment requirements.

Site-specific wetland delineation, critical habitat and/or species surveys, or other detailed field efforts may be required during Step 4. The results of the rare, threatened and endangered (T&E) species search conducted in Steps 1, 2, or 3 must be incorporated into the Step 4 ERA. If the U.S. Fish and Wildlife Service, the Wyoming Department of Fish and Game, or the Wyoming Natural Diversity Database is contacted to obtain a rare or T&E species of concern list, it will be necessary to determine whether the

contaminated site or the immediate vicinity surrounding the site contains habitat for these species. Relevant activities conducted during Steps 1, 2, and/or 3 should be incorporated into planning Step 4. Additional activities may not be necessary if the DEQ determines that information obtained in Steps 1, 2, and/or 3 is adequate.

The Step 4 baseline ERA methodology is based on U.S. Environmental Protection Agency (USEPA) and other federal ecological risk assessment guidance, but these instructions do not necessarily reiterate federal guidance. Rather, details specific to the VRP are provided that are not specifically addressed in other guidance documents. These instructions are intended to help the volunteer complete a Step 4 baseline ERA. The volunteer is encouraged to read and understand the federal ERA guidance because it provides a foundation for understanding the Wyoming VRP ERA process. While many ecological risk assessment procedural details are provided in these instructions, because of the myriad of possible approaches to assessing ecological risks, the instructions are not necessarily intended as a step by step prescription of required procedures and little information is provided for field methods. Rather, ERA knowledge, discretion, and communication with DEQ personnel are expected of the volunteer to adequately assess the potential for ecological risks posed by site-related contamination. To effectively apply the information in this document, the volunteer should have adequate knowledge of:

- Site assessment methods
- Ecotoxicology and ecological risk assessment principles and procedures
- Contaminant fate and transport processes, and
- Current VRP guidance documents.

SUMMARY OF CONTENTS

The VRP Step 4 baseline ERA includes three main components: the ERA work plan, additional data collection and field activities (if required), and the baseline ERA report. The Step 4 baseline ERA instructions are organized by each of these main components as follows:

- **Step 4a. Baseline Ecological Risk Assessment Work Plan.** This section describes the primary requirements for development of the work plan. A work plan(s) for the risk assessment and for additional data collection or any field efforts must be submitted to DEQ for approval prior to conducting the Step 4 ERA. The work plan includes the following four components:
  - **Step 4a-1. Problem Formulation.** This section describes information necessary to conduct a site-specific baseline ERA. This step should identify the ecological receptors to be evaluated in the baseline ERA, as well as reevaluate the Step 3 Preliminary Problem Formulation and Conceptual Ecological Exposure Model (CEEM) to determine whether updates to the Problem Formulation and/or CEEM are necessary.
  - **Step 4a-2. Data Adequacy.** This section of the work plan determines whether the existing data are adequate to move forward with Step 4. If not, data gaps are identified, and Step 4a-3 is implemented.
  - **Step 4a-3. Step 4 Data Collection and Field Activities.** If existing data are determined to be adequate, the process moves directly to Step 4c, the Step 4 baseline ERA report. If data gaps were identified in the data adequacy evaluation, the Step 4b data collection activities must be

implemented and the data compiled, validated, and presented to DEQ for approval prior to beginning the Step 4 baseline ERA.

  - **Step 4a-4. ERA Analysis and Characterization Approach.** This section of the work plan identifies the information required to quantify ecological risk, including exposure parameters for each of the ecological receptors identified in the problem formulation, toxicity reference values (TRVs), and overall methods and equations that will be used to perform the Step 4 Baseline ERA.

- **Step 4b. Baseline ERA Report.** Consistent with USEPA (1998), the baseline ERA report consists of the following sections:
  - **Step 4b-1. Problem Formulation.** The problem formulation from the work plan may be inserted completely or by reference. The problem formulation should incorporate any additional information identified during implementation of the work plan.
  - **Step 4b-2. Exposure Assessment.** This section describes the development of site-specific reasonable maximum exposure point concentrations (RMEPCs), and methods to estimate the exposure of selected ecological receptors to different media. Information developed in Step 4a-4 of the work plan is utilized herein, incorporating any new data collected during implementation of the work plan.
  - **Step 4b-3. Toxicity Assessment.** This section describes the process for selection of TRVs for the selected ecological receptors.
  - **Step 4b-4. Risk Characterization.** This section describes the calculation of numeric risk estimates, provides a description of the implications of these numeric estimates, and the characterization of those estimates with regard to uncertainties in the risk assessment and site conditions.

The above sections may be used as an outline for both the Step 4 ERA work plan and/or report. The work plan should contain a level of detail sufficient to give the DEQ confidence that the ERA report will be written in accordance to standard DEQ and USEPA risk assessment procedures. Background site information (e.g. site history, data evaluation, summary of habitats, etc.) contained in the ERA work plan need not be duplicated in the report, unless new information is available. The information and procedures included within each section of the Step 4 report may vary depending on the approach used to conduct the baseline ERA.

RELATIONSHIP TO OTHER GUIDANCE DOCUMENTS

The Step 4 baseline ERA is developed in consideration of instructions included in *Guidelines for Ecological Risk Assessment* (USEPA 1998). Additional guidance may be found in other USEPA documents or websites, including *Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments* (USEPA 1997), or the USEPA Region 8 Ecological Risk Assessment website (http://www.epa.gov/region8/r8risk/eco.html). Other federal agencies have ERA guidance that could be helpful, including *Selection of Assessment and Measurement Endpoints for Ecological Risk Assessments* (U.S. Army Environmental Command [USAEC 2002a]), *Technical Document for Ecological Risk Assessment: Planning for Data Collection* (USAEC 2002b), or *Risk Assessment Handbook Volume II: Environmental Evaluation* (U.S. Army Corps of Engineers [USACOE] 2010). The USEPA also periodically publishes “ECO Update” bulletins available on their

web site (http://www.epa.gov/superfund/programs/risk/ecoup/). The volunteer should be familiar with these documents.

The instructions contained in this memorandum are intended only to supplement other previously mentioned guidance by providing VRP-specific information, and to describe DEQ expectations for the completion of a baseline ERA. A list of reference documents used to develop these instructions and that may prove useful in conducting baseline ecological risk assessments appears at the end of this document.

Step 4a. Ecological Risk Assessment Work Plan

Prior to performing the Step 4 baseline ERA, an ecological risk assessment work plan must be developed and submitted to DEQ for approval. The work plan shall describe the goals and methods to be employed for completing the ERA. If the DEQ determined the previous information collected in Steps 1, 2 and 3 was adequate to conduct Step 4, the information presented during those previous steps may be referenced or incorporated completely in the work plan and/or report. However, because the Step 4 ERA is more complex than Fact Sheet #19 Steps 1, 2, or 3, additional effort and information, including additional data collection and site assessment, may be required. The baseline ERA work plan must identify and address these additional data requirements above and beyond Steps 1, 2, and 3 by evaluating and determining whether existing data and site assessment are adequate to proceed with Step 4. Overall, the baseline ERA work plan must provide a level of detail that allows DEQ to understand, evaluate, and approve the ERA approach.

STEP 4a-1.BASELINE ERA WORK PLAN: PROBLEM FORMULATION

Problem formulation is a process of describing the site and its ecology, and then selecting the contaminants, habitats, receptors, exposure media, and exposure pathways that are to be assessed given the ecological characteristics and other factors (e.g., regulatory status) of the site. The result of problem formulation should be an understanding of what is ecologically important at the site, and what the focus will be for the remainder of the ecological risk assessment. The problem formulation should describe assessment endpoints and measures, which are explicit ecological attributes that are to be protected.

Much of the problem formulation should have been performed during Step 3c-1. If the volunteer has completed Step 3, the report generated for Step 3 can be used as the basis of the problem formulation for the Step 4 baseline ERA work plan. The Step 3c-1 information need only be amended to incorporate any new information that has been gathered for the site during development of the Step 4 baseline ERA work plan. The volunteer should refer to Step 3c-1, Preliminary Problem Formulation, for information required to be included in this section.

STEP 4a-2. BASELINE ERA WORK PLAN: DATA ADEQUACY EVALUATION

This section of the work plan describes the process for and results of an evaluation as to whether the existing data are adequate to proceed forward with Step 4. The volunteer should rely on the analysis in Step 3 and verify that data are representative of the site. The DEQ requires this section in the work plan in order to determine that data are of sufficient quality and quantity so that exposure areas as well as the

site as a whole have been adequately characterized. Additionally, in Step 4 it is appropriate to identify spatial and temporal trends in all media potentially affected by a release from a site-related source. At a minimum, data must be available for every potentially impacted medium and for every COPEC. The number of samples must be adequate to represent the conditions and variability within each exposure area and to statistically evaluate each exposure area and develop an acceptable EPC for the potentially impacted medium and receptor(s). The volunteer should confer with DEQ during development of this section of the work plan, and refer to VRP Fact Sheet #8, *Site Characterization,* and VRP Fact Sheet #28, *Data Quality Objectives (DQOs),* for further information.

If data are not adequate, data gaps should be identified and described as part of the DQOs in the work plan. If existing data are determined to be adequate, the process moves directly to Step 4b, the Step 4 baseline ERA. If data gaps were identified in the work plan, Step 4a-3 data collection activities must be implemented and the data compiled, validated, and presented to DEQ for approval prior to beginning the Step 4 baseline ERA.

STEP 4a-3. BASELINE ERA WORK PLAN: DATA COLLECTION/FIELD ACTIVITIES

The work plan must detail additional data collection and/or field activities to fill the data gaps identified in Step 4a-2. Additional data collection needs may also be described and submitted as a stand-alone field sampling and analysis work plan. The type of information detailed in this section of the work plan (or separate work plan if deemed necessary) should include the sample types to be collected, number of samples to be collected, sampling schedule, sampling locations and analytical methods. Maps showing topography, hydrologic features, and sample locations relative to site boundaries, buildings, and other infrastructure should be provided.

There are numerous types of data collection and field activities that can be used to supplement an ecological risk assessment data set and refine assumptions used in a baseline ERA (i.e., tissue-based and/or field toxicity measures). The volunteer should refer to the various regulatory guidance documents and technical literature referenced in the bibliography of this memorandum, or utilize other scientific information to develop an adequate data collection plan.

STEP 4a-4. BASELINE ERA WORK PLAN: ERA APPROACH

This is the final section of the work plan. This section should identify the information required to quantify ecological risk, including but not limited to detailed descriptions of the following: methods used to select exposure parameters for each of the ecological receptors identified in the problem formulation, selection of TRVs, and methods and equations used to perform the Step 4 baseline ERA.

Step 4b. Baseline ERA

STEP 4b-1. BASELINE ERA: PROBLEM FORMULATION

Much of the problem formulation should have been developed during Step 3c (i.e., Preliminary Problem Formulation) and modified as necessary for the Step 4a ERA work plan. The information in the baseline ERA work plan can be used as the basis of the problem formulation for the Step 4 baseline ERA. The Step 3c-1 information need only be amended to incorporate any new information that has been gathered for the site during implementation of the Step 4a Baseline ERA work plan. The volunteer should refer to Step 3c-1, Preliminary Problem Formulation, for information required to be included in this section.

If the Step 4 data are different than those used in Step 3, or if different exposure areas have been defined, then the COPEC selection process may need to be repeated for Step 4 of the ERA utilizing the entire site data set as necessary to represent the newly defined site conditions. The volunteer should refer to Steps 3a, 3b, and 3c for detailed instructions necessary to select the COPECs. The list of COPECs may be further refined by considering additional chemical or site-specific information gathered during implementation of the ERA work plan.

STEP 4b-2. BASELINE ERA: EXPOSURE ANALYSIS

The exposure analysis presents the methods and results for quantifying ecological exposure. If the Step 4 data are different than those used in Step 3, or if different exposure areas have been defined, then the summary statistics calculated in Step 3 are not applicable and must be recalculated with the full site data set. The COPEC selection process needs to be repeated for Step 4 of the ERA to represent the newly defined site conditions, if applicable. The volunteer should refer to Step 3 for detailed instruction necessary for evaluation of site data and selection of COPECs.

<u>Exposure Estimation</u>

Exposure is estimated with the RMEPCs and receptor-specific exposure parameters. The RMEPCs calculated for Step 3c may be used herein unless additional data were collected or exposure areas were modified. The RMEPCs are combined with species-specific exposure information to calculate an estimated chronic daily exposure dose in milligrams per kilogram body weight per day (mg/kg bw-d) for each assessment species in each exposure area applicable for that receptor. Receptor species identified in the CEEM for each feeding guild should be used. Because toxicity data for assessment communities such as plants, invertebrates, and aquatic life are typically expressed as media concentrations (i.e., milligrams per kilogram [mg/kg] or milligrams per L [mg/L]) rather than doses, the calculation of exposure doses is not required for assessment communities. The equations used to estimate chronic daily intakes are presented in the following section.

The volunteer should be aware that DEQ may require evaluation of groundwater and/or pore water, in addition to surface water and/or sediment, to verify that there is no unacceptable ecological risk to aquatic media.

Exposure Equations for Assessment Species

The exposure equations used for calculating the COPEC doses for assessment species are provided in numerous ecological risk assessment guidance documents (USEPA 1989, 1993, 1997, 1998; 2005; USACOE 2010). For all assessment species, the estimated daily dose or intake due to incidental ingestion of soil or sediment, dietary items associated with the site, and drinking water for individual COPECs can be generally expressed as:

$$EDD = \left(Cs * Fs * DIR + \sum_{i=1}^{n} (Ciy * BAFi * Pi) + Cw * WIR \right) * AUF$$

Where:

EDD	= Estimated chronic daily dose (mg/kg bw-d)
Cs	= RMEPC for COPEC in soil or sediment (mg/kg)
Fs	= Fraction of soil or sediment in diet
DIR	= Dietary ingestion rate (kg diet/kg bw-d)
Ciy	= RMEPC concentration in dietary item *i* by exposure media *y*
BAFi	= Bioaccumulation factor for dietary item *i* from media *y*
Pi	= Proportion of dietary item *i* in diet of assessment species
Cw	= Concentration of COPEC *x* in drinking water (mg/L)
WIR	= Water ingestion rate (L/kg bw-d)
AUF	= Area use factor (site area/home range of assessment species; maximum value of 1)

This equation is modified to be species-specific by using exposure parameters to represent the estimated daily intake of COPECs via food, soil/sediment, and water for a particular species. The exposure parameters are described in more detail below.

Ecological Exposure Parameters

The exposure equations above contain many species-specific and chemical-specific ecological exposure parameters that may be used to calculate the exposure doses for assessment species. Species-specific exposure parameters include biological variables, such as dietary ingestion rate, foraging area, and area use factors (AUFs), which help define the exposure of each assessment species. The parameters Fs, DIR, Pi, WIR, and AUF will differ for each of the different assessment species. As noted previously, assessment communities are not addressed by dose calculation and do not have species-specific exposure parameters. When data are sufficient to estimate percentiles, conservative estimates of dietary ingestion rate, water ingestion rate, or home range values should be used (i.e., 90th percentiles for ingestion rates (USEPA 2013), 10th percentile for home range) to provide an upper bound estimate of potential exposure. An attempt should also be made to use ingestion rate and body weight parameters for the same species identified in the CEEM.

The parameter BAFi is chemical-specific and represents uptake or bioaccumulation from contaminated media by prey or forage items living in or associated with that medium. Bioaccumulation is modeled by multiplying the RMEPC by a receptor- and chemical-specific bioconcentration factor (BCF) or

bioaccumulation factor (BAF). Uptake also may be predicted using regression equations (e.g. refer to Fact Sheet #19 Technical Support Memorandum 3). Uptake may vary as a function of the contaminant concentration in the exposure medium. The BAFi is chemical specific and also will vary by dietary item. The bioaccumulation literature may categorize uptake into various types of uptake factors, such as sediment-to-biota accumulation factors (BSAFs) for uptake from sediment, BCFs which represent uptake only from water, and biomagnification factors (BMFs) which describe chemical transfer across food web trophic levels. Plants and terrestrial invertebrates are typically modeled as bioaccumulating contaminants from soil, whereas aquatic life are modeled as bioaccumulating contaminants from water. Benthic invertebrates are modeled as bioaccumulating contaminants from sediments. Species specific BCFs or BAFs may not be available in all cases; therefore, parameters may be extrapolated from "surrogate" species that best represent their life history attributes. With prior DEQ approval, the volunteer may collect site-specific data from which to estimate site-specific BCFs or BAFs. The volunteer is urged to review guidance and technical information regarding BAF/BCF/BSAF/BMF data and discuss the dietary pathway for each CEEM receptor with DEQ, prior to modeling dietary uptake.

The Cs, Ciy, and Cw parameters are site- and chemical-specific. For any given site or exposure area there may be one or more contaminated media that will be addressed. It is typically assumed that the aquatic-dependent receptors are primarily exposed to sediment, whereas the terrestrial receptors are primarily exposed to soil. The proportion of solid media in the diet of any given assessment species needs to be apportioned to allow evaluation of sediment and soil in the diet if the receptor is exposed to both media. With some exceptions, any assessment species at a site would be expected to be exposed to nearby surface water for drinking.

Default ecological exposure scenarios and parameters for the baseline ERA are not prescribed by DEQ, and so must be selected by the volunteer and then approved by DEQ. Exposure parameters can be obtained from review of peer-reviewed literature as well as state and federal ecological risk assessment guidance documents.

Exposure Doses by Receptor

Using the RMEPCs, appropriate exposure equations, and selected or calculated exposure parameters, the volunteer should calculate exposure doses (mg/kg bw-day) for each assessment species in each selected exposure area. These exposure doses and the RMEPCs for assessment communities are then used to estimate ecological risks.

STEP 4b-3. BASELINE ERA: TOXICITY ANALYSIS

Toxicity data for use in a baseline ERA include concentration-based benchmarks such as the ecological risk-based screening concentrations (ERBSCs), sediment quality criteria, or ambient water quality criteria for assessment communities. Toxicity data for assessment species are dose-based TRVs. These two types of toxicity values used in the baseline ERA are described below.

Concentration-Based Benchmarks

Concentration-based benchmarks (CBBs) are media-specific concentrations that will not result in adverse effects to a receptor. The ERBSCs are the default CBBs that should be applied by the volunteer to evaluate potential impacts to assessment communities. The RMEPCs are compared directly to CBBs for the most pertinent exposure media for a given assessment community. The RMEPC should be compared to an aquatic CBB for a COPEC in water to determine whether there is a potential for ecological effects to the aquatic life assessment community due to that COPEC. Soil CBBs for plants or invertebrates are compared to soil RMEPCs to determine if effects on vegetation or terrestrial invertebrates are likely. Sediment CBBs are compared to sediment RMEPCs to estimate potential impacts to benthic communities. Generally, this is the same comparison made to determine COPECs during Step 3, and the ERBSCs used during COPEC selection may be incorporated into the toxicity analysis for Step 4.

Other CBB values are available and may be selected by the volunteer for use in the baseline ERA if site conditions warrant the use of different values. Alternate values may be appropriate for a site that lacks the species that form the basis of an ERBSC. The volunteer should discuss the alternate benchmarks with DEQ prior to using them.

Toxicity Reference Values

The TRVs are species-specific doses of chemicals that have been shown to either have an adverse effect or not have an effect on the tested species. TRVs are derived from species-specific toxicity data (i.e., chronic lowest observed adverse effect levels [LOAELs], or chronic no observed adverse effect levels [NOAELs]) from regulatory or peer-reviewed literature documents. Typically, one TRV is derived for each taxonomic class represented by the assessment species for which numeric intake estimates will be made (e.g., birds, mammals). These data are then converted, using uncertainty factors (UFs), to ecological reference doses (ERfDs) considered to be representative of the assessment species. In general, ERfDs are site-specific and assessment species-specific. Possible sources of TRVs, and the process to convert TRVs to ERfDs, are presented in the following subsections. Other methods for selecting ecological toxicity data for use in the risk assessment are available. Some of these are discussed in the USEPA's Ecological Soil Screening Level (EcoSSL) guidance documents (USEPA 2013). For many chemicals, TRVs may be obtained from the EcoSSL documents (USEPA 2013) with no further research required because of the thorough research and evaluation that was used to establish these TRVs. The use of alternate methods of TRV selection should be approved by DEQ prior to implementation.

Some principal sources for TRVs include:

- USEPA EcoSSL
- USEPA's Integrated Risk Information System (IRIS)
- Summary reviews of available toxicity data (Sample et al. 1996)
- Primary literature sources (journal articles and scientific publications)
- Chemical-specific Toxicological Profiles produced by the Agency for Toxic Substances and Disease Registry (ATSDR)

- The National Institute of Occupational Safety and Health [NIOSH] Registry of Toxic Effects of Chemical Substances (RTECS)

Studies where the COPEC was administered orally (i.e., by gavage, incorporated into diet, or dissolved in drinking water) should be the primary sources used for the selection of TRVs. Some studies provide information in the form of a food or drinking water concentration (i.e., mg chemical/kg food or mg chemical/L water) as opposed to an administered dose (i.e. mg chemical/kg body weight per day [mg/kg bw-d]). In this case, the food or drinking water concentration must be transformed to a dose (mg/kg bw-d). This conversion requires knowledge of the amount of food eaten per day by the test species and its body weight. Preferably, this information is obtained from the source in which the toxicity information was found. However, such information is not always provided. In this event, daily food ingestion rates and/or body weights for the test species can often be obtained from other sources (e.g., USEPA 1988; USEPA 1993; Dunning 1993) and used to convert the chemical content of a food item into a TRV. For this conversion, it can be assumed that the effective dose of a chemical is 100 percent of the ingested dose (i.e., 100 percent bioavailability is assumed) unless data are available to the contrary.

When possible, a chronic NOAEL should be selected as the TRV. In addition, a chronic LOAEL from the same study could also be used to represent a lower bound on risk. In the absence of a chronic LOAEL or NOAEL, a no-observed-effect-level (NOEL), or a lowest-observed-effect-level (LOEL), or subchronic effects level may be selected. The actual effects threshold is likely to fall between the NOAEL and LOAEL, but these two values are to be substituted as the threshold doses because most often it is not possible to predict the actual effects threshold from data provided in the available literature.

Data from long-term or chronic toxicity studies are to be chosen when available; however, subchronic and/or acute data may be used if chronic data are unavailable. Studies must have included a minimum of two exposure doses or treatments, as well as unexposed controls, and the endpoint must be statistically significantly different than the controls, in order to obtain an appropriate NOAEL or LOAEL; more treatment levels are preferred. Single dose studies should be avoided unless no other data are available. If no TRV can be obtained or calculated for a particular chemical and/or assessment species and a TRV for a similar or surrogate chemical cannot be found, that contaminant is not evaluated quantitatively for that species, but should be assessed qualitatively. The lack of quantitative risk calculation for some chemicals should also be discussed in the uncertainty assessment with regard to the effect on risk estimates (i.e., lacking numeric risk estimates increases uncertainty and may bias risk estimates low because risk cannot be evaluated).

For many chemicals, there are several toxicity studies in various sources, which provide data regarding different toxicological endpoints and effects levels. The process of selecting an appropriate TRV requires an assessment of the appropriateness of the various endpoints and effects levels, as well as evaluating how well the toxicity test species represents the assessment species. In general, data indicative of overt health effects to individual organisms that resulted in effects that could have a negative impact on population success are preferred (USEPA 2013). These may include reproductive effects, decreased survival (i.e., mortality), or significant impacts on growth. Other less adverse effects endpoints, such as changes in organ weight or subtle physiological effects, should be used only in the absence of the preferred endpoints because these endpoints may not impair any given individual animals ability to

survive and reproduce, and may have no bearing on population success. Preference for particular endpoints is established as follows:

- Primary Significance – Effects of primary significance are those likely to be associated with decreased population success, such as:
    - Reproductive effects such as decreased fertility, teratogenicity, and developmental/fetal mortality, which could impact the species population;
    - Decreased survival, which could impact population numbers in future generations;
    - Decreased growth, which could limit or delay reproductive function; and
    - Severe and irreversible histopathological injury, such as advanced necrosis of, or serious damage to, organs such as the liver, kidneys, brain/central nervous system, and lungs, which could impact primary body functions and result in imminent mortality.
- Secondary Significance – Moderate alterations in function of organs and/or behavior that could result in decreased survival.
- Tertiary Significance – Alterations such as decreased liver size, increased chemical concentration in blood, or physiological changes that are not readily associated with decreased reproductive success, reduced survival, or increased mortality.

Carcinogenic endpoints are not considered appropriate for the selection of TRVs unless cancer is a well-demonstrated ecological effect of particular COPECs on the assessment species and may affect a sufficient proportion of the population at a rate likely to impact population success. This is in accordance with the current understanding that cancer is not generally considered to be a threat for most free-ranging wildlife species because most wildlife species are relatively short-lived and cancer is an event that affects single individuals. If the cancer rate was high enough to impact a population, it is likely that this would be evident as an impact on survival during the toxicity test (Suter 1993).

<u>Uncertainty and Extrapolation Factors</u>

Chronic LOAELs or NOAELs are not available for some chemicals; therefore, the available TRVs may be adjusted to represent the preferred endpoints using UFs. Uncertainty factors and their use are discussed in many risk assessment guidance documents and texts (Calabrese and Baldwin 1993, Suter 1993, USEPA 1998, USEPA 2013) and encompass extrapolations of effect, duration, and species. Alternative UFs may be proposed by the volunteer and used with DEQ approval. The lowest chronic NOAEL-based TRV from an acceptable study for each taxonomic class should always be used as the point of departure for developing an ERfD. DEQ requires that for each extrapolation required to estimate an ERfD from the selected TRV, UFs be applied as follows:

- LOAEL to NOAEL, UF = 10;
- Subchronic to chronic, UF = 10;
- Interspecific extrapolation, UF = 10; and/or
- Modifying factor to account for uncertainty not addressed per the above categories, UF varies from 1 to 10.

The methods of TRV extrapolation and derivation should be clearly presented in the risk assessment and discussed with DEQ prior to use.

Tissue-Based Toxicity Values

Tissue-based toxicity values are tissue concentrations that correspond to specific toxic effects in the test species. Tissue-based toxicity values may not be available for all COPECs or species, but may be used in cases where TRVs are unavailable. This type of toxicity information generally applies to chemicals that are slowly metabolized where tissue concentrations are fairly stable and do not change rapidly over time. Use of tissue-based toxicity values requires collecting tissue samples from the site and from an unimpacted reference area for comparison. If the volunteer desires to use tissue-based toxicity values, they must discuss this approach with DEQ during development of the ERA work plan (Step 4a).

Field Ecological Toxicity Measures

In the event that particular species or chemicals need to be assessed at a given site, and species-specific or chemical-specific toxicity data are not available for that species and/or chemical, then site-specific data may be gathered. Site-specific data can also identify site-specific changes in toxicity due to the presence of mixtures or site-related soil or sediment properties. These site-specific toxicity data may include testing the toxicity of a particular chemical in a laboratory using standard toxicity bioassays, or laboratory toxicity tests using site-related species. These tests are commonly used to determine if toxicity is likely to occur due to exposure to site media or to chemical mixtures. If bioassays indicate mortality is similar to controls and/or reference areas, it provides a line of evidence that adverse effects are not occurring. Typically these tests are applied to evaluate toxicity to aquatic life or benthic invertebrates, although plant toxicity testing is also done. These and other such measures are part of the field determination of site-specific measures and are used to fill data gaps or reduce the uncertainty in estimated or calculated ecological toxicity data. Approaches to conducting field ecological toxicity measures are described in many documents (e.g. Calabrese and Baldwin 1993; Suter 1993, Bartell et al., 1992, USEPA 1989).

STEP 4b-4. BASELINE ERA: RISK CHARACTERIZATION

The results of the exposure and toxicity analyses are combined in the risk characterization to calculate quantitative estimates of the potential for ecological risks. Risk characterization involves calculation, presentation, and description of the potential risks for the assessment communities and species. This includes discussion of the potential for the predicted risks to represent significant population level effects at the site and of uncertainties associated with the predicted risks.

Risk Estimation

Potential risks due to individual COPECs are expressed as hazard quotients (HQs). For assessment communities (i.e., terrestrial vegetation, terrestrial invertebrates, aquatic life, and benthic invertebrates), the HQ is the ratio of the media (i.e., soil, water, or sediment) concentration (the RMEPC) to the chemical-specific ERBSC or CBB. HQs for terrestrial vegetation and invertebrates are based on exposure to soil, HQs for aquatic life are based on exposure to surface water (maybe measured in groundwater or

porewater), and HQs for benthic invertebrates are based on exposure to sediment (maybe measured in surface water or porewaer).

HQs for assessment communities are calculated as follows:

$$HQ_{comm} = RMEPC_{medium} / CBB$$

Where:

HQ_{comm} is the hazard quotient for a particular COPEC and assessment community (unitless)

$RMEPC_{medium}$ is the reasonable maximum exposure point concentration of the COPEC in the medium of concern (mg COPEC/kg soil or sediment or mg COPEC/L water) associated with the assessment community

CBB is the ERBSC or other benchmark for the same medium of concern, COPEC, and the assessment community (mg COPEC/kg soil and sediment or mg COPEC/L water).

For assessment species, the HQ is the ratio of the total estimated daily dose of a COPEC to the ERfD.

$$HQ_{species} = EDD / ERfD$$

Where:

$HQ_{species}$ is the hazard quotient for a particular COPEC, assessment species, and exposure medium (unitless)

EDD is the total estimated daily dose of a given COPEC by an assessment species from a particular exposure medium (mg COPEC/kg body weight per day)

ERfD is the ecological reference dose for a given COPEC and assessment species (mg COPEC/kg body weight per day).

The HQs are then summed across all COPECs for each assessment community or species to obtain a hazard index (HI) for each receptor. This HI assumes that the receptors are exposed to the RMEPC for each COPEC. The HI is often considered to be a conservative estimate of the potential for risks to assessment communities or species because it assumes the effects of each of the COPECs are additive (i.e., the toxicity of the mixture of COPECs is equal to the sum of each COPEC in the mixture) based on exposure to all COPECs simultaneously at the RMEPC level.

If the HQ and/or HI for a COPEC exceed 1 for a particular assessment community or species, there is the potential for adverse ecological effects. If the HIs for all receptors are below 1, the site is presumed to not pose ecological risk, and pending DEQ approval, the VRP requirements are met. If the HI is above 1, the HQs may also be grouped according to toxic effect (e.g., impacts to survival versus impacts to growth) and effect-based HIs calculated for further understanding of the potential nature of the ecological effects.

The predicted ecological risks, expressed as HQs and HIs for each assessment community and assessment species, should be provided in tabular format. The HQs and HIs greater than 1 should also be discussed in the text. It may be useful for the volunteer to present the calculation of HQs and HIs for all COPECs by receptor and exposure medium on separate tables for each exposure area. All calculations should be presented in such a way that allows the DEQ to recalculate HQs if necessary. To summarize the HIs for each exposure area, the assessment endpoints evaluated for that area should be listed and the HI for each assessment species/community should be presented by medium. This allows for evaluation of potential ecological risks across all media, for each assessment endpoint, within each exposure area.

Calculation of the HQs for predicted tissue concentrations (i.e., body residues) may be conducted using the following equation:

$$HQ_{tissue} = C_{tissue} / TC_{tissue}$$

Where:

HQ_{tissue} is the hazard quotient for a particular COPEC in the tissue of a particular receptor (unitless)

C_{tissue} is the measured concentration of the COPEC in tissue (mg COPEC/kg tissue)

TC_{tissue} is the threshold concentration for the COPEC in tissue (mg COPEC/kg tissue).

Risk Description

The volunteer should discuss the potential for ecological risk within each of the exposure areas identified previously. A more detailed examination of the COPECs that were predicted to have the greatest potential for causing ecological risks, and a summary of the receptors or habitats most likely to be affected, should be included in this section. The volunteer should be careful not to make risk management recommendations in this section of the report.

Uncertainty Analysis

The risks estimated in the baseline ERA are estimates based on multiple assumptions about exposure, toxicity, etc. Uncertainty is inherent in each assumption within the ERA process and may result in an overestimation or underestimation of risks at the site. In order to present the risk estimates in the appropriate context for understanding their limitations, a quantitative or qualitative discussion of uncertainty must be included in all ERAs. The major uncertainties should be summarized by the volunteer, and when possible, an estimate of whether the uncertainty results in an overestimation or underestimation of ecological risks should be provided. Uncertainties that should be considered include:

- Uncertainty in the site characterization data and historical information about the site;
- Uncertainty in selection of COPECs;
- Uncertainty in the exposure assessment;
- Uncertainty in the toxicity criteria used;

- Uncertainty in the risk calculations and results, including uncertainty with any models or sensitivity analyses performed for models used.

Both the general uncertainties associated with the ERA process and uncertainties associated with the site-specific assumptions used in the Step 4 ERA must be presented. The uncertainty analysis should attempt to identify whether the uncertainty biases risk estimates high or low, or is unlikely to have any effect.

Summary and Conclusions

This section should summarize the results and provide final conclusions using the risk estimates, site data, current and future site conditions, and uncertainties evaluated in the ERA report. The volunteer should provide a description of likely ecological significance of the predicted ecological risks, including a description of risk to key receptors. Guidance documents such as the *Guidelines for Ecological Risk Assessment* (USEPA 1998) provide a framework for interpreting the significance of predicted ecological risk. Expert biological or ecotoxicological opinion may also be incorporated into this portion of the ERA.

Report

A risk assessment report must be prepared for all Step 4 baseline ERAs. This report must include a description of all methods used in conducting the risk assessment and summaries of all risk estimates for all media and exposure scenarios/exposure pathway combinations evaluated. The information in the report must be presented in a transparent manner such that all calculations can be reviewed and replicated by DEQ. In some cases, DEQ may request that the volunteer provide electronic copies of spreadsheets used in risk calculations.

MORE INFORMATION

To learn about VRP sites that may exist in your community, obtain copies of other VRP Fact Sheets/guidance documents, get answers to your questions, or volunteer for the program, contact DEQ at (307) 777-7752 or through the VRP web site at: http://deq.state.wy.us/volremedi/index.asp.

The VRP web site includes all of the Fact Sheets and other guidance documents for the VRP. This web site is updated frequently and includes the latest information about DEQ's progress in developing guidance, policy, and other supporting documents for the VRP.

For additional information regarding ecological risk assessments, the volunteer is referred to the following documents.

REFERENCES:

Bartell, S.M. R.H. Gardner, and R.V. O' Niell. 1992. *Ecological Risk Estimation*. Lewis Publishers. Chelsea, Michigan. 252 pp.

Calabrese, E.J. and L.A. Baldwin. 1993. *Performing Ecological Risk Assessments*. Lewis Publishers. Chelsea, Michigan. 257 pp.

Dunning, J.B., Jr. 1993. *CRC Handbook of Avian Body Masses*. CRC Press, Boca Raton, Florida.

Sample, B.E., D.M. Opresko and G.W. Suter II. 1996. *Toxicological Benchmarks for Wildlife: 1996 Revision*. Risk Assessment Program, Health Sciences Research Division. Oak Ridge, Tennessee. ES/ER/TM-86/R3. June. Available at: http://www.esd.ornl.gov/programs/ecorisk/documents/tm86r3.pdf

Suter, G.W. II. 1993. *Ecological Risk Assessment*. Lewis Publishers. Boca Raton, Florida. 538 pp.

USACOE. 2010. Risk Assessment Handbook Volume II: Environmental Evaluation. U.S. Army Corps of Engineers. December 31 2010. EM 200-1-4. Available at: http://publications.usace.army.mil/publications/eng-manuals/EM_200-1-4_Vol-02.pdf

USAEC. 2002a. Selection of Assessment and Measurement Endpoints for Ecological Risk Assessments. Technical Document for Ecological Risk Assessment. U.S. Army Environmental Command. February 2002. SFIM-AEC-ER-TR-2002018. Available at: http://aec.army.mil/usaec/cleanup/ecorisk02-0202.pdf

USAEC. 2002b. Technical Document for Ecological Risk Assessment: Planning for Data Collection. U.S. Army Environmental Command. January 2002. SFIM-AEC-ER-TR-2002017. Available at: http://aec.army.mil/usaec/cleanup/ecorisk01-0102.pdf

USEPA. 1988. *Recommendations for and Documentation of Biological Values for Use in Risk Assessment.* U.S. Environmental Protection Agency, Environmental Criteria and Assessment Office, Office of Health and Environmental Assessment, Office of Research and Development. Cincinnati, Ohio. EPA/600/6-87/008. February. Available at: http://www.epa.gov/iris/backgr-d.htm

USEPA. 1989. *Ecological Assessment of Hazardous Wastes Sites: A Field and Laboratory Reference*. U.S. Environmental Protection Agency, Environmental Research Laboratory. Corvallis, Oregon. USEPA600/3-89/013. March. Available at: http://rais.ornl.gov/homepage/ECOASR.PDF

USEPA. 1993. *Wildlife Exposure Factors Handbook.* Volumes I and II. U.S. Environmental Protection Agency, Office of Research and Development. Washington, DC. EPA/600/R-93/187a. December. Available at: http://rais.ornl.gov/homepage/WEFHV1.PDF

USEPA 1994. *Guidance for Data Quality Objectives Process.* U.S Environmental Protection Agency, Office of Research and Development, EPA/600/R-96/055, September 1994 Available at: http://www.clu-in.org/conf/tio/pasi_121603/epaqag4.pdf

USEPA. 1997. *Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments, Interim Final*. U.S. Environmental Protection Agency,

Office of Solid Waste and Emergency Response. USEPA540-R-97-006. OSWER 9285.7-25. PB97-963211. June. Available at: http://www.epa.gov/oswer/riskassessment/ecorisk/ecorisk.htm

USEPA. 1998. *Guidelines for ecological risk assessment*. EPA/630/R-95/002F. Risk Assessment Forum, U.S. Environmental Protection Agency, Washington, D.C.

USEPA. 2013. Ecological Soil Screening Level (EcoSSL) Reports and Guidance Documents. http://www.epa.gov/ecotox/ecossl/.

Acronym List

ATSDR	Agency for Toxic Substances and Disease Research
BAF	Bioaccumulation Factor
BCF	Bioconcentration Factor
BMF	Biomagnification factor
BSAF	Biota Sediment Accumulation Factor
BW	Body Weight
CAS	Chemical Abstract System
CBB	Concentration-Based Benchmark
CEEM	Conceptual Ecological Exposure Model
CO I	Contaminant of Interest
COPEC	Chemicals of Potential Ecological Concern
C_{tissue}	Concentration of COPEC in Biological Tissue
DEQ	Department of Environmental Quality
DIR	Dietary Ingestion Rate
DQO	Data Quality Objectives
EcoSSL	USEPA Ecological Soil Screening Level
EDD	Estimated Daily Dose
EDI	Estimated Daily Intake
EF	Extrapolation Factor
EPC	Exposure Point Concentration
ERA	Ecological Risk Assessment
ERBSC	Ecological Risk-Based Screening Concentration
ERfD	Ecological Reference Dose
HI	Hazard Index
HQ	Hazard Quotient
IR	Ingestion Rate
IRIS	Integrated Risk Information System
Kg	Kilogram
L	Liter
LD50	Lethal Dose for 50 Percent of the Test Population
LOAEL	Lowest Observed Adverse Effect Level
LOEL	Lowest Observed Effect Level
mg	Milligram
mg/kg	Milligram per Kilogram
mg/kg bw/d	Milligram per Kilogram Body Weight per Day
mg/L	Milligram per Liter
NIOSH	National Institute of Occupational Safety and Health
NOAEL	No Observed Adverse Effect Level
NOEL	No Observed Effect Level
ORNL	Oak Ridge National Laboratory
PCB	Polychlorinated Biphenyl
RMEPC	Reasonable Maximum Exposure Point Concentration
RTE	Rare, Threatened, or Endangered
RTECS	Registry of Toxic Effects of Chemical Substances
SC_{tissue}	Screening Concentration in Tissue
SVOC	Semi-Volatile Organic Compound
SUF	Site Use Factor
TRV	Toxicity Reference Value

95UCL	95th Percent Upper Confidence Limit on the Mean
UF	Uncertainty Factor
ug/kg	Microgram per Kilogram
ug/L	Microgram per Liter
USACOE	United States Army Corps of Engineers
USAEC	United States Army Environmental Command
USEPA	United States Environmental Protection Agency
USFWS	United States Fish and Wildlife Service
VOC	Volatile Organic Compound
VRP	Voluntary Remediation Program
WIR	Water Ingestion Rate