#### **EXECUTIVE SUMMARY**

#### **ES.1 BACKGROUND**

Lead poisoning in children is recognized as a major health problem in the United States. While there are many sources of lead in the human environment, lead-based paint hazards in residential housing are considered the primary source of lead exposure for children. To help develop a national strategy to eliminate lead-based paint hazards, the President of the United States signed into law the Residential Lead-Based Paint Hazard Reduction Act of 1992 (42 U.S.C. 4851). This legislation included an amendment to the Toxic Substances Control Act (Title IV: Lead Exposure Reduction), requiring the Administrator of the U.S. Environmental Protection Agency (EPA) to enact a variety of activities to identify and reduce environmental exposure to lead hazards. Specifically, §403 of TSCA (15 U.S.C. 2683) states:

"... the Administrator shall promulgate regulations which shall identify, for purposes of this title and the Residential Lead-Based Paint Hazard Reduction Act of 1992, lead-based paint hazards, lead-contaminated dust, and lead-contaminated soil."

Under §403, the Agency is required to identify what constitutes a lead-based paint hazard (i.e., conditions that cause exposure to lead-contaminated dust, soil, or paint that would result in adverse health effects to humans) and what constitutes lead contamination of dust and soil (i.e., the presence of lead levels which can pose a threat of adverse health effects). In particular, the §403 rule to be established by the Agency will set standards for lead levels in dust and soil to determine 1) whether a residential environment has lead-contaminated dust and soil, and 2) whether a lead-based paint hazard is present in a residential environment.

#### **ES.2 OBJECTIVES**

This report presents the methods and findings of a risk analysis, which provides a scientific foundation for the regulatory standards that the Agency will establish in response to §403. This risk analysis consists of two parts. Part I (Chapters 2 through 5) constitutes the risk assessment, or EPA's assessment of the health risks to young children from exposures to lead-based paint hazards, lead-contaminated dust, and lead-contaminated soil in the nation's housing. Part II (Chapter 6) constitutes an analysis of risk management options, which includes the Agency's approach to estimating how these risks are reduced following promulgation of the §403 rule and illustrates use of this methodology for a broad range of example options for the §403 standards.

The objective of the risk assessment is to characterize *baseline* health risks to young children from specific residential exposures to lead. The term *baseline* (or "pre-§403") refers to conditions in 1997, prior to promulgating any rule in response to §403. The objectives of risk management are to develop and apply methodology to determine how risks are expected to be reduced from baseline levels because of interventions conducted in response to the §403 rule (or "post §403"), and to develop an approach to estimate numbers of children and housing units that

would be directly impacted by the rule. Information presented in this risk analysis will ultimately be used to consider various standards for rulemaking and as input to the Regulatory Impacts Analysis (RIA) for the proposed rule, as well as any interim economic cost-benefit analyses.

#### ES.3 KEY ELEMENTS OF RISK ANALYSIS

Figure ES-1 provides an overview of the risk analysis conducted for the §403 regulation. In the risk assessment, hazard identification, exposure assessment, and dose-response assessment provide necessary information to risk characterization, where the baseline distribution of blood-lead concentrations for U.S. children aged 12 to 35 months (cited as "aged 1-2 years" in this report) is determined, along with baseline health risks resulting from residential exposure to lead. This overview focuses on the key issues addressed by this risk analysis in performing risk characterization and risk management. These key issues include: examining the population of interest; selecting the measurement and health endpoints; identifying data sources for this risk analysis; defining intervention strategies for this analysis; and applying statistical models in the risk analysis.

#### Population of interest

While the health risk associated with lead exposure is significant for all humans, young children are most sensitive in this regard. In particular, the scientific literature indicates that the following tend to be prevalent in children aged 1-2 years:

- ! a high level of hand-to-mouth activity, which increases the potential for ingesting lead-contaminated dust, soil, and paint
- ! a rapidly-developing central nervous system, making it highly susceptible to the effects of lead
- ! a peaking of the synaptic density of the frontal cortex of the brain; synaptic development can be disrupted or delayed as a result of lead exposure

Also, the scientific literature best characterizes the relationship between childhood blood-lead concentration and intelligence quotient (IQ) score within this age group (approximately a 0.25 drop in IQ score is predicted for every 1.0  $\mu$ g/dL increase in blood-lead concentration). These neurotoxicological effects of lead exposure at this age may be irreversible. Therefore, as the health effect and blood-lead concentration endpoints considered in this risk analysis have high sensitivity and are well characterized for this age group, and this age group is representative of the population addressed by the statute, the population of interest for this risk analysis was <u>U.S.</u> children aged 1-2 years.

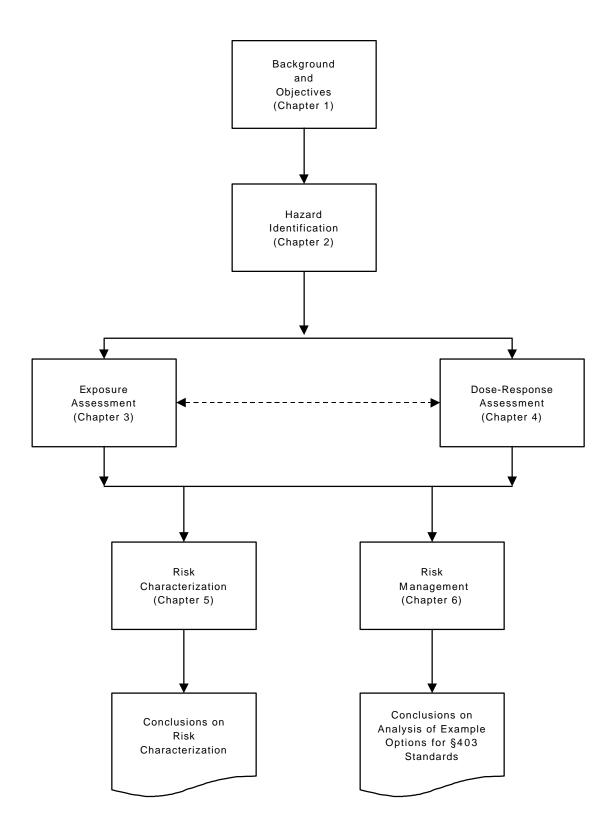


Figure ES-1. Overview of the Risk Analysis Approach.

#### Selecting the measurement and health endpoints

To characterize the health risk associated with lead exposures to children aged 1-2 years, this risk analysis considered the following: <u>elevated blood-lead concentration</u> and <u>IQ point deficit</u>. Blood-lead concentration is a measurement endpoint used in many previous studies to quantify the health effect associated with lead exposure. In their guidelines for childhood lead poisoning prevention, the Centers for Disease Control and Prevention (CDC) indicates that procedures to prevent adverse health effects from lead exposure are triggered when a child's blood-lead concentration exceeds specified thresholds. IQ point deficit is one of the many adverse health effects resulting from lead exposure and is used in this report to represent the neurotoxicological effects of lead. The risk characterization consisted of the following blood-lead concentration and health effect endpoints:

- ! The incidence of blood-lead concentration greater than or equal to  $10 \,\mu g/dL^1$
- ! The incidence of blood-lead concentration greater than or equal to  $20 \,\mu g/dL^2$
- ! The incidence of IQ score less than  $70^3$  resulting from childhood lead exposure
- ! The likelihood of an IQ score decline greater than or equal to 1 point due to childhood lead exposure
- ! The likelihood of an IQ score decline greater than or equal to 2 points due to childhood lead exposure
- ! The likelihood of an IQ score decline greater than or equal to 3 points due to childhood lead exposure
- ! Average IQ score decline in a child as a result of childhood lead exposure.

The latter four endpoints provide information on the distribution of IQ point deficit resulting from lead-based paint hazards.

<sup>&</sup>lt;sup>1</sup> A blood-lead concentration of 10  $\mu$ g/dL is the threshold at which CDC recommends frequent monitoring of the child and community-wide lead poisoning prevention activities. Lead-related reductions in intelligence, impaired hearing activity, and interference with Vitamin D metabolism have been documented in children with blood-lead concentrations as low as 10  $\mu$ g/dL.

 $<sup>^2</sup>$  A blood-lead concentration of 20  $\mu$ g/dL is the threshold at which CDC recommends a complete medical evaluation, an environmental assessment, and necessary environmental remediation for the child and his/her environment. Increased blood pressure, delayed reaction times, anemia, and kidney disease are among the adverse health effects seen at this level.

 $<sup>^{3}</sup>$  An IQ score of 70 is two standard deviations below the population mean and is used as an indicator of mental retardation.

#### Identifying data sources for this risk analysis

Data on the national distribution of blood-lead concentration in children aged 1-2 years and on environmental-lead levels in the nation's housing stock were obtained to address the above objectives. To the extent that they were available, data from recent, nationally representative surveys were used in this risk analysis.

The national distribution of baseline blood-lead concentrations in children aged 1-2 years was determined from data collected in Phase 2 of the third National Health and Nutrition Examination Survey (NHANES III), conducted from 1991-1994. Without disparaging the national representativeness of the NHANES III data, the use of NHANES III data in this risk analysis has the following limitations: blood-lead concentration data were sampled so that potential effects on seasonality will be missed, and any further reduction in blood-lead concentration that may have occurred between the middle of the survey and 1997 will not be captured.

Data on numbers of housing units and on children within specified housing groups were obtained from sources provided by the U.S. Bureau of the Census, such as the American Housing Survey. In addition, information used to translate blood-lead concentration to the above health effect endpoints was obtained from peer-reviewed articles in refereed journals.

Recognized as the leading source of data on environmental-lead levels in residential environments, the National Survey of Lead-Based Paint in Housing, conducted from 1989-1990 by the U.S. Department of Housing and Urban Development (HUD), was the primary source of data on baseline environmental-lead levels in dust and soil in the nation's housing stock. The design and findings of the HUD National Survey have been peer reviewed and published in several government reports. However, there are limitations associated with using the HUD National Survey data: limited numbers of environmental samples were taken at each housing unit, only 284 houses were sampled (which were all built prior to 1980), the study was conducted over five years ago, and a dust collection device other than the wipe collection method being adopted by the §403 rules was used. These limitations contribute to overall uncertainty in results within the risk analysis.

#### Defining intervention strategies for this analysis

As part of the approach to determine how environmental-lead levels may change upon implementing standards in response to §403, the Agency identified a limited set of intervention activities that were assumed to occur at housing units identified as exceeding one or more standards. A brief description of each intervention activity is provided in Table ES-1, along with when the activity is triggered at a specific residence and the assumed durations on the efficacy of the intervention. This report does not attempt to provide detailed protocols on how each intervention should be conducted. While the durations in Table ES-1 were based on review of available data in the scientific literature, it should be understood that most published studies on intervention effectiveness provide little or no information on efficacy beyond one or two years after performance of the intervention activities.

## Table ES-1. Interventions Defined for the §403 Risk Analysis, and the Assumed Duration of Time During Which Lead Levels Are Reduced in the Medium Targeted by the Intervention.

Intervention	When the Intervention is Assumed to be Triggered <sup>1</sup>	Assumed Procedures Defining the Intervention	Assumed Duration
Dust cleaning	After any interior paint intervention, after soil removal, or when dust- lead loadings on floors or window sills exceed hazard standards for dust	Clean the unit using HEPA vacuums and wet mopping	Dust: 4 years or permanent <sup>2</sup>
Soil removal	When average soil-lead concentration for the entire yard exceeds the hazard standard for soil	Soil from areas with elevated lead concentrations is removed and replaced with clean soil, or the areas are permanently covered. A dust cleaning intervention is assumed to follow soil removal.	Soil: Permanent Dust: Permanent
Abatement of exterior lead-based paint	When the level of lead in deteriorated paint on exterior surfaces exceeds the hazard standard for paint, and the amount (square footage) of such paint warrants an abatement	Deteriorated lead-based paint is removed, and the affected surface enclosed or encapsulated, if necessary, using currently acceptable practices and materials	Paint: 20 years
Maintenance of exterior lead-based paint	When the level of lead in deteriorated paint on exterior surfaces exceeds the hazard standard for paint, but the amount (square footage) of such paint does not warrant an abatement	Painted surfaces with deteriorated lead- based paint are repaired by feathering the edges of deteriorating paint and repainting with new, lead-free paint	Paint: 4 years
Abatement of interior lead-based paint	When the level of lead in deteriorated paint on interior surfaces exceeds the hazard standard for paint, and the amount (square footage) of such paint warrants an abatement	Deteriorated lead-based paint is removed, and the affected surface enclosed or encapsulated, if necessary, using currently acceptable practices and materials. A dust cleaning intervention is assumed to follow this intervention.	Paint: 20 years Dust: permanent <sup>2</sup>
Maintenance of interior lead-based paint	When the level of lead in deteriorated paint on interior surfaces exceeds the hazard standard for paint, but the amount (square footage) of such paint does not warrant an abatement	Painted surfaces with deteriorated lead- based paint are repaired by feathering the edges of deteriorating paint and repainting with new, lead-free paint. A dust cleaning intervention is assumed to follow this intervention.	Paint: 4 years Dust: 4 years

<sup>1</sup> The term "hazard standards" refers to standards to be established under §403 regulations against which to compare a residential environment when evaluating the presence and magnitude of lead-based paint hazards. These standards are expected to specify the condition and location of lead-based paint, and lead levels in dust and soil.

<sup>2</sup> Duration is assumed permanent if cleaning is accompanied by paint and soil abatements (20 years if accompanied by paint abatement).

#### Applying statistical models in the risk analysis

In characterizing the risks posed by lead exposure to the nation's population of children aged 1-2 years, the risk management analyses employed two statistical models: the Agency's Integrated Exposure, Uptake, and Biokinetic (IEUBK) Model for Lead in Children (version 0.99D), and an empirical regression model developed for this risk analysis. While both models use environmental-lead levels as measured in the HUD National Survey (as well as other factors) to estimate a geometric mean blood-lead concentration for children aged 1-2 years in the U.S. (not for individual children), they function and behave differently. The IEUBK model has been studied extensively, has been utilized at a wide number of sites, and has undergone peer review by EPA's Science Advisory Board. However, the IEUBK model was developed for applications that differ somewhat from this study. While the empirical model was developed specifically for this study, it is based on data collected in a single lead exposure study (The Rochester (NY) Lead-in-Dust study, as documented in Lanphear et al., 1995), has not undergone formal peer review, has not been applied elsewhere, and has not been studied in depth. Table ES-2 summarize the characteristics of these two models.

The empirical model was developed to address some aspects of lead exposure that were important to the risk management analyses but could not be directly addressed by the IEUBK model. These include predicting blood-lead concentration based on dust-lead loadings rather than concentrations, using data on lead loadings in window sill dust as well as floor dust, and representing the effect of pica tendency in the presence of deteriorated lead-based paint. However, the empirical model has its own limitations, such as the utility of using data from a single study to be nationally representative and the differences in sampling methodology between this study and the HUD National Survey. As no single model is optimal for application within this risk analysis, use of these models allows two sets of results to be observed, with each set having different advantages and limitations.

In the risk management methodology to evaluate example options for §403 standards, the IEUBK and empirical models were each used to obtain two distributions of blood-lead concentration: one resulting from exposure to environmental-lead levels existing prior to the proposed rulemaking (pre-§403), and one resulting from lead exposures following interventions that may occur at a residence in response to the proposed rule (post-§403). Then, for a given model, the extent to which the pre-§403 and post-§403 distributions differed was characterized by noting the percentage difference between key distribution parameters (the geometric mean and geometric standard deviation) for the two distributions. These differences were then applied to values of the parameters under the baseline distribution of blood-lead concentration (i.e., the pre-§403 distribution determined from Phase 2 of NHANES III). The result was an estimated national distribution of blood-lead concentrations that represented conditions after implementing the proposed §403 rule and that was directly comparable to the baseline distribution.

#### Table ES-2. Information on the Two Statistical Models Used to Predict the Distribution of Blood-Lead Concentration for Children Exposed to Specified Environmental-Lead Levels.

	IEUBK model	Empirical model
Input parameters and source of data inputs	! Mass-weighted floor dust-lead concentration (μg/g) for the unit (as estimated from HUD National Survey data, assuming Blue Nozzle vacuum collection techniques)	<ul> <li>Area-weighted floor dust-lead loading (µg/ft²) for the unit (as estimated from HUD National Survey data, assuming Blue Nozzle vacuum collection techniques)</li> </ul>
	<ul> <li>Average soil-lead concentration (µg/g) for the entire yard (as estimated from HUD National Survey data)</li> <li>IEUBK model default values were used for all other model parameters: lead in air, lead intake rates (from diet, water, soil, dust), and absorption</li> </ul>	<ul> <li>Area-weighted window sill dust-lead loading (μg/ft²) for the unit (as estimated from HUD National Survey data, assuming Blue Nozzle vacuum collection techniques)</li> <li>Average soil-lead concentration (μg/g) for the entire yard (as estimated from HUD National Survey data)</li> <li>Categorical variable indicating the extent to which deteriorated lead- based paint was present and whether the child puts paint chips in his/her mouth</li> </ul>
Endpoint predicted by the model (under conditions specified by the input parameter values)	Geometric mean blood-lead concentration for children, over the period of birth to seven years of age. Model predictions at age 24 months were used in risk management analyses.	Geometric mean blood-lead concentration for a group of children aged 12-31 months (the age range represented in the data used to develop the model)
Source of data for developing the model	Many scientific studies	Data from the Rochester Lead-in-Dust Study (Rochester, NY; 84% of the sampled units built prior to 1940, approximately 40% of the sampled children were African American)
Status of model evaluation	The IEUBK model is peer reviewed and is recommended as a risk assessment tool to support OSWER Interim Directive on Revised Soil Lead Guidance for CERCLA Sites and RCRA Facilities	Has not undergone model evaluation nor formal peer review except as part of this document

Baseline values for the seven health effect and blood-lead concentration endpoints defined earlier were calculated from the baseline distribution of blood-lead concentration. Similarly, endpoint values under post-§403 conditions were calculated from the post-§403 blood-lead concentration distribution. These two sets of endpoint values represent *population-based risks* of lead exposure to children aged 1-2 years. It was of interest to determine how risks declined from baseline to post-§403 conditions.

The IEUBK model and a third statistical model, the Rochester multimedia model, were used to determine *individual risks*, or risks associated with children exposed to specified environmental-lead levels. The Rochester multimedia model was developed as an intermediate

step in developing the empirical model from the Rochester Lead-in-Dust study data. This model predicts blood-lead concentration as a function of wipe dust-lead loadings on floors and window sills, dripline soil-lead concentration, and an indicator of paint/pica hazard. Soil-lead concentration is considered at the dripline as most of the Rochester study units had soil-lead concentration data only from the dripline. Individual risk characterization focused on the probability that a child has a blood-lead concentration greater than or equal to  $10 \mu g/dL$ . The Rochester multimedia model was used to predict this probability as a function of dust-lead loadings on floors and window sills, where dripline soil-lead concentration is assumed fixed at a specified value. The IEUBK model was used to predict this probability as a function of average soil-lead concentration for the yard, where dust-lead concentration is assumed fixed at a specified value.

When the interventions in Table ES-1 are performed in a given housing unit, the risk management analyses made assumptions on post-intervention lead levels for the media affected by each intervention. These assumptions are documented in Table ES-3.

Intervention	Assumed Post-Intervention Lead Levels in Affected Media			
	Floor dust-lead loading = the lower of 40 $\mu$ g/ft <sup>2</sup> and the pre-intervention level			
Dust cleaning	Floor dust-lead conc. is determined by the methods documented in Section 6.1			
	Window sill dust-lead loading = the lower of 100 $\mu$ g/ft <sup>2</sup> and the pre-intervention level			
	Soil-lead conc. = 150 $\mu$ g/g in areas where soil removal is conducted			
	Floor dust-lead loading = the lower of 40 $\mu$ g/ft <sup>2</sup> and the pre-intervention level			
Soil removal	Floor dust-lead conc. is determined by the methods documented in Section 6.1			
	Window sill dust-lead loading = the lower of 100 $\mu$ g/ft <sup>2</sup> and the pre-intervention level			
Abatement of exterior lead-based paint	0 ft <sup>2</sup> of deteriorated exterior lead-based paint			
Maintenance of exterior lead-based paint	0 ft <sup>2</sup> of deteriorated exterior lead-based paint			
	0 ft <sup>2</sup> of deteriorated interior lead-based paint			
Abatement of interior	Floor dust-lead loading = the lower of 40 $\mu$ g/ft <sup>2</sup> and the pre-intervention level			
lead-based paint	Floor dust-lead conc. is determined by the methods documented in Section 6.1			
	Window sill dust-lead loading = the lower of 100 $\mu$ g/ft <sup>2</sup> and the pre-intervention level			
Maintenance of interior	0 ft <sup>2</sup> of deteriorated interior lead-based paint			
lead-based paint	Floor dust-lead conc. is determined by the methods documented in Section 6.1			

Table ES-3.	Assumed Post-Intervention Lead Levels in Media Affected by a Particular
	Intervention.

#### ES.4 SUMMARY OF RESULTS

#### ES.4.1 RISK CHARACTERIZATION

The risk characterization was performed using the year 1997 as a point of reference. This year represents a baseline point of reference for environmental-lead levels and health effect and blood-lead concentration endpoints assuming any interventions or other activities conducted in response to the §403 standards would not yet have been implemented. Using data from the American Housing Surveys, this risk characterization predicts that the 1997 national housing stock contains 99,272,000 occupied housing units containing nearly eight million children aged 1 to 2 years. Nearly six million of these children reside within the nearly 75 million housing units built prior to 1980, which are of most importance to the §403 rule. As estimated by the National Survey of Lead-Based Paint in Housing, approximately 83% of pre-1980 housing is estimated to contain lead-based paint, and 18% is estimated to contain non-intact lead-based paint, defined in the HUD National Survey as greater than 5 ft<sup>2</sup> of peeling, chipping, or otherwise deteriorated lead-based paint.

Baseline estimates of the blood-lead concentration and health effect endpoints associated with children aged 1 to 2 years are provided in Table ES-4. These estimates are determined by assuming that the distribution of blood-lead concentration in children aged 1-2 years is lognormal with a geometric mean of  $3.14 \mu g/dL$  and a geometric standard deviation of  $2.09 \mu g/dL$  (as estimated from the NHANES III Phase 2 data) and by assuming specified relationships between blood-lead concentration and IQ decrement. According to this table, elevated blood-lead concentrations continue to be present within children aged 1-2 years; approximately 458,000 children (5.75%) aged 1-2 years are estimated to have blood-lead concentrations that exceed 10  $\mu g/dL$ . Approximately 9,150 children are expected to have an IQ score below 70 as a result of their exposure to lead.

#### Individual risks vs. population-based risks

The estimates in Table ES-4 represent risk to the entire population of children aged 1-2 years, given exposure to baseline levels of lead in the nation's housing stock (i.e., *population-based risks*). However, it is also of interest to characterize the probability of experiencing an elevated blood-lead concentration for children exposed to specific levels of lead in dust and soil (i.e., *individual risks*). Table ES-5 provides examples of estimated environmental-lead levels in soil and dust associated with a 5% likelihood that children exposed to such levels will have a blood-lead concentration at or above 10  $\mu$ g/dL. This table indicates that the 5% likelihood is unachievable when floor dust-lead concentrations are as high as 500  $\mu$ g/g. In addition, when dripline soil-lead concentrations range from 100 to 400  $\mu$ g/g and window sill dust-lead loadings range from 200 to 500  $\mu$ g/ft<sup>2</sup>, floor dust-lead loadings must be less than 10  $\mu$ g/ft<sup>2</sup> to achieve the 5% likelihood.

### Table ES-4. Estimated Baseline Number and Percentage of U.S. Children Aged 1-2 Years Having Specific Health Effect and Blood-Lead Concentration Endpoints.

	Baseline Estimates			
Health Effect and Blood-Lead Concentration Endpoints	Number of Children With the Attribute	Percentage of Children With the Attribute		
Blood-lead concentration greater than or equal to 20 µg/dL	46,800	0.588%		
Blood-lead concentration greater than or equal to 10 µg/dL	458,000	5.75%		
IQ score less than 70 <sup>1</sup>	9,150	0.115%		
IQ score decrement of at least 1 <sup>1</sup>	3,060,000	38.5%		
IQ score decrement of at least 2 <sup>1</sup>	863,000	10.8%		
IQ score decrement of at least 3 <sup>1</sup>	295,000	3.70%		
Average IQ decrement in a child, resulting from lead exposure	1.06			

<sup>1</sup> Resulting from lead exposure.

### Table ES-5. Examples of Environmental-Lead Levels Associated with a 5% Likelihood that a Child Exposed to Such Levels Would Have a Blood-Lead Concentration at or Above 10 µg/dL.

Model Used to Predict Blood- Lead Conc. (Targeted Medium)	Environmental-Lead Levels Considered at Fixed Values in the Model	Environmental-Lead Levels in the Targeted Medium Necessary to Control the Likelihood of a Child with Blood-Lead Concentration at or above 10 µg/dL to 5%	
IEUBK model	Floor dust-lead conc. = 100 µg/g	Soil-lead concentration = 370 µg/g	
(soil)	Floor dust-lead conc. = 200 µg/g	Soil-lead concentration = 240 µg/g	
	Floor dust-lead conc. = 500 µg/g	5% likelihood is unachievable at the given floor dust-lead concentration	
Rochester multimedia	Dripline soil-lead conc. = 100 $\mu$ g/g, Window sill dust-lead loading = 200 $\mu$ g/ft <sup>2</sup>	Floor dust-lead loading = 6.7 $\mu$ g/ft <sup>2</sup>	
model (dust on floors	Dripline soil-lead conc. = 100 $\mu$ g/g, Window sill dust-lead loading = 500 $\mu$ g/ft <sup>2</sup>	Floor dust-lead loading = 2.0 $\mu$ g/ft <sup>2</sup>	
or window sills)	Dripline soil-lead conc. = 400 µg/g, Window sill dust-lead loading = 200 µg/ft <sup>2</sup>	Floor dust-lead loading = 0.6 $\mu$ g/ft <sup>2</sup>	
	Dripline soil-lead conc. = 400 μg/g, Window sill dust-lead loading = 500 μg/ft <sup>2</sup>	Floor dust-lead loading = 0.2 $\mu$ g/ft <sup>2</sup>	
	Dripline soil-lead conc. = 100 $\mu$ g/g, Floor dust-lead loading = 25 $\mu$ g/ft <sup>2</sup>	Window sill dust-lead loading = 74 $\mu$ g/ft <sup>2</sup>	
	Dripline soil-lead conc. = 100 $\mu$ g/g, Floor dust-lead loading = 100 $\mu$ g/ft <sup>2</sup>	Window sill dust-lead loading = 26 $\mu$ g/ft <sup>2</sup>	
	Dripline soil-lead conc. = 400 $\mu$ g/g, Floor dust-lead loading = 25 $\mu$ g/ft <sup>2</sup>	Window sill dust-lead loading = $12 \mu g/ft^2$	
	Dripline soil-lead conc. = 400 $\mu$ g/g, Floor dust-lead loading = 100 $\mu$ g/ft <sup>2</sup>	Window sill dust-lead loading = 4.2 $\mu$ g/ft <sup>2</sup>	

Note: Dust-lead loadings in this table are assumed to reflect wipe collection methods. Graphical portrayal of the information presented in this table is found in Section 5.3.

#### ES.4.2 ANALYSIS OF EXAMPLE OPTIONS FOR RISK MANAGEMENT

To illustrate the methods developed in the risk management for evaluating various options for the §403 standards, the methods were applied to different sets of example standards. These examples are <u>not</u> meant to encompass all possible options for the §403 standards; the Agency will consider other sets of candidate standards.

Table ES-6 contains estimated percentages of the housing stock for which the interventions in Table ES-1 are expected to be triggered according to each of three sets of example options for dust and soil standards, and paint triggers (the example options are specified in the footnotes to this table). The number of pre-1980 housing units in which at least one intervention is triggered ranges from 16.5 million units (22.2%) under example set A (higher standards) to 46.2 million units (62.1%) under example set F (lower standards). Under example set C, at least one intervention would be triggered in approximately 28% of housing built prior to 1980 (20.7 million units) and in approximately 22% of the entire national housing stock (21.6 million units).

For each set of example options in Table ES-6, one or both of the dust-lead loading standards (primarily the window sill standard) were exceeded in more than half of the units in which at least one standard was exceeded. For those homes that did not exceed the example option for the dust standard, about 1% had soil lead concentrations in excess of the corresponding soil standard.

Tables ES-7a and ES-7b provide estimates of the health effect and blood-lead concentration endpoints for U.S. children aged 1-2 years, as calculated by the IEUBK model and the empirical model, respectively, under the three sets of example options for dust and soil standards and paint triggers considered in Table ES-6. For each endpoint and each example set, estimates based on the IEUBK model are less than those based on the empirical model. While the percentage difference from baseline differs considerably across the three example sets for all endpoints (especially under the IEUBK model), the endpoints most sensitive to the levels of the standards and triggers are the percentages of children with blood-lead concentrations at or above 20  $\mu$ g/dL or 10  $\mu$ g/dL, and the percentages of children with IQ score decrements of greater than 2 or 3.

#### ES.5 CONCLUSIONS

As estimated in this risk analysis, baseline distribution of childhood blood-lead concentrations in the U.S. indicates that elevated blood-lead concentrations remain prevalent. According to this distribution, approximately 785,000 children aged 1-5 years (3.85%) are estimated to have blood-lead concentrations at or above 10  $\mu$ g/dL, the level of concern identified by CDC. Among 1-2 year olds, the age group on which this risk analysis was focused, approximately 458,000 children (5.75%) are estimated to have blood-lead concentrations at or above 10  $\mu$ g/dL, and 46,800 children (0.59%) are estimated to have blood-lead concentrations at or above 20  $\mu$ g/dL. Evidence from previous studies indicate that high percentages of these children reside in certain environments, such as urban centers, older housing, or within low

## Table ES-6. Estimated Percentages1 of Occupied Housing Units in the 1997 U.S. HousingStock in Which Certain Interventions Are Triggered for Three Example Setsof Options for Dust and Soil Standards and Paint Triggers.

	Example Set A <sup>2</sup>		Examp	le Set C <sup>3</sup>	Example Set F <sup>4</sup>		
Intervention(s)	% Units Triggered	% of Pre- 1980 Units Triggered	% Units Triggered	% of Pre- 1980 Units Triggered	% Units Triggered	% of Pre- 1980 Units Triggered	
Dust cleaning, triggered by floor dust-lead loading	(*)	(*)	4.04	5.39	13.8	18.4	
Dust cleaning, triggered by window sill dust-lead loading	10.3	12.6	12.5	15.5	48.1	54.7	
Soil removal	0.215	0.287	2.49	3.32	11.8	15.8	
Exterior lead-based paint abatement	3.03	4.05	5.77	7.70	9.26	12.4	
Exterior lead-based paint maintenance	3.84	5.12	3.49	4.66	1.15	1.53	
Interior lead-based paint abatement	0.453	0.605	2.43	3.25	5.35	7.15	
Interior lead-based paint maintenance	2.80	3.73	2.92	3.90	1.08	1.45	
Dust cleaning, triggered by floor OR window sill dust-lead loading	10.3	12.6	13.9	17.3	50.6	58.0	
Dust cleaning OR soil removal	10.6	12.9	14.6	18.3	51.6	59.3	
Any intervention	17.5	22.2	21.8	27.8	53.7	62.1	

<sup>1</sup> To assist in interpreting the percentages in this table, the 1997 occupied housing stock is estimated to contain approximately 99,272,000 housing units, of which approximately 74,379,000 units are built prior to 1980.

<sup>2</sup> Example dust and soil standards are 400 µg/ft<sup>2</sup> for floors, 800 µg/ft<sup>2</sup> for window sills, and 5000 µg/g for soil. Dust standards assume wipe techniques. Paint intervention triggers are 10 ft<sup>2</sup> of deteriorated lead-based paint for paint maintenance, and 100 ft<sup>2</sup> of deteriorated lead-based paint for paint abatement.

<sup>3</sup> Example dust and soil standards are 100 µg/ft<sup>2</sup> for floors, 500 µg/ft<sup>2</sup> for window sills, and 2000 µg/g for soil. Dust standards assume wipe techniques. Paint intervention triggers are 5 ft<sup>2</sup> of deteriorated lead-based paint for paint maintenance, and 20 ft<sup>2</sup> of deteriorated lead-based paint for paint abatement.

<sup>4</sup> Example dust and soil standards are 25 µg/ft<sup>2</sup> for floors, 25 µg/ft<sup>2</sup> for window sills, and 500 µg/g for soil. Dust standards assume wipe techniques. Paint intervention triggers are 0 ft<sup>2</sup> of deteriorated lead-based paint for paint maintenance, and 5 ft<sup>2</sup> of deteriorated lead-based paint for paint abatement.

(\*) indicates that the estimate is essentially zero based on the available data.

Table ES-7a. Estimates of Health Effect and Blood-Lead Concentration Endpoints for<br/>Children Aged 1 to 2 Years Under the IEUBK Model and Percent Declines in<br/>These Estimates from Baseline for Three Example Sets of Options for Dust<br/>and Soil Standards and Paint Triggers.

	Estimate for Children Aged 1-2 Years <sup>1</sup>			Percent Decline in Estimate from Baseline (Table ES-4)			
Measure	Example Set A <sup>2</sup>	Example Set C <sup>3</sup>	Example Set F⁴	Example Set A <sup>2</sup>	Example Set C <sup>3</sup>	Example Set F <sup>₄</sup>	
Percent of children with blood-lead concentration greater than or equal to 20 µg/dL	0.290%	0.0539%	0.00198%	50.7%	90.8%	99.7%	
Percent of children with blood-lead concentration greater than or equal to 10 µg/dL	3.92%	1.66%	0.250%	31.8%	71.1%	95.7%	
Percent of children with IQ score less than 70 resulting from lead exposure	0.107%	0.0984%	0.0909%	7.0%	14.4%	21.0%	
Percent of children with IQ score decrement of at least 1 resulting from lead exposure	34.5%	28.3%	15.1%	10.4%	26.5%	60.8%	
Percent of children with IQ score decrement of at least 2 resulting from lead exposure	8.09%	4.31%	0.978%	25.1%	60.1%	90.9%	
Percent of children with IQ score decrement of at least 3 resulting from lead exposure	2.37%	0.858%	0.0976%	35.9%	76.8%	97.4%	
Average IQ score decrement per child resulting from lead exposure	0.964	0.848	0.666	9.1%	20.0%	37.2%	
Geometric mean blood-lead concentration (geometric standard deviation)	2.95 (2.00)	2.74 (1.84)	2.25 (1.70)	6.1%	12.7%	28.3%	

<sup>1</sup> To assist in interpreting the percentages in this table, the number of children aged 1-2 years in the 1997 national housing stock is estimated as 7,961,000.

<sup>2</sup> Example dust and soil standards are 400 µg/ft<sup>2</sup> for floors, 800 µg/ft<sup>2</sup> for window sills, and 5000 µg/g for soil. Dust standards assume wipe techniques. Paint intervention triggers are 10 ft<sup>2</sup> of deteriorated lead-based paint for paint maintenance, and 100 ft<sup>2</sup> of deteriorated lead-based paint for paint abatement.

<sup>3</sup> Example dust and soil standards are 100 µg/ft<sup>2</sup> for floors, 500 µg/ft<sup>2</sup> for window sills, and 2000 µg/g for soil. Dust standards assume wipe techniques. Paint intervention triggers are 5 ft<sup>2</sup> of deteriorated lead-based paint for paint maintenance, and 20 ft<sup>2</sup> of deteriorated lead-based paint for paint abatement.

<sup>4</sup> Example dust and soil standards are 25 μg/ft<sup>2</sup> for floors, 25 μg/ft<sup>2</sup> for window sills, and 500 μg/g for soil. Dust standards assume wipe techniques. Paint intervention triggers are 0 ft<sup>2</sup> of deteriorated lead-based paint for paint maintenance, and 5 ft<sup>2</sup> of deteriorated lead-based paint for paint abatement.

# Table ES-7b. Estimates of Health Effect and Blood-Lead Concentration Endpoints for<br/>Children Aged 1 to 2 Years Under the Empirical Model and Percent Decline<br/>in These Estimates from Baseline for Three Example Sets of Options for<br/>Dust and Soil Standards and Paint Triggers.

	Estimate for Children Aged 1-2 Years <sup>1</sup>			Percent Decline in Estimate from Baseline (Table ES-4)			
Measure	Example Set A <sup>2</sup>	Example Set C <sup>3</sup>	Example Set F⁴	Example Set A <sup>2</sup>	Exampl e Set C <sup>3</sup>	Exampl e Set F⁴	
Percent of children with blood- lead concentration greater than or equal to 20 µg/dL	0.458%	0.406%	0.317%	22.1%	31.0%	46.2%	
Percent of children with blood- lead concentration greater than or equal to 10 µg/dL	5.03%	4.70%	4.09%	12.5%	18.3%	28.9%	
Percent of children with IQ score less than 70 resulting from lead exposure	0.112%	0.110%	0.108%	2.7%	4.3%	6.0%	
Percent of children with IQ score decrement of at least 1 resulting from lead exposure	37.1%	36.3%	34.7%	3.6%	5.7%	9.8%	
Percent of children with IQ score decrement of at least 2 resulting from lead exposure	9.79%	9.30%	8.34%	9.4%	13.9%	23.0%	
Percent of children with IQ score decrement of at least 3 resulting from lead exposure	3.16%	2.93%	2.49%	14.6%	20.8%	32.6%	
Average IQ score decrement per child resulting from lead exposure	1.02	1.00	0.971	3.4%	5.7%	8.2%	
Geometric mean blood-lead concentration (geometric standard deviation)	3.07 (2.05)	3.03 (2.04)	2.95 (2.01)	2.3%	3.5%	5.9%	

<sup>1</sup> To assist in interpreting the percentages in this table, the number of children aged 1-2 years in the 1997 national housing stock is estimated as 7,961,000.

<sup>2</sup> Example dust and soil standards are 400 µg/ft<sup>2</sup> for floors, 800 µg/ft<sup>2</sup> for window sills, and 5000 µg/g for soil. Dust standards assume wipe techniques. Paint intervention triggers are 10 ft<sup>2</sup> of deteriorated lead-based paint for paint maintenance, and 100 ft<sup>2</sup> of deteriorated lead-based paint for paint abatement.

<sup>3</sup> Example dust and soil standards are 100 µg/ft<sup>2</sup> for floors, 500 µg/ft<sup>2</sup> for window sills, and 2000 µg/g for soil. Dust standards assume wipe techniques. Paint intervention triggers are 5 ft<sup>2</sup> of deteriorated lead-based paint for paint maintenance, and 20 ft<sup>2</sup> of deteriorated lead-based paint for paint abatement.

<sup>4</sup> Example dust and soil standards are 25 μg/ft<sup>2</sup> for floors, 25 μg/ft<sup>2</sup> for window sills, and 500 μg/g for soil. Dust standards assume wipe techniques. Paint intervention triggers are 0 ft<sup>2</sup> of deteriorated lead-based paint for paint maintenance, and 5 ft<sup>2</sup> of deteriorated lead-based paint for paint abatement.

income households, where there is typically a higher likelihood of encountering lead-based paint hazards.

Methodology was developed and applied for characterizing reductions in risk expected to result after interventions are conducted in response to the proposed rule. While examples of the risk reductions have been presented for selected sets of example options for §403 standards, they have been included primarily to illustrate application of the risk management methodology and are not necessarily meant to convey definitive patterns in risk measures across different sets of candidate standards. The Agency will apply the risk management methodology to evaluate specific options for environmental-lead standards.

A major limitation in the risk management methodology was the lack of nationallyrepresentative dust-lead loading data where samples were collected by wipe techniques. This data gap existed for both baseline (pre-§403) and post-§403 conditions. While approaches were used to help alleviate this data gap, such as conversions of dust-lead loading data from one sample collection method to another and assumptions on post-intervention dust-lead loadings, sensitivity analyses suggest that these approaches yielded estimates on numbers of affected housing units and on risk characterization having considerable uncertainty.

Other aspects of the data modeling and analysis approaches, as well as assumptions made in this process contribute to overall uncertainty in the results. Among these are the need to adjust dust-lead concentrations in the HUD National Survey to reflect underestimated sample weights, high levels of variability in the HUD National Survey data, the age of the studies and surveys providing data to this risk analysis, procedures to update the data to reflect 1997 conditions, modeling the relationship between blood-lead concentration and health effect measures, the need for data conversions, assumptions on lognormality in the data distributions, and how statistical models are applied in this setting. Despite the levels of uncertainty that they may generate, the approaches and assumptions taken in this analysis have a sound scientific basis.

This risk analysis indicates that while the presence of elevated blood-lead concentration and health effects associated with lead exposure have declined over time, many U.S. children continue to experience these health effects as a result of lead exposure. However, this risk analysis has shown that it is possible to achieve substantial and important reductions in the incidence of adverse health effects in U.S. children when implementing standards to reduce lead exposures under §403 rules.