RECOMMENDATIONS FOR DEFAULT AGE RANGE IN THE IEUBK MODEL

OVERVIEW

Since 1994, the Office of Land and Emergency Management (OLEM), formerly known as the Office of Solid Waste and Emergency Response (OSWER), has recommended the Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK model) as a risk assessment tool to support environmental cleanup decisions at current or future anticipated residential sites (U.S. EPA, 1994a,b). The IEUBK model uses empirical data from numerous scientific studies of lead uptake and biokinetics, contact rates of children with contaminated media, and data on the presence and behavior of environmental lead to predict a plausible distribution around the geometric mean (GM) of blood lead (PbB) for a hypothetical child or population of children.[1] The relative variability of PbB concentrations around the GM is defined as the geometric standard deviation (GSD). The GSD encompasses biological and behavioral differences, measurement variability from repeat sampling, variability as a result of sample locations, and analytical variability.[2] From this distribution, the IEUBK model estimates the risk (*i.e.*, probability) that a child's or a population of children's PbB concentration will not exceed a certain PbB level (U.S. EPA, 1994a, 1998, White et al., 1998).

The IEUBK model is utilized for achieving a risk reduction goal of limiting exposure to soil lead levels such that children (0-84 months old) would have no more than 5% risk of exceeding a certain blood lead level (PbB) (U.S. EPA, 1994a,b). In June 2012, Center for Disease Control and Prevention (CDC) adopted the 97.5th percentile blood lead concentration for children between 1-5 years old of the National Health and Nutrition and Nutrition Survey (NHANES) as the reference value to target intervention for individual children and communities with blood lead levels at and above that concentration (CDC, 2012). This reference value will be updated every 4 years based on

[1]The GM represents the central tendency estimate (*e.g.*, mean, 50th percentile) of PbB concentration of children from a hypothetical population (Hogan et al., 1998). If an arithmetic mean (or average) dietary intake is used, the model provides a central point estimate for risk of an elevated PbB level. By definition, a central tendency estimate is equally likely to over- or under-estimate the lead-intake at a contaminated site. Upper confidence limits (UCLs) can be used in the IEUBK model; however, the IEUBK model results could be interpreted as a more conservative estimate of the risk of an elevated PbB level. See U.S. EPA (1994b) for further information.

[2]The IEUBK model uses a log-normal probability distribution to characterize this variability (U.S. EPA, 1994a). The biokinetic component of the IEUBK model output provides a central estimate of PbB level, which is used to provide the geometric standard deviation (GSD). The GSD encompasses biological and behavioral differences, measurement variability from repeat sampling, variability as a result of sample locations, and analytical variability. In the IEUBK model, the GSD is intended to reflect only individual PbB variability, not variability in PbB levels where different individuals are exposed to substantially different media concentrations of lead. The recommended default value for GSD (1.6) was derived from empirical studies with young children where both blood and environmental lead concentrations were measured (White et al., 1998).

current PbB information from NHANES. At this time, the 97.5th percentile for children 1-5 years old is equivalent to 5 µg/dL (ACCLPP, 2012).

On December 22, 2016, EPA issued Directive 9200.2-167, *Updated Scientific Consideration for Lead in Soil Cleanups, which highlights the current science and risk assessment tools that Regions may consider when implementing the 1994 EPA Directive 9355.4-12, Revised Interim Soil Lead Guidance for CERCLA Sites and RCRA Corrective Action Facilities.* Today we recognize that the information provided in the 1994 Directive regarding blood lead levels may not be adequately protective for children and adults, as it does not reflect current scientific consensus and national public health recommendations regarding lead exposure and adverse health effects. The directive states:

> *The current scientific literature on lead toxicology and epidemiology provides evidence that adverse health effects are associated with blood lead levels (BLLs) less than 10 µg/dL. For example, EPA's Office of Research and Development reviewed the health effects evidence for lead in the 2013 Integrated Science Assessment for Lead (ISA for Lead) and found that several studies have observed "clear evidence of cognitive function decrements (as measured by Full Scale IQ academic performance and executive function) in young children (4 to 11 years old) with mean or group blood lead levels between 2 µg/dL and 8 µg/dL (measured at various life stages and time periods). "In addition, the National Toxicology Program's (2012) Monograph on Health Effects of Low-Level Lead found sufficient evidence of delayed puberty, reduced post-natal growth, and decreased hearing for children at BLLs below 10 µg/dL and adverse effects on academic achievement, IQ other cognitive measures, attention-related behaviors, and problem behaviors at BLLs below 5 µg/dL.*

The 2016 Directive recommends that Regions consider the best science when selecting a not – to exceed blood lead level for use in the IEUBK model.

RATIONALE AND RECOMMENDATION

NTP (2012) reported that children age 1-5 years consistently have higher blood Pb levels than do older children. NTP hypothesized that this was likely due to hand-to-mouth activity in young children. Similarly, CDC (2007) reported that several studies show a peak in children's blood Pb levels around 24 months of age. Neurological deficits have been associated with increased blood lead levels among children in this age range (NTP, 2012; see section 4.3.1) Thus, the focus of the IEUBK model on this age group is better aligned with the most exposed population.

To better align the CDC recommendation and the risk predictions for lead exposure at Superfund sites, the TRW Lead Committee recommends that the default age range in IEUBK model be modified to match the 1-5 year age range (12-72 months). See Figure 1.

IMPLEMENTATION

The default age range in the IEUBK model is a variable that may be changed by the user to assess site-specific exposure conditions. In addition to the default, there are a number of established age ranges and a user defined option that allows any interval of monthly exposures and calculations. Risk assessments should derive preliminary remediation goals (PRG) based on the age range that best represents the exposed population.

Aligning the default age range in the IEUBK model to match the age range used by CDC to establish the reference value does not eliminate this flexibility in the IEUBK model. Instead, it allows users to rapidly compare risk predictions from site exposures to the public health goal that is recommended by CDC.

The 12-72 month age range generally results in a lower PRG than the 0-84 (or 6-84) month age range because soil and dust ingestion rates are generally lower for children aged 0-12 and 72-84 months (see Figure Screen 2-12 on page 2-15 of US EPA, 1994a).

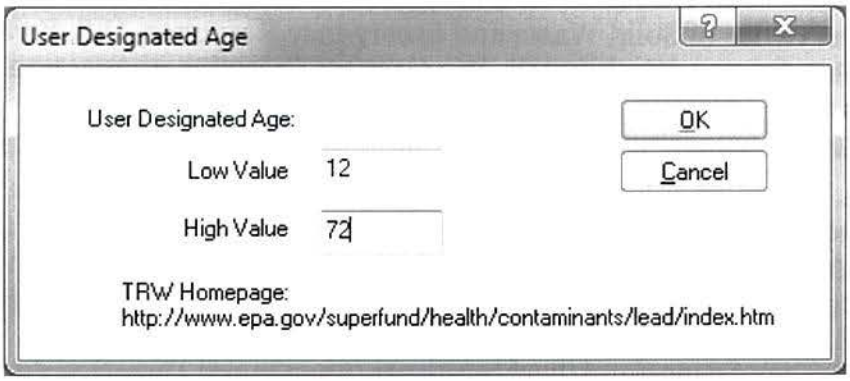

Figure 1. Recommended age range for human health risk assessment at Superfund sites.

REFERENCES

ACCLPP (Advisory Committee on Childhood Lead Poisoning Prevention). 2012. Low Level Lead Exposure Harms Children: A Renewed Call for Primary Prevention: Atlanta, GA. Centers for Disease Control and Prevention Available online at: http://www.cdc.gov/nceh/lead/ACCLPP/Final_Document_030712.pdf.

CDC (U.S. Centers for Disease Control and Prevention). 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. Atlanta, GA: Centers for Disease Control and Prevention (CDC). 1-15. Available online at: http://www.cdc.gov/mmwr/PDF/rr/rr5608.pdf.

CDC (U.S. Centers for Disease Control and Prevention). 2012. Low level exposure harms children: A renewed call for primary prevention. Report of the Advisory Committee on Childhood Lead Poisoning Prevention. January 4. Available online at: http://www.cdc.gov/nceh/lead/ACCLPP/Final_Document_030712.pdf.

NTP (National Toxicology Program). 2012. NTP Monograph: Health Effects of Low-Level Lead. June 2012. OHAT/NIEHS/DHHS. Available online at: http://ntp.niehs.nih.gov/NTP/ohat/Lead/Final/MonographHealthEffectsLowLevelLead_NewISSN_508.pdf

U.S. Environmental Protection Agency (U.S. EPA). 1994a. Guidance Manual for the IEUBK Model for Lead in Children. Office of Solid Waste and Emergency Response: Washington, DC. PB93-963510, OSWER #9285.7-15-1. February. Available online at: http://www.epa.gov/superfund/lead/products.htm.

U.S. EPA (U.S. Environmental Protection Agency). 1994b. OSWER Directive: Revised Interim Soil Lead Guidance for CERCLA Sites and RCRA Corrective Action Facilities. Office of Solid Waste and Emergency Response, U.S. Environmental Protection Agency. Washington, DC. OSWER Directive #9355.4-12. Available online at: www.epa.gov/superfund/health/contaminants/lead/products/oswerdir.pdf

U.S. EPA (U.S. Environmental Protection Agency). 1998. Memorandum: OSWER Directive: Clarification to the 1994 Revised Interim Soil Lead (Pb) Guidance for CERCLA Sites and RCRA Corrective Action Facilities. Office of Solid Waste and Emergency Response: Washington, DC. EPA/540/F-98/030, PB98-963244, OSWER #9285.7-52. March. Available from: http://epa.gov/superfund/lead/products/nhanes.pdf Directive #9200.4-27P. August. Available online at: http://www.epa.gov/superfund/lead/products/oswer98.pdf.

White, P.D.; Van Leeuwen, P.; Davis, B.D.; Maddaloni, M.; Hogan, K.A.; Marcus, A.H.; Elias, R.W. 1998. The conceptual structure of the integrated exposure uptake biokinetic model for lead in children. Environ Health Perspect 106 Suppl 6: 1513-1530. Available online at: http://ehpnet1.niehs.nih.gov