

Cleanup Levels for Lead-Contaminated Soils

Issue

What rule revisions (if any) are needed given current scientific information on child and adult health risks associated with lead exposure?

Problem Statement

There have been numerous scientific and regulatory developments since the 2001 amendments to the Model Toxics Control Act (MTCA) cleanup regulation. Ecology believes it is appropriate to review the cleanup standards for lead contaminated soils. The rationale includes:

- The current standard is based on preventing child exposure to soil that might cause blood lead concentrations greater than 10 ug/dL. There have been several studies completed since 2001 that have reported adverse health effects at blood lead levels below 10 ug/dL.
- In 2004, the MTCA Science Advisory Board recommended that Ecology review whether the underlying basis for the current MTCA cleanup level remains consistent with the MTCA statutory directives.

Background

The Ecology developed the MTCA Method A soil cleanup standard for lead (250 mg/kg) when the initial cleanup standards were published in 1991. This standard is applicable to all types of land uses including current and potential future residential properties, schools, parks and other areas where young children may be present on a regular basis.

Ecology reviewed the scientific basis for the Method A value for lead when preparing the 2001 rule revisions. Ecology used the Integrated Exposure Uptake and Biokinetic (IEUBK) model to predict the mean blood lead level and the probability that child blood lead levels would exceed 10 ug/dL (P₁₀) at different soil lead levels. Ecology found that a soil level of 250 mg/kg (MTCA Method A cleanup level) corresponds to a P₁₀ value of 1- 5%. Based on that review, Ecology elected not to revise the Method A soil cleanup level for lead.

New Scientific and Regulatory Information Since 2001 Rule Revisions

Since the 2001 rule revisions, there have been several important scientific and regulatory developments relevant to this rulemaking issue.

- Scientific Studies: There have been many studies completed since 2001 that have evaluated the health risks associated with lead exposure. These studies provide scientific

evidence that the physical and mental development of children can be adversely affected at blood lead levels below 10 ug/dL.¹ These studies also indicate that the dose-response relationship for lead and effects on neurological development (as measured by IQ scores) is non-linear with a steeper slope at lower blood lead concentrations.

- Refinements to Child Lead Exposure Models: Since the 2001 rule revisions, EPA has refined the Integrated Exposure Uptake and Biokinetic (IEUBK) model and developed an initial version of the All-Ages Lead Model (AALM).
 - The IEUBK model provides a tool for evaluating child health risks associated with exposure to lead-contaminated soils. Since the 2001 rule revisions, EPA has published guidance for addressing lead contamination at federal cleanup sites and made several modifications to the IEUBK model in order to incorporate newer information on lead exposure.²
 - EPA has also developed a new lead model (the All Ages Lead Model³) that is designed to evaluate health risks for all age groups. The AALM is a tool for estimating changes in lead concentrations in blood and other tissues/organs with different environmental exposures. As of March 2009, EPA was still working on several issues identified by the AALM Review Panel before releasing a revised version of the model for general use.
- MTCA Science Advisory Board Review of Areawide Soil Contamination Strategy: In 2004, Ecology asked the Board to review the scientific basis for soil guidelines that were part of a strategy to implement recommendations from a statewide task force. As part of that review, the Board recommended that Ecology review available scientific information and evaluate whether the current standard is consistent with the MTCA statutory and regulatory policies.

¹ Bellinger, D.C. and Needleman, H.L. (2003) Intellectual impairment and blood lead levels [letter]. *N. Engl. J. Med.* 349: 500; Canfield, R.L., Henderson, C.R., Cory-Slechta, D.A., Cox, C., Jusko, T.A. and B.P. Lanphear. 2003. Intellectual Impairment in Children with Blood Lead Concentrations below 10 ug per Deciliter. *N Engl. J. Med.* 348: 1517-1526; Tellez-Rojo, M.M.; Bellinger, D.C.; Arroyo-Quiroz, C.; Lamadrid-Figueroa, H.; Mercado-García, A.; Schnaas-Arrieta, L.; Wright, R.O.; Hernández-Avila, M.; Hu, H. (2006) Longitudinal associations between blood lead concentrations < 10 µg/dL and neurobehavioral development in environmentally-exposed children in Mexico City. *Pediatrics* 118: e323–e330; Chen A, Dietrich KN, Ware JH, et al. 2005. IQ and blood lead from 2 to 7 years of age: Are the effects in older children the residual of high blood lead concentrations in 2-year-olds? *Environ Health Perspect* 113(5):597-601. Chiodo LM, Jacobson SW, Jacobson JL. 2004. Neurodevelopmental effects of postnatal lead exposure at very low levels. *Neurotoxicol Teratol* 26(3):359-371.

² EPA has published several version of the IEUBK model since 2001. The refinements in each new version generally represent small changes to incorporate EPA's ongoing work on lead exposure and/or improvements in the model software. EPA has also published an updated users manual (EPA. 2002a. User's Guide for the Integrated Exposure Uptake Biokinetic Model for Children (IEUBK) Windows version. EPA 540-K-01-005) and guidance on specific topics (e.g. EPA. 2003. IEUBK Model Mass Fraction of Soil in Indoor Dust [M_{sd}] Variable. Produced by the Technical Review Workgroup for Lead.)

³ EPA/National Center for Environmental Assessment. 2005. Guidance Manual for the All-Ages Lead Model (AALM) Draft Version 1.05. Prepared by NCEA. Research Triangle Park, North Carolina.

- Scientific Review of Federal Blood Lead Screening Guidelines:** In 2004, the Centers for Disease Control and Prevention (CDCP) asked the Advisory Committee on Childhood Lead Poisoning Prevention (ACCLPP) to review the federal blood lead screening guidelines in light of more recent scientific studies on the relationships between blood lead concentrations and neurological development. The ACCLPP concluded that “...[r]esearch conducted since 1991 has strengthened the evidence that children’s physical and mental development can be affected at [blood lead levels] <10 µg/dL.”⁴ After considering the advisory committee findings, CDCP (2005) revised their statement on *Preventing Lead Poisoning in Young Children* to recognize the evidence of adverse health effects in children with blood lead concentrations below 10 µg/dL. Specifically, CDCP noted that no “safe” threshold for blood Pb had been identified and emphasized the importance of preventative measures.
- Review of the Scientific Basis for the National Ambient Air Quality Standards (NAAQS) for Lead:** In November 2004, EPA initiated a review of the air quality criteria for lead. That process was completed in November 2008 when EPA published a final rule revising the primary and secondary NAAQS for lead. In the final rule, EPA elected to lower the primary standard from 1.5 µg/m³ to 0.15 µg/m³.⁵ There are several key EPA conclusions that are relevant to the review of the MTCA standard for lead (1) young children remain the sensitive population and neurological development remains the primary health concern; (2) there are several health effects associated with blood Pb levels that are well below 10 µg/dL and EPA concluded that there is now no recognized safe level of lead in children’s blood; and (3) EPA chose to use an air-related IQ loss of 2 points as an “acceptable” or “target” public health goal.
- Updates to ATSDR Toxicological Profile for Lead:** In August 2007, the Agency for Toxic Substances and Disease Registry (ATSDR) completed an extensive review of toxicological and epidemiological studies on lead health effects.⁶ Consistent with the ACCLPP and EPA reviews, ATSDR noted that several studies have been published in recent years that support the view that there is no apparent threshold in the relationship between blood lead levels and neurobehavioral functions.
- Chemical Action Plan for Lead:** In early 2005, Ecology published a rule that describes methods and policies for identifying persistent and bioaccumulative toxins (PBT) and procedures developing strategies for reducing and phasing-out PBT uses and exposures. Ecology identified lead compounds as a PBT and worked with the Department of Health

⁴ Advisory Committee on Childhood Lead Poisoning Prevention (ACCLPP) (2007) Interpreting and managing blood lead levels <10 µg/dL in children and reducing childhood exposures to lead: Recommendations of CDC’s Advisory Committee on Childhood Lead Poisoning Prevention. Morbidity and Mortality Weekly Report. 56(RR–8). November 2, 2007.

⁵ U.S. Environmental Protection Agency. 2008. National Ambient Air Quality Standards for Lead. Final Rule. 73 FR 66964-67602. November 12, 2008.

⁶ Agency for Toxic Substances and Disease Registry /Department of Health & Human Services (USHHS). 2007. Toxicological Profile for Lead (Update).

to develop a draft chemical action plan for public review in 2008.⁷ In that document, Ecology and Health acknowledged that recent scientific information indicates that there are health risks at blood lead levels below 10 µg/dL and the draft action plan includes a recommendation that the Toxics Cleanup Program work with the MTCA Science Advisory Board and the Department of Health to review and (as appropriate) revise the MTCA soil cleanup standard for lead.

- **DOH Expert Panel Recommendations:** The Washington State Department of Health convened an expert panel in June 2008 to review and, as appropriate, update DOH’s guidelines related to lead exposure in children. The expert panel recommended that “...[t]he Department of Health should review and strengthen its guidelines regarding the appropriate medical responses for elevated blood lead levels.” In their report, the panel stated “... that there is no known “safe” threshold for lead. It also recognizes that lead levels between 5 and 9 µg/dL can be harmful to children...”⁸
- **Draft California Public Health Goal (PHG) for Lead:** The California Office of Environmental Health Hazard Assessment (OEHHA) has recently proposed updates to California’s public health goal for lead in drinking water (0.2 µg/dL)⁹ and soil-screening guidelines for lead contaminated soils (80 mg/kg for residential use and 320 mg/kg for commercial/industrial use).¹⁰ In both cases, OEHHA elected to replace the 10 µg/dL “level of concern” with a source-specific “benchmark change” of 1 µg/dL. Both proposals draw heavily from earlier work by OEHHA to identify a toxicity reference value for lead.¹¹

Rulemaking Options Being Considered

Ecology is considering several options for addressing this issue during the current rulemaking process. These include:

⁷ Department of Ecology and Department of Health. 2008. Washington State Lead Chemical Action Plan (Public Review DRAFT). Publication # 08-07-009.

⁸ Department of Health. 2008. Expert Panel Recommendations Child Lead Exposure. Environmental Health Division. Olympia WA.

⁹ Office of Environmental Health Hazard Assessment. 2009. Draft Public Health Goal for Lead in Drinking Water. Office of Environmental Health Hazard Assessment, California Environmental Protection Agency, Sacramento, CA.

¹⁰ Office of Environmental Health Hazard Assessment. 2009. Revised California Human Health Screening Level for Lead (Review Draft). Office of Environmental Health Hazard Assessment, California Environmental Protection Agency, Sacramento, CA.

¹¹ Office of Environmental Health Hazard Assessment. 2007. Development of health criteria for school risk assessment pursuant to Health and Safety Code Section 901(g): Child-specific benchmark change in blood lead concentration for school risk assessment. Office of Environmental Health Hazard Assessment, California Environmental Protection Agency, Sacramento, CA.

No Rule Changes: Under this option, Ecology would not modify the Method A soil cleanup level for lead this included in the current MTCA rule. The Method A soil cleanup level for unrestricted site uses would remain 250 mg/kg.

Use IEUBK Model to Develop Updated Method A Value for Unrestricted Land Uses: Under this option, Ecology would use the IEUBK model to develop an updated Method A soil cleanup level for lead. The updated value would take into account recent scientific information on lead exposure and health risks.

Use Other Models to Update Method A Value for Unrestricted Land Uses: Under this option, Ecology would use another lead model to update the Method A value. Ecology could use a slope factor model to predict changes in blood lead concentrations using simple linear relationships between blood lead levels and either lead uptake (biokinetic slope factor) or lead intake (intake slope factor). Under this approach, Ecology would evaluate the soil and dust exposure at different soil concentrations and establish a soil cleanup level based on incremental risks. This approach has been used by ATSDR and agencies in California and New Jersey to establish lead standards and guidelines. Ecology could also use the All Ages Lead Model when EPA scientists complete model revisions in response to comments from the EPA Science Advisory Board. Ecology could also use a cancer risk model to update the soil cleanup level using a cancer slope factor developed by the California Office of Environmental Health Hazard Assessment.

Update Method A value for industrial soils: Under this option, Ecology would use the EPA adult lead model, a cancer risk model using the OEHHA cancer slope factor or (if available) the EPA All Ages Lead Model to update the industrial soil cleanup level for lead.

Factors to Consider When Selecting an Option

Developing amendments to the MTCA cleanup regulation will require considering and balancing of a number of issues and interests. Ecology believes that the following factors need to be considered when evaluating rulemaking options:

- New scientific information and expert committee reports on the health effects in children at low levels of lead exposure.
- New scientific information and expert committee reports on the health effects in adults at low levels of lead exposure.
- New scientific information and expert committee reports related to the exposure and uptake from lead-contaminated soils.
- New evaluation tools and models that are available to characterize exposure and health risks associated with lead-contaminated soils.
- Regulatory policies and decisions made by other state and federal agencies.
- Whether particular options comply with key requirements of the Administrative Procedures Act.