Risk Assessment and Risk Management, I

Principles of Environmental Toxicology
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Learning Objectives

- Develop a basic understanding of risk assessment and its role within the risk management process.
- Differentiate between risk assessment and risk management.
- Develop a basic understanding of how to conduct and evaluate an uncertainty analysis for a risk assessment.

"Fear of danger is ten thousand times more terrifying than danger itself."

--Daniel Defoe (1660-1731)

Risk: Perceptions and Preferences

- Experts and the public often disagree about risk.
- People will accept risks 1,000 greater if they are voluntary (e.g. driving a car) than if they are involuntary (e.g. a nuclear disaster) [Starr 1969].
- Risk attributes that lead to cognitive bias:
  - Availability
    - Imagining scenarios
  - Anchoring
    - Background knowledge
  - Gain/Loss asymmetry
    - Loss is value greater
  - Threshold
    - Adverse to uncertainty

Toxicology and Risk Analysis

- Risk analysis is broadly defined to include risk assessment, risk characterization, risk communication, risk management, and policy relating to risk.

Society of Risk Analysis

Toxicology and Risk Analysis

- Risk assessment
  - Scientific evaluation of the probability of harm resulting from exposure to toxic substances. (EPA)
  - Risk characterization
  - A description of the nature and magnitude of health risk that combines results of exposure assessment and hazard identification and describes the uncertainty associated with each step. (NAS)
- Risk communication
  - The science of communicating effectively in situations that are of high concern, sensitive, or controversial. Risk communication principles serve to create an appropriate level of outrage, behavior modification, or mitigating response, that is in direct proportion to the level of risk or hazard. (Risk Communication Network)
- Risk management
  - Risk management is the decision-making process involving considerations of political, social, economic and science/engineering factors with relevant risk assessments relating to a potential hazard so as to develop, analyze and compare options and to select the optimal response for safety from that hazard. (Intl. Risk Governance Council)

Risk Triad

Risk Assessment

- Ecological Risk Assessment (ERA).
- Human Health Risk Assessment.

Ecological Risk Assessment

- Ecotoxicology
  - The study of the ways in which polluting agents disturb biological populations and communities.
- Ecological risk assessment.
  - Ecological field surveys in terrestrial and aquatic environments.
  - Fate and transport modeling.
  - Toxicity testing.
  - Bioaccumulation studies.
  - Risk characterization.
    - Population, community and ecosystem levels.

Human Health Risk Assessment

- Predictive modeling of the threat to human health posed by the exposure to toxicants.
- For constituents that are systemic toxicants, the threat can be expressed in terms of a hazard quotient.
- Hazard Quotient = Dose ÷ Toxicity Factor.
  - Toxicity factor can be "maximum safe intake"
  - A hazard quotient ≤ 1.0 is typically regarded as acceptable

Fundamentals of HHRA

- Systemic toxicity is a threshold phenomenon.
  - Increasing exposure (dose) of a chemical will cross a threshold when biological effects will start to occur.
  - The dose is the total dose attributable all routes of exposure.
- Cancer: non-threshold
- Toxicity factors for systemic toxicants are reference doses.
  - i.e., the "no effect" level.
- Dose and reference dose units.
  - mg of constituent per kg receptor body weight per day, or mg/(kg·d).

Fundamentals of HHRA

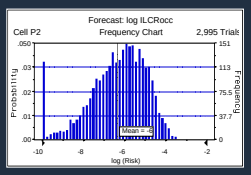
Dose is modeled with the following general equation (unit conversion factors are used as needed); e.g.:

$$\text{Dose} = \text{CC} \times \text{CR} \times \text{EF} \div (\text{BW} \times \text{UCF})$$

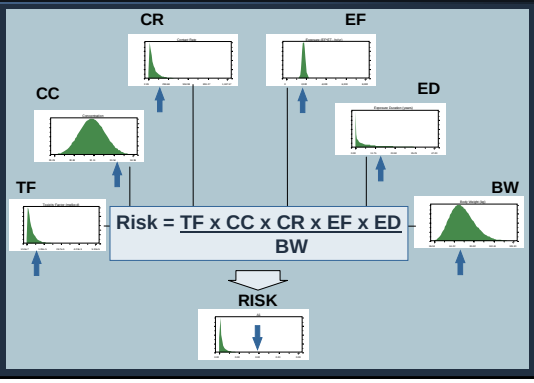
- CC — constituent concentration in the medium of potential concern (*e.g.*, mg/L).
- CR — contact rate with the medium of potential concern (L/d).
- EF — exposure frequency with the medium of potential concern (d/yr).
- BW — body weight (kg).
- UCF — unit conversion factor (e.g., d/yr).

Risk Models

- Deterministic: point estimates
  - Straight-forward; easier risk communication
- Probabilistic (stochastic): distributions
  - Uncertainty quantified; statistical representations



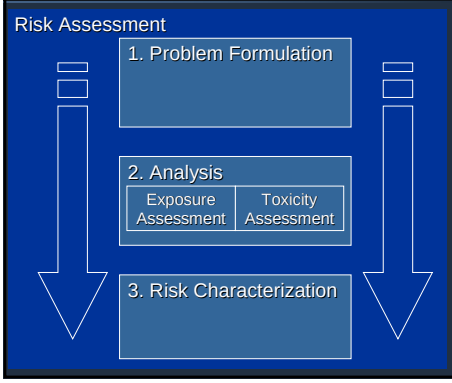
Risk Models: Deterministic vs. Probabilistic



Assessment vs. Management

- Separate, but integrated, processes.
- Risk manager's mission: protect human health.
  - i.e., be conservative.
- Risk assessor's mission: provide risk manager with best information possible.
  - i.e., be honest.
  - Traditional deterministic (i.e., point-estimate) risk assessments can confound risk assessment with risk management by compounding conservative assumptions.

Risk Assessment Framework



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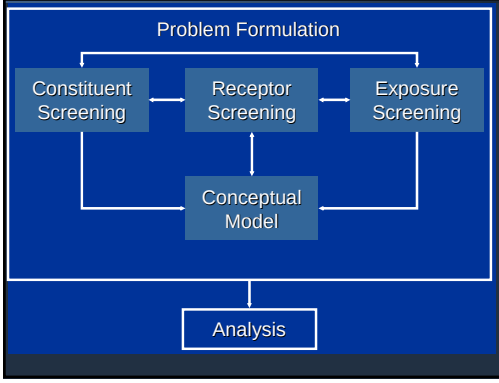
Problem Formulation



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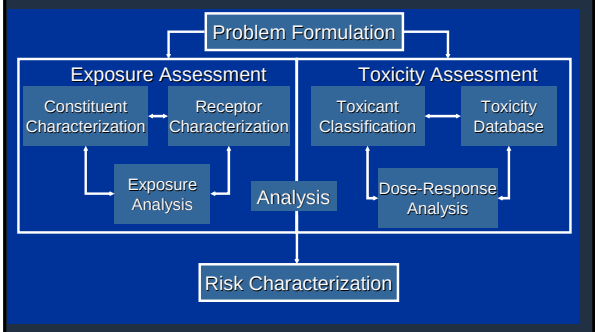
Analysis



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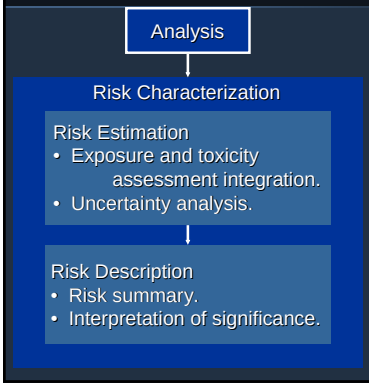
Risk Characterization



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RA Framework Summary

- Risk assessment: predictive modeling of potential human health threats.
- Risk assessment *vs.* risk management: distinct, but integrated processes.
- Risk assessment framework.
  - Problem formulation.
  - Analysis.
  - Risk characterization.
    - An iterative process.

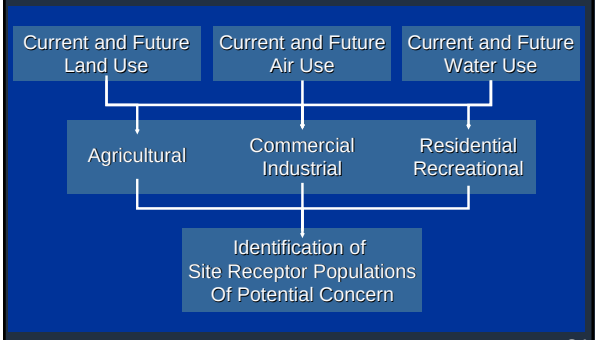
Problem Formulation

- Screening.
  - Identification of constituents of potential concern.
  - Identification of receptors of potential concern.
  - Identification of exposure pathways of potential concern.
- Conceptual modeling.

Constituent Screening

- Determine if [X] is a constituent of potential concern.
  - [X] → Applicable regulatory criterion?
  - [X] → Site-specific background distribution?
  - [X] → Conservative site specific objective?

Receptor Screening



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Exposure Pathway Screening

- Volatilization?
- Dust, Particulates?
  - Settling to water, populations?
- Release to surface water, sediments?
  - Drinking water, aquatic wildlife, groundwater, irrigation.
- Release to soils?
  - Groundwater, wells, agriculture, food chain biota.

Conceptual Modeling

- Summarizes and documents results of constituent, receptor, and exposure pathway screening.
- Forms the basis for subsequent quantitative modeling.
- Effective tool for communication and management.

Problem Formulation Summary

- Primarily a screening exercise.
- An exercise in conceptual model development assisted by rapid and simple quantitative modeling.
- Used to focus subsequent, intensive efforts, if any, on those variables and sub-processes which are likely to contribute most to the risk estimate.

Problem Formulation Summary

- Developing a working definition of “exposed population” (i.e., the receptor population of potential concern) may take more art than science.

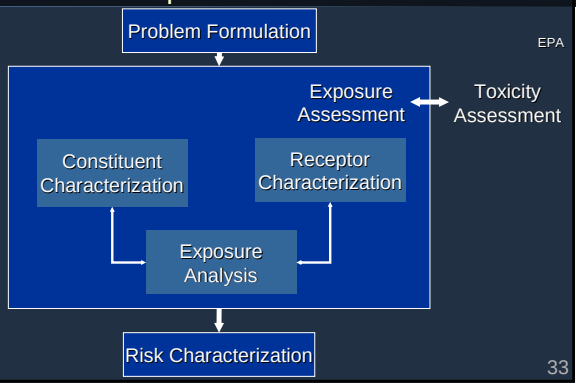
Problem Formulation Summary

- Quantitative aspects of screening constituents, pathways, and receptors are generally carried out deterministically.
- Future site use assumptions are important.
- Excellent process for project planning, not just as the first phase of a risk assessment carried out at the end of a site investigation.
- Really an ongoing process.

Analysis

- Exposure assessment.
  - Constituent characterization.
  - Receptor characterization.
  - Exposure analysis.
- Toxicity assessment.
  - Toxicant classification.
  - Toxicity databases.
  - Dose-response analysis.

Exposure Assessment



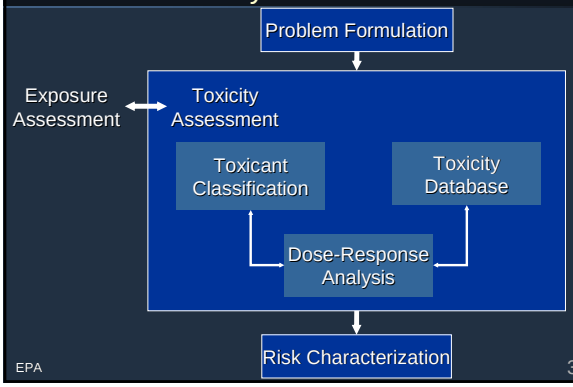
Exposure Assessment

- Best opportunity to introduce site specificity.
- Usually the most intensive aspect of quantitative risk modeling.
- Substantial amount of information available, and much of it is readily available.
- Need to consider bioavailability adjustment.
- For carcinogens, need to focus on incremental cancer risk.

Exposure Assessment

- For systemic toxins, need to consider dietary intake.
  - Qualitative consideration may suffice.
- Need to consider correlations.
- Need to consider spatial and temporal variability.
- Need to include likelihood of scenario occurrence in exposure quantifications.

Toxicity Assessment



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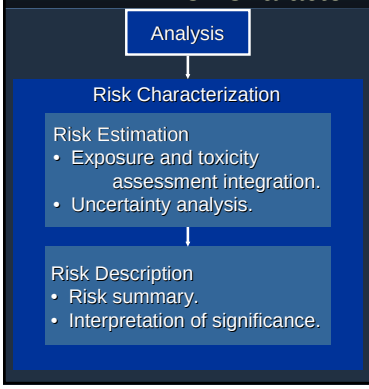
Toxicity Assessment

- Usually the most over-rated aspect of risk modeling, but often the most uncertain component.
- Good databases available.
- Most toxicity factors have enormous amount of lack of knowledge that is hard to reduce.
  - Expense of toxicological studies.
  - Inherent ignorance in extrapolating from animals to humans.
- Bioavailability adjustments.

Risk Characterization

- Risk estimation.
  - Exposure and toxicity assessment integration.
  - Uncertainty analysis.
- Risk description.
  - Risk summary.
  - Risk interpretation.

Risk Characterization



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Risk Description

- Summarization
  - Give a picture of the risk estimate.
  - Focus on the 95th percentile estimate.
  - Acknowledge the uncertainty.
- Interpretation
  - Put the estimated risk into a regulatory perspective.
  - Put the estimated risk into a real-world perspective.

Risk Characterization Summary

- Explain uncertainty of risk estimate.
  - Descriptive statistics, sensitivity to independent variables, and contributions of major model components; conduct value-of-information analysis and provide recommendations, if any, for further work.
- Focus on the 95th percentile of the risk estimate.
- Put the risk into regulatory and real-world contexts.

Assessment vs. Management

- Integrated, but separate, processes.
- Different missions.
  - Risk manager—be protective.
  - Risk assessor—be unbiased.
- Precaution required so as to not confuse the two missions and processes.

Overview of Statistics

- Statistical descriptors.
- Spatial and temporal analyses.

Measures of Central Tendency

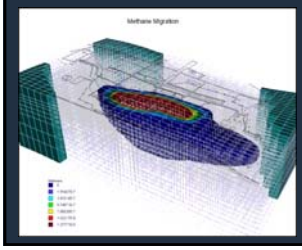
- Mean, μ
- Median, $p_{0.50}$
- Mode, m

Measures of Uncertainty

- Standard deviation, σ
- Variance, σ^2
- Coefficient of variation, σ/μ
- Range, υ-λ
- Informational entropy, H

Spatial & Temporal Analyses

- Geostatistics.
- Trend analysis.
- Predictive modeling.



Fundamental Probability Concepts

- Central Limit Theorem.
  - The sum of an infinite number of distributions, regardless of their form, is a normal distribution.
  - The product of an infinite number of distributions, regardless of their form, is a lognormal distribution.
- Uncertainty.
- Distribution development.
- Correlation analysis.
- Uncertainty, sensitivity, contribution, and value-of-information analyses.