

ECOLOGICAL RISK ASSESSMENT REQUIREMENTS OF THE TEXAS RISK REDUCTION PROGRAM (TRRP)

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The TRRP rule establishes requirements for corrective actions at Texas sites where a release of a chemical of concern (COC) has impacted the environment. The rule defines a three-tiered approach for evaluating risks to ecological receptors. Tier 1 sets forth criteria under which properties may be excluded from further assessment, based on the absence of any complete/ significant exposure pathways. If these exclusion criteria are not met, further evaluation under Tier 2 and/or Tier 3 is required. A Tier 2 screening-level ERA should scientifically eliminate COCs that do not pose an ecological risk, and define protective concentration levels (PCLs) for COCs that do. The ecological PCL is a media concentration that is protective of wider-ranging ecological receptors and benthic invertebrates within waters in the state, where appropriate. Persons may conduct an optional Tier 3 site-specific ERA to modify the Tier 2 PCLs and conclusions. Where a response action is required, persons may conduct an ecological services analysis (ESA) under Remedy Standard B to determine the appropriateness of leaving COCs in place above ecological PCLs and, where appropriate, to provide compensatory ecological restoration for managing residual ecological risk.

INTRODUCTION

Background and Overall Rule Requirements

In September 1999, the Texas Natural Resource Conservation Commission (TNRCC) adopted new rules to establish requirements for response actions at sites where a release of a chemical of concern (COC) has impacted the environment. The adopted rule, commonly referred to as the Texas Risk Reduction Program (TRRP) rule and codified in 30 TAC §350, outlines a comprehensive program that addresses the investigation of contaminated sites, establishes reasonable standards for notice, provides flexibility in calculating site-specific cleanup levels, and sets forth appropriate response actions to address the environmental contamination. The rule uses a tiered approach incorporating risk assessment techniques to help focus investigations, to determine appropriate protective concentration levels, and to set reasonable response objectives that will protect human health and the environment. The programs affected by the TRRP rule are, for the most part, regulated by the agency's Office of Permitting, Remediation, and Registration. These programs include State Superfund, Corrective Action Program, Voluntary Cleanup Program (VCP), Petroleum Storage Tank (PST), Industrial & Hazardous Waste, and Underground Injection Control (UIC). The TRRP rule (§350.2) does not obviate the need to meet any more stringent or additional requirements found in other rules for the covered program areas, or applicable federal requirements.

The TRRP process requires persons to implement a response action as needed to prevent human or ecological exposure to potentially harmful levels of COCs. Following discovery and notification of a COC release that is subject to these response action requirements, the first step of the TRRP process is to conduct an affected property assessment (§350.51) to define the nature and extent of affected environmental media (i.e., soil, sediment, surface water, groundwater). Initially, the person is required to complete the Tier 1 Exclusion Criteria Checklist to determine whether additional ecological evaluation is necessary (unless the person desires to enter the ecological risk assessment process at a higher tier). If further evaluation is necessary, the person may need to conduct a Tier 2 screening level ecological risk assessment (SLERA) and/or a Tier 3 site-specific ecological risk assessment (SSERA) in order to determine the applicable protective concentration levels (PCLs) for each affected media (see §350.77). Within the context of the overall TRRP process, the ecological risk assessment (ERA) is conducted to develop PCLs that are protective of potential ecological exposures. As defined in the TRRP rule (§350.4 (a)(27)), the ecological PCL is a concentration of a COC within an exposure medium (e.g., soil, sediment, surface water) that is protective of: 1) wider-ranging ecological receptors that may frequent the affected property and use less mobile receptors (e.g., plants, soil invertebrates, small rodents) as a food source, and 2) benthic invertebrates within waters in the state, where appropriate. More details regarding the ecological PCL are provided in text that follows (see discussion in Required Element 2). The ERA should be conducted in a manner that results in the protection of ecological receptors.

To evaluate the need for undertaking a response action, measured COC concentrations are compared to the lower of the human health PCL or ecological PCL for each COC (the lower of the two is called the critical PCL). If measured COC concentrations exceed the critical PCL for any COC, the person may either refine the PCLs by going to the next tier in the risk analysis (assuming the person is at Tier 1 or 2

for human health or Tier 2 for ecological) or implement a remedy pursuant to the TRRP requirements. Response actions must conform to one of two options for performance standards, termed Remedy Standard A or Remedy Standard B (§350.31). Under Remedy Standard A, affected media must be removed or decontaminated to permanently reduce COC concentrations below critical PCLs (§350.32). Under Remedy Standard B, removal, decontamination, or control measures may be applied to prevent exposure media exceeding critical PCLs (§350.33). In the case of a Standard B response action targeted toward ecological concerns, the person may conduct an Ecological Services Analysis to evaluate the net benefit of the response action to ecological resources (§350.77(f)(2)). Ecological risk management under Remedy Standards A and B is discussed in more detail in text that follows (see Ecological Risk Management Options).

Guidance Development

Through a multi-stakeholder ecological work group, TNRCC has developed the *August 2000 Guidance for Conducting Ecological Risk Assessments at Remediation Sites in Texas*, Draft Final (TNRCC, 2000) which is currently available on the TNRCC web site (<http://www.tnrcc.state.tx.us/permitting/trrp.htm>). This draft final guidance provides a detailed description of how to conduct ERAs using TNRCC's three-tiered approach, discusses the interface of the ERA program with the TRRP rule, and presents ecological risk management options. Case studies, appendices, and attachments are also included for illustrative purposes. The draft final guidance applies to sites within TNRCC's Remediation Division consistent with applicable program rules. The draft final guidance will remain in effect and should be used until it is replaced by final guidance, which should be available in late 2001 (check web site above for status). The guidance also discusses the interactions of the ERA process with the ecological services analysis process and the role that the Natural Resource Trustee agencies play in both under 30 TAC §7.124. The guidance itself is not a rule. The purpose of the guidance is to promote the development of consistent and technically defensible ERAs that are submitted under TNRCC's remediation programs. The guidance may also be used to gain technical advice and insight as to how the commission may evaluate an issue when considering particular facts and circumstances. This paper was largely developed using excerpts from the draft guidance.

Definition of an Ecological Risk Assessment and Overview of the Tiered Process

Ecological risk assessment is defined as a process that evaluates the likelihood that adverse ecological effects are occurring or may occur as a result of exposure to one or more stressors (U.S. EPA, 1992). Although a stressor may be any physical, chemical, or biological entity that can induce an adverse ecological response (U.S. EPA, 1992), only chemical stressors are subject to risk management decisions at response action sites. The primary functions of an ERA are to:

- determine whether actual or potential ecological risk exists at a remediation site;
- screen the COCs present to identify those that might pose an ecological risk, thereby focusing further efforts; and
- if necessary, generate ecologically-protective concentration levels to be used in evaluating response actions.

As outlined in the TRRP rule and illustrated in Figure 1, the TNRCC has developed a three-tiered approach to conducting ERAs. Persons may elect to commence the ERA process at any of the following tiers:

Tier 1 - Exclusion Criteria Checklist: The Tier 1 Checklist sets forth conditions under which an affected property¹ may be excluded from further ecological assessment, based on the absence of any complete or significant ecological exposure pathways. Affected properties that do not meet these exclusion criteria will require further evaluation under Tier 2 and/or Tier 3 of the ERA process, unless a reasoned justification and/or an expedited stream evaluation are appropriately used to conclude the ERA.

Tier 2 - Screening-Level Ecological Risk Assessment (SLERA): Under Tier 2, non-bioaccumulative COCs may be screened from further evaluation based on comparison to ecological benchmarks. If all COCs are not excluded on this basis, a conceptual exposure model is developed to characterize complete exposure pathways and representative receptors. Exposures are compared to literature-based effects levels using conservative exposure assumptions that may be later refined with available site-specific information. Tier 2 ecological PCLs are derived for any COCs that are retained.

Tier 3 - Site-Specific Ecological Risk Assessment (SSERA): Under optional Tier 3, ecological risk indicated from earlier tiers may be compared to site-specific “weight-of-evidence” information regarding the presence or absence of ecological effects. Such site-specific assessments may include analysis of tissue samples, toxicological testing of affected media, comparison of species diversity to reference areas, and/or other appropriate analyses. If effects are confirmed, these site-specific data may be employed to derive Tier 3 ecological PCLs for the relevant receptors and exposure media.

These three tiers are described in more detail in the text that follows.

TIER 1 EXCLUSION CRITERIA CHECKLIST

The purposes of the Tier 1 checklist (Figure 30 TAC §350.77 (b) in the rule) are to characterize the ecological setting of the affected property, and to determine the existence of complete and potentially significant ecological exposure pathways through the use of exclusion criteria. Exclusion criteria refer to those conditions at an affected property that preclude the need for a formal ERA because there are incomplete or insignificant ecological exposure pathways due to the nature of the affected property setting and/or the condition of the affected property media. The checklist is a standardized form consisting of mostly non-technical questions, which could be completed by nearly anyone who is familiar with the affected property. It must be

¹According to the TRRP rule, affected property is defined as the entire area (i.e., on-site and off-site; including all environmental media) which contains releases of COCs at concentrations equal to or greater than the assessment level applicable for residential land use and groundwater classification.

completed for all affected properties subject to TRRP (30 TAC §350.77(b)), unless a decision is made to begin the ecological evaluation at a higher Tier.

Completion of the Tier 1 checklist should result in the identification of any significant and complete or reasonably anticipated to be completed ecological exposure pathways. If the affected property meets the exclusion criteria, then the person has fulfilled the ERA obligation and is not required to conduct a Tier 2 or Tier 3 ERA unless changing circumstances result in the affected property not meeting the exclusion criteria (see §350.35 of the rule). If at any time after Tier 1 it becomes apparent that response actions to protect human health will also protect ecological receptors or if human health protective concentration levels are more conservative than ecological protective concentrations, then the ecological risk assessment may be terminated. If the exclusion criteria cannot be met, then the person may submit a reasoned justification for ending the ERA (as described at §350.77(a)), conduct an expedited stream evaluation (see Expedited Stream Evaluation...), or perform a Tier 2 SLERA or a Tier 3 SSERA. It should be noted that the intended purpose of the “reasoned justification” clause is primarily to take into consideration a planned response action that is designed to address human health exposure, but which coincidentally addresses ecological exposure as well.

Exclusion Criteria - Surface Water/Sediment Exposure

Subpart A of the checklist asks, “have COCs migrated and resulted in a release or imminent threat of release to either surface waters or to their associated sediments via surface water runoff, air deposition, groundwater seepage, etc.?” As they are not surface water in the state according to the Texas Surface Water Quality Standards (TSWQS, §307.3), wastewater treatment facilities and storm water conveyances/ impoundments authorized by permit are excluded from consideration. Although conveyances, decorative ponds, and portions of unpermitted process facilities may be surface waters in the State by definition, as long as these are not ultimately in contact with other surface waters in the State and are not utilized as valuable habitat for wildlife, these waters may also be excluded from consideration. For purposes of the checklist, “valuable habitat” refers to these types of waters (conveyances, decorative ponds, etc.) that are used consistently or routinely as a feeding area or sanctuary for wildlife (e.g., migratory waterfowl). If the affected property has had a release to surface water/sediment, it fails the checklist and will have to undergo additional ecological evaluation. However, this does not necessarily mean that a Tier 2 assessment must be conducted. As discussed in text that follows (see Expedited Stream Evaluation...), an expedited stream evaluation may be appropriate for the surface water/sediment release, depending on the type of water body. In any case, the person should complete the remainder of the checklist to determine if there is a complete and significant soil exposure pathway. If the soil pathway is incomplete or insignificant, further evaluations need only focus on the surface water/sediment exposure pathway.

Exclusion Criteria - Affected Property Setting

Subpart B of the checklist asks if, “the affected property is wholly contained within contiguous land characterized by: pavement, buildings, landscaped area, functioning cap, roadways, equipment storage area, manufacturing or process area, other surface cover or structure, or otherwise disturbed ground?” The affected property must be able to meet the qualifying condition regarding its attractiveness to ecological

receptors before the affected property setting question can be affirmatively answered. Field observations and discussions with others who are also familiar with the affected property, should be used to help determine the attractiveness of the affected property to ecological receptors. If the affected property is considered to be attractive to ecological receptors (including protected threatened/endangered species), the person should bypass the affected property setting question and proceed to the Soil Exposure exclusion criterion.

Obviously, if the affected property is not attractive to any wildlife due to a lack of habitat, there would be no reason to ascertain the presence of protected species. “Disturbed ground” primarily refers to a location that is predominantly urban or commercial/industrial in nature (and thus characterized by human presence and activities) where any ecological habitat that may have once existed has been altered, impacted, or reduced to a degree such that it is no longer conducive to utilization by ecological receptors. Closed “waste control units” with engineered covers are considered disturbed ground, provided they are meeting their design specifications. On the other hand, agricultural crops and, more often, pastureland are not usually considered disturbed ground because of their characteristics as both ecological receptors, and as potential habitat for other ecological receptors.

Exclusion Criteria - Soil Exposure

Subpart C of the checklist asks if, “COCs which are in the soil of the affected property solely below the first five feet beneath ground surface or does the affected property have a physical barrier present to prevent exposure of receptors to COCs in surface soil?” The rationale is that the first five feet beneath ground surface are considered to be the primary zone of active root growth for most plants in the state and therefore the depth to which most burrowing animals will dig. The physical barrier mentioned in this exclusion criterion may be either natural (e.g., geological formation) or man-made (e.g., asphalt or cement parking lot).

Exclusion Criteria - *De Minimus* Land Area

Regarding this exclusion criterion in Subpart D, the checklist states that in answering “Yes” to the question below, it is understood that all of the following conditions apply:

- The affected property is not known to serve as habitat, foraging area, or refuge to threatened/endangered or otherwise protected species. (Will likely require consultation with wildlife management agencies.)
- Similar but unimpacted habitat exists within a half-mile radius.
- The affected property is not known to be located within one-quarter mile of sensitive environmental areas (e.g., rookeries, wildlife management areas, preserves). (Will likely require consultation with wildlife management agencies.)
- There is no reason to suspect that the COCs associated with the affected property will migrate such that the affected property will become larger than one acre.

The checklist asks if, “the affected property consist of one acre or less and does it meet all of the conditions above (using human health protective concentration levels as a basis to determine the extent of the COCs)?” When evaluating the qualifying conditions, the TNRCC suggests that the person contact the appropriate wildlife management agencies

and/or consult other sources for information on threatened/ endangered or otherwise protected species. A sensitive environmental area is habitat that may require protection or special consideration because of the presence of particular ecological receptors and natural resources, or because legislatively-conferred protection (e.g., a national monument) has been established. Examples of sensitive environmental areas are provided in TNRCC (2000). Migration of soil COCs is primarily dependent upon the COC's fate and transport characteristics. Also, if the topography of the affected property is such that there is no surface water runoff (due to percolation and/or evaporation) or if the runoff is captured and treated and the area of the affected property up to the point of capture does not exceed one acre, it is likely that the areal extent of the affected property will not increase.

Expedited Stream Evaluation for Surface Water and Sediment Releases to Intermittent Streams Without Perennial Pools

Although a COC release to surface water or associated sediment is a complete pathway, an "expedited stream evaluation" may be used to show that this may not be a significant pathway when the water body and its surroundings meet certain conditions. More specifically, the release must be into an intermittent stream without perennial pools that does not support a benthic community needing to be protected. In addition, there should be no immediately apparent downstream impacts. If not meeting the surface water/sediment pathway criterion is the only reason the checklist was failed (i.e., the soil exposure pathway proved to be incomplete or insignificant), this expedited stream evaluation process may be used to conclude the ERA.

To ascertain whether or not an expedited stream evaluation is appropriate, the following conditions must all be met:

- The stream is intermittent (dries up completely at least one week a year) without perennial pools. [Intermittent streams with perennial pools are defined at §307.3 (a) of the TSWQS, as amended.]
- The stream is located in a disturbed area (generally, such situations occur in predominantly urban or commercial/industrial settings).
- The stream meets the acute water quality criteria specified in Table 1 of 30 TAC §307.6 (the TSWQS) or appropriate surrogate values if there is no criteria specified.
- There is a lack of appreciable instream, edge, or riparian habitat, forage, or shelter in or along the watercourse.
- The watercourse or surrounding vicinity is not known to serve as habitat, foraging area, or refuge to threatened/endangered or otherwise protected species.
- The area is not consistently or routinely used as valuable habitat for natural communities including birds, mammals, reptiles, etc.
- There are no impacts immediately evident in downstream areas where habitat is more likely to support wildlife.

If all of these conditions are met, the stream does not need any further evaluation unless more thorough downstream analyses reveal impacts. Details regarding the downstream impact determination are provided in TNRCC (2000). In this case, the stream may need to be evaluated as a potential secondary source of COCs. If any one of these conditions is not met, then the person will need to conduct a Tier 2 SLERA that

includes the water body in question, as well as any downstream resources that may be impacted.

Tier 2 Screening Level ERA (SLERA)

The purposes of the Tier 2 SLERA are to scientifically eliminate COCs that do not pose an ecological risk and to develop PCLs for those COCs that do pose an unacceptable risk to selected ecological receptors. The Tier 2 SLERA serves to identify COCs, exposure pathways, and ecological receptors of concern based on application of default exposure assumptions and literature-based effects levels. The TRRP rule at §350.77 (c) establishes ten minimum requirements to be satisfied when completing a Tier 2 SLERA. However, not all ten of these measures will always be necessary, as there are four points from which the person may show that there is no ecological risk and thus terminate the evaluation (they meet the conditions of required elements 1, 6, 7, or 8). Each required element is stated in the text that follows (in italics). The text following each element briefly explains the required element.

Required Element 1

The person shall “use affected property concentrations of non-bioaccumulative COCs to compare to established ecological benchmarks and/or use approved methodologies to develop benchmarks to determine potential effects and to eliminate COCs that do not pose unacceptable ecological risk (if all COCs are eliminated at this point, the ecological risk assessment process ends and the items listed in paragraphs (2) - (9) of this subsection are not required)”.

The TNRCC has developed a set of ecological screening benchmarks for water, sediment, and soil (see TNRCC, 2000). Benchmarks provide a simple approach to compare COC concentrations in media at the affected property to values that represent media concentrations that are presumed to be safe to biota with the likelihood of being the most exposed (i.e., aquatic life, benthic invertebrates, and plants and soil invertebrates). If a COC is present below background levels, or is present below benchmark levels and the COC is not a bioaccumulator for the media in question, further evaluation of that COC is not required. Where a COC can not be screened out by comparison with background or detection levels, and no benchmark exists or can be readily derived for a COC in a particular medium, then the person would be required to further evaluate that particular COC in the ERA.

Persons must determine if bioaccumulative COCs are present at the affected property in order to properly compare affected property concentrations to ecological screening benchmarks. Bioaccumulative COCs tend to increase in concentration within some organisms relative to their concentration in environmental media and dietary sources due to sequestration in certain body tissues. Biomagnification (i.e., bioaccumulation in successive trophic levels of a food chain) can result in concentrations of COCs that are many times greater than that found in environmental media. Bioaccumulation is an important aspect of ecological risk assessment because it can result in increased exposure to multiple trophic levels in comparison to COCs that do not bioaccumulate. Also, bioaccumulative COCs can be present at a concentration in environmental media that is protective for direct exposure, but that can pose indirect risk

to higher trophic levels. The ecological benchmarks evaluate direct exposure to specific media for selected receptors and are not expected to evaluate bioaccumulation concerns. Based on a consensus work group effort, the TNRCC has developed a list of bioaccumulative COCs for various media (see TNRCC, 2000). Where a bioaccumulative COC is present at an affected property above background, it must be carried forward into the ERA regardless of the benchmark comparison.

Required Element 2

The person shall “*identify communities (e.g., soil invertebrates, benthic invertebrates) and major feeding guilds (e.g., omnivorous mammals, piscivorous birds) and their representative species which are supported by habitats on the affected property for each complete or reasonably anticipated to be completed exposure pathway*”.

This required element addresses the question of what is being protected. By definition (§350.4 (a)(27)), ecological PCLs are primarily intended to be protective of more mobile or wide-ranging ecological receptors and, where appropriate, benthic invertebrate communities within waters in the state and are not intended to be directly protective of receptors with limited mobility or range (e.g., plants, soil invertebrates, and small rodents), particularly those residing within active areas of a facility, unless these receptors are threatened/ endangered species or unless impacts to these receptors result in disruption of the ecosystem or other unacceptable consequences for the more mobile or wide-ranging receptors (e.g., impacts to an off-site grassland habitat eliminate rodents which causes a desirable owl population to leave the area). Ecological communities are a collection of plant and animal populations occupying the same habitat in which the various species interact with one another. These communities consist of soil invertebrates, terrestrial vegetation, benthic invertebrates, water column invertebrates, algae, and rooted aquatic vegetation. COCs that exceed ecological (community-level) benchmarks but that do not subsequently prove to be a risk to higher trophic level receptors may still impact these community-level receptors. TNRCC (2000) provides details as to where the commission believes it to be unnecessary to determine an ecological PCL for sediment that is protective of the benthic invertebrate community.

“Feeding guilds” is the term used to refer to broad groups of related ecological receptors (e.g., piscivorous birds) that represent the variety of species potentially exposed to COCs at the affected property. Feeding guilds are based on a shared function within an ecosystem (i.e., same feeding strategy), similar potential for exposure, and physiological and/or taxonomic similarity. Identification of these ecological receptors is used to define food webs specific to potentially impacted habitats to be evaluated in the risk assessment. Habitat-specific food webs are developed for use in the ecological risk assessment to:

- Define direct and indirect exposure pathways
- Formulate assessment endpoints
- Develop mathematical relationships among guilds for estimating exposure
- Perform quantitative exposure analysis for ecological receptors

The TRRP rule defines “selected ecological receptors” as species that are to be carried through the ERA as representatives of the different feeding guilds and communities that are being evaluated. These representative species, often called

“measurement receptors”, may not actually occur at the affected property, but may be used to represent those within the feeding guild or community that may feed on the affected property. Representative ecological receptors should be chosen to ensure that the potentially complete exposure pathways to the associated ecological feeding guilds are included in the conceptual model.

In a Tier 2 SLERA, the potential for chemical toxicity is evaluated by estimating the total direct and indirect exposure of each measurement receptor to the COC and deriving a hazard quotient (see required elements 5 and 6). The goal for this analysis is to determine if the ecological risk requires further evaluation (i.e., a hazard quotient exceeding 1) and to develop ecological PCLs for the affected medium that will protect against chemical toxicity. The evaluation of the measure of effect to the assessment endpoint requires identification of a measurement receptor representative of the assessment endpoint. Hence a measurement receptor, specific to each feeding guild, may be selected as a species, population, community, or assemblage of communities.

Required Element 3

The person shall “*develop a conceptual model which graphically depicts the movement of COCs through media to communities and the feeding guilds*”.

The purpose of the conceptual model is to illustrate the complete or reasonably anticipated to be completed ecological exposure pathways that will be evaluated in the ERA. The conceptual model graphically depicts the movement of COCs from the source(s) through media to the feeding guilds or to the selected ecological receptors of those guilds (i.e., measurement receptors).

Required Element 4

The person shall “*discuss COC fate and transport and toxicological profiles*”.

A determination should be made as to whether the COCs at the affected property are likely to persist, be degraded, or move beyond the extent of contamination determined in the affected property assessment. During the assessment, the person characterizes the nature, extent, and potential fate and transport of COCs. This characterization includes physical, chemical and biological processes and the influence of these processes on the movement, persistence, form, toxicity, and availability of COCs to the degree necessary to understand and characterize risk.

Toxicological profiles can be found in the literature (e.g. Medline, AQUIRE, ECOTOX), and are used to quantify toxicity (e.g., dose-response) and to evaluate the likelihood of toxic effects in different groups of organisms. The toxicity profile should describe the toxic mechanisms of action, to the degree known or available, for the exposure routes being evaluated and the dose or environmental concentration that causes a specified adverse effect.

Required Element 5

The person shall “*prepare a list of input data which includes values from the literature (e.g., exposure factors, intake equations that account for total exposure, no*

observed adverse effect level (NOAEL) and lowest observed adverse effect level (LOAEL) values, references), any available site-specific data, and reasonably conservative exposure assumptions, and then calculate the total exposure to selected ecological receptors from each COC not eliminated according to paragraph (1) of this subsection and present these calculations in tables or spreadsheets”.

This required element provides for an initial exposure assessment incorporating reasonably conservative assumptions to minimize the potential for overlooking ecological risks. Conservative exposure variables related to bioavailability, home range, diet, body weight, and ingestion rates are selected that will be used in the calculation of the dose for the measurement receptors. The following general equation can be used to estimate oral exposure for wildlife receptors:

$$Dose_{oral} = \frac{\left[\left(IR_f \times C_f \times EMF_f \right) + \left(IR_w \times C_w \times EMF_w \right) + \left(IR_{so} \times C_{so} \times EMF_{so} \right) + \left(IR_{sed} \times C_{sed} \times EMF_{sed} \right) \right]}{BW}$$

where:

Dose _{oral}	=	estimated dose from ingestion (mg COC/kg body weight/day)
IR _f	=	ingestion rate of food (prey) (kg/day)
C _f	=	COC concentration in food (mg/kg)
EMF _f	=	exposure modifying factor for food (unitless)
IR _w	=	ingestion rate of water (L/day)
C _w	=	COC concentration in water (mg/L)
EMF _w	=	exposure modifying factor for water (unitless)
IR _{so}	=	ingestion rate of soil (kg/day)
C _{so}	=	COC concentration in soil (mg/kg)
EMF _{so}	=	exposure modifying factor for soil (unitless)
IR _{sed}	=	ingestion rate of sediment (kg/day)
C _{sed}	=	COC concentration in sediment (mg/kg)
EMF _{sed}	=	exposure modifying factor for sediment (unitless)
BW	=	body weight of receptor (kg)

Literature sources used for intake and exposure variables should be clearly indicated and justified in the ERA. For each COC with a complete exposure pathway that is not excluded by either a comparison with background concentrations² or ecological benchmarks, a toxicity reference value (TRV) should be developed from published studies and/or developed for potential receptor species. The TRV is used in the ecological hazard quotient methodology described in required elements 6 through 9 of the TRRP rule at §350.77(c). Two quotients are described in the rule, one based on “no unacceptable risk” derived from using NOAEL endpoints (required element 6), and a second based on “less conservative assumptions” derived from LOAEL endpoints (required element 7). Ecological effects of concern are those that can impact populations, such as development, reproduction, and survivorship. “NOAEL” endpoints reflect the highest exposure level that causes no statistically significant difference in effect compared with the controls. “LOAEL” endpoints reflect the lowest exposure level shown to produce similar adverse effects in a potential receptor species. The TRV_{NOAEL}

² Persons are not required to develop PCLs that are less than background (§350.78 (c)).

is derived for the measurement receptor from a review of NOAEL endpoints or estimates of such endpoints. The TRV_{LOAEL} is derived for the measurement receptor from a review of LOAEL endpoints or estimates of such endpoints.

Required Element 6

The person shall “utilize an ecological hazard quotient methodology to compare exposures to the NOAELs in order to eliminate COCs that pose no unacceptable risk (i.e., NOAEL hazard quotient #1); however, when multiple members of a class of COCs are present which exert additive effects, it is also appropriate to utilize an ecological hazard index methodology (if all COCs are eliminated at this point, the ecological risk assessment process ends and the items listed in paragraphs (7) - (9) of this subsection are not required)”.

Here hazard quotients (and hazard indices, as appropriate) must be calculated for each COC paired with each selected ecological receptor. A hazard quotient (HQ) states the ratio of the predicted exposure to an acceptable exposure, for a specific COC and a specific representative measurement receptor. An HQ (unitless) is calculated as follows:

$$HQ = \text{Exposure or Dose} / TRV$$

where:

Exposure = measured or estimated exposure point concentration (e.g., mg/L, mg/kg, etc.) or dose (e.g., mg/kg body weight/day);

TRV = Toxicity Reference Value (e.g., based on a NOAEL or LOAEL) in units matching the exposure point concentration or dose (from element 5).

Here the HQ is based on reasonably conservative exposure assumptions and a representative NOAEL-based TRV (TRV_{NOAEL}). COCs with a hazard quotient (and any associated hazard index) # 1 are dropped from further evaluation for that particular measurement receptor for that medium. If all COCs associated with a receptor are eliminated from the Tier 2 SLERA, no further evaluation of that receptor is required. Because HQs focus only on individual COCs, they do not represent the potential for effects to ecological receptors from COCs acting in concert as toxic agents. To address such concerns, a Hazard Index is calculated as sum of two or more hazard quotients for different COCs:

$$HI = \sum HQ_i$$

where:

$\sum HQ_i$ = The sum of all hazard quotients for COCs with a common toxic mechanism.

These hazard indices are calculated as a measure of the potential for impacts due to multiple COCs, but must be based on the assumption that the effects are additive. Therefore, this computation is limited to COCs with the same toxic mechanism (i.e., same mode and site of action). For example, HIs may be appropriate for PCBs, chlorinated benzenes, dioxins and furans, low molecular weight PAHs (generally, two or three rings), and high molecular weight PAHs (generally, four or more rings). For COCs

with the same toxic mechanism, the corresponding HI must also be # 1 for any of those COCs to be eliminated from further consideration in the Tier 2 SLERA.

Required Element 7

The person shall “*justify the use of less conservative assumptions to adjust the exposure and repeat the hazard quotient exercise in paragraph (6) of this subsection, once again eliminating COCs that pose no unacceptable risk and adding comparisons to the LOAELs for those COCs indicating a potential risk (i.e., NOAEL hazard quotient > 1); however, when multiple members of a class of COCs are present which exert additive effects, it is also appropriate to utilize an ecological hazard index methodology (if all COCs are eliminated at this point, the ecological risk assessment process ends and the items listed in paragraphs (8) - (9) of this subsection are not required)*”.

Required element 7 provides for the calculation of hazard quotients using TRVs based on both NOAEL and LOAEL toxicity data, but less conservative exposure assumptions are used at this step. Exposure variables that may be adjusted generally consist of bioavailability, area use factors and/or exposure frequency, and diet. These variables should be less conservative in their totality, and the person must justify the use of such data on the basis of site-specific information and/or a clear rationale showing that the assumptions are appropriate. If comparison of a less conservative exposure estimate with a NOAEL-based TRV results in an HQ (and any HI) # 1, the COC may be dropped from further evaluation in the Tier 2 SLERA. Dropping COCs with HQ or HIs derived from technically defensible, LOAEL-based TRVs that are less than 1 may be proposed, and supporting information included as part of the discussion of uncertainty (required element 8). HQs greater than 1 based on less conservative exposure assumptions and LOAEL-based TRVs provide a reasonable basis to begin remedial planning, as ecological impacts may be expected.

Required Element 8

The person shall “*develop an “uncertainty analysis” which discusses the major areas of uncertainty associated with the screening-level ecological risk assessment, including a justification for not developing PCLs for particular COCs/pathways, if appropriate (e.g., NOAEL hazard quotient > 1 > LOAEL hazard quotient, an evaluation of the likelihood of ecological risk, a discussion of the half-life of the COCs, etc.); however, when multiple members of a class of COCs are present which exert additive effects, it is also appropriate to utilize an ecological hazard index methodology (if all COCs are eliminated at this point, the ecological risk assessment process ends and the item listed in paragraph (9) of this subsection is not required)*”.

After calculating the HQs in required element 7 and analyzing the results of the risk assessment, the person will need to evaluate the uncertainty associated with the ERA in required element 8. A description of the nature of the uncertainties encountered should be clearly summarized. The uncertainty analysis can be used to justify the need for calculating or not calculating a PCL for a given COC (required element 9). This may be accomplished by considering indications of potential ecological risk in context with the likelihood of that risk. Factors that should be evaluated include the location and areal extent of the COCs, the degree to which the TRV is exceeded, and the expected half-life of the COCs in the particular environment. If, after completing the HQ exercises in the

preceding section it is determined that for a particular COC, the NOAEL HQ/HI > 1 but that the LOAEL HQ/HI < 1, the person may state in the uncertainty analysis 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 effects levels. However, the person will need to provide justification when the LOAEL HQ/HI approaches unity and there are indications that risk may have been underestimated in other areas. PCL calculations for a given COC can be justified qualitatively or quantitatively based on strengths and weaknesses in the data. In most cases, the uncertainty analysis will be qualitative in nature.

Required Element 9

The person shall “*calculate medium-specific PCLs bounded by the NOAEL and the LOAEL for those COCs which are not eliminated as a result of the hazard quotient exercises or the uncertainty analysis*”.

Ecological PCLs must be calculated for each COC that has not been eliminated from consideration under required elements 1, 6, 7, or 8 of the Tier 2 SLERA (§350.77(c)). Here a medium-specific PCL bounded by the NOAEL and LOAEL is calculated for each relevant measurement receptor. Since exposure for community-level receptors such as fish and benthic macroinvertebrates is generally expressed in terms of media concentration, any PCLs related to such receptors are based on a simple comparison of representative media concentrations to applicable TRVs. For wildlife receptors (where exposure may be due to ingestion of impacted food and/or media), there are a variety of techniques for deriving media-specific PCLs. These techniques are discussed in more detail in TNRCC (2000). When realistic exposure assumptions are incorporated into the analysis, the TNRCC can be reasonably assured that any COC having a LOAEL HQ \geq 1 resulting from the exercise in required element 7 has the potential to pose unacceptable ecological risk. This also means that remediation to a LOAEL-based PCL derived from realistic exposure assumptions may result in unacceptable ecological risk still remaining within that specific medium. The foundation for selecting a comparative PCL that is skewed toward either the NOAEL-based or LOAEL-based PCL should be made in the uncertainty analysis (required element 8).

Required Element 10

The person shall “*make a recommendation for managing ecological risk at the affected property based on the final ecological PCLs, unless proceeding under Tier 3 (may be included as part of the affected property assessment report, self-implementation notice, or the response action plan)*”.

The Tier 2 SLERA concludes with required element 10 where the person must make a recommendation as to how to manage the ecological risk at the affected property. If all COCs and/or pathways have been eliminated by this point, the person simply needs to state that the ERA guidance has been followed and there is no apparent unacceptable ecological risk at the affected property. However, if ecological PCLs were calculated in Tier 2, the person must do one or more of the following:

- Proceed to an optional Tier 3 site-specific ERA to develop final ecological PCLs or to determine that there is no apparent unacceptable ecological risk at the affected property; or,
- Compare the PCL values generated in Tier 2 to relevant human health protective levels (e.g., TRRP human health/groundwater PCLs generated at any tier) in order to determine the critical PCL and remediate to those levels; or,
- Evaluate and state whether the human health remedy would eliminate all ecological exposure pathways; or,
- Request to conduct an ecological services analysis (see Risk Management Options).

TIER 3 SITE-SPECIFIC ECOLOGICAL RISK ASSESSMENT (SSERA)

In accordance with 30 TAC §350.77 (d) of the TRRP rule, the purpose of the optional SSERA is to incorporate additional information obtained through the performance of site-specific studies designed to provide a more empirical evaluation of ecological risk at the affected property. A SSERA can be conducted when any of the Tier 2 PCLs are considered by the person to be inappropriate or not reflective of existing conditions at the affected property, or when otherwise elected. The Tier 3 SSERA can consist of any site-specific study approved by the TNRCC and can include, but is not limited to:

- development of site-specific bioaccumulation factors through the collection and analysis of tissue samples from appropriate ecological receptors;
- performance of toxicological testing of the impacted media via exposure to an appropriate test species;
- comparison of site data (e.g., macroinvertebrate diversity surveys) to like data from a reference area; and/or
- other studies designed to obtain a preponderance or “weight-of-evidence” to draw conclusions about ecological risk.

Because Tier 3 involves the collection of site-specific information, it can be costly and time-consuming; therefore, persons are strongly encouraged to communicate with the TNRCC ecological risk assessment staff regarding the study objectives, conceptual model, study methodology, and additional sampling and site investigations before proceeding. The result of the SSERA will be the development of site-specific Tier 3 PCLs, a determination that there is no ecological risk, or a conclusion that ecological risk is not apparent based on site-specific information.

ECOLOGICAL RISK MANAGEMENT OPTIONS

As a component of required element 10 of the Tier 2 SLERA, the person must provide risk management recommendations for the affected property if the affected media contains COCs in excess of applicable PCLs. Such risk management recommendations are confined to the response options available under Remedy Standard

A or Standard B of the TRRP rule. The remedy must address both human health and ecological exposure concerns. For this purpose, human health-based and ecological PCLs are compared to identify *critical PCLs* (i.e., the lowest concentration level) for each COC and affected medium, and the remedy is directed toward addressing media concentrations in excess of the PCLs. The remedy is complete when either Standard A or Standard B response objectives have been achieved, and all requisite reports have been approved by the TNRCC, and any necessary post-response action care has been performed and financial assurance has been maintained (see 30 TAC §350.34 and §§350.91-96). It is the responsibility of the person to select the appropriate remedy, but if Remedy Standard B is selected, the person must submit a Response Action Plan for review and approval by the TNRCC. For each COC where the ecological PCLs are determined to be the critical PCL and the corresponding media concentration of that COC exceeds the critical PCL, the person must consider the need to undertake further assessment (e.g., Tier 3 ERA) *or* select one or a combination of the available remedy options provided for under the TRRP rule. The remedy options are as follows:

- Remove (Remedy Standards A or B) – a removal remedy is the direct removal of concentrations of COCs that exceed the critical PCLs.
- Decontaminate (Remedy Standards A or B) – a decontamination remedy means a permanent and irreversible treatment process that results in the elimination of concentrations of COCs that exceed their respective critical PCLs.
- Control (Remedy Standard B only) – a control remedy contemplates physical and/or institutional controls that prevent the exposure of ecological receptors to concentrations of COCs that exceed their respective ecological PCLs.
- Ecological Services Analysis (Remedy Standard B only) – this remedy involves the completion of an ecological services analysis and, where appropriate, the completion of an on-site or off-site compensatory ecological restoration project. See discussion that follows.

Ecological Services Analysis

Where it has been determined that the ecological PCL is the critical PCL (i.e., the risk driver), or is the only PCL, the person may take action to remove, decontaminate, and/or control the impacted media and COCs. However, to provide additional flexibility to address ecological risk at those affected properties where concentrations of COCs do not exceed human health-based levels (either before or after a response action) but do exceed ecological PCLs, the commission is allowing the use of an ecological services analysis (ESA), as described below and at §350.33(a)(3)(B). The performance of the ESA and any required compensatory ecological restoration must be done in cooperation with and with approval from the Natural Resource Trustees for the State of Texas, including the TNRCC, the Texas Parks and Wildlife Department (TPWD), the Texas General Land Office (TGLO), the National Oceanic and Atmospheric Administration (NOAA), and the U.S. Department of the Interior (DOI), hereinafter collectively referred to as the “Trustees”. The use of this option allows the person to consider the potential impacts of the remediation activity as well as risks associated with exposure to COCs that exceed their respective PCLs. Thus the ESA considers the present and predicted ecological services of the affected property, as well as the beneficial and/or detrimental effects on services associated with potential response actions to address residual ecological risks. Furthermore, where appropriate and based upon the results of the ESA, a plan to provide compensatory ecological restoration, may also be combined with some

type of response action (e.g., hot spot removal, monitored natural attenuation) for the affected property. Compensatory ecological restoration addresses ecological concerns by providing or restoring alternative services when a response action at the affected property may cause additional unwarranted risks to ecological receptors.

If the ESA process is pursued, the person is required to consult with and obtain approval from the TNRCC and/or Trustees at two points in the process. First, when the person requests to perform an ESA remedy, the person must obtain the approval of the TNRCC, after the TNRCC has consulted with the Trustees. The TRRP rule requires that the TNRCC consult with the Trustees prior to approval of a person's request to conduct the ESA [§§350.33(a)(3)(B) and 350.77(f)(2)]. Second, if compensatory ecological restoration is proposed by the person or required by the Trustees as part of the remedy under the ESA option, the person must obtain approval from both the TNRCC and the Trustees [see §350.33(a)(3)(B)]. The culmination of the ESA is the preparation of an ESA report recommending a final remedy for the affected property. That remedy might be removal, decontamination, control, natural recovery, and/or compensatory ecological restoration. If the ESA demonstrates that compensatory ecological restoration is required or the person proposes to perform restoration, the person must provide a restoration project that produces ecological services greater than the ecological service decreases potentially associated with the continued exposure to COCs and/or any selected response action at the affected property [see §350.33(a)(3)(B)].

Memorandum of Understanding

A Memorandum of Understanding (MOU) between TNRCC and the Trustees has been developed to ensure the timely and efficient coordination of the consultation with the Trustees on a person's request to perform an ESA. This MOU was adopted by TNRCC as a rule (30 TAC §7.124) on April 4, 2001. The entire MOU can be reviewed at: <http://www.tnrcc.state.tx.us/oprd/index.html>. The user will then need to click on "View Rules", then "Chapter 7", then "§7.124". The MOU describes procedures for the distribution of relevant documents and coordination of meetings, provides deadlines for the submission of Trustee comments, and outlines a process for the resolution of conflicting comments. Upon TNRCC approval of the person's request to perform an ESA, the person must then coordinate the development of the ESA directly with the Trustees.

To facilitate the cooperative natural resource damage assessment process currently practiced in Texas, the Trustees will be provided notification from the TNRCC of those sites that reach required element 7 within a Tier 2 SLERA, as specified in the MOU. The Trustees at their discretion may or may not become involved at all referred affected properties. Trustees may choose to participate in the ERA process to ensure that natural resources under their jurisdiction are adequately protected and to obtain information that may be utilized in the natural resource damage assessment process. By participating in the ERA process, trustee staff may provide comments on the ERA being reviewed by the TNRCC ecological risk assessment staff. Persons may benefit from timely Trustee involvement in the ERA process through decreased costs associated with the coordination of risk assessment and injury determination, reduction of residual natural resources injury, and timely resolution of natural resource damages liability.

REFERENCES

Texas Risk Reduction Program (TRRP) Rule. 30 TAC § 350. September 17, 1999 Texas Register (24 TexReg 7413-7944).

TNRCC. 2000. Guidance for Conducting Ecological Risk Assessments at Remediation Sites in Texas. Draft Final. (August 28, 2000).

U.S. Environmental Protection Agency (U.S. EPA). 1992. Framework for Ecological Risk Assessment. Washington, DC: Risk Assessment Forum; EPA/630/R-02/011.

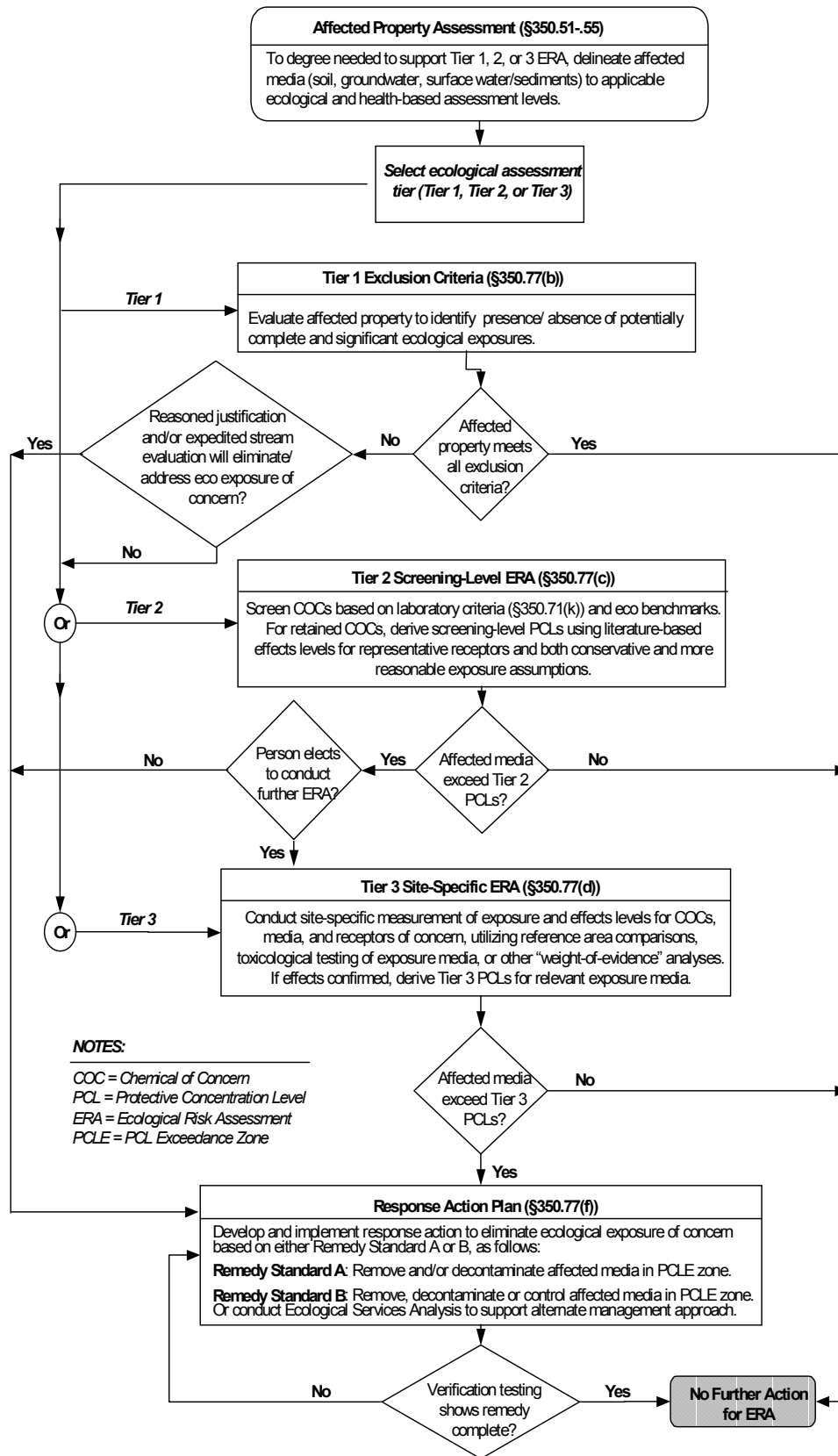


Figure 1. Overview of Tiered Ecological Risk Assessment Process

