

November 2004 (Finalized at 12/16/04 SAB Meeting)
**Status of Science Advisory Board Review of Ecology's Tiered Approach for
Addressing Lead-Contaminated Soils**

The Departments of Agriculture, Community, Trade and Economic Development (CTED), Ecology and Health chartered the Area-Wide Soil Contamination Task Force (Task Force) in January 2002 to consider the 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 report includes 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 approach¹ 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.

- **"Low" Concentrations of Lead in Soils:** The Task Force recommended that no further action be required or recommended at properties where soil concentrations are below the MTCA Method A Cleanup Level (250 mg/kg). The Method A Cleanup Level is established at a soil concentration that is unlikely to result in child blood lead levels > 10 ug/dL.
- **"Moderate" Concentrations of Lead in Soils:** The Task Force recommended that people and organizations be encouraged to (1) implement initial measures (e.g. soil covers, behavior changes) to reduce contact with such soils and (2) implement more permanent measures to prevent contact as property is developed or redeveloped. Ecology's working definition for "moderate" levels of lead are bounded by the MTCA cleanup level (250 mg/kg) and a soil concentration that is considered unlikely to result in child blood lead concentrations > 15 ug/dL. The upper end of the moderate range varies depending on whether a property is used as a residence (500 mg/kg), school/child care facility/park (700 mg/kg) or a commercial facility (1000 mg/kg).
- **"High" Concentrations of Lead in Soils:** The Task Force recommended that Ecology provide more formal review and oversight of cleanup measures for properties with "high" lead concentrations (i.e. soil concentrations the upper end of the moderate range). Although the level of oversight and priority for funding will be higher for properties with high concentrations, Ecology anticipates that the physical measures for dealing with high concentrations will be similar to the measures for properties with moderate concentrations (e.g. containment). The SAB agrees that areas with high concentrations merit more oversight and reliance on following traditional approaches to applying MTCA.

In January 2004, Ecology asked the Science Advisory Board to review the scientific information and methods that the Department used to develop the numerical soil concentrations used to define the "high", "moderate" and "low" concentration ranges. The Board met in January, March, May and June of 2004 to discuss a series of questions posed by Ecology. The following pages provide a summary of the Board's responses and concerns.

¹ There are several key assumptions that underlie the approach for addressing lead-contaminated soils: (1) children are the population group with the greatest susceptibility and exposure to lead; (2) scientists are currently unable to identify a threshold for lead toxicity in individual children and even if such a threshold could be identified for an individual child, it would be difficult to extrapolate such a finding to other children; (3) given current scientific information on the effects of low-level lead exposure, it is prudent to take reasonable steps to prevent exposure; (4) responses will vary depending on the exposure situation (e.g. schools) and soil lead concentrations; (5) responses will occur over an extended period of time.

Defining the Upper End of the Moderate Range

1. **Question:** Does the Science Advisory Board agree that the methods and assumptions used by Ecology to define the upper end of the moderate range are scientifically defensible?

Ecology proposed a series of soil concentrations for use in defining the upper end of the moderate range that vary depending on whether a property is used as a residence (500 mg/kg), school/child care facility (700 mg/kg) or a commercial facility/park (1000 mg/kg). The technical and policy rationale for selecting these concentrations includes the following:

- (1) Ecology's chose to define the upper end of the moderate soil concentration range at a level where it is unlikely (< 1-5%) that exposure will result in blood lead levels > 15 ug/dL;
- (2) Ecology believes that the IEUBK model is a sound method for identifying soil lead concentrations that are unlikely to result in blood lead concentrations > 15 ug/dL; and
- (3) Ecology believes that the methods and assumptions incorporated into the IEUBK model generally reflect a health protective approach for dealing with uncertainty and variability.

SAB Conclusions: The Board agreed that the methods and assumptions used by Ecology to define the upper end of the moderate range are scientifically defensible. However, given the rapidly evolving body of scientific information on the relationships between lead exposure and adverse health effects, the Board recommended that Ecology periodically review the working definition and evaluate whether the upper end of the moderate range should be lowered. In reaching their conclusion, the Board considered several aspects of this question:

- **Use of the IEUBK Model and Exposure Assumptions:** The Board concluded that (1) the IEUBK model was a sound approach for evaluating exposure to lead-contaminated soils and (2) the parameters and assumptions used by Ecology to estimate exposure are generally consistent with current EPA guidance materials.
- **Uncertainty and Variability:** The Board observed there are many sources of uncertainty and variability that complicate the preparation and interpretation of health risk assessments for lead and emphasized the importance of providing a clear discussion of these sources. With respect to lead – contaminated soils, important sources of uncertainty and variability include: (1) the quantitative relationship between low levels of lead exposure, the distribution of lead in the body and various health endpoints; (2) the extent of lead intake associated with dermal contact; (3) the transfer of lead between various environmental compartments (e.g. relationship between lead in outdoor soils and indoor dust; the extent of lead uptake in vegetables and fruits commonly grown in Washington; the relationship between the lead concentrations in soils and windblown dust); and (4) applicability of national exposure parameters to Washington state; (5) the nature and extent of non-soil lead exposure; and (6) variability in soil lead concentrations within a specific area or property.
- **Policy Choices:** The Board observed that the choice of the soil concentration used to define the upper end of the moderate range is driven by the choice of what constitutes a “high” blood lead concentration. The Board acknowledged this was largely a policy choice. However, the Board concluded (1) there is a general scientific consensus around the conclusion that blood lead concentrations > 15 ug/dL are harmful to children’s health and (2) Ecology’s use of this value (15 ug/dL) as the basis for defining the upper end of the moderate range is consistent with the policy choices inherent in the current CDCP guidelines.
- **Tiered Responses:** The Board observed that the overall strategy envisions greater oversight and/or reliance on the traditional MTCA process for properties found to have high lead levels). However, the Board also observed that people are being encouraged or required to implement similar types of physical measures (i.e. containment) at both moderate and high concentrations.

Defining the Lower End of the Moderate Range

2. **Question:** Does the Science Advisory Board agree that the methods and assumptions used by Ecology to define the lower end of the moderate range are scientifically defensible?

Ecology proposed to use the current MTCA Method A soil cleanup level (250 mg/kg²) to identify the lower end of the moderate range. The technical and policy rationale for the lower end of the moderate range includes the following: (1) Ecology's current policy is not to require further MTCA actions to address human health risks where soil levels are less than 250 mg/kg; (2) Ecology believes that the IEUBK model is a sound method; and (3) Ecology believes that the methods and assumptions incorporated into the IEUBK model reflect a health protective approach for dealing with uncertainty and variability.

SAB Conclusions: The Board agreed that the methods and assumptions for evaluating exposure and variability used by Ecology to define the lower end of the moderate range are scientifically defensible. However, the Board observed that (1) available scientific information does not permit the identification of safe or threshold concentration below which there are no health risks and (2) there is an emerging scientific consensus that blood lead concentrations of < 10 ug/dL can potentially be levels of concern with respect to children's health. Consequently, the Board recommended that Ecology review whether the underlying basis for the current MTCA cleanup level remains consistent with the MTCA statutory directives. In reaching their conclusion, the Board considered several aspects of this questions:

- **Use of the IEUBK Model and Exposure Assumptions:** The Board concluded that (1) the IEUBK model was a sound approach for evaluating exposure to lead-contaminated soils and (2) the parameters and assumptions used by Ecology to estimate exposure are generally consistent with current EPA guidance materials.
- **Uncertainty and Variability:** The Board observed there are many sources of uncertainty and variability that complicate the preparation and interpretation of health risk assessments for lead. (See summary of discussion under Question #1).
- **Science Choice:** The Board concluded that there is an emerging scientific consensus around the conclusion that blood lead levels of < 10 ug/dL can be harmful to children's health. Consequently, the Board expressed reservations about using the MTCA cleanup level (based on a blood lead level of 10 ug/dL) to distinguish between soils requiring some type of action and soils that require no further action.
- **Incremental Impact on Blood Lead Concentrations Resulting from Soil-Related Lead Exposure:** The Board recommended that Ecology consider soil-only impacts on blood lead concentrations when specifying low, moderate and high soil concentrations (in addition to considering lead exposure from all sources). Preliminary calculations indicate that a soil concentration of 250 mg/kg is associated with a soil-related change in blood lead concentrations of 4.5 – 5.8 ug/dL.
- **Risk Communication:** The Board recommended that Ecology and Health design their education materials and approaches to reflect the increasing level of risk as soil levels increase from low, to moderate to high. The agencies should focus efforts on areas with the greatest potential for elevated levels (e.g. areas of high density of former orchard areas) and opportunities for distributing information (e.g. real estate transactions). The Board also recommended that the term "moderate" might be more accurately replaced with the term "intermediate".

² The Method A soil cleanup levels was established at a soil concentration that is unlikely (< 1-5%) to result in blood lead levels above 10 ug/dL.

Responses at Properties Where Soil Lead Concentrations are < 250 mg/kg

3. **Question:** Does the Science Advisory Board believe there is a sound scientific justification for providing information on ways to reduce lead exposure in situations where soil concentrations are below the MTCA cleanup level (i.e. < 250 mg/kg)?

The Science Advisory Board expressed concerns about Ecology's use of a blood lead concentration of 10 ug/dL to distinguish between properties that require some action and those that require no further action. They noted that there is a growing scientific consensus that blood-lead levels below 10 ug/dL can produce adverse health effects. The Board recognized the difficulty of addressing concentrations lower than the MTCA cleanup level and identified two main options for addressing this concern: (1) re-evaluate a lower bound for the moderate range³ (See Question #2); and (2) expand the education and awareness campaign to include information and education materials on ways to reduce exposure to soil concentrations below 250 mg/kg.

SAB Conclusions: The Science Advisory Board concluded that there is a sound scientific justification for providing information on ways to reduce lead exposure in situations where soil concentrations are below the MTCA cleanup level (i.e. < 250 mg/kg). The Board believes this approach is consistent with (1) the evolving body of scientific information that suggests that blood lead concentrations of < 10 ug/dL can potentially be levels of concern to children's health and (2) the health-based tiered risk management approach recommended by the Area-wide Soil Contamination Task Force. In reaching their conclusion, the Board discussed several scientific and policy considerations:

- **Health Effects:** The Board observed that recent studies indicate that children may be adversely affected where exposure levels result in blood lead concentrations < 10 ug/dL and that available scientific evidence does not provide a sufficient basis for identifying a threshold below which adverse health effects are not expected.
- **Primary Prevention:** The Board observed that CDCP and other health groups have concluded there are no effective clinical interventions that are known to lower blood levels for children with blood lead concentrations < 10 ug/dL. Given the lack of effective intervention measures, the Board concluded that it is important for people to take steps to prevent exposure to elevated levels of lead in soils (e.g. primary prevention). Given that awareness and information are necessary prerequisites for taking such steps, the Board thought it would be appropriate to expand current awareness-building efforts because many people are unaware of the potential health risks and steps they can take to reduce exposure.
- **Risk Communication:** The Board observed there are many challenges associated with providing meaningful and understandable information on health risks. The Board recommended that Ecology and Health review the scientific basis for the approaches to risk communication and behavioral intervention. Materials should include information on steps for reducing lead exposure that can be taken by individuals and communities.
- **Practical Considerations:** The Board discussed the need for balancing the cost and resources associated with providing preventative information at levels below 250 mg/kg with the costs and resources of implementing an approach that focuses resources on areas with the highest contamination levels. The Board questioned whether expanding the education and awareness building effort would actually increase program costs because the agencies were already providing information materials.

Relative Sensitivity to Lead Exposure

4. **Question:** Does the Science Advisory Board believe that it is scientifically defensible to conclude that levels protective of young children also protect older children and adults?

One of the assumptions underlying Ecology's working definition for moderate levels of lead in soils is that levels that are protective of young children also protect older children and adults.

SAB Conclusions: The Board concluded that it is scientifically defensible to assume that soil concentrations that protect young children, on the average, also protect older children and adults (including sensitive adult populations (such as menopausal women) who may remobilize lead stored in bones. However, the Board recommended that Ecology revisit this assumption when EPA completes work on the All Ages Lead Model. The Board also recommended that Ecology monitor the progress of the Lead and Pregnancy Work Group (formed by the Advisory Committee on Childhood Lead Poisoning Prevention) which is currently reviewing available research on the relationship between prenatal exposure and children's health. The Board also believes there may be situations where exposure levels for adults and older children are higher than young children and actions/recommendations to reduce exposure should reflect such differences. In reaching their conclusion, the Board discussed several aspects of this issue:

- **Relative Susceptibility:** Studies indicate that younger children (less than 36 months) are more susceptible than older children and adults due to differences in exposure, biokinetics and neurological development. The Board observed that the current version of EPA Adult Lead Model is based on neurological effects in the developing fetus and are considered to be protective for other types of health effects in adults (e.g. hypertension).
- **Relative Exposure:** The Board discussed whether it was reasonable to assume that exposure levels for young children are greater than exposure levels for older children and adults. The Board observed there may be situations (e.g. gardening, workplace exposures, outdoor activities for older children that involve soil contact) where exposures for adults and older children exceed that for young children. In particular, the Board expressed concerns about work place exposure (e.g. orchard workers) or exposure through intensive gardening and recommended that education materials provide information about ways to reduce exposure in these situations.
- **Uncertainty and Variability:** The Board observed there are many sources of uncertainty and variability that complicate the preparation and interpretation of health risk assessments for lead (See Issue #2).

Migration of Lead in Surface Soils to Underlying Ground Water

5. **Question:** Does the Science Advisory Board agree that it is scientifically defensible to conclude that surface soil lead concentrations below 1000 mg/kg are unlikely to significantly impact ground water?

One of the assumptions underlying Ecology's working definition for lead-contaminated soils was that "...surface soils with lead concentrations below 1000 mg/kg are unlikely to pose a significant threat to ground water supplies...". Ecology's rationale includes:

- **Fate and Transport Modeling Performed to Support MTCA Amendments:** 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). Using that screening level, soil concentrations below 3000 mg/kg are considered unlikely to cause ground water concentrations greater than 15 ug/L).
- **Soil Profiles:** Soil profile data collected from orchards and areas near former smelters indicate that lead deposited at the surface remains in shallow soils (6-24 inches).

Status of SAB Review: Ecology presented information on this issue to the Board at the May Board meeting. The Board identified several concerns and requested that Ecology compile additional information relevant to this issue:

- **Fate and Transport Modeling:** The Board observed that the screening level derived for lead (3000 mg/kg) as part of the MTCA rulemaking process is not necessarily conservative. For example, the modeling performed by Ecology was done using a dilution attenuation factor (DAF) of 20 that is at the upper end of the range (DAF = 5-20) recommended by EPA recommended a DAF in the range of 5-20. The Board also noted that the lead partitioning coefficient (10,000) used by Ecology is quite high – particularly given that Ecology considered using a value of 1000 earlier in the rulemaking process. The partitioning coefficient for lead is very sensitive to pH. This is particularly relevant when considering the potential for ground water impacts in areas surrounding former smelters.
- **Ground water data:** The Board requested that Ecology review available ground water data that has been collected within known area-wide contamination areas to confirm that ground water impacts are not a concern.

Ecology is currently compiling additional information relevant to the fate and transport of lead and arsenic in shallow soils. Ecology plans to present this information at a future SAB meeting.

Future Information Collection and Review

6. **Question:** Given available information, where does the SAB recommend that Ecology focus future information collection and review?

SAB Conclusions: The Board identified several information collection activities as they discussed Ecology's proposal for identifying moderate levels of lead-contaminated soils. Ecology compiled and distributed a list of those suggestions prior to the June 22nd Board meeting. The Board concluded that the list appears reasonable and expressed a willingness to discuss this further as Ecology develops specific data collection plans. The unranked list and the Board's comments on individual items are summarized below:

- Collect and evaluate information on the variability in blood lead concentration in Washington children and the various risk factors that influence blood lead concentrations. The Board noted that current blood lead sampling is based on non-random sampling which prevents meaningful extrapolation to the general population.
- Collect and evaluate information on soil lead concentrations in Washington in order to better characterize the variability in lead concentrations and use that information when designing property-specific sampling efforts. The Board stated that it is important to identify factors that influence variability in soil concentrations.
- Collect and evaluate existing information on lead concentrations in vegetables grown in Washington. The Board noted this is a particular concern with respect to evaluating health risks associated with the consumption of commercial crops grown in area-wide contamination zones. The Board observed that use of data on lead concentrations in food from national surveys may not be appropriate for characterizing health risks in such situations.
- Collect and evaluate information on the relationship between soil pH levels and other factors that might influence the potential for lead in surface soils to migrate into underlying groundwater aquifers including considering various forms of lead. Stan Peterson suggested that Ecology consider the bioavailability of various forms of lead (and arsenic) as the science becomes available. He also asked whether worker exposure on existing agricultural lands is considered.
- Periodically review, evaluate and, as appropriate, revise the Method A soil cleanup level for lead based on scientific information on adverse health effects associated with blood lead concentrations below 10 ug/dL.
- Collect and evaluate information on soil lead concentrations along roads in Washington.
- The Board noted that outcome of the eventual SAB discussion about ecological impacts associated with arsenic- and lead-contaminated soils may point to additional data needs.