January 2, 2004

TO: Science Advisory Board Members

FROM: Dave Bradley, Toxics Cleanup Program

SUBJECT: Materials to Support Science Advisory Board (SAB) Review of the Ecology Working Definition of Moderate[1] Levels of Lead in Soils

The Areawide Soil Contamination Task Force submitted their recommendations to the Departments of Agriculture; Community, Trade and Economic Development (CTED); Ecology; and Health in June 2003. The Task Force provided the agencies with numerous recommendations including several that are related to implementation of the Model Toxics Control Act. In particular, the Task Force recommended that Ecology use an approach to address properties or areas with low-to-moderate levels of arsenic and lead that is different than the one used for properties or areas found to have high levels of arsenic and lead.

The Task Force did not identify a range of concentrations they considered to be low-to-moderate. However, concurrent with the Task Force deliberations, Ecology developed a working definition to support ongoing efforts to reduce the potential for children's exposure at schools, child care facilities and other land uses. The current working definition includes two parts:

- Schools, childcare centers, and residential land uses: The low-to-moderate range includes soils with arsenic concentrations of up to 100 parts per million (ppm) and lead concentrations of up to 500 – 700 ppm.

- Commercial properties, parks, etc. (i.e., properties where exposure of children is less likely or less frequent): The low-to-moderate range includes soils with arsenic concentrations of up to 200 ppm and lead concentrations of up to 700 – 1,000 ppm.

The Task Force briefly discussed the working definition and agreed with the Ecology's plans to have the SAB review the scientific rationale for the proposed definition.

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[1] The chartering agencies asked the Task Force to provide recommendations for addressing soils with low-to-moderate levels of arsenic and lead. This term was somewhat confusing because it appeared to mix two categories (e.g., "low" and "moderate"). Ecology has decided to refer to low levels as soil levels below MTCA cleanup levels.

Science Advisory Board Review

The Department is requesting that the SAB review the scientific and technical rationale for Ecology's working definition of moderate levels of arsenic and lead in soil. Specifically, Ecology is interested in the SAB's advice and opinions on whether Ecology's working definition is consistent with current scientific information.

Ecology is preparing discussion materials to support the SAB's review of this issue. The materials for lead-contaminated soils are attached to this memorandum. **Please note that we are not expecting that you will have reviewed these materials in detail prior to the January 12 meeting.** The attached materials include: (1) discussion materials that describe the technical and policy rationale for the Ecology working definition; (2) a set of questions for the SAB to consider as part of their review; and (3) a draft technical memorandum that was prepared by Landau Associates in May 2002 to support Task Force deliberations. Similar materials are being prepared for arsenic-contaminated soils and will be provided to the SAB in February 2004.

The January 12, 2004, Science Advisory Board Meeting

Ecology anticipates that discussions on the working definition will take place over several meetings. We have three main goals for the discussion on January 12. First, we want to provide you with background information on this issue. We are planning to present an overview of the final Task Force recommendations and summarize the technical and policy rationale for the working definition for lead-contaminated soils. Second, we will provide you with the opportunity to ask us any initial questions you might have on the project background and/or written materials. Third, we want to work with the SAB to establish a framework for discussing this issue. Toward that end, we would like the SAB to consider the following questions:

- Do the discussion materials provide you with a sufficient amount of information to discuss the working definition of lead-contaminated soils? If not, what additional information would you find useful?

- Does the list of Ecology questions address issues that you believe are relevant to defining moderate levels of lead-contaminated soils? Are there other questions that you believe the Department should be considering when evaluating this issue?

- What type of process does the SAB want to use when reviewing this issue? Does the SAB want to consider forming a subcommittee to assist in the review of this issue?

Based on these discussions, Ecology will prepare (1) any necessary supplementary materials on lead-contaminated soils and (2) discussion materials for arsenic-contaminated soils. These will be mailed to the SAB in mid-February.

We look forward to beginning to discuss this issue at the January 12, 2004, SAB meeting. If you have questions prior to the meeting, please contact either Dave Bradley (360/407-6907) or Dawn Hooper (360/407-7182).

DB:cp
Attachment

Lead-Contaminated Soils
Questions for the Science Advisory Board

Exposure Pathways

- When developing responses to elevated levels of lead in soils, Ecology's primary concern has been lead exposure that occurs as a result of incidental ingestion of soil and dust.

    - Several members of the Task Force and the general public questioned whether incidental ingestion of soil and dust was an important exposure pathway for young children. Is there sufficient scientific information to conclude that incidental ingestion of soil and dust represents an important exposure pathway for young children and adults?

    - Is the conclusion "dermal contact with lead-contaminated soils does not represent a significant contributor to overall lead exposure" consistent with current scientific information? If not, what approach should Ecology use to evaluate potential lead exposure resulting from dermal contact with lead-contaminated soils?

    - Is the conclusion "inhalation of wind-blown dust does not represent a significant contributor to overall lead exposure" consistent with current scientific information? If not, what approach(es) should Ecology use to estimate potential exposure levels? Are there situations where inhalation of wind-blown dust is a particular concern?

    - In evaluating lead-contaminated soils, we have assumed that lead concentrations resulting from the uptake of lead into homegrown fruits and vegetables are not significantly different than lead concentrations present in the national food supply. Is this assumption consistent with current scientific information?

    - Is the assumption that "soils with lead concentrations less than 1000 mg/kg do not pose a significant threat to ground water" consistent with current scientific information?

    - Are there circumstances (e.g., potential for colloidal transport, etc.) where the Science Advisory Board believes Ecology should take additional steps to evaluate and address potential ground water impacts?

Relationship Between Soil Concentrations and Exposure

- In developing the working definition, Ecology used two EPA models (the Integrated Exposure Uptake Biokinetic (IEUBK) and the Adult Lead Model (ALM) to evaluate health risks posed by lead contaminated soils.

    - Is Ecology's use of the IEUBK model to predict child blood lead concentrations associated lead-contaminated soils consistent with available scientific information?

- Is Ecology's use of the ALM to predict fetal blood lead concentrations associated lead-contaminated soils consistent with available scientific information?

- Are there other models and/or approaches that the SAB believes Ecology should consider when attempting to predict child or fetal blood lead concentrations resulting from exposure to lead-contaminated soils?

- Are the exposure parameters and assumptions used in the evaluation consistent with current scientific information?

- Is the approach used to evaluate uncertainty and variability consistent with current scientific information? Does the approach appropriately identify important sources of uncertainty and variability? Does the SAB believe there is sufficient information on the distribution of various input parameters to allow the preparation of a meaningful probabilistic risk assessment?

Health and Ecological Impacts

- In developing the working definition, Ecology used the blood lead screening guidelines developed by the Centers for Disease Control and Prevention (CDC) to identify risk management goals. Based on current scientific information, does the SAB believe that the CDC guidelines provide a risk management goal that is comparable (in terms of the level of protection) to the risk management goals under the Model Toxics Control Act for other hazardous substances?

- The working definition for moderate levels of lead-contaminated soils is based on human health considerations. Are there circumstances (e.g., particular land uses, regions, habitats) where the SAB believes additional steps to evaluate and address ecological impacts should be taken?

Information Collection

- Given the evaluation results, where does the SAB recommend that Ecology focus additional information collection efforts?

LEAD-CONTAMINATED SOILS

Discussion Materials

Prepared for Science Advisory Board

January 2004

Evaluation of Lead-Contaminated Soils

Summary

Regular exposure to elevated concentrations of lead cause several types of health problems. Infants and young children are particularly vulnerable to the effects of lead poisoning because lead can adversely affect the development of the brain and other parts of the nervous system. When an individual has been exposed to lead, the lead can be measured in the bloodstream. The Centers for Disease Control and Prevention (CDCP) considers that a child has elevated blood lead levels if his/her levels are equal to or greater than 10 ug/dL.

Ecology has evaluated the health risks posed by lead-contaminated soils to support decisions on how to implement recommendations the Department received from the Area-wide Soil Contamination Task Force. In performing that evaluation, Ecology made several underlying assumptions:

- Surface soils with lead concentrations below 1000 mg/kg are unlikely to pose a significant threat to ground water supplies.
- Lead exposure via dermal contact and inhalation of re-suspended soil are unlikely to be significant exposure pathways relative to ingestion of soil/dust, food and drinking water.
- EPA's Integrated Exposure Uptake and Biokinetic (IEUBK) and Adult Lead Models provide technically sound approaches for evaluating the relationship between soil lead concentrations and blood lead concentrations.
- Ecological impacts will be considered when deciding what should be done to address elevated levels of lead at individual properties.
- The blood lead screening guidelines by the Centers for Disease Control and Prevention (CDCP) provide a sound framework for evaluating and responding to lead-contaminated soils.
- The working definition will be periodically reviewed based on new information.

The IEUBK model was used to evaluate the risks to young children associated with exposure to lead-contaminated soils. The model was used to predict the average blood lead concentrations and the probability that a child will have blood Pb concentrations greater than 10 ug/dL (P_{10}) and 15 ug/dL (P_{15}) following exposure to different soil lead concentrations.

The IEUBK Model predicts that the CTE and P_{10} values will increase as soil lead concentrations increase. The model predicts that a soil concentration of 250 mg/kg (MTCA Method A cleanup level) corresponds to a P_{10} value of 1- 5%. When the analysis is based on the 12-36 month age interval, the P_{10} value is 5%. When the analysis is based on a broader age range (0 – 84 months), the IEUBK model predicts a P_{10} value of 1%. The probability (P_{15}) that blood lead concentrations will exceed 15 ug/dL at a soil concentration of 250 mg/kg is 0.1-0.3%.

Higher soil concentrations are associated with higher P_{10} and P_{15} values. For example, the P_{10} value at a soil concentration of 500 mg/kg ranges from 9.6 – 21.3%. The P_{10} and P_{15} values are influenced by assumptions on frequency of exposure. For example, if the exposure frequency is based on school or child care exposure scenarios (180-250 days/year), the P_{10} value at 500 mg/kg ranges from 3.4 – 7.9%.

Sensitivity analyses were performed to evaluate the impact of changes in model assumptions on predicted blood lead concentrations. The model predictions are sensitive to assumptions

regarding (1) Geometric Standard Deviation; (2) non-soil lead exposure; (3) soil ingestion rate; and (4) exposure frequency. The IEUBK model is similar to many other child lead exposure models. Predicted blood lead concentrations based on the IEUBK model tend to fall in the middle of the range of values from various models when similar lead exposure assumptions are used.

The EPA Adult Lead Model (ALM) was used to evaluate the health risks to fetuses of workers who might accumulate lead as result of non-residential exposure. Specifically, the model was used to estimate fetal blood concentrations associated with maternal exposure to lead-contaminated soils. Preliminary Remediation Goals (PRGs) represent soil concentrations where the probability that fetal blood concentrations will exceed 10 ug/dL (P_{10}) is less than 5%.

The ALM predicts a PRG of 800 mg/kg using the EPA default exposure parameters with regional information on maternal blood lead concentrations. Use of alternate exposure assumptions results in PRG values that range from 400 to 1460 mg/kg. For example, increasing the soil ingestion rate from 50 mg/day (the EPA default soil ingestion rate) to 100 mg/day results in a PRG of 400 mg/kg.

The model predictions are sensitive to assumptions regarding (1) Geometric Standard Deviation; (2) baseline maternal blood lead concentration; and (3) soil ingestion rate. EPA has found that blood lead concentrations predicted by the Adult Lead Model are similar to values predicted by other adult lead exposure models.

Ecology has developed a working definition for moderate levels of lead in soils for use in implementing the recommendations of the Area-Wide Soil Contamination Task Force. Moderate levels of lead contamination are defined as soils with lead concentrations between 250 mg/kg and 500 – 1000 mg/kg.

- The lower end of the range (250 mg/kg) is equal to the current MTCA Method A Cleanup Level and corresponds to a soil concentration where there is low probability (1- 5%) that blood lead concentrations will be above 10 ug/dL in young children.
- The upper end of the range varies depending on land use and corresponds to soil concentrations where there is a low probability (1-5%) that blood lead concentrations will exceed 15 ug/dL. The upper end of the range varies depending on whether a property is being used as a (1) residence (500 mg/kg); (2) school/child care facility (700 mg/kg) or (3) park or commercial property (1000 mg/kg).

Under the framework recommended by the Task Force, moderate soils would be addressed through a combination of (1) public education programs designed to increase awareness of contamination problems and encourage individuals to take steps to reduce exposure (2) low-cost contaminant measures that could be readily implemented by schools, homeowners, etc. to reduce the potential for contact with contaminated soils; (3) implementation of more permanent containment measures during construction and/or property redevelopment. Properties with lead concentrations above these ranges would continue to be evaluated and addressed on a site-specific basis under the Model Toxics Control Act or other appropriate authorities.

Section 1.0
Introduction

1.1 Background

In 1994, the Washington Legislature established the Model Toxics Control Act (MTCA) Policy Advisory Committee (PAC) to review implementation of MTCA. In their final report, the MTCA PAC recommended that Ecology take steps to more effectively address area-wide soil contamination. In early 2000, the Departments of Agriculture, Ecology, Health, and Community, Trade and Economic Development met several times to discuss this issue. The agencies identified several interconnected challenges posed by widespread low-to-moderate level soil contamination (See Table 1-1) and concluded that effective, long-term solutions to area-wide soil contamination problems would require looking beyond traditional cleanup processes and agency boundaries.

The Agencies chartered the Area-Wide Soil Contamination Task Force (Task Force) in January 2002 to consider the special challenges posed by area-wide soil contamination and recommend a statewide strategy for meeting those challenges. The Task Force submitted their final report to the four chartering agencies on June 30, 2003. The Task Force provided the agencies with numerous recommendations including several that are related to implementation of the Model Toxics Control Act. In particular, the Task Force recommended that Ecology use an approach to address properties or areas with "low-to-moderate"[2] levels of arsenic and lead that is different than the one used for properties or areas found to have "high" levels of arsenic and lead.

The Task Force did not identify a range of concentrations they considered to be low-to-moderate. However, concurrent with the Task Force deliberations, Ecology developed a working definition to support ongoing efforts to reduce the potential for children's exposure at schools, child care facilities and other land uses. The working definition has two parts:

- <u>Schools, childcare centers, and residential land uses</u>: The low-to-moderate range includes soils with average arsenic concentrations of <u>up to</u> 100 parts per million (ppm) and average lead concentrations of <u>up to</u> 500 – 700 ppm.
- <u>Commercial properties, parks, etc (i.e. properties where exposure of children is less likely or less frequent)</u>: The low-to-moderate range includes soils with average arsenic concentrations of up to 200 ppm and average lead concentrations of <u>up to</u> 700 – 1,000 ppm.

The Task Force briefly discussed the working definition and agreed with Ecology's plan to have the Science Advisory Board review the scientific and technical rationale for the concentration ranges reflected in the working definition.

[2] The chartering agencies asked the Task Force to provide recommendations for addressing soils with low-to-moderate levels of arsenic and lead. This term was somewhat confusing in that it appeared to mix two categories (e.g. low and moderate). Ecology has decided to refer to low levels as soil levels below the MTCA cleanup levels.

Table 1-1: Issues and Challenges Associated with Addressing Area-Wide Soil Contamination	
Potential for Exposure	Over the past 50 years, Washington's population growth has resulted in the conversion of many agricultural and forested areas and other open space into homes, schools or commercial uses. The population has also increased in areas affected by emissions from metal smelters. Population growth and changes in land use have combined to increase the potential that people will be exposed to area-wide soil contamination.
Geographic Scale	Available information indicates that several hundred thousand acres might contain elevated levels of arsenic and lead as a result of historic activities. Consequently, the geographic scale of areawide soil contamination is significantly greater than areas typically addressed by state and federal cleanup programs and includes many individual parcels of land.
Public Health	Numerous studies indicate that exposure to arsenic and lead in the environment can cause many different health problems in people. However, it is difficult to predict how arsenic or lead will affect a given person. Amounts that cause serious health problems for some people may have no effects on others. Small children are of particular concern because they are more likely than others to come into contact with contaminated soil and dust, in addition to being highly vulnerable to the effects of environmental lead.
Ecological Impacts	Numerous laboratory and field studies have found that arsenic and lead can adversely affect certain plant species at soil levels that are similar to levels commonly associated with areawide soil contamination. However, other field studies have documented healthy and thriving plant communities in areas with similar levels of arsenic and lead.
Financial Impacts	There are a number of potential direct and indirect costs associated with the presence of elevated levels of arsenic and lead in soils and/or implementing measures to reduce the potential for exposure. For example, homeowners and land developers who have purchased or built homes in areas with contaminated soils may face increased costs associated with paying for protective measures, reduction in property values, and difficulties in financing or selling homes. Local governments (e.g. school districts, health departments, etc.) may also face increased costs associated with responding to or assisting others to respond to elevated levels of arsenic and lead. Funding these activities is made more difficult by the fact that persons responsible for the contamination are often hard to identify and/or lack sufficient financial resources.
Public Awareness	People are often unaware that soil at their homes, future homes, children's schools, local parks, etc. may contain elevated levels of arsenic or lead. In these situations, they are unable to determine whether to take steps to reduce health or financial impacts.
Fairness	Any combination of measures to address elevated levels of arsenic and lead has the potential to appear unfair to one or more involved parties (e.g. current landowners, future landowners, parties responsible for the contamination, etc.).
Wide Variations in Soil Concentrations	Area-wide contamination does not appear to be distributed in an easily predictable manner. Consequently, site-specific evaluations/soil sampling is the only way to determine conclusively which properties are contaminated and which are not. However, soil testing raises a number of disclosure and liability issues.
Wide Variations in Risk Perception	Washington residents hold a wide range of opinions on the relative significance of the health and environmental risks posed by arsenic and lead. Some people perceive such risks as high while others consider them to be inconsequential. Studies show that people's perceptions on whether a risk is big or small are influenced by several factors including how familiar they are with a risk, how much control they can exercise over the risk, whether children are exposed to the risk, etc.
Scientific Uncertainty	The scientific methods used to investigate health and environmental risks (e.g. toxicology, epidemiology, etc.) are inherently imprecise and, consequently, open to varying interpretations. Some people note that scientists have not provided absolute scientific proof that people in Washington have been or are being harmed by area-wide soil contamination. The lack of such studies is not unique to Washington. However, the vast majority of health and environmental agencies in the United States (including Health and Ecology) now believe that the preponderance of scientific evidence supports the need to take reasonable steps to reduce exposure to arsenic and lead.

1.2 Lead Concentrations in Washington

The Task Force considered three main sources of elevated levels of arsenic and lead in soils: (1) past releases from smelters in Tacoma, Everett, Northport, Trail B.C. and Harbor Island; (2) past use of lead arsenate pesticides; and (3) past use of leaded gasoline. The following information on the range of soil lead concentrations is based on a review by Landau Associates (2003a):

- Smelters: A broad range of lead concentrations have been measured in soils collected from areas around current or former smelter site. Excluding the smelter properties and areas immediately adjacent to those properties (within 500 to 1000 ft), most of the lead contamination is present in the upper 6 to 18 inches (Landau 2003a). Lead concentrations in most shallow soil samples collected ranged from natural background levels (11 – 24 mg/kg statewide) to over 1,000 mg/kg, with some soil samples indicating the presence of lead over 3,000 mg/kg. The distribution of lead concentrations from several studies is shown in Appendix E. Sampling performed by Ecology, the Tacoma Pierce County Health Department and Public Health Seattle King County indicate that average lead concentrations at schools, child care facilities and parks are generally less than 400 ppm. The general trend from historic smelter stack emissions in Washington appears to be one of the highest concentrations near the smelter and decreasing concentrations with increasing distance in the prevailing wind direction. However, in all cases, there was significant variability in lead levels in soil.
- Lead arsenate pesticides: Lead arsenate was the primary arsenical pesticide[3] used in Washington from the early 1900s until about 1947 when it was replaced by new alternatives such as DDT. Studies completed by WSU of shallow orchard soils indicate residual lead concentrations range from background levels to concentrations up to 4,000 mg/kg (Peryea and Creger, 1994) Similar concentrations have been found during environmental site investigations on land parcels formerly occupied by orchards (Landau 2003a). Average concentrations for individual properties are typically much lower. The distribution of lead concentrations from several studies is shown in Appendix E. Current studies indicate that most of the lead deposited in surface soils remains in the upper 12 – 24 inches. For example, studies completed by WSU indicate that high concentrations of lead were limited to shallow soils (5 to 30 cm or 2 to 12 inch depth) and decreased sharply with depth. Most of the lead and arsenic was found in the upper 40 cm (16 inches) of soil, and concentrations were lower at the soil surface than deeper in the soil profile suggesting some downward movement.

1.3 Evaluation of Lead-Contaminated Soils

[3] Lead arsenate was typically used to control chewing insects. Though it was reportedly used on a wide variety of crops, its most extensive use was on apple and pear orchards to control the codling moth. Consequently, the highest accumulated concentrations of lead and arsenic in soil from historical lead arsenate use is expected to be in areas occupied by apple and pear orchards during the first half of the twentieth century. Lead arsenate was applied with increased frequency and in higher potency solutions during this time period because of the increasing resistance of the codling moth. Lead arsenate was used at far lower solution strengths with other crop types and was less frequently applied. Also other crop types changed more frequently relative to apple and pears. Consequently, metals soil concentrations are predicted to be highest associated with historical apple and pear cultivation relative to historical cultivation of other crops.

This discussion paper is the first of two[4] papers Ecology is preparing to support decisions on how to implement recommendations the Department received from the Area-wide Soil Contamination Task Force. Ecology chose to develop the materials for lead and arsenic separately because the methods used to evaluate lead-contaminated soils are different from the approaches used for arsenic and other hazardous substances. Different methods are used because (1) the adverse health effects of lead are evaluated in terms of the amount of lead in a child's or adult's bloodstream, (2) exposure to lead in soils and other environmental media is evaluated in terms of how such exposures influence blood lead concentrations and (3) the impact of a particular level of lead exposure resulting from contact with lead-contaminated soils is influenced by the amount of lead exposure from other sources (e.g. diet). Ecology has used two lead exposure models developed by the Environmental Protection Agency (EPA) to evaluate the health risks associated with lead-contaminated soils:

- The Integrated Exposure Uptake and Biokinetic (IEUBK) model is designed to evaluate the risks to young children posed by exposure to lead-contaminated soils.
- The Adult Lead Model (ALM) is designed to evaluate the health risks to the fetus of women who accumulate excess lead as a result of non-residential exposures.

This evaluation builds upon several evaluations that have been completed over the last several years. In particular, Landau Associates prepared an evaluation of health risks posed by arsenic and lead-contaminated soils (Landau, 2002) to support deliberations by the Area-wide Soil Contamination Task Force. In that evaluation, Landau Associates identified exposure scenarios and pathways and evaluated the potential health risks posed by exposure to arsenic- and lead-contaminated soils.

1.4 Assumptions Underlying the Evaluation of Lead-Contaminated Soils

There are several important assumptions that shaped the approach used to evaluate the health risks associated with exposure to lead-contaminated soils. These include:

- <u>Surface soils with lead concentrations below 1000 mg/kg are unlikely to pose a significant threat to ground water supplies</u>. Lead in soils may partition or leach from the soil phase into ground water. The document, *Cleanup Levels and Risk Calculations under the Model Toxics Control Act (CLARC) (Ecology 2001b)*, includes a soil screening value based on groundwater protection for lead (3000 mg/kg). Soil levels below 3000 mg/kg are considered unlikely to cause ground water concentrations greater than 15 ug/L). Conversely, soil concentrations above the soil screening values are considered to have some potential for causing ground water contamination and require a site-specific analysis. The soil screening level for lead (3000 mg/kg) is 5-10 times the average soil concentrations reported in areas surrounding the Tacoma and Everett smelters (excluding the former smelter property and areas within 500-1000 feet of the plant site) and properties where lead arsenate pesticides were applied (Landau, 2003a, 2003d). Soil profiles indicate that lead deposited at the surface remains in shallow soils (6-24 inches). Consequently, it is unlikely that a significant amount of lead will migrate from shallow

[4] Ecology is currently working on finishing a second document that addresses the health risks posed by arsenic-contaminated soils and describes the rationale for the range of arsenic concentrations reflected in the proposed working definition.

soils to soil to ground water in areas where average soil lead concentrations range from 100 to 1000 mg/kg.

- Lead exposure via dermal contact is unlikely to be a significant exposure pathway relative to ingestion of soil/dust, food and drinking water. Ingestion of lead in soils/dust, the diet, paint chips and/or drinking water are the primary routes of lead exposure for most children. Although dermal contact is considered to be a complete pathway for lead-contaminated soils, exposure via this pathway does not appear to be a significant contributor to overall exposure to lead-contaminated soils because (1) lead tends to tightly bind to soils which reduces the likelihood that it will disassociate from the soil that adheres to the skin surface and (2) lead has a relatively low ability to cross the skin even when is does disassociate from soil particles, and (3) screening level analyses indicate that exposure via dermal contact would be a minor contributor (< 1 - 10%) to overall exposure for young children. (See Appendix A)

- The IEUBK and Adult Lead Models provide technically sound approaches for evaluating the relationship between soil lead concentrations and blood lead concentrations. Ecology currently uses these models to establish site-site specific cleanup levels and believes they provide technically sound approaches for evaluating the health risks posed by lead-contaminated soils because (1) the models have a strong scientific foundation; (2) blood lead levels predicted by the IEUBK model have been found to be close to observed blood lead concentrations; (3) predictions based on the use of these models are similar to predicted blood lead concentrations based on other lead exposure models; (4) the models are used by EPA and other state environmental agencies to establish soil cleanup requirements.

- Ecological impacts will be considered when deciding what should be done to address elevated levels of lead at individual properties. The Task Force discussions and recommendations focused on the potential for impacts on human health and, consequently, the working definition for moderate levels of lead-contaminated soils is based on human health considerations. However, laboratory and field studies have found that lead may also adversely impact certain plant and wildlife species at soil levels that are similar to levels commonly associated with area-wide soil contamination (other field studies have documented healthy and thriving plant communities in areas with similar levels of lead). Screening level analyses (Landau, 2002) indicate that soil lead concentrations of 600 -1000 mg/kg are 1-20 times higher than ecologically based risk screening levels. The Task Force recommended that Ecology conduct or support studies that evaluate the potential ecological impacts associated with low-to-moderate levels of lead and arsenic in soils. In the agency response to the Task Force recommendations, Ecology stated that it intends to work with the Science Advisory Board on this issue. However, timeframes for identifying and conducting those evaluations are unclear and will be influenced by competing program priorities. Consequently, Ecology has based the working definition on human health considerations. In addition, Ecology has assumed that ecological risks will continue to be addressed when deciding what should be done to address elevated levels of lead at individual properties.

- The blood lead screening guidelines developed by the Centers for Disease Control and Prevention (CDCP) provide a sound framework for evaluating and responding to lead-contaminated soils. Regular exposure to elevated concentrations of lead can cause several types of health problems. Infants, young children and developing fetuses are particularly vulnerable to the effects of lead poisoning because lead can adversely affect the development of the brain and other parts of the nervous system. When an individual has been exposed to lead, the lead can be measured in the bloodstream. The CDCP has developed federal guidelines to assist public officials in identifying appropriate responses to findings of elevated blood levels (CDC 1991; CDCP 1997, 2002). Under the guidelines, a child is considered to have an elevated blood lead level if his/her levels are equal to or greater than 10 ug/dL. The guidelines also identify a series of responses for situations where a child is found to have blood lead concentrations above 10 ug/dL. For example, when a child has a blood level above 10 ug/dL but below 15 ug/dL, CDCP recommends that (1) health agencies provide educational materials on health effects and exposure reduction measures to the child's parents, (2) the parents and/or child implement precautionary measures[5] in order to reduce exposure and (3) the child should be retested after 3 to 6 months. EPA (2003d) and Ecology currently establish soil cleanup levels at soil concentrations where the probability that a young child will have a blood lead level above 10 ug/dL is estimated to be no more than 5 percent.

- The working definition will be periodically reviewed based on new information. There are several uncertainties and data gaps surrounding our understanding of the relationships between lead-contaminated soils and risks to human health and the environment. New information and/or tools for evaluating these relationships are being developed and may prompt future review and/or revisions to the working definition. Examples include:
    - Blood Lead Screening Guidelines: CDCP adopted the federal blood lead screening guidelines in 1991. There have been several studies completed since 1991 that have reported adverse health effects[6] at blood lead levels below 10 ug/dL (Lanphear et al., 2000; Canfield et al. 2003). A CDCP panel of lead experts is presently reviewing the blood lead screening guidelines in light of these more recent scientific studies.
    - EPA All-Ages Lead Model: EPA is currently developing a new lead exposure model that can be used to evaluate lead exposures for all age groups. The model is scheduled to be available for use in 2005.
    - Effectiveness of Public Education Efforts: Ecology and Health are working with the Tacoma Pierce County Health Department to evaluate the effectiveness of ongoing public education programs in terms of reducing exposure to arsenic and lead in soils.

1.5 Organization of the Discussion Paper

[5] If blood lead levels exceed 10 ug/dL, CDC recommends that precautionary measures be taken. Such measures include: Reduce soil/house dust exposures through regular hand and face-washing, replanting bare areas in yards/play areas, door mats, remove shoes at door, regular house vacuuming & dusting; maintain proper nutrition/Balanced diet to minimize lead absorption; run tap water for 15-30 seconds prior to drinking; and identify other potential sources (e.g. lead-based paint etc)

[6] The adverse health effects at or below 10 ug ug/dL are sub-clinical (i.e. cannot be diagnosed in an individual) and, consequently, are studied by comparing large groups of children who are exposed to lead with similar groups of children who have limited lead exposure.

The remainder of this discussion paper is organized into five sections and four exhibits. Ecology has used several acronyms or abbreviations in those sections and exhibits which are listed in Table 1-2. The five sections in the remainder of this discussion paper include:

- Section 2 provides a brief summary of information on the health effects associated with elevated blood lead concentrations;
- Section 3 provides an evaluation of potential health risks for children exposed to lead contaminated soils. This evaluation was performed using the Integrated Exposure Uptake and Biokinetic (IEUBK) model.
- Section 4 provides an evaluation of potential health risks for adults exposed to lead contaminated soils. This evaluation was performed using the EPA Adult Lead Model.
- Section 5 summarizes the technical and policy rationale for Ecology's working definition for moderate levels of lead in soils.
- Section 6 includes the list of references cited in Sections 1 through 5 and Appendices A through E.

Background or supporting information is provided in a series of Appendices:

- Appendix A - Dermal Exposure to Lead in Soils (Screening Level Analysis);
- Appendix B - Sensitivity Analyses for IEUBK Model;
- Appendix C - Incidental Soil/Dust Ingestion (Screening Level Analysis);
- Appendix D - Effectiveness of Public Education Measures; and
- Appendix E – Lead Concentrations in Washington.

Table 1-2

Definitions of Key Terms and Acronyms Used in The Discussion Paper

"ALM" is an acronym that refers to the Adult Lead Model developed by the Environmental Protection Agency.

"CDCP" or "CDC" are acronyms that refer to the Centers for Disease Control and Prevention (previously the Centers for Disease Control).

"CTE" and **"GM"** are acronyms that refer to the central tendency estimate or geometric mean blood lead concentrations predicted by the IEUBK and ALM at different soil lead concentrations.

"GSD" refers to the Geometric Standard Deviation which is an input parameter for both the IEUBK and Adult Lead Models. The GSD is a measure of variability intended to take into account several factors that cause different children or adults to have different blood levels when they are exposed to similar concentrations of lead.[7]

"IEUBK" is an acronym that refers to the Integrated Exposure Uptake Biokinetic Model developed by the Environmental Protection Agency.

"P_{10}" is an acronym that is used for the probability of exceeding a specified blood lead concentration (which is identified as a subscript). For example, P_{10} refers to the probability of exceeding a blood lead concentration of 10 ug/dL; P_5 refers to the probability of exceeding a blood lead concentration of 5 ug/dL; etc.

"PbB" is an acronym used for blood lead concentrations. PbB levels are generally reported in units of micrograms of lead per deciliter of blood (ug/dL).

"PbS" is an acronym used for soil lead concentrations. PbS levels are generally expressed in units of milligrams/kilogram (mg/kg) or parts per million (ppm)

[7] EPA (1994c) states that there are several sources of variability designed to be capture in the geometric standard deviation. These include (1) different environmental context (carpeting, amount of grass cover) that may affect contact with environmental lead; (2) behavioral differences; (3) different exposures/contact rates; (4) measurement variability; (5) biological diversity; and (6) food consumption differences.

Section 2
Health Effects

Section 2 Summary

Exposure to lead can cause several types of toxic effects. Infants, young children and fetuses are particularly vulnerable to the effects of lead poisoning because lead interferes with the development of the central nervous system. Scientists have not been able to identify a clear threshold below which there are no adverse health effects.

Health and environmental agencies currently consider that a blood lead concentration of 10 ug/dL or above is elevated and use this value as the basis for evaluating measures to reduce exposure. However, there have been several studies and evaluations completed in the last ten years that have reported adverse health effects at blood lead levels below 10 ug/dL. The Centers for Disease Control and Prevention (CDCP) is now reviewing the current guidelines in light of these newer studies.

Scientific research continues to improve our understanding of the relationships between lead exposure and adverse health effects. However, there are several issues that have not been fully resolved from a scientific standpoint. These include (1) quantitative relationships between health effects and blood lead concentrations, (2) threshold levels for various health effects and (3) variability in children and adult susceptibility to elevated lead exposure.

Exposure to lead can lead to several types of toxic effects (ATSDR, 1999; EPA, 2001a; Goyer and Clarkson, 2001). Lead has been found to affect nearly every organ system in the human body. Health effects range from subtle or biochemical effects to clinical effects. The most sensitive organ systems appear to be the nervous system (particularly for young children and infants), the cardiovascular system (e.g. hypertension) and the hematopoietic system (e.g. hemoglobin synthesis).

Infants, young children and fetuses are particularly vulnerable to the effects of lead poisoning because lead interferes with the development of the central nervous system. Over the last 30 years, there have been numerous cross-sectional and prospective epidemiology studies that relate blood lead levels at birth and early childhood with learning problems such as reduced intelligence and cognitive development. These studies have been reviewed and summarized by ATSDR (1999).

Scientists have not found sufficient evidence to identify a clear threshold below which there are no adverse health effects. However, the CDCP has developed federal guidelines to assist public officials in identifying appropriate responses to findings of elevated blood levels (CDCP 1991, 1997, 2002). Under the guidelines, a child is considered to have an elevated blood lead level if his/her levels are equal to or greater than 10 ug/dL. The guidelines also identify a series of responses for situations where a child is found to have blood lead concentrations above 10 ug/dL. For example, when a child has a blood level above 10 ug/dL but below 15 ug/dL, CDCP recommends that (1) health agencies provide educational materials on health effects and exposure reduction measures to the child's parents, (2) the parents and/or child implement precautionary measures[8] in order to reduce exposure and (3) the child should be retested after 3 to 6 months. EPA (2003d) and Ecology currently use the CDCP guidelines to establish soil cleanup levels for individual sites. Specifically, soil cleanup levels are generally established at soil concentrations where the probability that a young child will have a blood lead level above 10 ug/dL is estimated to be no more than 5 percent.

Table 2.1
Blood Lead Guidelines Established By The Centers for Disease Control

Blood Lead Level (ug/dL)	CDC Recommendation
< 10 ug/dL	Retest in 1 year. No additional action.
10-14 ug/dL	Family lead education, precautionary measures and followup testing
15-19 ug/dL	Education, precautionary measures, followup testing (if elevated levels persist – proceed with coordination of care and case management; consider environmental investigation and remediation
20-44 ug/dL	Case management, clinical management, environmental investigations and remediation
45-69 ug/dL	Within 48 hours, initiate case management, clinical management, environmental investigations and remediation
.> 70 ug/dL	Hospitalize child and begin medical treatment immediately

Scientists have made considerable progress in understanding the relationships between lead exposure and various adverse health effects. However, there are many questions that are not fully resolved from a scientific and regulatory standpoint. For example, there have been several studies completed since 1991 that have reported adverse health effects[9] at blood lead levels below 10 ug/dL (Lanphear et al., 2000, Canfield et al. 2003). CDC is presently reviewing the blood lead screening guidelines in light of newer scientific studies on the relationships between blood lead concentrations and IQ development. The following issues are relevant to this evaluation:

- <u>Quantitative Relationship Between Health Effects and Blood Lead Concentration:</u> IQ development is typically used as a surrogate for the wide range of potential neurological problems arising from childhood lead exposure. There have been several evaluations and reviews in the last 10 years which indicate that the relationship between dose (as

[8] If blood lead levels exceed 10 ug/dL, CDCP recommends that precautionary measures be taken. Such measures include: Reduce soil/house dust exposures through regular hand and face-washing, replanting bare areas in yards/play areas, door mats, remove shoes at door, regular house vacuuming & dusting; maintain proper nutrition/balanced diet to minimize lead absorption; run tap water for 15-30 seconds prior to drinking; and identify other potential sources (e.g. lead-based paint etc)

[9] The adverse health effects at or below 10 ug ug/dL are sub-clinical (i.e. cannot be diagnosed in an individual) and, consequently, are studied by comparing large groups of children who are exposed to lead with similar groups of children who have limited lead exposure.

measured by blood lead concentrations) and response (as measured by IQ score decrements) ranges from - 0.1 to - 0.9 IQ points for each ug/dL increase in blood lead concentration. Evaluations include:

- Schwartz (1994) conducted a meta-analysis using data from seven of these studies to estimate that increasing blood lead concentrations from 10 ug/dL to 20 ug/dL would result in a loss of 2.57 IQ points. Schwartz also found evidence to suggest greater IQ loss at lower blood lead concentrations. Specifically, Schwartz estimated an IQ reduction of 3.23 IQ points based on the three studies with mean blood lead concentrations below 15 ug/dL relative to a 2.32 reduction based on the four studies with mean blood lead concentrations at or above 15 ug/dL.
- Battelle (1998a, 2000) compiled the results of 18 studies that reported relationships between IQ development and lead exposure. Thirteen of the studies reported an inverse relationship between IQ development and blood lead concentrations between 10 and 20 ug/dL that range from a loss of 1.1 to 9 IQ points as blood lead concentrations increase from 10 – 20 ug/dL. EPA (2001a) concluded that it was reasonable to assume a loss of 0.257 IQ points per 1 ug/dL increase in blood lead concentration the following assumptions were reasonable when characterizing the health effects in young children associated with lead exposure[10].
- Canfield et al. (2003) recently published the results of a five year study in which they evaluated the relationship between blood lead concentrations and IQ scores. They found that blood lead concentrations and IQ scores were inversely related with each 10 ug/dL increase in average blood lead concentration associated with a 4.6 point decrease in IQ ($p = 0.004$). Of particular significance, the study found that incremental reductions in IQ were greatest among the 101 children whose maximum blood lead concentration remained below 10 ug/dL over the entire 54-month study period. Specifically, they estimated (using a non-linear model) that IQ declined by 7.4 points as blood lead concentrations increased from 1-10 ug/dL. The results of this study reinforce earlier conclusions regarding the lack of a threshold between IQ development and blood lead concentrations and suggest that the incremental reductions in IQ are greater than previously thought (particularly at exposure levels below 10 ug/dL).

- <u>Threshold for Health Effects</u>: The existence of a threshold for health effects is a key issue within the broader set of issues surrounding the relationship between blood lead concentrations and health effects. Current efforts to reduce lead exposure are based on the assumption that any level of exposure above zero may adversely affect children's health. Battelle (1998a, 2000) reviewed this issue to support EPA's rulemaking under Section 403 of the Toxics Substance Control Act. Based on that review, EPA (2000a) concluded that it was appropriate to assume that no threshold exists. In reaching this conclusion, EPA relied heavily on the evaluation by Schwartz (1994) who noted that the existence of a non-zero threshold would result in lower blood lead/lead intake slopes as blood lead concentrations declined (e.g the slope decreases as blood lead concentrations decrease). However, Schwartz found a larger effect was observed in four studies where

[10] The EPA Science Advisory Board reviewed the EPA analysis and concluded it was generally consistent with available scientific information.

mean blood lead levels were below 15 ug/dL (a decline of 0.323 IQ points (+/- 0.126) per unit increase in blood lead level (ug /dL) compared to three studies where the mean blood lead levels were greater than 15 ug/dL (a decline of 0.232 IQ points per unit increase in blood lead levels (+/- 0.040)). EPA concluded that the observed trends were inconsistent with the existence of a non-zero threshold. The EPA Science Advisory Board (EPA, 1998a) generally concurred that "...available data have not identified a clear threshold" and that the "... assumption of no threshold is both defensible and appropriate statistically". The results of Canfield et al. (see above) reinforce these earlier conclusions regarding the lack of a threshold for adverse effects on learning (as measured by IQ scores).

- Variability in Susceptibility to Elevated Lead Exposure: Available data indicate that children are more susceptible to the toxic effects of lead than adults. However, there is considerable variability among children in their response to similar levels of lead exposure. Such variability may arise due to genetic variations in lead metabolism, interactions with other chemicals, nutritional differences or other factors. For example, ATSDR (1999) summarized studies indicating that lead absorption and child susceptibility to lead are increased by several types of nutritional deficiencies (e.g. calcium, vitamin D, iron, zinc and others). Cadmium exposure also affects lead toxicity. Zinc and copper appear to have antagonistic effects. Evidence that lead increases the toxic effects of mercury. Studies also suggest that manganese may increase lead absorption and retention.

Section 3
Health Risks Associated With Child Exposure to Lead-Contaminated Soils

Section 3 Summary

EPA's Integrated Exposure Uptake and Biokinetic (IEUBK) model was used to evaluate the risks to young children associated with exposure to lead-contaminated soils. The model was used to predict the average blood lead concentrations and the probability that a child will have blood lead concentrations greater than 10 ug/dL (P_{10}) following exposure to different soil lead concentrations.

The IEUBK Model predicts that the CTE and P_{10} values will increase as soil lead concentrations increase. The model predicts that a soil concentration of 250 mg/kg (MTCA Method A cleanup level) corresponds to a P_{10} value of 1- 5%. When the analysis is based on the 12-36 month age interval, the P_{10} value is 5%. When the analysis is based on a broader age range (0 – 84 months), the IEUBK model predicts a P_{10} value of 1%. The P_{15} value at a soil concentration of 250 mg/kg is 0.1-0.3%.

Higher soil concentrations are associated with higher P_{10} and P_{15} values. For example, the P_{10} value at a soil concentration of 500 mg/kg ranges from 9.6 – 21.3%. The P_{10} and P_{15} values are influenced by assumptions on frequency of exposure. For example, if the exposure frequency is based on school or child care exposure scenarios (180-250 days/year), the P_{10} value at 500 mg/kg ranges from 3.4 – 7.9%.

Sensitivity analyses were performed to evaluate the impact of changes in model assumptions on predicted blood lead concentrations. The model predictions are sensitive to assumptions regarding (1) Geometric Standard Deviation; (2) non-soil lead exposure; (3) soil ingestion rate; and (4) exposure frequency.

The IEUBK model is similar to many other child lead exposure models. Predictions based on the IEUBK model tend to fall in the middle of the range of values from various models when similar lead exposure assumptions are used.

3.1 Introduction

Ecology used EPA's Integrated Exposure Uptake and Biokinetic (IEUBK) Model (IEUBKwin v1.0 (build 254)) (EPA, 2002a; 2003f) to evaluate the risks to young children associated with lead contaminated soils. Ecology decided to use this model based on the following considerations:

- <u>Scientific Foundation for the Model Structure</u>: The IEUBK model is a multi-compartment pharmacokinetic model that is linked to an exposure module and a probabilistic model of blood lead concentrations in young children (ages 0 – 84 months). The model was developed by EPA over a 10 year period and reflects current knowledge on how children are exposed to environmental lead and the physiological processes that determine blood lead concentrations (White, et al. 1998; EPA, 1994a, b). [11]

- Model Verification and Validation: EPA has developed and implemented a strategy to validate the IEUBK model which includes: (1) verification that the mathematical relationships have been correctly translated into computer code; and (2) evaluating whether the model results are in reasonable agreement with relevant observational data. EPA has completed an independent code verification and validation exercise and concluded that the computer model does accurately carry out the operations and calculations as designed (Zaragoza and Hogan, 1998). EPA has also compared blood lead concentrations predicted by the IEUBK model with those observed in children living near four hazardous waste sites (Hogan et al. 1998). Hogan et al. found that the IEUBK model did a reasonable job of predicting blood lead concentrations for children whose exposures were predominantly from their residences (e.g. spent less than 10 hours per week away from their homes). Specifically, the predicted blood lead concentrations were within 0.7 ug/dL of the observed geometric means at each site. In addition, the predictions of the percentage of children expected to have blood lead levels above 10 ug/dL were within 4% of the observed percentages at each site.
- Predicted Risks are Consistent With Predictions Using Other Exposure Models: The IEUBK model is conceptually similar to most other lead exposure models. Predictions based on the IEUBK model tend to fall in the middle of the range of values from various models when similar lead exposure assumptions are used. This is discussed in Section 3.4.
- Use by Federal and State Agencies: The IEUBK model is widely used by federal and state agencies to evaluate the risks of lead-contaminated soils. The Environmental Protection Agency recommends its use at contaminated sites being addressed under the federal Superfund program. Ecology currently uses the model to establish site-specific cleanup levels under the Model Toxics Control Act.
- Ease of Use: The IEUBK model is now available in a Windows format and EPA has prepared clear guidance materials on the use the model.

The remainder of this section is divided into three parts:

- Part 3.2 describes the methods and parameters used to characterize the potential risks to young children associated with exposure to lead in soil and dust;
- Part 3.3 summarizes the results of evaluations performed using the IEUBK Model; and
- Part 3.4 discusses the uncertainties associated with the methods and parameters used to characterize health risks and the relative sensitivity of the evaluation results to key variables and assumptions.

3.2 Methods and Parameters Used to Evaluate Risks Associated with Child Exposure to Lead Contaminated Soils

[11] Ecology's New Science Review and Asarco's comments on the Everett Smelter Cleanup Plan concluded that this model provides a scientifically defensible method for evaluating lead contamination in soils. However, Ecology and Asarco had several differences of opinion regarding individual input parameters for the model.

The IEUBK model is designed to evaluate lead exposures for young children (ages 0 – 84 months of age). The IEUBK model includes four main components:

- Exposure Component: The exposure component calculates lead intake (expressed as ug of lead/day) using information on environmental lead concentrations (i.e. soil/dust, water, diet and air) and consumption rates (e.g. amount of water consumed per day). Potential lead intakes were estimated by summing (1) lead intakes from air, drinking water and diet that are calculated using national default parameters specified by EPA (1994a, 1994b, 2003c, 2003f) and (2) lead intakes from soil and dust containing lead concentrations similar to the range of concentrations found in Washington soils.
- Uptake Component: The uptake component estimates the amount of lead that is transferred from the gastrointestinal tract or lungs to the blood using (1) estimates on the amount of lead that is ingested/inhaled (from the exposure component) and (2) information on the bioavailability of lead in various environmental media (e.g. soils).
- Biokinetic Component: The biokinetic component estimates the level of lead in the blood stream using information on (1) lead uptake and (2) the transfer of lead between the blood and other organs and its elimination from the body through excretory pathways. The output is expressed as a central tendency estimate (CTE) blood lead concentration.
- Probability Distribution Component: The probability distribution component produces graphs that display the probability that blood lead levels will exceed certain levels of concern (default = 10 ug/dL) for particular age groups or time periods using (1) the estimated CTE blood lead concentrations (from the biokinetic component) and (2) information on the variability of blood lead levels.

The steps involved in performing this assessment include the following:

- Select Model Input Parameters: The IEUBK model contains more than 100 input parameters that are initially set to default values. Of these parameters, there are 46 external parameters (e.g. soil concentration, soil dust intake rate, etc) that can be changed by the user based on site-specific data and/or new scientific information. Ecology used the EPA default parameters to prepare the baseline assessment (See Table 3-1).
- Run the IEUBK Model to Estimate Blood Lead Concentrations and Probability of Exceeding Blood Lead Concentrations: The IEUBK Model was run using different soil concentrations to calculate (1) an estimate of the geometric mean PbB (central tendency estimate (CTE)) and (2) an estimate of the probability that a child's blood lead concentrations would exceed 5[12], 10[13] or 15[14] ug/dL at different lead exposure levels. The percent probability of exceeding 5 ug/dL is referred to as P_5, the probability of exceeding 10 ug/dL is referred to as P_{10}, and the probability of exceeding 15 ug/dL is referred to as P_{15}.

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[12] A blood lead concentration of 5 ug/dL has been identified as one alternative approach for defining "elevated" blood lead levels (Bernard, 2003).

[13] A blood lead concentration of 10 ug/dL is the level currently identified as "elevated" by state and federal public health agencies and is used by Ecology as the basis for establishing soil cleanup levels under the Model Toxics Control Act.

[14] A blood lead concentration of 15 ug/dL is the level where CDCP recommends that remediation measures be taken when concentrations persist above 15 ug/dL for more than 3 months.

The IEUBK enables users to evaluate the impacts of increased lead exposures on all children (ages 0 – 84 months) or selected age intervals (e.g. 12-36 months). Agencies typically base risk management decisions at cleanup sites on evaluations of the broader age interval (0-84 months). However, studies indicate that younger children (e.g. 12-36 months) are more susceptible than children that are 2-4 years older due to (1) differences in neurological development and (2) greater contact with soil and dust (per unit of body weight) at the younger ages. Consequently, results are presented for both the 0 – 84 month and the 12-36 month intervals.

- Plot the Relationship Between Soil Concentrations and Probability of Exceeding Selected Blood Lead Concentrations: Ecology used the results from the various model runs to plot the relationships between the probability of exceeding selected blood lead concentrations (e.g. P_{10})level and soil concentrations. Ecology used the data plots to identify the soil concentration corresponding to a 5% probability of exceeding blood lead concentrations of 5, 10 and 15 ug/dL.
- Evaluate Uncertainty and Variability: Section 3.4 discusses the uncertainties associated with the methods and parameters used to characterize health risks and the relative sensitivity of the evaluation results to key variables and assumptions.

Table 3-1: Default Input Parameters for the IEUBK Model

Exposure Parameter	Units	Value						
Constants								
Indoor air lead concentration (% of outdoor)	%	30%						
Outdoor air concentration	µg/m^3	0.1						
Lead concentration in drinking water	ug/L	4						
Total lead absorption (air)	%	32%						
Total lead absorption (diet)	%	50%						
Total lead absorption (soil/dust)	%	30%						
Total lead absorption (water)	%	50%						
Soil/dust weighting factor (fraction soil)	%	45%						
Geometric Standard Deviation (GSD) for blood lead levels	Unitless	1.6						
Age-Specific Values								
		0-1	1-2	2-3	3-4	4-5	5-6	6-7
Time outdoors	hr/d	1.0	2.0	3.0	4.0	4.0	4.0	4.0
Ventilation rate	m^3/d	2.0	3.0	5.0	5.0	5.0	7.0	7.0
Dietary lead intake[15]	µg/d	3.16	2.60	2.87	2.74	2.61	2.74	2.99
Drinking water ingestion rate	L/d	0.2	0.5	0.52	0.53	0.55	0.58	0.59
Soil/dust ingestion rate	mg/d	85	135	135	135	100	90	85
Soil/Dust Relationships								
Soil concentrations	mg/kg	Variable						
Fraction of indoor dust lead attributable to soil	Unitless	$Pb_{dust} = (0.7 \times Pb_{soil}) + 10$[16]						

3.3 Results

The IEUBK Model was used to construct a series of tables to characterize the relationships between soil levels and blood lead concentrations. Table 3-2 shows the geometric PbB, Pb_5, Pb_{10} and Pb_{15} values predicted by the IEUBK model using the EPA default parameters and an age interval of 0-84 months. Table 3-3 shows the geometric PbB, Pb_5, Pb_{10} and Pb_{15} values predicted by the IEUBK model using the EPA default parameters and an age interval of 12-36 months.

- Exposure to background soil concentrations corresponds to a CTE value of 1.2 ug/dL. This level provides an upper bound on the potential reductions in blood lead concentrations resulting from measures to address contaminated soil and dust.

[15] EPA recently updated the default dietary lead intake values based on food residue and food consumption data collected subsequent to the initial development of the IEUBK model. These updated values are @ 40 percent of the previous default values.

[16] The multiple source analysis options for estimating dust concentrations includes contributions from soil and air. Use of the default assumptions for ambient air levels translates into an increment of 10 mg/kg in dust concentrations.

- CTE values predicted by the IEUBK model increase as soil concentrations increase. For children ages 0 – 84 months of age, the CTE values predicted by the model increase from 1.2 ug/dL at a soil concentration of 20 mg/kg to 9.1 ug/dL at a soil concentration of 1600 mg/dL.
- The probability that blood lead concentrations will exceed 10 ug/dL (P_{10}) also increases with increasing soil concentrations. For example, the IEUBK model predicts that a soil concentration of approximately 400 ppm corresponds to a P_{10} value of 5 percent (no more than a 5% chance of exceeding a blood lead concentration of 10 ug/dL) when the analysis is performed using the 0-84 month age interval.
- The predicted CTE value is not influenced by the choice of benchmark blood lead concentrations. However, the probability of exceeding a benchmark blood lead concentration is inversely related to the benchmark concentration. For example, the IEUBK model predicts there is a 43% probability that a child's blood lead concentration will exceed 5 ug/dL at a soil concentration of 400 ppm (as opposed to a 5% probability that blood lead concentrations will exceed 10 ug/dL) when the analysis is performed using the 0-84 month age interval. The probability that a child will have a blood lead concentration greater than 15 ug/dL (P_{15}) following exposure at 400 ppm is approximately 0.6%. The soil concentrations corresponding to a 5% probability that a child's blood lead level will exceed 5 ug/dL and 15 ug/dL are 120 ppm and 700 ppm, respectively.
- When the analysis is performed using the 12-36 month age interval, the general relationships between soil concentrations and blood lead concentrations are similar to those based on the 0-84 month age interval (e.g. increasing CTE and P_{10} values with increasing soil concentrations). However, for any given soil concentration, the predicted CTE and P_{10} values are 25 – 30 percent higher than the values predicted using the broader age interval. For example, the predicted CTE value at a soil concentration of 400 mg/kg is 5.8 ug/dL when the analysis is based on the 12-36 month age interval versus 4.6 ug/dL when the analysis is performed using the 0-84 month age interval. This means that predicted soil concentrations corresponding to a particular target risk level (e.g. P_{10} less than 5%) will be lower when the analysis is based on the 12-36 month age interval. For example, it was noted above that the IEUBK model predicts that a soil concentration of 400 mg/kg corresponds to a P_{10} of 5%. However, when the analysis is based on the 12-36 month age interval, the IEUBK model predicts that a soil concentration of approximately 250 ppm corresponds to a P_{10} of 5%. The soil concentrations corresponding to a 5% probability of exceeding the alternative target risk levels are 90 ppm (5 ug/dL) and 500 ppm (15 ug/dL).

Table 3-2: Modeled Blood-Lead Concentrations (0 - 84 months)

Soil-Lead Concentration (mg/kg)	CTE PbB (µg/dL)	P_5 % above 5 µg/dL	P_{10} % above 10 µg/dL	P_{15} % above 15 µg/dL
20	1.2	0.1	0.0	0.0
100	2.0	2.4%	0.03%	0.001%
200	2.8	12.1%	0.4%	0.02%
300	3.8	27.3%	1.9%	0.2%
400	4.6	43.2%	5.0%	0.6%
500	5.4	56.9%	9.6%	1.5%
600	6.2	67.7%	15.5%	3.0%
700	7.0	75.9%	22.0%	5.1%
800	7.7	81.9%	28.7%	7.7%
900	8.4	86.4%	35.4%	10.8%
1000	9.1	89.9%	41.7%	14.2%
Soil concentration predicted to result in P_5, P_{10} and P_{15} > 5%		120 ppm	400 ppm	700 ppm

Table 3-3: Modeled Blood-Lead Concentrations (12 - 36 months)

Soil-Lead Concentration (mg/kg)	CTE PbB (µg/dL)	P_5 % > 5 µg/dL	P_{10} % > 10 µg/dL	P_{15} % > 15 µg/dL
20	1.3	0.3%	0.001%	0.0%
100	2.4	5.7%	0.1%	0.004%
200	3.6	24.1%	1.5%	0.1%
300	4.7	45.6%	5.6%	0.7%
400	5.8	63.0%	12.6%	2.2%
500	6.9	75.2%	21.3%	4.9%
600	7.9	83.3%	30.5%	8.5%
700	8.8	88.6%	39.5%	12.9%
800	9.7	92.2%	47.6%	17.8%
900	10.6	94.5%	54.9%	23.0%
1000	11.4	96.1%	61.2%	28.1%
Soil concentration predicted to result in P_5, P_{10} and P_{15} > 5%		90 ppm	250 ppm	500 ppm

3.4 Uncertainty and Variability

The IEUBK model was used to predict soil concentrations that would be likely to cause blood lead concentrations greater than 5, 10 and 15 ug/dL in young children. However, there are several sources of uncertainty and variability that complicate the interpretation of the modeling results. These include:

- Uncertainty and variability in the amount of soil-related lead intake and uptake into the bloodstream;
- Uncertainty and variability in the relationship between soil lead uptake and changes in blood lead concentrations;
- Uncertainty and variability in the relationship between blood lead concentrations and adverse health effects; and
- Uncertainty and variability in the amount of non-soil lead exposure;

Previous evaluations and information in the scientific literature (EPA 2001e, Landau, 2002a; and Battelle, 1998a, 2000)[17] indicate that the model predictions are sensitive to assumptions in each of these areas. Each of these sources of uncertainty and variability are briefly discussed below.

- **Soil-Related Intake and Uptake into the Bloodstream**: The are several potential sources of uncertainty and variability that influence estimates of lead uptake and the interpretation of those estimates:
  - **Lead Uptake Predicted by the IEUBK Model**: The IEUBK model predictions are sensitive to the assumptions used to estimate the amount of lead uptake due to incidental ingestion of soil and dust. Those estimates depend upon the choice of several parameters including (1) soil/dust ingestion rates; (2) absorption fraction; (3) the relationship between soil and dust concentrations; (4) the relative contribution of indoor and outdoor exposure; and (5) exposure frequency. Ecology performed a screening level analysis using Monte Carlo simulation techniques to estimate a plausible range of lead uptake values associated with exposure to soils with a lead concentration of 400 mg/kg. (See Appendix C). A lead uptake value based on the IEUBK model results in an estimate that falls at the upper end of the calculated range (@ 90th percentile). Ecology evaluated the sensitivity of the model predictions to lead uptake values by evaluating two alternate assumptions corresponding to corresponding to ½[18] and 2[19] times the EPA default values. The results of these analyses are summarized in Table 3-4 and described in greater detail in Appendix B. If assumptions corresponding to 2 times the EPA default values are used,

[17] There are several model parameters where strong arguments could be made for the use of alternate values. However, many of these parameters appear to have minimal impact on predicted blood lead concentrations. For example, current information suggests that lead concentrations of lead in the ambient air are lower than the default value of 0.1 ug/m3. However, estimated lead intakes via inhalation are 50 – 100 times lower than estimated lead intakes associated with exposure to 200 ppm of lead in soils. Consequently, modifying this input parameter has little impact on predicted blood lead levels. This is consistent with observations by Mahaffey (1998) who noted that "... following the phaseout of lead from gasoline, ambient air concentrations have declined dramatically so that inhalation has become a small and typically non-significant exposure route in occupational exposures or situations in which the residence is located near a point source..."

[18] This is equal to a value that falls in between the 70 and 75th percentile of the calculated range of lead uptake values in Appendix C.

[19] This is equal to a value that falls above the 95th percentile of the calculated range of lead uptake values in Appendix C.

the soil concentration predicted to result in a P_{10} of 5% decreases from 400 mg/kg to 190 mg/kg. If assumptions corresponding to ½ the EPA default value are used, the soil concentration predicted to result in a P_{10} of 5% increases from 400 mg/kg to 810 mg/kg. Model results were also sensitive to changes in the assumptions on exposure frequency.

Table 3-4: Summary of Sensitivity Analyses to Evaluate How Soil Concentrations Corresponding to a P_{10} of 5% are Impacted by Choices of Various Input Parameters and Assumptions

Parameter	More Protective Assumptions		IEUBK Default	Less Protective Assumptions	
GSD[20]		310	400	550	
Dietary Exposure[21]		280	400	420	
Soil/Dust Ingestion/Uptake[22]		190	400	810	
Soil Pica Behavior	160	230	400	NA	NA
Exposure Frequency[23]	NA	NA	400	560	1400

- **Lead Enrichment in the Fine Fraction**: Studies indicate that exposure to soil via ingestion occurs mainly through the finer fractions. Enrichment factors (ratio of lead concentrations in finer fractions (< 250 um) to lead concentrations in soil samples with wider range of soil particle sizes (< 2 mm) ranging from 1.2 to 2 have been reported in various studies[24]. EPA (2003d) recommends that soil samples be sieved and that results from soil fractions smaller than 250 um be used with the IEUBK model. However, much of the information on lead concentrations in Washington soils is reported for the 2 mm size fraction. Consequently, comparisons based on current soils data are likely to underestimate the number of properties with soil concentrations above health-based values predicted by the IEUBK.

- **Soil Pica Behavior**: The IEUBK model uses age-specific soil and dust ingestion rates ranging from 85 to 135 mg/day which are based on the work of Calabrese et al. (1989). This is an estimate of the amount of inadvertent soil ingestion that normally occurs among children that occurs through the mouthing of objects or unintentional hand to mouth behavior. Theses rate do not take into account situations where children deliberately ingest soils and other materials (pica behavior). There is limited data available on the prevalence of pica behavior and soil ingestion rates associated with such

[20] The sensitivity analysis considered three GSD values: 1.4; 1.6 (EPA default); and 1.8.

[21] The sensitivity analysis considered three dietary intake values: (1) A range of values reflecting a continued reduction in lead concentrations in commercial foods (1.3 – 1.6 ug/day); (2) the EPA default values that reflect recent updates (2.6 – 3.16 ug/day); and (3) a range of values reflecting consumption of home grown fruits and vegetables grown in lead-contaminated soils (6.9 – 12.2 ug/day).

[22] The sensitivity analysis considered three values: EPA default values; 50% of EPA default values; and 2 times the EPA default values.

[23] The sensitivity analysis considered three exposure frequencies: 365 days/year (EPA default); 260 days/year and 104 days/year.

[24] Stern (1994) used an enrichment factor of 1.2 to convert soil concentrations into indoor soil derived dust concentrations. He estimated that the range of enrichment factors could be characterized by a triangular distribution (1.0, 1.2, 3.0) which has a mean value of 1.6. EPA collected soil and dust samples from homes at the Vasquez Boulevard/I-70 site near Denver CO and found that lead concentrations in dust were approximately 1.2 times higher than soil lead concentrations from the same property.

behavior. Battelle (1998a) reviewed the scientific literature available on this issue and reached the following conclusions: (1) prevalence of soil pica, exclusive of paint pica, is most likely between 10 and 20 percent in young children[25]; (2) soil pica behavior is episodic in nature[26]; and (3) Estimates of the amount of soil ingested during pica estimates vary widely among mass balance studies, from 500 to 13,000 mg/day[27]. The sensitivity of the model predictions to assumptions on soil pica behavior was evaluated using the three scenarios and parameters considered by Battelle (1998a). The results of this analysis/comparison are shown in Table 3-5 and described in greater detail in Appendix B. In general, lead uptake estimates that factor in soil pica behavior will increase the P_{10} values predicted for a given soil lead concentration with the magnitude dependent upon the assumptions for frequency and pica soil ingestion rates. For example, as shown in Table 3-4, consideration of pica behavior will result in lower soil lead concentrations associated with a P_{10} value of 5%.

- **Relationship Between Soil Lead Intake and Changes in Blood Lead Concentrations**: There is also uncertainty and variability associated with estimates on the relationship between lead uptake and blood lead concentrations. This relationship is influenced by many different factors which may vary between individuals, locations and timeframes. There are many aspects of this relationship that scientists do not fully understand and/or can not fully characterize in a mathematical equation. As noted above, EPA has compared blood lead concentrations predicted by the model with blood lead concentrations measured in several communities and concluded that the model does a reasonable job of predicting elevated blood lead concentrations. In addition, various attempts have been made to compare the predictions based on other child lead exposure models with predictions based on the IEUBK model. In general, the IEUBK model is structured in a way that produces soil/blood lead relationships that are similar to those in other child lead exposure models[28]. Table 3-5 summarizes those comparisons.

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[25] Battelle (1998a) concluded that the Boston and Baltimore portions of the USLADP provide the best estimates of soil pica behavior in the absence of paint pica (14.4 and 16.3 percent, respectively).

[26] Battelle (1998a) concluded that the Boston and Baltimore portions of the USLADP provide the best estimates of soil pica behavior in the absence of paint pica (14.4 and 16.3 percent, respectively). The frequency of soil pica episodes depends on many factors, including climate, access to bare soil, socioeconomic standing, age of child and parental supervision. In one study of 12 children identified by their parents to predisposed to pica for soil, only one child displayed soil pica during the two week observation period (Calabrese et al., 1997). Only one other study estimated annual rates for pica episodes (Stanek and Calabrese, 1995). This study, suggested that 33 percent of children would ingest more than 10 grams of soil on 1-2 days per year, and that 16 percent of children are expected to ingest more than 1 gram of soil on 35-40 days per year.

[27] The average daily ingestion over a year, however, may be much lower. Assuming the frequencies estimated by Stanek and Calabrese (1995), children who ingest 15 grams of soil on 1-2 days per year and 50 mg/day on remaining days would have an average daily soil intake of 132 mg/day over the course of a year. Children who ingest 1.5 grams of soil on 40 days per year and 50 mg/day on remaining days would have an average daily soil intake of 209 mg/day. A question, however, is whether the amount of lead in soil ingested on the small number of days where pica episodes occurred would be sufficient to elevate blood lead concentrations to unsafe levels. (Battelle, 1998a, p. 158).

[28] There are two basic approaches used to predict blood lead concentrations in children associated with exposure to lead-contaminated soils: (1) Slope factor models where PbB concentrations are estimated using a simple linear relationship between PbB concentrations and lead uptake or intake and (2) Mechanistic models attempt to simulate

Table 3-5: Comparison of Uptake Slope Factors Predicted From Lead Exposure Models (ug Pb/dL per ug Pb/day) (From EPA, 2001b)

Model	Ages	Uptake Slope Factor
IEUBK Model (EPA, 2002)	1-84 months	0.34
	25-48 months	0.33
Leggett Model (Pounds & Leggett 1998)	1-84 months	0.57
	25–48 months	0.63
O'Flaherty Model (O'Flaherty, 1998)	1-84 months	0.32
	25–48 months	0.26
ATSDR (1999)	1-84 months	0.17
Stern (1994)	1-84 months	0.26[29]
California (Carlisle & Wade, 1992)		0.07

- **Relationship between blood lead concentrations and adverse health effects:** The IEUBK model combines assumptions about lead exposure and uptake with assumptions on how lead behaves in the body to predict a CTE blood lead concentration and the probability that an individual child will exceed 10 ug/dL. The use and interpretation of the IEUBK results are complicated by uncertainties surrounding our understanding of how children respond to particular levels of lead exposure and the variability of those responses.
  - **Variability Among Individuals**: The GSD is a measure of variability intended to take into account several factors that cause different children to have different blood levels when they are exposed to similar concentrations of lead.[30] EPA (1994a) has established a default GSD of 1.6. The default value may over- or under-estimate the amount of variability in Washington State. If greater variability is present (higher GSD), a higher percentage of children would be predicted to have blood lead concentrations above a specified level. If less variability is present, a lower percentage of children would be predicted to have blood lead levels above a certain level. It is somewhat unclear, what variations are actually captured in the GSD value. However, the default value appears to reflect less variability than observed for other hazardous substances and endpoints. For example, NRC (1994) noted that preliminary studies on variations in cancer susceptibility suggest that variations in susceptibility can described in terms of a lognormal distribution, with 10% of the population being more or less susceptible than the median person. This corresponds to a GSD of 2.0. The sensitivity of the IEUBK model predictions to choice of GSD value was evaluated by comparing model predictions using GSD values of 1.4, 1.6 and 1.8. The results of that comparison are shown in Table 3-4.

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lead biokinetics as one or several interconnected tissue compartments that exchange lead via a central blood or plasma compartment.

[29] Stern (1994) specifies an intake slope factor that is characterized as a triangular distribution (0.056, 0.16, 0.18) with a mean of 0.13. Estimated uptake slope factor based on AF of 0.5.

[30] EPA (1994c) states that there are several sources of variability designed to be capture in the geometric standard deviation. These include (1) different environmental context (carpeting, amount of grass cover) that may affect contact with environmental lead; (2) behavioral differences; (3) different exposures/contact rates; (4) measurement variability; (5) biological diversity; and (6) food consumption differences.

In general, the use of larger GSD values in the evaluation results in lower soil concentrations associated with P_{10} values of 5%.

- **Uncertainty on Relationship Between Exposure and Health Effects at Low Exposure Levels:** Section 2 summarizes the findings of Canfield et al. (2003). The results of this study reinforce earlier conclusions regarding the lack of a threshold between IQ development and blood lead concentrations and suggest that the incremental reductions in IQ are greater than previously thought (particularly at exposure levels below 10 ug/dL).

- **Non-Soil Lead Exposure:** The IEUBK model enables the user to take into account lead exposures from non-soil sources (e.g. diet, lead-based paint, home remedies).

  - **Paint Pica Behavior**: The baseline analyses in Section 3.3 did not explicitly take into account additional lead exposure that might occur as a result of ingesting lead-based paint chips. As with soil pica behavior, there is limited data available on the prevalence, frequency and characteristics (e.g. amount of paint chips ingested per event) of paint pica behavior. In addition, there is considerable uncertainty on both the nature and frequency of paint pica behavior, variability across Washington and the relative impacts of short term exposure to concentrated levels of lead (e.g. several 1000 mg/kg) vs chronic exposure to lower lead concentrations found in soils and foods.

  - **Dietary Exposure:** The IEUBK model allows risk assessors to consider dietary lead intake when evaluating lead-contaminated soils. Lead may be present in a child's diet as a result of (1) lead present in commercially available foods and (2) lead present in homegrown fruits and vegetables. The IEUBK model includes default values for dietary lead intake based on national studies that reflect lead intake from commercially available foods. The default value may over- or under-estimate dietary lead intake for children in Washington State. If greater amounts of lead are present in a child's diet (either through commercially available or homegrown foods), the child would be more likely to have blood lead concentrations above 10 ug/dL as a result of exposure to lead-contaminated soils. If lower amounts of lead are present in a child's diet, the child would be less likely to have blood lead levels above 10 ug/dL as a result of exposure to lead-contaminated soils. The sensitivity of the model predictions to assumptions on dietary lead intake was evaluated using three different dietary lead intake values: (1) A range of values reflecting a continued reduction in lead concentrations in commercial foods (1.3 – 1.6 ug/day); (2) the EPA default values that reflect recent updates (2.6 – 3.16 ug/day); and (3) a range of values reflecting consumption of home grown fruits and vegetables grown in lead-contaminated soils (6.9 – 12.2 ug/day). The results of that comparison are shown in Table 3-4. In general, increased dietary intake results in lower predicted soil values associated with P_{10} values of 5%. The analysis also indicates that future reductions in dietary lead intake through the commercial food supply will have minimal impact on model predictions.

Section 4
Health Risks Associated with Adult Exposure to Lead-Contaminated Soils

Section 4 Summary

The EPA Adult Lead Model (ALM) was used to evaluate the health risks to fetuses of workers who might accumulate lead as result of non-residential exposure. Specifically, the model was used to estimate fetal blood concentrations associated with maternal exposure to lead-contaminated soils. Preliminary Remediation Goals (PRGs) represent soil concentrations where the probability that fetal blood concentrations will exceed 10 ug/dL is less than 5% .

The ALM predicts a PRG of 800 mg/kg using the EPA default exposure parameters with regional information on maternal blood lead concentrations. Use of alternate exposure assumptions results in PRG values that range from 400 to 1460 mg/kg. For example, increasing the soil ingestion rate from 50 mg/day (the EPA default soil ingestion rate) to 100 mg/day results in a PRG of 400 mg/kg.

The model predictions are sensitive to assumptions regarding (1) Geometric Standard Deviation; (2) baseline maternal blood lead concentration; and (3) soil ingestion rate. EPA has concluded that blood lead concentrations predicted by the Adult Lead Model are similar to values predicted by other adult lead exposure models.

4.1 Introduction

Young children are more vulnerable to the effects of elevated lead exposures than adults. Consequently, actions to prevent unacceptable health threats to children will generally be protective of adults. However, there are situations where children are not likely to be present or present on an infrequent basis (e.g. commercial facilities) In these situations, the most sensitive receptor is likely to be the fetus of a worker who accumulates excess lead as a result of non-residential exposure.[31]

EPA has established a lead soil screening value for commercial/industrial sites of 800 ppm (EPA, 2003b). This screening value represents a soil concentration where EPA estimates there is less than a 5% probability that fetal blood lead concentrations will exceed 10 ug/dL. The screening level is a lead concentration that EPA believes will protect human health under a wide range of exposure conditions at commercial and industrial sites.

EPA initially distributed the ALM in 1996. The model is based on an adult exposure model developed by Bowers et al. (1994). The Technical Review Work Group for Lead evaluated the ALM and other adult exposure models in 2001 (EPA, 2001b). The TRW concluded that the ALM provided estimates that were similar to the other models considered in the review. EPA is currently developing the All-Ages Model which will presumably replace the ALM when it becomes available (currently scheduled for 2005).

[31] Lead is associated with other types of health effects in adults. Stern (1996) used changes in blood pressure in adult males and the resulting increase in the incidence of hypertension to estimate health-protective soil concentrations. EPA (2001b) compared the two models and that "...since the simulation runs derived relatively similar soil lead PRGs for the Stern hybrid model and ALM, this would indicate that the EPA approach is protective for the male hypertension endpoint (assuming that Stern's quantitative cause and effect relationship between soil lead and blood pressure are correct)." (p. 34).

Ecology used the ALM to assess the health risks associated with adult exposure to lead-contaminated soils. The remainder of this section describes the methods and results of that evaluation and is divided into three parts:

- Part 4.2 describes the methods and parameters used to characterize the potential impacts of exposure to lead in soil and dust;
- Part 4.3 summarizes the results of analyses performed using the ALM; and
- Part 4.4 provides a brief discussion of the results and comparisons with estimates based on other adult lead exposure models.

4.2 Methods and Assumptions Used to Assess Risks Associated with Adult Exposure to Lead-Contaminated Soils

EPA developed the ALM to allow agencies to assess health risks associated with adult exposures to lead-contaminated soils in non-residential settings. The ALM is available on the EPA website in an Excel spreadsheet format and the model equation and recommended input parameters are shown in Figure 4-1. EPA (2003a) states that equations are based on several underlying assumptions:

- Blood lead concentrations for exposed adults can be estimated as the sum of an expected starting blood lead concentration in the absence of site exposure ($PbB_{adult,0}$) and an expected site related increase.

$$PbB_{adult,central} = PbB_{adult,0} + \Delta PbB_{soil}$$

- The site-related increase in blood lead concentrations (ΔPbB_{soil}) can be estimated using a linear biokinetic slope factor (BKSF) which is multiplied by the estimated lead intake.

$$\Delta PbB_{soil} = BKSF * \text{Estimated Lead Uptake}$$

- Estimated lead uptake can be related to soil lead levels using the soil lead concentration (PbS), the overall daily soil ingestion (IR_s), the estimated fractional absorption of ingested lead (AF_s) and exposure frequency (EF_s).

$$\text{Estimated Lead Uptake} = PbS * IR_s * AF_s * EF_s/AT$$

- Exposure to lead in soil may occur by ingesting soil-derived dust in the outdoor and/or indoor environments. The default value recommended for IRs (0.05 grams/day) is intended for occupational exposures that occur predominantly indoors. More intensive soil contact would be expected for predominantly outdoor activities such as construction, excavation, yard work, and gardening.
- A lognormal model can be used to estimate the inter-individual variability in blood lead concentrations (i.e. the distribution of blood lead concentrations in a population of individuals who contact similar environmental lead levels).

$$PbB_{adult,0.95} = PbB_{adult,central} * (GSD_{i,adult})^{1.645}$$

- Expected fetal blood lead concentrations (PbBfetal) are proportional (R) to maternal blood lead concentrations.

$$PbB_{fetal,0.95} = PbB_{adult,,0.95} * R$$

- The most sensitive receptor at these types of sites is the fetus of a worker who accumulates excess lead as a result of non-residential exposure.

Ecology used the model to estimate the soil lead concentration at which the probability of fetal blood lead concentrations exceeding 10 ug/dL is no greater than 0.05. The steps involved in preparing those estimates include the following:

- Select Model Input Parameters: EPA has published recommended default values for each of the model input parameters (see Figure 4.1). In general, Ecology used the recommended EPA values for this analysis. As discussed below, regional information on GSD and baseline PbB concentrations have been used in place of values based on all 50 states. The technical bases for these values are summarized below and discussed in EPA (2003a):
  - **$PbB_{95fetal}$** - This is the goal for the 95th percentile blood lead concentration for fetuses born to women having exposures to specified soil lead concentrations. As specified above, the goal is to estimate soil concentrations where the probability that fetal blood lead concentrations exceeds 10 ug/dL is no greater than 0.05. Consequently, the $PbB_{95fetal}$ is 10 ug/dL.
  - **R** - This is the constant of proportionality between fetal blood lead concentrations at birth and maternal blood lead concentrations (unitless). The EPA default value is 0.9. This value is based on studies by Goyer (1990) and Graziano et al. (1990) that explored the relationship between umbilical cord and maternal blood lead concentrations.
  - **$GSD_{i,adult}$** – This is an estimate of the individual geometric standard deviation of the blood lead concentration among adults of child-bearing age. The GSD accounts for the range of blood lead levels that would be expected in population exposed to similar lead concentrations taking into account differences in non-site lead exposures and inter-individual variability in lead intake, uptake and biokinetics. The exponent, 1.645 is the value of the standard normal deviate used to calculate the 95th percentile from a lognormal distribution of blood lead concentrations. EPA (2003a) identifies two default values: $GSD_{i,adult}$ = 1.8 (recommended for homogeneous populations) and $GSD_{i,adult}$ = 2.1 (recommended for more heterogeneous populations). EPA (2002b) has also reviewed the combined Phase I and II of NHANES III survey and prepared a series of tables which provide $PbB_{adult,0}$ and GSD values broken down by geographic region, race ethnicity and age. Because of the small sample sizes, EPA recommends that users not use data from the NHANES III survey that have been stratified by both geographic region and race/ethnicity. Consequently, Ecology selected several values for this analysis: (1) a $GSD_{i,adult}$ of 2.11 which is the GSD value for all women of childbearing age in the West Region[32], (2) a $GSD_{i,adult}$ value of 2.29 which is the GSD for Mexican-American women of child-bearing ages in all four geographic regions, (3) a $GSD_{i,adult}$ value of 2.16 which is the GSD for non-Hispanic black women of child-bearing ages in all four geographic regions, (4) a $GSD_{i,adult}$ value of 2.09 which is the GSD for non-Hispanic white women of child-

[32] EPA (2002b) presented the results of combined survey phases separately for the four regional quadrants in the NHANES III survey. Washington is part of the West Region which also includes Oregon, California, Arizona, New Mexico, Nevada, Utah, Idaho, Montana, Wyoming, Colorado, Hawaii and Alaska.

bearing ages in all four geographic regions, (5) a $GSD_{i,adult}$ value of 2.08 which is the GSD for all women (ages 17-25 years) in all four geographic regions, (6) a $GSD_{i,adult}$ value of 2.07 which is the GSD for women (ages 26-35 years) in all four geographic regions, and (7) a $GSD_{i,adult}$ value of 2.09 which is the GSD for women (ages 36-45 years) in all four geographic regions..

- **$PbB_{adult,0}$** - This represents a baseline geometric mean blood lead concentration that would be expected in a population of child-bearing women in the absence of soil-related exposure. Incremental blood levels predicted to occur due to soil-related exposures are added to the $PbB_{adult,0}$ to estimate the blood lead concentration that would impact a developing fetus. EPA (2003a) identifies a range of default values ($PbB_{adult,0}$ = 1.7 - 2.2) that reflects a plausible range based on NHANES III phase I data for Mexican-American, non-Hispanic black and white women of child-bearing age. EPA (2002b) has also reviewed the combined Phase I and II of NHANES III and prepared a series of tables which provide $PbB_{adult,0}$ and GSD values broken down by geographic region, race ethnicity and age. Because of the small sample sizes, EPA recommends that users not use data from the NHANES III survey that have been stratified by <u>both</u> geographic region and race/ethnicity. Consequently, Ecology selected two values for this analysis: (1) a $PbB_{adult,0}$ = 1.40 which is the geometric mean PbB for all women of childbearing age in the West Region, (2) a $PbB_{adult,0}$ value of 1.70 ug/dL which is the geometric mean PbB for Mexican-American women of child-bearing ages in all four geographic regions, (3) a $PbB_{adult,0}$ value of 1.78 ug/dL which is the geometric mean PbB for non-Hispanic black women of child-bearing ages in all four geographic regions, (4) a $PbB_{adult,0}$ value of 1.45 ug/dL which is the geometric mean PbB for non-Hispanic white of child-bearing ages in all four geographic regions, (5) a $PbB_{adult,0}$ value of 1.23 ug/dL which is the geometric mean PbB for women (ages 17-25 years) in all four geographic regions, (6) a $PbB_{adult,0}$ value of 1.55 ug/dL which is the geometric mean PbB for women (ages 26-35 years) in all four geographic regions, (7) a $PbB_{adult,0}$ value of 1.80 ug/dL which is the geometric mean PbB for women (36-45 years) in all four geographic regions.
- **AT** - This is the averaging time which represents the total period of time during which soil contact may occur. EPA recommends using an averaging time of 365 days/year which evaluating continuing, long term exposures.
- **BKSF** - The biokinetic slope factor is an estimate of the relationship between an increase in typical adult blood lead concentrations and average daily lead uptake (ug/dL blood lead increase per ug/day of lead uptake). The EPA default value is 0.4 ug/dL per ug/day. This value is based on EPA's analysis of data from studies by Pocock et al. (1983) and Sherlock et al. (1984).
- **IR** - This represents an estimate of the amount of soil and dust ingested by adults (including soil and soil-derived dust) expressed in units of grams/day. The EPA default value is 0.05 grams/day. However, EPA (2003b) has recommended that a higher value be used to evaluate potential risks for a construction scenario which may involve more soil contact intensive activities. EPA concluded that 50-200 mg/day is a more plausible range for adult contact intense soil exposures with reasonable support for use of 100 mg/day. Consequently, Ecology used two values (0.05 and 0.1) for this analysis.

  - **AF_s** - This represents the fraction of lead ingested in soil that is absorbed into the bloodstream from the gastrointestinal tract (unitless). EPA recommends the use of an AF_s value of 0.12.
  - **EF_s** - This represents an estimate of the number of days/year that a woman of child-bearing age would come into contact with lead-contaminated soils in a non-residential situation. The EPA default value is 219 days/year which is based on EPA guidance on for average time spent at work by both full-time and part-time workers.

- <u>Estimate Preliminary Remediation Goals (PRGs) at Which the Probability of Fetal Blood Lead Concentrations Exceeding 10 ug/dL is No Greater than 0.05</u>: The ALM was run using different combinations of input parameters. The results of those analyses are summarized in Tables 4-1 and 4-2.

Figure 4

Adult Lead Model

$$PRG = \frac{([PbB_{95\,fetal} / R_{r/m} * (GSD^{1.645})]) - PbB_{adult,O}) * AT}{BKSF * (IR_s * AF_s * EF_s)}$$

Where:

PRG = Preliminary Remediation Goal (mg/kg)
$PbB_{95fetal}$ = 95th percentile blood lead concentration in fetus (ug/dL)
$R_{f/m}$ = Fetal/maternal PbB ratio (unitless)
GSD = Geometric standard deviation PbB
$PbB_{adult,0}$ = Baseline PbB (ug/dL)
AT = Averaging time (days/yr)
BKSF = Biokinetic slope factor
IR_s = Soil and dust ingestion rate (g/d)
AF_s = Absorption fraction (unitless)
EF_s = Exposure frequency (days/yr)

Parameter	Description	Units	EPADefault	Analysis
PbB_{95}fetal	95th percentile blood lead concentration in fetus	ug/dL	10	10
R	Fetal/maternal PbB ratio	unitless	0.9	0.9
GSD	Geometric standard deviation PbB	unitless	1.8/2.1	Variable
PbB_o	Baseline PbB	ug/dL	1.7-2.2	Variable
AT	Averaging time	days/year	365	365
BKSF	Biokinetic slope factor	ug/dL per ug/day	0.4	0.4
IR	Soil/dust ingestion rate	g/day	0.050	0.05/0.1
AF	Absorption fraction	unitless	0.12	0.12
EF	Exposure frequency	days/year	219	219

4.3 Results

The ALM was run using different combinations of (1) geometric standard deviation ($GSD_{i,adult}$) values, (2) baseline blood lead levels ($PbB_{adult,0}$) and (3) soil ingestion rates. Table 4.1 summarizes the soil concentrations (e.g. Preliminary Remediation Goals (PRGs)) corresponding to < 5% probability that fetal blood concentrations will exceed 10 ug/dL. Table 4.2 displays the relationships between soil lead concentrations and predicted values for maternal blood lead concentrations, fetal blood lead concentrations and the probability that fetal blood concentrations exceed 10 ug/dL.

Table 4.1: Comparison of PRGs Calculated with the EPA Adult Lead Model

	IR_s = 0.05	IR_s = 0.10
West Region (all women of child-bearing age) $GSD_{i,adult}$ = 2.11 and $PbB_{adult,0}$ = 1.40	1300 mg/kg	650 mg/kg
All Regions (Mexican-American women) $GSD_{i,adult}$ = 2.29 and $PbB_{adult,0}$ = 1.70	800 mg/kg	400 mg/kg
All Regions (non-Hispanic black women) $GSD_{i,adult}$ = 2.16 and $PbB_{adult,0}$ = 1.78	940 mg/kg	470 mg/kg
All Regions (non-Hispanic white women) $GSD_{i,adult}$ = 2.09 and $PbB_{adult,0}$ = 1.45	1280 mg/kg	640 mg/kg
All Regions (women ages 17-25 years) $GSD_{i,adult}$ = 2.08 and $PbB_{adult,0}$ = 1.23	1460 mg/kg	730 mg/kg
All Regions (women ages 26-35 years) $GSD_{i,adult}$ = 2.07 and $PbB_{adult,0}$ = 1.55	1250 mg/kg	625 mg/kg
All Regions (women ages 36-45 years) $GSD_{i,adult}$ = 2.09 and $PbB_{adult,0}$ = 1.80	1050 mg/kg	525 mg/kg

Table 4-2: Modeled Blood Lead Concentrations

Soil-Lead Level (mg/kg)	Adult PbB (µg/dL) (Geometric Mean)		Fetal PbB (µg/dL) 95th Percentile		Probability PbB_{fetal} > 10 ug/dL (%)	
	GSD = 2.1	GSD = 2.3	GSD = 2.1	GSD = 2.3	GSD = 2.1	GSD = 2.3
200	1.8	2.0	5.5	7.0	0.7%	1.9%
400	2.1	2.3	6.3	8.1	1.2%	2.8%
600	2.4	2.6	7.2	9.1	1.8%	3.9%
800	2.7	2.9	8.1	10.1	2.7%	5.1%
1000	2.9	3.1	9.0	11.1	3.7%	6.5%
1200	3.2	3.4	9.8	12.1	4.8%	7.9%
1400	3.5	3.7	10.7	13.2	6.0%	9.4%
1600	3.8	4.0	11.6	14.2	7.4%	11.0%

4.3 Discussion

The ALM was used to predict soil concentrations (e.g. PRGs)) corresponding to < 5% probability that fetal blood concentrations will exceed 10 ug/dL. There are several sources of uncertainty and variability that complicate the interpretation of modeling results.

The model results depend upon the parameters chosen to estimate lead uptake from soil, dust and other sources. Ecology prepared several sensitivity analyses in order to evaluate how the choice of assumptions for key parameters and assumptions listed above influence PRG predictions. The results of these analyses are summarized in Table 4.3. PRG values ranged from 200 – 2000 mg/kg based on variations of individual parameters. A larger range of values could be generated using different combinations of alternatives.

Table 4.3: Comparison of PRGs Calculated with the EPA Adult Lead Model Using A Range of Alternate Input Parameters

Parameter	Less Protective		EPA Default		More Protective	
	Value	PRG	Value	PRG	Value	PRG
Maternal Baseline $PbB_{adult,0}$ (ug Pb/dL)	1.40	1000	1.7	800	2.0	600
Geo. Std. Deviation (GSD) (unitless)	2.07	1150	2.29	800	2.5	530
BKSF (ug Pb/dL per ug Pb/day)	0.36	860	0.4	800	4.5	700
Soil/Dust Ingestion Rate (g/day)	0.02	2000	0.05	800	0.2	200
Exposure Frequency (EFs) days/year	90	1900	219	800	260	660
Absorption Fraction (AF_s)(unitless)	0.08	1180	0.12	800	0.16	590
Fetal/maternal PbB ratio ($R_{f/m}$)			0.9	800		

The Technical Review Workgroup for Lead (EPA, 2001b) reviewed six biokinetic models that have been published in the peer-reviewed scientific literature. These models include two slope factor models (Stern (1996) and Carlisle and Wade (1992) and four multi-compartment models (Rabinowitz (1976), Bert (1989); Leggett (Pounds and Leggett, 1998) and O'Flaherty (1993, 1995, 1998). Each model was evaluated and compared to the Adult Lead Model using four general criteria: (1) completeness of the exposure model; (2) kinetic performance; (3) utility of model output; and (4) ease of use and flexibility. The TRW concluded:

> *...Although no single model reviewed by the TRW was judged to be a significant improvement over the ALM, various components from the different models were determined to offer refinements in adult lead modeling. These components could be integrated into a hybrid model; however, such modifications would require a long-term effort (i.e. months to years). The decision not to proceed with development of a hybrid model is discussed below. However, in lieu of such an effort, it is worth noting that the kinetic performance of all the models produced similar estimates of quasi-steady state PbB concentrations when exposure parameters were normalized across models (i.e. all were set to approximate ALM inputs). (EPA, 2001, p. ix)*

EPA's evaluation of this factor took into account several factors (1) how well the predicted results fit available data; (2) the biological basis for each model; (3) whether the model accommodates saturation kinetics; and (4) predictability (whether the model performs as expected when tested with different combinations of exposure, frequency, intensity and duration). EPA found that the various models used similar uptake slope factors to relate soil exposure (ug Pb/day) to blood lead concentrations (Table 4-4). As part of their evaluation, EPA (2001b) also compared the results predicted by the various models for a situation involving adult exposure to a soil lead concentration of 1000 mg/kg. Based on that evaluation, the ALM appears to predicts adult lead blood lead concentrations that are similar – but somewhat lower – than other available models (Table 4-5).

Table 4-4: Comparison of Uptake Slope Factors (USF) and Biokinetic Slope Factors (BKSF) From Adult Lead Exposure Models (ug Pb/dL per ug Pb/day) (From EPA, 2001b)

Model	Uptake Slope Factor
Adult Lead Model (EPA, 2003a)	0.4
California (Carlisle & Wade, 1992)	0.15[33]
Leggett Model (Pounds & Leggett 1998)	0.43
O'Flaherty Model (O'Flaherty, 1998)	0.32 0.26
Stern (1996)	0.26[34]

Table 4.5: Predicted Adult Blood Lead Concentrations (ug Pb/dL) at Soil Concentration of 1000 mg/kg based on Adult Lead Exposure Models (From EPA, 2001b)

Model	PbB
Adult Lead Model (EPA, 2003a)	3.7
Bert (1989) Model	3.4-4.0
California (Carlisle & Wade, 1992)	2.6
Leggett Model (Pounds & Leggett 1998)	4.1
O'Flaherty Model (O'Flaherty, 1998)	3.6-4.7
Rabinowitz (1976) Model	4.1
Stern (1996)	**[35]

[33] Carlisle & Wade (1992) specify an intake slope factor of 0.018. Estimated uptake slope factor based on an AF_s of 0.12.
[34] Stern (1994) specifies an intake slope factor that is characterized as a triangular distribution (0.056, 0.16, 0.18) with a mean of 0.13. Estimated uptake slope factor based on AF of 0.5.
[35] The Stern model is not structured to estimated blood lead concentrations that are comparable to the other models.

Section 5
Rationale for Working Definition of Moderate Levels of Lead in Soils

Section 5 Summary

Ecology has developed a working definition for moderate levels of lead in soils for use in implementing the recommendations of the Area-Wide Soil Contamination Task Force. Moderate levels of lead contamination are defined as soils with lead concentrations between 250 mg/kg and 500 – 1000 mg/kg.

- The lower end of the range (250 mg/kg) is equal to the current MTCA Method A Cleanup Level and corresponds to a soil concentration that is unlikely (< 5% probability) to result in blood lead concentrations greater than 10 ug/dL in children (12-36 months).
- The upper end of the range varies depending on land use and corresponds to soil concentrations that are unlikely (less than 5% probability) to result in blood lead concentrations greater than 15 ug/dL. The upper end of the range varies depending on whether a property is being used as a (1) residence (500 mg/kg); (2) school/child care facility (700 mg/kg) or (3) park or commercial property (1000 mg/kg).

Under the framework recommended by the Task Force, moderate soils would be addressed through a combination of (1) public education programs designed to increase awareness of contamination problems and encourage individuals to take steps to reduce exposure (2) low-cost contaminant measures that could be readily implemented by schools, homeowners, etc to reduce the potential for contact with contaminated soils; (3) implementation of more permanent containment measures during construction and/or property redevelopment. Properties with lead concentrations above these ranges would continue to be evaluated and addressed on a site-specific basis under the Model Toxics Control Act or other appropriate authorities.

5.1 Introduction

The MTCA Cleanup Regulation establishes a systematic approach for identifying, investigating and cleaning up properties where hazardous substances are present at levels that present a threat to human health and the environment. The rule provides Ecology with some flexibility in deciding (1) what types of actions are warranted to address soils that have concentrations that exceed cleanup standards for one or more substances, (2) the timing of those actions and (3) what situations are more appropriately addressed under other programs and/or authorities. The Task Force recommended that Ecology utilize that flexibility to develop procedures and policies for addressing areas or zones with “low-to-moderate” levels of contamination that are different than those that are applied to properties or areas with “high” levels of contamination. Specifically, the Task Force envisioned a framework where Ecology and other agencies rely more heavily on voluntary approaches and other laws and authorities to reduce exposure to low-to-moderate levels of arsenic and lead.

Full implementation of the Task Force recommendations will require Ecology to provide guidance on what concentrations of arsenic and lead constitute "low-to-moderate" concentrations. In preparing such guidance, the key question is:

Are there soil concentrations and/or exposure situations where it reasonable for Ecology to conclude that voluntary measures and actions under other authorities are appropriate ways to address arsenic and lead that are present in soils at concentrations that exceed MTCA cleanup standards given:

- *The potential health risks associated with exposure to arsenic and lead and the uncertainties surrounding those risk estimates;*
- *The variability in exposures and susceptibility among individuals;*
- *The potential for exposure to lead and arsenic from multiple sources; and*
- *The estimated effectiveness of measures implemented under other authorities (in terms of reducing exposure to contaminated soils) relative to the estimated effectiveness of measures that might be required under MTCA and the uncertainties that surround those estimates.*

5.2 Definition of Moderate Levels of Lead in Soils

Under the Ecology working definition, moderate levels of lead contamination are defined as soils with lead concentrations between 250 mg/kg and 500 – 1000 mg/kg.

- The lower end of the range (250 mg/kg) is equal to the current MTCA Method A Cleanup Level and corresponds to a soil concentration that is unlikely (< 5% probability) to result in blood lead concentrations greater than 10 ug/dL in young children.
- The upper end of the range varies depending on land use and corresponds to soil concentrations that are unlikely (less than 5% probability) to result in blood lead concentrations greater than 15 ug/dL in young children. The upper end of the range varies depending on whether a property is being used as a (1) residence (500 mg/kg); (2) school/child care facility (700 mg/kg) or (3) park or commercial property (1000 mg/kg).

The working definition reflects numerous assumptions regarding exposure, uncertainties associated with those assumptions and policy choices regarding what blood lead concentrations are high enough to warrant certain types of actions. Ecology considered several factors when developing the proposed definition:

- Policy Choices: The working definition reflects several underlying policy choices regarding what exposure levels are high enough to warrant certain types of actions. Some of those choices reflect explicit decisions made by the Department; other choices are implicit in the overall approach. In particular, the working definition for lead-contaminated soils reflects five policy choices:
    - Policy Basis for Identifying Soil Concentrations That Require No Further Action: Ecology decided that the MTCA cleanup standards provide a reasonable basis for identifying the lower end of the moderate range. The cleanup standards represent levels

where no further action is required under the MTCA regulation. Ecology currently establishes cleanup standards for lead at soil concentrations that are predicted to have a low probability of causing blood lead concentration in young children that equal or exceed 10 ug/dL. The 10 ug/dL value is based on the CDCP blood lead screening guidelines. CDCP currently considers a child to have an elevated blood lead level if his/her levels are equal to or greater than 10 ug/dL. The choice of 10 ug/dL is consistent with EPA policies for establishing soil cleanup levels under the federal Superfund program and identifying lead paint hazards under the Toxics Substances Control Act.

- Policy Basis for Identifying Soil Concentrations That Warrant Site-Specific Responses: Ecology decided to use a blood lead concentration of 15 ug/dL to define the upper end of the moderate concentration range. As summarized in Section 2, the CDCP generally recommends that (1) health agencies provide educational materials on health effects and exposure reduction measures to the child's parents, (2) the parents and/or child implement precautionary measures in order to reduce exposure and (3) the child should be retested after 3 to 6 months. These measures are similar to many of the steps recommended by the Areawide Task Force for low-to-moderate levels of soil contamination. The CDCP guidelines also recommend that some type of remediation measures might be necessary when a young child's blood levels persist in the 15-19 ug/dL range. Ecology's use of 15 ug/dL[36] to establish the upper end of the moderate range reflects a similar approach. Under the framework recommended by the Task Force, areas or properties with soil concentrations above the moderate range would be addressed on a site-specific basis under MTCA or another appropriate authority.

- Definition of Low Probability of Exceedances as 1-5 Percent: The IEUBK and ALM models are considered to sound methods for evaluating lead contamination problems and establishing soil cleanup requirements based on protecting children's health. However, as discussed in Section 3.4, there are several sources of uncertainty and variability that complicate the interpretation of model results. Various factors may lead to under- or overestimation of health risks. The use of a 1-5% is health protective approach that is consistent with current MTCA polices and procedures for establishing cleanup standards, EPA guidance for the use and interpretation of IEUBK results and the policy determinations made by EPA when identifying lead-based hazards under the Toxics Substances Control Act.

- Current Land Uses: Cleanup standards under MTCA and CERCLA are based on evaluation of both current and potential land uses. The implementation framework maintains that approach when considering long-term solutions for lead-contaminated soils. However, in order to make optimal use of resources during the immediate/intermediate time frames it will be important to tailor solutions to current land uses and exposures. Consequently, the definition of moderate levels of exposure takes into account different exposure patterns (particularly exposure frequency) associated with different land uses.

[36] The CDCP guidelines recommend that environmental investigations and remediation be considered when blood lead concentrations are exceed 19 ug/dL. Ecology selected the 15 ug/dL because of (1) recent studies indicating larger impacts of low-level lead exposure than indicated by previous studies and (2) the policies underlying the Model Toxics Control Act (e.g. protection of susceptible population groups, erring on the side of safety).

- Consideration of Ecological Impacts: The Task Force discussions and recommendations focused on the potential for impacts on human health and, consequently, the working definition for moderate levels of lead-contaminated soils is based on human health considerations. However, laboratory and field studies have found that lead may also adversely impact certain plant and wildlife species at soil levels that are similar to levels commonly associated with area-wide soil contamination (other field studies have documented healthy and thriving plant communities in areas with similar levels of lead). Screening level analyses (Landau, 2002) indicate that soil lead concentrations of 600 -1000 mg/kg are 1-20 times higher than ecologically based risk screening levels. The Task Force recommended that Ecology conduct or support studies that evaluate the potential ecological impacts associated with low-to-moderate levels of lead and arsenic in soils. In the agency response to the Task Force recommendations, Ecology stated that it intends to work with the Science Advisory Board on this issue. However, timeframes for identifying and conducting those evaluations are unclear and will be influenced by competing program priorities. Consequently, Ecology has based the working definition on human health considerations. In addition, Ecology has assumed that ecological risks will continue to be addressed when deciding what should be done to address elevated levels of lead at individual properties.

- Health Risk Estimates: Blood lead concentrations predicted by the IEUBK model depend on a wide range of exposure assumptions. P_{10} and P_{15} values for the three primary land use categories considered by the Task Force are summarized in Table 5.1. The evaluation indicates that:

  - The IEUBK model predicts that exposure to soils with lead concentrations below 250 mg/kg is unlikely (P_{10} = @5%) to result in PbB levels above 10 ug/dL among children 12-36 months old. When analysis is based on the broader age range (0 – 84 months), the IEUBK model predicts there is approximately a 1% probability that a random child will have a PbB value above 10 ug/dL.

  - The IEUBK model predicts that residential exposure to soils with lead concentrations below 500 mg/kg is unlikely (P_{15} = 4.9%[37]) to result in PbB levels above 15 ug/dL among children 12-36 months old. When the analysis is based on the broader age range (0-84 months), the IEUBK model predicts there is approximately a 1.5% probability that a random child will have a PbB value above 15 ug/dL.

  - The IEUBK model predicts that exposure to soils at schools and child care facilities with lead concentrations below 700 mg/kg is unlikely (P_{15} = 4.1%[38]) to result in PbB levels above 15 ug/dL among children 12-36 months old. Exposure assumptions include: (1) a child's intake of lead from other sources is equivalent to the default values in the IEUBK model; (2) children attend school/child care facilities 180-260 days per year. When the analysis is based on the broader age range (0 – 84 months), the IEUBK model predicts there is approximately a 1.5%[39] probability that a random child will have a PbB value > 15 ug/dL;

[37] Revised to be consistent with values in Table 5.1 (per SAB comments received at the January 12 meeting).
[38] Revised to be consistent with values in Table 5.1 (per SAB comments received at the January 12 meeting).
[39] Revised to be consistent with values in Table 5.1 (per SAB comments received at the January 12 meeting).

- The IEUBK model predicts that less frequent exposure in parks and commercial areas to soils with lead concentrations below 1000 mg/kg is unlikely (P_{15} = 0.5%[40]) to result in PbB levels above 15 ug/dL among children 12-36 months old. Exposure assumptions include: (1) a child's intake of lead from other sources is equivalent to the default values in the IEUBK model; (2) children play at parks and/or visit commercial facilities 2 days/week for 52 weeks. When the analysis is based on the broader age range (0 – 84 months), the IEUBK model predicts there is approximately a 0.1%[41] probability that a random child will have a PbB value above 15 ug/dL.
- Health risks associated with adult exposure in these situations are generally lower than estimated risks to children. However, measures to reduce exposures in commercial areas would be appropriate where a person is involved in soil intensive activities (particularly if conducted on a frequent basis).

Table 5.1 P_{10} and P_{15} Predicted by the IEUBK Model for Different Combinations of Soil Concentrations and Land Uses

Soil Concentration	Age Interval (months)	Residential Areas		Schools/Child Care Facilities		Commercial Facilities & Parks	
		P_{10}	P_{15}	P_{10}	P_{15}	P_{10}	P_{15}
250 mg/kg	0-84	1.0%	< 0.1%	0.3%	< 0.1%	< 0.1%	< 0.1%
	12-36	5.0%	0.3%	0.8%	< 0.1%	< 0.1%	< 0.1%
500 mg/kg	0-84	9.6%	1.5%	3.4%	0.4%	0.1%	< 0.1%
	12-36	21.3%	4.9%	7.9%	1.2%	0.3%	< 0.1%
700 mg/kg	0-84	22%	5.1%	9.5%	1.5%	0.4%	< 0.1%
	12-36	39.5%	12.9%	18.9%	4.1%	1.1%	< 0.1%
1000 mg/kg	0-84	41.7%	14.2%	22.7%	5.4%	1.5%	0.1%
	12-36	61.2%	28.1%	37.6%	11.9%	4.0%	0.5%

- Other Sources of Lead Exposure: Model predictions are influenced by assumptions regarding exposure to other sources of lead. In general, exposure to lead in the diet, drinking water and air have significantly declined over the last 10-20 years as a result of phasing out the use of leaded gasoline, lead-based paint and lead-soldered cans. Nationally, the median concentration of lead in the blood of children less than 5 years of age has dropped from @ 15 ug/dL (1976-1980) to @2.2 ug/dL (1999-2000). Mattuck et al. (2001) found declines of 4-7% per year between 1994 and 1999 and suggested that this could be attributed to continued reduction in dietary levels, replacement of older water supply pipes, and lead abatement at older housing. In addition, Mattuck et al. also noted that body burdens accumulated in utero are likely declining because women of child-bearing age were generally exposed to lower lead levels than older women who bore children in the 1980's and 1990's.
- Effectiveness of Interim Measures: One of the underlying assumptions is that implementation of exposure reduction measures will result in some reduction in exposure and

[40] Revised to be consistent with values in Table 5.1 (per SAB comments received at the January 12 meeting).
[41] Revised to be consistent with values in Table 5.1 (per SAB comments received at the January 12 meeting).

blood lead concentrations. However, there is limited information to confirm that assumption and/or predict the amount of exposure reduction. While not permanent remedies, available studies suggest that exposure reduction measures might result in an average reduction of 20%[42] in lead intake from soil and dust (relative to no-action). Using this assumption, the IEUBK model predicts that there is a 2.3% probability that a child (0-84 months in age) will have a blood lead concentration above 15 ug/dL following exposure to soil with 700 mg/kg.[43]

- Implementation Issues: Over the last several years, Ecology has worked with local health departments, school districts and park districts to collect and analyze soils from schools, child care facilities and parks. Many of the child use areas included in these investigations were found to have individual samples with lead concentrations that fall within the 250 – 700 mg/kg range (See Appendix E). However, there have been very few instances where the average concentrations in a play area exceed 250 mg/kg. The Department has not conducted similar investigations of residential properties. Residential areas near former smelter sites indicate that some properties will have levels that exceed 250 mg/kg. However, there is insufficient information this issue on a statewide basis.

- Consistency with Current Policies and Approaches: The recommended values appear reasonable relative to decisions in Washington and other parts of the United States.

  - Consistency With Decisions in Washington State: The range of lead concentrations defined as “moderate” are similar to cleanup standards, remediation levels and action levels established at Washington cleanup sites. Most of these differences are due to the use of a 15 ug/dL blood lead concentration to identify the upper end of the range instead of the 10 ug/dL concentration used as the basis for cleanup standards.

  - Consistency with decisions by EPA and state agencies in other parts of the United States: National Superfund guidance requires that decisions on residential properties must be reviewed by EPA headquarters if cleanup levels fall outside of the 500 to 1200 ppm range (Luftig, 1997). The recommended values are comparable to cleanup standards/remediation levels established for the Coeur d' Alene Basin[44] and lower than early action levels (2000 ppm) established for parks and other common use areas in the Coeur d'Alene River Basin (Quiring, 1999). However, a limited review of other cleanup sites indicates that the Coeur d'Alene site is an exception and cleanup standards for residential areas have generally been established at the lower end of the federal range

[42] EPA (1998), Niemuth et al. (2001) and Lorenzana et al. (2003) have reviewed available information on how effectively various measures are in terms of reducing blood lead concentrations. Each concluded that education and low-cost intervention can be effective in reducing lead exposure. Neimuth et al. found that blood lead concentrations have declined by approximately 25% following lead intervention. They concluded that approximately 2/3 of this reduction (16% decline) could be attributed to the lead intervention programs; the remaining 1/3 was attributed to general declines in blood lead concentrations that are occurring as a result of broader lead reduction efforts (e.g. phasing out use of leaded gasoline). At a soil concentration of 700 mg/kg, a 16% decline in blood lead concentration corresponds to a 20% decline in lead soil/dust intake (assuming that the full decline in blood lead concentration resulting from the intervention programs was due to reductions in lead intake from soil/dust).

[43] An assumption of 20% percent effectiveness has the practical effect of reducing soil/dust intake at 700 ppm to intake levels equivalent to those at soil concentration of 560 mg/kg.

[44] The State of Idaho has proposed a lead reduction strategy for the Coeur d'Alene Basin that includes education, institutional controls, remediation of popular recreation areas with soil concentrations greater than 700 ppm and remediation of residential yards, commercial properties and right-of-ways with lead levels greater than 1000 ppm.

[45]. For example, EPA Region 8 recently established a lead cleanup standard of 400 mg/kg for residential properties for a site outside Denver CO.

- The recommended values are generally consistent with recently published lead guidance published by EPA under the Toxics Substance Control Act: EPA has established standards for lead-based paint hazards in most pre-1978 housing and child occupied facilities. Under these regulations, EPA established a two-part hazard standard for lead-contaminated soils: (1) 400 ppm in play areas based on play area bare soil samples; and (2) an average of 1200 ppm in bare soils in the remainder of the yard. EPA recommends that homeowners implement interim measures to reduce or prevent children's exposure to lead in soils above these levels (e.g. covering bare soils, washable doormats, planting grass) and evaluate the need for more permanent controls on a site-specific basis. The play area standard is equal to the screening value used by the EPA Superfund program (400 ppm).

[45] Examples of site-specific cleanup standards include: ASARCO Globe Plant Site (Colorado) - 500 ppm (Residential Cleanup); RSR Corporation (Dallas TX) - 500 ppm (Residential Cleanup); ASARCO Ruston Site (WA) - 500 ppm (Residential Cleanup).

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Appendix A

Dermal Exposure to Lead in Soil

Soil/dust ingestion, dietary intake and drinking water are the primary sources of lead exposure. Although dermal contact is considered to be a complete pathway for lead-contaminated soils, a screening level analysis indicates that exposure via dermal contact would be a minor contributor (1 - 10%) to overall lead exposure relative to soil/dust ingestion.

Equations and Assumptions

The basic equations for estimating exposure to lead via (1) incidental ingestion of soil/dust and (2) dermal contact with contaminated soils are as follows:

Exposure Model for Incidental Ingestion of Soil and Dust

$$ADD_{ing} = \frac{PbS \cdot SIR \cdot AB1 \cdot EF \cdot ED}{ABW \cdot AT \cdot UCF_1}$$

Where:

ADD_{ing}	=	Average daily dose from incidental soil ingestion (mg/[kg·d])
ABW	=	Body weight (kg)
AB1	=	Gastrointestinal absorption factor (unitless)
AT	=	Averaging time (yr)
EF	=	Exposure frequency (unitless)
ED	=	Exposure duration (yr)
PbS	=	Lead concentration in soil (mg/kg)
SIR	=	Incidental soil ingestion rate (mg/d
UCF_1	=	Unit conversion factor (mg/kg)

Exposure Model for Dermal Contact

$$ADD_d = \frac{PbS \cdot SA \cdot AF \cdot ABS_d \cdot EF \cdot ED}{ABW \cdot AT \cdot UCF_1}$$

Where:

ADD_d	=	Absorbed daily dose from contact with soil (mg/[kg·d])
ABS_d	=	Dermal absorption factor (unitless)
ABW	=	Body weight (kg)
AF	=	Soil- to-skin adherence factor ($mg/cm^2 \cdot d$)
AT	=	Averaging time (yr)
EF	=	Exposure frequency (unitless)
ED	=	Exposure duration (yr)
PbS	=	Contaminant concentration in soil (mg/kg)

SA = Exposed surface area (cm^2)
UCF_1 = Unit conversion factor (mg/kg)

Assuming the values of ABW, AT, Cs, EF and ED are the same for dermal and oral exposure, the ratio of the exposure for dermal contact compared with soil/dust ingestion can be calculated using the following relationship:

$$ExposureRatio(ADD_d / ADDo) = \frac{SA \cdot AF \cdot ABS_d}{IR * ABS_o}$$

Screening level inputs for this equation were obtained from the MTCA Cleanup Regulation, EPA Guidance on the use of the IEUBK model and EPA guidance on dermal exposure assessment. They include:

- **Surface Area in Contact with Soil (SA)**: Exposure estimates are influenced by the assumptions made regarding the skin surface area that comes into contact with contaminated soils. The risk assessment methods in the MTCA Cleanup Regulations specify a dermal surface area of 2200 cm^2. EPA is currently preparing an updated guidance document for assessing risks associated with dermal exposure to contaminants in water and soils. The public review draft distributed in September 2001 recommends using a skin surface area of 2800 cm2 when estimating CTE and RME exposures. The recommended values are based on the assumption that exposed skin includes the head, hands, forearms, lower legs and feet and represent an average of the 50^{th} percentile values for males and females (< 1 years - < 6 years).
- **Soil Adherence Factor:** Exposure estimates are influenced by the assumptions made regarding the amount of soil that adheres to the skin's surface. The risk assessment methods in the MTCA Cleanup Regulation specify an Adherence Factor of 0.2 mg/cm^2 which was based on the recommendations in EPA Guidance available during the rule amendment process (EPA, 1989[46]; EPA, 1992; EPA, 1997). EPA is currently preparing an updated guidance document for assessing risks associated with dermal exposure to contaminants in water and soils. The public review draft distributed in September 2001 recommends using a soil adherence factor of 0.2 mg/cm2 when estimating RME exposures and a value of 0.04 mg/cm2 when preparing central tendency estimates. However, the draft guidance also includes a table of activity-specific surface area weighted soil adherence factors that range from 0.01 to 21 (geometric means) and 0.06 to 231 (95^{th} percentile values) (See table below).

Table A-1: Activity Specific Surface Area Weighted Soil Adherence Factors (Reproduced From EPA, 2001)

[46] The Exposure Factors Handbook provides estimates of 0.2 and 1.0 mg/cm2-skin as "reasonable" and upper bound values (respectively).

Exposure Scenario	Age (yrs)	Geometric Mean	95th Percentile
Indoor children	1-13	0.01	0.06
Daycare children (in- & outdoor)	1-6.5	0.04	0.3
Children playing (dry soil)	8-12	0.04	0.4
Children playing (wet soil)	8-12	0.2	3.3
Children-in-mud	9-14	21	231

- **Dermal Absorption Factor (ABS_d)**: There is very limited (if any) empirical information on the dermal absorption of lead and the degree of absorption in a given situation will depend on several factors. For example, Duff and Kissel (1996) have noted that soil properties and assumptions about soil loadings influence dermal absorption[47]. The risk assessment methods in the MTCA Cleanup Regulation specify a dermal absorption value of 0.01 (1 percent) for inorganic hazardous substances unless there is adequate scientific data to demonstrate that the use of an alternative or additional value would be more appropriate for the conditions present at the site. EPA (2001d) recommends that use of a dermal absorption factor of 0.001 for cadmium which displays soil binding characteristics similar to lead.
- **Soil/Dust Ingestion Rate (IR)**: The IEUBK model includes a default assumption for the amount of soil and dust ingested by young children. The default values range from 85 to 135 mg/day. These soil/dust ingestion rates represent central tendency estimates. The RME values in the MTCA regulation and EPA guidance is 200 mg/day.
- **Oral Absorption Factor (ABS_o)**: The IEUBK model includes a default assumption for the amount of ingested lead that is absorbed into the blood stream. The default value is 30 percent (0.30).

Results and Conclusions

Based on these inputs, the estimated ratio of dermal exposure to ingestion exposure for lead in soils ranges from < 1 to 10 percent.

Table A-2: Ratio of Dermal Exposure to Soil/Dust Ingestion Exposure

47 As soil loading increases, the fraction absorbed will be constant until a critical level is reached where the skin surface is uniformly covered by soil (mono-layer). The soil loading at which a mono-layer exists is dependent on grain size.

Model Run	Description	Ratio
1	CTE (SA = 2800; AF = 0.04; ABS_d = 0.01; SIR = 100; ABS_o = 0.3)	0.037
2	CTE (SA = 2800; AF = 0.04; ABS_d = 0.001; SIR = 100; ABS_o = 0.3)	0.004
3	RME (SA = 2800; AF = 0.2; ABS_d = 0.01; SIR = 200; ABS_o = 0.3)	0.093
4	RME (SA = 2800; AF = 0.2; ABS_d = 0.001; SIR = 200; ABS_o = 0.3)	0.019

However, it is important to recognize that there is limited information on the dermal absorption of lead. It is common practice in risk assessment to use default values of 0.01 or 0.001 as dermal absorption factors for assessing exposure to metals in soil. When a dermal absorption factor of 0.01 is used, the estimated ratio of dermal to ingestion exposure is equal to 4-10 percent. When a dermal absorption factor of 0.001 is used the estimated ratio of dermal exposure to ingestion exposure for lead in soils is < 1 to 2 percent. Consequently, not evaluating dermal absorption of lead contributes to an underestimation of risk – the magnitude of which depends on the unknown extent of dermal absorption.

Appendix B

Sensitivity Analyses for Input Parameters to IEUBK Model

The blood lead concentrations predicted by the IEUBK model depend upon the parameters used to estimate lead intake from soil, dust and other sources. This section evaluates the effect that variations in key exposure parameters have on the predicted blood lead concentrations. The sensitivity analysis addresses parameters that have been shown to have the greatest influence on model predictions in other evaluations (Battelle, 1998a, 2000; EPA 2001e; Landau, 2002a). Those parameters include:

- Geometric Standard Deviation (GSD);
- Dietary Lead Intake;
- Soil and Dust Intake:
- Soil Pica Behavior
- Exposure Frequency

The final part of this section includes a brief evaluation where the IEUBK model was run using different combinations of the various parameters (e.g. low end estimate, default and upper end estimate). In all cases, the sensitivity analyses are based on model results for the 0-84 month age interval. Similar results (in terms of impacts and relative sensitivity were found for more discrete age intervals (e.g. 12-36 months).

Intra-Individual Variability (Geometric Standard Deviation (GSD))

The GSD is a measure of variability intended to take into account several factors that cause different children to have different blood levels when they are exposed to similar concentrations of lead.[48] EPA (1994a) has established a default GSD of 1.6. The default value may over- or under-estimate the amount of variability in Washington State. If greater variability is present (higher GSD), a higher percentage of children would be predicted to have blood lead concentrations above a specified level. If less variability is present, a lower percentage of children would be predicted to have blood lead levels above a certain level.

EPA recommends that risk assessors use the EPA default value unless sufficient site-specific information is available to justify the use of an alternative value. Such information does not currently exist for Washington State. However, the sensitivity of the model predictions to choice of GSD value was evaluated using three different values:

- <u>Lower End Estimate (GSD = 1.4):</u> This value was selected to represent the lower end of the GSD range. The value is near the lower end of the range (1.3 – 1.79) reported by Marcus (1992). Battelle (1998a) used this value to represent the lower end of the range of GSD values when evaluating the risks associated with lead paint hazards. In addition, this value is similar to the GSD calculated by EPA Region VIII at the Vasquez Boulevard/I-70 Superfund site near Denver CO (EPA, 2001e). At the Colorado site, EPA used probability density functions to characterize key exposure parameters and combined those distributions using Monte Carlo techniques to develop an estimate of the

[48] EPA (1994c) states that there are several sources of variability designed to be capture in the geometric standard deviation. These include (1) different environmental context (carpeting, amount of grass cover) that may affect contact with environmental lead; (2) behavioral differences; (3) different exposures/contact rates; (4) measurement variability; (5) biological diversity; and (6) food consumption differences.

distribution of absorbed lead doses. The reported long-term variability generated by the Monte Carlo simulation (1.2 for 0-84 months and 1.4 for 24-36 months) were lower than the EPA default value.

- EPA Default (GSD = 1.6): This value is the EPA default value and was used to prepare the baseline analysis. EPA (1994a) explained that the default value is based on calculations from several studies: Midvale (GSD = 1.69); Baltimore (GSD = 1.53); and Butte MT (GSD = 1.60).
- Upper End Estimate (GSD = 1.8): This value was selected to represent the upper end of the GSD range. It represents the highest GSD value accepted by the IEUBK model. If the user enters a GSD value above 1.8, a warning screen will appear telling the user to select a different value. This GSD value is at the high end of the range of values (1.3 – 1.79) reported by Marcus (1992). Battelle (1998a) evaluated the impacts of using GSD values of 1.9 and 2.1 when evaluating the risks associated with lead paint hazards. The value of 2.1 was based on a GSD estimates in Phase I and II of the NHANES III survey.

Table B-1 shows the CTE and Pb_{10} values predicted by the IEUBK model using the EPA default parameters and a range of GSD values.

Table B-1: Sensitivity Analysis on How the CTE Blood Lead Concentrations and P_{10} Values Predicted by the IEUBK Model are Impacted by the Choice of Geometric Standard Deviation (Ages 0-84 Months)

Soil Concentrations	GSD = 1.4		GSD = 1.6		GSD = 1.8	
	CTE	P_{10}	CTE	P_{10}	CTE	P_{10}
300	3.8	0.2	3.8	1.9	3.8	4.8
400	4.6	1.1	4.6	5.0	4.6	9.4
500	5.4	3.5	5.4	9.6	5.4	14.9
600	6.2	7.8	6.2	15.5	6.2	20.8
700	7.0	14.0	7.0	22.0	7.0	26.8
Soil concentration predicted to increase probability of PbB > 10 ug/dL by 5 %	550		400		310	

Dietary Lead Intake

The IEUBK model allows risk assessors to consider dietary lead intake when evaluating lead-contaminated soils. Lead may be present in a child's diet as a result of (1) lead present in commercially available foods and (2) lead present in homegrown fruits and vegetables. The IEUBK model includes default values for dietary lead intake based on national studies that reflect lead intake from commercially available foods. The default value may over- or under-estimate dietary lead intake for children in Washington State. If greater amounts of lead are present in a child's diet (either through commercially available or homegrown foods), the child would be more likely to have blood lead concentrations above 10 ug/dL as a result of exposure to lead-contaminated soils. If lower amounts of lead are present in a child's diet, the child would be less likely to have blood lead levels above 10 ug/dL as a result of exposure to lead-contaminated soils.

The sensitivity of the model predictions to assumptions on dietary lead intake was evaluated using three different dietary lead intake values:

- Lower End Estimate (1.3 – 1.6 ug/day): This value was selected to represent the lower end of the dietary lead intake range. This range of values is 50% of the updated age-specific dietary lead intake values that represent the current EPA default values. This range was selected as a lower bound estimate of dietary lead intake based on two main assumptions: (1) levels of lead in the nation's food supply will continue to decline (although at a much lower rate) due to past actions to phase-out of the use of lead-solder in cans and leaded gasoline and (2) accumulation of lead in home grown fruits and vegetables will not result in lead concentrations that are significantly different from levels in commercially available foods. This range of values is similar to the lowest range of values considered by Battelle (1998a).
- EPA Default (2.6 – 3.16 ug/day): EPA (2003c) recently updated the IEUBK model's default values based on food residue data from the U.S. Food and Drug Administration Total Diet Study (FDA, 2001) and food consumption data from NHANES III (CDC, 1997).
- Upper End Estimate (6.9 - 12.2): This range of values was selected to represent the upper end of the range of dietary lead exposure. It assumes that 40% of the fruits and vegetables consumed by a child are homegrown and (2) average lead concentrations in homegrown fruits and vegetables are 0.05 ug/g.

Table B-2 shows the CTE and Pb_{10} values predicted by the IEUBK model using the EPA default parameters and the range of dietary lead intake values specified above.

Table B-2: Sensitivity Analysis on How the CTE Blood Lead Concentrations and P_{10} Values Predicted by the IEUBK Model are Impacted by the Choice of Dietary Lead Intake (Children Aged 0-84 Months)

Soil Concentrations	Lower End Estimates		EPA Default		Upper End Estimates	
	CTE	P_{10}	CTE	P_{10}	CTE	P_{10}
300	3.5	1.4%	3.8	1.9%	4.8	5.8%
400	4.4	4.0%	4.6	5.0%	5.6	10.8%
500	5.2	8.3%	5.4	9.6%	6.4	16.8%
600	6.0	13.9%	6.2	15.5%	7.1	23.4%
700	6.8	20.3%	7.0	22.0%	7.8	30.2%
Soil concentration predicted to increase probability of PbB > 10 ug/dL by 5 %	420		400		280	

Soil/Dust Lead Intake

The IEUBK model estimates lead intakes that result from incidental ingestion of soil and dust. At any given soil lead concentration, the estimated soil/dust intakes calculated by the IEUBK model depends on several factors: (1) soil/dust ingestion rates; (2) the mass fraction of house dust derived from soil (M_{sd}); (3) the ratio of soil to dust ingestion; and (4) estimates of the bioavailability of lead in soils and dust. The IEUBK model includes default values for each of these parameters which enables risk assessor to estimate lead intakes due to soil/dust ingestion at specified soil lead concentrations. The default value may over- or under-estimate the amount of lead intake due to ingestion of lead-contaminated soil or dust.

The sensitivity of the model predictions to assumptions on soil/dust lead intake was evaluated using three different combinations of input values:

- Lower End Estimate (50% of EPA Default Values): This range of values is equivalent to 50% of the EPA default values. The basis for these values is summarized in Exhibit C. In general, a series of probability density functions were used to characterize key exposure parameters and combined those distributions using Monte Carlo techniques in order to develop an estimate of the distribution of absorbed lead doses.

- EPA Default: The IEUBK model specifies default values for soil/dust ingestion (age-specific values that range from 85 to 135 mg/day); the ratio of lead concentrations in dust and soil (PbD = 0.7 * PbS + 10 mg/kg); the fraction of soil/dust ingested as soil (45%) and bioavailability of lead in soils/dust (30%).

- Upper End Estimate (@150% of EPA Default Values): This range of values is equivalent to the RME soil/dust ingestion rates specified in the MTCA Cleanup Regulation and EPA (1997a). Specifically, the age-specific soil/dust ingestion rates for the 1-2, 2-3 and 3-4 year age intervals (135 mg/day) was changed to 200 mg/day. The soil/dust ingestion rates for the other age intervals were adjusted using the same proportion (@ 150%). EPA default values were used for the other factors (e.g. bioavailability, etc).

Table B-3 shows the CTE and Pb_{10} values predicted by the IEUBK model using the EPA default parameters and the range of soil/dust lead intake alternatives shown above.

Table B-3: Sensitivity Analysis on How the CTE Blood Lead Concentrations and P_{10} Values Predicted by the IEUBK Model are Impacted by the Assumptions for Soil/Dust Lead Intake (Children Aged 0-84 Months)

Soil Concentrations	Lower End Estimates		EPA Default		Upper End Estimates	
	CTE	P_{10}	CTE	P_{10}	CTE	P_{10}
300	2.4	0.1%	3.8	1.9%	6.5	18.4%
400	2.8	0.4%	4.6	5.0%	8.1	32.7%
500	3.3	0.9%	5.4	9.6%	9.5	46.0%
600	3.7	1.7%	6.2	15.5%	6.7	57.2%
700	4.1	3.0%	7.0	22.0%	7.4	66.1%
Soil concentration predicted to increase probability of PbB > 10 ug/dL by 5 %	810		400		190	

Soil Pica Behavior

The IEUBK model uses age-specific soil and dust ingestion rates ranging from 85 to 135 mg/day which are based on the work of Calabrese et al. (1989). This is an estimate of the amount of inadvertent soil ingestion that normally occurs among children that occurs through the mouthing of objects or unintentional hand to mouth behavior. Theses rate do not take into account situations where children deliberately ingest soils and other materials (pica behavior).

There is limited data available on the prevalence of pica behavior and soil ingestion rates associated with such behavior. EPA (1998a) reviewed the scientific literature available on this issue and reached the following conclusions:

- *The prevalence of soil pica, exclusive of paint pica, is most likely between 10 and 20 percent in young children. For the purpose of this report, the Boston and Baltimore portions of the USLADP provide the best estimates of soil pica behavior in the absence of paint pica (14.4 and 16.3 percent, respectively).*
- *Soil pica behavior is episodic in nature. The frequency of soil pica episodes depends on many factors, including climate, access to bare soil, socioeconomic standing, age of child and parental supervision. In one study of 12 children identified by their parents to predisposed to pica for soil, only one child displayed soil pica during the two week observation period (Calabrese et al., 1997). Only one other study estimated annual rates for pica episodes (Stanek and Calabrese, 1995). This study, suggested that 33 percent of children would ingest more than 10 grams of soil on 1-2 days per year, and that 16 percent of children are expected to ingest more than 1 gram of soil on 35-40 days per year.*

- *Estimates of the amount of soil ingested during pica estimates vary widely among mass balance studies, from 500 to 13,000 mg/day. The average daily ingestion over a year, however, may be much lower. Assuming the frequencies estimated by Stanek and Calabrese (1995), children who ingest 15 grams of soil on 1-2 days per year and 50 mg/day on remaining days would have an average daily soil intake of 132 mg/day over the course of a year. Children who ingest 1.5 grams of soil on 40 days per year and 50 mg/day on remaining days would have an average daily soil intake of 209 mg/day. A question, however, is whether the amount of lead in soil ingested on the small number of days where pica episodes occurred would be sufficient to elevate blood lead concentrations to unsafe levels. (Battelle, 1998a, p. 158)*

The EPA Exposure Factors Handbook (EPA, 1997a) recommends that 10 g/day be used as a screening value when evaluating pica behavior. The Agency for Toxic Substances and Disease Registry currently uses a value of 5 g/day when preparing screening level analyses.

The sensitivity of the model predictions to assumptions on soil pica behavior was evaluated using the three scenarios and parameters considered by Battelle (1998a). These include:

- EPA Default: This alternative assumes that (1) a child plays in an area and/or comes into contact with contaminated soils/dust 365 days/year and (2) displays no pica behavior.
- Pica #1: This alternative assumes that a child has an average daily soil intake of 132 mg/day. This is based on the assumption that a child ingests 15 grams of soil on 1-2 days per year and 50 mg/day on remaining days. This corresponds to an additional 80 mg/day above the EPA default soil/dust ingestion rates.
- Pica #2: This alternative assumes that a child has an average daily soil intake of 209 mg/day. This is based on the assumption that a child ingests 1.5 grams of soil on 40 days per year and 50 mg/day on remaining days. This corresponds to an additional 160 mg/day above the EPA default soil/dust ingestion rates.

Table B-4 shows the CTE and Pb_{10} values predicted by the IEUBK model using the EPA default values and the range of assumptions on soil pica behavior shown above.

Table B-4: Sensitivity Analysis on How the CTE Blood Lead Concentrations and P_{10} Values Predicted by the IEUBK Model are Impacted by the Assumptions for Soil Pica Behavior (Children Aged 0-84 Months)						
Soil Concentrations	EPA Default		#1		#2	
	CTE	P_{10}	CTE	P_{10}	CTE	P_{10}
300	3.8	1.9%	5.6	10.9%	7.3	25.1%
400	4.6	5.0%	6.9	21.9%	9.0	41.2%
500	5.4	9.6%		%	10.6	54.9%
600	6.2	15.5%		%	12.1	65.6%
700	7.0	22.0%		%	15.5	73.6%
Soil concentration predicted to increase probability of PbB > 10 ug/dL by 5 %	400		230		160	

Frequency of Exposure

The IEUBK model predictions are based on the assumption that children are exposed to lead-contaminated soils for 365 days/year. However, this may result in predictions that over-estimate exposure in situations where children might be expected to come into contact with contaminated soils and dust on a less frequent basis.

The sensitivity of the model predictions to assumptions on exposure frequency was evaluated using three values:

- <u>365 days/year (EPA Default):</u> This alternative corresponds to an assumption that a child plays in an area and/or comes into contact with contaminated soils/dust 365 days/year.
- <u>250 days/year:</u> This alternative corresponds to an assumption that a child attends school or child care at a frequency of 5 days/week for either 36 weeks (school) or 50 weeks (child care facility). A value of 250 days/year corresponds to the upper end of this range.
- <u>100 days/year:</u> This alternative assumes that a child periodically visits and plays at a local park at a frequency of 2 days/week for 50 weeks (100 days/year)

Table B-5 shows the CTE and Pb_{10} values predicted by the IEUBK model using the EPA default parameters and the exposure frequencies shown above.

Table B-5: Sensitivity Analysis on How the CTE Blood Lead Concentrations and P_{10} Values Predicted by the IEUBK Model are Impacted by the Assumptions on Frequency of Exposure (Children Aged 0-84 Months)						
Soil Concentrations	365 days/year		250 days/year		100 days/year	
	CTE	P_{10}	CTE	P_{10}	CTE	P_{10}

300	3.8	1.9%	3.0	0.5%	1.8	0.01%
400	4.6	5.0%	3.6	1.5%	2.1	0.04%
500	5.4	9.6%	4.2	3.3%	2.3	0.1%
600	6.2	15.5%	4.8	6.0%	6.7	57.2%
700	7.0	22.0%	5.4	9.4%	2.9	0.4%
Soil concentration predicted to increase probability of PbB > 10 ug/dL by 5 %	400		560		1400	

The IEUBK model was also run using different combinations of these input parameters to identify the potential range of soil concentrations predicted to meet the MTCA health protection goal. The results of that analysis are summarized in Table B-6.

Table B-6: Range of Soil Lead Concentrations Predicted to Meet MTCA Health Protection Goal (no more than 5% probability of blood levels > 10 ug/dL) (0-84 months)

Model Runs	GSD	Soil/Dust Ingestion Rate	Dietary Lead Intake	Predicted Soil Lead Level (ppm)
1	1.8	150% of Default	HGV	120
2	1.8	Default	HGV	180
3	1.6	150% of Default	HGV	190
4	1.4	150% of Default	HGV	280
5	1.6	Default	Default	400
6	1.4	Default	Default	560
7	1.6	50% of Default	Default	810
8	1.4	50% of Default	50% of Default	1090

Appendix E

Sensitivity Analyses for the Adult Lead Model

- Maternal Blood Lead Concentration: The baseline blood lead concentration (PbBadult) is intended to represent the best estimate of a reasonable central value of blood lead concentration in women of child-bearing age who are not exposed to lead-contaminated soils. The EPA Technical Review Work Group for Lead (EPA 1996) recommended 1.7 – 2.2 ug/dL as a plausible range based on the results of Phase I of the NHANES III. However, blood lead concentrations in the U.S. populations have consistently declined in recent years. Therefore it is likely that blood lead concentrations have continued to decline since 1992, the last year of Phase 1 of the NHANES III (the basis for the EPA values).

Table X: Estimated Geometric Means and Geometric Standard Deviations of Blood Lead Concentrations (ug/dL) in U.S. Women 17-45 Years of Age (West Region) (From EPA, 2002)

Race/Ethnicity	N	GM	GM SE	GSD	PRG
All	1283	1.4	0.09	2.11	1,287
Non-Hispanic - white	266	1.3	0.08	2.08	1,410
Non-Hispanic - black	125	1.87	0.13	2.04	1,089
Mexican-American	821	1.59	0.05	2.31	842
Other	71	1.48	0.20	1.92	NR

- The Geometric Standard Deviation (GSD): The GSD is a measure of the inter-individual variability in maternal blood lead concentrations in a population whose members are exposed to the same non-residential environmental lead levels. The EPA Technical Review Work Group for Lead (EPA, 2003) estimated that 2.1 to 2.3 is a plausible range for the GSD.

- Biokinetic Slope Factor (BKSF): The BKSF parameter relates the blood lead concentration (ug Pb/dL0 to lead uptake (ug Pb/day). EPA (1996) recommends a default value of 0.4 ug Pb/dL blood per ug/Pb absorbed/day for the BKSF. The default value was based on data reported by Pocock et al. (1983) on the relationship between tap water lead concentrations and blood lead concentrations for a sample of adult males.

- Soil Ingestion Rate: EPA recommends the use of 50 mg/day as the default ingestion rate for indoor workers (EPA 2003). EPA and the Centers for Disease Control have each evaluated the effectiveness of education measures for reducing lead exposure. There is limited information to evaluate the effectiveness of education programs on blood lead concentrations. Ecology evaluated the residual risks posed by lead-contaminated soils based on a range of assumptions on effectiveness: (1) education and intervention reduce soil and dust exposure by 100%

(this is equivalent to the background scenario); (2) education and intervention reduce soil and dust exposure by 50%; and (3) education and intervention reduce soil and dust exposure by 25%.

- Fetal/Maternal Blood Lead Ratio:

- Slope Factor Models: Slope factor models where PbB concentrations are estimated using a simple linear relationship between PbB concentrations and lead uptake or intake (See Figure ___). A variety of slope factors for soils and/or dust ((ug Pb/dL)/(mg Pb/kg)) have been developed based on correlations between blood lead concentrations and soil and/or dust concentrations in different parts of the country. The range of values is shown in Table 4-___ (reproduced from ATSDR, 1999). Stern (1994) used a slope factor of 0.16 to relate to changes in blood lead concentrations to daily lead intake (ug Pb/dL/ug Pb/day).

Figure 4

Slope Factor Models

*Delta PbB = Lead Uptake (or Intake) * Slope Factor*

$$PRG = \frac{([PbB_{95}\,fetal / R * (GSD_{1.645})]) - PbB_o) * AT}{BKSF * (IR * AF * EF)}$$

Where:

PRG	=	Preliminary Remediation Goal (mg/kg)
PbB_{95}fetal	=	95th percentile blood lead concentration in fetus (ug/dL)
R	=	Fetal/maternal PbB ratio (unitless)
GSD	=	Geometric standard deviation PbB
PbB_o	=	Baseline PbB (ug/dL)
AT	=	Averaging time (days/yr)
BKSF	=	Biokinetic slope factor
IR	=	Soil and dust ingestion rate (g/d)
AF	=	Absorption fraction (unitless)
EF	=	Exposure frequency (days/yr)

- Mechanistic Models: Mechanistic models attempt to simulate lead biokinetics as one or several interconnected tissue compartments that exchange lead via a central blood or plasma compartment. There are three main mechanistic models available to evaluate the impacts of exposure to lead-contaminated soils on blood lead concentrations in young children: (1) the IEUBK model; (2) the Leggett model; and (3) the O'Flaherty model. Two approaches are used with these types of models to simulate the exchanges of lead between tissues and the central blood or plasma compartment. In the IEUBK and Leggett models, these exchanges are represented as first-order rate constants for the transfer of lead across compartment boundaries. Consequently, these models are also referred to as transport-limited or diffusion limited models because the rates of change of lead masses in the various compartments are assumed to be governed by rates of transfer across compartmental boundaries. In contrast, the O'Flaherty model is a flow-limited model in that the central compartment (plasma) is represented as a dynamic process that is characterized by volume and flow rather than as static flow. Lead is assumed to instantaneously partition between plasma and soft tissues and reach an equilibrium.

Appendix H

Effectiveness of Education and Interim Measures

Sensitivity Analyses to Evaluate the Impact of Assumptions on Effectiveness of Intervention Measures: EPA and the Centers for Disease Control have each evaluated the effectiveness of education measures for reducing lead exposure. There is limited information to evaluate the effectiveness of education programs on blood lead concentrations. Three alternative values were used in this evaluation: (1) education and intervention reduce soil and dust exposure by 100% (this is equivalent to the background scenario); (2) education and intervention reduce soil and dust exposure by 50%; and (3) education and intervention reduce soil and dust exposure by 25%.

Table 4.8 shows the CTE and Pb_{10} values predicted by the IEUBK model using the EPA default parameters and a range of assumptions regarding the effectiveness of public education and individual protection measures.

- The CTE blood lead concentrations predicted for a given soil concentration decrease as the assumed effectiveness of public education and individual protection measures increases.
- For any given soil concentration, the predicted probability that a child will have a blood level greater than 10 ug/dL decreases as the effectiveness of public education and individual protection measures increases. For example, assuming that public education and individual protection measures will reduce soil/dust exposure by 25% results in a moderate increase (from 400 to 550 ppm) in the soil concentration predicted to result in a 5% probability that a child's blood level will exceed 10 ug/dL.

Table 4.8: Sensitivity Analysis on How the CTE Blood Lead Concentrations and P10 Values Predicted by the IEUBK Model are Impacted by the Assumed Effectiveness of Public Education and Individual Protection Measures

Soil Concentrations	0% Decrease Soil-Related Exposure		25% Decrease Soil-Related Exposure		50% Decrease Soil-Related Exposure	
	CTE	P_{10}	CTE	P_{10}	CTE	P_{10}
300	3.8	1.9%	3.1	0.6%	2.5	0.2%
400	4.6	5.0%	3.8	2.0%	3.0	0.5%
500	5.4	9.6%	4.4	4.2%	3.4	1.2%
600	6.2	15.5%	5.1	7.4%	3.9	2.1%
700	7.0	22.0%	5.7	11.3%	4.3	3.5%
Soil concentration predicted to increase probability of PbB > 10 ug/dL by 5 %	400		550		780	

Table 1-2: Distribution of Lead Soil Concentrations Found in Surface Soils

Area	Depth	Units	N	10%	25%	50%	75%	90%	Max
Everett									
< 100 ft	0-6”	Samples	12			218			433
100 – 500 ft	0-6”	Samples	108			241			2540
500 – 1000 ft	0-6”	Samples	242			151			12,470
1000 – 2000 ft	0-6”	Samples	384			90			1059
> 2000 ft	0-6”	Samples	177			38			598
King County									
S. Vashon/Maury	0-6”	Samples							
King Cty Mainland	0-6”	Samples							
North Vashon	0-6”	Samples							
MVI Child Use Areas	0-6”	Dec. Unit Avg							
Manson Area									
All Tracts	0-12”	Tract Average							
All Tracts	0-12”	Samples							
Orchard Use	0-12”	Samples							
Mixed Use	0-12”	Samples							
Non-Orchard	0-12”	Samples							
University Place Homes	0-6”	Yard Composites							
Wenatchee									
Elementary Schools	0-2”	Samples							
Costco	0-24”	Samples							