PROBABILISTIC RISK ASSESSMENT FOR SUPERFUND SITES

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US EPA / OLEM / OSRTI
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OVERVIEW

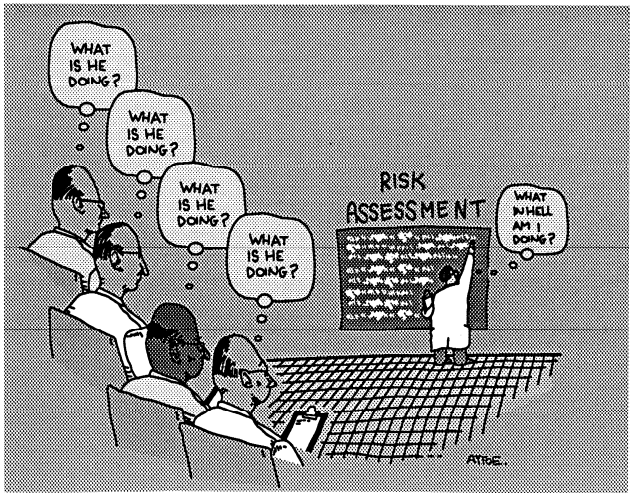
Risk Assessment in Superfund

Review of Deterministic Risk Assessment

Motivations for Conducting a Probabilistic Risk Assessment

Probabilistic Risk Assessment Overview

Technical and Policy Recommendations



ORIGINS OF RISK ASSESSMENT FOR SUPERFUND

Defining Risk Assessment

RISK ASSESSMENT IS CONTEXTUAL

Engineering/Structural

Ecological

Financial/Business

Human Health

Security:
Vulnerability and Threat

WHY IS RISK ASSESSMENT IMPORTANT?

"Risk is a common metric that lets us distinguish the environmental heart attacks and broken bones from indigestion or bruises."

EPA Administrator William K. Reilly
Aiming Before We Shoot:
The Quiet Revolution in Environmental Policy
Address to the National Press Club
September 26, 1990

EPA DEFINITION OF RISK ASSESSMENT

Risk:

A measure of the probability that damage to life, health, property, and/or the environment ***will occur*** as a result of a given hazard

Risk Assessment:

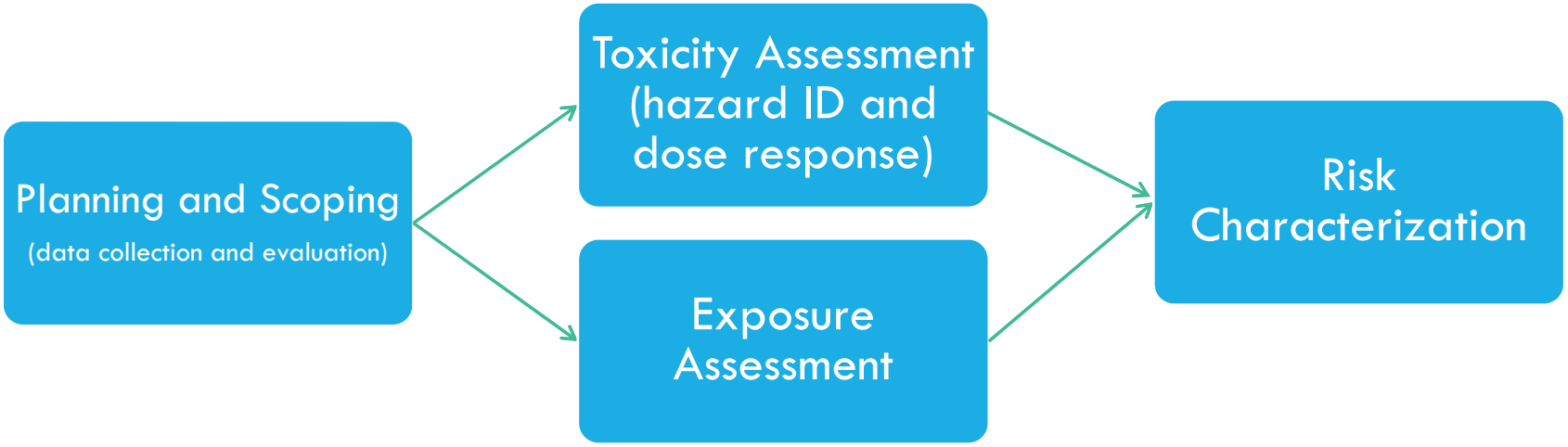
Qualitative and quantitative evaluation of the risk posed to human health and/or the environment by the actual or potential presence and/or use of specific pollutants

From EPA's "Terms of Environment" Glossary

DETERMINISTIC RISK ASSESSMENT

Planning and Scoping
Exposure Assessment
Toxicity Assessment
Risk Characterization

OVERVIEW



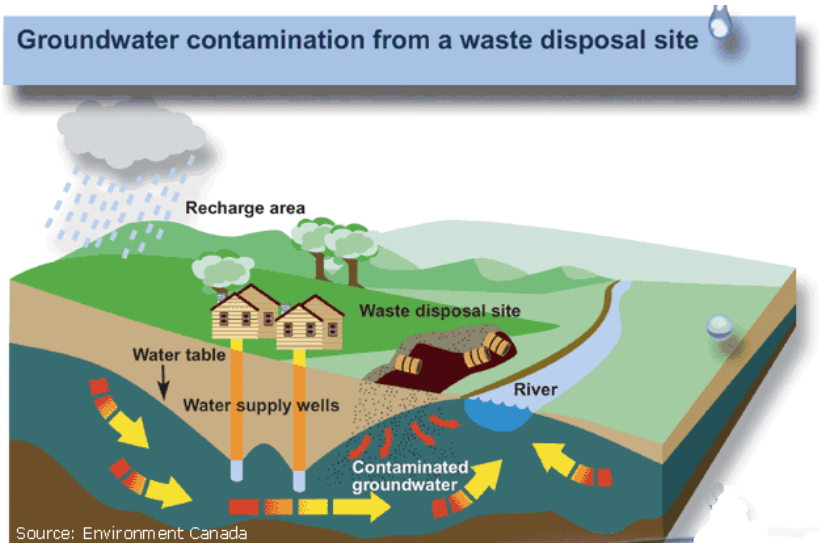
http://www.epa.gov/oswer/riskassessment/risk_superfund.htm

MOTIVATING EXAMPLE

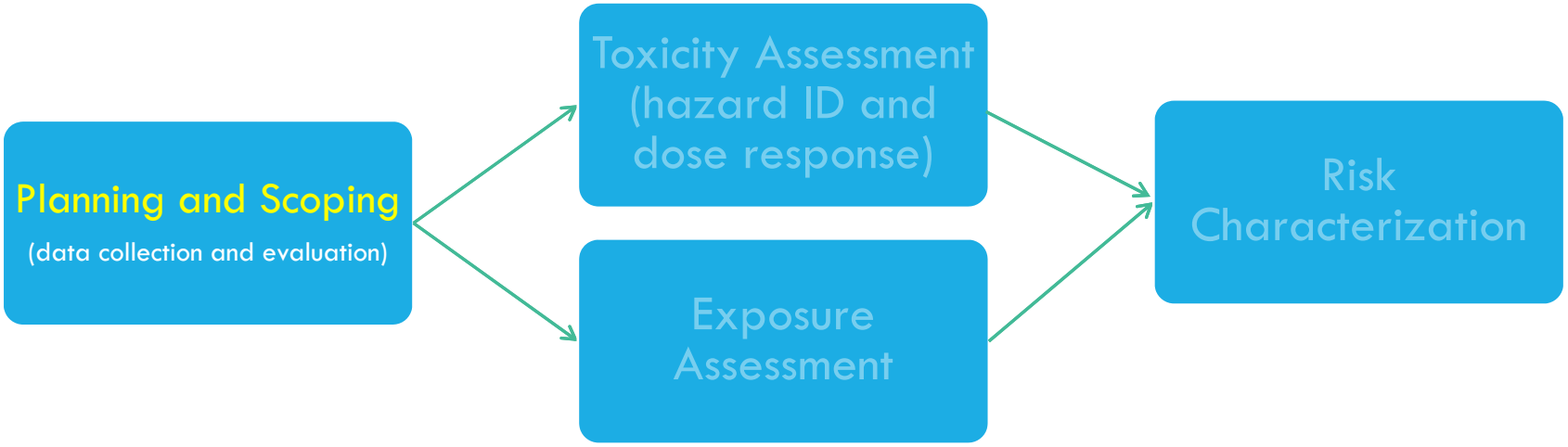
The town of Kemical has detected "badmium" in its water supply at a level of 0.65 mg/liter.

An investigation found the water supply could have been contaminated for the past 30 years.

- Does badmium pose a risk to the health of the residents of Kemical?
- Should EPA take action to clean up the badmium contamination?
- How much badmium does EPA need to clean up to protect the people of Kemical?



PLANNING AND SCOPING



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PLANNING AND SCOPING

Planning & Scoping looks at the "big picture" of data collection and information needed for the risk assessment on the Superfund site.

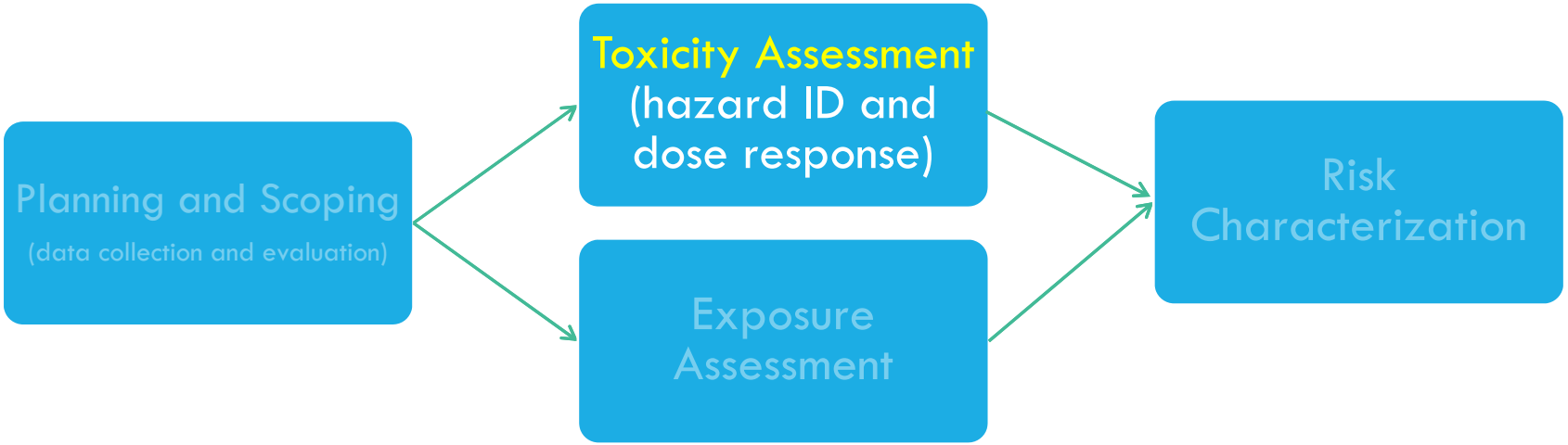
Addresses the Questions:

- *What contaminants are present at the site?*
- *What concentration?*
- *Where are they?*

Data Collection & Evaluation

- Site History
- Develop a sampling and analysis plan for site investigation
- Identify Chemicals of Potential Concern (COPCs) & Relevant Toxicity Values

TOXICITY ASSESSMENT



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SM4

TOXICITY ASSESSMENT

Toxicity Assessment: the **investigation** of how **toxic** a contaminant may be to **human health**

- Relies on published, peer reviewed toxicity data
- IRIS, PPRTVs, etc.

Tries to address:

- What kind of harm are you dealing with?
- What health effects may occur?
- How much exposure is needed to cause harm?

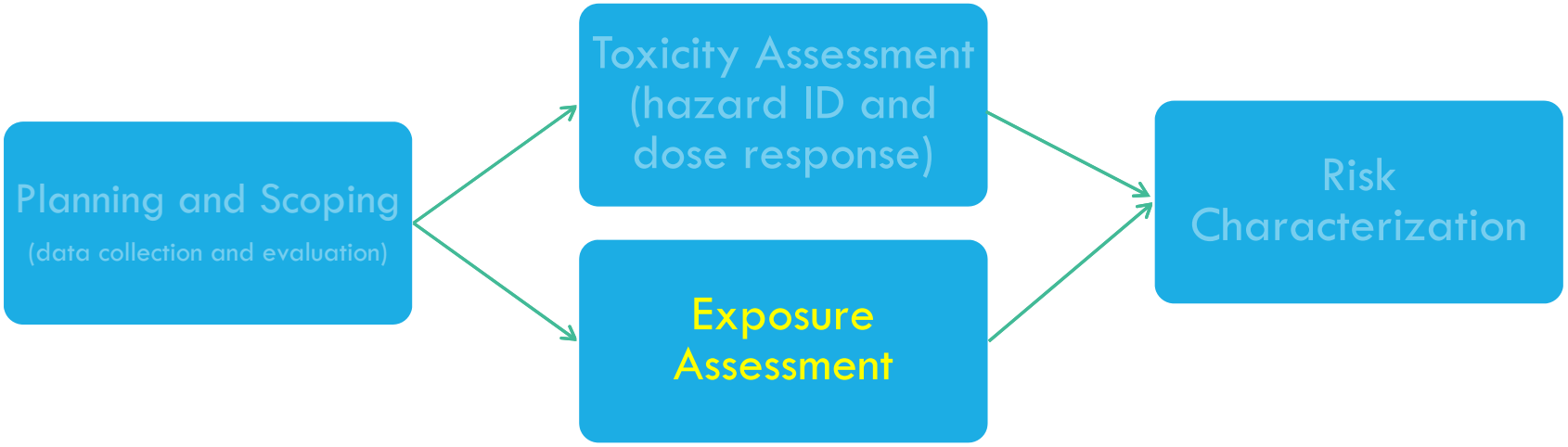
Hazard Identification: the process of determining whether a chemical can **cause adverse health effects**, and what those effects might me.

Slide 13

SM4 I think you need to make clear here that we rely on published, peer review toxicity values, with IRIS being the primary source. toxicity assessment is not a site-specific decision

Scozzafava, MichaelE, 10/11/2016

EXPOSURE ASSESSMENT



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EXPOSURE ASSESSMENT

Identifying the **pathways** by which toxicants may reach individuals, estimating how much of a chemical an individual is likely to be exposed to, and estimating the **number likely to be exposed**

(EPA's Terms of Environment)

Addresses the Questions:

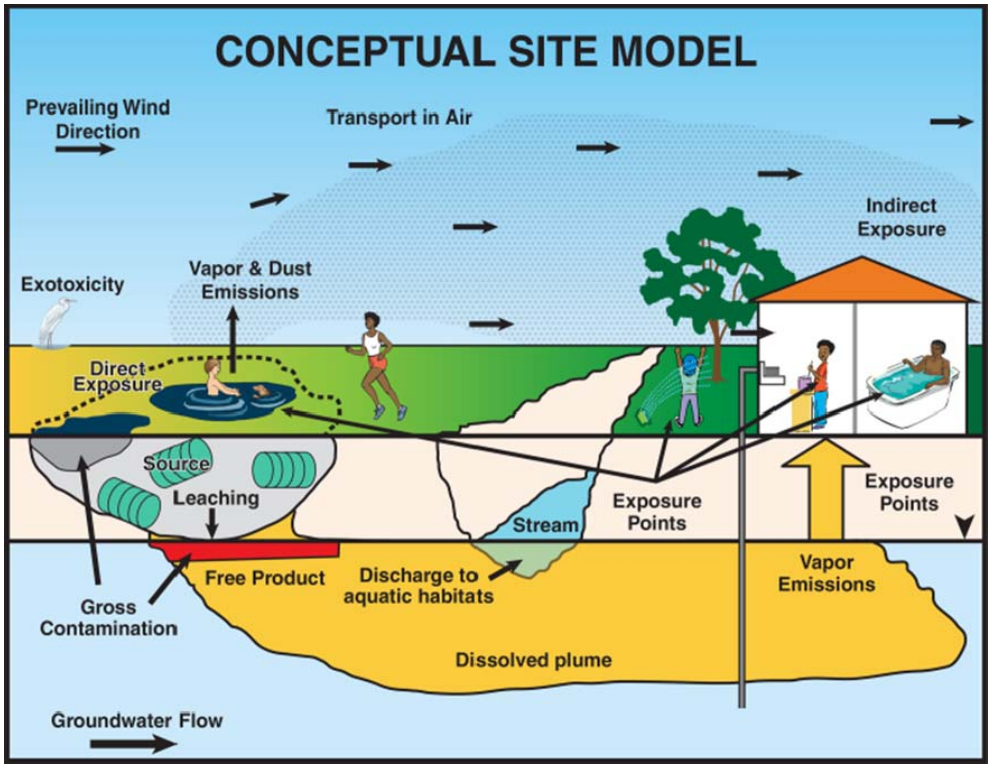
- Who is exposed?
- How are they getting exposed?
- How much are they exposed to?
- How long are they exposed?

SM3

EXPOSURE ASSESSMENT

Identify:

- Source of contamination
  - What media are contaminated?
- Potential receptors
  - Adults, Children
  - Residential, Commercial
  - Sensitive Populations
- Pathways for exposure
  - Inhalation
  - Ingestion
  - Dermal Contact



Slide 16

SM3 slide is very small/hard to see
Scozzafava, MichaelE, 10/11/2016

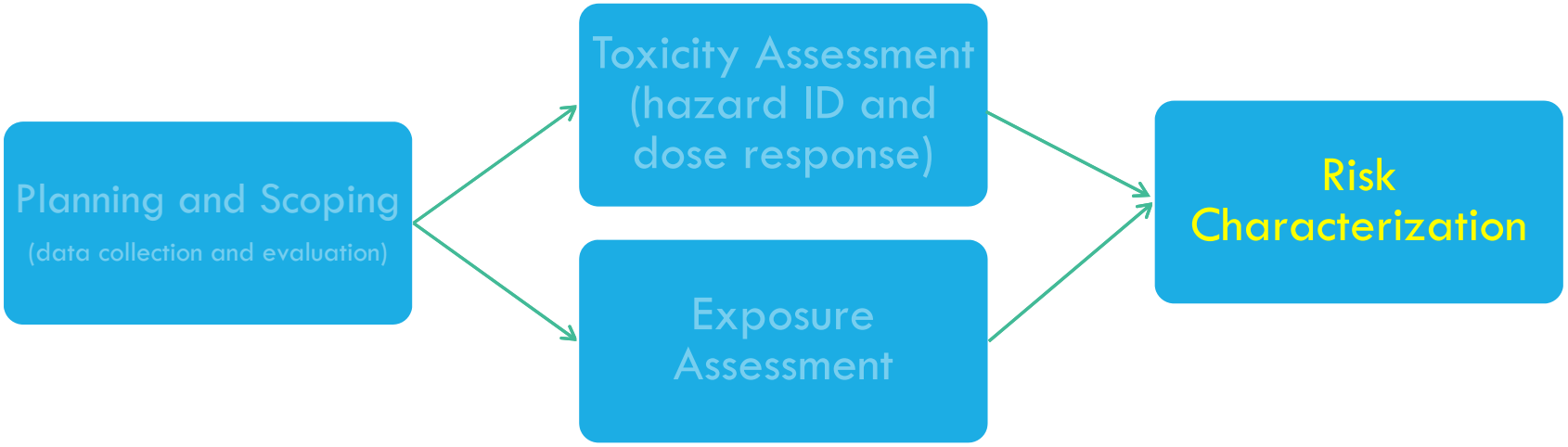
SIMPLIFIED EXPOSURE EQUATION

$$Chronic\ Daily\ Intake = \frac{Concentration \cdot Contact\ Rate \cdot Exposure\ Duration}{Body\ Weight \cdot Averaging\ Time}$$

Where do these numbers come from?

- Concentration: Measured concentration on the site
- Contact Rate: Defaults from exposure factors handbook – 2.5L water/day, 100mg soil/day
- Exposure Duration: Cancer, 70 years
- Body Weight: Default from Exposure Factors Handbook, 70kg
- Averaging Time: Cancer, 70 years x 365 days/year

RISK CHARACTERIZATION



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RISK CHARACTERIZATION

Estimate the potential for human health (or ecological effects) occurring from exposure to a stressor, and evaluate the uncertainty involved

- Which contaminants are causing risks to human health?
- Which exposure pathways are creating risk?

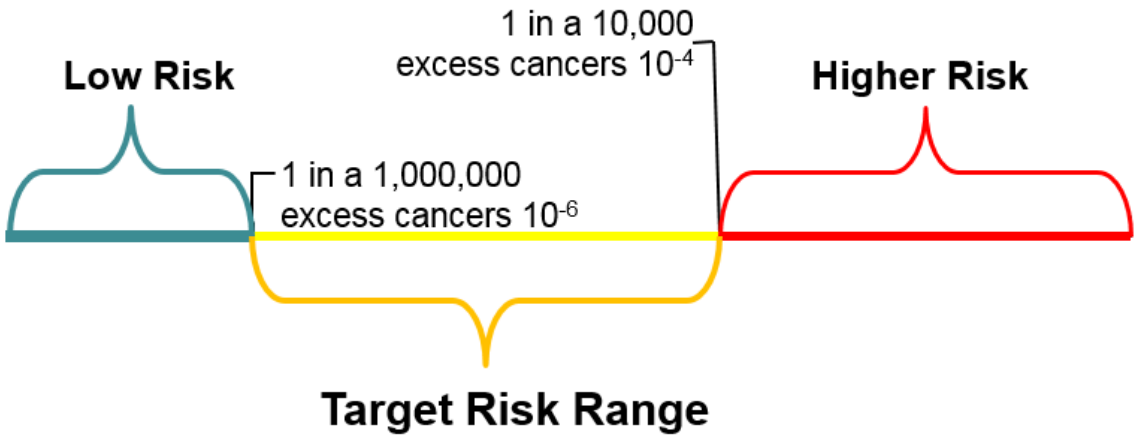
Typical steps:

1. Review information
2. Quantify Risk (equations from RAGS)
3. Combine risks across exposure pathways
4. Consider site specific studies
5. Summarize Results

RISK CHARACTERIZATION

Target Risk Range (Cancer)

- The superfund remedial program has a target cancer risk range of 10^{-4} to 10^{-6}
- This range is considered to be protective



RISK CHARACTERIZATION

Hazard Index (Non-Cancer)

- Sum of hazard quotients for multiple substances over multiple exposure pathways
- Hazard Quotient: ratio of site specific chemical exposure over a reference dose (at which no adverse health effects are likely to occur)

$$HQ = \frac{Daily\ Intake}{Reference\ Dose}$$

SIMPLIFIED EXAMPLE

The town of Kemical has detected "badmium" in its water supply at a level of 0.65 mg/liter. An investigation found the water supply could have been contaminated for the past 30 years. The slope factor of "badmium" is 0.15 $(mg/kg\text{-}day)^{-1}$.

What is the cancer risk?

$$Cancer\ Risk = Chronic\ Daily\ Intake \cdot Slope\ Factor$$

$$Chronic\ Daily\ Intake = \frac{Concentration \cdot Contact\ Rate \cdot Exposure\ Duration}{Body\ Weight \cdot Averaging\ Time}$$

$1.04 \cdot 10^{-4}$ is within the acceptable risk range, but fairly high.

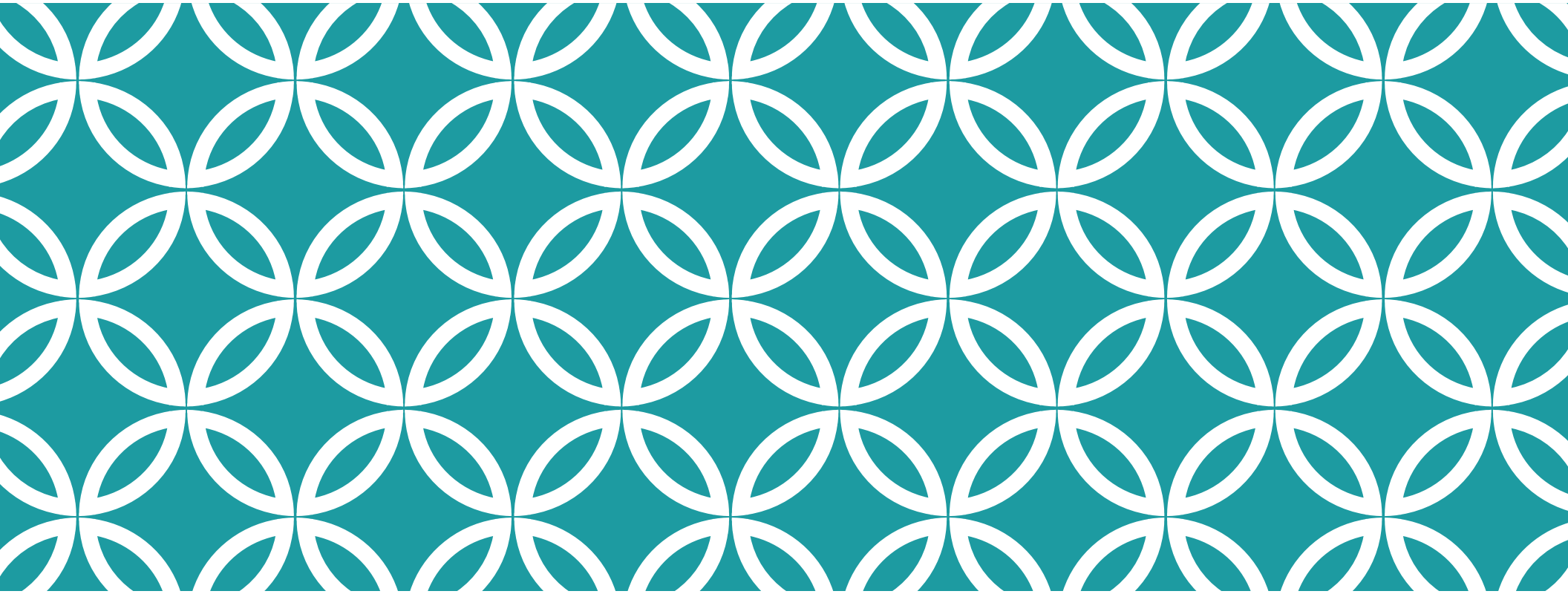
UNCERTAINTY

Uncertainty Analysis

- Explore uncertainties in risk estimates
- Minimize underestimation of potential risk

Typical Superfund Uncertainty

- Environmental sampling
- Laboratory analysis
- Dose-response toxicity assessment
- Exposure assessment



PROBABILISTIC RISK ASSESSMENT

Motivation
3-Tier Process
Tips & Tricks

MOTIVATION

Uncertainty Analysis

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- Minimize underestimation of potential risk

Typical Superfund Uncertainty

- Environmental sampling
- Laboratory analysis
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- Exposure assessment

very qualitative

MOTIVATION

Uncertainty Analysis

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Typical Superfund Uncertainty

- ~~Environmental sampling~~ Experimental Design
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very qualitative

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- ~~Environmental sampling~~ Experimental Design
- ~~Laboratory analysis~~ QA/QC, replicates
- Dose-response toxicity assessment
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very qualitative

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Typical Superfund Uncertainty

- ~~Environmental sampling~~ Experimental Design
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- ~~Dose-response toxicity assessment~~ Explicit Uncertainty Factors
- Exposure assessment

very qualitative

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Typical Superfund Uncertainty

- ~~Environmental sampling~~ Experimental Design
- ~~Laboratory analysis~~ QA/QC, replicates
- ~~Dose-response toxicity assessment~~ Explicit Uncertainty Factors
- **Exposure assessment**

very qualitative

EXPOSURE UNCERTAINTY & VARIABILITY

Exposure Assumptions

- Exposure Durations
  - Acute
  - Short-Term
  - Sub Chronic
  - Chronic
- Exposure Scenarios
- Behaviors
- Physical Characteristics
- Contact Rates

$$CDI = \frac{Concentration \cdot Contact\ Rate \cdot Exposure\ Duration}{Body\ Weight \cdot Averaging\ Time}$$

- Concentration: Measured concentration on the site
- Contact Rate: Defaults from exposure factors handbook – 2.5L water/day, 100mg soil/day
- Exposure Duration: Cancer, 70 years
- Body Weight: Default from Exposure Factors Handbook, 70kg
- Averaging Time: Cancer, 70 years x 365 days/year

EXPOSURE UNCERTAINTY & VARIABILITY

Exposure Assumptions

- Exposure Durations
  - Acute
  - Short-Term
  - Sub Chronic
  - Chronic
- Exposure Scenarios
  - Residential, Commercial
- Behaviors
- Physical Characteristics
- Contact Rates

…so what is this value?

$$CDI = \frac{Concentration \cdot Contact\ Rate \cdot Exposure\ Duration}{Body\ Weight \cdot Averaging\ Time}$$

- Concentration: central tendency
- Contact Rate: 90th percentile adult intake
- Exposure Duration: Cancer, lifetime
- Body Weight: average adult weight
- Averaging Time: Cancer, every day for life.

PROBABILISTIC RISK ASSESSMENT

Overview
PRA Process
Example

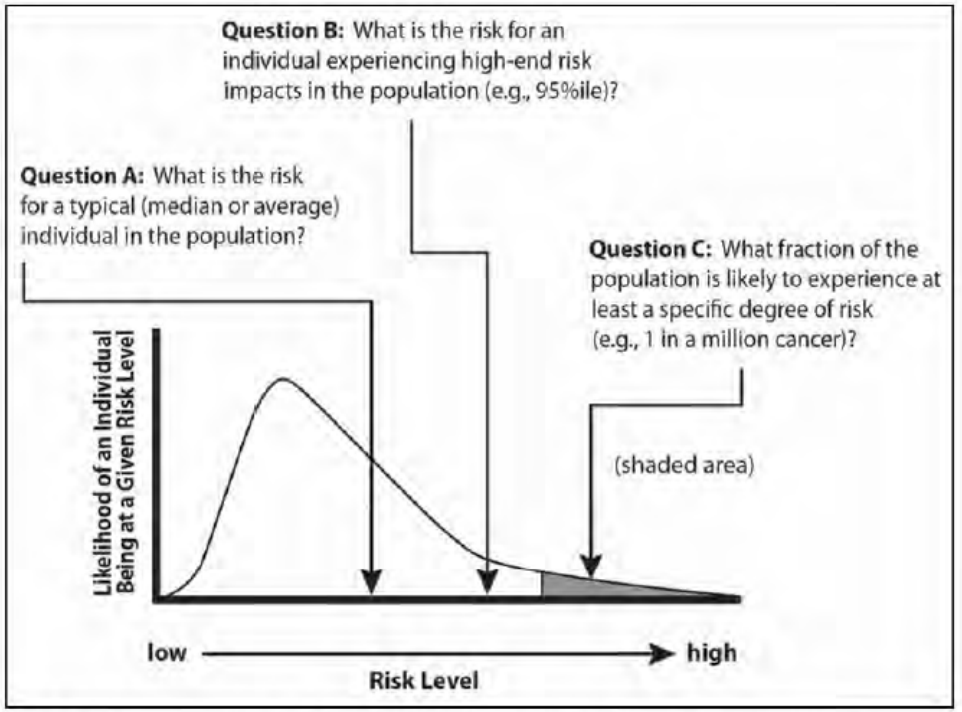
PROBABILISTIC RISK ASSESSMENT (PRA)

Quantify Uncertainty in Exposure & Risk

- Replace point estimates with site specific, relevant distributions
- Use Monte Carlo simulation to develop a risk **distribution**
- Use the risk distribution to better understand population wide risk

However…

- Still follows RAGS guidance
- Does not incorporate uncertainty in dose-response
- Not a tool to get a higher cleanup level



DETERMINISTIC VS. PROBABILISTIC RISK

[Concentration in environment] x [Exposure Duration] x [Ingestion or Inhalation Rate] x [Toxicity Factor] = **RISK**

Central tendency (average) values for all parameters [c] x [e] x [i] x [t] =

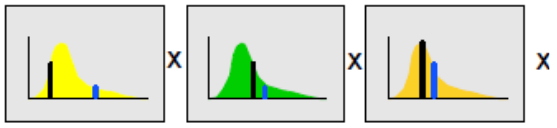
High-end values for some or all parameters [C] x [E] x [I] x [T] =

Yields a reasonable estimate for average or typical individual

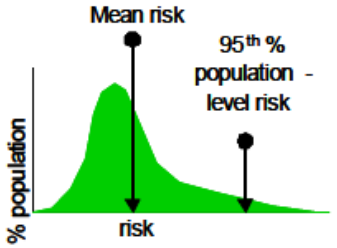
Risk

Yields estimate that is likely biased high (conservative)

[Concentration in environment] x [Exposure Duration] x [Ingestion or Inhalation Rate] x [Toxicity Factor] = **RISK**



x [T] =



BENEFITS OF PRA

Risk assessments have a lot of poorly characterized variability and uncertainty – PRA quantitatively and explicitly describes the distribution of risk

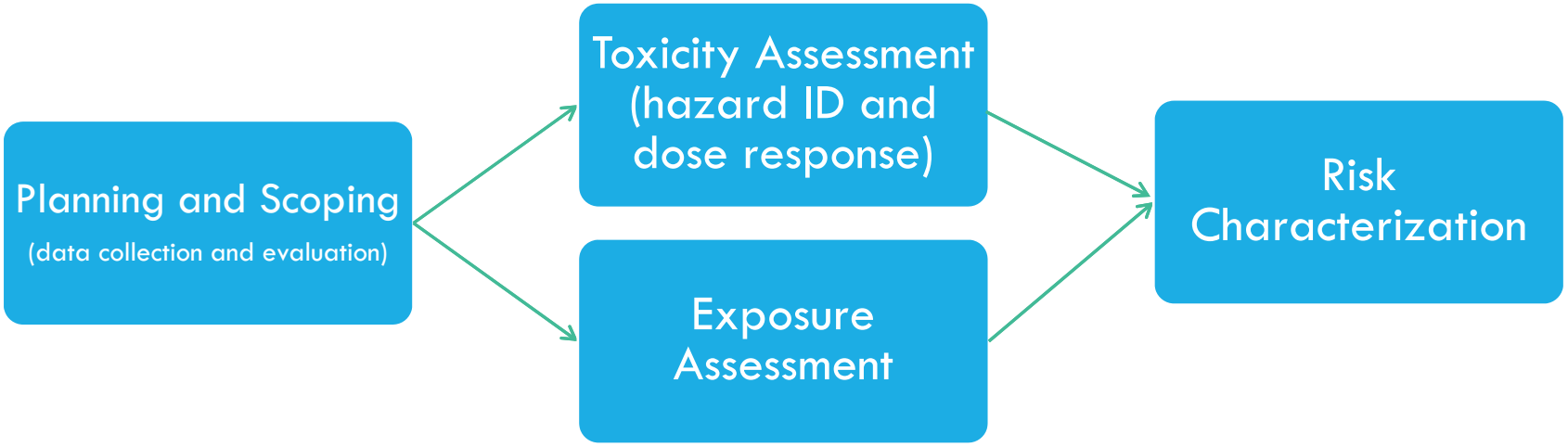
Helps stakeholders understand how different parameter assumptions affect conclusions

"Apples to Apples" incorporation of parameter assumptions

May be particularly appropriate for:

- Dealing with environmental justice issues raised by inter-individual variability
- Data rich sites
- Exploring the impact of exposure assumptions
- Helping decide between different risk management decisions

RISK ASSESSMENT OVERVIEW



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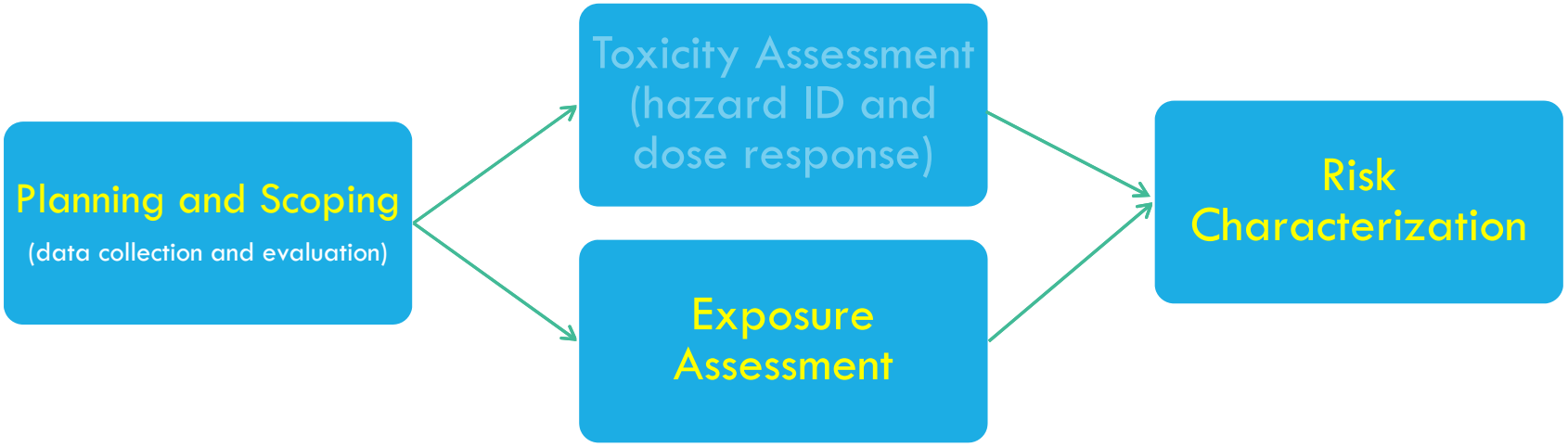
PROBABILISTIC RISK ASSESSMENT



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PLANNING AND SCOPING

All Stakeholders should agree to use probabilistic risk assessment

Why are you doing a PRA?

What percentiles are you using for decision making?

What are your decision criteria?

Before starting, identify:

- Parameters with **variability** (eg. age of current population)
- Parameters with **uncertainty** (eg. age composition of future population)
- **Variable *and* uncertain** parameters (eg. chemical concentration)

EXPOSURE ASSESSMENT

Exposure Terms:

- Relevant distributions – national or site specific
  - Exposure Factors Handbook
  - NHANES
  - Peer reviewed publications
  - Site Specific Data
- **Point estimates for the deterministic risk assessment should be drawn from the same distributions as are used in the PRA**

Chemical Concentrations:

- Exposure Point Concentration – upper bound on the mean
- Parametric Distribution – fit a distribution to site data
- Non-parametric Distribution – bootstrap from site data

RISK CHARACTERIZATION

Monte Carlo Simulation using standard risk equations

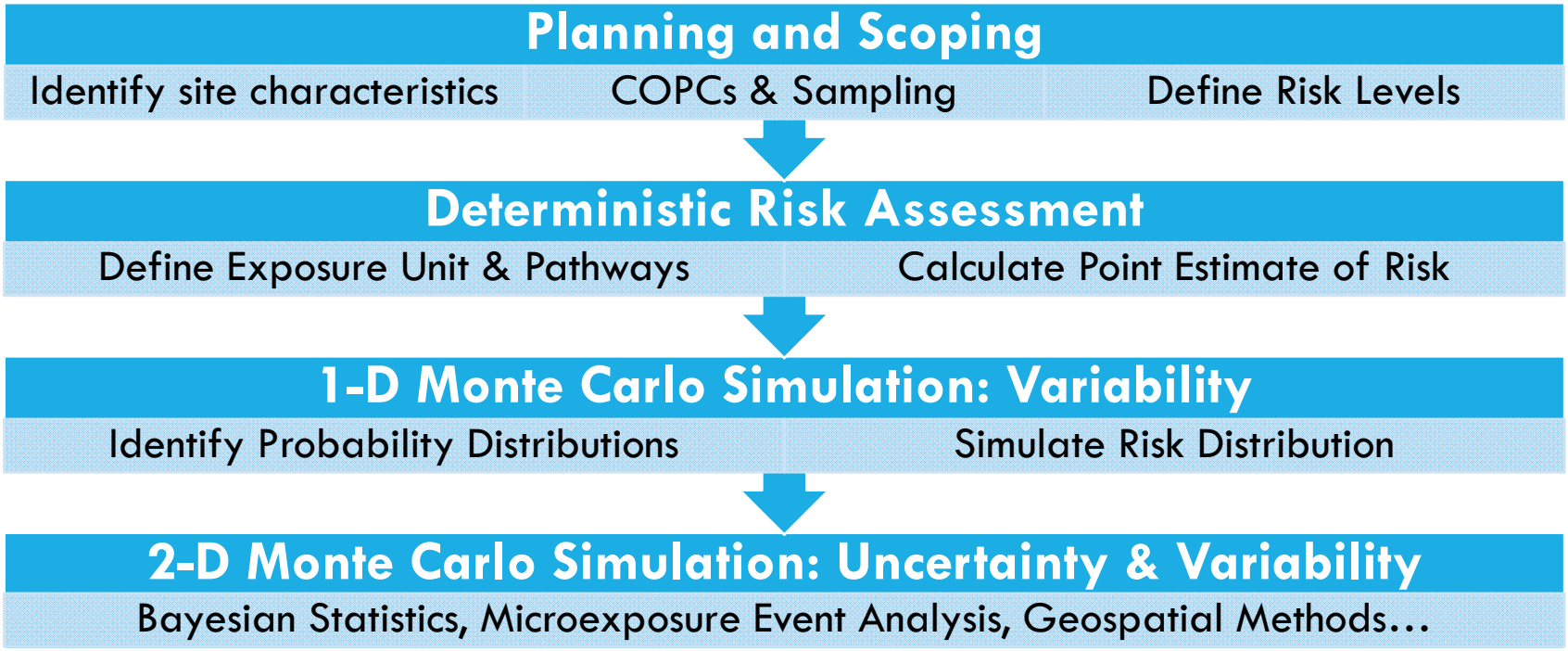
Repeated random sampling used to generate simulated data for a mathematical model

- Generate random draws from defined probability distributions
- Incorporate samples into risk assessment equations
- Develop distribution for risk

Risk equations draw randomly from exposure distributions

May require multiple rounds of refinement

PRA PROCESS (RAGS III)



PRA PROCESS

After each tier is a decision making point:

"Do I have sufficient data to make a risk management decision?"

- Review uncertainty and sensitivity analysis
- Identify data gaps/needs
- Communicate with all stakeholders

Before starting the next tier:

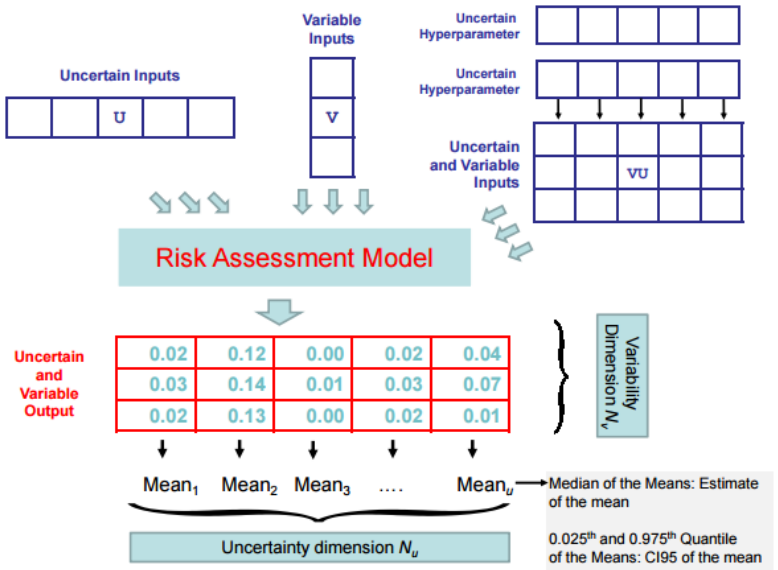
- Is refining the current tier sufficient?
- Refine the work plan
- Collect additional data

This is an *iterative* process

2D MONTE CARLO

EPA Guidance states that a tier 3 assessment is a 2-D Monte Carlo Simulation

- **Mathematical Definition**: "A two-dimensional Monte-Carlo simulation is a Monte-Carlo simulation where the distributions reflecting variability and the distributions representing uncertainty are sampled separately in the simulation, so that variability and uncertainty in the output may be assessed separately."
- RAGS III lumps other statistical techniques in with 2D MC simulation



REPORTING THE RESULTS OF A PRA

Is there unacceptable risk at your site?

Transparent explanation of decision points

Baseline, Deterministic Risk Assessment

Risk Distribution from PRA

Sensitivity Analysis:

- Multiple Simulations with range of uncertainty
- Distribution of RME
- Correlation between variables – Pearson or Spearman Rank

EXAMPLE: 1D MCA

PRA uses the same equations as a deterministic risk assessment:

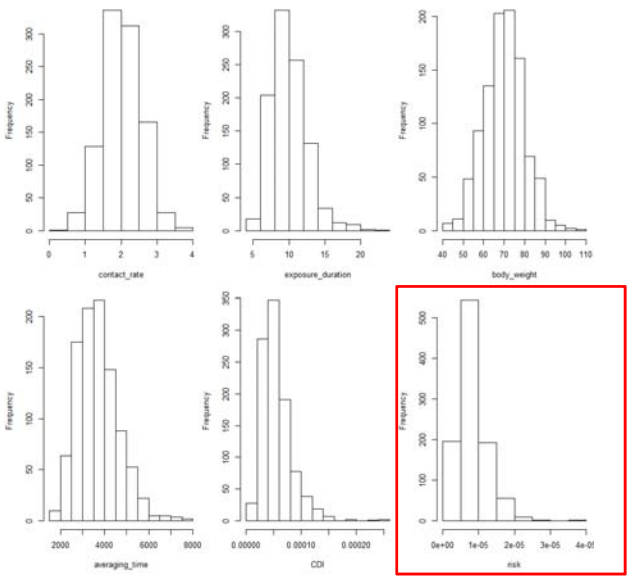
$$Chronic\ Daily\ Intake = \frac{Concentration \cdot Contact\ Rate \cdot Exposure\ Duration}{Body\ Weight \cdot Averaging\ Time}$$

$$Cancer\ Risk = Chronic\ Daily\ Intake \cdot Slope\ Factor$$

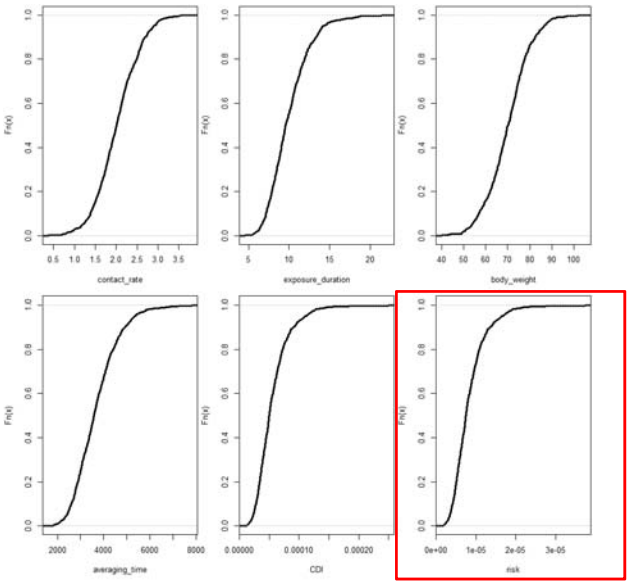
Variable	Type of Input	Case 1: Base	Case 2: More uncertainty	Case 3: Longer exposure
Concentration	Point Estimate	.65 mg/L	.65 mg/L	.65 mg/L
Contact Rate	Distribution	Normal, μ = 1, σ=.25	Normal, μ = 1, σ=.25	Normal, μ = 1, σ=.25
Exposure Duration	Distribution	T-Lognormal, μ=10, σ=2.5	T-Lognormal, μ=10, σ=5	T-Lognormal, μ=15, σ=5
Body Weight	Distribution	Normal, μ = 70, σ=10	Normal, μ = 70, σ=10	Normal, μ = 70, σ=10
Averaging Time	Distribution	365 x ED	365 x ED	365 x ED
Slope Factor	Point Estimate	0.15 $(mg/kg\text{-}day)^{-1}$	0.15 $(mg/kg\text{-}day)^{-1}$	0.15 $(mg/kg\text{-}day)^{-1}$

RESULTS: CASE 1 – BASE CASE

Histogram of Monte Carlo Results



Cumulative Distribution Function



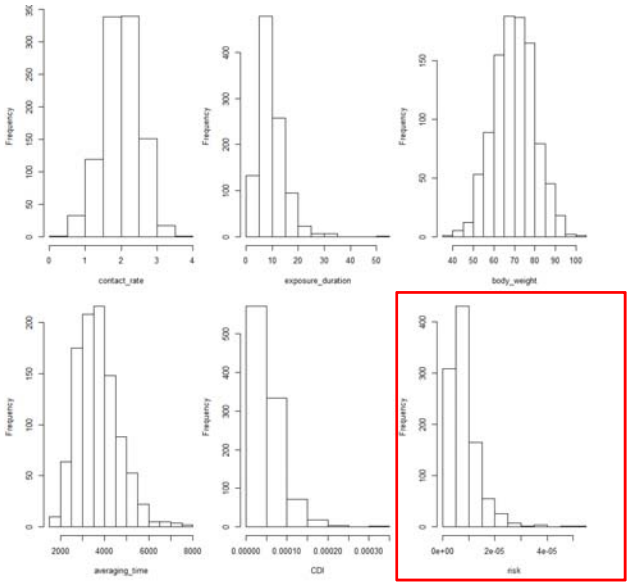
Mean: $8.31 \cdot 10^{-6}$

95th Percentile: $\mathbf{1.64 \cdot 10^{-5}}$

Max: $3.75 \cdot 10^{-5}$

RESULTS: CASE 2 – MORE UNCERTAINTY

Histogram of Monte Carlo Results



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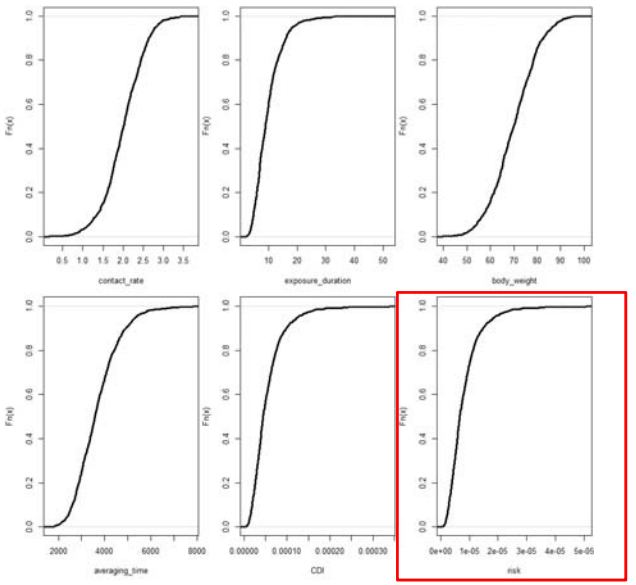


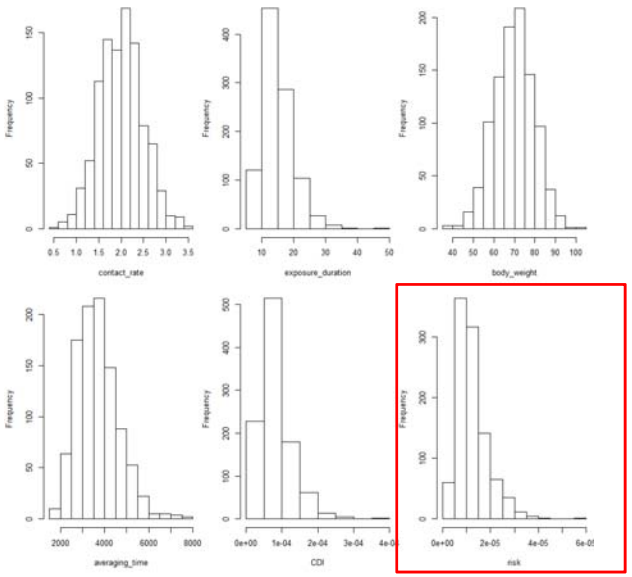
Mean: $8.12 \cdot 10^{-6}$

95th Percentile: $\mathbf{1.86 \cdot 10^{-6}}$

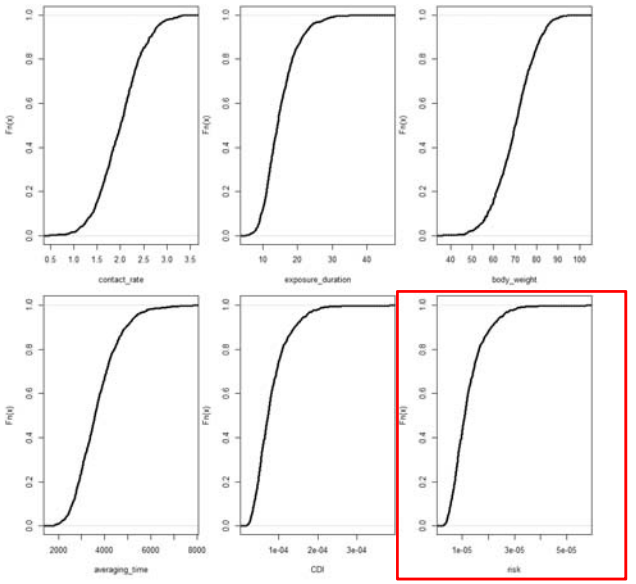
Max: $5.8 \cdot 10^{-5}$

RESULTS: CASE 3 – LONGER EXPOSURE

Histogram of Monte Carlo Results



Cumulative Distribution Function

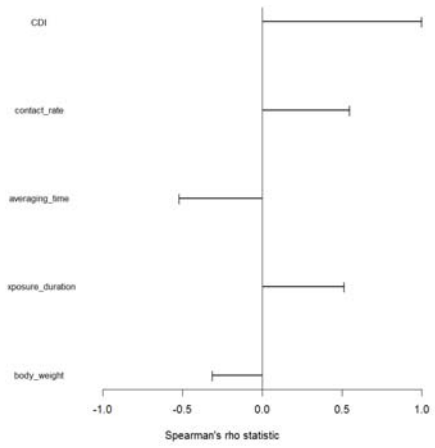
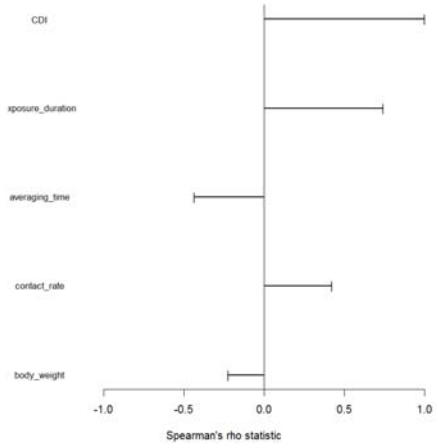
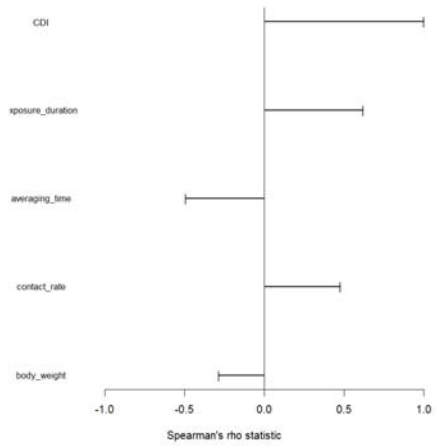


Mean: $1.23 \cdot 10^{-5}$

95th Percentile: 2.52· 10^{-5}

Max: $5.75 \cdot 10^{-5}$

SENSITIVITY

Scenario 1	Scenario 2	Scenario 3
		

RESULTS

1-D Monte Carlo Simulation, Qualitative Sensitivity Analysis

- Maximum 95th percentile of Risk: $2.52 \cdot 10^{-5}$
- Minimum 95th percentile: $1.86 \cdot 10^{-6}$
- **All values were within risk range**

Compare to point estimate – $1.04 \cdot 10^{-4}$

Questions to consider:

- Did the sensitivity analysis flag any parameters for further evaluation?
- How comfortable are we with our parameter estimates?
- Is a 2D simulation necessary?

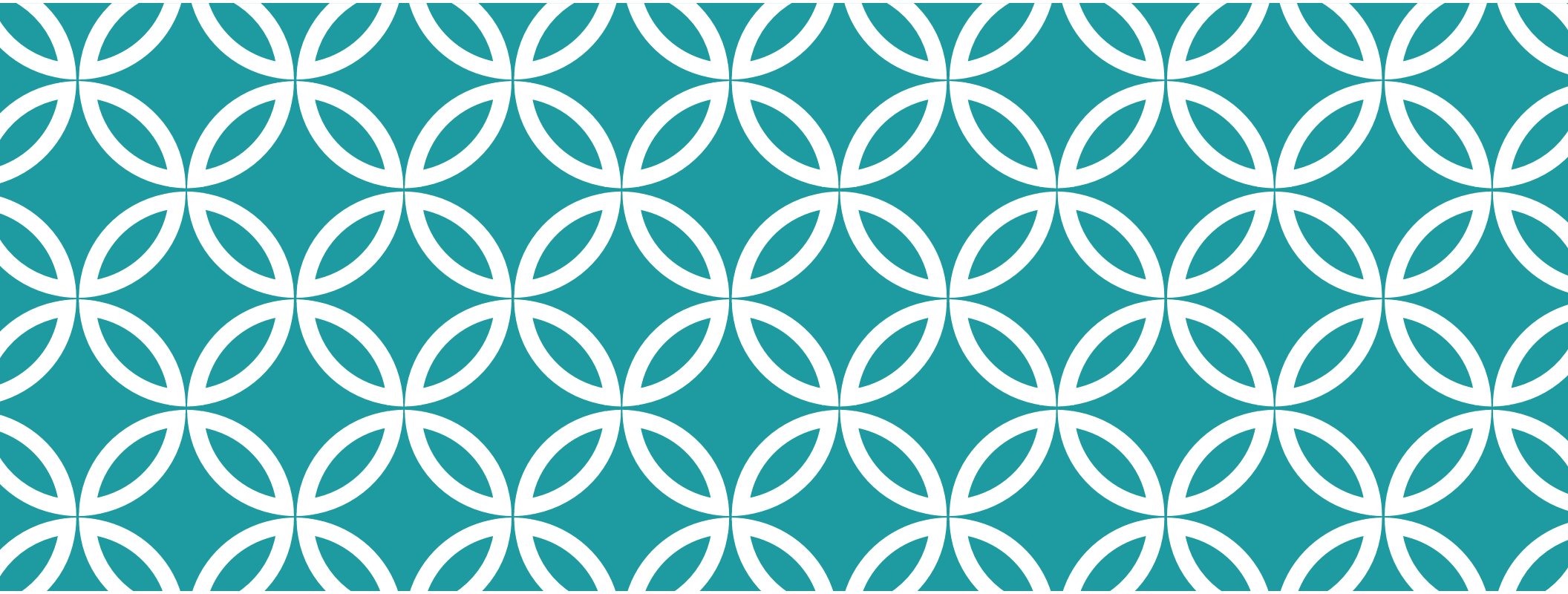
. . . SO WHAT CAN I *DO* WITH A PRA?

Inform Uncertainty Analysis

Inform Risk Management Decisions

Decide Cleanup Levels, provided you have

- Extensive supporting evidence for distributions & decision points
- Clear case of what PRA adds over a deterministic risk assessment



RECOMMENDATIONS

Technical Considerations
Mathematical Issues
Policy
Resources

TECHNICAL CONSIDERATIONS

Conducting a PRA is not a trivial exercise

Understand why you're doing a PRA

Software: *(not an EPA endorsement)*

- Excel
- Proprietary Software (Oracle Crystal Ball, Palisade's @Risk)
- **Open Source** – R (mc2d), Python

Consult with the project team to make sure everyone is able to collaborate on analysis

MATH/STAT CONSIDERATIONS

Choosing distributions:

- Site specific data
- Peer reviewed national data sets

Parametric Distributions

- Fit a distribution to relevant data
- Provide statistical support for decision
- Some may take on negative values – be aware and address that!

Empirical Distributions

- Empirical data needs sufficient sample size for boot strapping
- Be wary of truncating or manipulating distributions

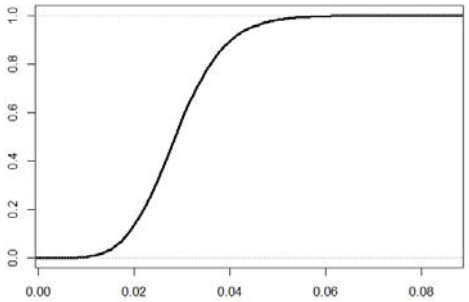
MATH/STAT CONSIDERATIONS

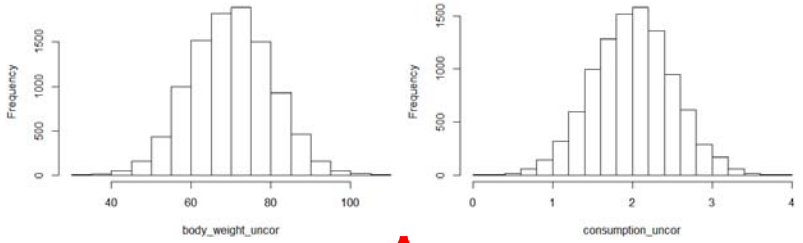
Variable correlation

- Empirically, many risk parameters are correlated
- Explicitly incorporate this into the model

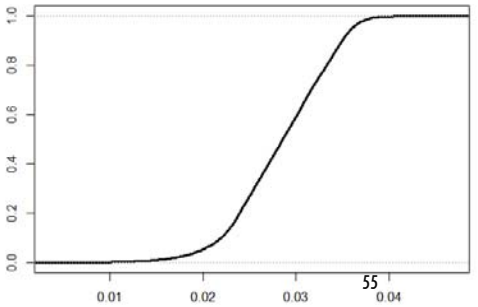
Example: Body Weight & Consumption

95th percentile: 0.044





95th percentile: 0.036



MATH/STAT CONSIDERATIONS

DON'T SIMPLIFY EARLY: $f\left(E(x)\right) \neq \mathrm{E}\left(f(x)\right)$

POLICY REMINDERS

Follow Risk Assessment Guidance for Superfund (RAGS)

Toxicity Assessment (dose response) *is not probabilistic*

Deterministic Risk Assessment is *always* the first step

Submit a work plan for review before starting

TIPS FOR SUCCESS

Early engagement

Iterative process

- Communicate results to stakeholders at each tier (or sooner!)
- Revisit assumptions and inputs as necessary

Transparency

- Provide stakeholders with simulation code
- Present input distributions up front
- Report the full risk distribution
- Conduct a robust sensitivity analysis

RESOURCES

Superfund:

- Risk Assessment Guidance for Superfund (A, B, C, D, E, F)
- RAGS III: Probabilistic Risk Assessment
- OSWER Directive 9200.1-120
- PRG for Radionuclides

Other EPA resources:

- Exposure Factors Handbook
- Risk Assessment Forum PRA whitepaper
- EPA Office of the Science Advisor PRA FAQ

Non-EPA:

- NAS Science & Decisions (Silver Book)
- mc2d (R): tools for Two-Dimensional Monte Carlo Simulations

Superfund PRG guidance on Radiation Risk Assessment

- *Radiation Risk Assessment at CERCLA Sites: Q&A* (5/2014) OSWER Directive 9200.4-40
  - » PRA may be used to provide quantitative estimates of the uncertainties in the risk assessment.
  - » PRA may be used as a supplement to, not instead of, deterministic (point estimate) methods.
- Retains guidance from 1999
  - » Radiation Risk Assessment at CERCLA Sites: Q&A (12/99) OSWER Directive 9200.4-31P