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VBI70 Workgroup Risk Assessment Presentation

Chris Weis
Regional Toxicologist
U.S. EPA Region 8
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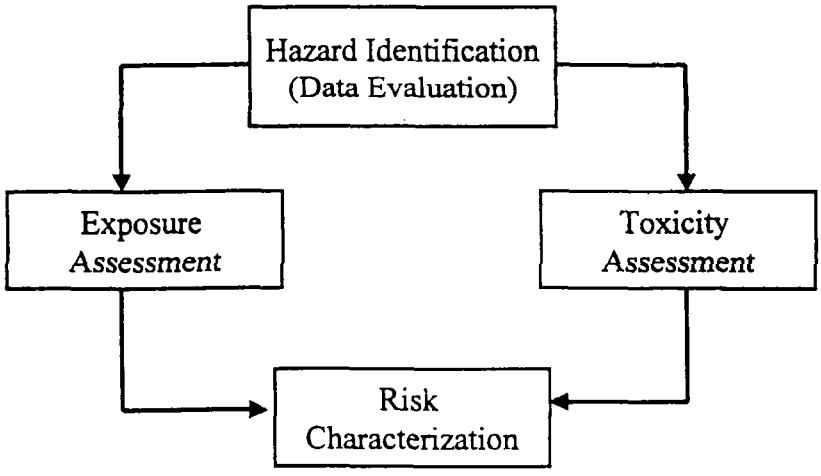
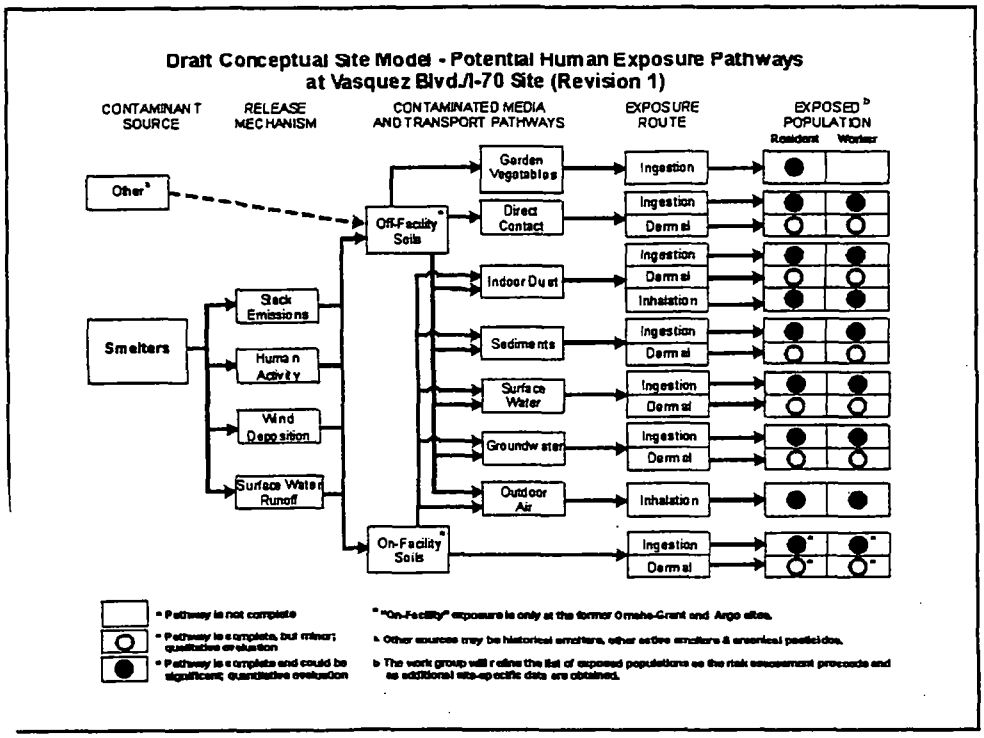
Risk Assessment Process





Estimating Exposure to Soil Contaminants

$$Intake\ (or Dose) \approx \frac{C \times IR \times ABS \times EF \times ED}{BW \times AT}$$

Where: C = soil and dust concentration – collected now, data C term + build this

IR = ingestion rate – difficult to measure.

ABS = absorbed fraction (bioavailability)

EF = exposure frequency – how often

ED = exposure duration – for how long (years...)

BW = body Weight – library parameter – avg + ranges of body weight

AT = averaging time

Exposure Evaluation for Soil and Dust

ingested dose

$$DI = DI_{Soil} + DI_{Dust}$$

$$DI_{Soil} = C_{Soil} \times \left[\left(\frac{IR_{soil}}{BW} \times \frac{EF \times ED}{AT} \right)_{Child} + \left(\frac{IR_{soil}}{BW} \times \frac{EF \times ED}{AT} \right)_{Adult} \right]$$

$$DI_{Dust} = C_{Dust} \times \left[\left(\frac{IR_{Dust}}{BW} \times \frac{EF \times ED}{AT} \right)_{Child} + \left(\frac{IR_{Dust}}{BW} \times \frac{EF \times ED}{AT} \right)_{Adult} \right]$$

How will EPA address soil and dust ingestion?

$$IR_{Soil} = IR_{Total} \times F$$

– Fraction of time or s.

$$IR_{Dust} = IR_{Total} \times (1 - F)$$

what is left over from soil.

F = fraction of total that is soil

	Parameter	Child		Adult	
		Avg	RME	Avg	RME
BW	Body weight (kg)	15 (a)	15 (a)	70 (a)	70 (a)
IR	Intake rate (total) (mg/day)	ATSDR 100 (a) adjust for PICA.	200 (a)	50 (a)	100 (a)
F	Fraction of total that is soil	0.45 (c)	0.45 (c)	0.45 (c)	0.45 (c)
EF	Exposure frequency (days/yr)	350 (b)	350 (a)	350 (b)	350 (a)
ED	Exposure duration (yrs)	2 (b)	6 (a)	7 (b)	24 (a)
AT	Averaging time (days) RME	9*365 (noncancer) 70*365 (cancer)	30*365 (noncancer) 70*365 (cancer)	9*365 (noncancer) 70*365 (cancer)	30*365 (noncancer) 70*365 (cancer)
D0	Background concentration in dust (mg/kg)	To be based on site specific data (default = 0)			
ksd	Increase in dust per unit in soil (mg/kg per mg/kg)	To be based on site specific data (default = 0.8)			

3 types
root crops
leafy veg.
fruiting
garden veggies.

How will EPA address vegetable ingestion??

many
however types
of veggies
found

$$DI = DI_{type\,1} + DI_{type\,2} + \ldots\ldots\ldots DI_{type\,n}$$

$$DI_{type\,i} = C_i \times \left[\left(\frac{IR_i \times EF \times ED}{AT} \right)_{Child} + \left(\frac{IR_i \times EF \times ED}{AT} \right)_{adult} \right]$$

ok.ic

Table 1
Summary of Homegrown Vegetable Intake Values

Homegrown Vegetable Intake (g ww/kg-day)	Asparagus EFH, T 13-35		Beets EFH, T 13-37		Broccoli EFH, T 13-38		Cabbage EFH, T 13-39		Carrots EFH, T 13-40		Corn EFH, T 13-41		Cucumbers EFH, T 13-42		Lettuce EFH, T 13-45		Lima Beans EFH, T 13-46	
	P50	P95	P50	P95	P50	P95	P50	P95	P50	P95	P50	P95	P50	P95	P50	P95	P50	P95
Age 1-2																		
Age 3-5											1	5.35						
Age 6-11											0.513	3.37						
Age 12-19											0.343	1.88						
Age 20-39			0.285	0.999					0.199	0.756	0.371	2.64	0.309	1.49			0.234	1.1
Age 40-69	0.4	1.24	0.397	1.15	0.351	0.815	0.713	5.29	0.367	1.01	0.516	3.22	0.684	3.27	0.491	1.05	0.293	1.71
Average, Age 1-5 [a]	0.95	2.00	0.81	1.73	0.84	1.31	1.70	8.52	0.67	1.42	1.00	5.35	1.18	3.83	1.17	1.69	0.63	2.26
Average, Age 6-69	0.40	1.24	0.34	1.07	0.35	0.82	0.71	5.29	0.28	0.88	0.44	2.78	0.50	2.38	0.49	1.05	0.26	1.41
Total population	0.40	1.63	0.40	1.36	0.29	0.97	0.78	2.35	0.33	1.08	0.48	3.37	0.54	2.79	0.28	1.03	0.29	1.69

Notes:
Blank cell indicates that data not available.
[a] If data not available for child, the child vegetable intake is based on the average adult vegetable intake for age 6-69 multiplied by a conversion factor of 2.38 for P50 values and 1.61 for P95 values. These conversion factors are estimated by comparing total vegetable time-weighted intakes for the 1-5 age group and 6-69 age group presented in Table 13-13 of USEPA's 1997 Exposure Factors Handbook.

Table 1
Summary of Homegrown Vegetable Intake Values

Homegrown Vegetable Intake (g ww/kg-day)	Okra EFH, T 13-47		Onions EFH, T 13-48		Peas EFH, T 13-52		Peppers EFH, T 13-53		Pumpkins EFH, T 13-56		Snap Beans EFH, T 13-57		Tomatoes EFH, T 13-59		White Potatoes EFH, T 13-60	
	P50	P95	P50	P95	P50	P95	P50	P95	P50	P95	P50	P95	P50	P95	P50	P95
Age 1-2													1.66	10.7		
Age 3-5											1.16	4.88	1.25	6.25		
Age 6-11			0.228	1.36	0.387	1.4	0.162	0.77			0.642	2.75	0.755	5.7	1.76	6.52
Age 12-19			0.142	0.759	0.358	0.822					0.504	1.79	0.521	1.94	1.22	3.11
Age 20-39			0.191	0.935	0.254	1.36	0.119	0.624	0.477	2.67	0.496	1.64	0.515	2.1	1	3.08
Age 40-69	0.307	1.14	0.172	0.69	0.304	1.3	0.166	0.744	0.523	3.02	0.561	1.77	0.746	3.05	1.31	5.29
Average, Age 1-5 [a]	0.73	1.84	0.44	1.51	0.78	1.97	0.35	1.15	1.19	4.58	1.16	4.88	1.46	8.48	3.15	7.25
Average, Age 6-69	0.31	1.14	0.18	0.94	0.33	1.22	0.15	0.71	0.50	2.85	0.55	1.99	0.63	3.20	1.32	4.50
Total population	0.30	1.21	0.21	0.91	0.32	1.46			0.56	1.79	0.57	2.01	0.74	3.54	1.27	4.76

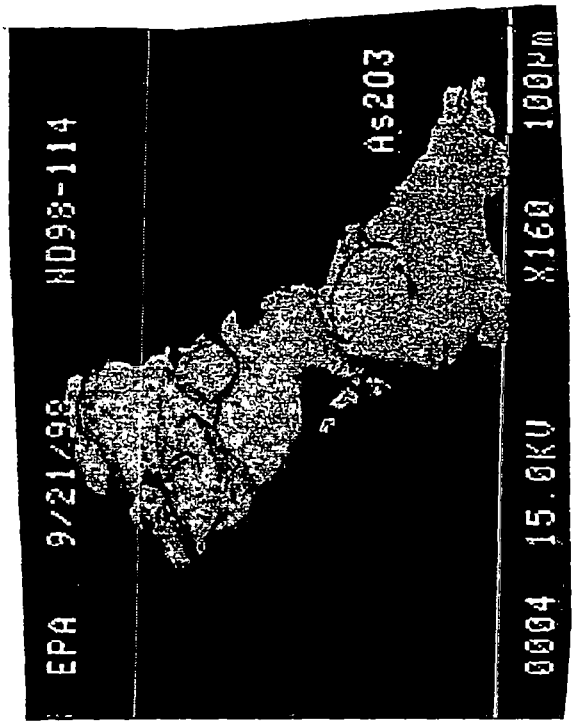
Notes:
Blank cell indicates that data not available.
[a] If data not available for child, the child vegetable intake is based on the average adult vegetable intake for age 6-69 multiplied by a conversion factor of 2.38 for P50 values and 1.61 for P95 values. These conversion factors are estimated by comparing total vegetable time-weighted intakes for the 1-5 age group and 6-69 age group presented in Table 13-13 of USEPA's 1997 Exposure Factors Handbook.

Exposure for Home Grown Vegetables

Parameter		Child		Adult	
		Avg	RME	Avg	RME
IRi	Intake rate (g ww/kg bw/day)	Vegetable type specific; data are available in EFH; see next page			
EF	Exposure frequency (days/yr)	350 (b)	350 (a)	350 (b)	350 (a)
ED	Exposure duration (yrs)	2 (b)	6 (a)	7 (b)	24 (a)
AT	Averaging time (days)	9*365 (noncancer) 70*365 (cancer)	30*365 (noncancer) 70*365 (cancer)	9*365 (noncancer) 70*365 (cancer)	30*365 (noncancer) 70*365 (cancer)

Bioavailability

- Is a measure of the fraction of material compartment ingested which is absorbed into the blood;
- is commonly measured for pharmaceutical drugs, food additives, and environmental contaminants;
- can be estimated using animal models
  Swine study.



Objectives of the Bioavailability Study

- to determine whether VBI70 Soil arsenic is absorbed to a lesser or greater extent than freely soluble arsenic in water; and
- to estimate a site specific absorption fraction for soil arsenic which is protective…but plausibly applicable for human health risk assessment at the VBI70

ABS

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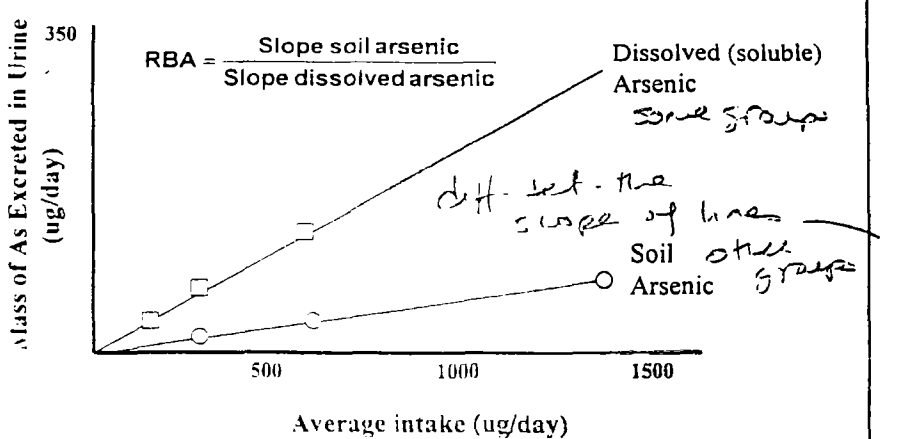
Arsenic Bioavailability in Pigs

*RBA = "Ratio of slopes" for two **linear** responses*



Proposed Bioavailability Study Design

Group	Number Animals	Test Substance	Dose Route	Dose (ug As/kg-day)
1	4	Control	oral	0
2	4	NaAs	oral	50
3	4	NaAs	oral	125
4	4	Test Soil #1	oral	50
5	4	Test Soil #1	oral	125
6	4	Test Soil #2	oral	50
7	4	Test Soil #2	oral	125
8	4	Test Soil #3	oral	50
9	4	Test Soil #3	oral	125
10	4	Test Soil #4	oral	50
11	4	Test Soil #4	oral	125