Position Paper on Common Issues Encountered
During the Review of Ecological Risk Assessments

September 2005

TCEQ developed a detailed ecological risk assessment (ERA) guidance document (TNRCC, 2001) that was released in December 2001[1]. This guidance should be used by persons performing ERAs to comply with TRRP (30 TAC §350), the Risk Reduction Rules (30 TAC §335), or the PST Rules (30 TAC §334). Although the guidance document does not address every possible aspect of an ERA, if used by experienced risk assessors, it is expected that ERAs submitted to the agency will be evaluated and approved with minimal revisions and comment exchange. Since the 2001 guidance release, we continue to see many commonalities in the problems we encounter and the comments we make on submitted ERAs. With this in mind, ERA Program staff has developed this paper to share our position on the most commonly encountered problematic issues in our review of ERAs. When used in concert with the agency's ERA guidance, it is our hope that this issue paper may provide more specific insight on common pitfalls to avoid. This document serves to augment, not replace, the existing ERA guidance. The positions presented here are reflective of the more common site circumstances; however, these positions can vary based on extenuating site-specific information or concerns. Revisions to the current positions on these existing issues, as well as additions of new issues, will be made periodically to this paper. Please contact any of the TCEQ ERA Program staff listed below if you have any questions regarding this issue paper or the agency's ERA Program in general [2].

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[1]Any reference to the TCEQ Guidance includes future updates to the original 2001 document.

[2]This document should be cited as: TCEQ. 2005. Position Paper on Common Issues Encountered During the Review of Ecological Risk Assessments. Remediation Division. September. http://www.tceq.state.tx.us/assets/public/remediation/eco/positionpaper.pdf

Index of Issues.

1. Issue: Documenting and explaining all inputs and calculations within the ERA.

In general, an ERA should outline the required elements of the agency's ERA guidance, and focus on describing the project-specific approach for addressing those elements. For ease of review and transparency, all dose, hazard quotient and protective concentration level (PCL) calculations should be provided. These may be presented in tabular form or spreadsheets in a stepwise manner, with each component of the equation listed with its corresponding result. Paramount to this is a clear indication of the values used for the exposure point concentrations (e.g., 95% UCL, maximum) for each exposure medium along with all exposure parameters. A reference and rationale (where appropriate) should be provided for all receptor exposure assumptions (e.g., diet, body weight, food and media ingestion rates, uptake factors, home range, feeding territory). Where multiple values or equations for an input are provided in a reference such as those listed in the U.S. EPA's *Wildlife Exposure Factor Handbook* (U.S. EPA, 1993) or the U.S. EPA's *Screening Level Ecological Risk Assessment Protocol for Hazardous Waste Combustion Facilities* (U.S. EPA, 1999), a rationale for the selected input should be made (e.g., selection based on average of adult body weights or selection based on the most appropriate habitat type for the affected property in question).

Changes to the inputs (exposure point concentrations, exposure assumptions) with the second round of hazard quotient calculations should be clearly explained. As the risk assessment progresses through the refined hazard quotient calculations, tables should reflect what chemical of concern (COC) and receptor combinations are dropped/retained. Without all of this information, it is impossible to adequately verify the hazard quotients and PCLs determined in the ERA. Also see the related discussion in Issue 6 on toxicity reference values (TRVs).

2. Issue: Providing a general property description.

Risk assessments often dive into the calculation aspects of the evaluation without providing the context of the environmental setting. Key to the determination of the conceptual model and the identification of measurement receptors, is an understanding of the habitats associated with the affected property. We suggest that ERAs provide some discussion of the site or surrounding areas with regard to activities, land use, and/or habitat types. Topography, proximity to water bodies, areas of groundwater seepage, types of vegetation, vegetation density, and vegetation height could be discussed to some degree. The ERA should also discuss the details of any site visit that may have been performed with the goal of surveying the flora and fauna associated with the site. Additionally, general information regarding the operational history of the site would be beneficial, particularly as it relates to exposure areas and COC selection. **It is absolutely necessary that the ERA include some maps and figures that diagram the affected property, surrounding land use, and the sample locations.** Persons may reference other documents for detailed information, provided these documents are clearly identified and available to the risk assessor.

3. Issue: Documenting and explaining the benchmark screening process.

When there is no TCEQ benchmark for the COC, benchmarks should be proposed. When a benchmark is proposed, the source or methodology should be noted and fully cited. If a benchmark is not proposed, the COC should be retained and evaluated further. As part of this screening process, tables should identify any bioaccumulative COCs, show the benchmarks used, the source of the benchmarks, and corresponding background values where appropriate. Tables should provide a side-by-side comparison of the COC maximum concentration with the appropriate benchmark, and there should be a column for each media that indicates if the COC was screened out based on the benchmark comparison, background concentration comparison, and/or consideration of bioaccumulation. The table should also reflect detection levels where the chemical was below detection, rather than simply denoting a dash or NA.

4. Issue: Identifying all feeding guilds at the affected property.

Often, not all feeding guilds supported by the habitats on an affected property are proposed for evaluation. As stated in the TCEQ Guidance, after the type(s) of habitat that can be supported by or on the affected property has been determined, the feeding guilds comprising the food web of that habitat(s) need to be identified. The TCEQ Guidance illustrates the food webs of the seven major habitats found in Texas. Not all of the feeding guilds may need to be mathematically evaluated in the ERA, but they all need to be somehow addressed (e.g., a justifiable rationale could be provided that states that the protection of one guild will protect another as well). The ERA could discuss the selected receptor’s likelihood of exposure and sensitivity to COCs, as compared to those guilds that were not quantitatively addressed. The discussion could also emphasize habitat availability and the likelihood that any of the guilds could/would use the affected area for foraging. By not addressing all potentially impacted feeding guilds, a cascading effect is created throughout the ERA that affects the assessment endpoints, the measurement endpoints, the measurement receptors, the food webs, and the conceptual model.

5. Issue: Calculating hazard quotients using NOAEL and LOAEL TRVs.

ERAs often exhibit some procedural inconsistencies in the risk calculations with regard to the required elements that are outlined in the TRRP rule and the TCEQ Guidance. The correct procedure is as follows: Hazard quotients (HQs) using the no observed adverse effect level (NOAEL) toxicity reference value (TRV) and both the NOAEL and lowest observed adverse effect level (LOAEL) TRVs are to be calculated according to §350.77(c)(6) and (7) of the TRRP rule, respectively. Where only one of these TRVs is available from the literature, uncertainty factors presented in the TCEQ Guidance can be used for extrapolation to the other. The initial HQ calculation (required element 6) should use the NOAEL and reasonably conservative exposure factors. In the refined HQ calculation (required element 7), the exposure factors (e.g., diet, bioavailability, home range, mobility, and life-cycle attributes) can be adjusted and both NOAEL and LOAEL TRVs are used in the estimate. If the results of these calculations indicate that NOAEL HQ > 1 > LOAEL HQ, then the development of PCLs may not be warranted as the PCL would normally lie between a lower-bound NOAEL-based value and an upper-bound LOAEL-based value. However, even in this event, the justification for not developing a PCL should be based on the strengths and weaknesses in the data and should be discussed in the uncertainty analysis. The TCEQ Guidance outlines the methods for determining a final ecological PCL for a COC that lies between the NOAEL and the LOAEL-based values and should be reviewed prior to PCL calculation. Where a receptor species is selected as a surrogate for a threatened/endangered species, the PCL must be based on a NOAEL TRV only.

6. Issue: Providing documentation for TRVs.

The text and the tables in an ERA should provide justification and references for the TRVs provided for each COC/receptor pair. TRVs used in the ERA should be thoroughly documented and discussed. Documentation should include: a reference for the TRV study, study species, study endpoints, duration of tests, type of TRV (e.g., chronic NOAEL, LD_{50}, subchronic LOAEL), application of uncertainty factors, use of allometric scaling factors to convert test species TRVs to wildlife TRVs, (see following issue) and the basis for selection of each TRV. Risk assessments often fail to discuss why a particular TRV is selected; they simply indicate the TRV and the effect, which is inadequate. If a literature compilation document (e.g., Oak Ridge National Laboratory) is used as a source of toxicity values, the original literature source listed in the compilation document should be cited and reviewed for applicability. Note that compilations of TRVs often do not use the body scaling approach preferred by the TCEQ, which is described in Sample and Arenal (1999) and discussed in Issue 7.

In addition to compilation references, persons should consult the open literature to obtain toxicity values for the COCs, or for suitable surrogate compounds. Relevant toxicological endpoint(s) associated with the surrogate selection should be reviewed to evaluate whether the candidate surrogate is appropriate given the selected receptors/food web. If this is not possible, persons should strive to qualitatively evaluate potential risks in the uncertainty analysis. This could include a discussion of the relative toxicity associated with similarly structured chemicals or the chemical class in general, fate and transport characteristics relative to ecological exposure, the expected bioavailability of the COC at the affected property, relative distribution of the COC, and/or a discussion of available toxicity information (that may not reflect a preferred effects endpoint). Also see Issue 26 for more discussion on the use of the uncertainty analysis.

7. Issue: Using scaling factors for TRV development.

Regarding the use of scaling factors to convert NOAEL and LOAEL values from those for test species to wildlife species, the agency advocates the use of COC-specific allometric scaling factors as discussed in Sample and Arenal (1999), rather than earlier methods outlined in Sample et al., (1996). This revised approach is discussed in the TCEQ Guidance and should be used in ERAs submitted to the agency. Risk assessments often ignore this completely, especially where compilation references are used as the source for TRVs.

8. Issue: Calculating food and soil/sediment ingestion rates.

There has been much concern over consistency issues with the use of food ingestion rates, soil/sediment ingestion rates, percent incidental soil/sediment ingestion, and wet weight versus dry weight. For instance, the TCEQ ERA guidance recognizes both U.S. EPA (1993), henceforth the Handbook, and U.S. EPA (1999), henceforth the Combustion guidance, as being reliable sources of life history and toxicity information, respectively, for ecological receptors. However, there is some concern over using the receptor food ingestion rates from the Handbook and the soil/sediment ingestion rates from the Combustion guidance to calculate the dose. Ideally when these two ingestion rates are converted to the same units and are both in dry weight, the resulting quotient from dividing the soil/sediment ingestion rate by the food ingestion rate will be equal to the percent soil ingestion for the receptor described by Beyer et al. (1994) or other similar reference that quantifies incidental soil/sediment ingestion. Unfortunately, this is not often the case when using these values from these different sources.

It would appear that since Table 5-1 in the Combustion guidance lists both of these ingestion rates and since the footnotes in this table indicate that the soil/sediment ingestion rates are in dry weight and are calculated from measured percentages of soil/sediment ingestion from the Beyer et al. (1994) study, that using only this source would be a solution. However, there appear to be some miscalculations in the food ingestion rates in the Combustion guidance, most of which can be attributed to using an inappropriate percent moisture when converting dry weight (DW) to wet weight (WW). Nevertheless, as presented in the Combustion guidance, the concept of using food ingestion rates derived from the Nagy (1987) allometric equations in combination with the percent soil/sediment ingestion values obtained from the Beyer et al. study to estimate soil/sediment ingestion rates is sound.

Therefore, for consistency purposes, it is strongly preferred that the Nagy (1987) allometric equations as presented in Section 3.1 of the Handbook be used to derive a food ingestion rate for the receptor, even if the receptor is one of the species presented in the Handbook (e.g., robin) and a food ingestion rate from other sources is already listed. The person should use the general equations for all birds (Equation 3-3) and all mammals (Equation 3-7); however, several additional equations are available for use for different types of birds (passerines, nonpassarines, and seabirds), mammals (rodents and herbivores), and iguanid lizards (herbivores and insectivores). It is important to remember that the Nagy (1987) equations are unit specific (grams or kilograms) for body weight and that conversion from grams to kilograms and normalization to body weight should only occur after the equation has been solved, as shown in the example below. Also, the resultant allometric food ingestion rate is in DW. The food ingestion rate can be converted to WW as needed to be consistent with the individual food components (i.e., prey and vegetation) in order to calculate the dose from food. As presented in the Combustion guidance, the percent moisture content of food is assumed to be 88% for plant matter (herbivores), 68% for animal matter (carnivores), and 78% for an equal portion of plant and animal matter (omnivores). This means that the DW food ingestion rate would need to be divided by 0.12, 0.32, or 0.22, respectively, in order to obtain the corresponding WW value. Additional percent moisture content of more specific prey is presented in Table 4-1 of the Handbook and includes: 68% for small fish (piscivores), 79% for aquatic invertebrates (aquatic invertivores), and 71% for terrestrial invertebrates (terrestrial invertivores).

Also for consistency purposes, the percent soil/sediment ingestion for that receptor should be obtained, extrapolated, or estimated from the Beyer et al. study or other comparable sources. The premise here is that when comparing diets and feeding strategies of ecological receptors, it is much easier to comprehend the relative percentages of soil/sediment in the diet than it is the relative soil/sediment ingestion rates. For those receptors where no source of percent soil/sediment ingestion can be found, reasonable surrogates can be used (e.g., red fox for coyote, swift fox, and weasel). For those receptors where no source can be found and no surrogate seems appropriate, a reasonable estimation can be proposed. For example, it is expected that raptors will have a low percentage of soil/sediment ingestion (e.g., 2%) while those receptors with diets consisting of a significant portion of soil/benthic invertebrates will have a considerably higher soil/sediment ingestion. In the case of the robin, although the Beyer et al. study did not evaluate the robin, it did evaluate the woodcock. If the woodcock was assumed to eat 100% soil invertebrates which resulted in 10.4% soil ingestion, then a robin eating 50% invertebrates could be assumed to ingest 5.2% soil. This percent soil/sediment value (DW) should then be multiplied by the allometric food ingestion rate (DW) to obtain the soil/sediment ingestion rate (DW), as shown in the example below. This soil/sediment ingestion rate (DW) can then be multiplied by the representative concentration of the COC to obtain the dose from the medium.

Example Estimation of the Food Ingestion Rate (IR_{food}) and Soil/Sediment Ingestion Rate (IR_{soil}) for the Raccoon:

1. Obtain a representative body weight (in grams or kilograms) from the Handbook:
   BW = 5600 g or 5.6 Kg (average of all adult body weights)

2. Obtain the Nagy (1987) allometric equation for all mammals from the Handbook (Equation 3-7):
   IR_{food} (g/day DW) = 0.235 * $BW^{0.822}$ or
   IR_{food} (Kg/day DW) = 0.0687 * $BW^{0.822}$

3. Calculate IR_{food}.:
   IR_{food} g/day DW = 0.235 * ($5600^{0.822}$) or IR_{food} Kg/day DW = 0.0687 * ($5.6^{0.822}$)
   IR_{food} g/day DW = 0.235 * 1205.07 — IR_{food} Kg/day DW = 0.0687 * 4.12
   IR_{food} g/day DW = 283.19 — IR_{food} Kg/day DW = 0.283

4. Convert IR_{food} g/day into Kg/day (if the gram-specific equation was used):
   IR_{food} Kg/day DW = 283.19 ÷ 1000
   IR_{food} Kg/day DW= 0.283

5. Normalize IR_{food} to body weight of raccoon:
   IR_{food} Kg DW/Kg BW-day = 0.283 Kg/day DW ÷ 5.6 Kg
   IR_{food} Kg DW/Kg BW-day = 5.06E-02

6. Obtain percent soil ingestion from Beyer et al. (1994) or comparable source:
Percent soil ingestion for racoon = 9.4% (or 0.094)

7. Multiply normalized IR_{food} DW by the percent (fraction) soil ingestion to obtain a soil ingestion rate IR_{soil} :
IR_{soil} Kg DW/Kg BW-day = 5.06E-02 * 0.094
IR_{soil} Kg DW/Kg BW-day = 4.75E-03

8. To obtain IR_{food} WW, divide the body weight-normalized IR_{food} DW by the fraction of dry weight in the food of the diet:
IR_{food} Kg WW/Kg BW-day = 5.06E-02 ÷ 0.22 (for omnivore)
IR_{food} Kg WW/Kg BW-day = 2.3E-01

9. Issue: Including soil/sediment as part of the total diet.

The percentage of food items in the diet of the measurement receptors should sum to 100% and not be normalized to include the soil/sediment ingestion rate. See Section 3.9.2.3 in the TCEQ Guidance for further discussion.

10. Issue: Protecting the benthic community, evaluating risks to upper trophic level receptors, and using the expedited stream evaluation.

There appears to be some confusion about the intent and text in the TCEQ Guidance regarding water bodies where there is a diminished benthic community that does not warrant the development of a benthic PCL for sediment. The TCEQ Guidance (and recent updates) identifies certain water bodies and conditions where the benthic community may be diminished for reasons unrelated to releases of COCs from an affected property subject to the TRRP regulation. For these water bodies (e.g., intermittent streams, creeks, or ditches, without perennial pools, or those that are concrete-lined on the bottom and sides), TCEQ believes it is unnecessary to determine an ecological PCL for sediment that is protective of the benthic invertebrate community. However, this does not preclude an evaluation of risks to higher trophic level organisms that may forage in these types of water bodies or nearby water bodies (that could become impacted as a result of sediment COC transport). This is often omitted completely. Nor does this preclude the agency from requiring additional evaluations at these types of locations on a case-by-case basis where significant exposure conditions warrant (e.g., acutely toxic concentrations, presence of non-aqueous phase liquid).

Regarding the "Expedited Stream Evaluation" (see Section 2.6 of the Guidance), the idea is to take a subset of those water bodies identified as not needing a benthic PCL (i.e., intermittent streams without perennial pools) and determine if there is a need to develop PCLs for the higher trophic level receptors, without going through a formal Tier 2 assessment. If the water body qualifies for the expedited stream evaluation, then there is no need to perform a Tier 2 ERA on the intermittent section of the stream or ditch. That evaluation moves downstream to an area that is more conducive to aquatic life and/or wildlife. To restate, just because a water body is recognized as not needing a benthic PCL, it does not preclude the evaluation of risk to higher trophic level receptors, either through a Tier 2 assessment, or in the case of intermittent streams without perennial pools, through an expedited stream evaluation.

11. Issue: Excluding routinely dredged water bodies (and benthic PCL exclusion).

The exclusion regarding the development of sediment PCLs for routinely dredged water bodies only includes the portion of the channel that is actually dredged at a frequency of every three years or less. Risks to benthic communities that are potentially exposed to COCs in the sediments that are not routinely dredged (such as shallow waters near the banks that are not used for shipping traffic) should be evaluated where the exposure pathway is complete.

12. Issue: Evaluating PAHs, particularly in sediment.

Although sediment benchmarks are provided for individual PAH compounds, low and high molecular weight PAHs (marine only), and total PAHs, the benchmarks for total PAHs are the most relevant for evaluating risk in an ERA. This is because PAHs almost always occur in the environment as mixtures. Values for individual and low and high molecular weight (MW) PAHs are provided as guidelines to aid in the determination of disproportionate concentrations of more toxic individual PAHs within the mixture that may be masked by the total. Therefore, PAHs may be screened out using the total PAH benchmark even if individual, low MW, or high MW PAH benchmarks are exceeded. This reflects a policy shift from that in the original 2001 Guidance. However, any exceedances of individual, low MW, or high MW PAH secondary effect levels (see Table A-2 of Appendix A of the TCEQ Guidance, and recent updates) may indicate adverse effects and therefore should be further discussed (e.g., in the uncertainty analysis).

If appropriate, individual PAHs that exceed the secondary effect levels should be retained beyond the benchmark screening step (required element 1). The total PAH benchmarks are based on the thirteen parent PAH compounds listed in Table 3-3 of the ERA guidance (personal communication with Don MacDonald; October, 2003), meaning that if the person wishes to use a total PAH benchmark for screening, it is appropriate to have a value for all thirteen PAHs included in the sum. This is accomplished by using proxy values for the analyzed but undetected PAHs, and adding them to the concentrations of the detected PAHs for comparison to the total benchmark, assuming that the individual PAH has not been eliminated in accordance with the criteria at §350.71(k) of the TRRP rule. (A general discussion of proxy values is provided in §350.51(n) and appropriate methods for the determination of proxy values will be defined in the TRRP guidance titled *Determining Representative Concentrations* (RG-366/TRRP-15)). However, when significantly less than the thirteen parent PAHs are determined to be COCs, or if all of the thirteen parent PAHs are not included in the analyte list, screening must be based on individual PAH benchmarks.

13. Issue: Evaluating reptiles and amphibians qualitatively and/or quantitatively.

Reptiles and amphibians are often not identified as measurement receptors in the ERA or are not evaluated in any appreciable manner. It is acknowledged that there may not be oral dose toxicity data for amphibians and reptiles for all COCs. Limited ecotoxicological information on reptiles and amphibians is presented in Sparling et al., (2000) and Pauli et al., (2000). Immersion and dermal absorption data are also available.

Immersion and dermal absorption are appropriate pathways for evaluation in place of or in conjunction with oral dose data, particularly for amphibians. In the event that no amphibian toxicity data (e.g., LC_{50} data) for the specific COCs can be found, if it can be shown that surface water concentrations meet water quality standards and sediment concentrations are protective of benthic invertebrates, then amphibians can be assumed to be protected. Additional effort may be required for threatened/endangered species. For example, persons can apply a safety factor of some sort or be more rigorous in evaluating data (e.g., use maximum concentrations or other more conservative statistics).

For threatened/endangered species of reptiles with no toxicity data, a TRV for a bird with a similar diet can be used in combination with reptile life history information (e.g., body weight, food ingestion rate) to calculate a dose and a hazard quotient. Although the agency does not normally encourage across-class extrapolations, this is preferable where a threatened/endangered species may occur at a site. Exposure factors for the reptiles should be documented/justified. If this approach is used, it is recommended that an uncertainty factor of 10 be used for the across-class extrapolation. All assumptions here will need to be discussed in the uncertainty analysis.

Where there are no threatened/endangered species concerns, qualitative evaluations of potential risks to reptiles are encouraged and could include an evaluation of the literature to identify:

- General information concerning reptilian sensitivity to broad classes of chemicals, as appropriate to the affected property
- Body tissue residue studies associated with effects regarding the subject COCs
- Residue studies at COC-impacted and non-impacted sites
- General population studies at impacted and non-impacted sites with similar COCs, and
- Blood-dosing studies related to effects associated with site chemicals.

In any case, the ERA could also provide a discussion of the likelihood of exposure to site COCs given the niche of the reptiles, and the fate and transport characteristics of the COCs in affected media.

14. Issue: Using the reasoned justification clause.

In general, TCEQ supports the early closure of sites and their exclusion from the ERA process where appropriate. To this end, the reasoned justification clause in the TRRP rule (see §350.77 (a)) was developed to consider a planned response action that is designed to address human health exposure, but which coincidentally addresses ecological exposure as well, thus allowing the ERA to be concluded without having to conduct a Tier 2/3 ERA. Any submittals under the reasoned justification clause should contain the following:

- A clear statement that identifies the document as being a reasoned justification proposal
- An identification of all potential ecological exposure pathways and, if applicable, how human health protection numbers (e.g., total soil combined PCLs) are protective of ecological receptors
- A discussion, if applicable, of how the proposed remediation that is primarily for purposes of protecting human health will coincidentally address ecological risk by eliminating ecological exposure pathways.

Be advised that this concept is limited to response actions for soil, since surface water/sediment response actions are usually performed to reduce ecological receptor exposure, not human health exposure, and would therefore not really be consistent with the intent of the rule.

NOTE: This issue has been included in the proposed TRRP Rule amendments. The proposed revision will recognize any remediation (i.e., not just that for human health reasons) that is protective of ecological receptors.

15. Issue: Evaluating soil vs. sediment as an exposure medium.

The TRRP rule defines the material lying below surface waters, including intermittent streams, as sediment. It is appropriate to evaluate ecological exposure from both the dry stream bottom, and from sediment associated with intermittent streams. Hence, persons should evaluate exposure to land-based ecological receptors when the stream bottom is dry, and should perform normal surface water/sediment evaluations for times when the stream bottom is wet. Consider that a terrestrial receptor (e.g., rabbit, fox) may forage along the dry stream bottom during arid times, and that an aquatic-based receptor (e.g., muskrat, raccoon) may forage within the stream during times that the stream contains water. The exposure duration for a particular receptor can be adjusted to reflect the usual dry/wet cycles for the water body in question. The TCEQ Guidance allows the evaluation of one scenario or the other based on site-specific considerations; however, a convincing, well-documented argument for not quantitatively evaluating the remaining scenario must be made in the uncertainty analysis. More discussion of this issue is provided in Section 3.9.2.6 of the ERA Guidance.

16. Issue: Discussing/documenting background concentrations.

Risk assessments often fail to provide the history/rationale for the development of background concentrations. If the TCEQ Remediation Division program area has already approved property-specific background concentrations, a reference to the document(s) proposing the background values and the TCEQ approval correspondence should be provided. The TCEQ ecological risk assessor can then discuss/verify this with the project manager. It would also be helpful, but not a requirement, to include these documents/correspondence as attachments to the risk assessment, along with a map that indicates the sample locations for the background determination. The risk assessment should always indicate if the background values are site-specific or statewide medians (for metals in soils). If the risk assessment itself is being used as a vehicle to propose property-specific background concentrations, this can be difficult without prior coordination with the project manager, risk assessor, natural resource trustees, and TCEQ statistician (in some cases).

17. Issue: Evaluating soil vs. sediment, including consideration of background.

Sediment background concentrations should not ordinarily be equated with soil background, including use of the Texas statewide median values for soils defined in the TRRP rule. Normally, the use of soil background concentrations to evaluate sediment constituents is not appropriate since the aquatic and terrestrial sediment and soil environments (chemistry and biology) are dissimilar and cannot be used interchangeably. For ephemeral streams, however, this approach (use of soil background concentrations) may be useful where perennial pools do not occur, and there is adequate justification provided to evaluate the stream bottom as soil only (see Issue 15).

18. Issue: Evaluating surface soil and sediment sample depth.

Historical soil data collected from depths of 0-2 feet and sometimes 0-5 feet is often presented as "surface soil" data in ERAs. For ecological exposure pathways, the TRRP rule defines the soil zone extending from ground surface to 0.5 feet in depth as surface soil (§350.4 (a)). Persons should consider if use of 0-2 or 0-5 feet sample data may "dilute out" surface soil concentrations if the majority of the soil contamination is in the first half foot. Persons could compare soil concentrations for samples collected in the same bore hole at separate depths, or persons could compare the maximum concentrations for each COC for samples collected in the first half foot, with those collected at deeper depths. This would be an appropriate approach to demonstrate that the use of data from deeper soil intervals is a conservative representation of the actual surface soil concentrations at a site.

Since the TRRP rule has been in effect since September 1999, persons should be aware that TCEQ ERA staff are becoming less willing to accept this historical data in lieu of surface soil samples collected in the first half foot of soil. Alternatively, if burrowing receptors are evaluated or food/prey items may occur at depths greater than 0.5 feet, the soil data used in the exposure calculations should conservatively reflect actual subsurface soil concentrations. Assessment planning should consider potential ecological exposure areas and potential receptors, rather than attempting to apply data intended to support human health considerations to ecological exposure scenarios.

Regarding sediment sample depth, sediments within the top 4 inches (10 centimeters) are often considered to represent the biologically active zone, which is usually the sediment interval evaluated in an ERA. However, this is not always the case. Selection of a particular sediment sample depth for use in the ERA should be supported with a discussion of any observations of the biologically active zone for the particular sample site. Field sampling crews should be aware that it is important to make these observations and judgments in the field when sediment samples are collected.

Persons should reference Sections 1.5 and 3.9.2.6 of the ERA Guidance for additional discussions related to affected property assessment considerations and the point of exposure for ecological receptors.

19. Issue: Documenting the presence/absence of threatened/endangered species.

ERAs often do not clearly present the evidence used to conclude that threatened/endangered species are not present at the affected property, or they fail to discuss threatened/endangered species at all. Both federally-listed <u>and</u> state-listed species should be addressed. In order to eliminate a threatened/endangered species as being potentially present, an ERA should provide supporting documentation from a wildlife management agency to confirm the absence of the protected species on the affected property.   Where input in sought from a wildlife management agency, it is preferable to consult with the Texas Parks and Wildlife Department (TPWD) rather than the U.S. Fish and Wildlife Service, since there are more state-protected species than federally-protected species, and the county lists provided by the TPWD reflect both state and federal species. Celeste Brancel with TPWD's Wildlife Habitat Assessment Program, Threatened and Endangered Species Office is the current contact. However, due to time constraints associated with the remediation program, it is often not possible for persons to obtain a consultation with a wildlife management agency.

In this case, the person should provide a convincing discussion of the lack of suitable habitat by comparing the available habitat with the habitat needs of threatened/endangered species that could possibly occur in the county. It is not enough to simply state that no protected species are known to occur at an affected property. This is different from a supported statement that none are expected to occur based on the available habitat and the needs of a threatened/endangered species. A copy of the county list should be included to support this discussion. The TCEQ will also consider testimony from local experts (e.g., an academician) regarding the likelihood that a particular protected species could occur at the site. Lack of visual observation of a protected species on the affected property is an insufficient justification alone, as is a lack of a "critical habitat" designation.

If the presence or absence of a protected species cannot be determined, then the species should be considered as being present and potentially impacted. The ERA must then demonstrate through exposure or PCL calculations that the species will either not be impacted or that protective PCLs will be developed. These demonstrations are usually accomplished by calculating the exposure and evaluating the risk to a receptor that is a surrogate (a receptor from the same feeding guild) for the protected species.   The ERA should also explain why the particular receptor chosen is a suitable surrogate for the sensitive species, as this discussion is often omitted in ERAs. If a suitable surrogate receptor cannot be found, then the protected species must be included in the risk assessment as a measurement receptor and evaluated for exposure and food chain effects. This is accomplished by using life history information (e.g., body weight, diet composition, home range) for the protected species in conjunction with body scaled TRVs, allometric equations, and any appropriate uncertainty factors to estimate risk. It is inappropriate to eliminate the surrogate or the protected species from evaluation based on a lack of data or uncertainty in the available data.

20. Issue: Using an EMF for migratory species, including threatened/endangered species.

Often, persons propose to use an exposure modifying factor (EMF) to adjust for migration of a measurement receptor. For example, an EMF of 0.5 may be proposed in the refined HQ calculations where a particular bird is assumed to be at the affected property six months out of the year. In this case, applying an EMF may be inappropriate. The measurement receptors represent their respective feeding guilds as a whole, and all guilds will probably have permanent residents present at an affected property. Thus, all the receptors should normally be evaluated as permanent residents, unless it can be shown that the measurement receptor is the most exposed member of the guild even with the adjustment for migration. Where a threatened/endangered species is present, is migratory, and cannot be represented by a surrogate, it is appropriate to make an exposure adjustment for this particular receptor only (not the guild as a whole) provided that any resulting PCL is based solely on the NOAEL TRV. Of course this would dictate that there are separate calculations made for the threatened/endangered species and a different receptor representing the guild as a whole.

21. Issue: Using AUFs and consideration of preferential foraging.

Area use factor (AUF) adjustments are often proposed based on literature values for the foraging/home range of a measurement receptor. Sometimes these adjustments fail to recognize that ecological receptors will only forage in areas of suitable habitat (e.g., wooded areas for gray foxes; smaller waterways and lakes for mink) in and adjacent to an affected property. Typical AUF calculations are often represented by a simple ratio where the size of the affected property (that was not excluded by the Tier 1 Checklist) is divided by the size of the home range or foraging area for the receptor in question. Ordinarily, if the home range of the receptor were less than the size of the affected property, the AUF would not be adjusted (the default value of 1 would be used), and this is appropriate for the initial assessment in Required Element 6. However, almost always, the affected property does not consist entirely of suitable habitat. Therefore, it is preferred that for the refined assessment (Required Element 7), that the person only consider the amount of available suitable habitat on the affected property when determining an appropriate AUF. Occasionally, the affected property may be located within or adjacent to highly developed industrial areas or other land uses or topography that is not suitable for a particular receptor. An ecological receptor that occurs within any limited available habitat of this type of affected property may be restricted to this limited area, regardless of the size of its typical home range, because there is no other suitable habitat available nearby (i.e., the suitable habitat of the affected property becomes an ecological island). In this case, the default value of 1 would be appropriate.

22. Issue: Documenting metal speciation.

If it is concluded that PCL derivation (and remediation) is unwarranted based on the form of the metal used in the original toxicity study used to derive the TRV, the preferred justification is property-specific data documenting the form of the metal present. Alternatively, persons may provide a detailed justification that addresses the known site chemistry and fate processes that influence the chemical form of the COC in the environment, a literature reference and rationale regarding the assumed chemical form, a literature reference regarding the alternate toxicity values, and/or literature sources for any assumed physicochemical properties. In general, metals are assumed to be in the bioavailable form (or bioaccumulative form) unless sufficient analytical data are available to identify the metal species that are present.

23. Issue: Using AVS/SEM to evaluate metal bioavailability and sediment toxicity.

It is acknowledged that the acid volatile sulfide/simultaneously extracted metals (AVS/SEM) methodology is widely used and is recognized in TCEQ's ERA guidance. While AVS/SEM is understood to be a geochemically feasible method to predict the potential biological availability of metals found in sediments, it is necessary to recognize that this technique is also bound by a number of assumptions and limitations. These include: the high potential for changes in sediment geochemistry to occur; the fact that most benthic invertebrates tend to concentrate in the oxidized sediments where occurrence of sulfides is not favored and the method does not consider the ingestion of sediment by receptors; and that the methodology is only applicable in anaerobic sediments and for a limited number of metals. Additional limitations of this methodology are discussed in an article in the SETAC Globe (Morse and Rickard, 2004). It would be inappropriate to use this method to make any assertions regarding potential risks to organisms exposed to sediments containing metals without considering these limitations.

Since the method only applies to some sediments, at some times, for some metals, it should be used conservatively. In addition, the outcome of the entire ERA should never be placed solely on the AVS/SEM methodology. However, using the AVS/SEM analysis to adjust the bioavailability of the metals to a reduced (but non-zero) amount, combined with the adjustment of other exposure factors (e.g., using a 95% UCL instead of the maximum concentration), would yield more meaningful results that could be presented in the uncertainty analysis discussion. These results, coupled with the supported conclusions from the uncertainty analysis that the risk is overstated, would provide a more desirable weight-of-evidence rationale for obviating the risk to benthic invertebrates.

The AVS/SEM theory is intended to be used to address the bioavailability and toxicity of metals in sediments. An excess of AVS compared to SEM on a molar basis predicts that metals will be bound to the sediments and will not occur in interstitial water and thus will not be bioavailable to benthic organisms through associated exposure routes (dermal, gills, water ingestion). This theory does not appear to address sediment and food ingestion, and subsequent food chain transfer. However, persons have attempted to use the AVS/SEM theory to conclude that there are no risks to upper trophic level receptors based on site-specific AVS/SEM ratios. Since there appear to be few, if any, studies addressing food chain transfer, it is not currently advisable to use AVS/SEM results to evaluate risks to upper trophic level receptors until such time when more definitive studies are available. Additional information on this issue is being sought from stakeholders.

24. Issue: Evaluating the indirect sediment exposure pathway (fish and invertebrates as food) for bioaccumulative COCs.

The aquatic portion of an ERA should consider exposure to bioaccumulative COCs in sediments through the use of sediment uptake factors for that portion of the measurement receptor's diet that is sediment based. Often, sediment uptake through the food chain is not represented in the ERA calculations. Instead, prey tissue concentrations for aquatic invertebrates and/or fish are estimated using bioconcentration factors (BCFs) based on surface water concentrations. In these cases, sediment food chain transfer to invertebrates and fish is not modeled for any receptor. Certainly, it is appropriate to evaluate exposure from COC transport through the water column to aquatic biota; however, TCEQ believes that the evaluation of COC uptake from the water column alone will greatly underestimate or overlook the potential for exposure to sediment COCs in the food chain.

For bioaccumulative COCs, it may be appropriate to assume a "generic" fish prey species receives an equal proportion of uptake from the water column and sediments by using a water-based uptake factor for 50% of the diet, and a sediment-based uptake factor for the remainder of the uptake in order to predict fish tissue concentrations that reflect exposure from both water and sediments. Similarly, persons can apply the same approach to receptors that may ingest water column invertebrates or benthic invertebrates depending on the feeding habits of the measurement receptor. Consideration of fish mobility and extent of sediment contamination should be made as well. The use of food chain multipliers (FCM) as an estimation of the fish tissue concentration could also be considered. For example, one could determine a sediment to invertebrate BSAF, then apply a FCM for the invertebrate to fish pathway.

25. Issue: Determining measurement receptor selection for indirect sediment exposure for piscivorous/invertivorous birds.

Risk assessments often fail to select an avian receptor that will conservatively reflect sediment exposure. For instance, we often recommend that the spotted sandpiper should be selected as a measurement receptor over the great blue heron. The lower body weight and higher sediment ingestion rate make the sandpiper a better representative species for determining risk from sediment. If sandpipers or other smaller shorebirds are not present because of lack of habitat, a smaller wading bird (e.g., green heron, yellow or black-crowned night heron) is preferred over the great blue heron. In some risk assessments, a heron or kingfisher is designated as the only avian predator with the assumption that fish will dominate the bird's diet. In general, TCEQ prefers that persons model birds that are more likely exposed to COCs due to their feeding strategy and food type. Birds with lower body weights and higher percentages of invertebrates in the diet are generally preferred to maximize the exposure from impacted sediment.

26. Issue: Using the uncertainty analysis appropriately.

Usually, the function of the uncertainty analysis is primarily to describe the potential for under- or overestimation of risks. This element of the discussion should not be omitted. Beyond this, the uncertainty analysis serves other purposes in the context of the TRRP ERA requirements. When used properly, the TRRP rule specifies that the uncertainty analysis can be used to justify the need for calculating <u>or not</u> calculating a PCL for a given COC/receptor pair. This may be accomplished by considering indications of potential ecological risk in context with the likelihood of that risk at the affected property. Factors that should be evaluated include the location and aerial extent of the COCs, the degree to which the TRV is exceeded, and the expected half-life of the COCs in the particular environment. In any event, the uncertainty analysis should not be used as a means to dismiss the need for a PCL where conservative assumptions are not adjusted throughout the risk assessment such that the hazard quotient calculations are inflated. Rather than carry this over-conservatism into the uncertainty analysis discussion, TCEQ prefers that the exposure assumptions available for adjustment be modified in Required Element 7 such that the results are best estimates of either acceptable risk or risk that requires a risk management decision.

An example of how the uncertainty analysis can be used to determine the appropriateness of PCL development is as follows: If, after completing the HQ calculations it is determined that for a particular COC, the NOAEL HQ/HI > 1 but that the LOAEL HQ/HI < 1, the uncertainty analysis may state that no PCL is necessary for that COC. This is justified because, ideally, any potential media remediation would be to a PCL that is bounded by these two effect levels. However, additional justification would be needed in the uncertainty analysis when the LOAEL HQ/HI approaches unity and there are indications that risk may have been underestimated in other areas. HQs/HIs greater than 1 based on less conservative exposure assumptions and LOAEL-based TRVs provide a reasonable basis to develop PCLs for consideration in remediation planning, as ecological impacts may be expected.

27. Issue: Identifying and using uptake factors.

Uptake factor terminology should distinguish when food exposure is or is not considered in the value (e.g., media only exposure as BCF and media and food exposure as BAF). For COCs with Log K_{ow} values greater than five, biomagnification up to the trophic level of the prey item must be considered in determining total dose to wildlife, unless COC-specific justification is provided (e.g., measurement receptor/guild is capable of metabolizing COC). A default uptake factor of 1 is often assumed when uptake factors are not readily available. This would be inadequate for COCs with Log K_{ow} values greater than five, as the potential for biomagnification is present. Section 3.9.2.1 and Box 3-3 of the ERA Guidance discuss the selection and use of uptake factors. References used to obtain uptake factors should be clearly documented. Where a particular reference provides individual values (i.e., mean, median, 90th percentile), the selected value should be clearly identified. Where a particular formula in a reference is used to derive an uptake factor, this should be clearly indicated.

28. Issue: Distinguishing between wet weight/dry weight-based inputs.

TCEQ requires that soil and sediment data be reported on a dry weight basis. Therefore, it is important to ensure that ingestion rates for soil and sediment are also presented on a dry weight basis. A common mistake is to estimate media ingestion rates as a percentage of a wet weight-based food ingestion rate. Food ingestion rates may be expressed on either a dry weight or wet weight basis. Therefore, the person should ensure that this is consistent with any uptake values used. In other words, both the food ingestion rate and the uptake factor should be expressed on a dry-weight or wet-weight basis. With this in mind, where allometric equations are used to determine food ingestion rates, persons should be aware that these values are usually expressed on a dry weight basis. Body weight is always expressed on a fresh (wet weight) basis. Any dry/wet weight conversions should be clearly explained in the text or tables of the risk assessment, including the reference/assumptions for percent moisture in the food/prey. See related discussion in Issue 8.

29. Issue: Evaluating the groundwater-to-surface water/sediment pathways.

For sites where there is a groundwater release to surface water and sediment, the groundwater release itself is often not evaluated in the scope of the ERA. Groundwater data should be evaluated for potential risks to ecological receptors, and where appropriate, groundwater-to-surface water (${}^{SW}GW$) or groundwater-to-sediment (${}^{Sed}GW$) PCLs should be developed that are protective of ecological receptors.

Be aware that TRRP requires that persons use concentrations measured in groundwater at or immediately upgradient of the zone of groundwater discharge to surface water to determine if COCs in groundwater have discharged to surface water (§350.51 (f)). TRRP further states that the prescribed groundwater-to-surface water POE is within the groundwater (§350.37 (I)). This requirement is based on the premise that groundwater concentrations will be a conservative indicator of surface water concentrations and that the assessment is appropriate for the affected property considering the hydrogeology (§350.51 (a)). In essence this means that for the groundwater-to-surface water pathway, TRRP requires that persons rely on groundwater data rather than surface water data to evaluate this pathway. The text box in Section 3.9.2.6 of the ERA Guidance provides an example calculation for the determination of a groundwater PCL protective of an upper trophic level receptor, with the incorporation of a groundwater-to-surface water dilution factor. Furthermore, groundwater releases to surface water should also be evaluated for potential risks to aquatic life and compliance with the state and federal water quality criteria.

It is certainly appropriate to sample and analyze surface water as part of an ERA. The key point is that where the only mechanism of release is via groundwater, the TRRP rule requires that groundwater data, rather than surface water data, be used primarily to address this pathway. Ambient surface water data should be evaluated in the context of the ERA where potential surface water impacts result from multiple pathways (e.g., spills, runoff) and/or historical impacts are present. Surface water data can also be used to verify the validity of a site-specific groundwater-to-surface water dilution factor or to supplement groundwater data whenever well placement at the groundwater/surface water POE is compromised.

Sediment sampling and analysis is appropriate for groundwater releases to sediment. In most cases, sediment samples should be collected in the expected area of groundwater discharge to the sediment whenever COCs are present **above detection** in groundwater at the interface wells. Compliance with the surface water RBEL **has no relevance** to the question whether sediment should be sampled in the interface area. This sediment data would then be evaluated within the normal context of an ERA.

More discussion of the groundwater-to-surface water/sediment pathways, and the use of dilution factors for these pathways, is provided in TRRP-24 (TCEQ, 2002).

30. Issue: Applying the *de minimus* soil exclusion criterion in the Tier 1 checklist.

It is appropriate to apply the results of the first two soil exclusion criteria (Subparts B and C) in the Tier 1 Checklist to the conditions and questions associated with the *de minimus* criterion (Subpart D). For example, let's say that by using human health PCLs, it was determined that the affected property is ten acres in size. Nine of the ten acres are characterized by various types of disturbed ground (e.g., pavement, buildings, process areas), so these nine acres of the affected property meet the conditions of Subpart B (i.e., it is not attractive to wildlife or livestock). In this scenario, these nine acres would be excluded under Subpart B and the remaining one acre would be evaluated in Subpart D. If the conditions of the *de minimus* criterion were met for this one acre, then the entire affected property would have been excluded under a combination of the Subpart B and D criteria. It is important to remember that the qualifying conditions of Subparts B and D must be met before the applicable exclusion criteria can be considered.

Acronyms.

AUF – area use factor
AVS – acid volatile sulfide
BAF – bioaccumulation factor
BCF – bioconcentration factor
BSAF – biota sediment accumulation factor
COC – chemical of concern
DW – dry weight
EMF – exposure modifying factor
ERA – ecological risk assessment
FCM – food chain multiplier
HI – hazard index
HQ – hazard quotient
K_{ow} – octanol water partition coefficient
LOAEL – lowest observed adverse effect level
MW – molecular weight
NOAEL – no observed adverse effect level
PAH – polycyclic aromatic hydrocarbon
PCL – protective concentration level
POE – point of exposure
^{Sed}GW – groundwater-to-sediment PCL
SEM – simultaneously extracted metal
SETAC – Society of Environmental Chemistry and Toxicology
^{SW}GW – groundwater-to-surface water PCL
TCEQ – Texas Commission on Environmental Quality
TNRCC – Texas Natural Resource Conservation Commission
TRRP – Texas Risk Reduction Program
TRV – toxicity reference value
UCL – upper confidence limit
WW – wet weight

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