Use of Probabilistic Risk Assessment in Office of Solid Waste & Emergency Response

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Policy Statement

In the 1995 Risk Characterization memorandum, Administrator Carol Browner (U.S. EPA, 1995) stated,

- *…we must fully, openly, and clearly characterize risks. In doing so, we will disclose the scientific analyses, uncertainties, assumptions, and science policies which underlie our decisions…There is value in sharing with others the complexities and challenges we face in making decisions in the face of uncertainty.*

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Overview

- Use of Probabilistic Risk Assessment (PRA) differs among EPA program offices
  - Reflects different regulatory requirements and decision-making procedures
- Tiered approach to use of PRA
  - Decision depends on:
    - Level of effort (time, cost)
    - Potential benefits
    - Value added

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OSWER Program Offices

Two main OSWER programs use PRA:

- Office of Solid Waste (OSW)
- Office of Superfund Remediation and Technology Innovation (OSRTI)

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Office of Solid Waste

- Used in several national programs
- Main focus is on modeling leaching, fate and transport processes

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PRA Regulatory Support in OSW

- Toxicity Characteristic rule – probabilistic modeling in the early 1990s
  - identified wastes as hazardous if they contain certain constituents at or above listed levels due to their leaching potential and health threat if consumed in drinking water
- RCRA hazardous waste listing determinations
  - chlorinated aliphatics production, dyes and pigments production, inorganic chemicals manufacturing

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Typical Regulatory PRA Tools Used in OSW/RCRA

- 3MRA (Multimedia, Multipathway, Multireceptor Risk Assessment) System
  - Integrated multimedia release, fate, transport, exposure and risk model
- IWEM (Industrial Waste Management Evaluation Manual)
  - Assist user in determining the most appropriate waste management unit design to minimize or avoid groundwater impacts

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Typical Regulatory PRA Tools Used in OSW/RCRA (cont'd)

- EPACMTP (EPA's Composite Model for Leachate Migration and Transformation in Products)
  - Simulation model for subsurface fate and transport of contaminants released from land disposal sites
- DRAS (Delisting Risk Assessment Software) model
  - Support RCRA hazardous waste delisting decisions

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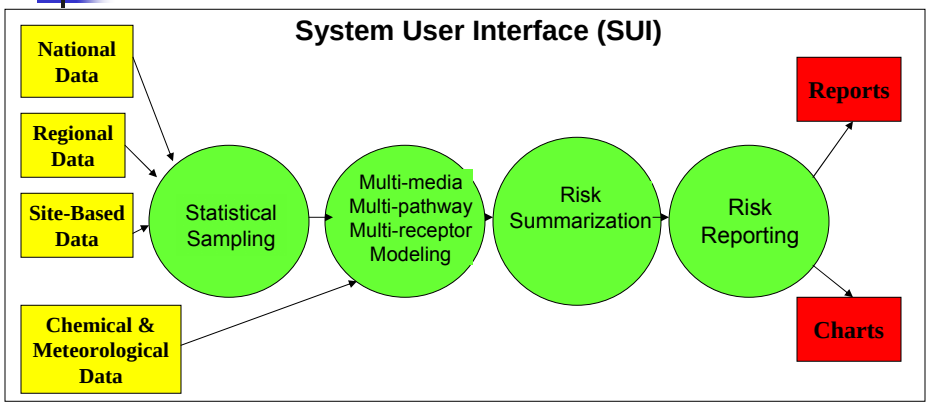
Simplified View of Multimedia, Multipathway, Multireceptor Risk Assessment (3MRA) System



Data | Site-Based Modeling | Data Compression | Results

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The 3MRA Methodology

- Statistical Sample of Industrial Sites
- Site-based human and ecological exposure/risk assessment
- Tiered data selection (site-specific, regional, and national)
- 2-stage Monte Carlo
- Probability-based design to facilitate uncertainty and sensitivity analyses
- Externally peer reviewed and independently tested

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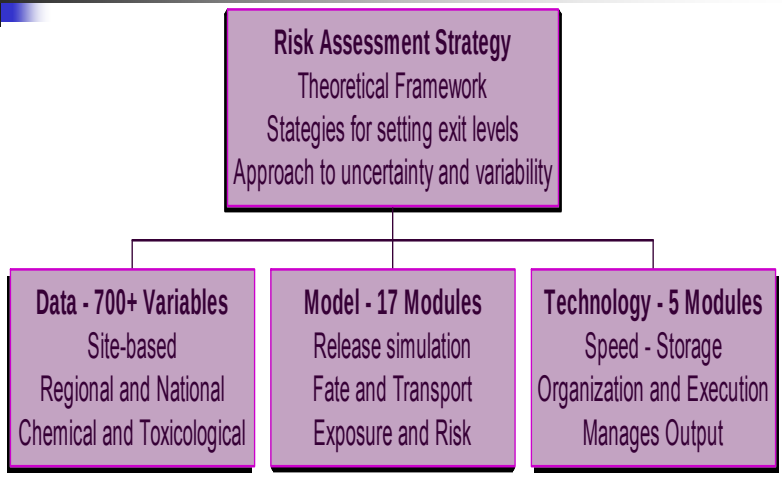
Major Components of 3MRA



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3MRA Outputs

National roll-up of risks

Human health population-based and ecological site estimates of risk and hazard

Alternative measures of protection

- Probability of protection (% of population, % of sites)
- Protection as a function of distance from facility
- Protection per receptor type
- Protection per combination of receptor and pathway

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Use of PRA in Superfund

- All site-specific assessments begin with the "point estimate" approach
- Variability is accounted for by estimating exposure for the average (CTE) and high end (RME) receptor
- Uncertainty is accounted for by using the 95% UCL of the mean concentration

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Use of PRA in Superfund

- *Risk Assessment Guidance for Superfund (RAGS) Volume III: Part A, Process for Conducting Probabilistic Risk Assessment* (2001)
- How to decide if/when PRA is valuable at a site
- General and detailed guidance on how to implement PRA when appropriate
- Applicable to both human and ecological risk assessments

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Human Health Risk Assessment

- Used mostly at large sites (following application of tiered process)
- Focused on characterizing variability and/or uncertainty in human exposure parameters (e.g., soil intake, water intake, exposure frequency and duration)

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Human Health Example

- Goal: assess variability in exposures of residents to arsenic in soil via 3 pathways:
  - outdoor soil ingestion
  - indoor dust ingestion
  - garden vegetable ingestion

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Human Health Example

- Random Variables
  - Exposure frequency (days/yr)
  - Exposure duration (years)
  - Intake rate of soil + dust (mg/day)
  - Intake rate of garden vegetables (g/day)
  - Fraction of dust that derives from soil

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Human Health Example
Risk from Arsenic in Soil

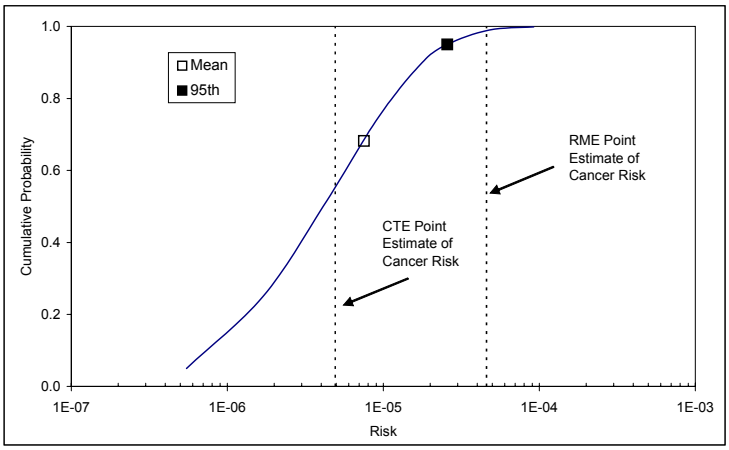
		Point Est		Monte Carlo Simulation				
Pathway	Variable	CTE	RME	Dist Type	Parameters			PDF
All	C(bulk soil)	70	70	Const				70
	oSF	1.5	1.5	Const				1.5
	BWc	15	15	Const				15
	BWa	70	70	Const				70
	EF	234	350	Triangular	200	234	365	234
	EDc	2	6	Calculated from variables				1.8
	EDa	7	24	Calculated from variables				7.2
	EDt	9	30	Custom				9
Soil/Dust	IR(total)child	100	200	LN	100	53		100
	IR(total)adult	50	100	Calculated (adult = 0.5*Child)				50
	Fs	0.45	0.45	Uniform	0	1		0.5
	D0	11	11	Const				11
	Ksd	0.06	0.06	Const				0.06
	RBA	0.42	0.42	Const				0.42
Veg	IR/BW	0.492	5.04	Custom				0.429
	Loss	0.86	0.86	Const				0.86
	Kgv	0.0016	0.0016	Const				0.0016
	G0	12	12	Const				12
	Kyg	0.031	0.031	Const				0.031
	F(inorganic)	0.6	0.6	Const				0.6

Human Health Example - Risks from Arsenic in Soil Example Empiric Distributions

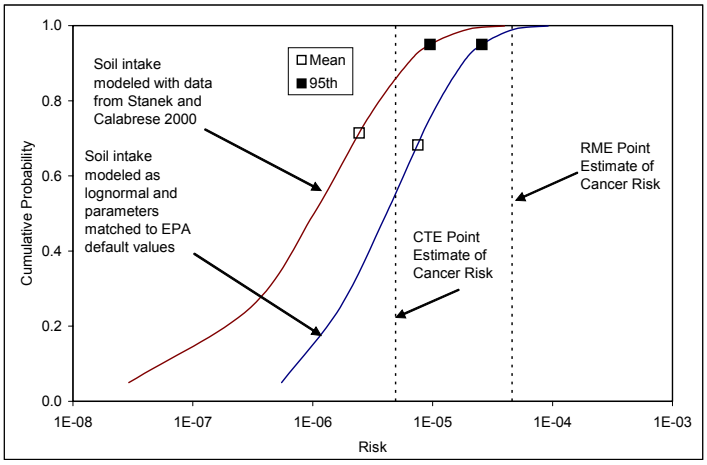
Exposure Duration (yrs) EFH Table 15-167		Veg Intake (kg/kg/day EFH Table 13-33	
Value	Cum prob	Value	Cum prob
1	0.00	1.80E-03	0.00
1.9	0.05	1.91E-02	0.05
2	0.10	3.83E-02	0.10
3	0.25	1.14E-01	0.25
9	0.50	4.92E-01	0.50
16	0.75	1.46E+00	0.75
26	0.90	2.99E+00	0.90
33	0.95	5.04E+00	0.95
41	0.98	8.91E+00	0.99
47	0.99	1.12E+01	1.00
55	0.998		
59	0.999		
87	1.000		

Human Health Example Risk from Arsenic in Soil

Comparison of Risk Distributions with Point Estimates



Human Health Example
Risk from Arsenic in Soil
Assessing the Effect of a Different PDF for Soil Intake



Use of PRA in Interim Asbestos Risk Methodology

- OSWER is developing a risk methodology for assessing cancer risks associated with inhalation of asbestos
- First application of PRA techniques by OSWER in an exposure-response assessment
- Draft methodology will be submitted for consultation and review by the SAB in 2007

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Interim Asbestos Risk Methodology (cont.)

- Interim methodology will be provided to IRIS program for consideration in their update of the IRIS assessment
- Builds on key concepts used in current EPA risk methodology:
  - Meta-analysis of epidemiology data
  - Linear relative risk model for lung cancer
  - Relative risk model for mesothelioma with a cubic time function

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Interim Asbestos Risk Methodology (cont.)

- Probability distributions are used to quantify uncertainties associated with:
  - Estimates of exposure (variability and uncertainty of measurements)
  - Estimates of disease incidence (random variation in number of cases, errors in disease classification)

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Interim Asbestos Risk Methodology (cont.)

- Potency of asbestos is predicted for different "bins" of asbestos, which are related to mineral type and fiber dimensions
- The OSWER methodology uses bin-specific potencies to calculate the distribution of risks associated with a site-specific mixture

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Ecological Risk Assessment

- Applications are usually simple (not full-blown Monte Carlo simulations)
- Use distribution of exposure levels to characterize variability in exposure of small-home range individuals
- Use variability in exposure parameters (e.g., dietary fractions) to characterize variability in exposure of large home range receptors

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Ecological Risk Assessment (cont'd)

- May consider variability and uncertainty in toxicity reference values (TRVs)
- When evaluating feeding guilds, use the distribution of species-specific toxicity values (species sensitivity distribution) to select a low-end TRV value
- Use the range from the NOAEL to the LOAEL to characterize uncertainty in the TRV

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Ecological Risk Assessment

- Focus is often on populations, rather than individuals
  - Interested in the distribution of risks across individuals in a population
- Risk is characterized as Hazard Quotient (HQ)

  HQ = Concentration / TRV
- HQ ≤ 1.0 indicates low risk to the individual
- Risks to the population are judged by frequency and magnitude of individual HQs > 1

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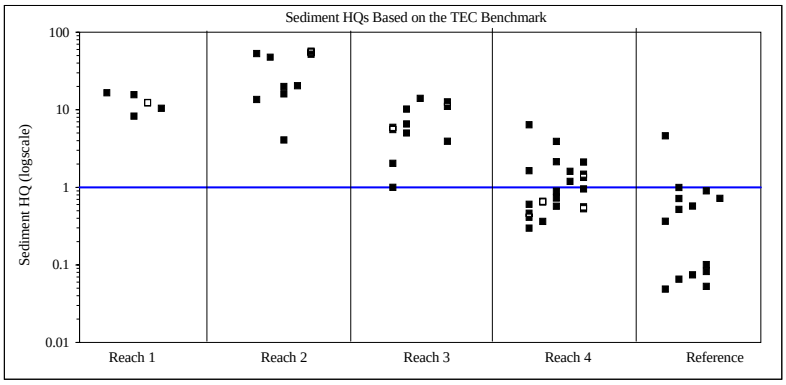
Ecological Example

Exposure of Benthic Organisms to Zn in Sediments



Ecological Example

Frequency and Magnitude of HQ Values > 1 for Benthic Organisms

Panel A: Based on TECs

Analyte	Elk Creek Downstream		
	Freq. of HQs > 1.0	Freq. of HQs > 10	Range of HQs > 1.0
Aluminum	1/10	0/10	1.3-1.3
Arsenic	0/10	0/10	12/12
Cadmium	10/10	9/10	6.7-69
Copper	9/10	5/10	1.7-54
Lead	10/10	9/10	10-220
Manganese	10/10	4/10	2.2-16
Silver	4/10	0/10	2.3-8.5
Zinc	10/10	9/10	4.1-57

Panel B: Based on PECs

Analyte	Elk Creek Downstream		
	Freq. of HQs > 1.0	Freq. of HQs > 10	Range of HQs > 1.0
Aluminum	0/10	0/10	--
Arsenic	7/10	0/10	1.1-2.7
Cadmium	10/10	2/10	1.3-14
Copper	6/10	1/10	2-12
Lead	10/10	5/10	2.8-62
Manganese	10/10	0/10	1.2-8.8
Silver	1/10	0/10	2.3-2.3
Zinc	10/10	5/10	1.1-15

Note: Difference in results between TEC (Threshold Effect Concentration) and PEC (Probable Effect Concentration) helps characterize uncertainty in the TRV

On-going Activities

- OSWER is working with the Risk Assessment Forum
- OSWER is assessing the need for additional guidance and training to facilitate appropriate uses of PRA

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