Risk Assessment and Risk Management, II

Principles of Environmental Toxicology
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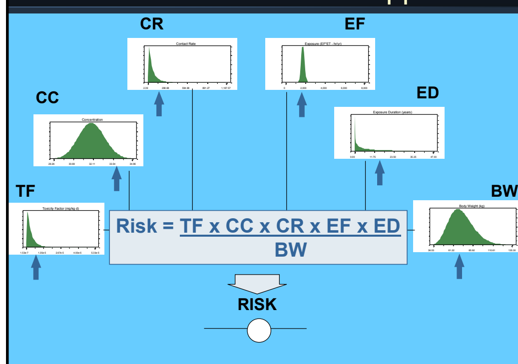
Modeling Risks

- “All models are wrong; some models are useful.” George Box

Why Model Risks?

- Generally, modeling is performed to:
  - Better understand a system.
  - Make predictions.
- Specifically, risk modeling is often necessary because:
  - Acceptable risk levels are not measurable.
  - Direct sampling is not feasible.

Point-Deterministic Approach



Monte Carlo Simulation

Definition

- A technique by which a prediction is calculated repeatedly using randomly selected what-if trials.
- The results of numerous trials are plotted to represent a frequency distribution of possible outcomes allowing the likelihood of each such outcome to be estimated.

Monte Carlo Simulation

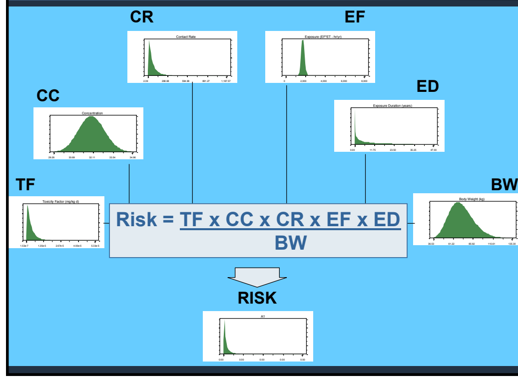
History

- Games of chance were used in the late 19th and early 20th centuries to infer outcomes.
  - e.g., π was estimated by how often a haphazardly tossed pin intersected lines on a grid.
    - The term, “Monte Carlo,” came into use to describe this process at Los Alamos National Laboratory in the late 1940s. Intensive application of the process started in the 1950s.

Available Tools

- Excel® or Lotus® Monte Carlo simulation add-in programs.
- Crystal Ball®
  - User friendly.
  - Good graphics.
- @Risk®
  - Powerful.
  - Large selection of distributions.

Stochastic Approach



Stochastic vs. Deterministic

- Similarities
  - Both approaches operate on the same fundamental model structure.
  - Both approaches generally utilize the same data.

Stochastic vs. Deterministic, 2

- Differences.
  - Stochastic approach utilizes complete distributions; deterministic approach utilizes a single point from each (specified or unspecified) distribution.
  - Stochastic approach quantifies uncertainty; deterministic approach does not.

Stochastic vs. Deterministic, 3

- Differences.
  - Stochastic approach is generally more time and resource intensive than the deterministic approach.
  - Stochastic approach is capable of providing more realistic predictions; deterministic approach is more general.

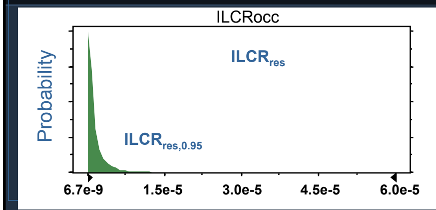
Comparison

Parameter	Deterministic	Stochastic
Precision	No information	Quantified
Accuracy	Conservatively biased	Relatively unbiased
Representative-ness	No information	Statistics are representative
Comparability	Not comparable	Statistics are comparable
Completeness	Incomplete	Complete
Robustness	Non-robust	Robust

Case Histories

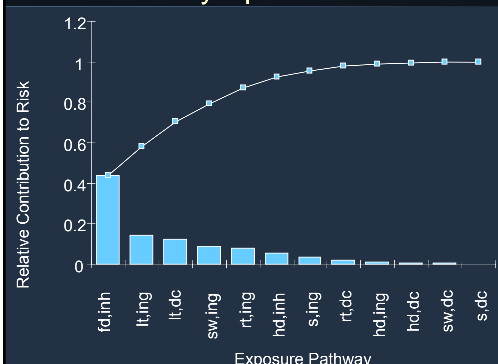
- As-contaminated mine site in British Columbia, Canada.
- Pb-contaminated smelter site in Utah.
- ^{226}Ra-contaminated smelter site in Idaho.
- Catacarb release at a refinery in California.

As-Contaminated Mine Site

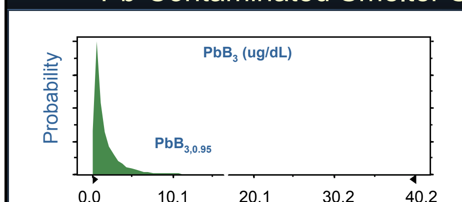


- Mean $2x10^{-6}$ (2 in one million)
- Median $5x10^{-7}$ (5 in ten million)
- 95th%ile $8x10^{-6}$ (8 in one million)
- Pt.-det. estimate $1.0x10^{-3}$ (1 in one thousand) >> 99.9th%ile (bounding est.)
- Difference 120x

Pathway-Specific Contribution

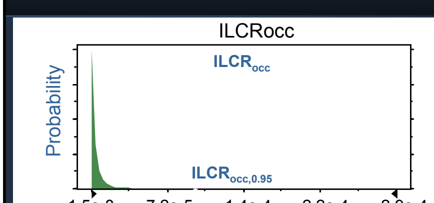


Pb-Contaminated Smelter Site



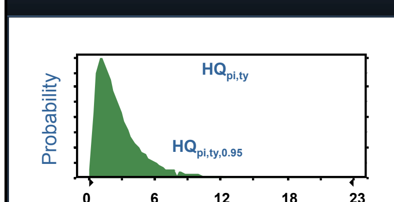
- Mean 2 ug/dL
- Median 1.2 ug/dL
- 95th%ile 9 ug/dL
- Pseudo-sto. est. 17 ug/dL > 98th%ile (potential bounding est.)
- Overestimation 1.9x

^{226}Ra-Contaminated Smelter



- Mean $8x10^{-6}$ (8 in 1 million)
- Median $6x10^{-7}$ (6 in 10 million)
- 95th%ile $4x10^{-5}$ (4 in 100 thousand)
- Pt.-det. estimate $2x10^{-3}$ (2 in 1 thousand), >> 99.9th%ile (bounding est.)
- Overestimation 50x

Catacarb Release at a Refinery

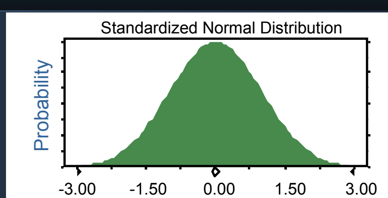


- Mean 3
- Median 2
- 95th%ile 8
- Pt.-det. estimate 60 >> 99.9th%ile (bounding est.)
- Difference 8x

Common P. Distributions

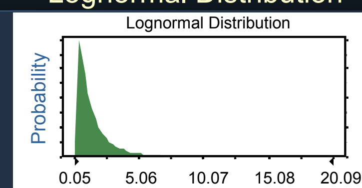
- Normal
- Lognormal
- Uniform
- Loguniform
- Beta
- Gamma
- Exponential
- Custom
- Triangular

Normal Distribution



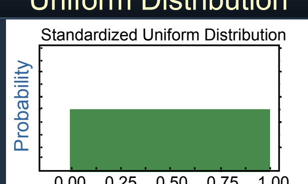
- Bell-shaped curve.
- Unbounded.
- Most commonly known distribution due to extensive use in classical statistics.
  - Definition: N(μ, σ).

Lognormal Distribution



- Logarithms of values are normally distributed.
- Used to represent positively skewed data.
- Commonly used to describe environmental and biological variables.
  - Definition: LN(μ, σ, λ).

Uniform Distribution



- All values between the bounds occur with equal likelihood.
  - Definition: U(λ, υ).

Stochastic *vs.* Deterministic

- Virtually all non-trivial models, which are simplified representations of reality, are inherently uncertain.
- Deterministic modeling is relatively simple and is less demanding of time and resources.
- Stochastic modeling is more realistic and quantifies uncertainty.
- Monte Carlo simulation is a standard stochastic modeling algorithm.

Stochastic *vs.* Deterministic, 2

- Monte Carlo simulation software and compatible hardware are readily available.
- Deterministic modeling is a good screening tool.
- Most valid concerns about Monte Carlo simulation apply equally or more so to deterministic techniques.
- Deterministic risk models are an easier task in risk communication.

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.

Risk Management

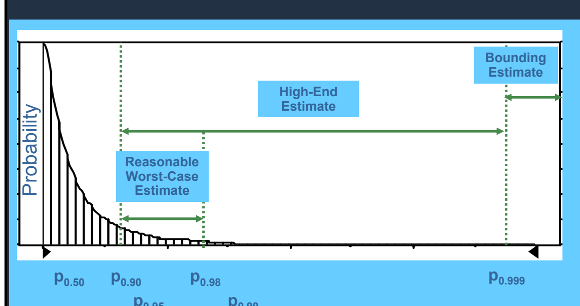
- Decision criteria.
- Value-of-information analysis and further site characterization.
- Decision analysis and remedy selection.

Decision Criteria

USEPA’s Nine-Criteria Decision Model

- Threshold criteria
  - Protection of human health and the environment.
  - Compliance with legally applicable or relevant and appropriate standards, requirements, criteria, or limitations.
- Balancing criteria
  - Long-term, short-term performance.
  - Reduction of waste volume or toxicity.
  - Implement-ability; cost.
- Modifying criteria
  - State acceptance.
  - Community acceptance.

Valid High-End Risk Estimate



Valid High-End Risk Estimate?

- High-end estimate defined by USEPA (1992) as being within the 90th to 99.9th percentiles.
  - Reasonable worst-case estimate defined by USEPA (1992) as being within the 90th to 98th percentiles.
  - Bounding estimate defined by USEPA (1992) as being above the 99.9th percentile.
    - Precedent: Established decision criterion range for the USEPA's LEAD model is within the 90th to 95th percentiles.

Value-of-Information Analysis

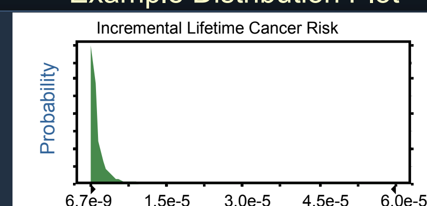
- Value-of-information analysis.
  - A logical way of assessing and communicating the need, or lack thereof, for further information.
  - Having more data is not better if it the data do not contribute to a significantly better decision.
- Help identify bias and uncertainty.

Uncertainty-Type Analyses

Graphical Methods

- Distribution plot
- Tornado plot
- Pareto plot

Example Distribution Plot



Statistics

mean, μ: 2×10^{-6}

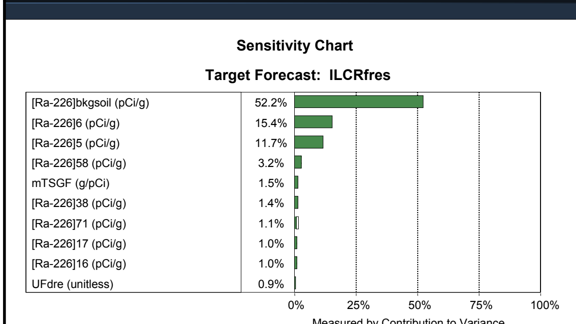
standard deviation, σ: 6×10^{-6}

coefficient of variation, σ/μ: 3

95th percentile, $p_{0.95}$: 8×10^{-6}

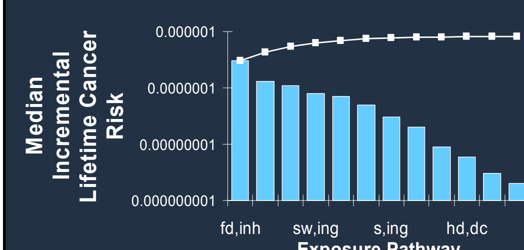
Deterministic estimate: 1.0×10^{-3}

Example Tornado Plot



Example Pareto Plot

Pathway-Specific Contribution Analysis



Value-of-Information Analysis, 2

- Identification of biases and uncertainties.
- Evaluation of type(s) of biases (i.e., high or low) and uncertainties (i.e., variability or ignorance).
- Evaluation of feasibility of reducing biases and those uncertainties
  attributable to ignorance.

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Computer-Aided Decisions

- Real-time, interactive software available.
- Helps to effectively allocate finite resources among competing objectives.
- Facilitates identification of relevant goals, objectives, and criteria.
- Forces quantification of value judgements, subjectivity, and uncertainty.

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Computer-Aided Decisions, 2

- Supports and enhances identification, development, and evaluation of alternative remedies.
- Supports value-of-information analyses.
- Builds consensus.
- Provides a defensible record of the decision-making process.

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Computer-Aided Decisions, 3

- Approach
  - Establish goals defined in terms of measurable objectives or criteria.
  - Identify and develop alternative remedies.
  - Technical evaluation of objectives and criteria
    - *e.g.*, assessment of cost, risk, and public acceptance.
  - Weight objectives and criteria according to values.
  - Generate composite scores for each alternative.
  - Evaluate uncertainties in results.

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Risk Management Summary

- Risk-based decision criteria used for contaminated sites are very conservative.
- Value-of-information analysis is an excellent means of determining and communicating the need, if any, for further site characterization efforts.
- Real-time decision analysis techniques offer an effective means to facilitate and optimize remedy selection.

Summary

- Risk assessment is an iterative predictive modeling process.
- Risk assessment is distinct, but related to, risk management.

Summary, 2

- Problem formulation.
  - Should begin with project planning and should be conducted continuously throughout a site investigation.
  - A screening process to identify constituents, receptors, and exposure pathways of potential concern.
  - Deterministic risk assessments can be used effectively for screening.
  - Documented in the form of a conceptual model.

Summary, 3

- Analysis.
  - Exposure assessment: usually the most intensive aspect of quantitative risk modeling.
  - Toxicity assessment: excellent databases available from which distributions can be derived.
  - Exposure and toxicity often need to be adjusted for bioavailability.

Summary, 4

- Risk characterization.
  - A deterministic assessment is often useful for screening to limit stochastic modeling efforts.
  - Focus on the 95th percentile of the estimate risk distribution.
  - Put the risk estimate into regulatory and real-world perspectives.

Summary, 5

- Risk management.
  - Value-of-information analysis is an excellent means of determining and communicating the need, if any, for further site characterization efforts.
  - Real-time decision analysis techniques offer an effective means to facilitate and optimize remedy selection.

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Summary, 6

- Stochastic *vs.* deterministic risk modeling.
  - Stochastic risk modeling is often a very cost effective approach to risk assessment.
  - Monte Carlo simulation is the most versatile and easily understood technique for stochastic modeling.

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Summary, 7

- Stochastic modeling is capable of yielding results of higher quality than those yielded by deterministic modeling.
- Most concerns about stochastic modeling apply equally or more so to deterministic modeling.

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