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# New supplementary guidance for ecological risk assessments at contaminated sites under the Federal Contaminated Sites Action Plan

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# Overview of ERA Guidance Development

- **Comprehensive Ecological Risk Assessment Guidance – General Methods**
- **2 Technical Modules in Appendices**
  - Guidance on how to develop Site Specific Toxicity Reference Values
  - Guidance on how to select appropriate Toxicity Tests
- **Additional Technical Modules will be added in future**
  - Guidance on identifying and determining causation of Non-Chemical Stressors

# Comprehensive ERA Guidance

- Technical guidance for all phases of the ERA (problem formulation, exposure assessment, effects assessment and risk characterization)
- Supplemental to CCME 1996, 1997 guidance
- Based on Weight of Evidence Approach to Ecological Risk Assessment
- Promotes identifying lines of evidence early and carrying them through in the risk assessment
- Promotes documenting that risk was addressed comprehensively (e.g. all receptors, all contaminants)

# Current Status of FCSAP Comprehensive ERA Guidance

- **First draft currently under internal review**

- **Next steps include:**
  - **Translation**
  - **External review**
  - **Release of document**

# Technical Modules

- **Module 1:**
  Guidance on how to develop Site Specific Toxicity Reference Values (TRVs).

- **Module 2:**
  Guidance on how to select appropriate Toxicity Tests for Ecological Risk Assessment.

# Technical Module 1: Development of Specific TRVs

- Version for comments published in 2009 .
- Final version will be published in the two official languages in 2010.
- The module will assist the users in the development of TRV as site specific reference level for the ecological risk assessment at Federal Contaminated Sites .
- The module provides guidance on :
  - the application of published TRV;
  - the development of TRV while putting a emphasis on their development based on the literature

# Technical Module 1: Development of Specific TRVs

- A TRV is a Toxicity Reference Value
- The choice or the development of TRV occur during the effects assessment phase of an ecological risk assessment.
- A TRV is:
  - An exposure concentration or dose for a contaminant of potential concern (COPC) that is not expected to cause an unacceptable level of effect in a receptor of concern (ROC).
  - TRVs are contaminant-specific, receptor-specific and possibly site-specific.

# Technical Module 1: Development of Specific TRVs

- TRVs can be divided into three categories according to their development and their application :
  - **Dose-based TRVs:**
    - mg/kg per day
    - species of higher trophic levels exposed via ingestion
  - **Concentration-based TRVs in media:**
    - mg/kg or mg/L
    - species of lower trophic levels exposed via direct contact
  - **Concentration-based TRVs in tissues :**
    - mg/kg
    - Mainly used for bioaccumulative contaminants
    - Critical body residue (CBR) is another term that is often used to refer to a tissue-based TRV.

# Technical Module 1: Development of Specific TRVs

- TRVs would be developed for most ROC/COPC combinations on federal sites.
- To this general rule, the main exceptions would be for:
  - Situations where there are no relevant published toxicity data and where site-specific toxicity testing is not an option.
  - For those ROCs with measurement endpoints relying on direct measures of effects in the field or laboratory (e.g., using benthic community structure or sediment toxicity testing to assess potential effects to benthic infauna from exposure to a mixture of COPCs).
  - When no *a priori* acceptable effects levels have been selected.

# Technical Module 1: Development of Specific TRVs

- In combination with the estimate of exposure, TRVs are used to calculate hazard quotients in the risk characterization phase:

$$HQ = \frac{\text{Exposure}}{TRV}$$

# Technical Module 1: Development of Specific TRVs

- Review of published TRVs
- Derivation of site-specific TRVs, including:
  - Literature-based TRVs
  - Modifying existing guidelines to develop site-specific TRVs
  - TRVs based on site-specific toxicity testing

# Technical Module 1: Development of Specific TRVs

- Published TRVs:
  - Example of sources:
    - Oak Ridge National Laboratory [ORNL] guidance documents;
    - US EPA Eco-SSLs;
    - CEAEQ.
  - Several instances of published TRVs based on no-observed-adverse-effects levels (NOAELs) or lowest-observed-adverse-effects levels (LOAELs).

# Technical Module 1: Development of Specific TRVs

Literature-based site-specific TRVs

1. Compile effects studies from the literature to develop a dose-response or concentration-response data set (See technical module 1, table 2):
   - risk assessor should document the type of literature review conducted;
   - primary literature sources should be retrieved and consulted;
   - allows user to assess the study design and data quality.
2. Primary literature should be assessed in terms of data quality and relevance.
3. Derivation Methods for TRVs:
   - Options will vary according to the quantity and specificity of toxicity data used, and the objectives set in the ERA's problem formulation.
   - TRV derivation process should be well documented to ensure transparency.
   - Options for TRV derivation for situations ranging in data availability from low to high:
     - Quantitative Structure-Activity Relationships (QSARs)
     - Single Study TRV
     - Dose- or Concentration-response Relationships
     - Species Sensitivity Distributions (SSDs)
4. Uncertainty and Extrapolations

# Technical Module 1: Development of Specific TRVs

Modifying existing guidelines to develop site-specific TRVs

- Typically, guidelines are developed by regulatory authorities with the objective of establishing safe limits of exposure for ecological receptors within the entire jurisdiction.
- Are usually intended to be conservative to protect the most sensitive species from chronic, long-term exposures to contaminants
- In theory there are various approaches that can be applied to derive site-specific TRVs from guidelines. Some of these include:
  - Application of the background concentration
  - Recalculation of the guideline
  - Application of effects ratio

# Technical Module 1: Development of Specific TRVs

Site-specific toxicity test-based TRVs

- Cover by Technical module 2

# Technical Module 2: Selecting Toxicity Tests for ERAs

- Overview of Different Roles of Toxicity Testing in Ecological Risk Assessment (Line of Evidence, TRV development, etc.)
- Guidance on Interpretation of Toxicity Test Results in a Risk Assessment Weight-of-Evidence Framework
- **Guidance on Selecting Appropriate Toxicity Tests for Ecological Risk Assessment**
- *Format: Guidance Text and Interactive Excel Tables*

# Technical Module 2: Selecting Toxicity Tests for ERAs

**Key Information in 3 Excel Tables:**

- **Table 1:** Demonstrates linkage between receptor types, applicable ecosystem types, test media and what pathways are being simulated
- **Table 2:** Generates a list of all applicable toxicity testing protocols by ecosystems and receptor types
- **Table 3:** Evaluates the suitability of the tests selected in Table 2 :
  - Utility for Risk Assessment
  - Organism/Substrate Characteristics
  - Logistics and Planning

# Technical Module 2: Selecting Toxicity Tests for ERAs

**Table 1. Linkage between receptor types, applicable ecosystem types, toxicity test media, pathways**

Receptor Group: Terrestrial Primary Producer

Organism Type: Moss, grass, shrub, tree, forb

Organism Type ID: PP-Plant

Applicable Ecosystem Types: Terrestrial – human influenced land (all land uses), wildland (all types)

Test Media: Soil

Pathways Simulated: Translocation through roots from soil and porewater; direct contact between roots and soil.

# Technical Module 2: Selecting Toxicity Tests for ERAs

**Table 2: List of toxicity tests, classification, and relevant reference protocols**

Species – Duration – Endpoint: Terrestrial Plants (various) – 14, 21 d – germination, survival & growth

Organism Type ID: PP-Plant

Scientific Name: Various

Classification: Chronic

Relevant Reference Protocols: EPS 1/RM/45 (Environment Canada, 2004)

# Technical Module 2: Selecting Toxicity Tests for ERAs

**Table 3: Summary of factors to consider in selection of toxicity tests for risk assessment purposes**

**Utility for Risk Assessment:**

- Availability of Toxicity Data: ++
- Relevance of Control: +
- Statistical Power: +
- Multiple and Chronic Endpoints: ++
- Geographic Suitability: ++
- Tissue Production: +

**Logistics and Planning Factors:**

- Laboratory Handling: +
- Organism source: +
- Seasonal Availability: +
- Sample Volumes: +
- Availability of Method: ++
- Cost per Sample: $$
- Caveats: Y

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