Phase I Predictive Ecological Risk Assessment Guidance

Overview with Mine Site Example

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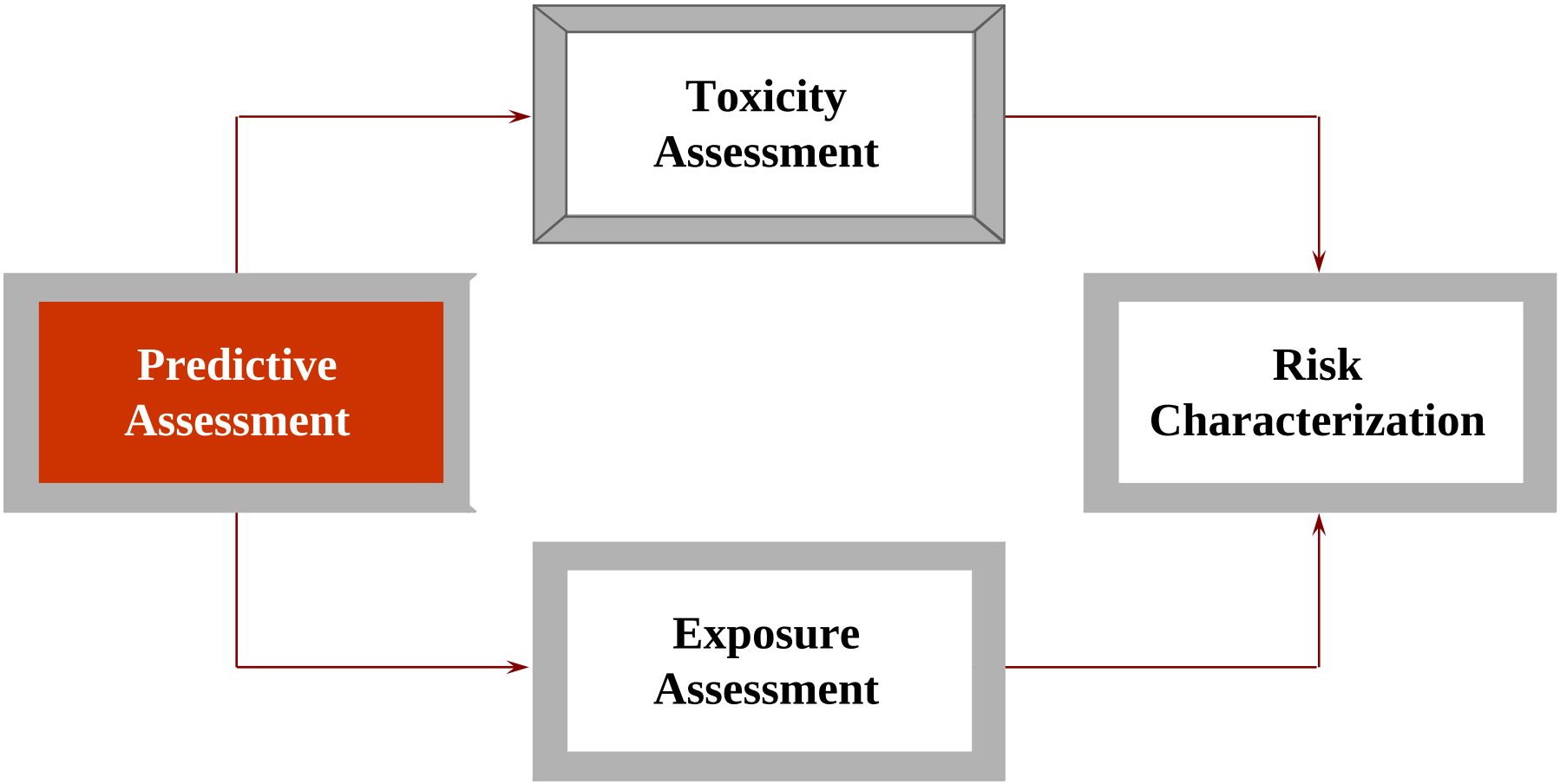
Phase I Predictive Ecological Risk Assessment



Phase I Predictive Ecological Risk Assessment Guidance

Quantitative Assessment (with Toxicity Criteria)

Steps

1. Select representative species for assessment
2. Select assessment and measurement endpoints
3. Conduct exposure assessment (typically “modeled” with protective assumptions)
4. Select protective toxicity criteria
5. Risk characterization(generation of hazard quotients and indices with available toxicity criteria and exposure information).

Step 1. Select Representative Species For Assessment

It is not possible to assess all species occurring or expected to occupy the site: select “representative species” for each trophic level or feeding guild.

Selection Criteria for Representative Species

Examples: see DTSC Guidance for full listing

- Ecological Factors: important prey species
- Toxicological Factors: species similar to those used in standard laboratory bioassays
- Exposure Potential: high site fidelity or likelihood of occurrence in specified habitat
- Societal Factors: representative of possible state or federally protected species occurring at the site

Example Terrestrial Representative Species

Representative Species (Terrestrial Mine Site)

Guild	Species Selected	Attributes
1º Producer	"Plant"	▪Base of the food chain
Detritivore	"Invertebrate"	▪Critical prey species ▪Nutrient recycling
1º Consumers	Ground Squirrel	▪Eats primarily plant material (herbivore) ▪High site fidelity ▪Burrows
	White Crown Sparrow	▪Eats primarily plant material (herbivore)

Representative Species (Terrestrial Cont.)

Guild	Species Selected	Attributes
2º Consumer	Shrew	▪Eats invertebrates (Invertivore) ▪High site fidelity ▪Burrows ▪High exposure potential
	Robin	▪Eats invertebrates and some plant material ▪High exposure potential

Representative Species (Terrestrial Cont.)

Guild	Species Selected	Attributes
3º Consumers**	Coyote	▪Eat mostly small mammals (carnivore) ▪Societal value ▪Further assess food chain impacts
**Consider size of affected habitat	Hawk	

Example Wetland Representative Species

Representative Species (Wetland Mine Site)

Guild	Species Selected	Attributes
1º Producer	Algae Macrophyte (rooted aquatic plant)	▪Base of the food chain
Detritivore/ 1º Consumer	Zooplankton (free floating invertebrates) Benthic Invertebrates	▪Critical prey species ▪Nutrient recycling

Representative Species (Wetland Cont.)

Guild	Species Selected	Attributes
1º & 2º Consumers	"Fish"	▪Eats invertebrates ▪Important prey species ▪Societal and recreational value
	Yellow-legged frog (e.g., tadpole stage)	▪Eats plant material and invertebrates ▪Important prey species ▪High societal value (endangered species)
	Rail (marsh bird)	▪Eats benthic invertebrates ▪High site fidelity ▪High exposure potential ▪Societal value

Representative Species (Wetland Cont.)

Guild	Species Selected	Attributes
3º Consumers**	River Otter	▪Eat fish and aquatic invertebrates
	Great Blue Heron	▪Societal value
**Consider size of affected habitat		▪Further assess food chain impacts

Representative Species (Cont.)

What about other common or expected terrestrial species, for example the soil/sediment microbial community (bacteria/fungi decomposers), amphibians (adult stages), or reptiles (snakes, lizards, turtles)?

- Lack of toxicity information
- Assume protection of other species assessed in the risk assessment is protective of these species or communities.

Describe in the Uncertainty Assessment.

Step 2. Select Assessment and Measurement Endpoints

- Focuses the risk assessment
  - What are we trying to protect?

Select Assessment and Measurement Endpoints

Assessment Endpoints

- Attribute(s) considered to be critical to the function of the biological community or population - may assign "level of protection"
- Focus of the risk assessment.

Measurement Endpoints

- Measurable change that is used to evaluate effects of chemical(s) on selected assessment endpoints.

Assessment and Measurement Endpoints: Mine Site Example (Terrestrial Habitat Examples, Not Inclusive)

Assessment Endpoints	Representative Species	Example Measurement Endpoints
Protect and maintain a health plant community	"Plant"	◆**Soil Toxicity Values (mg/kg)**** ◆**Soil Porewater Tox. Values (µg/L)**** ◆**Plant Distribution/Abundance Surveys. Compare to reference site.** ◆**Plant Tissue Concentrations** ◆**Soil Toxicity Tests**
Protect and maintain a healthy soil invertebrate community **Provide prey for upper trophic level species**	"Invertebrate"	◆**Soil Toxicity Values (mg/kg)**** ◆**Soil Toxicity Tests** ****Low effects level**
Protect _____ populations: survival and reproductive success.	**Ground Squirrel** **Shrew** **Robin** **White-Crowned Sparrow**	◆**Toxicity reference values or Doses (mg/kg day^{-1})** **NOAELs**

Representative Species/Assessment Endpoints Selection

Completed.

- **Next Step: Exposure Assessment**

Step 3. Exposure Assessment

Key Concepts:

- **Exposure Point Concentration (EPC)**
- **Wildlife Exposure Factors**
- **Tissue Concentrations and Food Chain Modeling****
  - Important concepts:
    - Bioconcentration
    - Bioaccumulation
    - Biomagnification
- **Bioavailability**

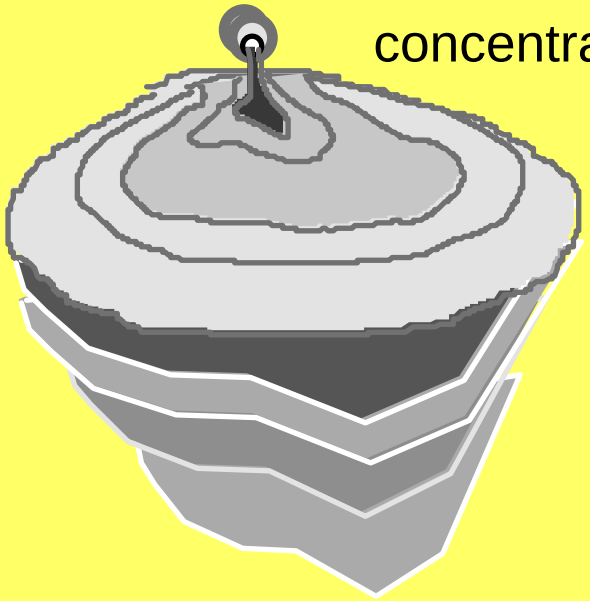
****Important Consideration: Chemical and physical properties assessment of each COPEC**

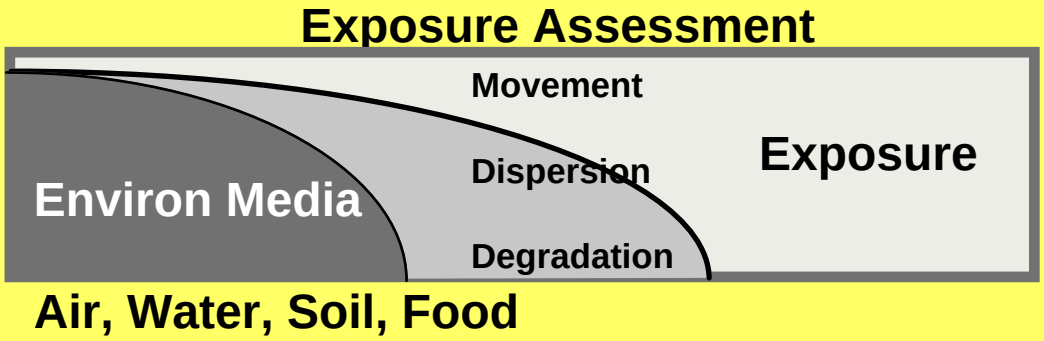
Exposure Assessment

Key Concept

Exposure Point Concentration (EPC)

95th UCL on the arthmetic mean and/or Maximum concentration (e.g., soil, water, tissue)





Exposure Assessment

Key Concept (EPCs Cont.)

Representative Species	Potentially Site Relevant Media of Concern	Exposure Point Concentration
Plants	•Soil •Sediment •Groundwater •Surface water	EPC_{soil} $EPC_{sediment}$ $EPC_{groundwater}$ $EPC_{surface\ water}$
Invertebrates	•Soil •Sediment •Surface water	EPC_{soil} $EPC_{sediment}$ $EPC_{surface\ water}$

Exposure Assessment

Key Concept (EPCs Cont.)

Representative Species	Potentially Site Relevant Media of Concern	Exposure Point Concentration (EPC)
Wildlife	•Soil •Sediment •Surface water (including groundwater seeps)	EPC_{soil} $EPC_{sediment}$ $EPC_{surface\ water}$
	•Tissue conc. or body burden of prey species (modeled or directly measured)	EPC_{plant} $EPC_{invertebrate}$ $EPC_{small\ mammal}$

Exposure Assessment

Key Concept - Wildlife Exposure Factors

Parameter	Some Information Sources
Dietary Preferences	◆USEPA Wildlife Exposure Factors Handbook (1993) ◆DFG California Species Database ◆OEHHA Cal/Ecotox Database
Feeding Rates	◆Nagy (2001) ◆OEHHA Cal/Ecotox Database
Soil/Sediment Ingestion Rates	◆Beyer et al. (1994) ◆OEHHA Cal/Ecotox Database ◆Hui and Beyer (1998)
Home or Foraging Range	◆USEPA Wildlife Exposure Factors Handbook (1993) ◆DFG California Species Database
Body Weights	◆USEPA Wildlife Exposure Factors Handbook (1993) ◆CRC Handbook (1995) ◆OEHHA Cal/Ecotox Database ◆Nagy (2001)

Exposure Assessment

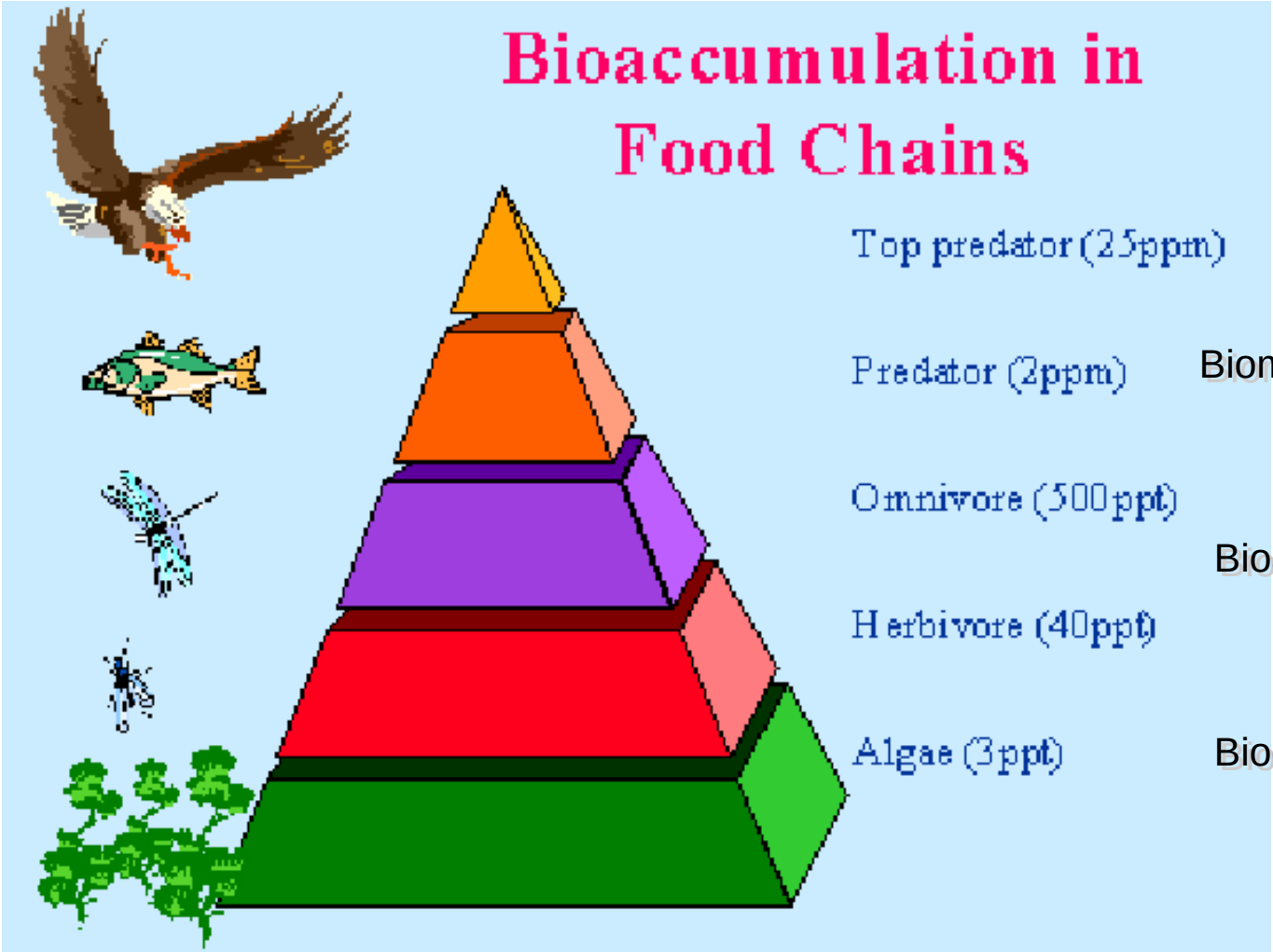
Key Concept: Tissue Concentrations and Food Chain Modeling

Definitions:

- Bioconcentration
- Bioaccumulation
- Biomagnification

**Important consideration: assess chemical and physical properties of each COPEC

Exposure Assessment



Biomagnification

Bioaccumulation

Bioconcentration

Exposure Assessment: Terrestrial Mine Site Example (Main COPEC Arsenic)

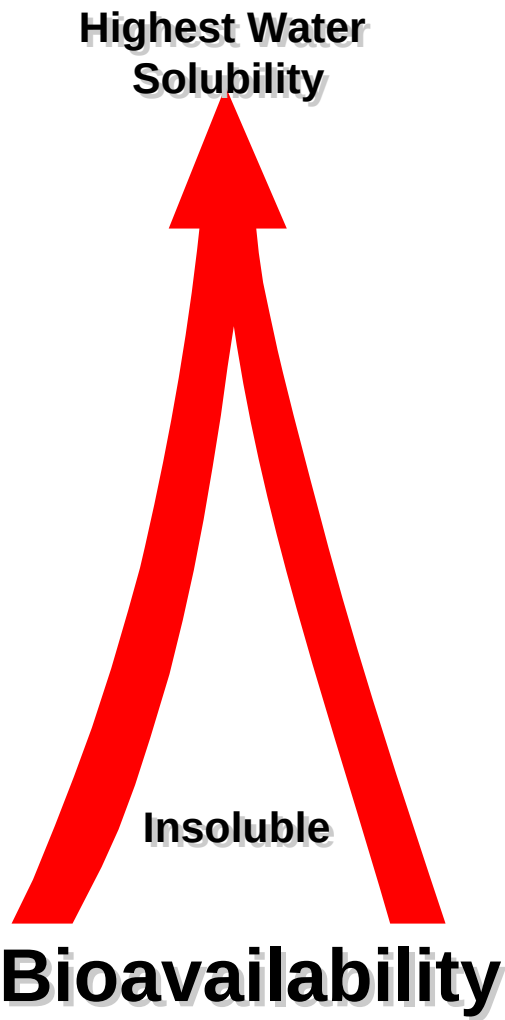
Key Concept: Chemical-Physical Properties Assessment

- Arsenic (C.A.S. 7440-38-2) naturally occurring element in the earth's crust.
- Inorganic arsenic usually found combined with one or more other elements such as oxygen, chlorine, and sulfur.
- Arsenic combined with carbon and hydrogen is referred to as organic arsenic. The organic forms are usually less toxic than the inorganic forms.
- Inorganic arsenic compounds are solids at normal temperatures and are not likely to volatilize.
- Due to human activities, such as mining or smelting, naturally immobile arsenics can be mobilized and be found in higher concentrations than where they existed naturally.

Key Concept: Bioavailability

Potential Forms of Arsenic in the Environment

- **Sodium arsenite**
- **Arsenic acids**
- **Manganese or iron arsenic complexes**
- **Arsenic trisulfide**



Exposure Assessment: Terrestrial Mine Site Example

Hypothetical Exposure Data

Soil/Tailings Site EPC_{soil} (0 to 6 ft below surface):

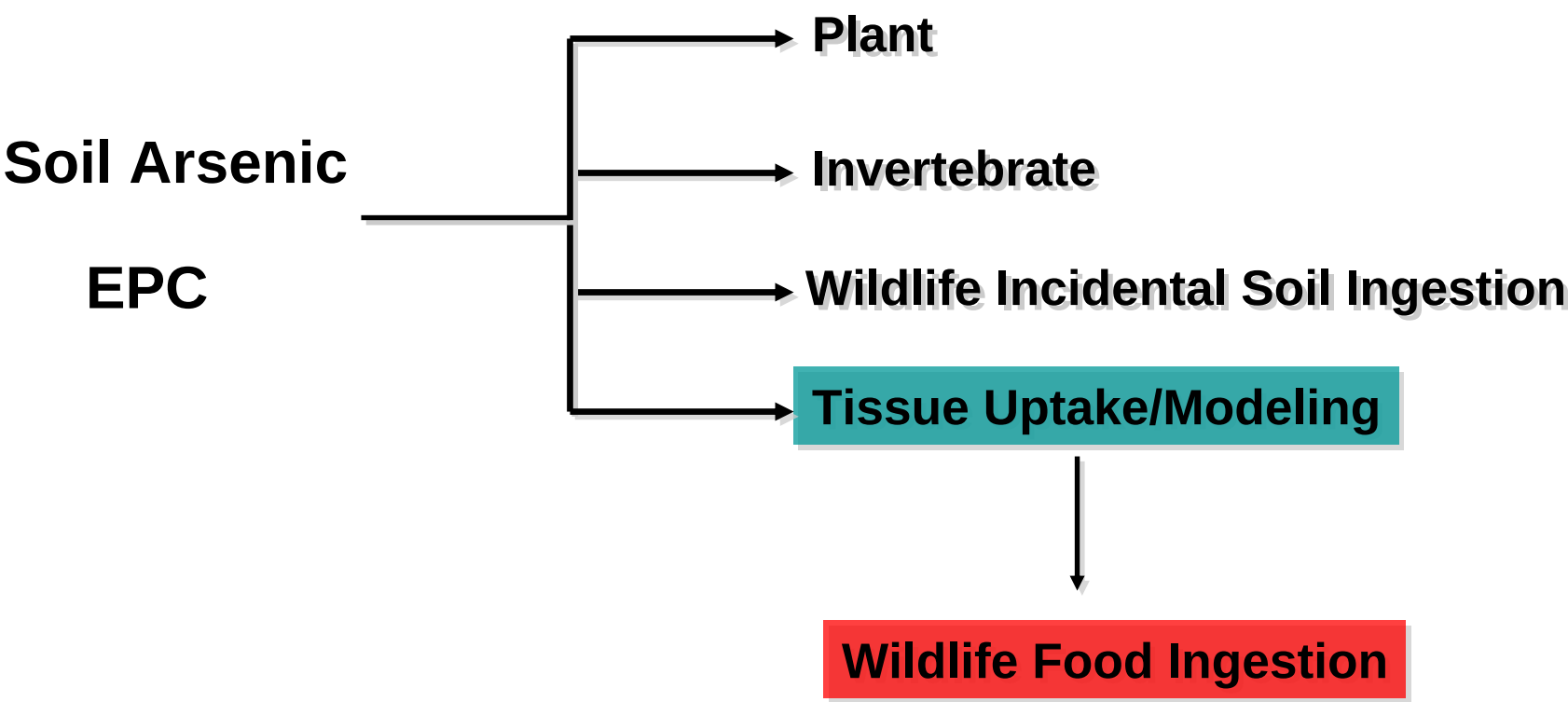
2.5 Acre Site

$Arsenic_{[Max]}$ = 119 mg/kg

$Arsenic_{[95th\ UCL]}$ = 81 mg/kg

$Arsenic_{[Background]}$ = 15 mg/kg

Exposure Assessment: Terrestrial Mine Site Example



Exposure Assessment: Terrestrial Mine Site Example

Tissue Uptake/Modeling

Estimate Prey Tissue Concentrations Using Literature-Derived Bioaccumulation Factors (BAFs)

Herbivore (plant eating)

$$EPC_{soil} * BAF_{plants} = EPC_{plants}$$ (Plant Tissue Conc.)

Invertivore (invertebrate eating)

$$EPC_{soil} * BAF_{invert} = EPC_{invert}$$ (Invert. Tissue Conc.)

Carnivore (flesh eating)

$$EPC_{soil} * BAF_{prey} = EPC_{prey}$$ (Small Mammal Tissue Conc.)

Exposure Assessment: Terrestrial Mine Site Example

Tissue Uptake/Modeling

Estimate Prey Tissue Concentrations of Arsenic Using Literature-Derived Bioaccumulation Factors (BAFs)

Feeding Guild	EPC_{Soil} (mg/kg)	Arsenic BAF** (point estimate or regression)	Arsenic EPC_{Tissue} (mg/kg)
HERBIVORE	119	$BAF_p = 0.03752 * EPC\ soil$ where p = plants	4.46
INVERTIVORE	119	$Ln(BAF_i) = 0.0706 * ln(EPC\ soil) – 1.421$ where i =earthworm	0.34
CARNIVORE	119	$Ln(BAF_m) = 0.8188 * ln(EPC\ soil) – 4.8471$ where m = small mammal prey	0.39

**BAF Source: USEPA EcoSSL Guidance

Exposure Assessment: Terrestrial Mine Site Example

Wildlife Food Ingestion

Parameters Used to Estimate Food Ingestion in Wildlife: Example 1

Literature-Derived Parameters to estimate Ornate Shrew Food and Soil Ingestion Rates

- Average ornate shrew body weight (BW) = 0.0055 kg[1]
- Adult ornate shrew consumes 0.0011 kg invertebrates/day[2]
- Adult ornate shrew incidentally ingests 4% of its total food intake as soil[3]
- Adult ornate shrew forages over 0.2 acre max. (assume contaminated area encompasses shrew's foraging range)[4]

Sources: 1. CRC Handbook of Mammalian Body Masses (1995); 2. Nagy (2001) insectivorous mammal dry matter intake; 3. Beyer et al. (1994) average estimate for voles/mice; 4. Foraging range of the vagrant shrew (surrogate) US Forest Service **(2007).**

Exposure Assessment: Terrestrial Mine Site Example

Wildlife Food Ingestion

Parameters Used to Estimate Food Ingestion in Wildlife: Example 2

Literature-Derived Parameters to estimate Ground Squirrel Food and Soil Ingestion Rates

- Average ground squirrel body weight (BW) = 0.584 kg[1]
- Adult ground squirrel consumes 0.047 kg plant material/day[2]
- Adult ground squirrel incidentally ingests 5.0 % of its total food intake as soil[3]
- Adult ground squirrel forages over 0.5 acre max. (assume contaminated area encompasses squirrels foraging range)[4]

Sources: 1. CRC Handbook of Mammalian Body Masses (1995); 2. Nagy (2001) herbivorous mammal, dry matter intake; 3. Beyer et al. (1994) estimate; 4. California's Wildlife (DFG website): average home/foraging range estimate.

Exposure Assessment: Terrestrial Mine Site Example

- For purposes of this site scenario, we will assume that wildlife receive their primary exposure (dose) via ingestion of food (EPC_{tissue}) and ingestion of soil (EPC_{soil}).

- Other exposure routes, including dermal adsorption and inhalation (i.e., dusts), are considered minor relative to the other exposure routes above, and are not directly quantified.

- Surface water ingestion from a nearby wetland may be a relevant exposure pathway, however, for purposes of time, these calculations are not evaluated in this example.

Exposure Assessment: Terrestrial Mine Site Example

Example Wildlife Dose Calculation (mg/kg BW Day^{-1}):

Daily intake by mammal = CM * CR * FI * AF * BW^{-1}

CM = concentration in media of concern (EPC_{soil} and EPC_{tissue})

CR = contact rate (e.g., amount ingested)

FI = fraction of time spent on site

AF = adsorption factor (e.g., fraction absorbed by the gut)

BW = body weight of species

Exposure Assessment: Terrestrial Mine Site Example

Shrew-Specific Intake Algorithm:

Daily intake = {(Invertebrate [As] mg/kg * Shrew Ingestion Rate) + (Soil [As] * % soil in diet * Shrew Ingestion Rate)} * FI * AF * BW^{-1}

$$= \frac{\{(0.34_{\text{mg/kg}} * 0.0011_{\text{kg food/day}}) + (119_{\text{mg/kg}} * 0.04 * 0.0011_{\text{kg food/day}})\} * 1 * 1}{0.0055 \text{ kg BW}}$$

Maximum Daily Shrew Intake = **1 mg/kg BW Day^{-1}**

Exposure Assessment: Terrestrial Mine Site Example

Squirrel-Specific Intake Algorithm:

Daily intake = {(plant [As] mg/kg * Squirrel Ingestion Rate) + (Soil [As] * % soil in diet * Shrew Ingestion Rate)} * FI * AF * BW^{-1}

$$= \frac{\{(4.46_{\text{mg/kg}} * 0.047_{\text{kg food/day}}) + (119_{\text{mg/kg}} * 0.05 * 0.0024_{\text{kg food/day}})\} * 1 * 1}{0.584 \text{ kg BW}}$$

Maximum Daily Squirrel Intake = **0.38 mg/kg BW Day^{-1}**

Exposure Assessment: Terrestrial Mine Site Example

Completed.

- Next Step: Toxicity Assessment

Step 4. Toxicity Assessment

- **Toxicity Criteria used in the Phase I Risk Assessment**
  - Usually not site-specific
  - Based primarily on laboratory testing results from the scientific literature**

    ****Caveat: bioavailability of chemical in the field may not equal bioavailability of chemical tested in the laboratory**

  - No observable adverse effect level (NOAEL)
  - Lowest observable adverse effect level (LOAEL).

Toxicity Assessment

Some Sources for Wildlife TRVs

Representative Species	Source	Web Link
Birds & Mammals	USEPA Region 9 Biological Technical Assistance Group (BTAG)	http://www.dtsc.ca.gov/AssessingRisk/eco.cfm
Plants Invertebrates Birds Mammals	USEPA Ecological Soil Screening Levels Guidance (EcoSSLs)	http://www.epa.gov/ecotox/ecossl/SOPs.htm
	Oakridge National Laboratory (ORNL)	http://www.esd.ornl.gov/programs/ecorisk/ecorisk.html
Amphibians	Environment Canada	http://www.cws-scf.ec.gc.ca/publications/AbstractTemplate.cfm?lang=e&id=321
	USEPA	http://www.epa.gov/waterscience/criteria/aqlife.html
Algae, Invertebrates (freshwater & marine), Fish	USEPA Ambient Water Quality Criteria	http://www.epa.gov/waterscience/criteria/aqlife.html
Benthic Invertebrates (freshwater & marine sediment)	National Oceanic and Atmospheric Administration (NOAA)	http://response.restoration.noaa.gov/book_shelf/122_squirt_cards.pdf
Fish (sediment)	NOAA	http://www.nwfsc.noaa.gov/publications/displayallinfo.cfm?docmetadataid=3323 http://www.nwfsc.noaa.gov/publications/displayallinfo.cfm?docmetadataid=3906 http://www.nwfsc.noaa.gov/publications/displayallinfo.cfm?docmetadataid=3999

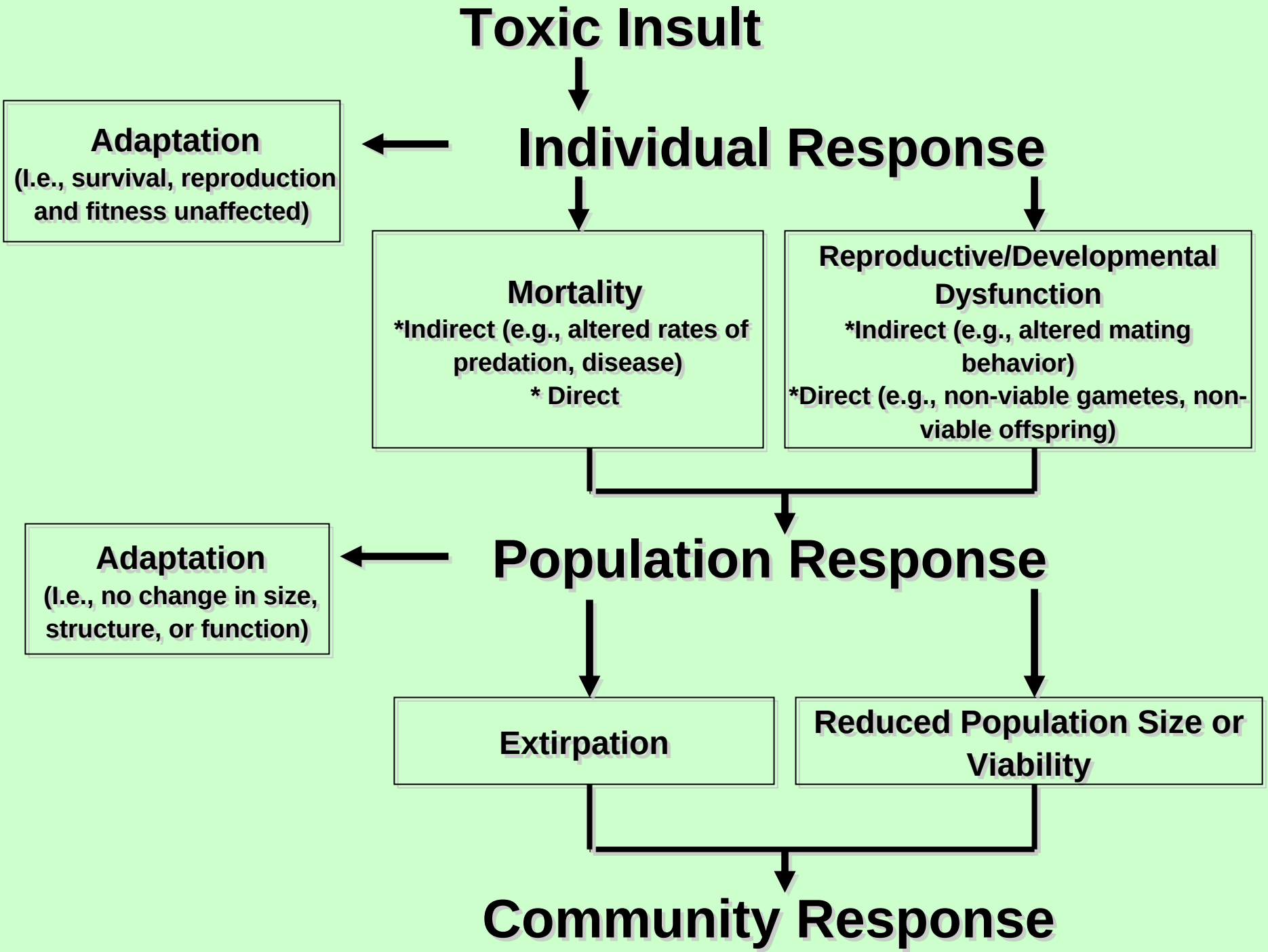
Toxicity Assessment

- **Toxicity Criteria used in the Risk Assessment (Cont.)**
  - Chronic no observable adverse effect level (NOAEL). Represents a “safe” dose (i.e., without adverse effect)
  - Chronic lowest observable adverse effect level (LOAEL) or lowest adverse effect concentration (LOAEC). Represents dose or media concentration that potentially causes an adverse effect
  - Relate to assessment and measurement endpoints
  - Assign level of protection required by risk assessment.

Toxicity Assessment

- **Toxicity Criteria used in the Phase I Risk Assessment (Cont.)**
  - Toxicity Reference Values (TRVs)
    - Plants and Invertebrates: LOAEC-based (toxicity and ecological literature supports even with some loss of individuals, population/community survives)
    - Wildlife (mammals & birds): NOAEL-based** (lack of literature/precedent: unknown how loss of individuals may affect population, therefore use most protective toxicity criteria)

**assume NOAEL also protective of endangered species


Toxic Insult
Individual Response
Adaptation
(I.e., survival, reproduction and fitness unaffected)
Mortality
*Indirect (e.g., altered rates of predation, disease)
* Direct
Reproductive/Developmental Dysfunction
*Indirect (e.g., altered mating behavior)
*Direct (e.g., non-viable gametes, non-viable offspring)
Population Response
Adaptation
(I.e., no change in size, structure, or function)
Extirpation
Reduced Population Size or Viability
Community Response

Toxicity Assessment: Terrestrial Mine Site Example

What is the "population" we are trying to protect? (refer back to the assessment endpoints)

- **Population of plants and animals inhabiting the 2.5 acre site?**
- **Population of plants and animals in Placer County?**
- **Population of plants and animals in Sierra Foothills habitats?**
- **Population of plants and animals in California?**

Toxicity Assessment: Terrestrial Mine Site Example

Selected Toxicity Reference Values
(Arsenic Example)

Representative Species	Value	Source Test Chemical
Plant	18 mg/kg soil Geometric mean of NOAEC & LOAEC	USEPA EcoSSLs Arsenates and Arsenites
Invertebrate	60 mg/kg soil LOAEC	ORNL Potassium arsenate
Bird	5.5 mg/kg BW day^{-1} NOAEL	BTAG Sodium arsenate
Mammal	0.32 mg/kg BW day^{-1} NOAEL	BTAG Sodium arsenite

Toxicity Assessment

Completed.

- **Next Step: Risk Characterization**

Step 5. Risk Characterization

- **Quantify Potential Ecological Hazards**

Hazard Quotient or Index (HQ or HI) =

$$\frac{\text{EPC}}{\text{Toxicity Reference Value (NOAEL/LOAEL/LOAEC)}}$$

If HQ or HI > 1 → **unacceptable risk? confirm via Phase II**

Risk Characterization: Terrestrial Mine Site Example

Representative Species	Exposure Values	Toxicity Value	Hazard Quotient (HQ)	Confidence in the HQ	
				Exposure Potential	Toxicity Value
Plant	119 mg/kg (Max) 81 mg/kg (95th UCL)	18 mg/kg soil	7 5	Low**	High
Invertebrate	119 mg/kg (max) 81 mg/kg (95th UCL)	60 mg/kg soil	2 1.3	Low	Low
Bird (White-Crowned Sparrow)	1.4 mg/kg BW day^{-1} (MAX)	5.5 mg/kg BW day^{-1}	0.3	Low	Moderate

**Low confidence in exposure assumptions; however, we assume a protective "worst case" or highly bioavailable exposure scenario.

Risk Characterization: Terrestrial Mine Site Example

Representative Species	Exposure Values	Toxicity Value	Hazard Quotient (HQ)	Confidence in the HQ	
				Exposure Potential	Toxicity Value
Mammal (Ground Squirrel)	0.38 mg/kg BW day^{-1} (MAX)	0.32 mg/kg BW day^{-1}	1.2	Low	High
	0.37 mg/kg BW day^{-1} (95th UCL)		1.2		
Mammal (Ornate Shrew)	1.0 mg/kg BW day^{-1} (MAX)		3.2	Low	High
	0.71 mg/kg BW day^{-1} (95th UCL)		2.2		

**Low confidence in exposure assumptions; however, we assume a protective "worst case" or highly bioavailable exposure scenario.

Risk Characterization

Report

- Representative species
- Assessment/measurement endpoints
- HQs and HIs (and all supporting data to reproduce calculations)
- Draw together various lines-of-evidence
- Uncertainty Assessment
  - Exposure assumptions
  - Toxicity assumptions

If Required: Establish Soil-Based Ecological Preliminary Remediation Goals (Consider arsenic and other chemicals)

Risk Management Decision-Making and Ecological Risk

- **Lines-of-Evidence Needed for Risk-Management Decision Making:**
  - Identified chemicals of concern and potential exposure pathways
  - Range of representative species evaluated (i.e., including special status species)
  - Persistence and bioaccumulation potential of chemical(s) of concern
  - Bioavailability

Risk Management Decision-Making and Ecological Risk

- **Lines-of-Evidence Needed for Risk-Management Decision Making (Cont.)**
  - Uncertainty contained in exposure models (e.g., estimated intake levels and site use factors)

Risk Management Decision-Making and Ecological Risk

- **Lines-of-Evidence Needed for Risk-Management Decision Making (Cont.)**

  - Magnitude of the hazard quotients or hazard indices generated from the NOAEL or LOAEL toxicity values

Risk Management Decision-Making and Ecological Risk

- **Lines-of-Evidence Needed for Risk-Management Decision Making (Cont.)**
  - Toxicological endpoint of the toxicity value used to calculate the hazard quotients or indices (i.e., NOAEL, LOAEL)
  - Cumulative risk (i.e., risks derived from more than one chemical exposure, risks evaluated site-wide)
  - Toxicological endpoint, laboratory species tested, and magnitude of any uncertainty factors used to develop the final toxicity value (i.e., that value proposed to calculate a target cleanup level)
  - Estimated and potentially field-verified toxicity evaluations

Risk Management Decision-Making and Ecological Risk

- **Lines-of-Evidence Needed for Risk-Management Decision Making (Cont.)**
  - Any potential adverse effects of remediation on sensitive ecological habitats.
  - Current and future land use

Risk Characterization: Terrestrial Mine Site Example

Risk Management Decision Point

Looks like there could be a problem for terrestrial plants and small mammals. Options:

- Remediate
  - Demonstrate protection of human health is protective of ecological receptors (including wetland species, if present)
  - cleanup to levels protective of human health (i.e., residential) or cleanup to background

– OR –

- Further Study - Phase II Validation Study, including one or more of the following options:
  - Bioavailability/bioaccessibility assessment
  - Exposure reassessment (collect site plant/invert. tissues)
  - Toxicity bioassays
  - Prepare refined soil cleanup levels

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