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The Role of Risk Assessment and Site Considerations in Risk Management Decision Making

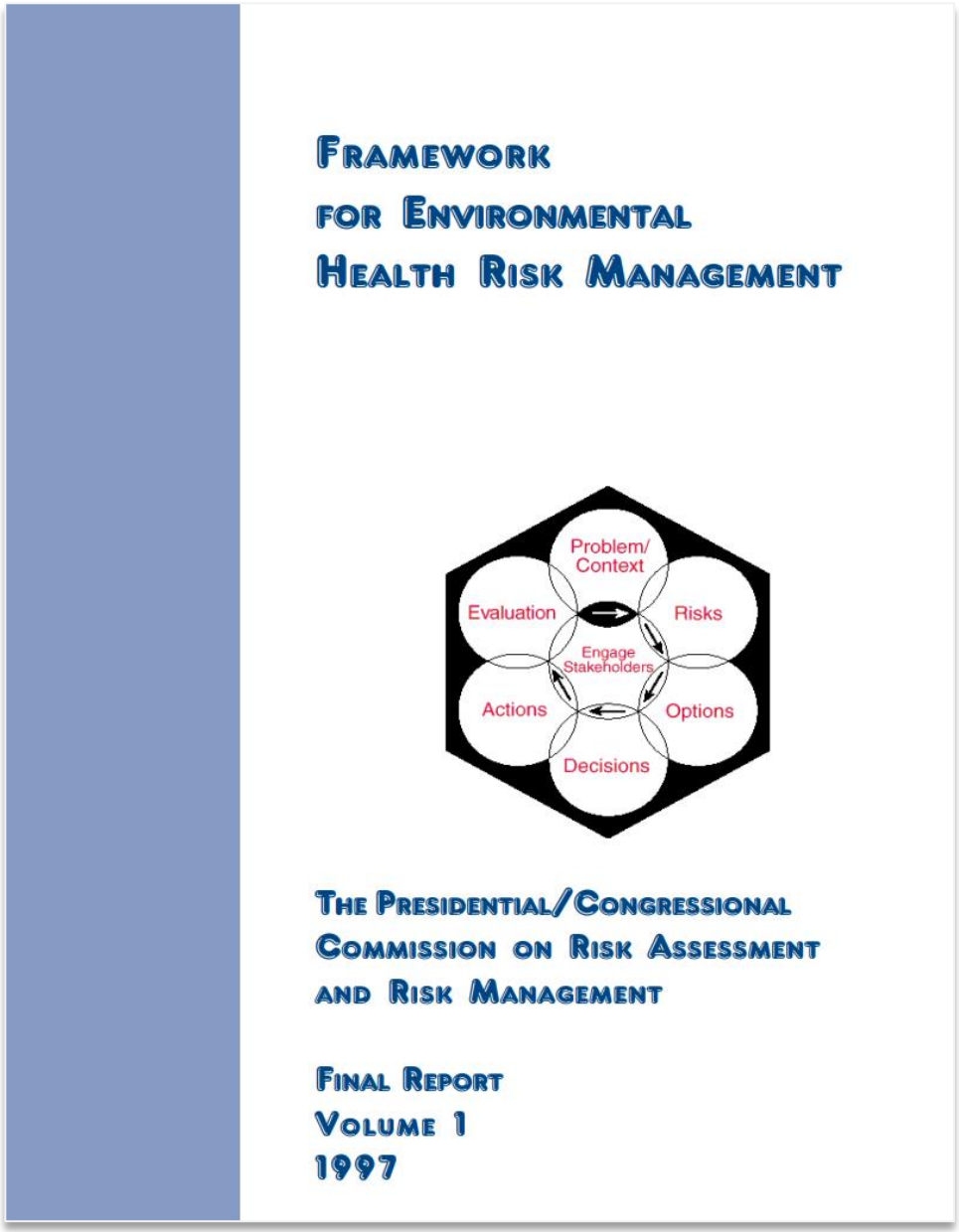
RCRA Corrective Action Webinar

October 6, 2020

What is Risk Management?

"Risk management is the process of **identifying, evaluating, selecting, and implementing** actions to reduce risk to human health and to ecosystems.

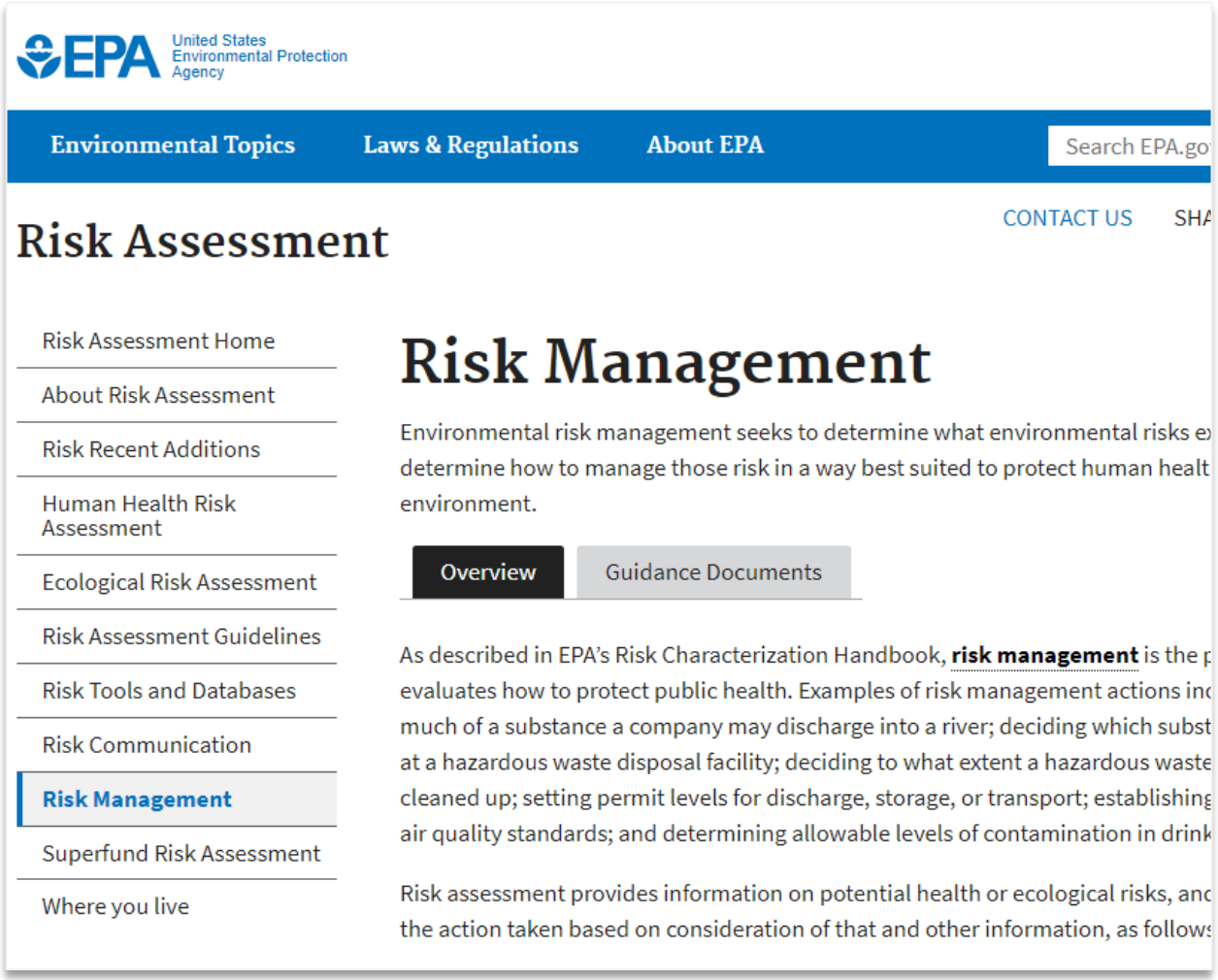
The **goal of risk management is scientifically sound, cost-effective, integrated actions that reduce or prevent risks** while taking into account social, cultural, ethical, political, and legal considerations."



What is Risk Management?

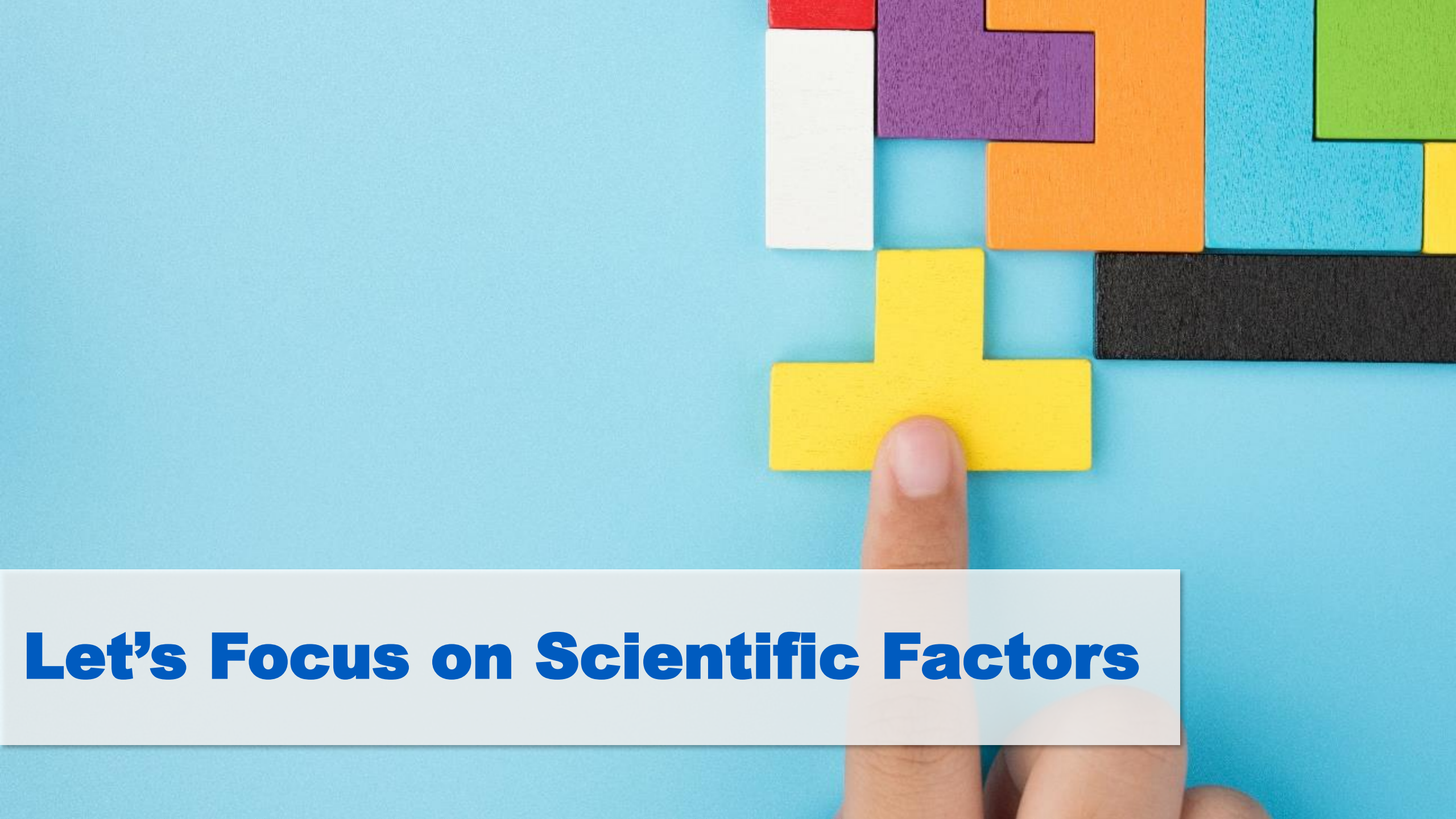
"Environmental risk management seeks to determine what environmental risks exist and then determine how to manage those risks in a way best suited to protect human health and the environment."

Cites EPA's December 2000 *Risk Characterization Handbook* as source for deciding factors



What are the Key Factors for Consideration

- **Scientific Factors:** Risk assessment, which addresses toxicology, exposure, statistics, etc.
- **Technological Factors:** Feasibility, impacts, and range of risk management options
- **Economic Factors:** Costs, benefits, and impacts of potential actions
- **Laws and Regulatory Requirements:** Legal mandates, flexibility, and constraints
- **Sustainability:** Life cycle, multimedia, and long-term impacts
- **Public and Social Factors**
  - Factors that may affect the susceptibility of an individual or a definable group to risks from a particular stressor
  - Environmental justice concerns
- **Political Factors:** Inter-agency/inter-governmental interactions, plus interactions with officials, special interest groups, or concerned citizens

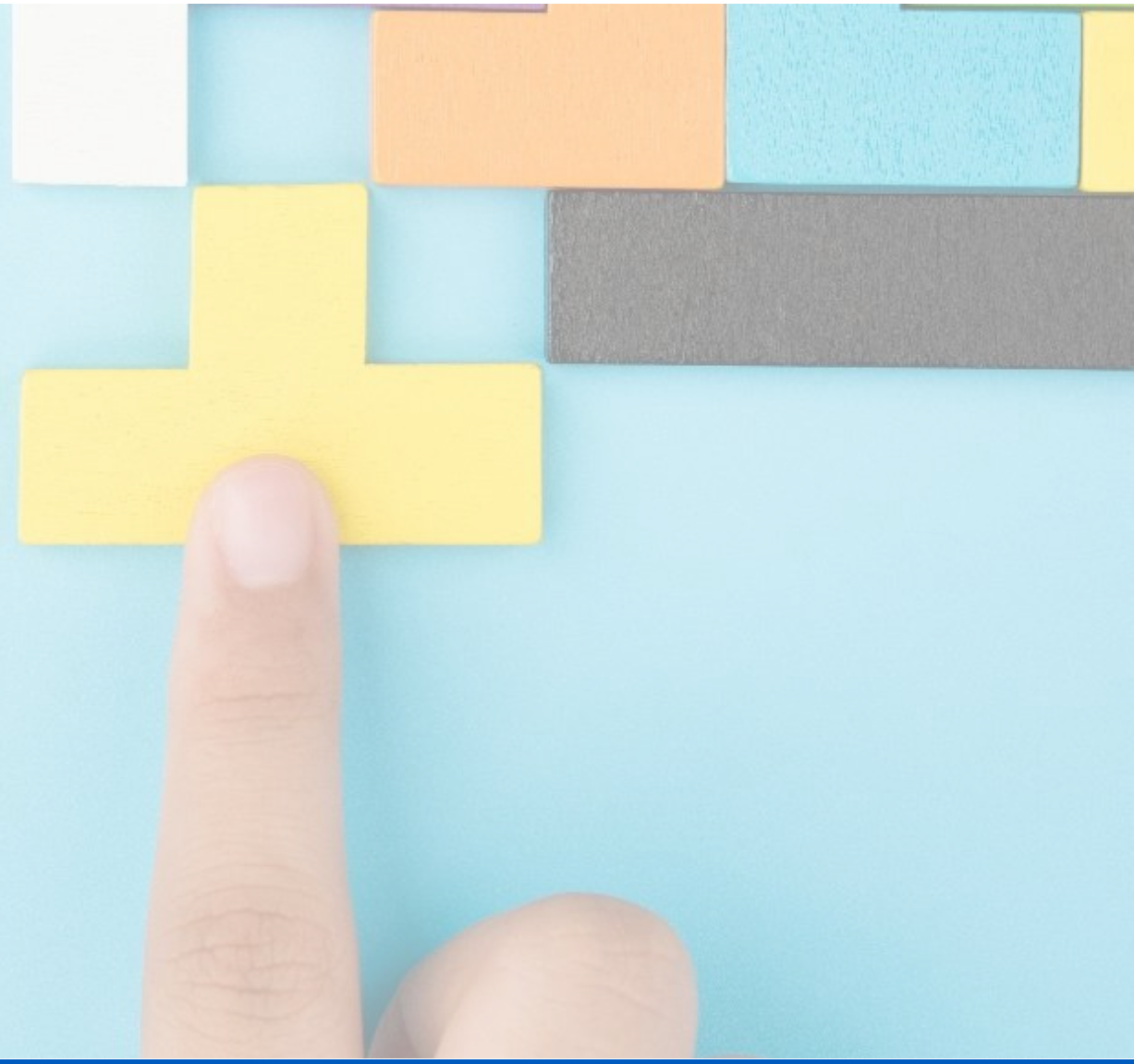


Let’s Focus on Scientific Factors

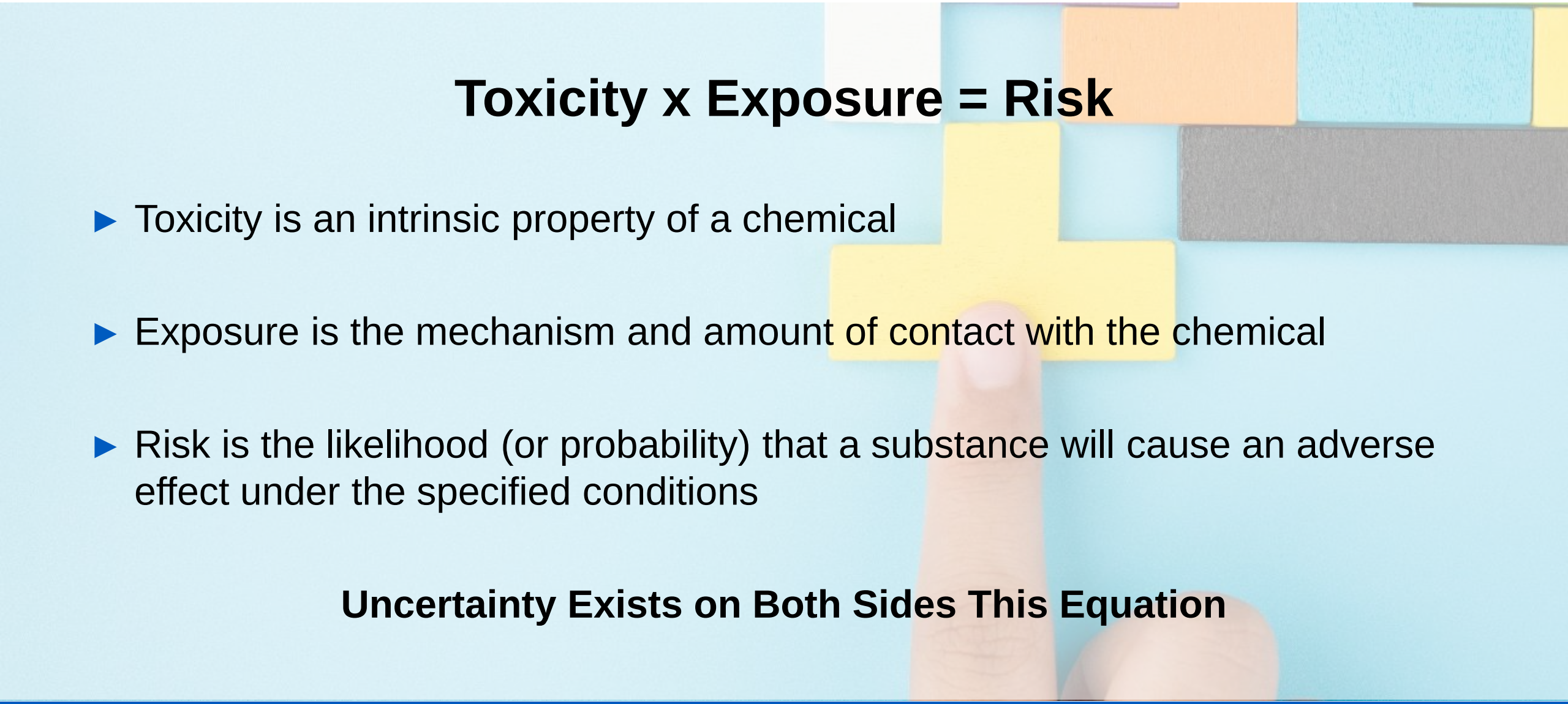
Scientific Factors

- What falls into the category of scientific factors?
  - Risk assessment
  - Site conditions
  - Technological feasibility

- To what degree to some of these factors interact and require cross-consideration?



Risk Assessment



Toxicity x Exposure = Risk

- Toxicity is an intrinsic property of a chemical
- Exposure is the mechanism and amount of contact with the chemical
- Risk is the likelihood (or probability) that a substance will cause an adverse effect under the specified conditions

Uncertainty Exists on Both Sides This Equation

Toxicity Assessment

Sources of Toxicity Data

- **Human Data**
  - Epidemiological studies
  - Accidental intoxication exposures
- **Animal Studies**
  - In vivo bioassays
    - Long-term rodent studies
    - Ecotoxicological studies
  - In vitro bioassays
    - Mutagenicity assays
    - Tissue models
- **Indirect Methods**
  - Structure-activity relationships
  - High throughput computational methods

Toxicity Assessment

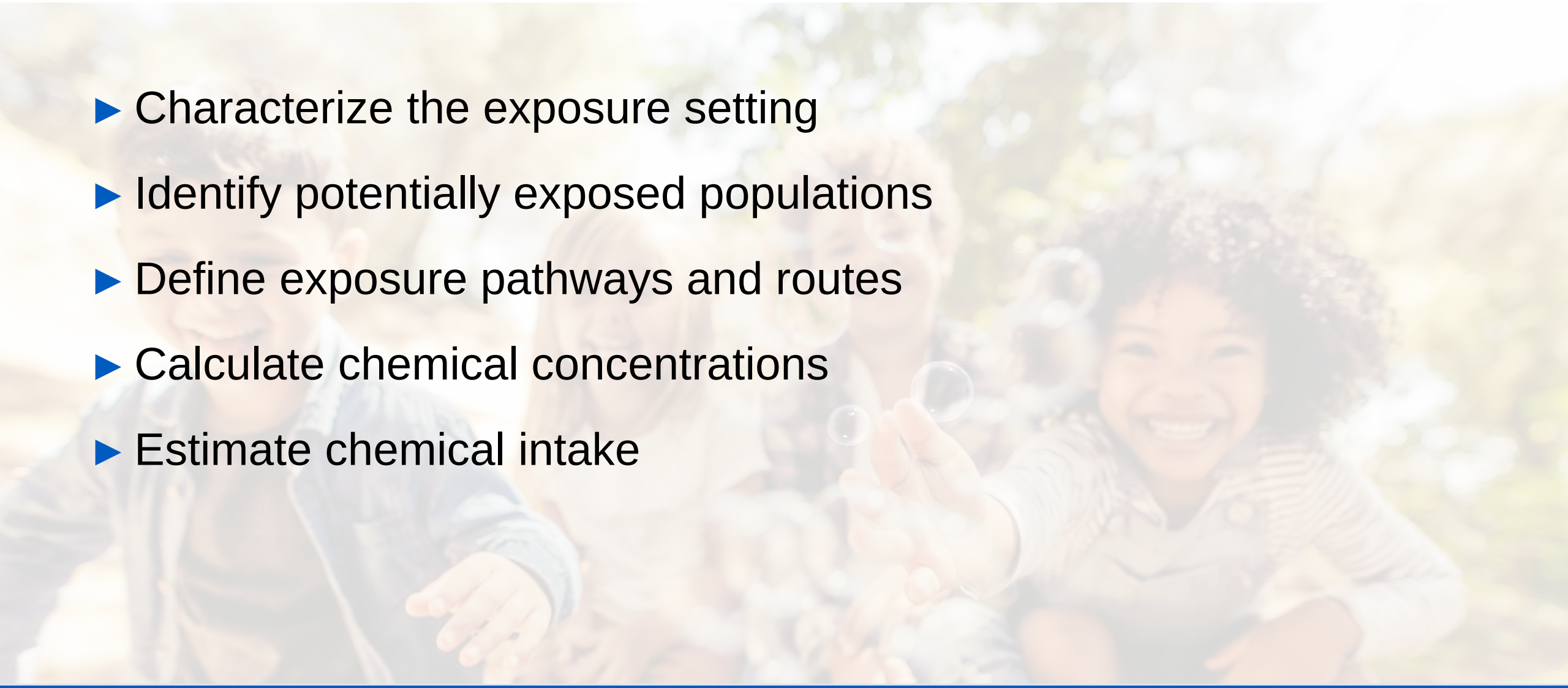
- Evaluate noncancer and cancer health effects
- Human Noncancer Effects
  - Reference Dose or RfD/RfC (mg/kg/day)
  - Estimate of the daily exposure to humans that is likely to be without adverse effects during a lifetime
- Cancer Effects
  - Slope factor (1/mg/kg/day)
  - Typically the 95% confidence limit on the inferred slope of the low-dose portion of the dose-response curve.
  - Represents the upper-bound lifetime probability of an individual developing cancer as a result of exposure to 1 mg/kg/day of a potential carcinogen
  - Weight-of-evidence classification

Uncertainty in Toxicity Assessment

- What are the main uncertainties in assessing toxicity?
  - Research subject
  - Length of study
  - Route of exposure
  - Study dosage
  - Lack of data
- How do we address these uncertainties?
  - Uncertainty factors
  - 5-year reviews

Exposure Assessment

Elements of Exposure Assessment



- Characterize the exposure setting
- Identify potentially exposed populations
- Define exposure pathways and routes
- Calculate chemical concentrations
- Estimate chemical intake

Characterize the Exposure Setting

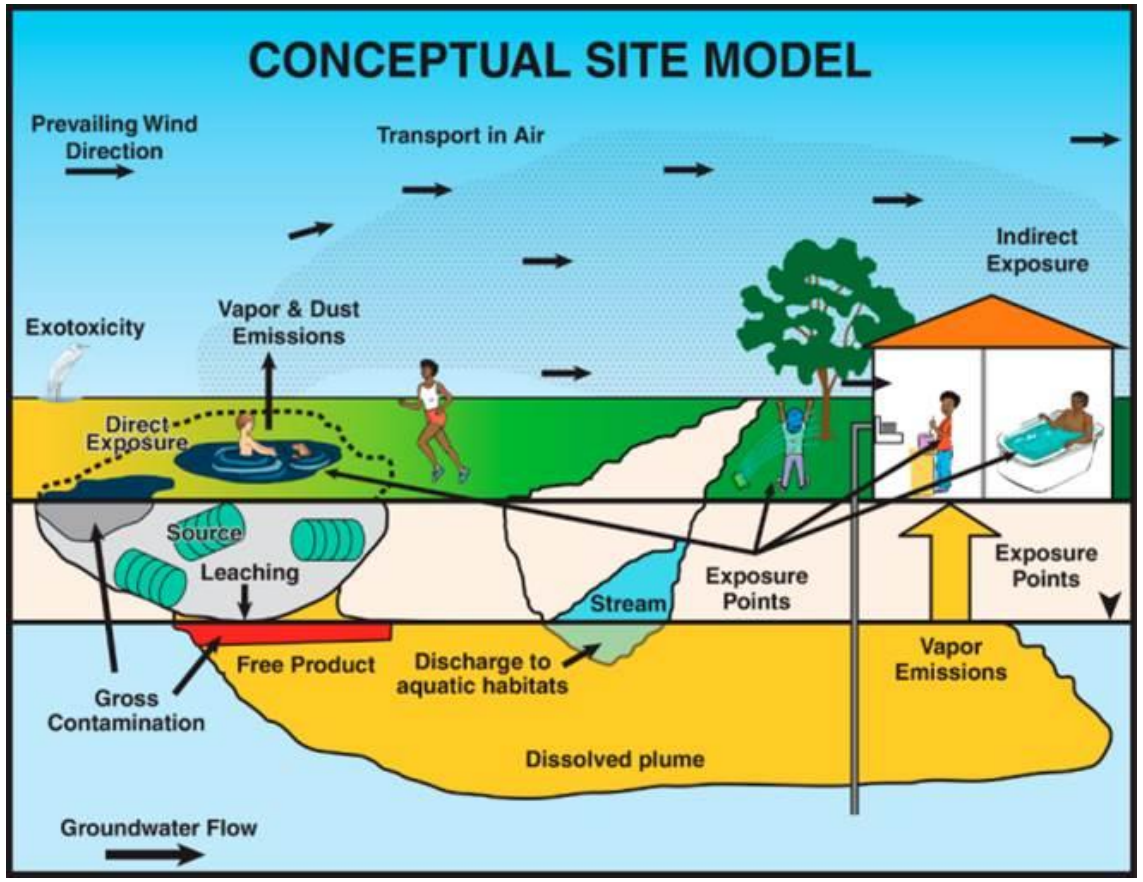
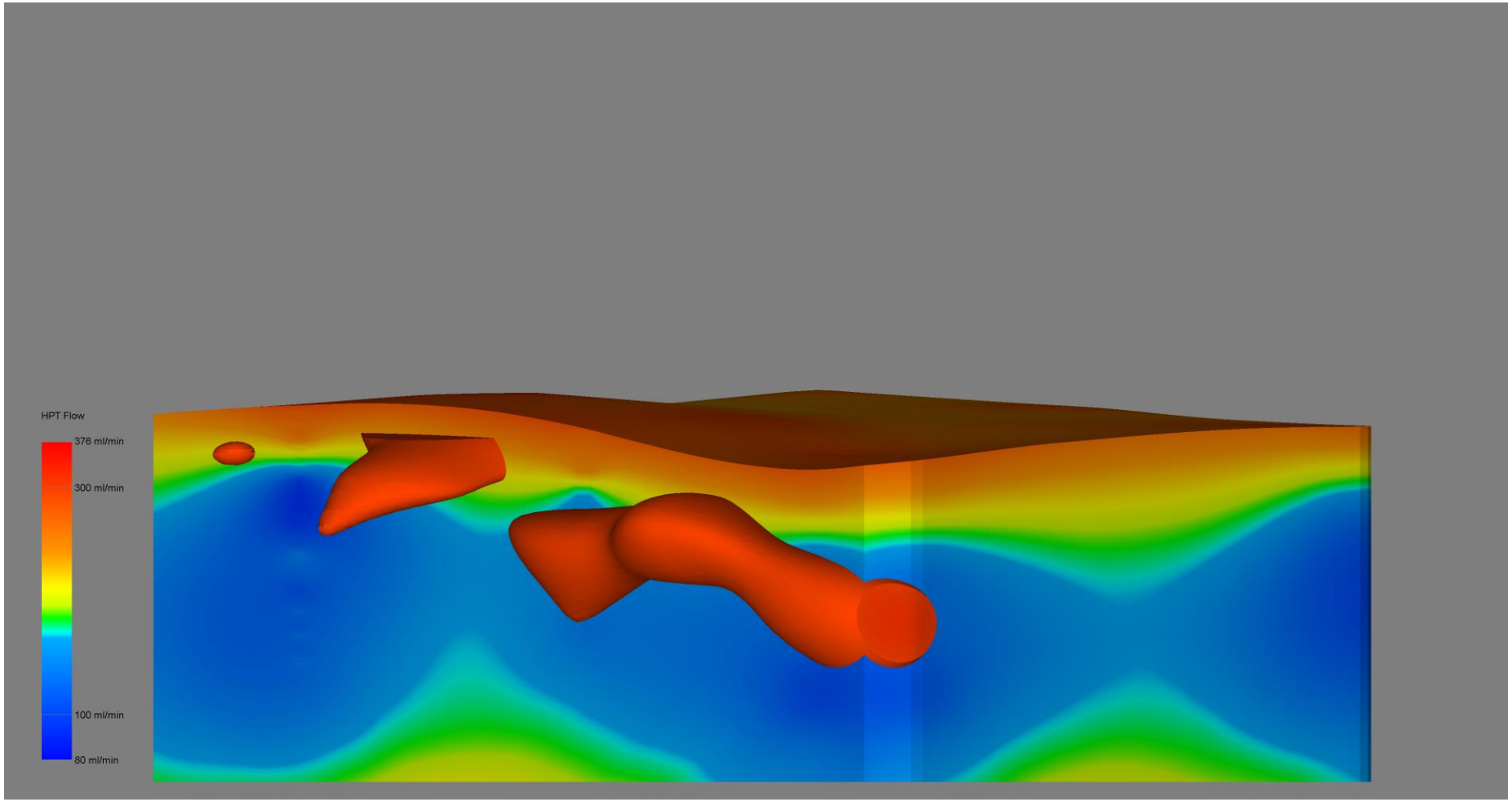


Figure Source: ITRC 2012 ISM-1

- Develop conceptual site model
  - Sources of contamination
  - Fate and transport of constituents
  - Current and likely future land and water uses
- Impacted media
- Industrial vs. residential setting
- Available habitat

Accurate CSM



- Site contamination depicted with permeability
- Plume predominantly in low permeability zone
- Limited migration potential

Identify Populations and Pathways

► Potentially Exposed Populations

- Identify current and future populations
- Consider on- and off-site populations

► Potentially Completed Pathways

- Must have source, transport mechanism, point of contact, exposure route

► Exposure Routes

- Ingestion (soil, water, produce, fish/meat)
- Dermal contact
- Vapor inhalation
- Dust inhalation

Example for Pathway-Exposure CSM

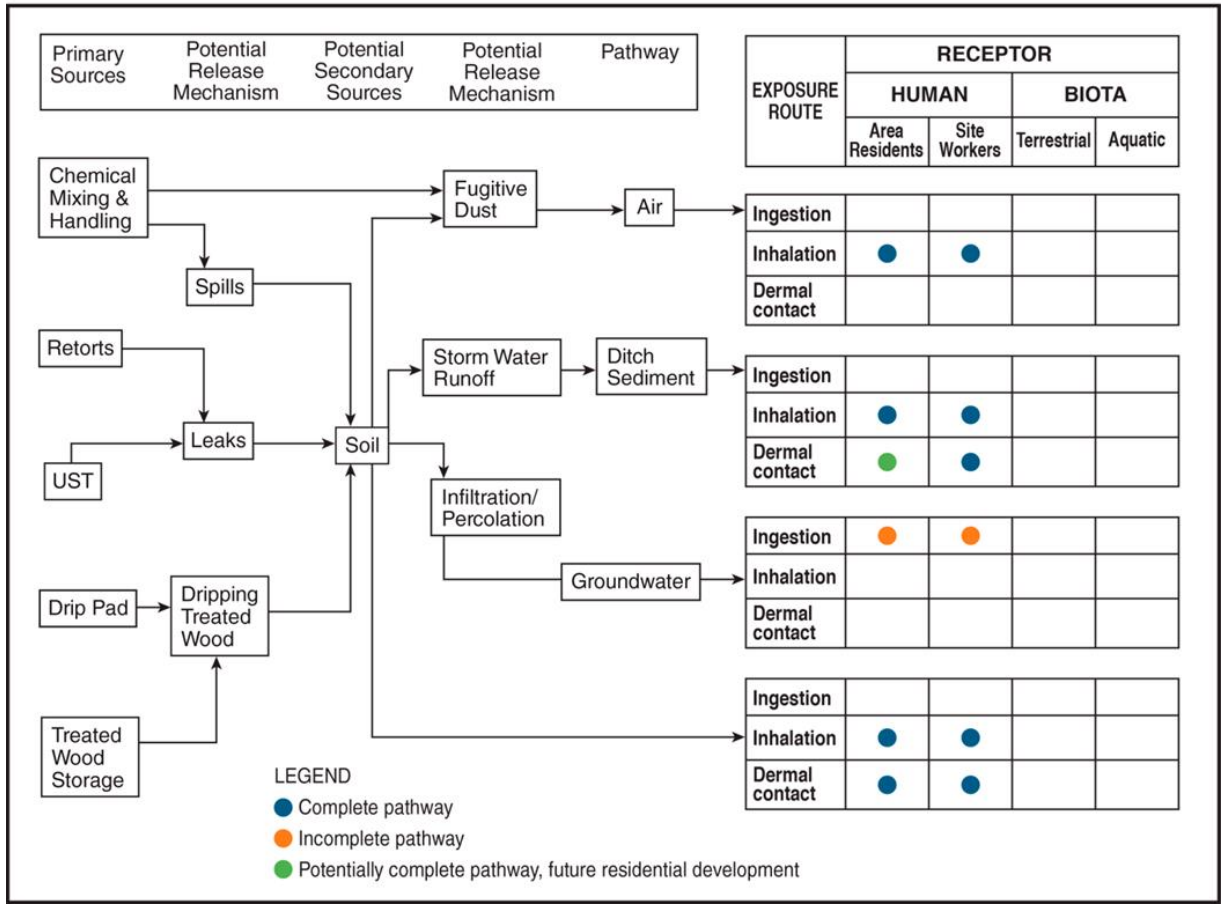


Figure Source: ITRC Risk-3 IBT

Calculating Exposure Concentration

- Identify a concentration representative of concentration population will experience across the area and duration of exposure
- Upper confidence limit on the mean
  - Conservative estimate of the average
  - Account for uncertainty of limited data sets
- Fate and transport models

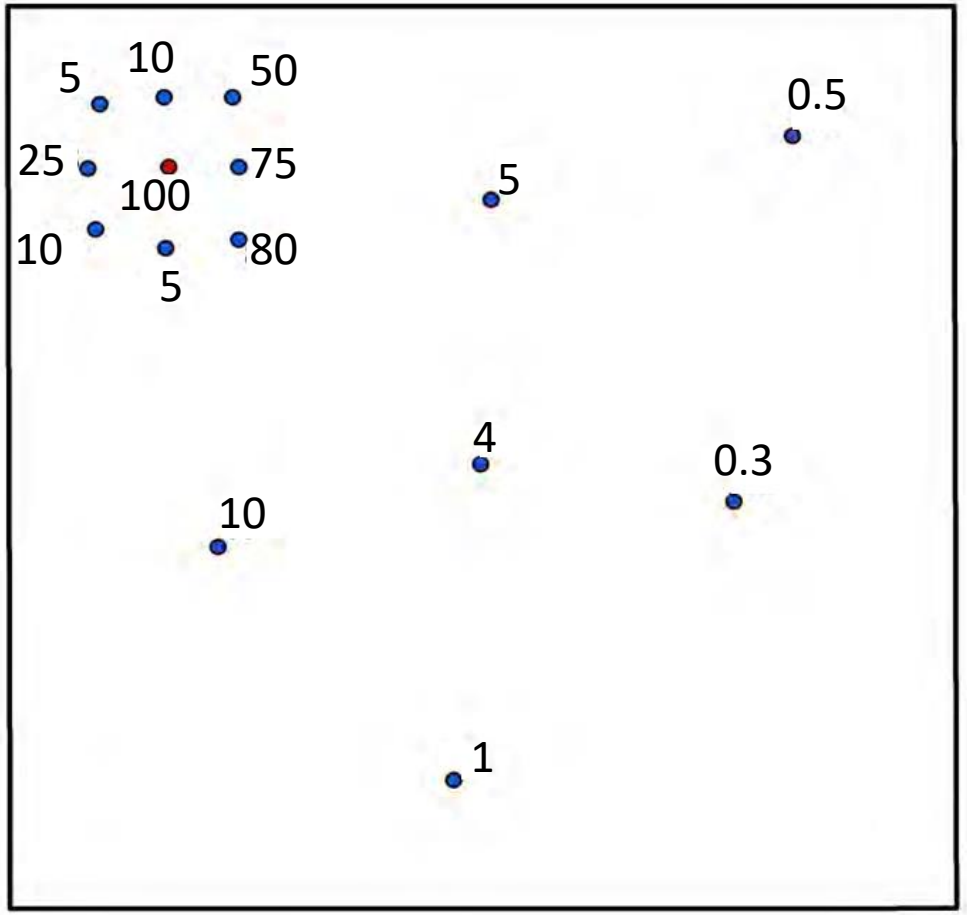
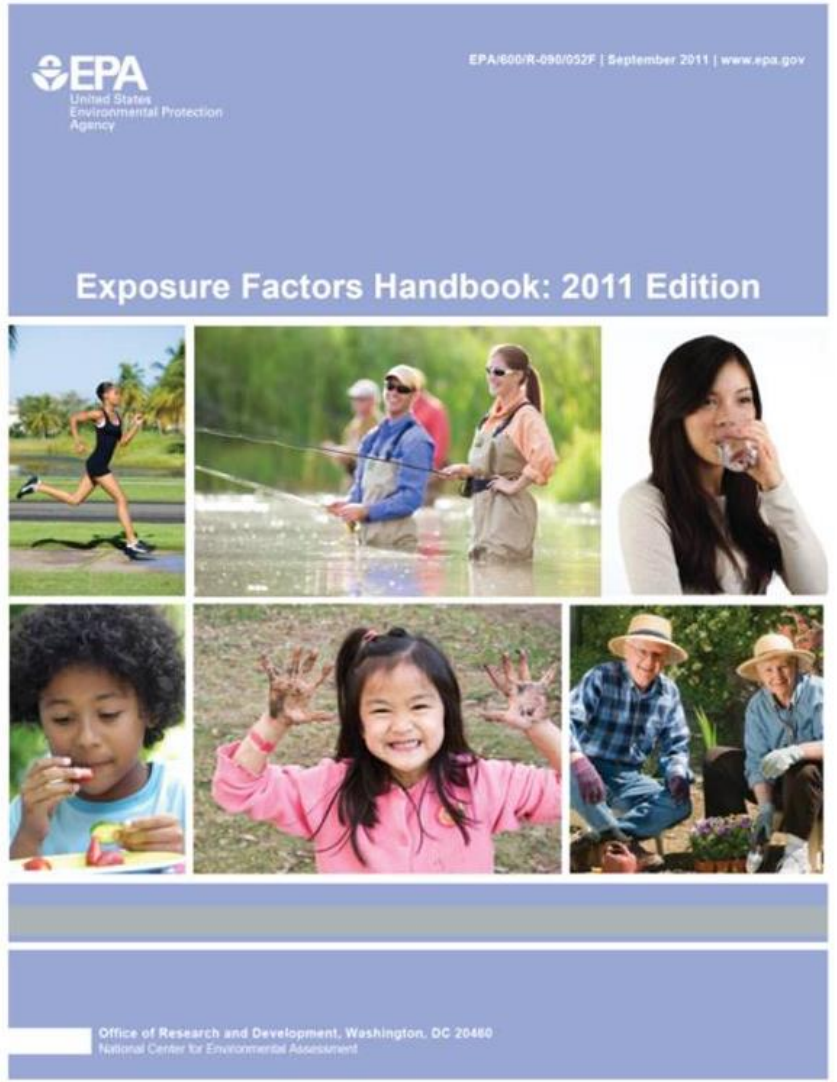


Figure Source: ITRC Risk-3 IBT

Estimate Chemical Intake

$$\text{dose} = C \cdot \left(\frac{IR \cdot EF \cdot ED}{BW \cdot AT} \right)$$

dose	=	mg chemical per kg body weight per day
C	=	contaminant concentration (mg/L)
IR	=	intake rate (L/day)
EF	=	exposure frequency (days/year)
ED	=	exposure duration (years)
BW	=	body weight (kg)
AT	=	averaging time (days)



USEPA Exposure Factors Handbook, 2011

Uncertainty in Exposure Assessment

- What are the main uncertainties in the exposure assessment?
  - How well can we predict the future?
  - Do people behave like we think?
  - Actual vs. default assumptions?
  - How accurately do we estimate chemical concentrations?
- How do we address these uncertainties?’
  - RME and CT evaluations
  - Detailed CSM
  - Probabilistic modeling
  - Site-specific exposure factors
  - 5-Year reviews

Risk Characterization

Risk Characterization

- Noncancer risk characterization
  - Hazard Quotient = Intake / RfD
  - **If Hazard Index > 1, there is concern for potential health risks**
- Cancer risk characterization
  - Risk = Intake x Slope Factor
  - **If Risk > range of one in 10,000 (1E-04 or 10^{-4}) to one in a million (1E-06 or 10^{-6}) there is a concern for potential health risks**
- Add chemical hazard/cancer risks to obtain pathway hazard/cancer risk
- Add pathway hazard/cancer risks to obtain total hazard/cancer risk

Presentation of Risk

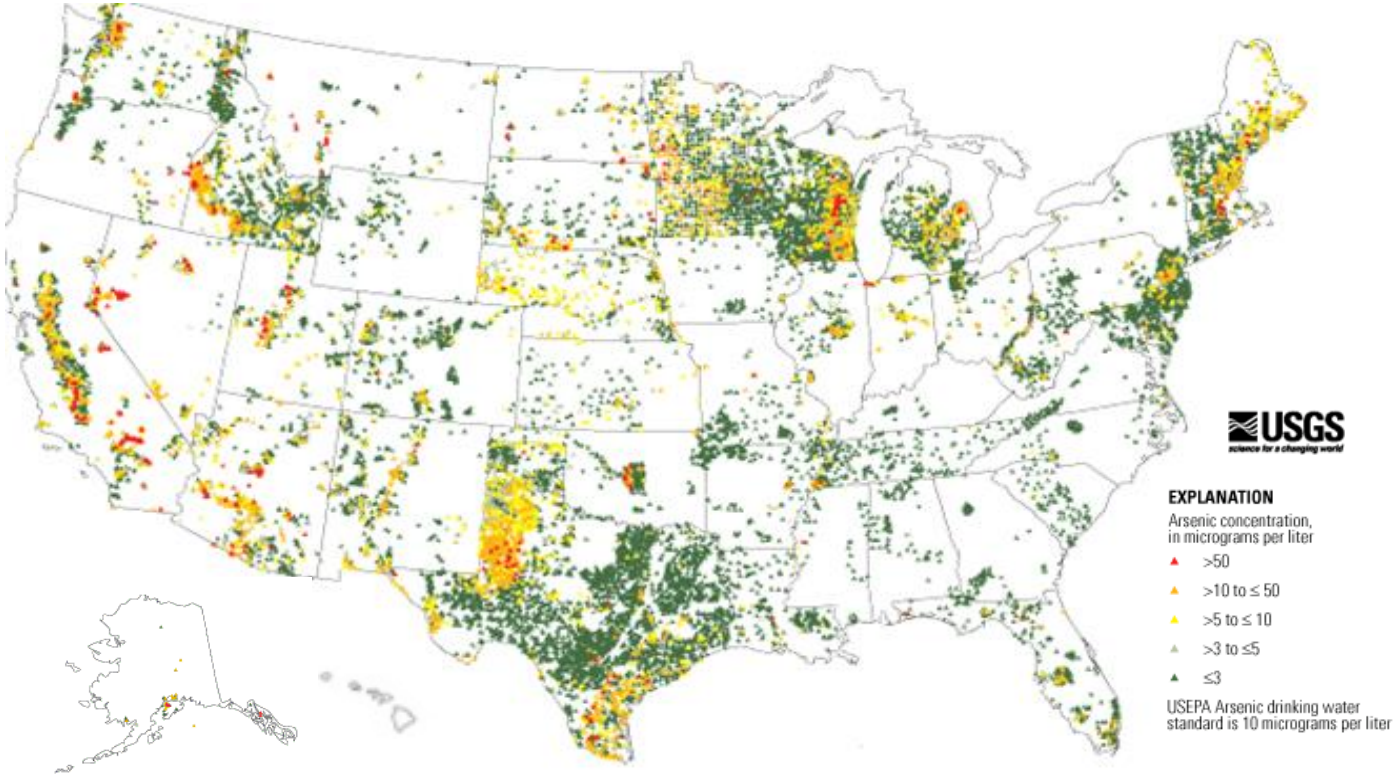
- Sum by
  - Chemical
  - Pathway
  - Medium

Chemical	Incidental Ingestion of Soil		Dermal Exposure to Soil		Dermal Exposure to Groundwater		Total Hazard and Risk	
	HQ	Cancer Risk	HQ	Cancer Risk	HQ	Cancer Risk	HI	Cancer Risk
Arsenic	0.02	1E-07	0.002	1E-08	0.1	5E-07	0.1	6E-07
B(a)P	--	4E-05	--	2E-05	--	2E-07	--	6E-05
						TOTAL	0.1	6E-05

$$\text{Cumulative Risk} = \sum_i \text{Risk}_i \qquad \text{HI} = \sum_i \text{HQ}_i$$

Uncertainty in Risk Characterization

- What are some key areas of uncertainty in the risk characterization
  - Background
  - Bias
  - Cancer risk range
- How do we address these uncertainties?
  - Understand and account for background
  - Detailed qualitative descriptions of areas of bias
  - Probabilistic model of uncertainty



Background Arsenic in Groundwater

Figure Source: USGS.
Available from http://water.usgs.gov/nawqa/trace/arsenic/

Key Risk Management Considerations

Cleanup Levels

- Risk Management Strategy: Use EPA RSLs or other published screening levels
- Limitation: Based on default scenarios and assumptions
  - May not reflect actual site conditions
  - May not account for exposures already addressed in risk assessment
  - Inconsistent methods of applying cleanup levels vs developing exposure concentrations in risk assessment
- How can we address these limitations?
  - Site-specific cleanup levels
  - Statistical application of cleanup levels

Example EPA RSL

4.1.1.3 Carcinogenic

The residential soil land use equation, presented here, contains the following exposure routes:

- incidental ingestion of soil

$$SL_{res\text{-}soil\text{-}ca\text{-}ing}\left(\frac{mg}{kg}\right) = \frac{TR \times AT_{res}\left(\frac{365\ days}{year} \times LT\ (70\ years)\right)}{CSF_o\left(\frac{mg}{kg\text{-}day}\right)^{-1} \times RBA \times IFS_{res\text{-}adj}\left(\frac{36{,}750\ mg}{kg}\right) \times \left(\frac{10^{-6}\ kg}{mg}\right)}$$

where:

$$IFS_{res\text{-}adj}\left(\frac{36{,}750\ mg}{kg}\right) = \left(\frac{EF_{res\text{-}c}\left(\frac{350\ days}{year}\right) \times ED_{res\text{-}c}\ (6\ years) \times IRS_{res\text{-}c}\left(\frac{200\ mg}{day}\right)}{BW_{res\text{-}c}\ (15\ kg)} + \frac{EF_{res\text{-}a}\left(\frac{350\ days}{year}\right) \times \left(ED_{res}\ (26\ years) - ED_{res\text{-}c}\ (6\ years)\right) \times IRS_{res\text{-}a}\left(\frac{100\ mg}{day}\right)}{BW_{res\text{-}a}\ (80\ kg)}\right)$$

- dermal contact with soil

$$SL_{res\text{-}soil\text{-}ca\text{-}der}\left(\frac{mg}{kg}\right) = \frac{TR \times AT_{res}\left(\frac{365\ days}{year} \times LT\ (70\ years)\right)}{\left(\frac{CSF_o\left(\frac{mg}{kg\text{-}day}\right)^{-1}}{GIABS}\right) \times DFS_{res\text{-}adj}\left(\frac{103{,}390\ mg}{kg}\right) \times ABS_d \times \left(\frac{10^{-6}\ kg}{mg}\right)}$$

where:

$$DFS_{res\text{-}adj}\left(\frac{103{,}390\ mg}{kg}\right) = \left(\frac{EF_{res\text{-}c}\left(\frac{350\ days}{year}\right) \times ED_{res\text{-}c}\ (6\ years) \times SA_{res\text{-}c}\left(\frac{2373\ cm^2}{day}\right) \times AF_{res\text{-}c}\left(\frac{0.2\ mg}{cm^2}\right)}{BW_{res\text{-}c}\ (15\ kg)} + \frac{EF_{res\text{-}a}\left(\frac{350\ days}{year}\right) \times \left(ED_{res}\ (26\ years) - ED_{res\text{-}c}\ (6\ years)\right) \times SA_{res\text{-}a}\left(\frac{6032\ cm^2}{day}\right) \times AF_{res\text{-}a}\left(\frac{0.07\ mg}{cm^2}\right)}{BW_{res\text{-}a}\ (80\ kg)}\right)$$

- inhalation of volatiles and particulates emitted from soil

$$SL_{res\text{-}soil\text{-}ca\text{-}inh}\left(\frac{mg}{kg}\right) = \frac{TR \times AT_{res}\left(\frac{365\ days}{year} \times LT\ (70\ years)\right)}{IUR\left(\frac{\mu g}{m^3}\right)^{-1} \times \left(\frac{1000\ \mu g}{mg}\right) \times EF_{res}\left(\frac{350\ days}{year}\right) \times \left(\frac{1}{VF_{ulim}\left(\frac{m^3}{kg}\right)} + \frac{1}{PEF\left(\frac{m^3}{kg}\right)}\right) \times ED_{res}\ (26\ years) \times ET_{res}\left(\frac{24\ hours}{day}\right) \times \left(\frac{1\ day}{24\ hours}\right)}$$

- Total

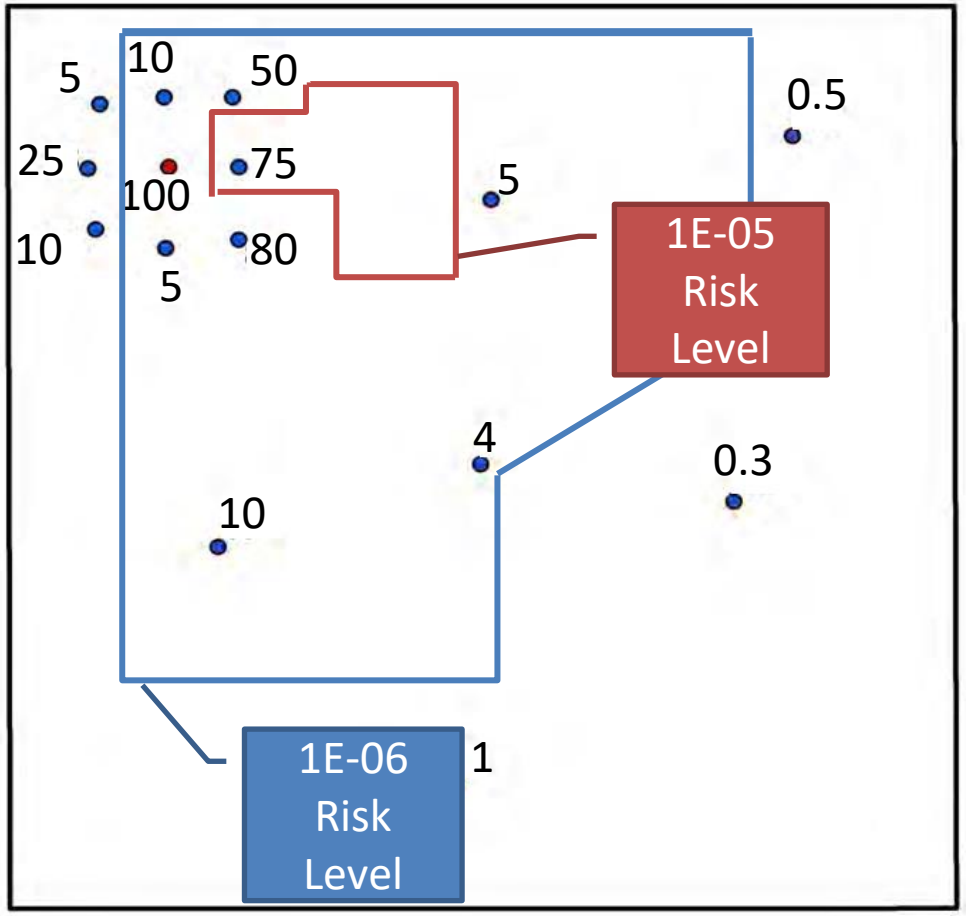
$$SL_{res\text{-}soil\text{-}ca\text{-}tot}\left(\frac{mg}{kg}\right) = \frac{1}{\frac{1}{SL_{res\text{-}soil\text{-}ca\text{-}ing}} + \frac{1}{SL_{res\text{-}soil\text{-}ca\text{-}der}} + \frac{1}{SL_{res\text{-}soil\text{-}ca\text{-}inh}}}$$

Source: USEPA RSL User's Guide May 2020

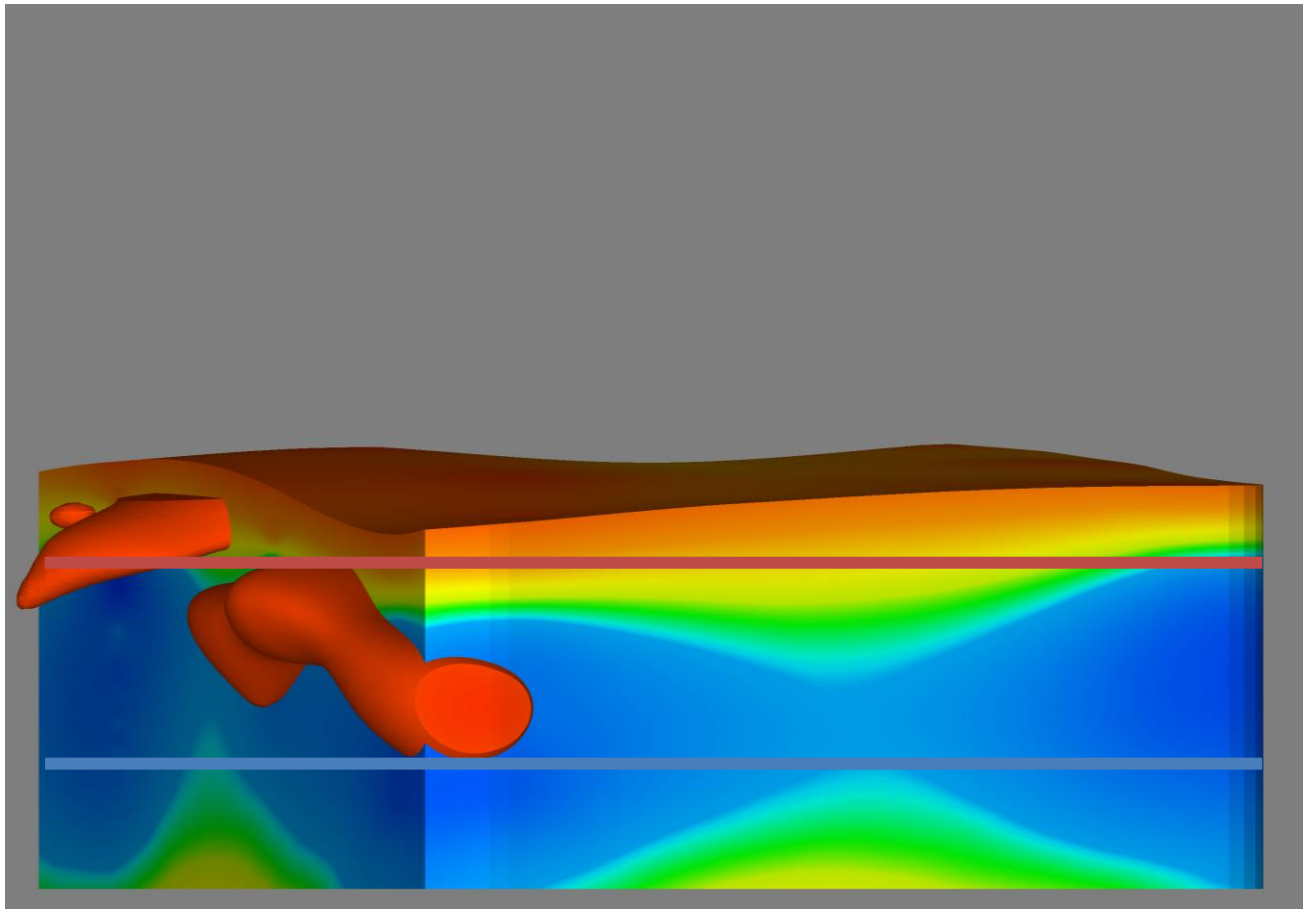
Selecting Target Risk Levels

- Risk Management Strategy: Default to 1E-06
- Limitation: Assumes risk reduction is directly proportional to target cancer risk
  - Contamination isn't evenly distributed
  - Risk isn't evenly distributed laterally or vertically
  - Inter-relationship between risk level and technological practicability
- How can we address these limitations?
  - Generate risk contours to evaluate distribution of risk across the site at different risk levels
  - Evaluate remediation costs vs. benefits at different risk levels

Example/Hypothetical Site



Hypothetical Exposure Area



What Does This Mean For Risk Management Decisions?

- Understand your risk assessment
- Toxicity uncertainties
  - Toxicology is a dynamic field – keep abreast of potential changes
  - Be aware – 5-year reviews
- Exposure uncertainties
  - Calculate both RME and central tendency evaluations
  - Make sure the exposure areas and assumptions fit the site circumstances
  - Account for background
  - Beware of over-simplified CSMs
- Give probabilistic modeling a try
- Site-specificity is your friend

Questions?

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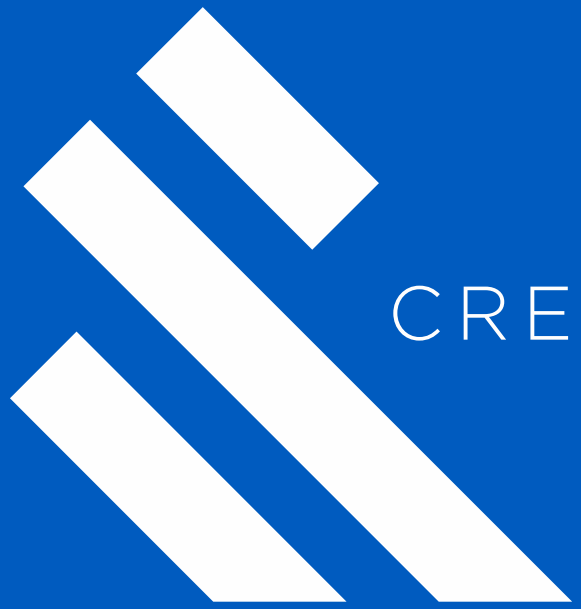

CREATE AMAZING.