U.S. EPA SAB Lead Review Panel
Final Comments from Dr. Philip Goodrum

Supplement A

IEUBK Model Runs for Dust Pb = 0 mg/kg

LEAD MODEL FOR WINDOWS Version 1.1

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Model Version: 1.1 Build11
User Name: Goodrum
Date: 7/25/2010
Site Name: None
Operable Unit: None
Run Mode: Multirun of Baseline PbB when PbD = 0 mg/kg; PbS = 0 to 100 in 7 increments
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Multiple Runs: NO. 1 Medium: Soil (mg/kg)

****
INPUT VARIABLES
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****** Air ******

Age	Conc (µg Pb/m³)
.5-1	0.100
1-2	0.100
2-3	0.100
3-4	0.100
4-5	0.100
5-6	0.100
6-7	0.100

Indoor Air Pb Concentration: 100.000 percent of outdoor.

Other Air Parameters:

Age	Time Outdoors (hours)	Ventilation Rate (m³/day)	Lung Absorption (%)
.5-1	1.000	5.400	42.000
1-2	2.000	8.000	42.000
2-3	3.000	9.500	42.000
3-4	4.000	10.900	42.000
4-5	4.000	10.900	42.000
5-6	4.000	10.900	42.000
6-7	4.000	12.400	42.000

****** Diet ******

Age	Diet Intake (µg Pb/day)
.5-1	2.260
1-2	1.960
2-3	2.130
3-4	2.040
4-5	1.950
5-6	2.050
6-7	2.220

****** Drinking Water ******

Water Consumption:

Age	Water (L/day)
.5-1	0.200
1-2	0.500
2-3	0.520
3-4	0.530
4-5	0.550
5-6	0.580
6-7	0.590

Drinking Water Concentration: 4.000 µg Pb/L

****** Soil& Dust ******

Age	Soil (µg Pb/g)	House Dust (ug Pb/g)
.5-1	0.000	0.000
1-2	0.000	0.000
2-3	0.000	0.000
3-4	0.000	0.000
4-5	0.000	0.000
5-6	0.000	0.000
6-7	0.000	0.000

****** Alternate Intake ******

Age	Alternate (µg Pb/day)
.5-1	0.000
1-2	0.000
2-3	0.000
3-4	0.000
4-5	0.000
5-6	0.000
6-7	0.000

****** Maternal Contribution: Infant Model ******

Maternal Blood Concentration: 0.847 µg Pb/dL

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CALCULATED BLOOD LEAD AND LEAD UPTAKES:
****

Year	Air (µg/day)	Diet (µg/day)	Alternate (µg/day)	Water (µg/day)
.5-1	0.227	1.111	0.000	0.393
1-2	0.336	0.964	0.000	0.983
2-3	0.399	1.049	0.000	1.024
3-4	0.458	1.007	0.000	1.046
4-5	0.458	0.964	0.000	1.088
5-6	0.458	1.014	0.000	1.148
6-7	0.521	1.099	0.000	1.168

Year	Soil+Dust (µg/day)	Total (µg/day)	Blood (µg/dL)
.5-1	0.000	1.731	1.0
1-2	0.000	2.283	1.0
2-3	0.000	2.472	0.9
3-4	0.000	2.511	0.9
4-5	0.000	2.510	0.8
5-6	0.000	2.620	0.8
6-7	0.000	2.788	0.8

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Multiple Runs: NO. 2   Medium: Soil (mg/kg)

****
INPUT VARIABLES
****

****** Air ******

Age	Conc (µg Pb/m³)
.5-1	0.100
1-2	0.100
2-3	0.100
3-4	0.100
4-5	0.100
5-6	0.100
6-7	0.100

Indoor Air Pb Concentration: 100.000 percent of outdoor.

Other Air Parameters:

Age	Time Outdoors (hours)	Ventilation Rate (m³/day)	Lung Absorption (%)
.5-1	1.000	5.400	42.000
1-2	2.000	8.000	42.000
2-3	3.000	9.500	42.000
3-4	4.000	10.900	42.000
4-5	4.000	10.900	42.000
5-6	4.000	10.900	42.000
6-7	4.000	12.400	42.000

****** Diet ******

Age	Diet Intake (µg Pb/day)
.5-1	2.260
1-2	1.960
2-3	2.130
3-4	2.040

4-5	1.950
5-6	2.050
6-7	2.220

****** Drinking Water ******

Water Consumption:

Age	Water (L/day)
.5-1	0.200
1-2	0.500
2-3	0.520
3-4	0.530
4-5	0.550
5-6	0.580
6-7	0.590

Drinking Water Concentration: 4.000 µg Pb/L

****** Soil& Dust ******

Age	Soil (µg Pb/g)	House Dust (ug Pb/g)
.5-1	16.667	0.000
1-2	16.667	0.000
2-3	16.667	0.000
3-4	16.667	0.000
4-5	16.667	0.000
5-6	16.667	0.000
6-7	16.667	0.000

****** Alternate Intake ******

Age	Alternate (µg Pb/day)
.5-1	0.000
1-2	0.000
2-3	0.000
3-4	0.000
4-5	0.000
5-6	0.000
6-7	0.000

****** Maternal Contribution: Infant Model ******

Maternal Blood Concentration: 0.847 µg Pb/dL

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CALCULATED BLOOD LEAD AND LEAD UPTAKES:

****

Year	Air (µg/day)	Diet (µg/day)	Alternate (µg/day)	Water (µg/day)
.5-1	0.227	1.109	0.000	0.392
1-2	0.336	0.961	0.000	0.981
2-3	0.399	1.047	0.000	1.022
3-4	0.458	1.005	0.000	1.044
4-5	0.458	0.963	0.000	1.087
5-6	0.458	1.013	0.000	1.147
6-7	0.521	1.098	0.000	1.167

Year	Soil+Dust (µg/day)	Total (µg/day)	Blood (µg/dL)
.5-1	0.188	1.916	1.1
1-2	0.298	2.576	1.1
2-3	0.298	2.766	1.0
3-4	0.299	2.807	1.0
4-5	0.222	2.730	0.9
5-6	0.200	2.818	0.9
6-7	0.189	2.975	0.8

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Multiple Runs: NO. 3 Medium: Soil (mg/kg)

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INPUT VARIABLES

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****** Air ******

Age	Conc (μg Pb/m³)
.5-1	0.100
1-2	0.100
2-3	0.100
3-4	0.100
4-5	0.100
5-6	0.100
6-7	0.100

Indoor Air Pb Concentration: 100.000 percent of outdoor.

Other Air Parameters:

Age	Time Outdoors (hours)	Ventilation Rate (m³/day)	Lung Absorption (%)
.5-1	1.000	5.400	42.000
1-2	2.000	8.000	42.000
2-3	3.000	9.500	42.000
3-4	4.000	10.900	42.000
4-5	4.000	10.900	42.000
5-6	4.000	10.900	42.000
6-7	4.000	12.400	42.000

****** Diet ******

Age	Diet Intake (μg Pb/day)
.5-1	2.260
1-2	1.960
2-3	2.130
3-4	2.040
4-5	1.950
5-6	2.050
6-7	2.220

****** Drinking Water ******

Water Consumption:

Age	Water (L/day)
.5-1	0.200
1-2	0.500
2-3	0.520
3-4	0.530
4-5	0.550
5-6	0.580
6-7	0.590

Drinking Water Concentration: 4.000 μg Pb/L

****** Soil& Dust ******

Age	Soil (μg Pb/g)	House Dust (ug Pb/g)
.5-1	33.333	0.000
1-2	33.333	0.000
2-3	33.333	0.000
3-4	33.333	0.000
4-5	33.333	0.000
5-6	33.333	0.000
6-7	33.333	0.000

****** Alternate Intake ******

Age	Alternate (μg Pb/day)
.5-1	0.000
1-2	0.000
2-3	0.000
3-4	0.000
4-5	0.000
5-6	0.000
6-7	0.000

****** Maternal Contribution: Infant Model ******

Maternal Blood Concentration: 0.847 μg Pb/dL

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CALCULATED BLOOD LEAD AND LEAD UPTAKES:
****

Year	Air (µg/day)	Diet (µg/day)	Alternate (µg/day)	Water (µg/day)
.5-1	0.227	1.106	0.000	0.392
1-2	0.336	0.959	0.000	0.978
2-3	0.399	1.044	0.000	1.020
3-4	0.458	1.003	0.000	1.042
4-5	0.458	0.962	0.000	1.085
5-6	0.458	1.012	0.000	1.146
6-7	0.521	1.097	0.000	1.166

Year	Soil+Dust (µg/day)	Total (µg/day)	Blood (µg/dL)
.5-1	0.375	2.099	1.2
1-2	0.594	2.867	1.2
2-3	0.596	3.059	1.1
3-4	0.597	3.101	1.1
4-5	0.444	2.949	1.0
5-6	0.400	3.016	0.9
6-7	0.378	3.162	0.9

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Multiple Runs: NO. 4 Medium: Soil (mg/kg)

****
INPUT VARIABLES
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****** Air ******

Age	Conc (µg Pb/m³)
.5-1	0.100
1-2	0.100
2-3	0.100
3-4	0.100
4-5	0.100
5-6	0.100
6-7	0.100

Indoor Air Pb Concentration: 100.000 percent of outdoor.

Other Air Parameters:

Age	Time Outdoors (hours)	Ventilation Rate (m³/day)	Lung Absorption (%)
.5-1	1.000	5.400	42.000
1-2	2.000	8.000	42.000
2-3	3.000	9.500	42.000
3-4	4.000	10.900	42.000
4-5	4.000	10.900	42.000
5-6	4.000	10.900	42.000
6-7	4.000	12.400	42.000

****** Diet ******

Age	Diet Intake (µg Pb/day)
.5-1	2.260
1-2	1.960
2-3	2.130
3-4	2.040
4-5	1.950
5-6	2.050
6-7	2.220

****** Drinking Water ******

Water Consumption:

Age	Water (L/day)
.5-1	0.200
1-2	0.500
2-3	0.520
3-4	0.530
4-5	0.550
5-6	0.580
6-7	0.590

Drinking Water Concentration: 4.000 µg Pb/L

****** Soil& Dust ******

Age	Soil (µg Pb/g)	House Dust (ug Pb/g)
.5-1	50.000	0.000
1-2	50.000	0.000
2-3	50.000	0.000
3-4	50.000	0.000
4-5	50.000	0.000
5-6	50.000	0.000
6-7	50.000	0.000

****** Alternate Intake ******

Age	Alternate (µg Pb/day)
.5-1	0.000
1-2	0.000
2-3	0.000
3-4	0.000
4-5	0.000
5-6	0.000
6-7	0.000

****** Maternal Contribution: Infant Model ******

Maternal Blood Concentration: 0.847 µg Pb/dL

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CALCULATED BLOOD LEAD AND LEAD UPTAKES:

****

Year	Air (µg/day)	Diet (µg/day)	Alternate (µg/day)	Water (µg/day)
.5-1	0.227	1.104	0.000	0.391
1-2	0.336	0.956	0.000	0.976
2-3	0.399	1.042	0.000	1.018
3-4	0.458	1.001	0.000	1.041
4-5	0.458	0.961	0.000	1.084
5-6	0.458	1.011	0.000	1.145
6-7	0.521	1.096	0.000	1.165

Year	Soil+Dust (µg/day)	Total (µg/day)	Blood (µg/dL)
.5-1	0.561	2.282	1.3
1-2	0.889	3.157	1.3
2-3	0.892	3.350	1.2
3-4	0.895	3.394	1.2
4-5	0.665	3.168	1.1
5-6	0.599	3.213	1.0
6-7	0.567	3.349	0.9

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Multiple Runs: NO. 5 Medium: Soil (mg/kg)

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INPUT VARIABLES

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****** Air ******

Age	Conc (µg Pb/m³)
.5-1	0.100
1-2	0.100
2-3	0.100
3-4	0.100
4-5	0.100
5-6	0.100
6-7	0.100

Indoor Air Pb Concentration: 100.000 percent of outdoor.

Other Air Parameters:

Age	Time Outdoors (hours)	Ventilation Rate (m³/day)	Lung Absorption (%)
.5-1	1.000	5.400	42.000
1-2	2.000	8.000	42.000

2-3	3.000	9.500	42.000
3-4	4.000	10.900	42.000
4-5	4.000	10.900	42.000
5-6	4.000	10.900	42.000
6-7	4.000	12.400	42.000

****** Diet ******

Age	Diet Intake (µg Pb/day)
.5-1	2.260
1-2	1.960
2-3	2.130
3-4	2.040
4-5	1.950
5-6	2.050
6-7	2.220

****** Drinking Water ******

Water Consumption:

Age	Water (L/day)
.5-1	0.200
1-2	0.500
2-3	0.520
3-4	0.530
4-5	0.550
5-6	0.580
6-7	0.590

Drinking Water Concentration: 4.000 µg Pb/L

****** Soil& Dust ******

Age	Soil (µg Pb/g)	House Dust (ug Pb/g)
.5-1	66.667	0.000
1-2	66.667	0.000
2-3	66.667	0.000
3-4	66.667	0.000
4-5	66.667	0.000
5-6	66.667	0.000
6-7	66.667	0.000

****** Alternate Intake ******

Age	Alternate (µg Pb/day)
.5-1	0.000
1-2	0.000
2-3	0.000
3-4	0.000
4-5	0.000
5-6	0.000
6-7	0.000

****** Maternal Contribution: Infant Model ******

Maternal Blood Concentration: 0.847 µg Pb/dL

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CALCULATED BLOOD LEAD AND LEAD UPTAKES:

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Year	Air (µg/day)	Diet (µg/day)	Alternate (µg/day)	Water (µg/day)
.5-1	0.227	1.102	0.000	0.390
1-2	0.336	0.954	0.000	0.973
2-3	0.399	1.040	0.000	1.015
3-4	0.458	0.999	0.000	1.039
4-5	0.458	0.960	0.000	1.083
5-6	0.458	1.011	0.000	1.144
6-7	0.521	1.095	0.000	1.164

Year	Soil+Dust (µg/day)	Total (µg/day)	Blood (µg/dL)
.5-1	0.746	2.465	1.4
1-2	1.183	3.446	1.4
2-3	1.186	3.640	1.4
3-4	1.191	3.686	1.3

4-5	0.886	3.386	1.2
5-6	0.799	3.410	1.1
6-7	0.755	3.535	1.0

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Multiple Runs: NO. 6 Medium: Soil (mg/kg)

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INPUT VARIABLES

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****** Air ******

Age	Conc (µg Pb/m³)
.5-1	0.100
1-2	0.100
2-3	0.100
3-4	0.100
4-5	0.100
5-6	0.100
6-7	0.100

Indoor Air Pb Concentration: 100.000 percent of outdoor.

Other Air Parameters:

Age	Time Outdoors (hours)	Ventilation Rate (m³/day)	Lung Absorption (%)
.5-1	1.000	5.400	42.000
1-2	2.000	8.000	42.000
2-3	3.000	9.500	42.000
3-4	4.000	10.900	42.000
4-5	4.000	10.900	42.000
5-6	4.000	10.900	42.000
6-7	4.000	12.400	42.000

****** Diet ******

Age	Diet Intake (µg Pb/day)
.5-1	2.260
1-2	1.960
2-3	2.130
3-4	2.040
4-5	1.950
5-6	2.050
6-7	2.220

****** Drinking Water ******

Water Consumption:

Age	Water (L/day)
.5-1	0.200
1-2	0.500
2-3	0.520
3-4	0.530
4-5	0.550
5-6	0.580
6-7	0.590

Drinking Water Concentration: 4.000 µg Pb/L

****** Soil& Dust ******

Age	Soil (µg Pb/g)	House Dust (ug Pb/g)
.5-1	83.333	0.000
1-2	83.333	0.000
2-3	83.333	0.000
3-4	83.333	0.000
4-5	83.333	0.000
5-6	83.333	0.000
6-7	83.333	0.000

****** Alternate Intake ******

Age	Alternate (µg Pb/day)
.5-1	0.000
1-2	0.000

2-3	0.000
3-4	0.000
4-5	0.000
5-6	0.000
6-7	0.000

****** Maternal Contribution: Infant Model ******

Maternal Blood Concentration: 0.847 µg Pb/dL

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CALCULATED BLOOD LEAD AND LEAD UPTAKES:
****

Year	Air (µg/day)	Diet (µg/day)	Alternate (µg/day)	Water (µg/day)
.5-1	0.227	1.100	0.000	0.389
1-2	0.336	0.951	0.000	0.971
2-3	0.399	1.038	0.000	1.013
3-4	0.458	0.998	0.000	1.037
4-5	0.458	0.958	0.000	1.081
5-6	0.458	1.010	0.000	1.143
6-7	0.521	1.094	0.000	1.163

Year	Soil+Dust (µg/day)	Total (µg/day)	Blood (µg/dL)
.5-1	0.930	2.646	1.5
1-2	1.475	3.733	1.6
2-3	1.480	3.929	1.5
3-4	1.485	3.978	1.4
4-5	1.106	3.604	1.2
5-6	0.997	3.607	1.1
6-7	0.943	3.721	1.1

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Multiple Runs: NO. 7   Medium: Soil (mg/kg)

****
INPUT VARIABLES
****

****** Air ******

Age	Conc (µg Pb/m³)
.5-1	0.100
1-2	0.100
2-3	0.100
3-4	0.100
4-5	0.100
5-6	0.100
6-7	0.100

Indoor Air Pb Concentration: 100.000 percent of outdoor.

Other Air Parameters:

Age	Time Outdoors (hours)	Ventilation Rate (m³/day)	Lung Absorption (%)
.5-1	1.000	5.400	42.000
1-2	2.000	8.000	42.000
2-3	3.000	9.500	42.000
3-4	4.000	10.900	42.000
4-5	4.000	10.900	42.000
5-6	4.000	10.900	42.000
6-7	4.000	12.400	42.000

****** Diet ******

Age	Diet Intake (µg Pb/day)
.5-1	2.260
1-2	1.960
2-3	2.130
3-4	2.040
4-5	1.950
5-6	2.050
6-7	2.220

****** Drinking Water ******

Water Consumption:

Age	Water (L/day)
.5-1	0.200
1-2	0.500
2-3	0.520
3-4	0.530
4-5	0.550
5-6	0.580
6-7	0.590

Drinking Water Concentration: 4.000 µg Pb/L

****** Soil& Dust ******

Age	Soil (µg Pb/g)	House Dust (ug Pb/g)
.5-1	100.000	0.000
1-2	100.000	0.000
2-3	100.000	0.000
3-4	100.000	0.000
4-5	100.000	0.000
5-6	100.000	0.000
6-7	100.000	0.000

****** Alternate Intake ******

Age	Alternate (µg Pb/day)
.5-1	0.000
1-2	0.000
2-3	0.000
3-4	0.000
4-5	0.000
5-6	0.000
6-7	0.000

****** Maternal Contribution: Infant Model ******

Maternal Blood Concentration: 0.847 µg Pb/dL

****
CALCULATED BLOOD LEAD AND LEAD UPTAKES:
****

Year	Air (µg/day)	Diet (µg/day)	Alternate (µg/day)	Water (µg/day)
.5-1	0.227	1.097	0.000	0.388
1-2	0.336	0.949	0.000	0.968
2-3	0.399	1.035	0.000	1.011
3-4	0.458	0.996	0.000	1.035
4-5	0.458	0.957	0.000	1.080
5-6	0.458	1.009	0.000	1.141
6-7	0.521	1.093	0.000	1.162

Year	Soil+Dust (µg/day)	Total (µg/day)	Blood (µg/dL)
.5-1	1.114	2.827	1.6
1-2	1.765	4.019	1.7
2-3	1.772	4.217	1.6
3-4	1.779	4.268	1.5
4-5	1.326	3.821	1.3
5-6	1.196	3.803	1.2
6-7	1.130	3.907	1.1

U.S. EPA SAB Lead Review Panel
Final Comments from Dr. Philip Goodrum

Supplement B

IEUBK Model Runs for Dust Pb = 10 + 0.70 x Soil Pb (mg/kg)

LEAD MODEL FOR WINDOWS Version 1.1

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Model Version: 1.1 Build11
User Name: Goodrum
Date: 7/25/2010
Site Name: None
Operable Unit: None
Run Mode: Multirun of Baseline PbB when PbD = 10 + 0.7 x PbS; PbS = 0 to 100 mg/kg in 7 increments
==

Multiple Runs: NO. 1   Medium: Soil (mg/kg)

****
INPUT VARIABLES
****

****** Air ******

Age	Conc (µg Pb/m³)
.5-1	0.100
1-2	0.100
2-3	0.100
3-4	0.100
4-5	0.100
5-6	0.100
6-7	0.100

Indoor Air Pb Concentration: 100.000 percent of outdoor.

Other Air Parameters:

Age	Time Outdoors (hours)	Ventilation Rate (m³/day)	Lung Absorption (%)
.5-1	1.000	5.400	42.000
1-2	2.000	8.000	42.000
2-3	3.000	9.500	42.000
3-4	4.000	10.900	42.000
4-5	4.000	10.900	42.000
5-6	4.000	10.900	42.000
6-7	4.000	12.400	42.000

****** Diet ******

Age	Diet Intake (µg Pb/day)
.5-1	2.260
1-2	1.960
2-3	2.130
3-4	2.040
4-5	1.950
5-6	2.050
6-7	2.220

****** Drinking Water ******

Water Consumption:

Age	Water (L/day)
.5-1	0.200
1-2	0.500
2-3	0.520
3-4	0.530
4-5	0.550
5-6	0.580
6-7	0.590

Drinking Water Concentration: 4.000 µg Pb/L

****** Soil& Dust ******

Multiple Source Analysis Used
Average multiple source concentration: 10.000 µg/g

Mass fraction of outdoor soil to indoor dust conversion factor: 0.700
Outdoor airborne lead to indoor household dust lead concentration: 100.000
Use alternate indoor dust Pb sources? No

Age	Soil (µg Pb/g)	House Dust (ug Pb/g)
.5-1	0.000	10.000
1-2	0.000	10.000
2-3	0.000	10.000
3-4	0.000	10.000
4-5	0.000	10.000
5-6	0.000	10.000

6-7	0.000	10.000

****** Alternate Intake ******

Age	Alternate (µg Pb/day)
.5-1	0.000
1-2	0.000
2-3	0.000
3-4	0.000
4-5	0.000
5-6	0.000
6-7	0.000

****** Maternal Contribution: Infant Model ******

Maternal Blood Concentration: 0.847 µg Pb/dL

****
CALCULATED BLOOD LEAD AND LEAD UPTAKES:
****

Year	Air (µg/day)	Diet (µg/day)	Alternate (µg/day)	Water (µg/day)
.5-1	0.227	1.109	0.000	0.393
1-2	0.336	0.962	0.000	0.981
2-3	0.399	1.047	0.000	1.023
3-4	0.458	1.006	0.000	1.045
4-5	0.458	0.963	0.000	1.087
5-6	0.458	1.014	0.000	1.147
6-7	0.521	1.098	0.000	1.168

Year	Soil+Dust (µg/day)	Total (µg/day)	Blood (µg/dL)
.5-1	0.138	1.866	1.0
1-2	0.219	2.498	1.1
2-3	0.219	2.688	1.0
3-4	0.220	2.728	1.0
4-5	0.163	2.671	0.9
5-6	0.147	2.765	0.9
6-7	0.139	2.925	0.8

==

Multiple Runs: NO. 2 Medium: Soil (mg/kg)

****
INPUT VARIABLES
****

****** Air ******

Age	Conc (µg Pb/m³)
.5-1	0.100
1-2	0.100
2-3	0.100
3-4	0.100
4-5	0.100
5-6	0.100
6-7	0.100

Indoor Air Pb Concentration: 100.000 percent of outdoor.

Other Air Parameters:

Age	Time Outdoors (hours)	Ventilation Rate (m³/day)	Lung Absorption (%)
.5-1	1.000	5.400	42.000
1-2	2.000	8.000	42.000
2-3	3.000	9.500	42.000
3-4	4.000	10.900	42.000
4-5	4.000	10.900	42.000
5-6	4.000	10.900	42.000
6-7	4.000	12.400	42.000

****** Diet ******

Age	Diet Intake (µg Pb/day)
.5-1	2.260
1-2	1.960
2-3	2.130
3-4	2.040
4-5	1.950

5-6	2.050
6-7	2.220

****** Drinking Water ******

Water Consumption:

Age	Water (L/day)
.5-1	0.200
1-2	0.500
2-3	0.520
3-4	0.530
4-5	0.550
5-6	0.580
6-7	0.590

Drinking Water Concentration: 4.000 µg Pb/L

****** Soil& Dust ******

Multiple Source Analysis Used
Average multiple source concentration: 21.667 µg/g

Mass fraction of outdoor soil to indoor dust conversion factor: 0.700
Outdoor airborne lead to indoor household dust lead concentration: 100.000
Use alternate indoor dust Pb sources? No

Age	Soil (µg Pb/g)	House Dust (ug Pb/g)
.5-1	16.667	21.667
1-2	16.667	21.667
2-3	16.667	21.667
3-4	16.667	21.667
4-5	16.667	21.667
5-6	16.667	21.667
6-7	16.667	21.667

****** Alternate Intake ******

Age	Alternate (µg Pb/day)
.5-1	0.000
1-2	0.000
2-3	0.000
3-4	0.000
4-5	0.000
5-6	0.000
6-7	0.000

****** Maternal Contribution: Infant Model ******

Maternal Blood Concentration: 0.847 µg Pb/dL

****
CALCULATED BLOOD LEAD AND LEAD UPTAKES:
****

Year	Air (µg/day)	Diet (µg/day)	Alternate (µg/day)	Water (µg/day)
.5-1	0.227	1.105	0.000	0.391
1-2	0.336	0.957	0.000	0.977
2-3	0.399	1.043	0.000	1.018
3-4	0.458	1.002	0.000	1.041
4-5	0.458	0.961	0.000	1.084
5-6	0.458	1.012	0.000	1.145
6-7	0.521	1.097	0.000	1.166

Year	Soil+Dust (µg/day)	Total (µg/day)	Blood (µg/dL)
.5-1	0.484	2.207	1.2
1-2	0.768	3.038	1.3
2-3	0.770	3.231	1.2
3-4	0.773	3.274	1.2
4-5	0.574	3.078	1.0
5-6	0.518	3.132	1.0
6-7	0.489	3.272	0.9

==

Multiple Runs: NO. 3 Medium: Soil (mg/kg)

****
INPUT VARIABLES
****

****** Air ******

Age	Conc (µg Pb/m³)
.5-1	0.100
1-2	0.100
2-3	0.100
3-4	0.100
4-5	0.100
5-6	0.100
6-7	0.100

Indoor Air Pb Concentration: 100.000 percent of outdoor.

Other Air Parameters:

Age	Time Outdoors (hours)	Ventilation Rate (m³/day)	Lung Absorption (%)
.5-1	1.000	5.400	42.000
1-2	2.000	8.000	42.000
2-3	3.000	9.500	42.000
3-4	4.000	10.900	42.000
4-5	4.000	10.900	42.000
5-6	4.000	10.900	42.000
6-7	4.000	12.400	42.000

****** Diet ******

Age	Diet Intake (µg Pb/day)
.5-1	2.260
1-2	1.960
2-3	2.130
3-4	2.040
4-5	1.950
5-6	2.050
6-7	2.220

****** Drinking Water ******

Water Consumption:

Age	Water (L/day)
.5-1	0.200
1-2	0.500
2-3	0.520
3-4	0.530
4-5	0.550
5-6	0.580
6-7	0.590

Drinking Water Concentration: 4.000 µg Pb/L

****** Soil& Dust ******

Multiple Source Analysis Used
Average multiple source concentration: 33.333 µg/g

Mass fraction of outdoor soil to indoor dust conversion factor: 0.700
Outdoor airborne lead to indoor household dust lead concentration: 100.000
Use alternate indoor dust Pb sources? No

Age	Soil (µg Pb/g)	House Dust (ug Pb/g)
.5-1	33.333	33.333
1-2	33.333	33.333
2-3	33.333	33.333
3-4	33.333	33.333
4-5	33.333	33.333
5-6	33.333	33.333
6-7	33.333	33.333

****** Alternate Intake ******

Age	Alternate (µg Pb/day)
.5-1	0.000
1-2	0.000
2-3	0.000
3-4	0.000
4-5	0.000
5-6	0.000
6-7	0.000

****** Maternal Contribution: Infant Model ******

Maternal Blood Concentration: 0.847 µg Pb/dL

****
CALCULATED BLOOD LEAD AND LEAD UPTAKES:
****

Year	Air (µg/day)	Diet (µg/day)	Alternate (µg/day)	Water (µg/day)
.5-1	0.227	1.101	0.000	0.390
1-2	0.336	0.953	0.000	0.972
2-3	0.399	1.039	0.000	1.014
3-4	0.458	0.999	0.000	1.038
4-5	0.458	0.959	0.000	1.082
5-6	0.458	1.010	0.000	1.143
6-7	0.521	1.095	0.000	1.164

Year	Soil+Dust (µg/day)	Total (µg/day)	Blood (µg/dL)
.5-1	0.828	2.545	1.4
1-2	1.313	3.574	1.5
2-3	1.317	3.769	1.4
3-4	1.322	3.816	1.3
4-5	0.984	3.483	1.2
5-6	0.887	3.498	1.1
6-7	0.838	3.618	1.0

==

Multiple Runs: NO. 4 Medium: Soil (mg/kg)

****
INPUT VARIABLES
****

****** Air ******

Age	Conc (µg Pb/m³)
.5-1	0.100
1-2	0.100
2-3	0.100
3-4	0.100
4-5	0.100
5-6	0.100
6-7	0.100

Indoor Air Pb Concentration: 100.000 percent of outdoor.

Other Air Parameters:

Age	Time Outdoors (hours)	Ventilation Rate (m³/day)	Lung Absorption (%)
.5-1	1.000	5.400	42.000
1-2	2.000	8.000	42.000
2-3	3.000	9.500	42.000
3-4	4.000	10.900	42.000
4-5	4.000	10.900	42.000
5-6	4.000	10.900	42.000
6-7	4.000	12.400	42.000

****** Diet ******

Age	Diet Intake (µg Pb/day)
.5-1	2.260
1-2	1.960
2-3	2.130
3-4	2.040
4-5	1.950
5-6	2.050
6-7	2.220

****** Drinking Water ******

Water Consumption:

Age	Water (L/day)
.5-1	0.200
1-2	0.500
2-3	0.520
3-4	0.530
4-5	0.550
5-6	0.580
6-7	0.590

Drinking Water Concentration: 4.000 µg Pb/L

****** Soil& Dust ******

Multiple Source Analysis Used
Average multiple source concentration: 45.000 µg/g

Mass fraction of outdoor soil to indoor dust conversion factor: 0.700
Outdoor airborne lead to indoor household dust lead concentration: 100.000
Use alternate indoor dust Pb sources? No

Age	Soil (µg Pb/g)	House Dust (ug Pb/g)
.5-1	50.000	45.000
1-2	50.000	45.000
2-3	50.000	45.000
3-4	50.000	45.000
4-5	50.000	45.000
5-6	50.000	45.000
6-7	50.000	45.000

****** Alternate Intake ******

Age	Alternate (µg Pb/day)
.5-1	0.000
1-2	0.000
2-3	0.000
3-4	0.000
4-5	0.000
5-6	0.000
6-7	0.000

****** Maternal Contribution: Infant Model ******

Maternal Blood Concentration: 0.847 µg Pb/dL

****
CALCULATED BLOOD LEAD AND LEAD UPTAKES:
****

Year	Air (µg/day)	Diet (µg/day)	Alternate (µg/day)	Water (µg/day)
.5-1	0.227	1.097	0.000	0.388
1-2	0.336	0.948	0.000	0.968
2-3	0.399	1.035	0.000	1.010
3-4	0.458	0.995	0.000	1.034
4-5	0.458	0.957	0.000	1.080
5-6	0.458	1.008	0.000	1.141
6-7	0.521	1.093	0.000	1.162

Year	Soil+Dust (µg/day)	Total (µg/day)	Blood (µg/dL)
.5-1	1.169	2.881	1.6
1-2	1.852	4.104	1.7
2-3	1.859	4.303	1.6
3-4	1.867	4.354	1.5
4-5	1.391	3.886	1.3
5-6	1.255	3.862	1.2
6-7	1.187	3.963	1.1

==

Multiple Runs: NO. 5 Medium: Soil (mg/kg)

****
INPUT VARIABLES
****

****** Air ******

Age	Conc (µg Pb/m³)
.5-1	0.100
1-2	0.100
2-3	0.100
3-4	0.100
4-5	0.100
5-6	0.100
6-7	0.100

Indoor Air Pb Concentration: 100.000 percent of outdoor.

Other Air Parameters:

Age	Time Outdoors	Ventilation Rate	Lung Absorption

Age	Time Outdoors (hours)	Ventilation Rate (m^3/day)	Lung Absorption (%)
.5-1	1.000	5.400	42.000
1-2	2.000	8.000	42.000
2-3	3.000	9.500	42.000
3-4	4.000	10.900	42.000
4-5	4.000	10.900	42.000
5-6	4.000	10.900	42.000
6-7	4.000	12.400	42.000

****** Diet ******

Age	Diet Intake (µg Pb/day)
.5-1	2.260
1-2	1.960
2-3	2.130
3-4	2.040
4-5	1.950
5-6	2.050
6-7	2.220

****** Drinking Water ******

Water Consumption:

Age	Water (L/day)
.5-1	0.200
1-2	0.500
2-3	0.520
3-4	0.530
4-5	0.550
5-6	0.580
6-7	0.590

Drinking Water Concentration: 4.000 µg Pb/L

****** Soil& Dust ******

Multiple Source Analysis Used
Average multiple source concentration: 56.667 µg/g

Mass fraction of outdoor soil to indoor dust conversion factor: 0.700
Outdoor airborne lead to indoor household dust lead concentration: 100.000
Use alternate indoor dust Pb sources? No

Age	Soil (µg Pb/g)	House Dust (ug Pb/g)
.5-1	66.667	56.667
1-2	66.667	56.667
2-3	66.667	56.667
3-4	66.667	56.667
4-5	66.667	56.667
5-6	66.667	56.667
6-7	66.667	56.667

****** Alternate Intake ******

Age	Alternate (µg Pb/day)
.5-1	0.000
1-2	0.000
2-3	0.000
3-4	0.000
4-5	0.000
5-6	0.000
6-7	0.000

****** Maternal Contribution: Infant Model ******

Maternal Blood Concentration: 0.847 µg Pb/dL

****
CALCULATED BLOOD LEAD AND LEAD UPTAKES:
****

Year	Air (µg/day)	Diet (µg/day)	Alternate (µg/day)	Water (µg/day)
.5-1	0.227	1.092	0.000	0.387
1-2	0.336	0.944	0.000	0.963
2-3	0.399	1.031	0.000	1.006
3-4	0.458	0.992	0.000	1.031
4-5	0.458	0.955	0.000	1.077
5-6	0.458	1.007	0.000	1.139
6-7	0.521	1.092	0.000	1.160

Year	Soil+Dust (µg/day)	Total (µg/day)	Blood (µg/dL)
.5-1	1.508	3.214	1.8
1-2	2.386	4.630	1.9
2-3	2.397	4.833	1.8
3-4	2.409	4.889	1.7
4-5	1.797	4.287	1.5
5-6	1.622	4.225	1.3
6-7	1.534	4.307	1.2

===

Multiple Runs: NO. 6 Medium: Soil (mg/kg)

****

INPUT VARIABLES

****

****** Air ******

Age	Conc (µg Pb/m³)
.5-1	0.100
1-2	0.100
2-3	0.100
3-4	0.100
4-5	0.100
5-6	0.100
6-7	0.100

Indoor Air Pb Concentration: 100.000 percent of outdoor.

Other Air Parameters:

Age	Time Outdoors (hours)	Ventilation Rate (m³/day)	Lung Absorption (%)
.5-1	1.000	5.400	42.000
1-2	2.000	8.000	42.000
2-3	3.000	9.500	42.000
3-4	4.000	10.900	42.000
4-5	4.000	10.900	42.000
5-6	4.000	10.900	42.000
6-7	4.000	12.400	42.000

****** Diet ******

Age	Diet Intake (µg Pb/day)
.5-1	2.260
1-2	1.960
2-3	2.130
3-4	2.040
4-5	1.950
5-6	2.050
6-7	2.220

****** Drinking Water ******

Water Consumption:

Age	Water (L/day)
.5-1	0.200
1-2	0.500
2-3	0.520
3-4	0.530
4-5	0.550
5-6	0.580
6-7	0.590

Drinking Water Concentration: 4.000 µg Pb/L

****** Soil& Dust ******

Multiple Source Analysis Used
Average multiple source concentration: 68.333 µg/g

Mass fraction of outdoor soil to indoor dust conversion factor: 0.700
Outdoor airborne lead to indoor household dust lead concentration: 100.000
Use alternate indoor dust Pb sources? No

Age	Soil (µg Pb/g)	House Dust (ug Pb/g)
.5-1	83.333	68.333
1-2	83.333	68.333
2-3	83.333	68.333
3-4	83.333	68.333

4-5	83.333	68.333
5-6	83.333	68.333
6-7	83.333	68.333

****** Alternate Intake ******

Age	Alternate (µg Pb/day)
.5-1	0.000
1-2	0.000
2-3	0.000
3-4	0.000
4-5	0.000
5-6	0.000
6-7	0.000

****** Maternal Contribution: Infant Model ******

Maternal Blood Concentration: 0.847 µg Pb/dL

****
CALCULATED BLOOD LEAD AND LEAD UPTAKES:
****

Year	Air (µg/day)	Diet (µg/day)	Alternate (µg/day)	Water (µg/day)
.5-1	0.227	1.088	0.000	0.385
1-2	0.336	0.940	0.000	0.959
2-3	0.399	1.027	0.000	1.002
3-4	0.458	0.988	0.000	1.027
4-5	0.458	0.953	0.000	1.075
5-6	0.458	1.005	0.000	1.137
6-7	0.521	1.090	0.000	1.159

Year	Soil+Dust (µg/day)	Total (µg/day)	Blood (µg/dL)
.5-1	1.844	3.544	1.9
1-2	2.916	5.150	2.1
2-3	2.931	5.359	2.0
3-4	2.947	5.421	1.9
4-5	2.201	4.687	1.6
5-6	1.987	4.587	1.4
6-7	1.880	4.649	1.3

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Multiple Runs: NO. 7 Medium: Soil (mg/kg)

****
INPUT VARIABLES
****

****** Air ******

Age	Conc (µg Pb/m³)
.5-1	0.100
1-2	0.100
2-3	0.100
3-4	0.100
4-5	0.100
5-6	0.100
6-7	0.100

Indoor Air Pb Concentration: 100.000 percent of outdoor.

Other Air Parameters:

Age	Time Outdoors (hours)	Ventilation Rate (m³/day)	Lung Absorption (%)
.5-1	1.000	5.400	42.000
1-2	2.000	8.000	42.000
2-3	3.000	9.500	42.000
3-4	4.000	10.900	42.000
4-5	4.000	10.900	42.000
5-6	4.000	10.900	42.000
6-7	4.000	12.400	42.000

****** Diet ******

Age	Diet Intake (µg Pb/day)
.5-1	2.260
1-2	1.960
2-3	2.130

3-4	2.040
4-5	1.950
5-6	2.050
6-7	2.220

****** Drinking Water ******

Water Consumption:

Age	Water (L/day)
.5-1	0.200
1-2	0.500
2-3	0.520
3-4	0.530
4-5	0.550
5-6	0.580
6-7	0.590

Drinking Water Concentration: 4.000 µg Pb/L

****** Soil& Dust ******

Multiple Source Analysis Used
Average multiple source concentration: 80.000 µg/g

Mass fraction of outdoor soil to indoor dust conversion factor: 0.700
Outdoor airborne lead to indoor household dust lead concentration: 100.000
Use alternate indoor dust Pb sources? No

Age	Soil (µg Pb/g)	House Dust (ug Pb/g)
.5-1	100.000	80.000
1-2	100.000	80.000
2-3	100.000	80.000
3-4	100.000	80.000
4-5	100.000	80.000
5-6	100.000	80.000
6-7	100.000	80.000

****** Alternate Intake ******

Age	Alternate (µg Pb/day)
.5-1	0.000
1-2	0.000
2-3	0.000
3-4	0.000
4-5	0.000
5-6	0.000
6-7	0.000

****** Maternal Contribution: Infant Model ******

Maternal Blood Concentration: 0.847 µg Pb/dL

****
CALCULATED BLOOD LEAD AND LEAD UPTAKES:
****

Year	Air (µg/day)	Diet (µg/day)	Alternate (µg/day)	Water (µg/day)
.5-1	0.227	1.084	0.000	0.384
1-2	0.336	0.935	0.000	0.955
2-3	0.399	1.023	0.000	0.999
3-4	0.458	0.985	0.000	1.024
4-5	0.458	0.951	0.000	1.073
5-6	0.458	1.003	0.000	1.135
6-7	0.521	1.088	0.000	1.157

Year	Soil+Dust (µg/day)	Total (µg/day)	Blood (µg/dL)
.5-1	2.178	3.872	2.1
1-2	3.441	5.667	2.4
2-3	3.461	5.881	2.2
3-4	3.481	5.948	2.1
4-5	2.604	5.085	1.8
5-6	2.351	4.947	1.6
6-7	2.225	4.991	1.4

U.S. EPA SAB Lead Review Panel
Final Comments from Dr. Philip Goodrum

Supplement C

Delta Pb Method – Letter from P. Goodrum to K. Klein of DTSC Dated January 29, 2010

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From:
Dr. Phil Goodrum, ARCADIS

Date: ARCADI
January 29, 2010

S Project No.:
B0066128.0000.00003

Subject:
Review of May 2009 Revised California Human Health Screening Level for Lead

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In May 2009, the California Office of Environmental Health Hazard Assessment (OEHHA) issued a proposal to change the California Human Health Soil Screening Level (CHHSL) for lead for both residential (child) and commercial/industrial (adult) receptor scenarios (OEHHA, 2009). The change was motivated by a meta-analysis of epidemiological studies linking lead in exposure media to decreased performance on IQ tests in children. OEHHA defined a new child-specific health guidance value (HGV) for lead as follows: an incremental change in blood lead concentration, or ∆PbB, of 1 microgram lead per deciliter (µg/dL) for the 90^{th} percentile of the PbB distribution. This would replace the previous HGV defined as follows: a PbB of 10 µg/dL at the 99^{th} percentile of the blood lead distribution. The ∆PbB threshold is intended to reflect a 97.5% upper confidence limit on the slope of the IQ versus PbB curve. Therefore, the new CHHSLs represent "concentrations in soil that have no more than a 2.5% probability of decreasing IQ by more than 1 point in a 90th percentile child or fetus" (OEHHA, 2009). An important source of uncertainty in the application of the ∆PbB concept is the treatment of non-site related (i.e., background) sources of lead. The incremental increase in PbB implies that the increase is above some baseline level. This concept has important implications for the backcalculated soil Pb concentration (PbS) which determines the CHHSL.

This white paper briefly reviews the mathematical concepts underlying the regulatory models used for assessing lead risks to different receptor populations, and examines the implications of the proposed changes. This white paper is not intended to challenge or endorse the decision to adopt an HGV of ∆PbB

1 μg/dL; rather, it explains how and why background levels of lead in soil should be incorporated in the calculation of the CHHSL.

1. Lead Models Require a Calculation of GM and Specification of GSD

From a mathematical perspective, the primary regulatory models that relate lead concentrations in exposure media to blood lead concentrations (i.e., Leadspread, IEUBK, and ALM) all rely on two key concepts:

1) The exposure (dose) model includes central tendency point estimates of exposure variables and the output from the exposure model is an estimate of the central tendency of average daily dose (either intake or uptake, depending on the model) in units of micrograms of lead per day (μg/day) and corresponding central tendency blood lead concentration (PbB) in units of micrograms per deciliter (μg/dL). The central tendency statistic for PbB is assumed to be the geometric mean (GM), not the arithmetic mean.

2) Interindividual variability in estimates of blood lead is represented by a two-parameter lognormal distribution. In statistics, there are many different conventions for the set of parameters that define a lognormal distribution, and any set of parameters can be converted to a different set. Common examples of sets of two parameters include:

    a. Arithmetic mean and arithmetic standard deviation
    b. Geometric mean and geometric standard deviation (GSD)
    c. Any two percentiles

For convenience, regulatory models use the [GM, GSD] set of parameters where the GM is calculated by the model (see #1 above) and the GSD (a unitless measure of spread) is specified by the risk assessor based on regulatory guidance (USEPA, 2009). The lognormal distribution can be specified as follows:

PbB ~ Lognormal (GM, GSD)

which means that PbB is distributed as a lognormal distribution with a specified GM and GSD.

2. Regulatory Criteria are Associated with an Upper Percentile of a Lognormal Distribution

The lead models are used to estimate upper percentiles of the lognormal distribution of PbB. Equation 1 provides the mathematical relationship between a value at the p^{th} percentile (X_p) of the PbB distribution (units of μg/dL), GM (units of μg/dL), and GSD (unitless):

$$X_p = GM \times GSD^{z_p} \qquad \text{Equation 1}$$

where z_p is the standard normal deviate, or "z-score," which corresponds to the cumulative probability of a standard normal distribution with arithmetic mean = 0 and standard deviation = 1. In other words, z_p is the p^{th} percentile of the standard normal distribution. Z-scores are well approximated in Excel with the function *normsinv(p)*, where "p" is the cumulative probability (or percentile) of interest. Examples of z-scores commonly associated with selected percentiles are given below.

cumulative probability (p)	z-score (z_p)
0.500	0.000
0.750	0.674
0.841	1.000
0.900	1.282
0.950	1.645
0.990	2.326
0.999	3.000

The convenience of Equation 1 is that we can easily rearrange the terms to solve for GM as a function of X_p:

$$GM = \frac{X_p}{GSD^{z_p}} \qquad \text{Equation 2}$$

In addition, we can express the concept of an incremental change (∆PbB) for the X_p percentile in mathematical terms:

$$X_p + \Delta X_p = (GM + \Delta GM) \times GSD^{z_p} \qquad \text{Equation 3}$$

Rearranging Equation 3 to solve for ∆GM yields a solution for the change in the GM that yields a corresponding change in the X_p percentile:

$$GM + \Delta GM = \frac{X_p + \Delta X_p}{GSD^{z_p}}$$

Subtracting GM from both sides yields ∆GM:

$$\Delta GM = \frac{X_p + \Delta X_p}{GSD^{z_p}} - GM \qquad \text{Equation 4}$$

Substituting Equation 2 into Equation 4 yields Equation 5:

$$\Delta GM = \frac{X_p + \Delta X_p}{GSD^{z_p}} - \frac{X_p}{GSD^{z_p}} = \frac{\Delta X_p}{GSD^{z_p}} \qquad \text{Equation 5}$$

Equation 5 provides a convenient expression that converts the HGV metric for the percentile (∆PbB of 1 µg/dL) to a corresponding change in the GM. For example, the change in GM that corresponds to a ∆PbB of 1 µg/dL for the 90th percentile (z_p = 1.282) of the PbB distribution with GSD = 1.8 is calculated as follows:

$$\Delta GM = \frac{1}{1.8^{1.282}} = 0.471 \text{ µg/dL}$$

Therefore, because the increment in PbB does not change the GSD, the new lognormal distribution that accommodates a ∆PbB of 1 µg/dL at the 90th percentile can be expressed as:

PbB ~ Lognormal (GM + 0.471, GSD)

We can think of the original GM (prior to introducing site-specific soil exposure) as the central tendency PbB that corresponds to all exposure pathways except for incidental ingestion of site-related sources of Pb in soil. With Leadspread, this would include dose equations that incorporate variables representing background levels of lead in air, lead in water, and home-grown produce (plus any other miscellaneous source). With ALM, the contributions of non-site sources to the PbB distribution are implicit in the specified baseline PbB (rather than dose equations for each source of Pb).

3. Soil Lead Concentration (PbS) is a Combination of Background and Site-Related Sources

The Leadspread and ALM models were developed to facilitate calculations of soil lead concentrations (PbS) that correspond to upper percentiles of the PbB distribution (HGVs). When used in a "forward calculation," site-specific data are collected to estimate an arithmetic mean PbS and the model gives the parameters of the PbB distribution (GM, GSD) and corresponding percentiles. It is assumed that PbBs for exposed adults can be estimated as "…*the sum of an expected starting blood lead concentration in the absence of site exposure (PbB$_0$) and an expected site-related increase in PbB*" (USEPA, 2003, page 4). The ALM Equation 1 (USEPA, 2003) is given by Equation 6 below:

$$PbB_{adult,\ central} = PbB_{adult,0} + \frac{PbS \times BKSF \times IR_S \times AF \times EF}{AT} \qquad \text{Equation 6}$$

where

$PbB_{adult,\ central}$	=	central estimate (GM) of PbB (µg/dL) in adults (i.e., women of child-bearing age) that have site exposure to soil lead at concentration, PbS
PbB_0	=	typical PbB (µg/dL) in adults in the absence of exposure to the site media

PbS	=	soil lead concentration (µg Pb/g soil)
IR_s	=	average daily soil ingestion rate (including soil-derived indoor dust) (g soil/day)
AF_s	=	oral absorption fraction for lead in soil and soil-derived dust (unitless)
EF	=	exposure frequency (days/yr)
AT	=	averaging time (days/yr)

Three key concepts are conveyed by this equation: 1) in the absence of exposure to site exposure media that are being assessed (i.e., soil), the GM PbB is greater than zero, and represented by a "background" GM PbB that reflects empirical data for the U.S. adult population (note that USEPA recently updated the default estimate of PbB_0 to 1.9 µg/dL (USEPA, 2009); 2) PbS is the average lead concentration that would be measured in site soils; and 3) even if there were no site-related contribution of lead to PbS, we would still expect a contribution to the GM PbB due to exposure to ambient levels of lead in soil on the site. Thus, PbS is the sum of ambient soil lead (PbS_0) and site-related soil lead (PbS_s):

$$PbS = PbS_0 + PbS_s \quad \text{Equation 7}$$

Combining Equations 6 and 7 yields a more general form of the familiar ALM equation:

$$PbB_{adult,\ central} = PbB_{adult,0} + (PbS_0 + PbS_s) \times \frac{BKSF \times IR_S \times AF \times EF}{AT} \quad \text{Equation 8}$$

4. Defining ∆PbB in terms of GM, Percentile, and Site-related PbS

Returning to the lognormal distribution model, the central tendency estimates represent the GM parameter, so Equation 8 can be expressed in terms of corresponding GMs:

$$GM = GM_0 + GM_{PbS_0} + GM_{PbS_s} \quad \text{Equation 9}$$

where "baseline" PbB is represented by the sum of the first two terms, and the third term, GM_{PbSs}, is the incremental increase in baseline GM PbB associated with site-related soil exposure:

$$GM = GM_0 + GM_{PbS_0} + \Delta GM \quad \text{Equation 10}$$

For non-residential scenarios, because the receptor of concern is the fetus, a fetal/maternal blood lead ratio (R) is used to determine the corresponding PbB in the fetus:

$$GM_{fetus} = \left(GM_{adult,\ 0} + GM_{adult,\ PbS_0} + \Delta GM_{adult}\right) \times R \quad \text{Equation 11}$$

Therefore, DTSC's proposed change to an HGV of ∆PbB 1 µg/dL in the receptor of concern (i.e., developing fetus for ALM) can be expressed as a relationship between the incremental change in the p^{th} percentile (ΔX_p) of the PbB distribution, the equivalent ∆GM (based on Equation 5), and the site-related contribution to soil lead, PbS_s:

$$\Delta GM = \frac{\Delta X_p}{GSD^{z_p}} = PbS_s \times \frac{BKSF \times IR_S \times AF \times EF \times R}{AT} \qquad \text{Equation 12}$$

Rearranging Equation 12 to solve for PbS_s yields:

$$PbS_s = \frac{\Delta X_p}{GSD^{z_p}} \times \frac{AT}{BKSF \times IR_S \times AF \times EF \times R} \qquad \text{Equation 13}$$

Finally, combining Equation 7 and 13, we obtain an expression for the backcalculated total PbS (background and site-source combined) that achieves a ∆PbB criteria at a specified percentile:

$$PbS = PbS_0 + \frac{\Delta X_p}{GSD^{z_p}} \times \frac{AT}{BKSF \times IR_S \times AF \times EF \times R} \qquad \text{Equation 14}$$

Therefore, the final CHHSL needs to reflect the combination of background and site-related sources of Pb in soil. As shown by Equation 14, the mathematical solution is simply the sum of ambient soil lead (PbS_0) and site-related soil lead (PbS_s) that corresponds to a ∆PbB at the specified percentile. The sum represents the expected mean concentration that would be measured (site and non-site sources combined).

5. Microsoft Excel® Worksheet to Implement Guidance

OEHHA's proposed guidance incorporates a number of changes in the application of the models, but not to the underlying equations that define the model. Lead risks for residential scenarios will continue to be evaluated using DSTC's Leadspread model while risks for non-residential (e.g., commercial/industrial) scenarios will be evaluated with USEPA's Adult Lead Model (ALM). Therefore, because the lognormal distribution applies to both models, Equation 14 can be used to examine the implications of the new guidance.

An Excel workbook entitled "ALM-delta PbB.xls" is attached and may be used to implement the new guidance for non-residential scenarios based on the ALM. The first worksheet (Table 1 ALM – Baseline PbB) includes Table 1, which lists the inputs and outputs for three receptor scenarios: Adult Resident, Commercial/Industrial Worker, and Construction Worker. A key to the 19 variables listed in the table is given below.

Table 1 Key

1. **Baseline $PbB_{0, GM}$** – (user-defined) baseline blood lead concentration associated with exposure to non-site sources of lead (e.g., water, diet, air, soil, etc.). A default value of 1.0 µg/dL is suggested based on USEPA's recent updated estimate for the U.S. population (USEPA, 2009). This value can be set to zero in order to isolate the contribution of soil to the incremental change in PbB. OEHHA set the value to zero (see Table 2 of OEHHA, 2009).

2. **Perc_Soil** - (user-defined) percentage of Baseline $PbB_{0, GM}$ that can be attributable to ingestion of background soil. A placeholder value of 10% is shown. This value is used to calculate Baseline PbS. Alternatively, Items 1 and 2 can be skipped and the Baseline PbS can be entered based on samples collected from an appropriate reference area.

3. **Baseline PbS** – (calculated or user-defined) same as PbS_0 described in **Equation 7** above. Default is for this value to be calculated automatically, however, the value can also be typed in.

4. **GSD_i** - (user-defined) geometric standard deviation blood lead concentration. A value of 1.8 is suggested based on USEPA's recent updated estimate for the U.S. population (USEPA, 2009).

5. **F(x)** – (user-defined) percentile of the lognormal distribution corresponding to the CHHSL. The new guidance changes the focus from the 99^{th} to the 90^{th} percentile.

6. **Baseline $PbB_{a, percentile}$** – (calculated) adult PbB at specified percentile, calculated using **Equation 1** above.

7. **$R_{fetal/maternal}$** - (user-defined) PbB ratio to estimate corresponding PbB for fetus.

8. **Baseline $PbB_{f, percentile}$** – (calculated) fetal PbB at specified percentile, calculated as the product of Items 6 and 7.

9. **$\Delta PbB_{f, percentile}$** – (user-defined) change in fetal blood lead at the percentile of interest. This is the new HGV of 1.0 µg/dL proposed by OEHHA.

10. **Target PbB_f** – (calculated) total target fetal blood lead concentration, calculated as the sum of Items 8 an 9.

11. **$\Delta GM\ PbB_f$** – (calculated) change in fetal blood lead concentration at the geometric mean of a lognormal distribution, calculated using **Equation 2** above.

12. **ΔPbS** – (calculated) change in soil concentration attributable to change in fetal blood lead concentration, calculated based on **Equations 7** and **13** above.

13. **Target PbS** – (calculated) sum of baseline PbS and ∆PbS.

14. **$BKSF_s$** – (user-defined) biokinetic slope factor.

15. **IR_s** – (user-defined) soil and dust ingestion rate.

16. **AF_s** – (user-defined) absorption fraction for lead in soil.

17. **AF_d** – (user-defined) absorption fraction for lead in dust (not used in this specific set of examples).

18. **EF** – (user-defined) exposure frequency.

19. **AT** – (user-defined) averaging time.

The incremental change in soil lead concentration that yields an incremental change in PbB at the 90th percentile is given by **∆PbS** (Item 12). This is equal to the Target PbS (Item 13) only if the background soil lead concentration is 0 mg/kg. OEHHA proposed using **∆PbS** to determine the CHHSL, which is equivalent to setting the background soil lead concentration to 0 mg/kg. The CHHSL should reflect the measurable concentration of lead in soil, which is the sum of the background and site-related sources (i.e., Target PbS).

Table 1 summarizes the user-defined inputs that yield baseline soil lead concentrations, the ∆PbS that corresponds to the proposed ∆PbB, and the final Target PbS (or CHHSL). Figure 1 in the Excel workbook shows the relationship between Target PbS and the Perc_Soil variable when baseline PbB is defined as 1.0 µg/dL.

Table 1. Example calculations of CHHSLs that yield ∆PbB of 1 µg/dL for the developing fetus at the 90th percentile.

Soil Lead Concentration (mg/kg)	Receptor Scenario Using ALM		
	Adult Resident	Commercial/ Industrial Worker	Construction Worker
Baseline PbS	44	61	29
∆PbS	227	318	153
Target PbS (or CHHSL)	271	379	182

References

California Office of Environmental Health Hazard Assessment (OEHHA). 2009. Revised California Human Health Screening Level for Lead (Review Draft). May 14.

USEPA. 2003. Recommendations of the Technical Review Workgroup for Lead for an Approach to Assessing Risks Associated with Adult Exposures to Lead in Soil. Technical Review Workgroup for Lead, Washington DC. EPA-540-R-03-001.

USEPA. 2009. Update of the Adult Lead Methodology's Default Baseline Blood Lead Concentration and Geometric Standard Deviation Parameters. OSWER 9200.2-82. June 26.

Table 1. Application of Delta PbB Methodology with Adult Lead Model (ALM)
Background Defined by Geometric Mean Baseline Blood Lead Concentration

Item	Variable	Description	Units	Receptor Scenario: Adult Resident [a]	Receptor Scenario: Commercial / Industrial Worker [a]	Receptor Scenario: Construction Worker [b]
1	Baseline $PbB_{a, GM}$	baseline (adult) PbB at geometric mean	µg/dL	1.0 [e]	1.0 [e]	1.0 [e]
2	Perc_Soil	percent of baseline $PbB_{a, GM}$ attributable to ingestion of background soil	percent	10%	10%	10%
3	Baseline PbS	baseline soil Pb that yields $PbB_{a, GM}$	ppm	43.5	60.8	29.2
4	GSD_i	geometric standard deviation PbB	--	1.8 [e]	1.8 [e]	1.8 [e]
5	F(x)	upper percentile of lognormal distribution (expressed as fractile)	--	0.90	0.90	0.90
6	Baseline $PbB_{a, percentile}$	baseline (adult) PbB at upper percentile	µg/dL	2.1	2.1	2.1
7	$R_{fetal/maternal}$	fetal/maternal PbB ratio	--	0.9 [d]	0.9 [d]	0.9 [d]
8	Baseline $PbB_{f, percentile}$	baseline (fetal) PbB at upper percentile	µg/dL	1.9	1.9	1.9
9	Δ $PbB_{f, percentile}$	change in (fetal) PbB at upper percentile	µg/dL	1.0	1.0	1.0
10	Target PbB_f	target (fetal) PbB	µg/dL	2.9	2.9	2.9
11	Δ GM PbB_f	change in geometric mean (fetal) PbB	µg/dL	0.47	0.47	0.47
12	Δ PbS [c]	change in soil Pb attributable to Δ $PbB_{f, percentile}$	ppm	227	318	153
13	Target PbS	Baseline PbS + Δ PbS	ppm	271	379	182
Exposure Variables						
14	$BKSF_S$	biokinetic Slope Factor	µg/dL per µg/day	0.4 [d]	0.4 [d]	0.4 [d]
15	IR_S	soil ingestion rate	g/day	0.05 [f]	0.05 [f]	0.10 [g]
16	AF_o	absorption fraction (oral)	--	0.12 [d]	0.12 [d]	0.12 [d]
17	AF_d	absorption fraction (dermal)	--	NA [h]	NA [h]	NA [h]
18	EF	exposure frequency	days/yr	350 [i]	250 [i]	5 [i]
19	AT	averaging time	days/yr	365 [j]	365 [j]	7 [j]
				2.9	2.9	2.9

Abbreviations:

µg/dL = micrograms per deciliter
g/day = grams per day
NA = not applicable
Δ = delta or incremental change
PbB = blood lead concentration
ppm = parts per million
F(x) = cumulative probability

Notes:

[a] Resident represents female adult (ages 17 - 45 years).

[b] Construction worker represents female adult (ages 17- 45 years).

[c] Back-calculated value based on Equation 4 in USEPA, 2003a.

[d] Default CTE value (USEPA, 2003a).

[e] Default CTE value for all U.S. populations (USEPA, 2009).

[f] Default CTE value for soil ingestion for adults that are not engaged in contact-intensive activities such as construction work (USEPA, 2003a; 2007).

[g] Default value for construction workers (soil contact-intensive activities) (USEPA, 2007).

[h] Consistent with USEPA (2003a; 2004; 2007) guidance, dermal exposures to lead in aqueous and non-aqueous media were not quantitatively evaluated with the ALM due to the uncertainty in assigning a dermal absorption fraction that would apply to the numerous inorganic forms of lead that are typically found in environmental settings.

[i] Consistent with USEPA (2003b), a time-weighted approach was used to evaluate potential lead risks for these receptors. Construction

[j] Applying the time-weighted approach as noted in [j] above, the resulting averaging time is set equal to 7 days/week.

References:

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USEPA. 2003b. Assessing Intermittent or Variable Exposures at Lead Sites. OSWER Directive #9285.7-76. EPA-540-R-03-008. November.

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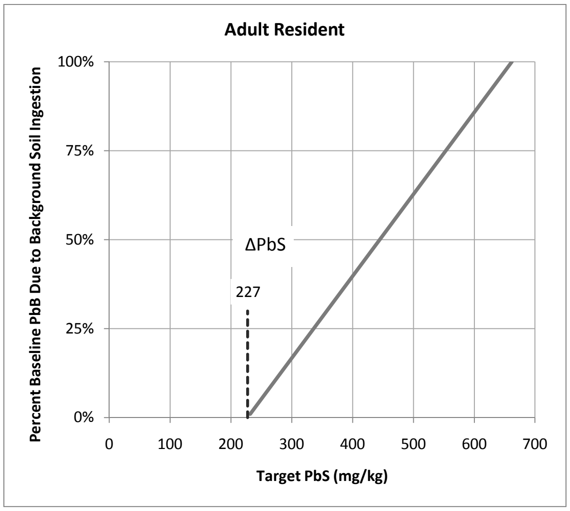
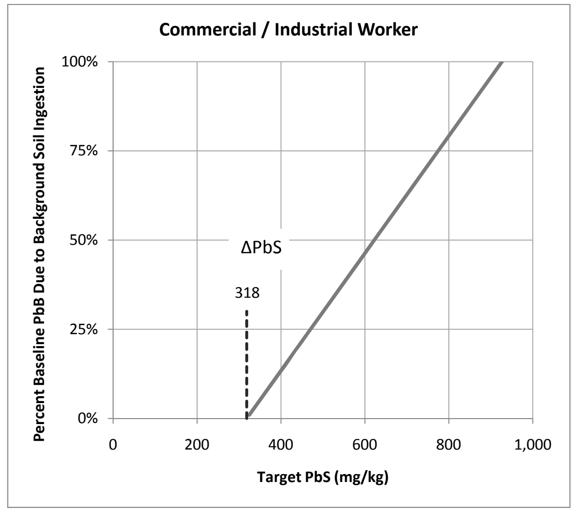
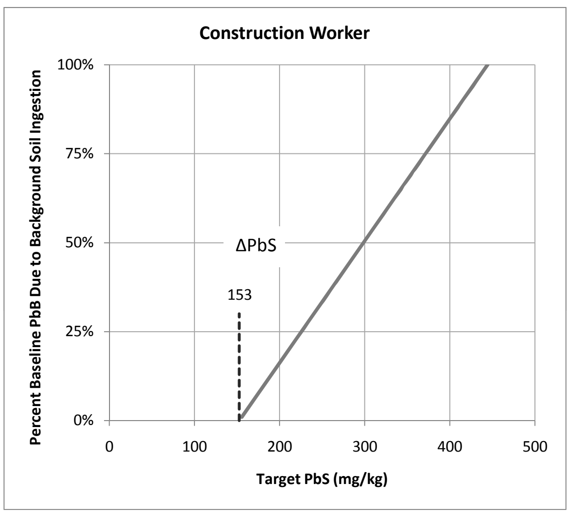
Figure 1. Application of Delta PbB Methodology with Adult Lead Model (ALM)
Background Defined by Geometric Mean Baseline Blood Lead Concentration







U.S. EPA SAB Lead Review Panel
Final Comments from Dr. Philip Goodrum

Supplement D

Soil and Dust Ingestion Rate for Adults and Children

Supplement D to Comments from Philip Goodrum

Soil Ingestion Rate for Adults and Children

This information was prepared by Philip Goodrum for USEPA Region 8 and is published in the following document.

CITATION: USEPA. 2001. ROCKY FLATS. TASK 3 REPORT AND APPENDICES: CALCULATION OF SURFACE RADIONUCLIDE SOIL ACTION LEVELS FOR PLUTONIUM, AMERICIUM, AND URANIUM

A.1.1.2 JUSTIFICATION FOR ADULT SOIL INGESTION INPUT VARIABLE

The limited data available on soil ingestion rates in adults poses a challenge when attempting to develop a probability distribution that characterizes interindividual variability. The following discussion provides highlights of the available empirical data, and an overview of the reasoning used in developing the recommended distribution.

Empirical data on adult soil ingestion rates are available from two studies (Calabrese et al., 1990; Calabrese et al., 1997a), each conducted concurrently with a study of childhood soil ingestion rates. The 1990 study was conducted in Amherst, MA, while the 1997 study was conducted in Anaconda, MT. The purpose of these pilot studies was to verify the tracer mass balance methodology used in the child studies, rather than to investigate the amount of soil normally ingested by adults. Nevertheless, as indicated by the authors, it does offer an estimate of the amount of soil ingested by the adult subjects in the study over a period of several consecutive days for each of three or four weeks. With the mass balance methodology, soil ingestion is estimated by subtracting the quantity of trace element in food and soil capsules from the total amount excreted in feces. For both studies, the soil capsules administered to subjects contained different amounts of soil obtained from the same soil library, originally collected from locations in Amherst, MA.

A more detailed summary of the best tracer methodology used to estimate soil ingestion rates is given in the discussion on the probability distribution developed to characterize soil ingestion rates in children in this Appendix A. Stanek and Calabrese (1995a) recommend estimating a distribution of soil ingestion rates from this type of study based on the median of the best tracers for each subject week. On the basis of percent recoveries, the four best tracers were determined to be aluminum, silicon, yttrium, and zirconium for the 1990 study, and the same set plus titanium for the 1997 study. Results of the 1990 study reported by week and tracer are given in Table A-2.

Table A-1. Calabrese et al., 1990 (Table 7, p. 93) study results by week and tracer element based on median Amherst soil concentrations. Statistics are the mean/median ingestion rates among n = 6 subjects.

Study Week	Soil Ingestion (mg/day) by Tracer [mean/median]			
	Al	**Si**	**Y**	**Zr**
1	110 / 60	30 / 31	63 / 44	134 / 124
2	98 / 85	14 / 15	21 / 35	58 / 65
3	28 / 66	-23 / -27	67 / 60	-74 / -144

The data may also be grouped by individual and tracer element, and averaged across all three weeks, as shown in Table A-3. Corresponding estimates for each of the six individuals are given in Figure A-2.

Table A-2. Calabrese et al., 1990 (Table 8, p. 94) study results by individual and tracer element based on median Amherst soil concentrations [for n = 3 weeks]. Also see Figure A-2.

Subject Statistics	Soil Ingestion (mg/day) by Tracer				Arithmetic Mean of 4 Tracers	Median of 4 Tracers
	Al	Si	Y	Zr		
minimum	1	7	27	17	19	22
maximum	173	99	111	216	133	117
mean	77	5	53	33	63	55
median	57	1	65	-4	54	36
standard deviation	65	55	51	141	42	39

[1]Statistics include negative estimates, which are an indication of the measurement error associated with mass balance fecal tracer studies; 3/6 estimates were negative for Si and Zr while 1/6 was negative for Y, as shown in Figure A-2.

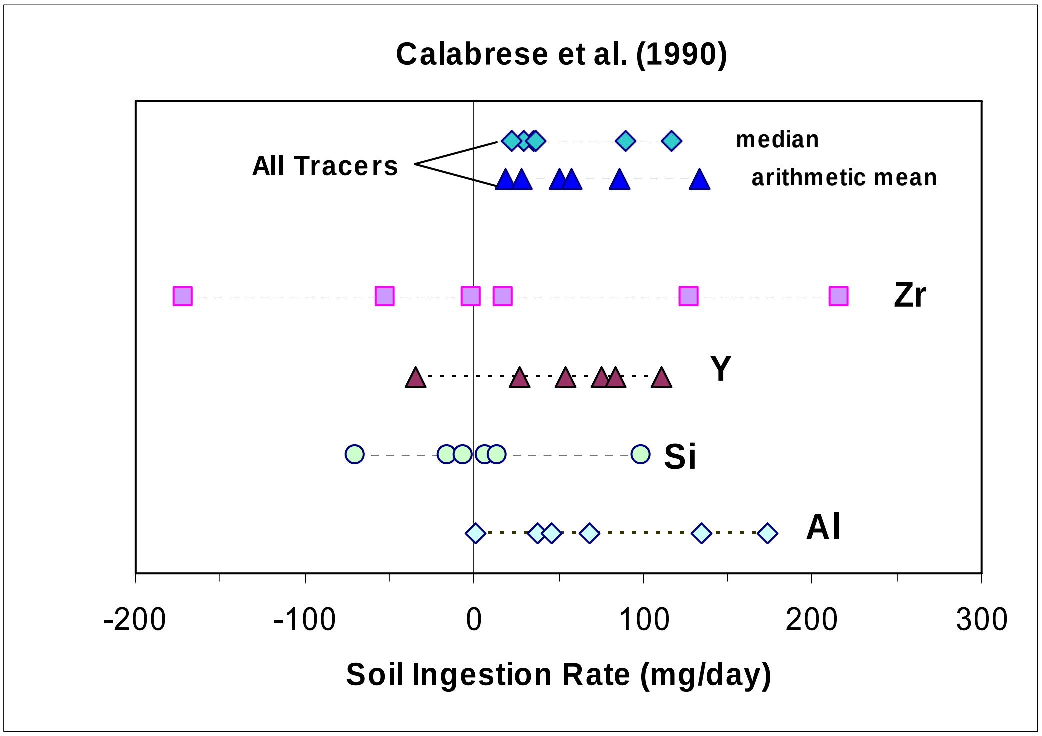


Figure A-1. Calabrese et al. (1990) results for four best tracers showing three week average estimates for each of n = 6 individuals. Summary statistics (median, AM) across trace elements are also shown. Summary statistics across individuals are given in Table A-3.

For the three weeks of data (Table A-2), the minimum, non-negative average soil ingestion rate (i.e., averaged across all six subjects) is given by Si (14 mg/day), while the maximum is given by Zr (134 mg/day). For the six subjects (Table A-3), the minimum, non-negative average soil ingestion rate (i.e., averaged across all three weeks) is given by Al (1 mg/day), while the maximum is given by Zr (216 mg/day). If the estimates are further averaged across individuals (including negative estimates), the mean soil ingestion rate ranges from 5 to 33 mg/day, while the median ranges from -4 to 65 mg/day.

A more informative metric of interindividual variability may be to combine the trace element concentrations by individual. As shown in Figure A-2, the AM and median soil ingestion estimates for n = 6 subjects ranges from 19 to 133 mg/day and 22 to 117 mg/day, respectively.

Calabrese et al. (1997a) provide a second set of pilot study data for comparison to the Calabrese et al. (1990) data. This study was conducted with n = 10 subjects over a four week period using capsules with the same soil as the 1990 study (Amherst), but a different geographic location for incidental soil ingestion (Anaconda). The authors focus on uncertainties associated with particle size, highly variable food/soil transfer factors across trace elements for a subject-day, and distinction between soil and dust ingestion.

Data were presented in a slightly different format than the 1990 study, making direct comparisons difficult. In the 1997 study, selected statistics of the average daily non-capsule soil ingestion among 10 adults are given by study week (1 to 4), rather than by subject and week. Data were limited to 5 of 8 trace elements (Al, Si, Ti, Y, and Zr) for which concentrations were found to be homogeneous across different particle sizes. Results of the 1997 study by week and tracer are given in Table A-4. Table A-5 and Figure A-3 provide additional summary statistics for Week 1, when no soil capsule was administered.

Table A-3. Calabrese et al. (1997a) (Table 4, p. 251) study results by week and tracer element based on median Amherst soil concentrations. Statistics are the mean/median among n = 10 subjects for each week.

Study Week[1]	**Soil Ingestion (mg/day) by Tracer [mean/median]**				
	Al	**Si**	**Ti**	**Y**	**Zr**
1	12 / 5	-20 / -24	100 / 126	187 / -40	-11 / -25
2	20 / 14	-7 / -3	708 / 358	219 / 69	-31 / -43
3	22 / 38	31 / -1	1013 / 251	414 / 159	9 / -37
4	-115 / -93	-127 / -108	132 / 19	84 / 197	-350 / -342

[1]Mass of soil administered in capsules: week 1: 0 mg/day; week 2: 20 mg/day; week 3: 100 mg/day; week 4: 500 mg/day.

Table A-4. Calabrese et al. (1997a) (Table 4, p. 251) study results by tracer element for week one [no soil capsule]. Also see Figure A-3.

Subject Statistics	Soil Ingestion (mg/day) by Tracer				
	Al	**Si**	**Ti**	**Y**	**Zr**
Minimum	-21	-59	-1969	-376	-81
Maximum	67	64	1240	2059	133
Mean	12	-20	100	187	-11
Median	5	-24	126	-40	-25
Standard dev.	31	37	876	707	57

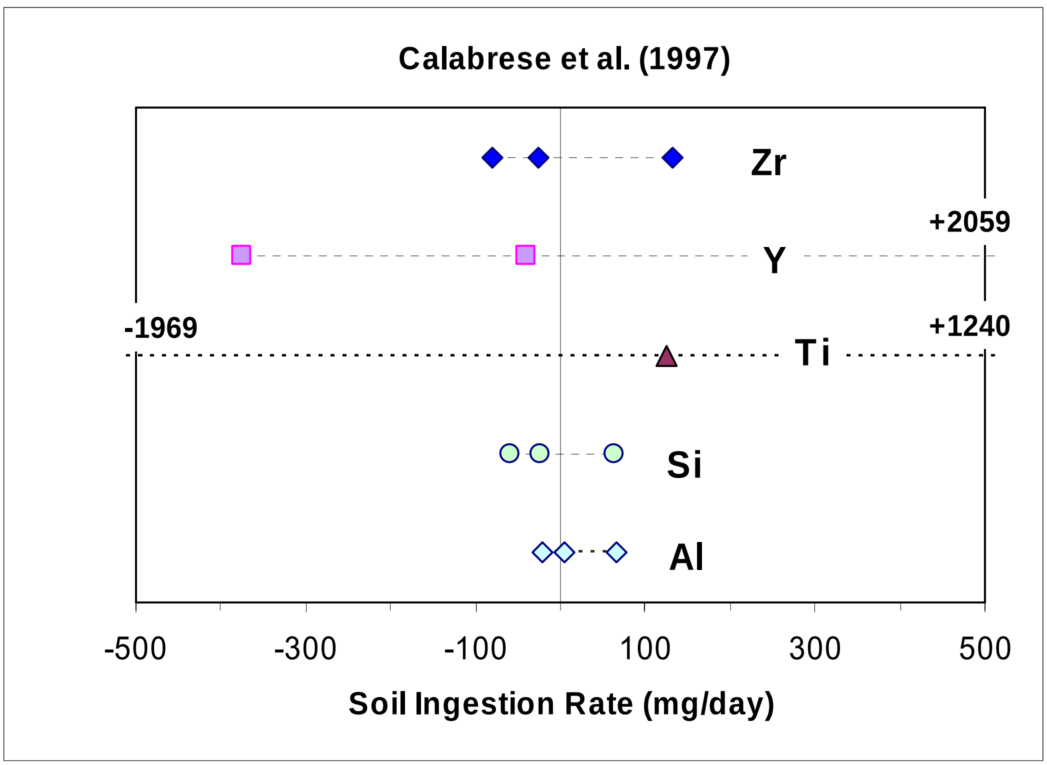


Figure A-2. Calabrese et al. (1997a) results for five best tracers showing (min, median, max) of average estimates for n = 10 individuals during week one. Summary statistics are given in Table A-5.

Table A-5. Calabrese et al. (1997a) (Table 9, p. 255) study results for 10 adults overall (Anaconda) and for four weeks, using trace elements Al, Si, Ti, Y, and Zr with the lowest food/soil ratio on any given subject-day. Also see Figure A-4.

Statistics	Soil Ingestion (mg/day) by Best Tracer				
	Med 4[1]	Best[2]	2nd	3rd	4th
minimum	-400	-452	-410	-835	-753
maximum	620	1177	2473	1039	6353
mean	6	136	99	-8	189
standard dev.	165	308	561	314	1074
5^{th} %ile	-189	-144	-318	-443	-398
25^{th} %ile	-55	-31	-46	-102	-73
50^{th} %ile	-11	21	-5	-11	-9
75^{th} %ile	34	305	43	55	62
95^{th} %ile	331	797	1362	654	1317

[1]Median soil ingestion rate among the four best trace elements on each subject-day.
[2]Frequency of best tracers for 40 subject-weeks: Al (42%), Si (10%), Ti (25%), Y (20%), and Zr (3%).

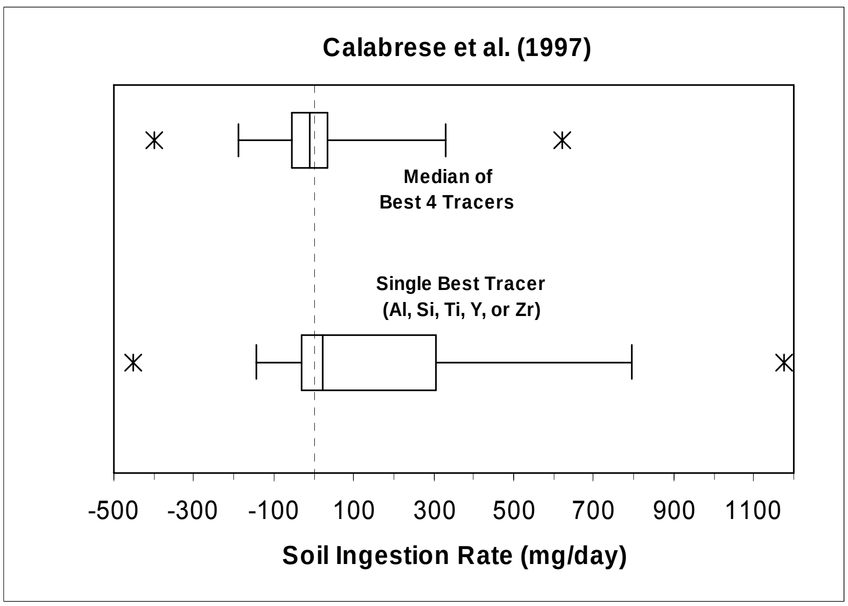


Figure A-3. Calabrese et al. (1997a) results for median of four best trace elements and the single best trace element on each subject-day. Box and whisker plots represent distributions for interindividual variability based on 10 subjects with soil ingestion rates averaged over four weeks. Summary statistics are given in Table A-6.

The 1997 study also presents selected statistics for the distribution of soil ingestion rates using different combinations of trace elements for any given subject day. Table A-6 and Figure A-4 provide the results for the median of the best trace elements and the single best trace element on each subject-day.

An uncertainty associated with both studies is the calculation of negative ingestion rates on many subject-days. Negative ingestion rates occur due to complexities in the tracer mass balance methodology, such as the assumed transit time in the GI tract and the non-soil sources of tracer elements. For the 1990 study, the trace element with the most variable results (given by the reported SD in Table A-3) is Zr (SD = 141 mg/day), while the least variable is Si (SD = 55 mg/day). The distribution of ingestion rates by individual is more clearly shown in Figure A-2. For the 1997 study (Figure A-3), the most variable soil ingestion estimates during week one are given by Ti (SD = 876), while the least variable is Al (SD = 31). The authors conclude that the broad range in estimates for different trace elements implies that a simple average estimate (over all trace elements) provides little insight into adult soil ingestion since estimates based on different trace elements for the same adults and time periods are so highly variable (Calabrese et al., 1997). An alternative approach based on the "best" trace element for any given day still yields a negative ingestion rate for nearly half of the study weeks.

Basis for Uniform (0, 130) Distribution – Based on the small sample sizes and the prevalence of negative ingestion rates, no attempt was made to evaluate a variety of probability distributions for either study. The range of plausible ingestion rates for adults varies depending on which trace elements are examined. The 1990 study suggests that ingestion rates averaged over a three-week period may vary from a minimum of less than 1 mg/day (truncating negative values to 0) to a maximum of 216 mg/day (for Zr). When results for individual trace elements are combined by calculating a simple/arithmetic mean or median for each subject, the plausible range across subjects is approximately 20 to 130 g/day.

The 1997 study suggests that interindividual variability may be even greater than that of the 1990 study. When trace element results are combined by calculating the median of the four best tracers on any subject-day, the plausible range is [– 400 mg/day to + 620 mg/day], with 5th and 95th percentiles [–189 mg/day, 331 mg/day]. For individual trace element results (e.g., best tracer for each of 40 subject-weeks), the frequency of selection of trace elements ranged from a high of 42% of subject-weeks for Al to a low of 3% for Zr. Ti (25%), Y (20%), and Si (10%) give intermediate contributions. If the most variable of the trace elements are excluded from the analysis (Y and Ti), the results of the individual trace element concentrations suggest a plausible range that is more similar to the 1990 study. For example, the maximum values for Al, Si, and Zr are 67, 64, and 133 mg/day, respectively.

One of the limitations in empirical data such as soil ingestion rate data is that measurements over a short time period (i.e., weeks) are used to estimates long-term average behavior. Typically, interindividual variability measured over a period of days or weeks will overestimate variability over an one-year period or longer. This is because most individuals will tend to experience a wide range of conditions over a long time period (e.g., years), and very high (or low) estimates measured during one week are likely to be offset by different exposures the next. This process is sometimes referred to as "averaging towards the mean", and presents a major challenge in applying short-term survey data to risk assessments. A reasonable assumption is that the plausible range of soil ingestion rates offered by these two studies is more extreme (i.e., conservative) than may be necessary.

Conversely, the fact that the sample sizes are small suggests that there is a good chance that the true range of soil ingestion rates among the population has not been measured. The intent in using a uniform distribution to describe interindividual variability is not to represent the range (minimum and maximum) of ingestion rates in a statistical sense (i.e., the individuals with the extreme lowest and highest ingestion rates). Rather, the goal is to characterize a range of long-term average ingestion rates that includes the RME individual.

A range of 0 to 130 mg/day was selected based on professional judgment. Since negative ingestion rates are reasonable results given the uncertainty in the mass balance methodology, but unreasonable as inputs to an exposure model, 0 mg/day was selected as the plausible minimum value. The maximum of 130 mg/day is greater than 80% of the individual trace element results for the 1990 study, and approximately equal to the maximum value when trace element results are averaged for each individual. Similarly, the maximum of 130 mg/day is greater than approximately 80% of the results in the 1997 study based on the "median of four best tracers" approach, and is equal to or greater than three of five single tracer results for Al, Si, and Zr. For the remaining two trace elements, Ti and Y, the standard deviations are very high (876 and 707 g/day, respectively). The low frequency of selection of these tracers as "best" tracer elements for the 40 subject weeks (see Table A-6, footnote 2) suggests that this high variability has more to do with measurement error than with inherently high interindividual variability in soil ingestion.

Given a plausible range, but no further information regarding the shape or spread of the distribution (e.g., mean, SD), a uniform distribution was selected. A uniform distribution assigns equal probability to any value within the range, rather than weighting certain values by ascribing a nonuniform shape. This can be contrasted with a normal or lognormal distribution, for which values at the tails of the distribution are much less likely than those nearer to the mean or median. For example, if a lognormal distribution was selected with a mean of 57 mg/day and SD of 65 mg/day (loosely based on results for aluminum in the 1990 study), an ingestion rate of 100 mg/day would be the 86^{th} percentile of the distribution (i.e., less than 15% of values are expected to be greater than 100), whereas with the uniform distribution, nearly one-fourth (25%) of the values are expected to be greater than 100 mg/day. In general, compared with a uniform distribution, the use of an untruncated lognormal distribution can be expected to yield lower values in the central, or mid-percentiles of the distribution, and higher values in the upper tail of the uniform distribution. Figure A-5 clearly illustrates this concept. In this example, the two distributions intersect at approximately the 90^{th} percentile, yielding higher soil ingestion rates with a lognormal distribution beyond this point. Until the data accommodate a more rigorous evaluation of the shape of the distribution, uncertainty associated with the use of a uniform distribution will remain unresolved.

Why Use a Probability Distribution Instead of a Point Estimate? – The use of a probability distribution instead of a point estimate when data are limited is a judgment call that requires consideration of two key factors: (1) the objectives of the Monte Carlo modeling approach, and

(2) the representativeness, quantity, and quality of the available data. For this analysis, the ultimate goal is to use quantitative information on variability in exposure to help inform the risk management decisions at Rocky Flats. An important component of a Monte Carlo simulation is the sensitivity analysis, which can help to focus the interpretation of the risk distributions on the key variables. Variables that are represented by point estimates are essentially excluded from the sensitivity analysis because they do not contribute to variability in the risk estimates. Secondly, while the empirical data are sparse, it is reasonable to assume that the two studies were appropriately conducted and that the subjects are representative surrogates for a larger population of adults. In other words, the main deficiency is that there are too few measurements to evaluate additional distributions with any confidence. The selection of a uniform distribution reflects a balance between the available data, and the information that can be provided for the risk management decision by allowing the adult soil ingestion rate to contribute to the overall sensitivity analysis. In addition, the parameters selected for the uniform distribution (min, max), while largely based on judgment, were informed by the available data and do reflect an effort to yield higher soil ingestion rates in the risk model than would otherwise have been obtained with selections of other probability distributions.

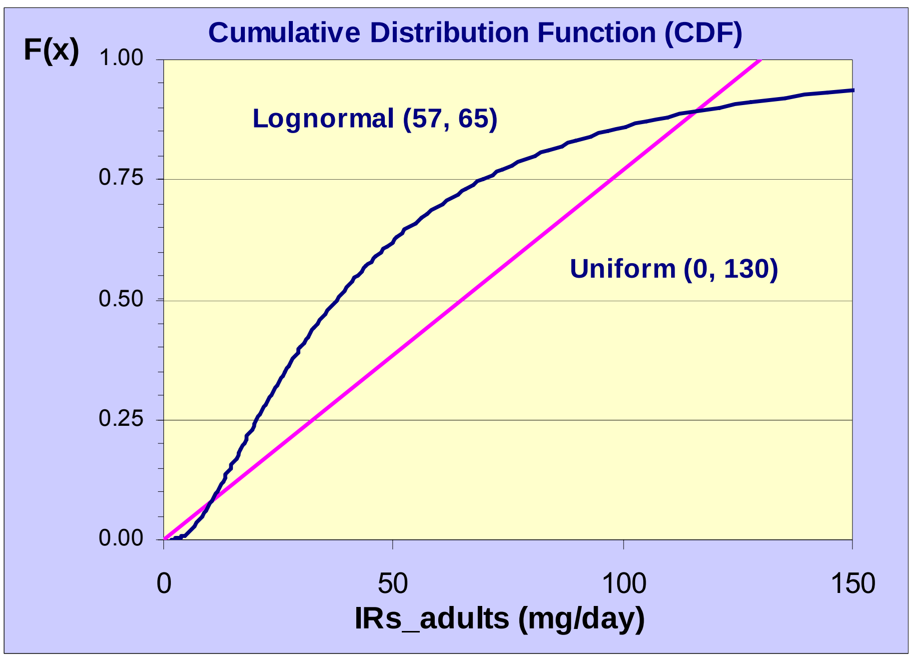


Figure A-4. Comparison of the Uniform (0, 130) and the Lognormal (57, 65) distribution based on the Calabrese et al. (1990) results for Al. Higher soil ingestion rates are approximately 90% more likely with the use of a uniform distribution (in this example). The uniform is truncated at the maximum value of 130 mg/day, whereas the lognormal is untruncated at the high-end and will yield ingestion rates greater than 130 mg/day approximately 8% of the time.

Table A-6. Confidence ratings for soil ingestion rate for adults (IRs_adult).

Considerations	Rationale	Rating
Study Elements		
• Level of peer review	Relevant analyses on data from two study populations are given in the peer review literature.	High
• Accessibility	Papers are available from peer review journals. One study is evaluated in the *Exposure Factors Handbook* (U.S. EPA, 1997).	High
• Reproducibility	Methodology is presented in literature but not always at the level of the individual subject-day-trace element level. Therefore, the summary results cannot be reproduced from the original data.	Medium
• Focus on factor of interest	Studies are designed as pilot studies to validate the mass balance tracer methodology applied to children; adult subjects were fed capsules of soil, and trace element from capsule and food were subtracted from total excreted to yield estimates of incidental soil/dust ingestion.	Medium
• Representativeness of study population	Adults ages 22 to 45 years, both male and female, including relevant geographic location (West). Small sample sizes (n = 6, n = 10) and study duration (four weeks or less) plus uncertainty in activities and hobbies during study period.	Low
• Primary data	Analyses are based on primary data, with emphasis on two studies (n = 6 and n = 10).	High
• Currency	Studies conducted within the past 15 years.	High
• Adequacy of data collection period	Data collected over seven consecutive days in September. Difficult to assess if conditions during period reflected a peak period of exposure to soil. Not adequate for estimating long-term average behavior because study period was short and did not include multiple time points. Insufficient data to generate reliable estimates of day-to-day variability.	Medium
• Validity of approach	Fecal tracer mass balance technique is generally considered to be the most reliable technique, despite difficulties in validation. Uncertainties include high inter-trace element variability and low precision of recovery for certain subject days, possibly due to absorption of trace elements and variability in GI transit times within subjects and between subjects. Best tracer methodology was developed to identify trace element(s) on each subject-day that had the lowest food/soil ratio.	Medium
• Study size	See representativeness above.	Low
• Characterization of variability	Use of uniform distribution reflects high uncertainty in interindividual variability due to small sample size and inconsistent results by trace elements. No attempt was made to quantify intraindividual variability in order to derive a distribution relevant to long-term average.	Low
• Lack of bias in study design (high	Use of soil capsules ensures a higher quantity of trace elements excreted, but numerous days yielded negative mass	Low

Considerations	Rationale	Rating
rating is desirable)	balance results, especially for the study with n = 10 for which nearly 50% of subject-days had negative estimates.	
• Measurement error	Potential for inaccurate mass balance calculation due to absorption of trace elements and variability in GI transit times. See bias discussion above.	Low
Other Elements		
• Number of studies	Two studies using same methodology on populations in different geographic areas.	Medium
• Agreement between researchers	General agreement that studies are best available. Not much debate yet on selection of probability distributions to characterize variability.	Medium
Overall Confidence Rating	Primary data but small sample sizes. Repeat measurements over three to four week period, although no attempt to quantify intra-individual variability. Uncertainty in mass balance methodology given the number of days of negative ingestion rate estimates.	Low

SOIL INGESTION RATE IN CHILDREN (AGES 0 TO 6 YEARS)

A review of the literature on soil ingestion rates was conducted in order to develop a probability distribution function for use in Monte Carlo simulations. The probability density function is intended to characterize interindividual variability in long-term average soil ingestion rates among children. The following discussion explains the general fecal tracer study methodology used to indirectly assess ingestion rates. The most relevant empirical data are summarized, and justification for the most applicable distribution for Rocky Flats is offered.

Extrapolation from Short-term to Long-term Average Ingestion Rate – While the goal is to characterize interindividual variability in ingestion rates over long time periods (e.g., years), the study designs capture short periods (e.g., days). Different approaches can be used to extrapolate from the short-term data to a long-term estimate of variability. The simplest approach is to assume that the variability measured over a period of days is representative of the variability over a period of years. This is a common assumption in risk assessment, and is presumed to be protective of the exposed population because it will tend to overestimate variability in long-term average ingestion rate. The degree to which it may overestimate is unquantifiable without additional empirical data over longer time periods (e.g., repeated sampling of the same study population). An alternative approach that has been applied to estimates of soil ingestion rates in children is to use the information available on intraindividual variability over a short time period (e.g., 8 days) to extrapolate to estimates of intraindividual variability over a one-year period. By repeating this process for the entire study population, an estimate of interindividual variability in one-year average ingestion rates is obtained. The results of this statistical approach, along with the relevant studies that describe the statistical analysis of available data, are presented below as the basis for the probability distribution developed for the assessment at Rocky Flats.

A.1.2.1 PROBABILITY DISTRIBUTION

The following probability distribution was developed for use in probabilistic risk calculations:

IRs_child ~ Truncated Lognormal (47.5, 112, 0, 1,000) mg/day

The truncated lognormal distribution is defined by four parameters:

• arithmetic mean	47.5	mg/day
• standard deviation	112	mg/day
• minimum	0	mg/day
• maximum	1,000	mg/day

For the RESRAD model, the same distribution can be used by converting the units from (mg/day) to (g/yr):

• mean	47.5	mg/day x 0.001 g/mg x 365 day/yr =	17.34 g/yr
• standard dev	112	mg/day x 0.001 g/mg x 365 day/yr =	40.88 g/yr
• minimum	0	mg/day x 0.001 g/mg x 365 day/yr =	0 g/yr
• maximum	1,000	mg/day x 0.001 g/mg x 365 day/yr =	365 g/yr

Therefore, applying the same assumptions as the Standard Risk equations, the equivalent distribution for the child rural resident for use in RESRAD is:

IRs_child ~ Truncated Lognormal (17.34, 40.88, 0, 365) g/yr

The basis for the probability distribution is presented in the sections that follow. By applying an upper truncation limit to the lognormal distribution, both the central tendency and the variance of the distribution will be reduced when the distribution is used in a Monte Carlo simulation. A comparison of summary statistics for the lognormal and truncated lognormal is given in Table A-8. By imposing a relatively high upper truncation limit of one gram per day (1,000 mg/day, which is equivalent to the 99.8th percentile of the lognormal distribution), the "effective" mean and standard deviation (SD) of this distribution are reduced by 6% and 28.6%, respectively (see Figure A-6 below, which shows % change in SD as a function of truncation).

Table A-7. Comparison of summary statistics for the lognormal distribution for soil ingestion rate for children when an upper truncation limit of 1,000 mg/day is used.

Summary Statistic	IRs_child (mg/day)	
	Untruncated	Truncated[1]
mean	47.5	44.6
Stand. Dev.	112.0	79.9
Minimum	0	0
25th %ile	7.4	7.4
50th %ile	18.5	18.5
75th %ile	46.8	46.5
90th %ile	107.5	106.1
95th %ile	177.0	172.9
96th %ile	204.6	198.9
99th %ile	450.7	411.4
Maximum	∞	1,000.0

[1] Mean and standard deviation are exact solutions; percentiles are estimated by Monte Carlo simulation using 10,000 iterations and Latin Hypercube sampling.

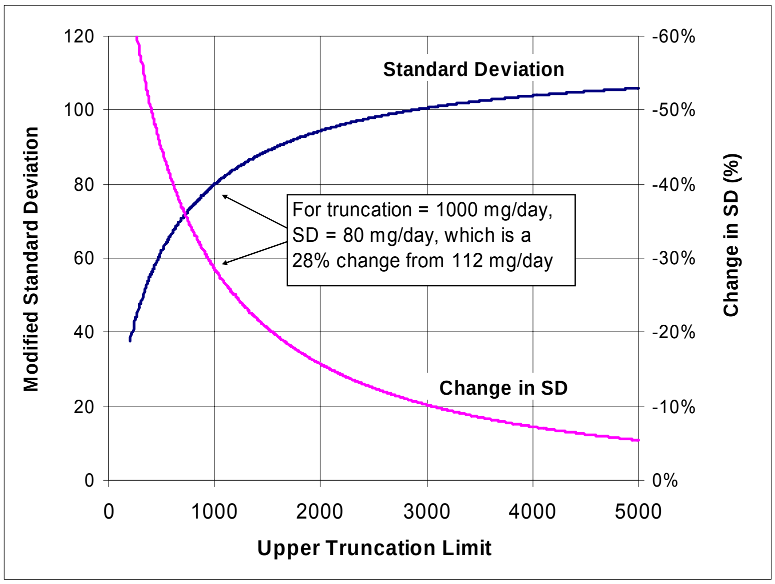


Figure A-5. Effect of upper truncation limit on the standard deviation of the lognormal distribution for soil ingestion rate for children.

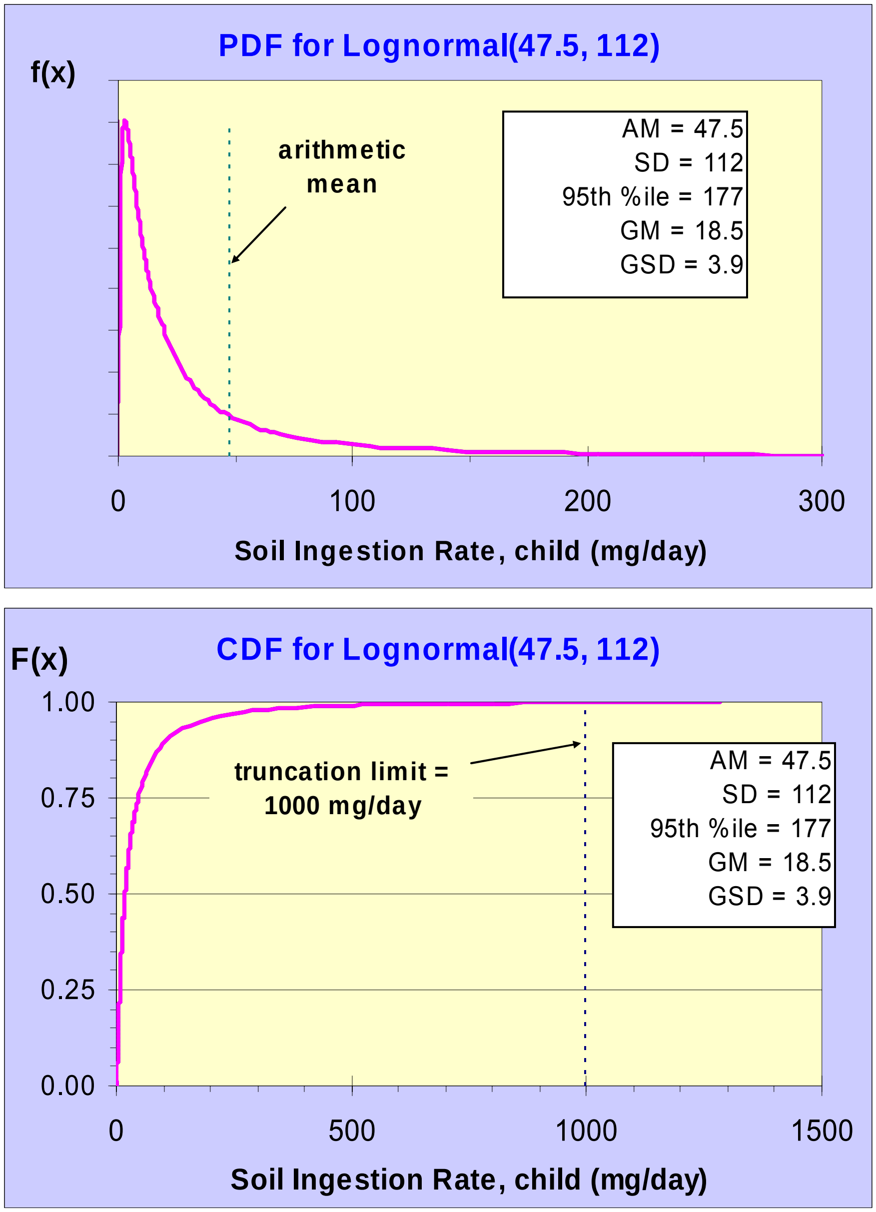


Figure A-6. Probability density function and cumulative distribution function views of the probability distribution for child soil ingestion rate (mg/day). Parameter values given in text boxes correspond to the untruncated lognormal probability distribution.

A.1.2.2 UNCERTAINTIES IN THE PROBABILITY DISTRIBUTION

There are multiple sources of uncertainty associated with the probability density function developed to characterize interindividual variability in childhood soil ingestion rates. Stanek et al. (2001) gives a comprehensive summary of potential biasing factors:

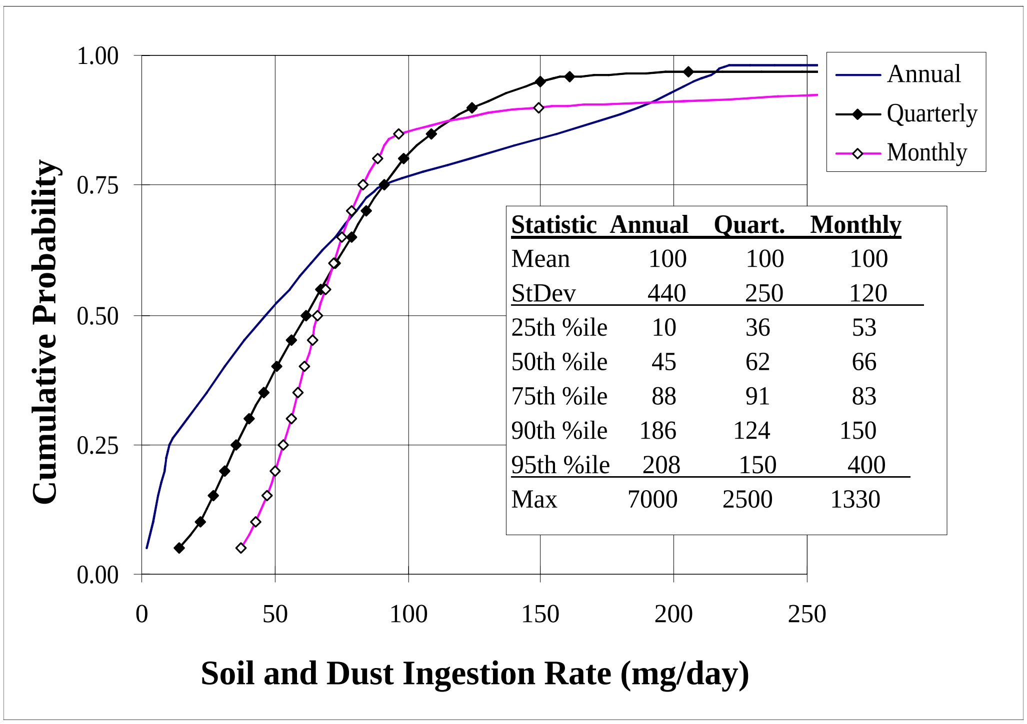
- Determining trace element concentrations in non-soil sources;
- Estimating gastrointestinal transit time from food to fecal samples;
- Implementing exclusion criteria to remove unreliable daily estimates for certain tracer elements;
- Inconsistency among tracer elements in daily estimates;
- Assuming that intra-individual variability is characterized by a lognormal distribution, and that all individuals exhibit the same intra-individual variability; and
- Selecting a maximum value for truncating the probability density function that characterizes inter-individual variability

Selection of a Single Data Set **–** Multiple studies have been conducted on different study populations, including Anaconda, Amherst, and Washington State. As discussed above, the Anaconda study is considered to be more representative of the variability in soil ingestion rates among children that may be exposed in a residential scenario at Rocky Flats. It may be tempting to combine the data sets in order to increase the sample size and capture the "heterogeneity" among subpopulations of children in different locations. Given the number of differences in study design, data analysis, and population characteristics, it is not appropriate to combine the data for purposes of characterizing variability in soil ingestion rates. The different data sets do provide a measure of uncertainty, and it might be of interest to develop separate probability density functions for each data set. This level of quantitative uncertainty analysis is beyond the scope of this appendix.

Uncertainty Due to Model Time Step **–** A model time step is essentially an averaging time—it refers to the time period represented by a random value selected from a probability distribution. For most Monte Carlo models, a single random value is selected to represent a long-term average value. For example, for a single iteration of the model (representing a hypothetical child), a random value may be selected from the empirical distribution function in order to represent the average daily ingestion rate over seven years. This is a simplifying assumption given the lack of longitudinal data on ingestion rates among individuals. An alternative would be to represent the seven-year average value by selecting seven random year values, essentially simulating an individual's exposures over time. In general, distributions based on estimates of short-term surveys will tend to overestimate the variability in long-term average values. Until repeat measures are used to estimate ingestion rates among a population, intraindividual variability will remain an unquantifiable source of uncertainty.

The importance of the model time step assumption can be explored. Explicit model time steps can be employed to simulate an individual's exposures over time. For example, Stanek (1996) applies an annual time step because he assumes that the empirical distribution described above represents interindividual variability over a one-year period (i.e., a single random sample from this distribution represents the average IR_{soil} for an individual for the year). According to the central limit theorem, the SD of the sample distribution is inversely proportional to the square root of *n*. Thus, decreasing the time step from one year to one month would increase the number of random samples needed to estimate the average annual ingestion rate, and effectively reduce the SD of the distribution by a factor of approximately 3.5 (Goodrum et al., 1996). The effect that changing the model time step has on the distribution of IR_{soil} is summarized in Figure A-8.

Several alternative approaches to simulating intraindividual variability could be explored, but were not in this analysis. For example, the method suggested by Stanek (1996) could be used to derive the response error variance of the best subject-day estimates of IR_{soil} given by the Daily Estimate Method. The resulting empirical distribution could be considered a measure of both the latent distribution and short-term variability in IR_{soil}. The model time step could then be used to explore the effect of uncertainty in extrapolating distributions over different time intervals. Another approach would be to auto correlate random samples by constraining the sample space to a percentile range of the cumulative probability density function. For example, if an individual was assumed to have a high latent exposure (e.g., more than 88 mg/day, the upper quartile of the IR_{soil} probability density function), each consecutive random value could be weighted to the upper quartile (i.e., greater than 75^{th} percentile) of the distribution. This approach would simulate both the underlying, latent distribution (i.e., relatively high IR_{soil}), as well as the stochastic, short-term variability in average ingestion rates for each consecutive time step (i.e., between 88 and 7,000 mg/day).



Statistic	Annual	Quart.	Monthly
Mean	100	100	100
StDev	440	250	120
25th %ile	10	36	53
50th %ile	45	62	66
75th %ile	88	91	83
90th %ile	186	124	150
95th %ile	208	150	400
Max	7000	2500	1330

Figure A-7. Cumulative distributions of soil and dust ingestion rates based on different model time steps using Monte Carlo simulations of n = 5,000 iterations and the Amherst cohort (Calabrese et al., 1989).

The methodology and data analysis associated with the published estimates of child soil ingestion rates is complex. An overview of the methodology is given below in order to highlight the major assumptions and uncertainties associated with the development of the distribution.

A.1.2.2.1 FECAL TRACER METHODOLOGY FOR ESTIMATING SOIL INGESTION RATE

Empirical estimates of soil ingestion rates (IR_{soil}) in children have been made by backcalculating the mass of soil and/or dust a subject would need to ingest to achieve a tracer element mass measured in collected excreta (i.e., feces and urine) (Calabrese et al., 1996). Equation 1 gives the general expression for the trace element ("tracer") mass balance:

$$[tracer]_{out} - [tracer]_{in,nonsoil} = [tracer]_{in,soil}$$

where $[tracer]_{out}$ is the average daily tracer mass (μg) measured in feces and urine, $[tracer]_{in,\,non\text{-}soil}$ is the average daily tracer mass measured in non-soil ingesta (i.e., food, water, toothpaste, and medicines), and $[tracer]_{in,\,soil}$ is the estimated average daily tracer mass in ingested soil. Dividing all terms by the measured tracer concentration in soil (μg/g) yields an estimate of the average daily soil ingestion rate, as given by Equation 2:

$$\frac{[tracer]_{out} - [tracer]_{in,nonsoil}}{\frac{[tracer]_{soil}}{[soil]}} = \frac{[tracer]_{in,soil}}{\frac{[tracer]_{soil}}{[soil]}} = [soil] = IR_{soil}$$

A.1.2.2.2 EMPIRICAL DATA

Three seminal studies, briefly summarized below, used this mass-balance approach and were considered appropriate for quantifying variability and uncertainty in IR_{soil}. Pathways for non-soil/non-food intake of tracers (e.g., inhalation and dermal absorption) and excretion (e.g., sweat and hair) were not measured in these studies and are thought to be minor components of the overall tracer mass balance (Barnes, 1990).

Calabrese et al. (1989) – Eight trace elements (Al, Ba, Mn, Si, Ti, V, Y, and Zr) were measured in a mass-balance study of 64 children ages one to four years over eight days (i.e., four days per week for two weeks) during late September and early October. Participants represent a nonrandom study population selected from day-care centers and volunteer families in an academic community in Amherst, MA. A single composite soil sample was collected from up to three outdoor play areas identified by parents as locations where subjects spent the most time. Similarly, indoor dust samples were vacuumed from floor surfaces that parents reported to be common play areas during the study. Each week, duplicate food samples were collected for three consecutive days, and fecal samples (excluding diaper wipes and toilet paper) were collected for four consecutive days for each subject. A total of 128 subject-week estimates of IR_{soil} were made. Also, since food and fecal samples were collected on multiple days per subject, a total of 439 subject-day estimates of IR_{soil} were also made (Stanek and Calabrese, 1995a). For each subject-week-day, a maximum of eight estimates of IR_{soil} were made, each estimate corresponding to a unique trace element.

Davis et al. (1990) – Three trace elements (Al, Si, and Ti) were measured in a mass-balance study of 101 children ages 2 to 7 years over four consecutive days during the summer. Participants represent a random sample of the population in a three-city area of southeastern Washington State. A single composite soil sample was collected from outdoor play areas identified by parents. Indoor dust samples were collected by vacuuming floor surfaces of the child's bedroom, the living room, and the kitchen, as well as by sampling the household vacuum cleaner. Information on dietary habits and demographics was collected in an attempt to identify behavioral and demographic characteristics that influence soil ingestion. Although duplicate food and fecal samples (including diaper wipes and toilet paper) were collected on a daily basis, samples for each individual were pooled to derive a one-week average estimate of IR_{soil}. A total of 101 subject-week estimates of IR_{soil} were made. For each subject-week, a maximum of three estimates of IR_{soil} were made, each estimate corresponding to a unique trace element.

Calabrese et al. (1997a) – Eight trace elements (Al, Si, Ti, Ce, Nd, La, Y, and Zr) were measured in a mass-balance study of 64 children ages 1 to 3 years over seven consecutive days during September. Participants were selected from a stratified simple random sample of approximately 200 households from six geographic areas in and around Anaconda, MT. A single composite soil sample was collected from up to three outdoor play areas identified by parents as locations where subjects spent the most time. Similarly, indoor dust samples were vacuumed from floor surfaces that parents reported to be common play areas during the study. Duplicate food and fecal tracer element samples were collected for 448 and 339 subject-days, respectively. A total of 64 subject-week estimates of IR_{soil} were made; subject-day estimates of IR_{soil} have recently been published (Stanek and Calabrese, 1999; 2000; Stanek et al., 2001a). Three trace elements (Ce, La, and Nd) were not used to estimate IR_{soil} because soil concentrations of these elements were found to vary by particle size (Calabrese et al., 1996). For each subject-week, a maximum of five estimates of IR_{soil} were made, each estimate corresponding to a unique trace element. Final soil ingestion estimates are based on soil particle size less than 250 μm (as opposed to 2,000 μm).

Table A-8. Confidence ratings for soil ingestion rate for children (IRs_child) for Rural Resident scenario.

Considerations	Rationale	Rating
Study Elements		
• Level of peer review	Relevant analyses on data from two study populations are given in the peer review literature.	High
• Accessibility	Papers are available from peer review journals and are evaluated in *Exposure Factors Handbook* (U.S. EPA, 1997).	High
• Reproducibility	Methodology is presented in literature but without original survey data so results cannot be reproduced.	Medium
• Focus on factor of interest	Studies are designed to quantify incidental ingestion of soil by children, including soil transported indoors (dust).	High
• Representativeness of study population	Key study represents children of relevant ages (1 to 3 years), both male and female, including relevant geographic location (West). Difficult to assess representativeness of race and socio-economics, and potential bias (underestimation) introduced by selection of population near a smelter site who may have altered exposure patterns in response to educational outreach.	Medium
• Primary data	Analyses are based on primary data.	High
• Currency	Studies conducted within the past 10 years.	High
• Adequacy of data collection period	Data collected over seven consecutive days in September. Difficult to assess if conditions during period reflected a peak period of exposure to soil. Not adequate for estimating long-term average behavior because study period was short and did not include multiple time points. Insufficient data to generate reliable estimates of day-to-day variability.	Medium
• Validity of approach	Fecal tracer mass balance technique is generally considered to be the most reliable technique, despite difficulties in validation. Uncertainties include high inter-trace element variability and low precision of recovery for certain subject days, possibly due to absorption of trace elements and variability in GI transit times between subjects and within subjects.	Medium
• Study size	Both the number of subjects and duration of study period affect the quantity of subject-days of data. Sixty-four children were studied in two key studies, ranging from 5 to 8 days.	Medium
• Characterization of variability	High uncertainty in use of lognormal distribution to characterize intra-individual variability in order to extrapolate to long-term average ingestion rates. Method does not account for potential correlation between mean and SD on an individual child basis (all children are assumed to exhibit the same short-term variability. Lognormal distribution fit to reported percentiles is adequate, but uncertainty in upper truncation limit (1,000 mg/day).	Low

Considerations	Rationale	Rating
• Lack of bias in study design (high rating is desirable)	Key study population is from relevant geographic location, but potential bias from selection of population near a smelter site. Soil was sieved to yield a more representative size fraction of soil for exposure. Exclusion criteria remove daily estimates for selected trace elements thought to be unreliable, but cutoff is subjective.	Medium
• Measurement error	Potential for inaccurate mass balance calculation due to absorption of trace elements and variability in GI transit times.	Medium
Other Elements		
• Number of studies	Two key studies using same methodology on populations in different geographic areas.	Medium
• Agreement between researchers	General agreement that studies are the best available. Not much discussion yet on selection of probability distributions to characterize variability.	Medium
Overall Confidence Rating	Variability over one week period may overestimate variability extrapolated to one year. Uncertainty in mass balance methodology, and assumption associated with selection of probability distribution type and parameters. Recent, primary data from representative population, and moderate sample size.	Medium

A.1.2.3 INTERPRETATION OF INTER-TRACER VARIABILITY IN SOIL INGESTION

Trace elements were selected for estimating soil ingestion in these mass-balance studies because they are natural constituents of soil, present in relatively low concentrations in food, poorly absorbed in the GI tract, and not inhaled in appreciable amounts (Barnes, 1990). Theoretically, each trace element should yield the same estimate of daily soil ingestion using Equation 2. However, the following sources of measurement error are attributed to the high inter-tracer variability and low precision of recovery observed for many subject-days in each study:

- High element concentration in food, yielding a high food-to-soil (F/S) ratio (Calabrese and Stanek, 1991);
- Variability in food transit times between subjects and between subject-days for a given child resulting in input/output misalignment errors, and lower precision of recovery for elements with higher F/S ratios (Stanek and Calabrese, 1995b); and
- Incomplete collection of both inputs (e.g., additional non-soil sources of tracer) and outputs (e.g., fecal samples on diaper wipes and toilet paper; urine samples for elements with low fecal-to-urine ratios).

The adult validation study by Calabrese et al. (1989, 1990) demonstrated that negative soil ingestion estimates occur more frequently for trace elements with high F/S ratios. At a low dose of soil (100 mg/day), 7 of 48 (15%) subject-days displayed negative IR, while at a high soil dose (500 mg/day), no subjects displayed negative IR. The adult study by Calabrese et al. (1997a), which used a slightly different set of trace elements, demonstrated a sufficiently high recovery for most elements to quantify ingestion rates in the range 20 to 500 mg/day. These results may also apply to children, keeping in mind potential differences in the following areas among different age groups: GI transit times, absorption efficiencies, F/S ratio, and variability in daily tracer ingestion (Calabrese and Stanek, 1991). For the studies with children, negative IR estimates were observed on 12 to 44% of subject-days (depending on the trace element) by Calabrese et al. (1989); 12 to 32% by Davis et al. (1990); and approximately 55% (preliminary assessment of Al and Si) by Calabrese et al. (1997a). Given that high inter-tracer variability in subject-day estimates of IR_{soil} is a function of both tracer-specific properties and input/output errors, it is unlikely that a reliable estimate of IR_{soil} for all subject-days can be derived from any single trace element. This is confirmed by the differences in estimates of ingestion rates among different tracers. For example, tracer-specific estimates of median IR_{soil} in the Calabrese et al. (1989) study range by an order of magnitude (i.e., 9 to 96 mg/day). The following two methodologies have been developed to identify the set of trace elements that is likely to provide the most reliable estimate of IR_{soil}.

Best Tracer Method (BTM) **–** Each subject-week estimate of IR_{soil} is based on the trace element(s) with the best (i.e., lowest) F/S ratios for that week (Stanek and Calabrese, 1995b). This approach reduces the effect of transit time errors (i.e., poor temporal correspondence between food and fecal samples). Potential bias from other sources of error for specific tracers may be reduced by estimating the median of multiple tracers with low F/S ratios for a subject-week. Stanek and Calabrese (1995a) recommend estimating the distribution of IR_{soil} based on the median of the four best tracers for each subject-week. Using this approach, data from the Calabrese et al. (1989) and Davis et al. (1990) studies were combined to yield 229 subject-week estimates of IR_{soil} representing 165 children between the ages of 0 and 6.

Daily Estimate Method **–** A single estimate of IR_{soil} is made for each tracer-subject-day for each child (Stanek and Calabrese, 1995a; 2000). A maximum of eight such estimates (one per tracer) was determined for each of 64 children in the Calabrese et al. (1989) study. This approach establishes a set of criteria to identify tracer-subject-day estimates that may be unreliable for each subject-week, based on the relative standard deviation (RSD) given by Equation 3:

$$\Delta_i = max(50, d_i e^{[1.5 - 0.35 \, ln(d_i)]})$$

$$\delta_i = \left| d_{ij} - d_i \right|$$

$$RSD_i = \frac{\Delta_i}{\delta_i}$$

where d_i is the median IR_{soil} for the i^{th} day of a given subject-week, d_{ij} is the IR_{soil} for the j^{th} tracer on the i^{th} day of a given subject-week, Δ_i is the maximum of either 50 mg/day or a function of d_i, and δ_i is the absolute value of the difference between a single tracer element and the median among the group of tracers on a given day. Stanek and Calabrese (1995a) limited the maximum value of Δ_i to 50 mg/day to reduce any bias associated with low median estimates of IR_{soil}. If, for a given d_i, δ_i more than Δ_i, then RSD less than 1.0 and element j is identified as an outlier estimate of IR_{soil}. The median of the remaining tracers for each subject-day was considered the best estimate of IR_{soil}.

The Daily Estimate Method attempts to correct for positive and negative mass-balance errors at the level of the subject-day. This approach reduces the effect of transit time errors by directly linking the passage of food and fecal samples for each daily estimate. Like the BTM approach, it reduces tracer-specific source errors by calculating the median of multiple tracer estimates. An advantage of this approach over BTM is that it also allows for an estimate of intraindividual (within subject) variability in IR_{soil}. After applying the RSD exclusion criteria to the Calabrese et al. (1989) Amherst data, daily estimates of IR_{soil} (based on the median of tracer-specific estimates) were available for at least four days for all subjects, and at least six days for 94% of the subjects (Stanek and Calabrese, 1995a). Assuming each subject's daily IR_{soil} is lognormally distributed, subject-specific parameters for lognormal probability density functions were defined based on the mean and variance of the 4 to 8 daily IR_{soil} values. Each lognormal probability density function was then used to define daily ingestion rates over a 365-day period. The use of a lognormal distribution (instead of other right-skewed distribution) is an acknowledged source of uncertainty that was not explored further due to the limited number of days of data for each individual (Stanek and Calabrese, 1995a). A similar approach could not be applied to the Davis et al. (1990) data because daily estimates of IR_{soil} were combined to define subject-weeks. This approach was also applied to the Calabrese et al. (1997a) Anaconda data (Stanek and Calabrese, 2000) as summarized in Table A-10 in Section 1.2.5.

A.1.2.4 EVALUATION OF SHORT-TERM AND LONG-TERM EMPIRICAL DISTRIBUTION FUNCTION'S (EDF) FOR SOIL INGESTION RATE

As of 1994, estimates of childhood soil ingestion rates from short-term studies were assumed to be representative of long-term rates. U.S. EPA (1994 a, b) recommended a default central tendency estimate (CTE) of IR_{soil} = 135 mg/day for ages 12 months to less than 48 months based on a review of mean tracer-specific estimates given by Binder, et al. (1986), Clausing, et al. (1987), Calabrese et al. (1989), and Davis et al. (1990). Currently, only two of the mass balance fecal tracer studies are suitable to estimate daily soil ingestion rates needed to develop estimates of long-term average rates: (1) Amherst, MA (Calabrese et al., 1989; Stanek and Calabrese, 1995a) and (2) Anaconda, MA (Calabrese et al., 1997a; Stanek and Calabrese, 2000; Stanek et al., 2001a). Table A-10 summarizes the estimates of interindividual variability in IR_{soil} derived from the results of the three soil ingestion studies with children that used a mass-balance approach. An empirical cumulative distribution function (ECDF) was developed from the summary statistics derived by the Daily Estimate Method (i.e., Daily Mean, 1+) applied to both the Amherst and Anaconda data. These studies and the statistical approach were selected for the following reasons:

- The ingestion rates estimated by Calabrese et al. (1989) generally have less uncertainty related to input/output misalignment error than the estimates by Davis et al. (1990). For example, nearly 90% of the subject-weeks reported by Calabrese et al. (1989) had at least two trace elements with F/S ratios lower than the lowest F/S ratios reported in the Davis et al. (1990) study (Stanek and Calabrese, 1995b). In addition, although titanium (Ti) has relatively low F/S ratios in both studies, it displayed exceptionally high source error (Calabrese and Stanek, 1995; Stanek et al., 2001). Consequently, Ti, one of only three tracers used in Davis et al. (1990), may provide unreliable estimates of IR_{soil}.

- The Daily Estimate Method is preferred over BTM because (1) it identifies sources of potential measurement error at the level of the subject-day rather than the subject-week, and (2) intraindividual variability in IR_{soil} can be quantified and extrapolated over longer time periods. Both of the studies by Calabrese (1989; 1997a) data are amenable to this method, whereas the Davis et al. (1990) estimate of IR_{soil} is for subject-weeks.

Three key assumptions were made in developing a probability distribution from each of the Calabrese data sets using the Daily Estimate Method:

(1) Subject-day estimates of IR_{soil} are reasonable approximations of the combined ingestion of outdoor soil and indoor dust. For simplicity, Stanek and Calabrese (1995a) based all soil ingestion estimates on trace element concentrations in soil, not dust. Theoretically, if concentrations in soil and dust were the same, this approach would correctly account for ingestion from both sources. Relative differences in average concentrations between outdoor soil and indoor dust for the Calabrese et al. (1989) study range from 6 to 55% for different trace elements (Stanek and Calabrese, 1992). Calabrese et al. (1989) proposed apportioning residual fecal tracers using a time-weighting approach, which assumes that soil ingestion is proportional to time spent in a particular location. This is also a simplistic approach since soil and dust exposure may vary due to differences in hand-to-mouth activity, weather, and degree of adult supervision. For the data used to generate a probability density function for Rocky Flats, no attempt was made to account for potential differences between soil and dust ingestion rates.

(2) A reasonable upper bound for variability in the long-term average ingestion rate is 1,000 mg/day. This assumption reflects an understanding of both intraindividual and interindividual ingestion rates. There is considerable intraindividual variability over a one-year period with respect to the frequency and magnitude of soil ingestion. While most children ingest relatively small amounts of soil on most days, occasionally they will ingest large quantities (i.e., more than 1,000 mg/day). Therefore, while the annual average IR_{soil} may be low for a given child, day-to-day variability may result in several subject-days of high IR_{soil} per year. This hypothesis is suggested by U.S. EPA (1994a) and supported by soil ingestion studies by Calabrese et al. (1989) and Wong (1988), as summarized by Calabrese and Stanek (1993). In the Calabrese et al. (1989) study, one child ingested an estimated 20 to 25 grams of soil on 2 of 8 days (Calabrese, et al., 1993). A second child displayed more consistent but less striking soil pica in which high soil ingestion (1 to 3 g/day) was observed on 4 of 7 days (Calabrese et al., 1997b). Wong observed soil pica (i.e., more than 1.0 g/day) in 9 of 84 individual subject-days (10.5%) for Jamaican children ages 0.3 to 7.5 years, and at least 1 of 4 days for 5 of 24 (20.8%) children of normal mental capability. One mentally retarded child displayed consistently extreme soil pica over the four days (48.3, 60.7, 51.4, and 3.8 g soil).

    Stanek and Calabrese (1995a) fit individual subject-day estimates from Calabrese et al. (1989) to lognormal distributions to estimate the number of days per year each child might be expected to ingest more than 1.0 g/day. Model-based predictions suggest the majority (62%) of children will ingest more than 1.0 g soil on 1 or 2 days/yr, while 42%

and 33% of children were estimated to ingest more than 5 and more than 10 g of soil on 1 or 2 days/yr, respectively.

(3) The developmental period during which the frequency and magnitude of soil ingestion is likely to be the greatest coincides with the period of peak hand-to-mouth activity (i.e., ages 1 to 4 years). It should be noted that empirical data from the mass-balance studies do not provide any evidence that children ages 1 to 4 years ingest more soil than other age groups (Calabrese and Stanek, 1994).

For simplicity, it is assumed that random values selected from this distribution are independent for each time step of exposure. In other words, the latent distribution of individual ingestion rates is assumed to be equal for all individuals in the population. It is more plausible that patterns of soil ingestion rate for an individual are a combination of a latent distribution and some measure of day-to-day variability. Several approaches may be used to simulate this type of exposure pattern in a population. Stanek (1996) combined a latent distribution and response error distribution (for tracers Al, Si, Y) to define an empirical distribution, and then extrapolated the empirical distribution over 365 days. The same approach was employed for the Anaconda data (Stanek and Calabrese, 2000), resulting in 75% lower values for the 365-day average than for the daily values. The resulting distributions are given in Table A-10. The response error variance was calculated as the variance in subject-day estimates of $\ln(IR_{soil})$ divided by the number of subject-day estimates for a given child. The average response error variance among all 64 Amherst subjects was 0.47, while the average number of subject-days per child was 6.1. Converting to an anti-logarithm estimate, the average standard deviation (SD) in daily soil ingestion was approximately 66 mg/day.

A similar approach was used to determine variance estimates for the Anaconda data (see Table IV of Stanek and Calabrese, 2000). For purposes of comparison, day-to-day variance in soil ingestion from the Anaconda study (excluding titanium and Tukey far-out) was reported as 9,094 (SD = 95 mg/day), whereas day-to-day variance from the Amherst study (including aluminum, silicon, yttrium, zirconium) was 15,528 (SD = 124 mg/day). These expressions provide the only quantitative measure of intraindividual variability in IR_{soil}.

Extrapolating the empirical distribution over 365 days assumes that the response error variance measured over a short-term period (i.e., subject-week) is the same as the variance over a long-term period (i.e., 365 days). In addition, it assumes that the variance is independent of the average daily IR_{soil} for a given subject week. The upper tail of the empirical distribution may be underestimated if a positive correlation exists between the mean and variance of IR_{soil} for a given subject-week. This source of uncertainty could be explored for both Amherst and Anaconda subject-day estimates, but was not for this analysis.

A.1.2.5 FINAL SELECTION OF PROBABILITY DISTRIBUTION FOR SOIL INGESTION RATE

The Anaconda data (Calabrese et al., 1997a) are generally considered to be more representative of the potentially exposed population of children at the Rocky Flats:

- Study population is from the West (Montana);

- Soil was sieved at 250 μm, a more representative size fraction for particle adherence to hands, and also the size fraction with the least uncertainty in trace element concentrations;
- Exclusion criteria for daily tracer estimates resulted in a much larger database of subject-day estimates from which to develop statistical summaries. Exclusion criteria applied to the Anaconda data eliminated estimates based on Ti, and Tukey outlier criteria excluded 18 of 2,984 element-subject days (i.e., 0.45%) compared with 31.9% that would have been eliminated if the Amherst outlier criteria had been applied (Stanek and Calabrese, 2000). Outlier criteria applied to the Amherst study resulted in exclusion of 37.5% of the data (Stanek and Calabrese, 2000).

It is unclear what factors are responsible for study-to-study differences in soil ingestion rates, as was observed between the Amherst and Anaconda cohorts. The empirical distribution function is a convenient distribution for characterizing the data sets given a relatively high portion of negative values reported for ingestion rate. Non-negative continuous distributions fit to the empirical distribution function, such as lognormal, gamma, and Weibull, generally yield poor fits, as discussed by Schulz (2001). Alternatively, a series of mixed distributions or conditional distributions could be developed to make use of parametric distributions such as the lognormal for all non-negative values; these approaches are not presented in the literature.

While the percentile data can be entered into a Monte Carlo analysis as an empirical distribution function, a decision would still be needed regarding the minimum and maximum values of the distribution. Since negative values cannot be employed in a risk assessment, a lower truncation limit of 0 mg/day must be used, and could be assumed to define the minimum. This truncation limit is extended to all of the percentile values corresponding to non-negative ingestion rates. For the Anaconda data, negative values were obtained for the 25th percentile (IR_{soil} = -3 mg/day), which carries through to the best linear unbiased predictor estimates as high as the 7th percentile (see Table A-10) (Stanek et al., 2001, Table 3). The empirical distribution function developed by Stanek et al. (2001) for the long-term average ingestion rates was employed in this analysis (last column in Table A-10), and can be approximated by a lognormal distribution. For purposes of maximum likelihood estimates of the mean and SD of the lognormal distribution, a maximum of 150 mg/day was applied (slightly greater than the 99th percentile value of 137 mg/day). The choice of the maximum value for truncation can be an important source of uncertainty in risk estimates if there is a high positive correlation between risk and IR_{soil}, especially at the upper tail of the risk distribution (e.g., greater than 90th percentiles). The goodness-of-fit techniques are also sensitive to the choice of maximum values on the empirical distribution function.

Table A-9. Distribution of soil ingestion rates (mg/day) based on different methods of analyzing trace element-specific data from mass-balance studies.

Summary Statistic	Amherst, MA (n = 64) Calabrese et al., 1989; Stanek and Calabrese, 1995a					Davis et al., 1990	Anaconda, MT (n = 64) Calabrese et al., 1997a; Stanek and Calabrese, 2000; Stanek et al., 2001a			
	Median Al, Si, Ti	**Median[a]** *Top 4*	**Daily[b] Mean, 1+**	**Latent[c] Al, Si, Y**	**Empirical[d] Al, Si, Y**	**Median Al, Si, Ti**	**Median[e] Top 4**	**Daily[b] Mean, 1+**	**365-day average[h]**	**BLUP[i]**
N	128[f]	128[f]	440[g]	391[g]	391[g]	101[f]	64[f]	427[g]	427[g]	64[f]
Min	< 0	< 0	< 0	0	0	< 0	< 0	< 0	< 0	< 0
Max	11,874	11,415	7,703	470	745	905	380	219	165	137
Mean	147	132	179	20	26	69	7	31	23	na
SD	1,048	1,006	na	26	47	146	75	56	na	na
Percentile										
5th	< 0	< 0	na	2	2	< 0	< 0	< 0	< 0	< 0
10th	< 0	< 0	na	4	3	< 0	< 0	< 0	< 0	2
25th	6	9	10	7	6	15	< 0	< 0	< 0	12
50th	30	33	45	12	13	44	< 0	17	13	25
75th	72	72	88	24	28	116	27	53	40	42
90th	188	110	186	43	56	210	73	111	83	75
95th	253	154	208	60	89	246	160	141	106	91

[a] Best Tracer Method; median of best 4 of 8 tracers (i.e., 4 lowest F/S ratios) for a given subject-week (Table 6, Stanek and Calabrese, 1995b).
[b] Daily Estimate Method; mean of subject-day estimates for 1 to 8 days, where each day includes at least one (1+) trace element (Table 6, Stanek and Calabrese, 1995b; Table 2, Stanek and Calabrese, 2000).
[c] Latent distribution for tracers (Al, Si, and Y); mean (2.5) and variance (0.89) of subject-day log (soil ingestion) fit to a lognormal distribution and randomly sampled 2,000 times (Stanek, 1996, p.883).
[d] Empirical distribution for tracers (Al, Si, and Y); combines between-subject variance (latent variance divided by the number of subject-day estimates for each child (Stanek, 1996). Empirical distribution estimated as the sum of 2,000 random samples from the latent and response error distribution, see footnote c) and within-subject variance (response error distribution—parameters fit to lognormal probability density function {mean = 0, variance = 0.47}). Response error variance calculated as the mean of the within-subject standard error distributions.
[e] Best Tracer Method; median of best 4 of 5 tracers (i.e., lowest F/S ratios) for a given subject-week (Table 13, Calabrese et al., 1997a).
[f] Number of subject-weeks represented by summary statistics.
[g] Number of subject-days represented by summary statistics.
[h] Extrapolation to 365-day average versus variance components for subjects, days, and error—represented by a "shrinkage constant", yields 25% lower values (e.g., 95th percentile reduces from 141 mg/day to 106 mg/day) (Stanek and Calabrese, 2000; p. 632, last paragraph).
[i] Stanek et al. (2001a, Table 3) and reanalysis of Stanek and Calabrese (1999) results by T. Schulz (2001) (Table 1) based on best linear unbiased predictors and small sample variance for subject-days.

A lognormal distribution with an AM of 47.5 mg/day and SD of 112 mg/day was fit to the percentile data using @Risk's Best Fit software (version 3.1). A tabular and graphical summary of the distribution is presented in Figure A-7. The reasonable maximum exposure (RME) point estimate recommended for children (U.S. EPA, 1991a) of 200 mg/day is approximately the 96th percentile of this distribution. The lognormal distribution is bounded at 0 by definition, but has an infinite right tail. Given the importance of the soil ingestion rate variable in risk assessment, it is prudent to impose an upper truncation limit so that each iteration of the Monte Carlo simulation yields plausible results. The choice of an upper truncation limit is a professional judgment that weighs the confidence in the empirical data, the skewness of the probability distribution fit to the data, and a rule of thumb to avoid overly truncating the distribution (i.e., select values that remove less than 1% of the distribution). For this analysis, an upper truncation limit of 1,000 mg/day was chosen. This value is the 99.8th percentile of the distribution, and therefore constrains only 0.2% of the values.

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