5.0 RISK CHARACTERIZATION

Chapter 5 of the §403 risk analysis report documented the final portion of the risk assessment phase of the §403 risk analysis, in which the methods introduced in the earlier chapters of the §403 risk analysis report were applied to characterize risks associated with current (i.e., baseline) lead exposures for children aged 1-2 years. The baseline distribution of blood-lead concentration in this population was characterized using data from Phase 2 of the Third National Health and Nutritional Examination Survey (NHANES III), conducted from 1991 to 1994. Alternative pre-§403 risk estimates were also calculated as a function of environmental-lead levels by using data from the HUD National Survey as input to the IEUBK and empirical models. Both individual risk estimates (i.e., risks associated with specific environmental-lead levels) and population-based risk estimates (i.e., average risks over the entire nation) were presented. As mentioned in Section 2.0, the specific blood-lead concentration and health effect endpoints used to measure the risks of lead exposure to children aged 1-2 years were

- Incidence of blood-lead concentration greater than or equal to 10 µg/dL
- Incidence of blood-lead concentration greater than or equal to 20 µg/dL
- Incidence of IQ score less than 70 in the population of U.S. children, which results from lead exposure
- Incidence of IQ score decrement (in the population of U.S. children) greater than or equal to 1 resulting from lead exposure
- Incidence of IQ score decrement (in the population of U.S. children) greater than or equal to 2 resulting from lead exposure
- Incidence of IQ score decrement (in the population of U.S. children) greater than or equal to 3 resulting from lead exposure
- Average IQ decrement within the population of U.S. children that results from lead exposure.

The risk characterization included a sensitivity and uncertainty analysis where possible alternatives to various approaches taken and assumptions made in the risk characterization were identified and incorporated into the analysis, and the resulting impact on the risk estimates was evaluated. This analysis resulted in a measure of the uncertainty associated with the risk estimates due to methodological assumptions, thereby producing a range of estimates within which the true risk may reasonably be expected to fall. Section 5.1 of this chapter contains the following additional sensitivity and uncertainty analyses that were performed and documented since the §403 risk analysis report was published:

- Calculate individual risks associated with specified lead levels in floor-dust and soil, as predicted by the HUD model introduced in Section 4.1 and the alternative multimedia models presented in Section 4.2.

- Calculate estimates assuming a 50% decline in the estimated geometric mean blood-lead concentration of children aged 1-2 years from the estimate generated from Phase 2 of NHANES III (in addition to the estimates associated with 10%, 20%, and 30% declines that were presented in Section 5.4.3 of the §403 risk analysis report).

- Calculate model-based estimates of the pre-§403 blood-lead distribution under revised environmental-lead levels (from the HUD National Survey) input to the models, with the revisions representing the potential change in these levels that may have occurred since the survey was performed.

- Calculate baseline estimates of the IQ-related health effect endpoints assuming that specified non-zero thresholds exist in the relationship between blood-lead concentration and IQ.

5.1 RISK CHARACTERIZATION SENSITIVITY AND UNCERTAINTY ANALYSIS

The following subsections present the results of additional sensitivity and uncertainty analyses performed to gauge the level of uncertainty in baseline risk estimates associated with methodological assumptions. These results should be considered with those presented in the sensitivity and uncertainty analyses in Section 5.4 of the §403 risk analysis report to characterize overall uncertainty associated with the methods and assumptions taken in the risk assessment.

5.1.1 Estimates of Individual Risks from Applying the HUD Model

In Section 5.3 of the §403 risk analysis report, the concept of *individual risks* was introduced, and estimates of individual risks associated with lead exposure in children were generated by fitting the IEUBK and Rochester multimedia models to specified environmental-lead levels. Briefly, within the context of the §403 risk analysis, individual risks refer to the risks associated with a young child's exposure to specified levels of environmental-lead. Once environmental-lead levels were specified for each medium, the model-predicted blood-lead concentration at these levels, along with the assumption that blood-lead concentrations have a lognormal distribution with a specified variability, were used to estimate the percentage of children exposed to the specified set of environmental-lead levels that would have elevated blood-lead concentrations (i.e., at or above 10 µg/dL). Then, those sets of environmental-lead levels associated with estimated elevated blood-lead percentages of 1%, 5%, and 10% were identified and presented in Tables 5-5 through 5-7 and Figures 5-7 and 5-8 of Section 5.3 of the §403 risk analysis report. The IEUBK model was used to identify soil-lead concentrations associated with these elevated blood-lead percentages (at specified dust-lead loadings), while the Rochester multimedia model was used to identify (wipe) dust-lead loadings associated with these elevated blood-lead percentages (at specified soil-lead concentrations). These results contributed to the information which EPA used in proposing dust and soil levels of concern in the §403 proposed rule. See Section 5.3 of the §403 risk analysis report for additional details.

As discussed in Section 4.1 of this report, the HUD model was published shortly after the §403 risk analysis report was finalized, and some commenters to the §403 proposed rule suggested that it be considered within the §403 risk analysis. The HUD model can be used in the same manner as the

§403 risk analysis models to predict individual risks associated with exposure to a specified set of environmental-lead levels. Therefore, this section presents estimates of individual risks based on fitting the HUD model to specified environmental-lead levels and compares these risk estimates with those based on the IEUBK model (for soil) or the Rochester multimedia model (for dust). Supporting summaries and discussion for comparing HUD model results with those of the multimedia models developed for the §403 risk analysis are presented in Appendix F.

Soil-Lead Concentrations

When fitting the HUD model to evaluate individual risks associated with yard-wide average soil-lead concentration, the model's soil-lead parameters were set to the following values:

- ExtType = 0 (indicating that soil was sampled rather than exterior dust)
- ExtLoc = 0.5 (indicating that the total soil sampled was a rough average of drip-line and non-drip-line soil)

Figure 5-1 plots estimates of the percentage of children's blood-lead concentrations at or above 10 µg/dL as a function of soil-lead concentration, as predicted by the IEUBK model and the HUD model. The left-most panel in Figure 5-1 corresponds to the results of IEUBK model fits at specified dust-lead concentrations (100, 200, and 500 µg/g) and is identical to Figure 5-7 in the §403 risk analysis report. The middle and right-most panels of Figure 5-1 correspond to fits of the HUD model at specified dust-lead loadings (5, 10, 20, 25, 40, 50, 100 and 200 µg/ft^2) and differ according to the assumed geometric standard deviation (GSD) associated with the blood-lead concentration distribution (GSD=1.6 for the middle panel; GSD=1.72 for the right-most panel). A GSD of 1.72 was estimated within the HUD model publication (Lanphear et al., 1998).

The IEUBK and HUD model fits portrayed in Figure 5-1 are not directly comparable as the IEUBK model controls for dust-lead *concentration* while the HUD model controls for dust-lead *loading*. However, the plots do suggest that the predicted patterns of change in blood-lead concentration with soil-lead concentration differ considerably for the two models.

Table 5-1a, identical to Table 5-5 of the §403 risk analysis report, presents the soil-lead concentrations for which the IEUBK model-predicted percentages of children having blood-lead concentrations of at least 10 µg/dL equal 1%, 5%, and 10% assuming dust-lead concentrations of 100, 200, and 500 µg/g. Table 5-1b presents the soil-lead concentrations for which the HUD model-predicted percentages of children having blood-lead concentrations of at least 10 µg/dL equal 1%, 5%, and 10% assuming the dust-lead loadings considered in the HUD model panels of Figure 5-1. Table 5-1b (HUD model) indicates that, for all dust-lead loadings considered, the soil-lead concentrations estimated to maintain risks at 1% and 5% are less than 400 µg/g; even a soil-lead concentration of less than 6 µg/g would not achieve these levels of protection if children

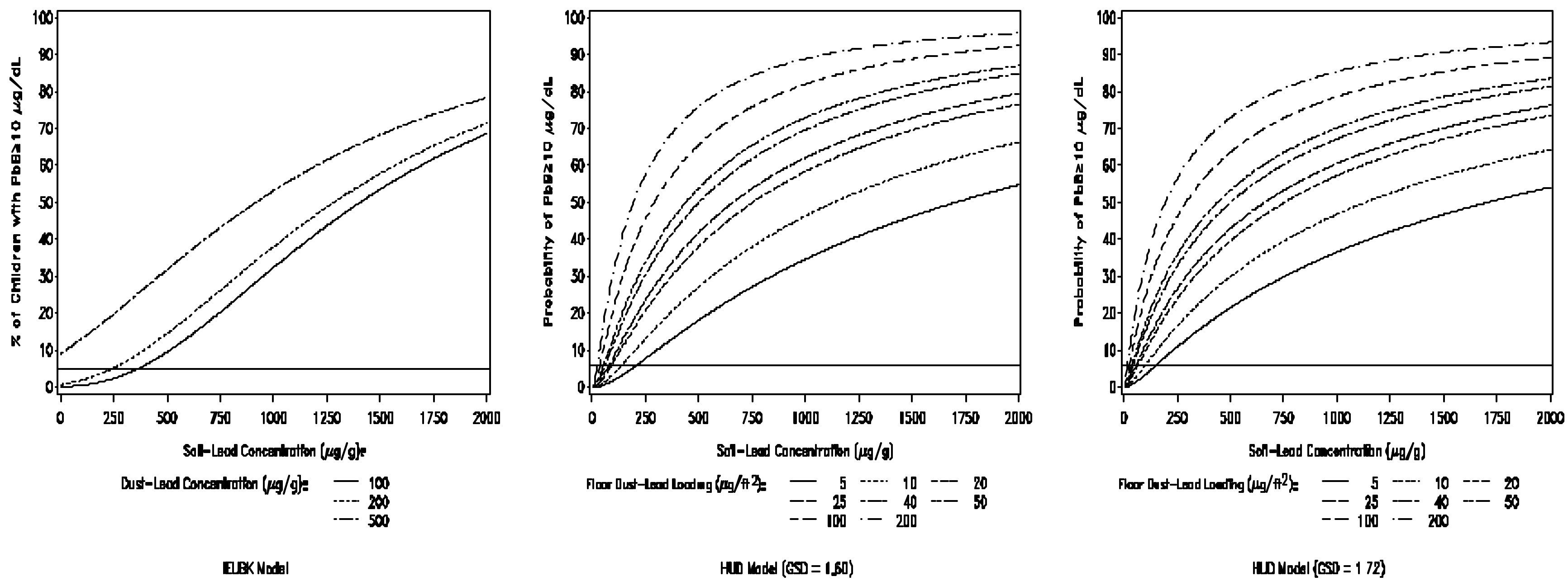

Figure 5-1. Percentage of Children's Blood-Lead Concentrations, as Predicted by the IEUBK and HUD Models, That Will Exceed or Equal 10 μg/dL as a Function of Yard-Wide Average Soil-Lead Concentration and at Fixed Levels of Dust-Lead Concentrations or Loadings

Table 5-1a. Yard-Wide Average Soil-Lead Concentrations at Which the Percentage of Children Aged 1-2 Years With Blood-Lead Concentration At or Above 10 μg/dL is Estimated by the IEUBK Model at 1, 5, or 10%, for Three Assumed Dust-Lead Concentrations (Table 5-5 in §403 risk analysis report).

Floor Dust-Lead Concentration (μg/g)	Soil-Lead Concentration (μg/g)		
	1%	5%	10%
100	155	365	515
200	35	245	395
500	Not achievable	Not achievable	25

Table 5-1b. Yard-Wide Average Soil-Lead Concentrations at Which the Percentage of Children Aged 1-2 Years With Blood-Lead Concentration At or Above 10 μg/dL is Estimated by the HUD Model at 1, 5, or 10%, for Eight Assumed Dust-Lead Loadings and Two Assumed Geometric Standard Deviations

Floor Dust-Lead Loading (μg/ft^2)	Soil-Lead Concentration (μg/g)		
	1%	5%	10%
GSD = 1.60			
5	74.4	186.2	303.7
10	49.4	123.7	201.8
20	32.9	82.3	134.2
25	28.8	72.1	117.6
40	21.8	54.7	89.2
50	19.1	47.9	78.2
100	12.7	31.9	52.0
200	8.5	21.2	34.5
GSD = 1.72			
5	45.9	132.4	232.8
10	30.5	88.0	154.8
20	20.3	58.5	102.9
25	17.8	51.3	90.2
40	13.5	38.9	68.4
50	11.8	34.1	60.0
100	7.9	22.7	39.9
200	5.2	15.1	26.5

were exposed to dust-lead loadings of 40 µg/ft^2 or more. Based on Table 5-1b, if dust-lead loadings are equal to 5 µg/ft^2, a soil-lead concentration of approximately 300 µg/g (100 µg/g) maintains the percentage of blood-lead concentrations greater than or equal to 10 µg/dL at 5% for a GSD of 1.60 (1.72).

Floor Dust-Lead Loadings

Figures 5-2 and 5-3 plot the estimated percentages of children having blood-lead concentrations at or above 10 µg/dL as a function of floor dust-lead loadings as predicted by the HUD model and the Rochester multimedia model assuming GSDs of 1.60 and 1.72, respectively, on the blood-lead distribution. Soil-lead concentrations are assumed to be fixed at 100, 400, 1200, 2000 and 5000 µg/g and, for the Rochester multimedia model, window sill dust-lead loadings are assumed to be fixed at 200 and 500 µg/ft^2. In each figure, the left-most panel contains estimates based on fitting the HUD model. The Rochester multimedia model panels for GSD equal to 1.60 and soil-lead concentrations of 100 and 400 µg/g were presented in Figure 5-8 in the §403 risk analysis report.

Tables 5-2 and 5-3 present the floor dust-lead loadings that are predicted by the HUD model and Rochester multimedia model, respectively, to maintain the percentage of children having blood-lead concentrations above or equal to 10 µg/dL at 1%, 5%, and 10% for specified levels of soil-lead concentration, window sill dust-lead loading and GSD. Approximate 95% upper confidence bounds, which account for the variability of parameter estimates from the Rochester multimedia model, are also provided in Table 5-3. See Appendix C2, Section 5.0 of the §403 risk analysis report for the methodology used to compute these confidence bounds. The rows of Table 5-3 corresponding to a GSD of 1.60 and soil-lead concentrations of 100 and 400 µg/g are identical to Table 5-6 in the §403 risk analysis report (after correcting an error in the computation of the confidence bounds).

Some key findings noted when comparing the individual risk estimates presented in Appendix F between the HUD model and Rochester multimedia model include the following:

- At very low floor dust-lead loadings (i.e., 1-5 µg/ft^2), the HUD model and the Rochester multimedia model yield similar predictions for the geometric mean blood-lead concentration, which also results in similar predictions for the health-effect endpoints that are calculated directly from this geometric mean (e.g., percentage of children with blood-lead concentration at or above a specified threshold; average IQ decrement resulting from lead exposure). However, due to the forms of these models and concerns involving the accuracy of very low dust-lead measurements, any conclusions made at such low dust-lead loadings must be made with caution.

- The predicted geometric mean blood-lead concentration under the HUD model ranges from 20% to nearly 60% higher than the prediction under the Rochester multimedia model as floor dust-lead loadings increase from 15 to 100 µg/ft^2 and

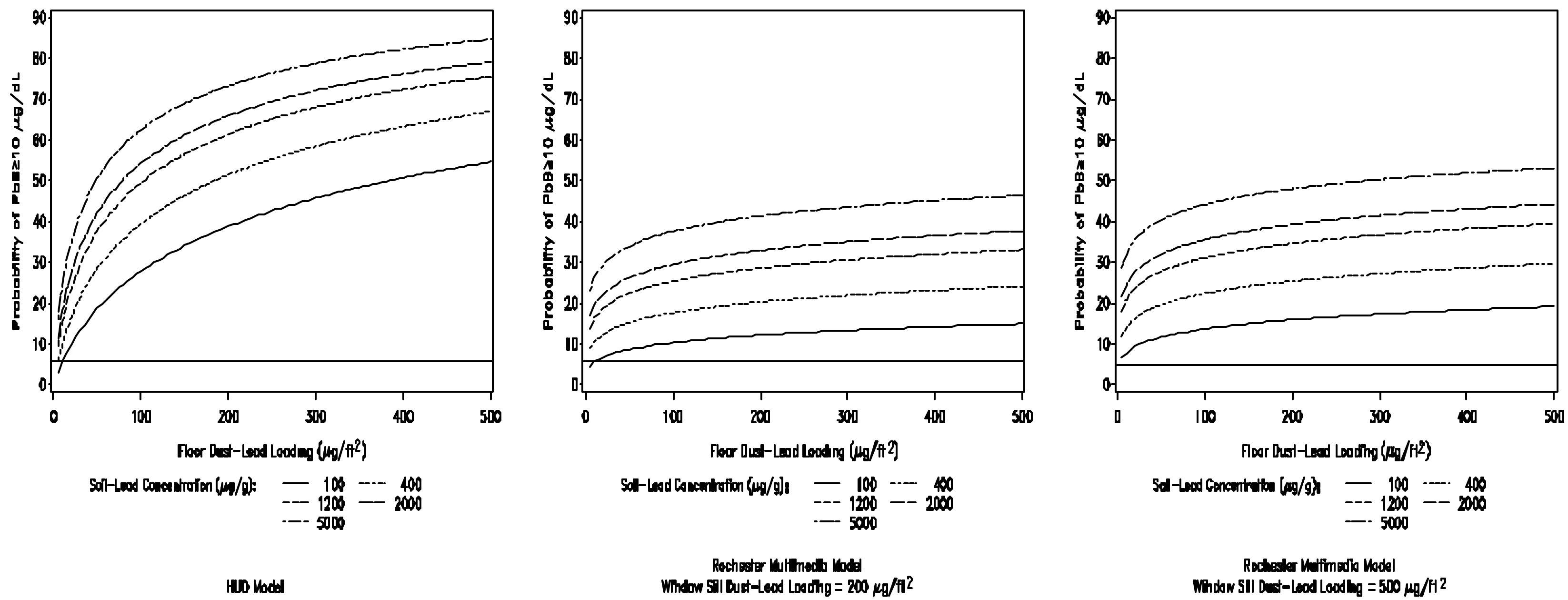

Figure 5-2. Percentage of Children's Blood-Lead Concentrations, As Predicted By the HUD Model and the Rochester Multimedia Model, That Will Exceed or Equal 10 µg/dL as a Function of Floor Dust-Lead Loading for Five Soil-Lead Concentrations and Two Window Sill Dust-Lead Loadings (Geometric Standard Deviation=1.60)

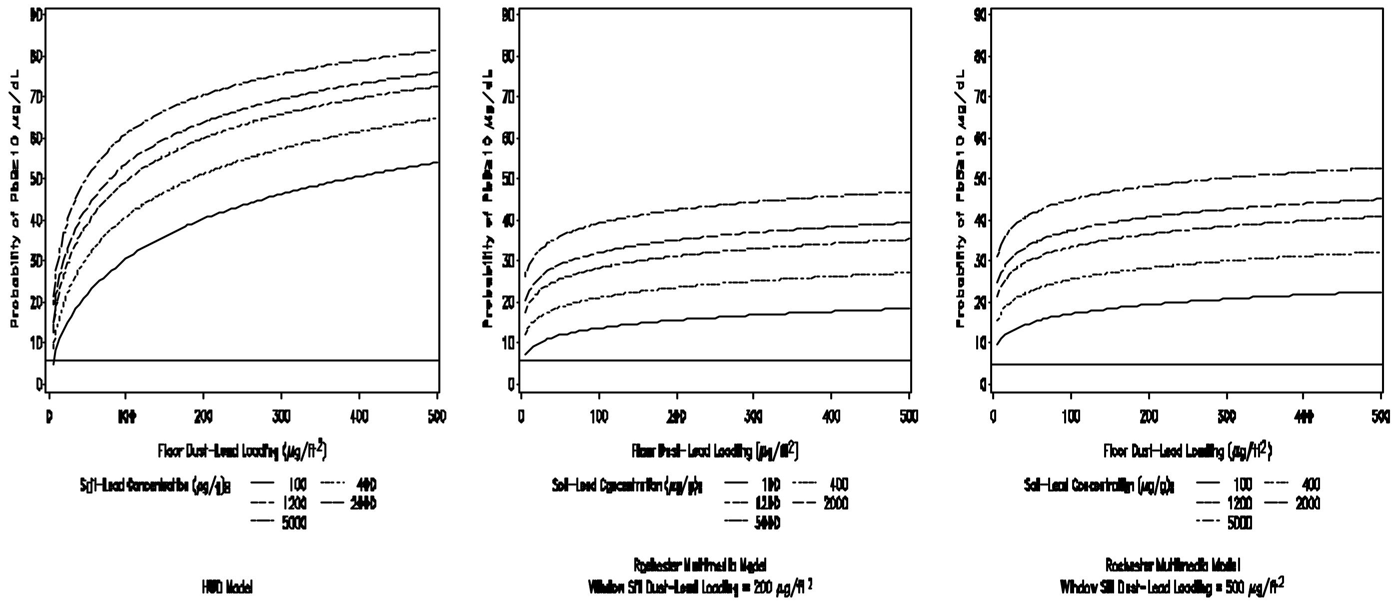

Figure 5-3. Percentage of Children's Blood-Lead Concentrations, As Predicted By the HUD Model and the Rochester Multimedia Model, That Will Exceed or Equal 10 µg/dL as a Function of Floor Dust-Lead Loading for Five Soil-Lead Concentrations and Two Window Sill Dust-Lead Loadings (Geometric Standard Deviation=1.72)

Table 5-2. Floor Dust-Lead Loadings at Which the Percentage of Children Aged 1-2 Years With Blood-Lead Concentration At or Above 10 μg/dL is Estimated by the HUD Model at 1, 5, or 10%, for Five Assumed Soil-Lead Concentrations and Two Assumed Geometric Standard Deviations

Soil-Lead Concentration (μg/g)	Floor Dust-Lead Loading (μg/ft^2)		
	1%	5%	10%
GSD = 1.60			
100	1.88	8.93	20.49
400	0.90	4.29	9.83
1200	0.50	2.40	5.49
2000	0.39	1.83	4.19
5000	0.24	1.12	2.58
GSD = 1.72			
100	0.83	5.01	13.05
400	0.40	2.40	6.26
1200	0.22	1.34	3.50
2000	0.17	1.02	2.67
5000	0.10	0.63	1.64

Table 5-3. **Floor Dust-Lead Loadings at Which the Percentage of Children Aged 1-2 Years With Blood-Lead Concentration At or Above 10 μg/dL is Estimated by the <u>Rochester Multimedia Model</u> at 1, 5, or 10%, for Five Assumed Soil-Lead Concentrations, Two Assumed Window Sill Dust-Lead Loadings, and Two Assumed Geometric Standard Deviations (expanded version of Table 5-6 in §403 risk analysis report).**

Soil-Lead Concentration (μg/g)	Window Sill Dust-Lead Loading (μg/ft^2)	Floor Dust-Lead Loading (μg/ft^2)					
		1%		5%		10%	
		Estimate	95% Upper Confidence Bound [1]	Estimate	95% Upper Confidence Bound [1]	Estimate	95% Upper Confidence Bound [1]
GSD = 1.60							
100	200	0.05	0.37	6.70	22.00	89.08	327.73
	500	0.02	0.14	2.00	8.93	26.62	92.01
400	200	0.00	0.04	0.61	2.81	8.13	20.32
	500	0.00	0.02	0.18	1.12	2.43	9.24
1200	200	0.00	0.01	0.09	0.59	1.22	4.86
	500	0.00	0.00	0.03	0.22	0.36	1.99
2000	200	0.00	0.00	0.04	0.28	0.50	2.47
	500	0.00	0.00	0.01	0.10	0.15	0.96
5000	200	0.00	0.00	0.01	0.07	0.10	0.69
	500	0.00	0.00	0.00	0.02	0.03	0.25
GSD = 1.72							
100	200	0.00	0.04	1.11	4.90	21.87	67.96
	500	0.00	0.01	0.33	1.95	6.54	24.54
400	200	0.00	0.00	0.10	0.64	2.00	7.04
	500	0.00	0.00	0.03	0.24	0.60	3.00
1200	200	0.00	0.00	0.02	0.12	0.30	1.59
	500	0.00	0.00	0.00	0.04	0.09	0.61
2000	200	0.00	0.00	0.01	0.06	0.12	0.77
	500	0.00	0.00	0.00	0.02	0.04	0.29
5000	200	0.00	0.00	0.00	0.01	0.03	0.20
	500	0.00	0.00	0.00	0.00	0.01	0.07

[1] The 95% upper confidence bounds here differ from those in Table 5-6 of the §403 risk analysis report. The values here are corrected for a mistake in the original computations.

as soil-lead concentrations decrease from 2000 ppm to 10 ppm (assuming, for the Rochester multimedia model, that window sill dust-lead loadings are at their estimated national median level; Tables F-1 and F-2 of Appendix F). Note that for a fixed value of the geometric standard deviation (GSD) for the blood-lead distribution, the average IQ decrement in the population that is associated with lead exposure is a multiple of the geometric mean (as calculated in the §403 risk analysis). Therefore, similar differences in predictions between the two models would occur for average IQ decrement.

- If the geometric standard deviation (GSD) associated with the blood-lead distribution is fixed, then as floor dust-lead loadings increase beyond 10 µg/ft^2, the predicted percentage of children with blood-lead levels at or above 10 µg/dL increases at a much faster rate under the HUD model (at a constant soil-lead level). For example, if window sill dust-lead loading is at its estimated national median and soil-lead concentration is below 2000 ppm, the predicted percentage under the HUD model is at a minimum twice as large as the prediction under the Rochester multimedia model . This difference in predictions gets even greater as the assumed soil-lead concentration gets lower. For example, at a GSD of 1.6, a floor dust-lead loading of 100 µg/ft^2, and a soil-lead concentration of 10 ppm, the prediction is over 7 times higher for the HUD model compared to the Rochester multimedia model (13.1% versus 1.76%; Tables F-3 and F-4 of Appendix F).

5.1.2 Estimates of Individual Risks from Applying the Alternative Rochester Multimedia Model

The approach to estimating individual risks that was discussed and applied (using the IEUBK model and Rochester multimedia model) in Section 5.3 of the §403 risk analysis report and was applied using the HUD model in Section 5.1.1 above was also applied using the alternative Rochester multimedia model ("Model A") that was documented in Section 4.2 of this report. Recall that this model uses 1) average dust-lead loadings on uncarpeted floors, 2) average dust-lead loadings on window sills, 3) yardwide average dust-lead concentration, and 4) the percentage of painted components containing deteriorated lead-based paint as predictor variables. The blood-lead concentration predicted by this model is an estimate of the geometric mean of the distribution of blood-lead concentration, which is assumed to be lognormal with geometric standard deviation 1.6. The resulting distribution is then used to estimate the percentage of children with blood-lead concentration at or above 10 µg/dL. This subsection documents the results of estimating individual risks based on the alternative Rochester multimedia model.

In this analysis, it is assumed that the given residential environment for which individual risks will be estimated has no deteriorated lead-based paint (as was done in Section 5.3 of the §403 risk analysis report). Then, levels of two of the remaining three predictor variables are fixed, and the level of the third variable is determined so that either 1%, 5%, or 10% of children exposed to the combined lead levels given by the three predictor variables would be predicted to have a blood-lead concentration at or above 10 µg/dL.

Table 5-4a contains the estimated floor dust-lead loading at which the predicted percentage of children with blood-lead concentration at or above 10 µg/dL is either 1%, 5%, or 10%, given that window sill dust-lead loading is at either 200 or 500 µg/ft^2, and soil-lead concentration is at either 100 or 400 µg/g. Table 5-4b contains the estimated window sill dust-lead loading at which the predicted percentage of children with blood-lead concentration at or above 10 µg/dL is either 1%, 5%, or 10%, given that floor dust-lead loading is at either 25 or 100 µg/ft^2, and soil-lead concentration is at either 100 or 400 µg/g. These two tables correspond to Tables 5-6 and 5-7, respectively, in Section 5.3 of the §403 risk analysis report, where the estimates were based on the original Rochester multimedia model. Finally, Table 5-4c contains the estimated yard-wide average soil-lead concentration at which the predicted percentage of children with blood-lead concentration at or above 10 µg/dL is either 1%, 5%, or 10%, given that floor dust-lead loading is at either 25 or 100 µg/ft^2, and window sill dust-lead loading is at either 200 or 500 µg/ft^2. (A corresponding table for the soil-lead concentration does not exist in Section 5.3 of the §403 risk analysis report as the soil-lead concentration predictor variable in the original Rochester multimedia model assumed only dripline soil rather than a yard-wide average, and the IEUBK model did not accept dust-lead loadings as input.)

Effect on risk analysis: If the target percentage of children with elevated blood-lead concentration is 5%, the estimates in Table 5-4a (fourth column) are only slightly higher than the corresponding estimates in Table 5-6 of the §403 risk analysis report, suggesting that at the fixed levels of soil-lead concentration and window sill dust-lead loading, the corresponding floor dust-lead loading is nearly the same for the two methods determined by the two forms of the multimedia model. However, at a soil-lead concentration of 100 µg/g, the estimated floor dust-lead loadings are considerably smaller (and below 50 µg/ft^2) than in Table 5-6 of the §403 risk analysis report under 10% risk and considerably larger (but still below 1 µg/ft^2) under a 1% risk.

For window sills (Table 5-4b), estimated dust-lead loadings are reduced under the alternative Rochester multimedia model compared to the estimates in Table 5-7 of the §403 risk analysis report at the 5% and 10% risk levels. At the 5% risk level, the estimated window sill dust-lead loadings were at 40 µg/ft^2 or lower at the specified soil-lead and uncarpeted floor dust-lead levels (Table 5-4b, fourth column).

Yardwide average soil-lead concentration needed to be below 150 µg/g at each of the specified levels of floor and window sill dust-lead loadings to achieve risks of 10% or lower, and at 32 µg/g or lower to achieve risks of 5% or lower (Table 5-4c). The estimated soil-lead concentration increases as the two specified dust-lead loadings decrease, illustrating how the soil-lead standard could become less stringent as the dust-lead loading standards became more stringent.

Table 5-4a. **Uncarpeted Floor Dust-Lead Loadings at Which the Percentage of Children Aged 1-2 Years With a Blood-Lead Concentration At or Above 10 μg/dL is Estimated by the Alternative Rochester Multimedia Model (A) at 1%, 5%, or 10%, Under Fixed Levels of Yardwide Average Soil-Lead Concentration and Window Sill Dust-Lead Loading**

Yardwide Average Soil-Lead Conc. (μg/g)	Window Sill Dust-Lead Loading ($\mu g/ft^2$)	Uncarpeted Floor Dust-Lead Loading ($\mu g/ft^2$) at Which the Estimated % of Children With Blood-Lead Concentration At or Above 10 μg/dL is ...		
		1%	5%	10%
100	200 500	0.48 0.25	7.9 4.1	35 18
400	200 500	0.12 0.06	1.9 1.0	8.7 4.5

Note: The percentages of 1%, 5%, and 10% were determined assuming that the blood-lead distribution is lognormal with geometric mean as predicted by the alternative Rochester multimedia model (A) and a geometric standard deviation of 1.6.

Table 5-4b. **Window Sill Dust-Lead Loadings at Which the Percentage of Children Aged 1-2 Years With a Blood-Lead Concentration At or Above 10 μg/dL is Estimated by the Alternative Rochester Multimedia Model (A) at 1%, 5%, or 10%, Under Fixed Levels of Yardwide Average Soil-Lead Concentration and Uncarpeted Floor Dust-Lead Loading**

Yardwide Average Soil-Lead Conc. (μg/g)	Uncarpeted Floor Dust-Lead Loading ($\mu g/ft^2$)	Window Sill Dust-Lead Loading ($\mu g/ft^2$) at Which the Estimated % of Children With Blood-Lead Concentration At or Above 10 μg/dL is ...		
		1%	5%	10%
100	25 100	0.78 0.11	40 5.7	320 46
400	25 100	0.11 0.02	5.6 0.80	45 6.5

Note: The percentages of 1%, 5%, and 10% were determined assuming that the blood-lead distribution is lognormal with geometric mean as predicted by the alternative Rochester multimedia model (A) and a geometric standard deviation of 1.6.

Table 5-4c. <u>Yardwide Average Soil-Lead Concentration</u> at Which the Percentage of Children Aged 1-2 Years With a Blood-Lead Concentration At or Above 10 μg/dL is Estimated by the <u>Alternative Rochester Multimedia Model (A)</u> at 1%, 5%, or 10%, Under Fixed Levels of Dust-Lead Loadings for Uncarpeted Floors and Window Sills

Uncarpeted Floor Dust-Lead Loading (μg/ft²)	Window Sill Dust-Lead Loading (μg/ft²)	Yardwide Average Soil-Lead Concentration (μg/g) at Which the Estimated % of Children With Blood-Lead Concentration At or Above 10 μg/dL is ...		
		1%	5%	10%
25	200 500	2.0 1.0	32 17	140 73
100	200 500	0.50 0.26	8.0 4.2	35 18

Note: The percentages of 1%, 5%, and 10% were determined assuming that the blood-lead distribution is lognormal with geometric mean as predicted by the alternative Rochester multimedia model (A) and a geometric standard deviation of 1.6.

5.1.3 Considering Potential Declines in Blood-Lead Concentration from NHANES III Phase 2 Measures

The results of this subsection are an extension of the analysis in Section 5.4.3 of the §403 risk analysis report. In that subsection, the geometric mean blood-lead concentration of 3.14 μg/dL for children aged 1-2 years, estimated from data collected in Phase 2 of NHANES III (1991-1994), was assumed to be either 10%, 20%, or 30% lower, and the resulting impact on the baseline risk estimates was investigated. This analysis was performed due to the likelihood of continued decline in blood-lead concentrations in the U.S. population that has occurred in recent years. It was desired to augment this analysis by considering an additional assumption on the percentage decline since Phase 2 of NHANES III: 50%.

Table 5-5 presents the baseline estimates of the blood-lead concentration and health effect endpoints for children aged 1-2 years, where <u>each</u> blood-lead concentration measurement in Phase 2 of NHANES III was reduced by the same amount: 10%, 20%, 30%, or 50%. Thus, the analysis assumed a constant percentage decline for the entire blood-lead concentration distribution as characterized by Phase 2 of NHANES III. This table is an extension of the results presented in Table 5-11 of the §403 risk analysis report and includes the baseline estimates reported in the risk analysis for comparison purposes (i.e., where no reduction is assumed).

Note that within NHANES III, the estimated geometric mean blood-lead concentration for children aged 1-2 years declined from 4.05 μg/dL in Phase 1 to 3.14 μg/dL in Phase 2, representing a 22.5% decline. This is within the range of declines being considered in the

Table 5-5. Sensitivity Analysis for the Estimated Baseline Number and Percentage of Children Aged 1-2 Years Having Specific Health Effect and Blood-Lead Concentration Endpoints, Assuming Various Percentage Declines in Blood-Lead Concentration Since Phase 2 of NHANES III

Health Effect and Blood-Lead Concentration Endpoints	Numbers (%) of Children Aged 1-2 Years				
	Risk Analysis Estimate (Table 5-1 of the §403 risk analysis report)	Percentage Decline in Blood-Lead Concentration Since NHANES III Phase 2			
		10%	20%	30%	50%
PbB $ 20 μg/dL	46,800 (0.588%)	30,900 (0.388%)	18,900 (0.238%)	10,600 (0.133%)	2,130 (0.0268%)
PbB $ 10 μg/dL	458,000 (5.75%)	340,000 (4.27%)	239,000 (3.00%)	156,000 (1.96%)	46,800 (0.588%)
IQ score less than 70	9,130 (0.115%)	8,610 (0.108%)	8,160 (0.102%)	7,760 (0.098%)	7,140 (0.0897%)
IQ score decrement $ 1	3,060,000 (38.5%)	2,640,000 (33.2%)	2,190,000 (27.6%)	1,740,000 (21.8%)	863,000 (10.8%)
IQ score decrement $ 2	863,000 (10.8%)	669,000 (8.40%)	493,000 (6.19%)	340,000 (4.27%)	117,000 (1.47%)
IQ score decrement $ 3	294,000 (3.70%)	213,000 (2.68%)	146,000 (1.83%)	91,900 (1.15%)	25,200 (0.317%)
Average IQ score decrement	1.06	0.951	0.845	0.740	0.528
Geometric Mean (μg/dL)	3.14	2.82	2.51	2.20	1.57

sensitivity analysis within Table 5-5. However, due to the NHANES III survey design and how this survey was performed, caution must be taken when interpreting observed differences in results between the two phases of this survey.

Effect on risk analysis: According to Table 5-5, if it were assumed that a 50% across-the-board decline in blood-lead concentration (resulting in a national geometric mean blood-lead concentration of 1.57 μg/dL), this would reduce the estimated number of children whose blood-lead concentration was at or above 20 μg/dL from 46,800 to 2,130, a decline of 95%, while the estimated number at or above 10 μg/dL would be reduced by nearly 90%, to 46,800 children. The 50% decline resulted in percentage declines of 72%, 86%, and 91% for numbers of children with IQ score decrements of 1, 2, or 3, respectively, as a result of lead exposure. The estimated average IQ decrement in the population due to lead exposure is cut in half under this assumption (from 1.06 to 0.53 points), matching the assumed 50% decline in blood-lead concentration because the IQ/blood-lead concentration relationship is assumed to be linear across the entire range of blood-lead concentration. The effects of the lower assumed percentage declines (10%-30%) were discussed in Section 5.4.3 of the §403 risk analysis report.

The results in Table 5-5 are based on the assumption that the blood-lead concentrations for each child in the population have been reduced by the same percentage since Phase 2 of NHANES III. In reality, different subgroups have achieved different rates of change over this time. However, considering different percentage declines for different subgroups would be very difficult, and the resulting estimates of the health effect and blood-lead concentration endpoints would likely differ only slightly from that observed in Table 5-5.

5.1.4 Considering How Baseline Environmental-Lead Levels May Have Changed Since the HUD National Survey

Although interim data from the NSLAH (Section 3.1) have recently been made available to this risk analysis and have been summarized throughout this report, the fact that the public could not have reviewed these summaries during the public comment period limits the extent to which these data could be considered in the rulemaking. Therefore, for purposes of the rulemaking, data from the HUD National Survey continue to be the only nationally-representative data source on baseline environmental-lead levels in the nation's housing stock. Nevertheless, it was desired to estimate how changes in these environmental-lead levels that have occurred since the HUD National Survey was conducted would affect the baseline (i.e., pre-§403) risk characterization. Therefore, a sensitivity analysis was performed where the HUD National Survey data was adjusted to reflect possible change in the distribution over time. The adjusted data would yield a surrogate distribution of baseline environmental-lead levels. Several alternative adjustments would be considered, and risk estimates based on each set of adjusted data would be calculated.

To help in determining appropriate adjustments to the HUD National Survey data, the summaries presented in Section 3.2 of this document compared the distribution of dust-lead and soil-lead data reported in the HUD National Survey with distributions from other studies performed more recently, but typically in specific locations that may not necessarily be nationally-representative. These summaries showed that the distributions were quite consistent across studies, suggesting that the distributions based from the HUD National Survey data, even after converting from Blue Nozzle dust-lead loadings to wipe-equivalent loadings, are likely adequate for characterizing environmental-lead levels even up to ten years after the survey. In fact, the HUD National Survey data distributions were often centered at lower lead levels than in the other studies. (A primary exception was household average dust-lead loadings, where data from the interim NSLAH were considerably lower than in other studies, including the HUD National Survey. It is currently uncertain of the degree to which the observed distribution from the interim NSLAH reflects actual declines in dust-lead levels since the HUD National Survey.) Furthermore, the nature of the distribution appears to be affected by housing age, with higher lead levels associated with older housing.

For this sensitivity analysis, the following five alternatives for adjusting the HUD National Survey data were made, in an effort to reflect more current environmental-lead levels in households:

- Average dust-lead loading and dust-lead concentration reduced by 20%, (yard-wide) average soil-lead concentration reduced by 20%

- Average dust-lead loading/concentration reduced by 50%, average soil-lead concentration reduced by 50%

- Average dust-lead loading/concentration reduced by 50%, average soil-lead concentration reduced by 0%

- Average dust-lead loading/concentration reduced by 0%, average soil-lead concentration reduced by 50%

- Average dust-lead loading/concentration increased by 25%, average soil-lead concentration increased by 25%.

The dust-lead loading assumptions are assumed to be for both floors and window sills and are made to the reported Blue Nozzle loadings (i.e., those estimates used as input to the empirical model). The same changes are assumed for Blue Nozzle floor dust-lead concentration, which is used as input to the IEUBK model.

Each of the above five sets of alternatives implies that the same percentage change would be applied to data from each housing unit in the HUD National Survey. Thus, the resulting national distribution of baseline environmental-lead levels would be a simple shift in the current distribution used in the §403 risk analysis, with no change in the variability associated with the distribution. Insufficient data exist to determine how a distribution's variability may have changed, so it is assumed to remain unchanged. Within each set, different percentage changes are considered for dust-lead loading and soil-lead concentration to allow for added flexibility in how lead levels may have changed in different media. Four of the five sets represent declines over time, which are expected due to the increased prevalence of homes with no lead-based paint in the housing stock and the reduced likelihood of residual contamination associated with leaded gasoline emissions. Nevertheless, one set representing an increase is considered, due to the potential for the new survey to include housing with generally higher levels than those houses included in the original survey and the continued potential for deteriorated lead-based paint and other lead sources to contaminate dust and soil.

Note that in all five sets of adjustments, the assumed within-house geometric standard deviation (GSD) remains equal to 1.6. Alternative values of this GSD assumption were considered in the sensitivity analysis presented in Section 5.4.6 of the §403 risk analysis report.

Table 5-6 presents the pre-§403 model-based estimates for the health effect and blood-lead concentration endpoints, under each of the above five sets of data adjustments, as calculated based on blood-lead distribution generated from IEUBK and empirical model fits. For comparison purposes, the table includes the estimates assuming no adjustments (i.e., as the data were used in the §403 risk analysis) as reported in Table 5-2 of the §403 risk analysis report.

Table 5-6. Sensitivity Analysis on How Changes in Household Average Baseline Dust-Lead Loadings/Concentrations and Soil-Lead Concentration Impact Pre-§403 Estimates of Health Effect and Blood-Lead Concentration Endpoints for Children Aged 1-2 Years

Assumed Percentage Change in Average Dust-Lead Loadings and Concentrations (Both Floor and Window Sill) and in Yard-wide Average Soil-Lead Concentration						
Dust:	**No change**	**20% decrease**	**50% decrease**	**50% decrease**	**No change**	**25% increase**
Soil:	**No change**	**20% decrease**	**50% decrease**	**No change**	**50% decrease**	**25% increase**
Predicted Health Effect And Blood-Lead Concentration Endpoints (Based on Empirical Model)						
PbB $20 (%)	0.0278	0.0212	0.0117	0.0187	0.0176	0.0364
PbB $10 (%)	1.54	1.28	0.849	1.17	1.13	1.85
IQ < 70 (%)	0.0997	0.0983	0.0957	0.0977	0.0974	0.101
IQ decrement $1 (%)	34.5	31.8	26.5	30.6	30.1	37.2
IQ decrement $2 (%)	4.53	3.87	2.74	3.61	3.49	5.27
IQ decrement $3 (%)	0.718	0.584	0.373	0.532	0.509	0.877
Avg. IQ decrement	0.932	0.896	0.825	0.880	0.873	0.969
Predicted Health Effect And Blood-Lead Concentration Endpoints (Based on IEUBK Model)						
PbB $20 (%)	2.24	1.39	0.427	0.957	1.44	3.06
PbB $10 (%)	12.4	9.33	4.60	7.28	9.70	15.3
IQ < 70 (%)	0.146	0.131	0.110	0.121	0.132	0.160
IQ decrement $1 (%)	50.4	45.1	34.6	40.3	46.4	55.4
IQ decrement $2 (%)	19.9	15.8	8.97	12.8	16.4	23.8
IQ decrement $3 (%)	8.95	6.46	2.90	4.92	6.72	11.3
Avg. IQ decrement	1.40	1.24	0.978	1.12	1.26	1.56

Effect on risk analysis: The greatest total decline in baseline environmental-lead levels being considered is the set containing 50% declines in both dust- and soil-lead levels (i.e., the fourth column of Table 5-6). Under the empirical model, Table 5-6 indicates that the most sensitive endpoints to the 50% decline in both dust-lead and soil-lead are the incidence of IQ decrement of at least 3 and the incidence of blood-lead concentration of at least 10 µg/dL, where declines of 48% and 45%, respectively, were observed in these estimates relative to no decline in environmental-lead levels. The empirical model-based estimates appear to be more sensitive to changes in soil-lead concentration than in dust-lead concentration, as lower estimates were observed when soil-lead concentrations declined by 50% (and no change was made to dust-lead loadings) than when dust-lead loadings declined by 50% (and no change was made to soil-lead concentrations). This is explained by the empirical model's larger slope estimate for soil-lead concentration than for dust-lead loading in either floors or window sills (Table 4-3 of the §403 risk analysis report).

When the IEUBK model is used to estimate the distribution of blood-lead concentration, corresponding declines of 68% and 63% were observed for incidence of IQ score decrement at or above 3 and for incidence of blood-lead concentration at or above 10 µg/dL, respectively, when 50% declines are assumed for both dust-lead and soil-lead concentration (Table 5-6). However, in this same scenario, the greatest decline (81%) among the endpoints is observed with the incidence of blood-lead concentration at or above 20 µg/dL. This is a considerable decline compared to the 24% decline for this endpoint observed under the empirical model. Contrary to the type of finding observed under the empirical model, the IEUBK model-based estimates appear to be more sensitive to changes in dust-lead concentration than in soil-lead concentration, as lower estimates were observed when dust-lead concentrations declined by 50% (and no change was made to soil-lead concentrations) than when soil-lead concentrations declined by 50% (and no change was made to dust-lead concentrations).

Under both models, the last column in Table 5-6 shows that only modest increases in the risk estimates were observed under the one adjustment assumption involving increases in environmental-lead levels (i.e., 25% increases in both dust-lead and soil-lead levels).

5.1.5 Impact on the Estimated Incidence of IQ Point Decrement Assuming Certain Thresholds on the IQ/Blood-Lead Relationship

As discussed in Chapter 4 of the §403 risk analysis report, results of the meta-analysis documented in Schwartz (1994) indicate that an average IQ point loss of 0.257 is predicted for every 1.0 µg/dL increase in blood-lead concentration, with no evidence of a threshold in this relationship (i.e., non-zero blood-lead concentration below which the predicted IQ point loss is zero). These results were used in the §403 risk analysis to characterize the IQ/blood-lead relationship. Section 2.3 of this report provides additional justification for making these assumptions.

As discussed in Section 2.3, some researchers have suggested that a non-zero threshold exists in the IQ/blood-lead relationship. While no consensus on a single threshold has been adopted among those making this conclusion, and such conclusions are occasionally made by visual inspection of data rather than on statistical criteria, this sensitivity analysis considers the impact of assuming non-zero blood-lead concentration thresholds on the baseline and model-based pre-§403 risk estimates. A non-zero threshold will result in reduced estimates for health effects measured by IQ decrement, as children with blood-lead concentrations below the threshold will have an estimated IQ decrement of zero due to lead exposure.

Estimates of the IQ decrement parameters under the following thresholds are presented in this subsection: 1, 2, 3, 5, 8, and 10 µg/dL. In addition, the estimates under an assumed "threshold" of 0 µg/dL (i.e., those measured in the §403 risk analysis and meaning that any blood-lead level, regardless of how small, would have an adverse effect on a child's IQ score) are presented for comparison purposes. The candidate threshold of 8 µg/dL has been suggested by Rabinowitz et al. (1992), as discussed in Section 2.3. The candidate threshold of 10 µg/dL was selected as it represents the action level reported by the Centers for Disease Control and Prevention (Section 2.5.1 of the §403 risk analysis report). It also is representative of the higher-level thresholds reported by some early studies;

thresholds any higher than 10 µg/dL would result in extremely low (and likely very underestimated) risk estimates and have been discounted by more recent studies. Levels of 1, 2, 3, and 5 µg/dL represents possible candidates of a very low, but positive, threshold. Such thresholds would not be detectable by many studies in the literature as they tend to fall below the range of observed data or the detection limit of the blood-lead measurement procedure.

The assumption of a positive threshold requires a minor modification to the method used to predict IQ score decrement based on blood-lead concentration. An average IQ point loss of 0.257 continues to be predicted for every 1.0 µg/dL increase in blood-lead concentration, but only above the assumed blood-lead concentration threshold value. Thus, if T represents the threshold, then the predicted IQ score decrement at a blood-lead concentration of C would equal 0.257*(C-T) if C is greater than T, or zero if C is less than or equal to T. While the methodology used to obtain risk estimates remains the same as that documented in Appendices E1 and E2 of the §403 risk analysis report, slight differences were required for calculating the average and standard deviation of IQ decrement, as this measure was no longer assumed to be lognormally distributed. See Appendix B for how these statistics are calculated assuming a non-zero threshold.

Table 5-7 presents the estimated percentages of children with IQ score decrements greater than or equal to 1, 2, or 3, and the average and standard deviation IQ point decrement under assumptions of an IQ score decline of 0.257 points for every 1.0 µg/dL increase in blood-lead concentration above the specified threshold. These estimates are presented assuming the baseline blood-lead distribution (top section of the table), the pre-§403 distribution as generated by IEUBK model fits (middle section of the table), and the pre-§403 distribution as generated by the empirical model fits (bottom section of the table) for children aged 1-2 years.

Effect on risk analysis: The magnitude of the assumed blood-lead concentration threshold has a considerable impact on the percentage of children affected by decrements in IQ score. As seen in Table 5-7, while the §403 risk analysis estimated an average IQ decrement of 1.06 points occurs due to lead exposure across the population of children aged 1-2 years, this average declines by approximately 44% under a assumed threshold of 2 µg/dL (0.588 points) and by 90% under a threshold of 8 µg/dL (0.103 points). An estimated 38.5% of children aged 1-2 years were expected to experience an IQ score decrement of at least 1 if a threshold was not assumed. This percentage is decreased by approximately 50% under a threshold of 2 µg/dL (19.6%) and by 90% under a threshold of 8 µg/dL (3.5%). The percentage decline is decreased in magnitude as the lower limit of IQ score decrement increases to 3, but it remains at least a 39% decline for a threshold of 2 µg/dL and 83% for a threshold of 8 µg/dL.

Table 5-7. Sensitivity Analysis on the Assumed Blood-Lead Concentration Threshold on IQ Decrement and Its Impact on the Pre-§403 Estimates of IQ Decrement Endpoints for Children Aged 1-2 Years

Assumed Threshold (µg/dL)	% of Children Aged 1-2 Years with a Specified IQ Decrement Due to Lead Exposure[1]			Average IQ Decrement (# points)[2]	Standard Deviation of IQ Decrement[2]
	IQ Decrement $ 1	IQ Decrement $ 2	IQ Decrement $ 3		
Baseline Estimates (Section 5.1.1 of §403 risk analysis report)					
0	38.5	10.8	3.70	1.06	0.895
1	27.3	8.08	2.88	0.804	0.891
2	19.6	6.10	2.26	0.588	0.860
3	14.2	4.66	1.80	0.428	0.802
5	7.83	2.80	1.16	0.233	0.666
8	3.50	1.40	0.627	0.103	0.494
10	2.15	0.915	0.429	0.0638	0.408
Pre-§403 Estimates Based on IEUBK Model-Generated PbB Distribution (Section 5.1.2 of §403 risk analysis report)					
0	50.4	19.9	8.95	1.40	1.35
1	39.3	16.0	7.42	1.15	1.35
2	30.8	13.0	6.19	0.921	1.33
3	24.4	10.6	5.20	0.738	1.28
5	15.7	7.27	3.73	0.483	1.15
8	8.58	4.31	2.35	0.273	0.964
10	5.96	3.13	1.76	0.194	0.854
Pre-§403 Estimates Based on Empirical Model-Generated PbB Distribution (Section 5.1.2 of §403 risk analysis report)					
0	34.5	4.53	0.718	0.932	0.538
1	20.4	2.76	0.464	0.675	0.537
2	12.0	1.71	0.330	0.442	0.514
3	7.14	1.07	0.202	0.271	0.453
5	2.61	0.443	0.0926	0.0972	0.309
8	0.652	0.130	0.0312	0.0224	0.162
10	0.278	0.0613	0.0158	0.00912	0.108

[1] A 0.257 IQ decrement is assumed for each 1.0 µg/dL increase in PbB above the assumed threshold (see Section 4.4.1 of the §403 risk analysis report). Thus, the following hold:

- P[IQ $ 1] = P[PbB $ (threshold + 3.9 µg/dL]
- P[IQ $ 2] = P[PbB $ (threshold + 7.8 µg/dL)]
- P[IQ $ 3] = P[PbB $ (threshold + 11.7 µg/dL)]

[2] Average and standard deviation of IQ decrement are calculated assuming no IQ decrement occurs below the assumed threshold, and a 0.257 IQ decrement is assumed for each 1.0 µg/dL increase in PbB above the threshold.

Similar patterns of decline were seen for the pre-§403 estimates generated under the IEUBK and empirical model-based blood-lead distributions, with the empirical model predicting greater reductions for the larger thresholds. These model-based estimates were used in the procedure to characterize changes from baseline that occur in a post-§403 environment, which is addressed in Chapter 6.