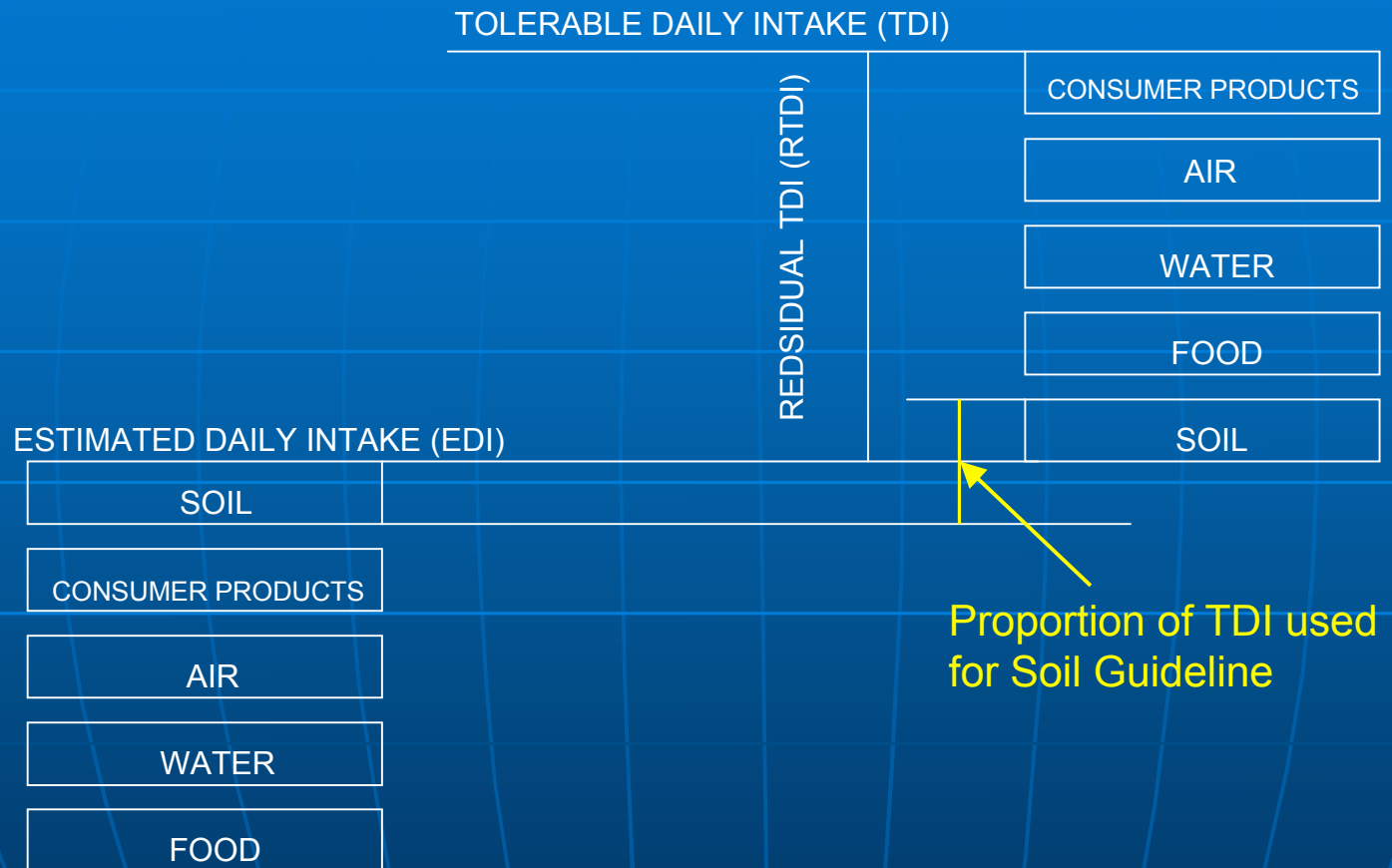

Risk Assessment When Background Exposures Exceed Toxicological Limits

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Introduction

- Consideration of background + site exposure in risk assessment, CCME risk-based guideline derivation
- Risk assessment: total exposure = site + background
- Guidelines: “residual TDI” approach

Residual TDI Approach



Source: CCME (2006)

Introduction

$$HQ = \frac{EDI + EXP}{TDI}$$

$$SQG_{HH} = \frac{(TDI - EDI) \times SF \times BW}{IR \times AF \times ET} + BSC$$

Introduction

- What happens when background exposure (EDI) exceeds allowable exposure (TDI)?
 - Occurs for several substances; mainly metals but some organics
- No allowable site exposure
- Can't calculate soil guideline

Why does EDI exceed TDI?

- Uncertainty/variability in EDI
- Uncertainty/conservatism in TDI
- Narrow range of essential and toxic doses
- Background dose is potentially hazardous

Possible Approaches

- Are the EDI and TDI appropriate?
 - Confirm/re-evaluate TDI
 - Confirm/re-evaluate EDI
 - Adjustment of EDI for relative bioavailability?
 - Separation of inhalation exposure?

Possible Approaches

- Allow exposures to exceed EDI by defined amount
 - Variability in EDI may be 20% to 50% or more
 - Allow site exposure to be 10% of EDI (for example)
 - Approach still considers background exposures
 - Allows exposure to exceed TDI

Possible Approaches

- Exclude the EDI from calculations
 - Set allowable exposure at 20% of TDI
 - Similar to many other jurisdictions
 - Background exposure is not addressed quantitatively
 - Total exposure exceeds TDI

Possible Approaches

- Adopt an upper percentile background concentration
 - May be unnecessarily conservative for substances where soil exposure is small portion of EDI
 - No consideration of exposure through other media
 - No consideration of dose at which health effects are expected
 - Variability in background concentrations

Possible Approaches

- Probabilistic evaluation of EDI and increasing soil concentrations
 - Allow a certain % increase in mean and 90th percentile EDI or increase in proportion of population exceeding TDI
 - More direct consideration of uncertainties and population variability
 - Still allows exposure over TDI
 - Data-intensive; professional judgment

Possible Approaches

- Combination of 2 or more approaches
 - For example, use the lower of 10% of EDI and 20% of TDI

Example - Zinc

- TDI = 490 ug/kg-bw/d
- EDI = 565.6 ug/kg-bw/d
- Background concentration = 72 mg/kg (range 5 – 300 mg/kg)
- Guideline based on 10% of EDI = 2200 mg/kg
- Guideline based on 20% of TDI = 22,000 mg/kg

Implications/Discussion

- Regardless of approach, exposure > TDI
- What about substances with EDI close to TDI?
- Should different substances be treated the same?
 - Essential nutrients, other natural substances, persistent organic pollutants

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