# Risk Assessments in RCRA

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# Risk Assessments in RCRA

- Goal: To relate the most important aspects of risk assessment in a pragmatic fashion for consideration as you advance risk management decisions
- The following discussion is designed to inform you of some basics w/r/t risk assessment, but primarily help you focus on:
  - A better appreciation for the uncertainty which undermines risk-based decision making
  - The most important considerations w/r/t risk management
  - The most common flaws in PRP risk assessments which you can watch out for

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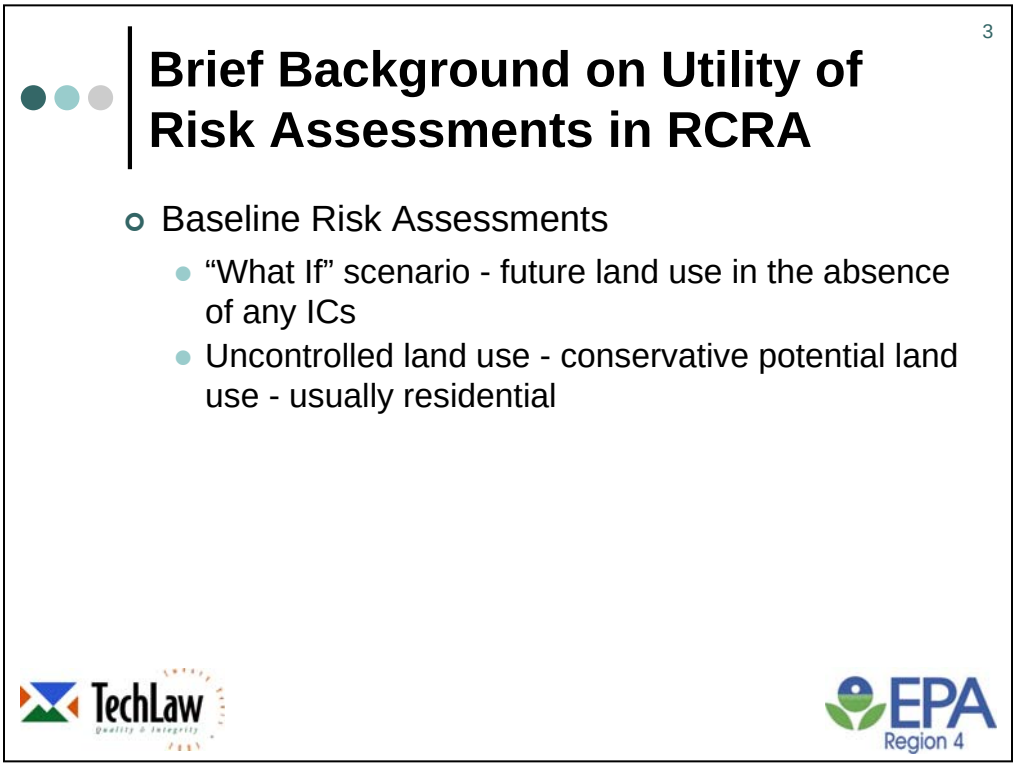


Forms the basis and need for ICs, often

# Brief Background on Utility of Risk Assessments in RCRA

- Site-Specific Risk Assessments
  - Depending on requirements of your program, these can help you get to the point with less effort and money, but don't assess full spectrum - assess most likely exposures
  - Pragmatism/Realism - still, focus is on RME condition

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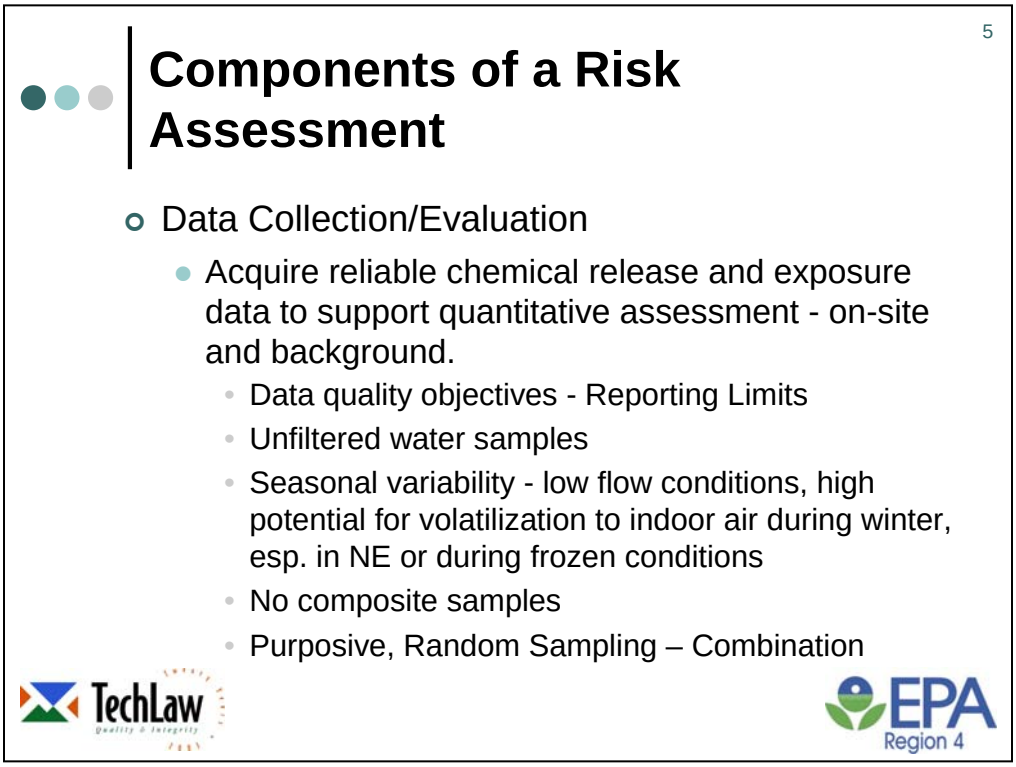


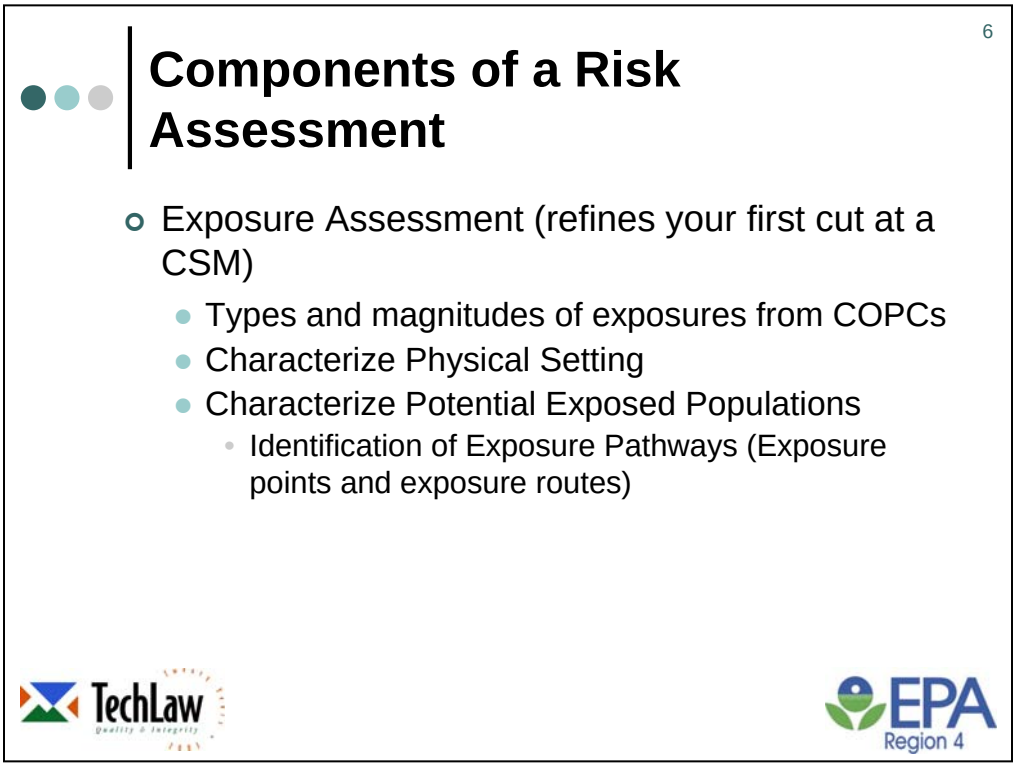

Data quality objectives w/r/t screening criteria - ensure reporting limits are stringent enough to note potential exceedance, if present.

Seasonal variability - low flow conditions in streams during summer based on low occurrence of precipitation or depressed groundwater, low potential for volatilization during spring (precipitation drives downward migration), high potential for volatilization to indoor air during winter, esp. in NE or during frozen conditions.

Purposive sampling - helps characterize the site w/r/t chemical release

Random sampling - helps support statistically viable data sets for use in characterizing potential exposure

Out of necessity, we rely on a combination - recognizing limitations and conservative bias (b/c of targeting impacted areas and variability which is brought into combined dataset).




Estimate the types and magnitudes of exposures from COPCs present at or migrating from a site.

Characterize Physical Setting (climate, meteorology, geologic setting, vegetation, soil type, hydrology, presence of surface water)

# Components of a Risk Assessment

- Exposure Assessment (cont'd)
  - Complete and Potentially Complete Exposure Pathways
    - e.g., Groundwater
    - Reasonable Maximum Exposure v.s Central Tendency
    - 95UCL as EPC for both
    - Use of Max and Mean if data sets are small, not statistically viable
  - Acute vs. Chronic Risks - Hotspots?

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Complete and Potentially Complete Exposure Pathways

e.g., Groundwater - Drinking water source? Now - or in future? Tricky for long-term exposure - dynamic medium. Look at center of plume - or max detects? Aquifer classification?

Reasonable Maximum Exposure vs. Central Tendency

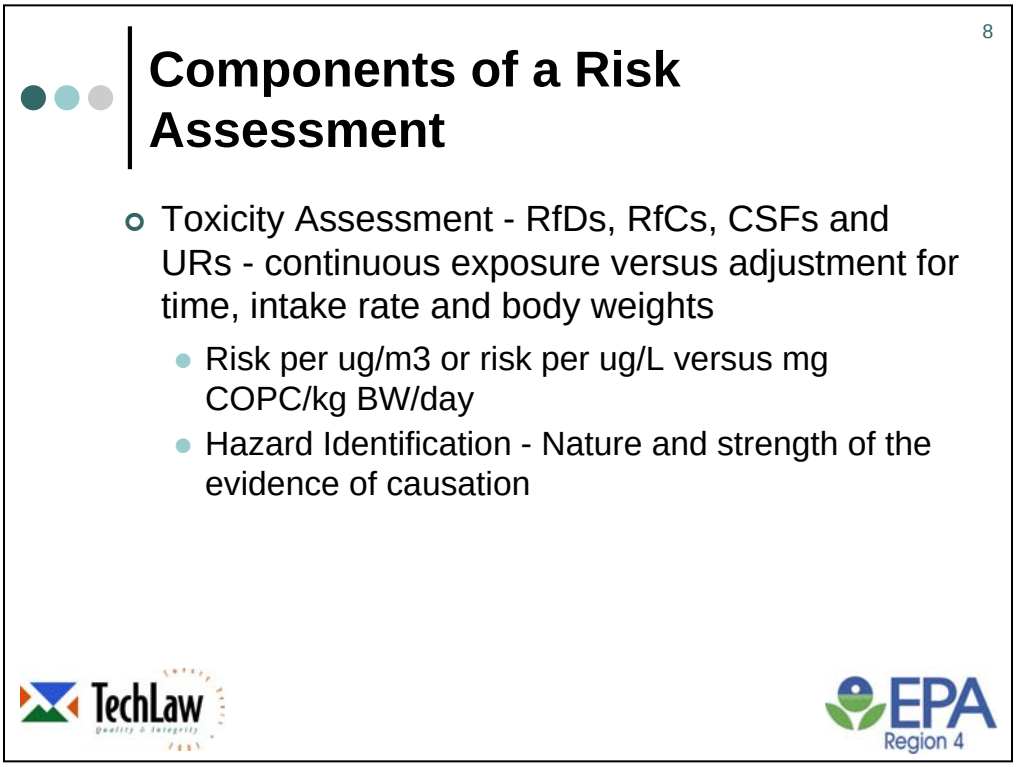
95UCL as EPC for both

Use of Max and Mean if data sets are small, not statistically viable.

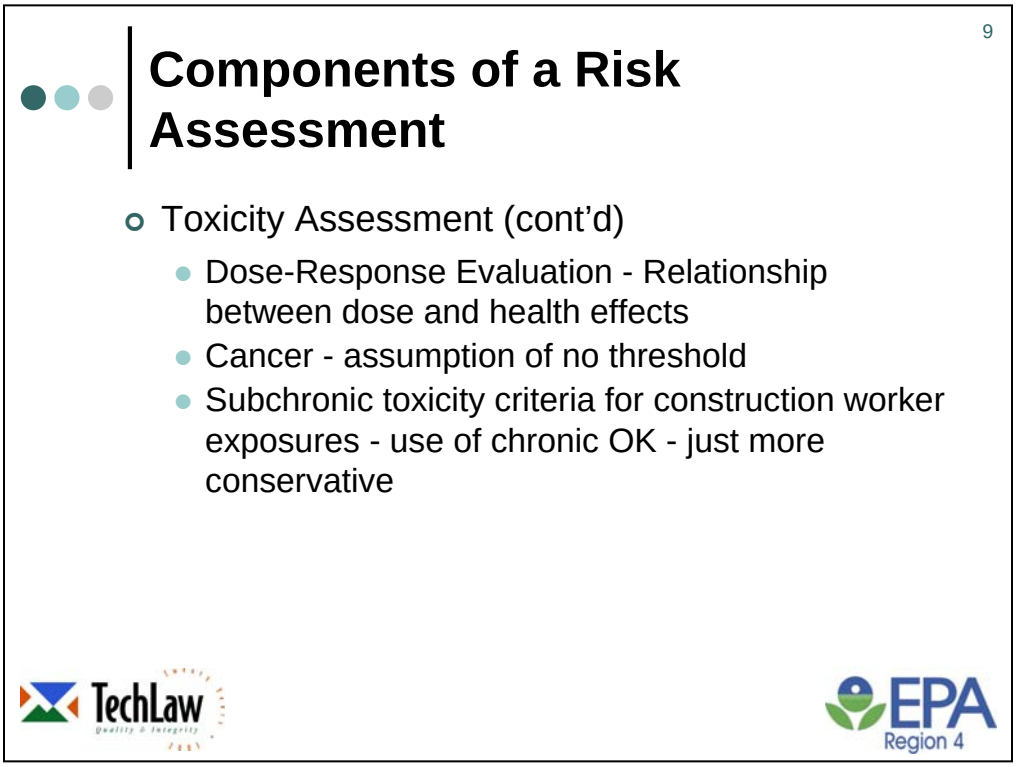
Acute vs. Chronic Risks-

Very elevated?

Hotspots near discrete work stations? Localized land use activities?




Hazard Identification - Determining whether an agent can cause an increase in the incidence of a given adverse health effect. Nature and strength of the evidence of causation.

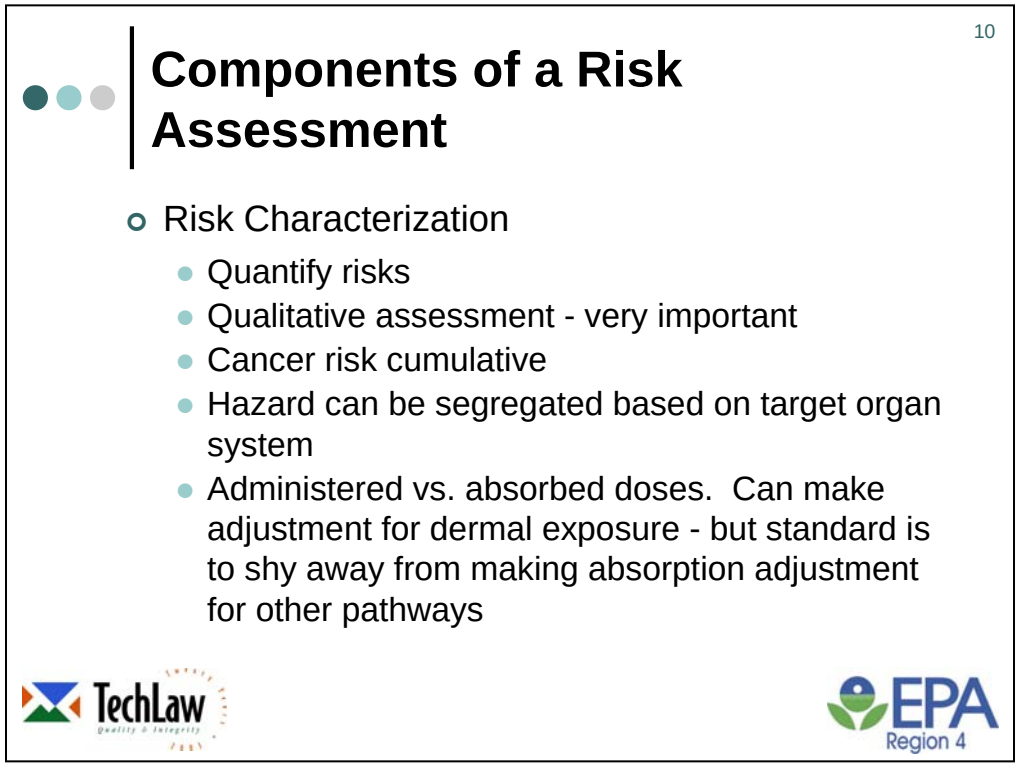



Dose-Response Evaluation - Quantitatively evaluating the toxicity information and characterizing the relationship between dose and the incidence of adverse health effects in exposed population.

Cancer - assumption of no threshold - single exposure can lead to uncontrolled cellular proliferation

Your risk assessor will focus on the veracity of the info, consider it for background.

Subchronic toxicity criteria for construction worker exposures - if they use chronic- just more conservative (see HEAST)




Administered vs. absorbed doses. Can make adjustment for dermal exposure - but standard is to shy away from making absorption adjustment for other pathways. Can entertain argument for gastrointestinal absorption adjustments, but anything with greater than 50% absorption is assumed to be associated with 100%. Needs to be accompanied by strong arguments.

# Components of a Risk Assessment

- Uncertainty Analysis
  - Generally undervalued - but may be most important part of risk evaluation
  - Provides basis for confidence in quantitative point estimates

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# Consideration of the NCP Risk Range (Risk Management)

- Degree of uncertainty and conservatism inherent in the risk assessment
- Complexity of the COPC list - One COPC vs. Many w/ varied exposure pathways

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# Important Considerations/Crucial Problem Areas

- Selecting Preeminent COPCs
- Selecting Representative or Maximally Exposed Populations for Management Basis
- Maintaining Common Sense Approach - Don't Get Wrapped Up in Minutia

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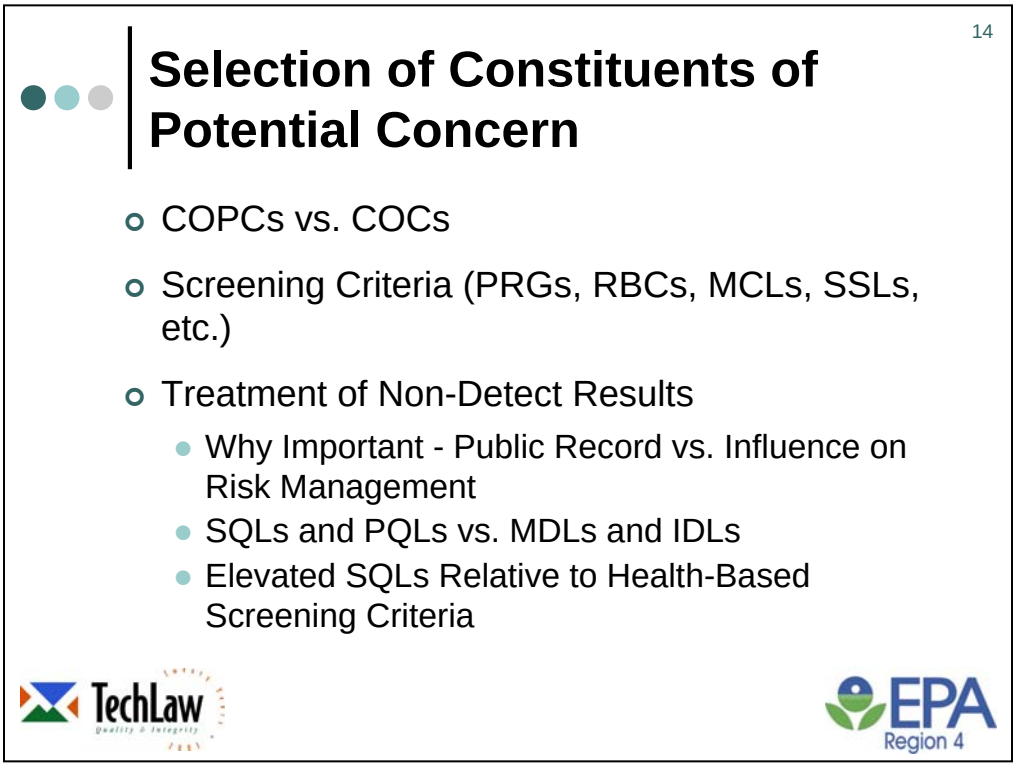


Screening Criteria (PRGs, RBCs, MCLs, SSLs, etc.)

Dependent on Media, Pathway and Receptor Populations at Issue

# Selection of Constituents of Potential Concern

- Treatment of Non-Detect Results (cont'd)
  - Development of Exposure Point Concentrations
    - Zero
    - One-half the SQL or MDL? - Impact of variability vs. RAGS, 1989
    - Equal to the SQL or MDL? - Impact of variability vs. RAGS, 1989

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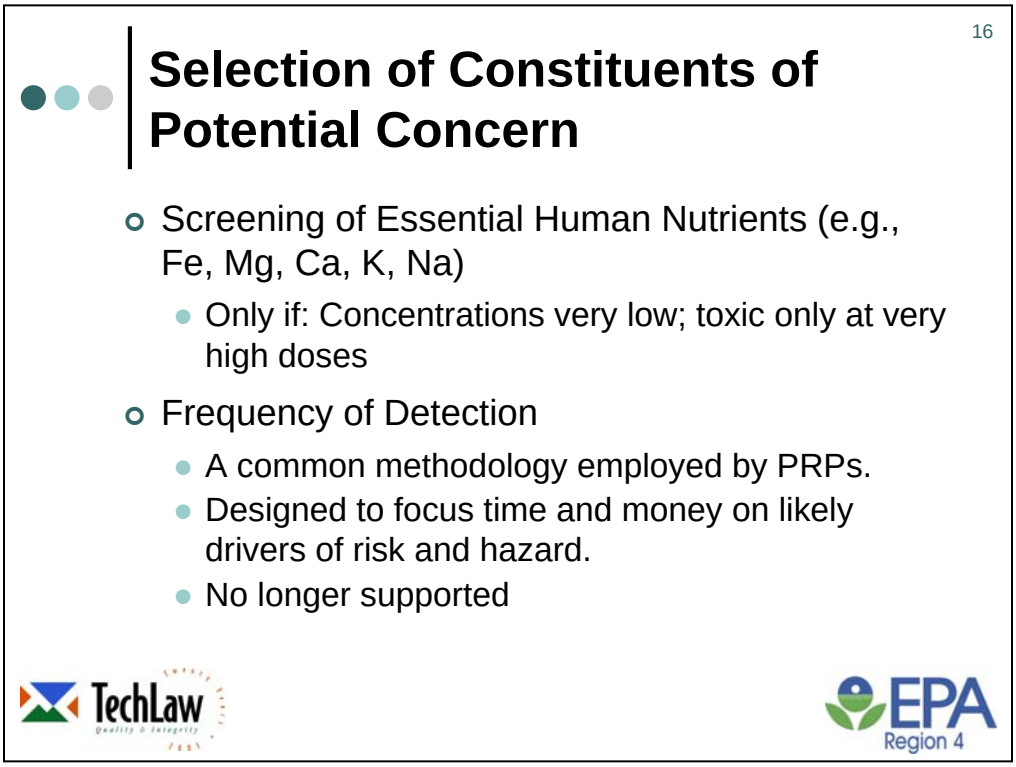



Screening of Essential Human Nutrients (e.g., Fe, Mg, Ca, K, Na)

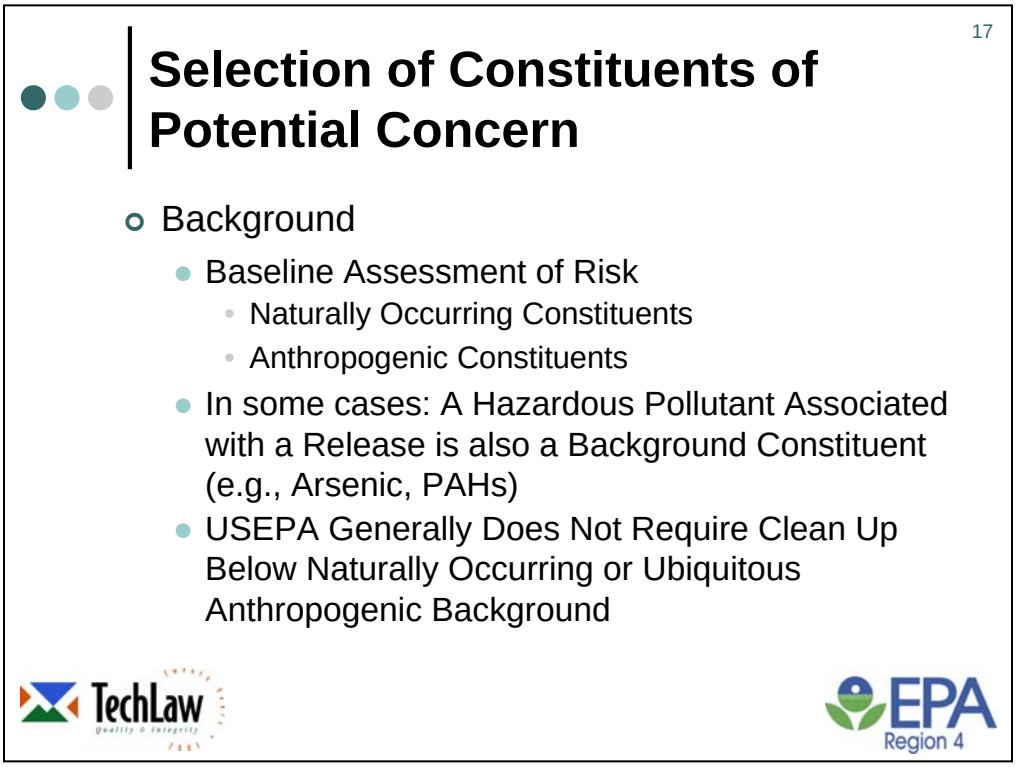
Only if:

Present at very low concentrations (i.e., only slightly elevated above background)

Toxic only at very high doses (i.e., much higher than those which could reasonably be associated with the site).

Was designed to help risk assessors focus time and money on the likely drivers of risk and hazard.

No longer supported with the advent and general widespread availability of health-based screening criteria.




USEPA Generally Does Not Clean up to Concentrations Below Naturally Occurring or Ubiquitous Anthropogenic Background, Based On: Cost Effectiveness, Technical Practicability, Potential for Recontamination

# Selection of Constituents of Potential Concern

- Background (cont'd)
  - Background Screening History
    - RAGS, 1989 Cautioned Against Screening w/r/t Background
    - PRPs Were Allowed this Option
    - Refined Guidances in 1997 and in 2002
- Baseline (Total) Risk, Site-Related Risk, Residual (Background) Risk
  - Clean Up May/May Not Eliminate a Source Caused by Background

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History:

RAGS, 1989 Cautioned Against Screening COPCs Based on Background

Still, Many PRPs Were Allowed to Screen Based on Comparison to Background.

Refined Guidances Started Appearing in 1997 and in 2002 Several Definitive Guidances Were Generated.)

Even Though Clean Up May or May Not Eliminate a Source of Risks Caused by Background Levels

# Selection of Constituents of Potential Concern

- Consideration of Background in Risk Management
  - Contribution of Background Risk May Refine COC Clean Up Levels
- Consideration of Background in Risk Communication
  - Background Risk Levels Are Important to the Public

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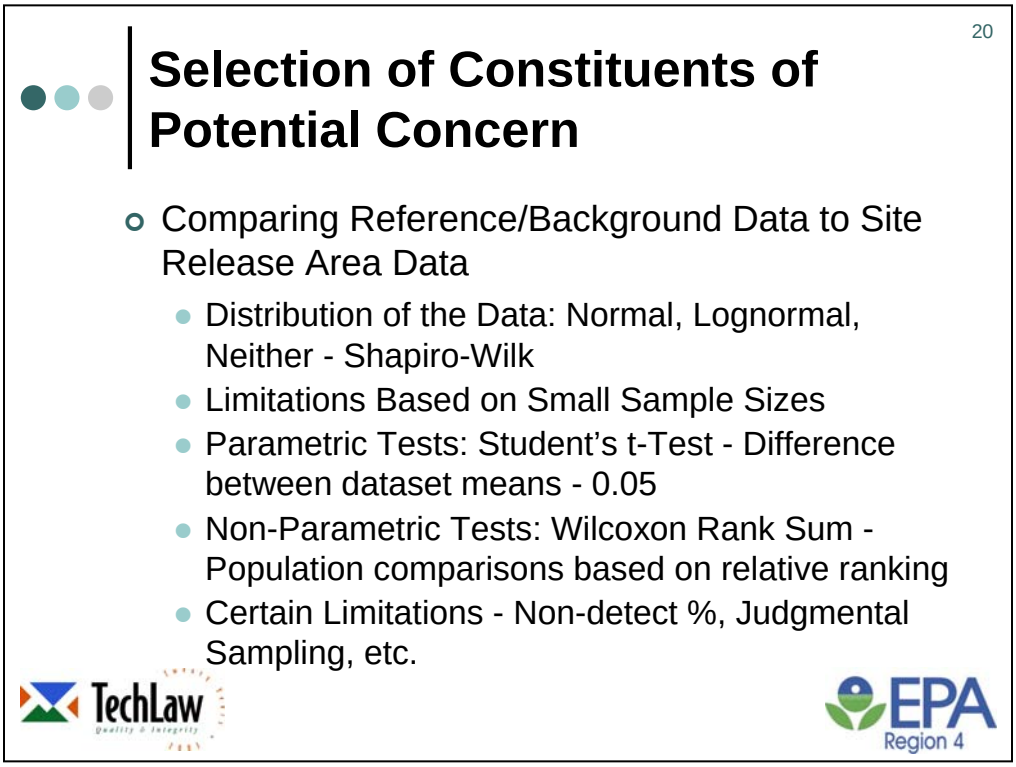
Background Risk Levels Are Important to the Public

Can Impact Daily Activities

Can Put Site-Related Impacts in Perspective




Parametric Tests

Common: Student's t-Test - Tests for a difference between discrete dataset means - 0.05

Non-Parametric Tests - No Assumptions About Dataset Distribution - Outliers, Non-detect Data

Common: Wilcoxon Rank Sum - Tests whether measurements from one population tend to be larger (or smaller) than those from another population based on relative ranking (in a single list).

# QA/QC Samples

- Blank Samples - Positive Results if > 10 X Detection in Blanks
- J-Coded Values - Treat as Detections

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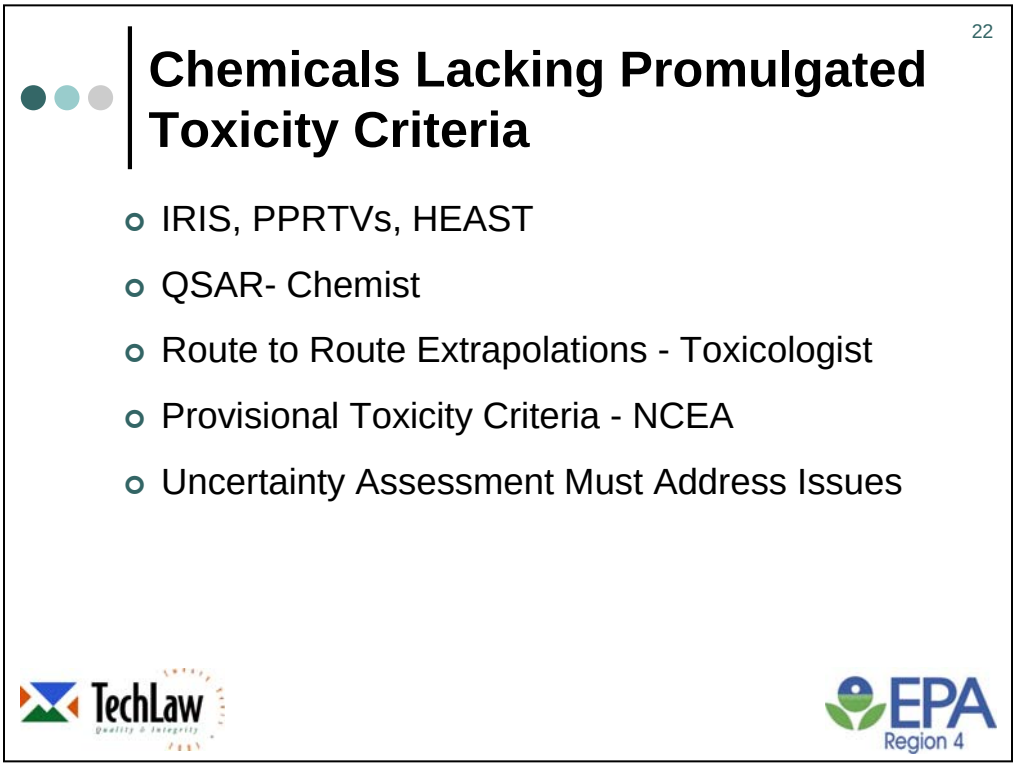
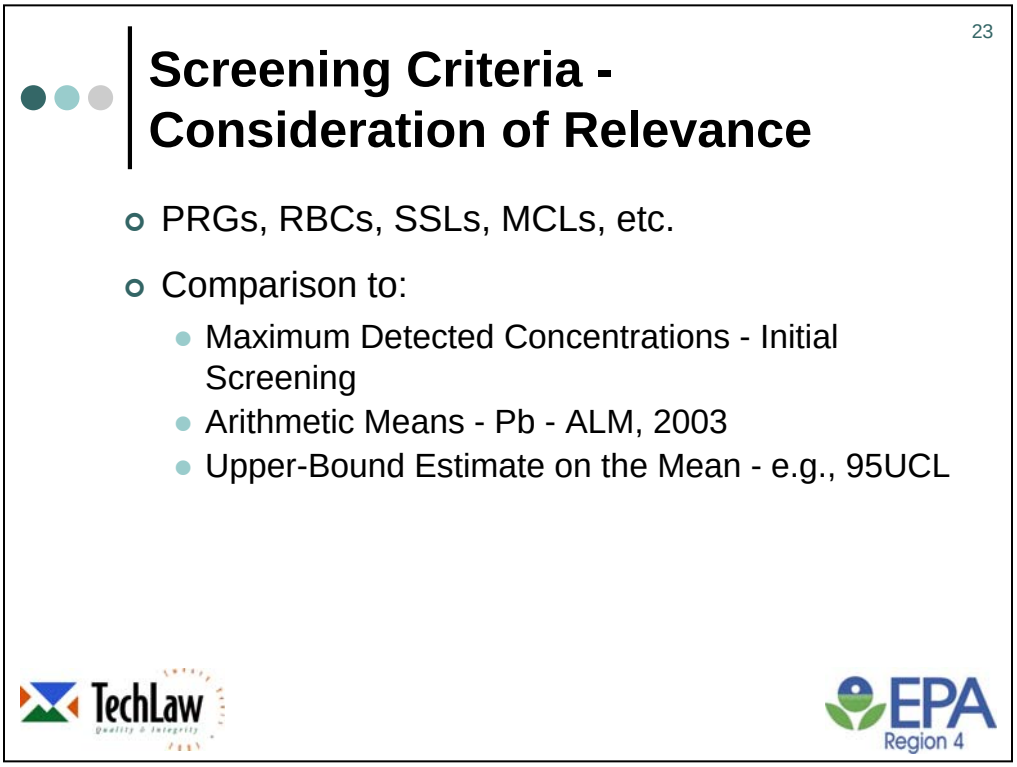



Integrated Risk Information System (IRIS), PPRTVs, HEAST

Quantitative/Structure-Activity Relationships - Chemist

Route to Route Extrapolations, Unless Contraindicated - Toxicologist

Uncertainty Assessment Must Address Attendant Issues to Greatest Extent Possible

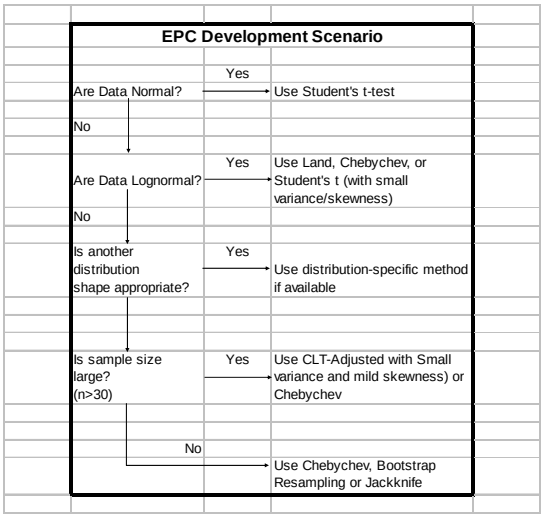



Upper-Bound Estimate on the Mean - e.g., 95% Upper Confidence Limit on the Mean

Brief Background on Basis for 95UCL as the Exposure Point Concentration

Can Refine The COPC List

# Exposure Point Concentration (EPC) Development

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# Reference List - Risk Assessment Guidance - Most Helpful

- General Background and Overview/ Understanding
  - *Risk Assessment Guidance for Superfund, Volume 1, Human Health Evaluation Manual (Part A)*, (EPA/540/1-89/002), December, 1989
  - *Memorandum: Role of the Baseline Risk Assessment in Superfund Remedy Selection Decisions*, April, 1991
  - *Land Use in the CERCLA Remedy Selection Process*, May, 1995

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# Reference List - Risk Assessment Guidance - Most Helpful

- General Background and Overview/ Understanding (cont'd)
  - *Human Health Risk Assessment Protocol for Hazardous Waste Combustion Facilities*, April, 1998; errata, 1999
  - *Supplemental Guidance for Developing Soil Screening Levels for Superfund Sites*, March, 2001

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# Reference List - Risk Assessment Guidance - Most Helpful

- Data Usability
  - *Guidance for Data Usability in Risk Assessment*, April, 1992
- Exposure Point Concentrations
  - *Supplemental Guidance to RAGS: Calculating the Concentration Term*, June, 1992
  - *The Lognormal Distribution in Environmental Applications*, December, 1997

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# Reference List - Risk Assessment Guidance - Most Helpful

- Exposure Point Concentrations (cont'd)
  - *Human Health Risk Assessment Protocol for Hazardous Waste Combustion Facilities*, April, 1998; errata, 1999
  - *Calculating Upper Confidence Limits for Exposure Point Concentrations at Hazardous Waste Sites*, December, 2002

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# Reference List - Risk Assessment Guidance - Most Helpful

- Screening Criteria Development
  - *Soil Screening Guidance: Technical Background Document*, May, 1996
  - *Supplemental Guidance for Developing Soil Screening Levels for Superfund Sites*, March, 2001

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# Reference List - Risk Assessment Guidance - Most Helpful

- Selected Contaminant-Specific Guidance
  - Lead
    - *Recommendations of the Technical Review Workgroup for Lead for an Interim Approach to Assessing Risks Associated with Adult Exposure to Lead in Soil*, January, 2003
  - PAHs
    - *Provisional Guidance for Quantitative Risk **Assessment** of Polycyclic Aromatic Hydrocarbons*, July 1993

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# Reference List - Risk Assessment Guidance - Most Helpful

- Selected Contaminant-Specific Guidance (cont'd)
  - Dioxin - PCDD/PCDF
    - *Exposure and Human Health Reassessment of 2,3,7,8-Tetrachlorodibenzo-p-dioxin (TCDD) and Related Compounds*, September, 2000
- Exposure Factors/Parameter Values
  - *Exposure Factors Handbook*, August, 1997
  - *Human Health Risk Assessment Protocol for Hazardous Waste Combustion Facilities*, April, 1998; errata, 1999

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# Reference List - Risk Assessment Guidance - Most Helpful

- Exposure Factors/Parameter Values
  - *Supplemental Guidance for Developing Soil Screening Levels for Superfund Sites*, March, 2001
  - *Child-Specific Exposure Factors Handbook*, September, 2002
  - *Risk Assessment Guidance for Superfund, Volume 1, Human Health Evaluation Manual (Part E): Supplemental Guidance for Dermal Risk Assessment*, July, 2004

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# Reference List - Risk Assessment Guidance - Most Helpful

- Presentation and Format for Risk Assessments
  - *Risk Assessment Guidance for Superfund, Volume 1, Human Health Evaluation Manual (Part D): Standardized Planning, Reporting and Review of Superfund Risk Assessments*, December, 1997
- Sediments
  - *Contaminated Sediment Management Strategy*, April, 1998

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# Reference List - Risk Assessment Guidance - Most Helpful

- Combustion Risk Assessment
  - *Human Health Risk Assessment Protocol for Hazardous Waste Combustion Facilities*, April, 1998; *errata*, 1999
  - *Risk Burn Guidance for Hazardous Waste Combustion Facilities*, July, 2001
- Radionuclides
  - *Soil Screening Guidance for Radionuclides*, October, 2000

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# Reference List - Risk Assessment Guidance - Most Helpful

- Background
  - *Guidance for Characterizing Background Chemicals in Soil at Superfund Sites*, June, 2001
  - *Guidance for Comparing Background and Chemical Concentrations in Soil for CERCLA Sites*, September, 2002

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# Reference List - Risk Assessment Guidance - Most Helpful

- Vapor Intrusion
  - *Draft Guidance for Evaluating the Vapor Intrusion to Indoor Air Pathway from Groundwater and Soils*, December, 2002
  - *User's Guide for Evaluating Subsurface Vapor Intrusion into Buildings*, June, 2003

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# Reference List - Risk Assessment Guidance - Most Helpful

- Toxicity Values Hierarchy
  - *Human Health Toxicity Values in Superfund Risk Assessments*; Memorandum, OSWER Directive 9285.7-53, December, 2003
- Dermal Exposure
  - *Risk Assessment Guidance for Superfund, Volume 1, Human Health Evaluation Manual (Part E): Supplemental Guidance for Dermal Risk Assessment*, July, 2004

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# Risk Assessment vs. Risk Management

- Common Sense
- Consider Expressions of Risk and Hazard as Ranges
- NCP Relative Risk Range
- Every Step Is a Mini Cost-Benefit Decision/Analysis
  - Inherent Conservatism in the Face of Uncertainty

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# Risk Assessment vs. Risk Management

- Is a fairly well defined process - but significant room for improvement in Uncertainty Analysis - Pay attention to this section and ask questions regarding what your common sense tells you could be substantive impacts to Risk Management

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