OFFICE OF LAND AND EMERGENCY MANAGEMENT
WASHINGTON, D.C. 20460

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MEMORANDUM

SUBJECT: Updated Residential Soil Lead Guidance for CERCLA Sites and RCRA Corrective Action Facilities

FROM: Barry N. Breen
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TO: Regional Administrators, Regions 1 - 10

PURPOSE

Reducing childhood lead exposure is an Environmental Protection Agency (EPA) priority. Consistent with the best available science, the Agency's Strategy to Reduce Lead Exposures and Disparities in U.S. Communities, and the Federal Action Plan to Reduce Childhood Lead Exposures and Associated Health Impacts, the Office of Land and Emergency Management (OLEM) is updating its residential soil lead regional screening level (RSL) and regional removal management level (RML) for the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), commonly known as "Superfund" remedial and removal programs, respectively, and Resource Conservation and Recovery Act (RCRA) Corrective Action program. The information and recommendations in this guidance also apply to federal facility cleanup programs subject to CERCLA section 120, and potentially to federal agencies using response action authorities delegated to them under Executive Order 12580 (OFR, 1987).

Screening Residential Soil Lead Sites

What is a regional screening level (RSL)? RSLs are screening tools used to help identify and define areas that may need further evaluation.

What is a removal management level (RML)? RMLs are screening tools used to help prioritize and define areas that may pose the greatest threat to human health.

The RSLs and RMLs are generally not default preliminary remediation goals (See Footnote 11) and cleanup levels.

When evaluating residential sites with soil lead contamination,[1] OLEM recommends:

[1]For the purpose of this guidance, a residential site with soil lead contamination (residential lead site) is defined as any areas where children have unrestricted access to lead contaminated soil which include, but are not limited to, properties containing single- and multi-family dwellings, apartment complexes, vacant lots in residential areas, schools, day-care

Regional Screening Level

- EPA regions should use a residential soil lead RSL of 200 parts per million (ppm).[2]
- However, EPA regions should use a RSL of 100 ppm[3] if an additional source of lead is identified (e.g., lead water service lines, lead-based paint, non-attainment areas where the air lead concentrations exceed National Ambient Air Quality Standards [NAAQS]). The recommended RSL of 100 ppm considers aggregate lead exposure and increased risk to children living in communities with multiple sources of lead contamination. In making site-specific decisions on when to use an RSL of 100 ppm, EPA regions may use national data sets identified by OLEM for this purpose. EPA regions may also use site-specific sources of information (e.g., data from the local health department or local public water system), alone or in combination with national data sets, to select an appropriate RSL of either 100 ppm or 200 ppm. EPA regions should document the site-specific rationale for the selected RSL.
- Federal-led RCRA corrective action residential soil lead cleanups should use an RSL of 200 ppm or 100 ppm based on the factors discussed above. EPA strongly encourages states that are authorized for RCRA Corrective Action to use these RSLs in their state-led residential soil lead cleanups.

Removal Management Level

- EPA regions should use a residential soil lead RML of 200 ppm.

NOTICE

Please note, the statements in this document are intended solely as guidance. This document is not intended, nor can it be relied upon, to create any rights enforceable by any party in litigation with the United States. EPA will accept public input and evaluate new scientific evidence, as appropriate.

BACKGROUND

Two guidance documents, (1) Revised Interim Soil Lead Guidance for CERCLA Sites and RCRA Corrective Action Facilities (USEPA, 1994) and (2) Clarification to the 1994 Revised Interim Soil Lead (Pb) Guidance

centers, community centers, playgrounds, parks and other recreational areas and green ways. Under CERCLA and RCRA Corrective Action, screening and cleanup decisions for residential land use are based the most sensitive receptor (young children less than 7 years old). See USEPA, 1998 and 2003.

[2] Since 1994, OLEM has recommended the Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK) as a risk assessment tool to support environmental cleanup decisions at current and future anticipated residential sites (USEPA, 1994). The IEUBK predicts blood lead levels in young children (birth to 7 years of age) exposed to lead from several sources of exposure and routes. The current version of the model (IEUBKv2) with 5 µg/dL as the 95th percentile target blood lead level and national default lead concentrations predicts a soil lead concentration of approximately 200 ppm. The geometric mean blood lead level is 2.3 µg/dL.

[3] The IEUBKv2 with 3.5 µg/dL as the 95th percentile target blood lead level and national default lead concentrations predicts a soil lead concentration of approximately 100 ppm. The geometric mean blood lead level is 1.7 µg/dL. EPA has not evaluated the IEUBKv2 below 5 µg/dL (upper percentile of the blood lead distribution) (Brown et al., 2022). EPA has a qualitative understanding of uncertainties that may exist in applying the model outside the evaluated range, which is consistent with EPA Guidance on the Development, Evaluation, and Application of Environmental Models (See definition of mechanistic model, page 44, USEPA, 2009). EPA has used models outside the evaluated range when deemed necessary and appropriate for human health risk assessments.

for CERCLA and RCRA Corrective Action Facilities (USEPA, 1998), established OLEM's previously recommended approach for evaluating and cleaning up Superfund and RCRA Corrective Action sites with soil lead contamination. Broadly, these directives recommended a residential soil lead RSL of 400 ppm based on 10 µg/dL as the 95th percentile target blood lead level, described how to develop preliminary remediation goals (PRGs) and cleanup levels, and described a strategy to manage multiple sources of lead exposure. At the time, a blood lead level above 10 µg/dL was recognized to be associated with adverse health outcomes in children (USEPA, 1994). The science on lead has since evolved and demonstrates additional adverse health effects of lead exposure and at lower levels than previously known.

Best Available Science and Data

In 2012, the National Toxicology Program (NTP) Monograph on Health Effects of Low-Level Lead examined the evidence for adverse health effects at blood lead levels of up to 5 µg/dL and 10 µg/dL and found sufficient evidence of many different types of health effects below both levels. The NTP concluded, "In children, there is sufficient evidence that blood [lead] Pb levels <5 µg/dL are associated with increased diagnosis of attention-related behavioral problems, greater incidence of problem behaviors, and decreased cognitive performance as indicated by (1) lower academic achievement, (2) decreased intelligence quotient (IQ), and (3) reductions in specific cognitive measures" (HHS, 2012, page xviii). Further, the NTP found "sufficient evidence that blood Pb levels <5 µg/dL are associated with antisocial behavioral problems or actual criminal behavior in children from 6 to 15 years of age." For adults, the NTP found "sufficient evidence that blood Pb levels <5 µg/dL are associated with decreased renal function" and "sufficient evidence that maternal blood Pb levels <5 µg/dL are associated with reduced fetal growth" (Ibid.). Although the evidence was less definitive, the NTP also found associations of blood Pb levels <5 µg/dL with delayed puberty and decreased kidney function in children and with essential tremor in adults. The NTP concluded "that there is sufficient evidence that blood Pb levels <10 ug/dL in adults are associated with adverse effects on cardiovascular function" (HHS, 2012, page xxii).

EPA's 2013 Integrated Science Assessment for Lead (ISA) states "It is clear that Pb [lead] exposure in childhood presents a risk; further, there is no evidence of a threshold below which there are no harmful effects on cognition from Pb [lead] exposure" (USEPA, 2013, page xxxviii). Although the ISA reports, "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 Pb [lead] levels measured at various life stages and time periods between 2 and 8 µg/dL," (USEPA, 2013, page xxxiii) it is critical to note that there is not a threshold for toxicity somewhere between blood lead levels of 2 and 8 µg/dL. Rather, a "threshold for cognitive function decrements is not discernable from the available evidence" (USEPA, 2013, page 1-20). Although there are a greater number of studies available to support effects at 5 µg/dL, cognitive function decrements in children have been found at all levels examined, including at levels as low as 2 µg/dL as identified in the 2013 ISA. The ISA also concludes that lead exposure has a causal relationship with hypertension and coronary heart disease (USEPA, 2013, page 1-29). The recommended RSLs of 200 ppm and 100 ppm are predicted using the current version of the Integrated Exposure Uptake Biokinetic Model for Lead in

Children (IEUBK) to result in geometric mean blood lead levels (2.3 µg/dL and 1.7 µg/dL, respectively) that are 0.3 µg/dL above and below, respectively 2 µg/dL.

The Agency for Toxic Substances and Disease Registry's 2020 Toxicological Profile for Lead reviewed 694 epidemiological studies that evaluated the health effects of lead in all organ systems. This updated Toxicological Profile concluded that "[f]or the most studied endpoints (neurological, renal, cardiovascular, hematological, immunological, reproductive, and developmental), effects occur at the lowest PbBs [blood leads] studied (≤5 µg/dL)" (ATSDR, 2020, page 3). Some of the more recent studies included in the Toxicological Profile provide "supporting evidence that exposures to Pb [lead] may produce effects on cognitive function in populations whose PbBs [blood leads] are well below 5 µg/dL and may extend to levels below 1 µg/dL" (ATSDR, 2020, page 168).

RATIONALE FOR UPDATED GUIDANCE

As previously stated, evolving science on lead has demonstrated additional adverse impacts of lead exposure well below 10 µg/dL since the 1994 guidance was issued. Moreover, children could be exposed to multiple sources of lead other than contaminated soil/dust (e.g., lead water service lines, lead-based paint, or non-attainment areas where the air lead concentrations exceed NAAQS) at Superfund and RCRA Corrective Action sites. Studies[4] conducted at or near Superfund sites provide evidence that aggregate lead exposure has generally resulted in blood lead levels that are higher than those of most U.S. children as indicated by the observation of a disproportionate number of elevated blood lead levels in such communities. Further, the 2013 ISA found that childhood, race and ethnicity, proximity to lead sources, residential factors (housing age), and poor nutrition may lead to increased risk of lead related health effects (USEPA, 2013, Table 1-7, page 1-79).

While evidence shows adverse health effects at the lowest levels studied, CERCLA and the National Oil and Hazardous Substances Pollution Contingency Plan (NCP) mandate that EPA develop protective exposure levels for our sites, establishing a risk management paradigm informed by many factors including health effects at issue and the population at risk. Based on the best available science, OLEM is recommending a lower residential soil lead RSL and RML of 200 ppm and further reducing the RSL to 100 ppm when there is aggregate lead exposure. Lowering the RSL and RML is expected to increase the number of residential properties evaluated for potential cleanup under CERCLA and RCRA Corrective Action authorities.

From a risk management perspective, effectively assessing potential impacts to children from lead exposure[5] informs further evaluation of the site. This information is integral to selecting the most appropriate combination of CERCLA or RCRA Corrective Action response actions to reduce the risk from site-specific lead contamination. Through these recommendations, EPA is helping ensure that Superfund and RCRA Corrective Action residential soil lead cleanups adequately reduce childhood exposures, which, if unaddressed, could lead to lifelong adverse health effects.

[4] Klemick et. al., 2020; Khoury and Diamond, 2003; Terragraphics, 2004; Frank, et. al., 2019; Zota, et. al., 2011; Ye, et. al., 2022; U.S. EPA, 2013.

[5] CERCLA and RCRA Corrective Action residential soil lead cleanups protect the most sensitive receptor and thereby protect all other residents in the process (including pregnant women, older children, and other adults).

IMPLEMENTATION

Managing and Prioritizing Residential Soil Lead Cleanups

This guidance should be considered for all residential lead sites subject to CERCLA response and RCRA Corrective Action authorities, including those previously addressed and/or deleted from the National Priorities List (NPL).[6] EPA expects that a significant number of residential properties could undergo evaluation and cleanup because of this guidance. The existing prioritization process, which occurs at the regional level,[7] will continue. That process entails review of existing site information and overall risk in a manner consistent with the NCP and national program guidance and policies. EPA regions should work collaboratively with state, tribal, and public health agencies to prioritize addressing sites, considering factors such as current levels of exposure and communities with increased risk. Consistent with national policy, EPA will make resource decisions for residential lead sites in a manner that balances resources across all Superfund sites.

Evaluations of previously addressed sites could be conducted in support of a CERCLA five-year review or other technical review. EPA regions should consider historical site-specific documentation to determine: the extent of previous cleanup, including cleanup levels and the remedial and/or removal action objectives; the exposure assumptions used in the risk assessment at the time of response selection, including the use of site-specific environmental data (e.g., lead concentrations in various media and bioavailability); if the current version of the IEUBK blood lead level estimates are consistent with revised target blood lead levels outlined in this guidance (5 µg/dL or 3.5 µg/dL 95th percentile target blood lead level); and other appropriate considerations. EPA regions should include an assessment of the actual exposure scenarios (e.g., gardening, excavation, age of children in contact with soil, paved and unpaved surfaces) throughout both the remediated and un-remediated areas within the site, in addition to evaluating whether potential changes in cleanup levels are necessary and appropriate.

Because EPA expects a significant number of properties to undergo evaluation, EPA regions are not expected to be able to address all properties immediately. As EPA regions are prioritizing residential lead sites for evaluation and potential cleanup, OLEM continues to recommend early risk reduction strategies, which could include a combination of engineering controls (e.g., reliable barriers to mitigate risk from lead exposure) and non-engineering response actions (e.g., education and health intervention programs in conjunction with exposure reduction actions like institutional controls).[8] EPA will continue

[6] Regarding completed residential soil lead cleanups, there are post-remedy review authorities for RCRA cleanups; one is the authority to reopen permits based on new information.

[7] EPA intends to engage with other Federal agencies conducting actions under CERCLA or RCRA Corrective Action associated with lead releases from these Federal Facilities, with input from state and tribal environmental agencies, to develop a Federal Facility-specific implementation guidance. EPA's Federal Facilities Restoration and Reuse Office (FFRRO) works with EPA regions and other federal agencies to develop creative, cost-effective solutions to environmental challenges at Federal Facility Superfund Sites. When prioritizing properties at federal facilities, other federal agencies serving as the lead for these facilities should discuss prioritizing reassessment and potential response actions with its cleanup regulators (e.g., EPA and the state at NPL Sites or Sites with Superfund Alternative Approach Agreements).

[8] See Use of Early Actions at Superfund National Priorities List Sites and Sites with Superfund Alternative Approach Agreements, August 23, 2019.

to take appropriate and timely response actions under available CERCLA or RCRA Corrective Action authorities at sites where the release of lead poses an imminent and substantial danger to public health.

Integration of Removal and Remedial Authorities at Residential Lead Sites

It is important to consider the statutory and regulatory differences between removal actions and remedial actions, as well as each authority's limitation. When CERCLA was enacted, the general intent was for the program to use emergency or time-critical removal authority to address the most immediate threats, to consider the use of non-time critical removal authority when a planning period of at least six months exists before on-site activities must be initiated, and to use remedial authority for the less immediate threats. Absent time sensitivity, remedial authority generally would be used to address complex site problems that will likely require a costly, complicated response. It is important to carefully consider the specifics of each site and to clearly document the basis for determining the appropriate authority given site circumstances. Emergency and time-critical removal authorities should continue to be used in alignment with agency statutes, regulations, policy, and guidance to address the most immediate public health and environmental threats.

Collaboration at Superfund Residential Lead Sites

Multiple sources of lead contamination could be present at Superfund sites where children are at risk. The Superfund program promotes collaboration to provide a more holistic approach to reducing lead exposures at residential lead Superfund sites. Many federal, local, state, and tribal agencies have diverse legal authorities to address sources of lead exposure in communities; therefore, EPA Regions should collaborate with these entities as part of an overall site management strategy to prevent and reduce lead exposures in communities.[9]

Developing PRGs and Cleanup Levels for Residential Lead Sites

OLEM recommends using the most current version of the IEUBK to assess risk from exposure or potential exposure to soil lead contamination.[10] In the absence of more stringent regulations and standards constituting applicable, or relevant and appropriate requirements (ARARs), OLEM recommends that regions should use the most current version of the IEUBK with 5 µg/dL as the 95th percentile target blood lead level and site-specific environmental data (e.g., lead concentrations in various media and bioavailability) to develop PRGs[11] and cleanup levels for residential land use. If an

[9] The Superfund program conducted the Superfund Lead Collaboration Pilot to gather best practices for enhancing collaboration when multiple sources of lead are identified in communities near Superfund residential lead sites. OLEM will recommend these best practices where appropriate.

[10] Risk assessment questions can be directed to the site's risk assessor or the Technical Review Workgroup for Metals and Asbestos (TRW) Lead Committee. See https://www.epa.gov/superfund/lead-superfund-sites-risk-assessment.

[11] See 40 C.F.R. § 300.430(e)(2)(i) ("Initially, preliminary remediation goals are developed based on readily available information, such as chemical-specific ARARs [applicable or relevant and appropriate requirements] or other reliable information…. Remediation goals [cleanup levels] shall establish acceptable exposure levels that are protective of human health and the environment and shall be developed by considering the following: (A) Applicable or relevant and appropriate requirements under federal environmental or state environmental or facility siting laws, if available."). See USEPA, 1997.

additional source of lead (e.g., lead water service lines, lead-based paint, non-attainment areas where the lead concentrations exceed NAAQS) is identified, OLEM recommends 3.5 µg/dL as the 95th percentile target blood lead level. This adjustment considers increased risk to children living in communities with multiple sources of lead contamination. EPA regions should adjust PRGs and cleanup levels to account for uncertainty, technical limitations (i.e., detection/quantification limits),[12] and site-specific soil lead background.

Consistent with the Role of Background in the CERCLA Cleanup Program, cleanup levels should not be set at values below natural or anthropogenic background. When the IEUBK-derived cleanup level is lower than site-specific background, the cleanup level should be set at background. EPA regions should consult the 2002 Guidance for Comparing Background and Chemical Concentrations in Soil for CERCLA Sites when establishing site-specific soil lead background. In addition to the use of statistical tests, an important component of defining background concentrations is the choice of appropriate background samples, which should include consideration of the conceptual site model, natural geological lead sources for the locality, and historical/current anthropogenic activities unrelated to site releases of lead. Careful choice of residential soil samples representing discrete exposure units is also important (e.g., segregating yard samples from the house drip zone, which often has elevated lead concentrations resulting from exterior paint debris). Additional information is contained in Frequently Asked Questions About the Development and Use of Background Concentrations at Superfund Sites: Part One, General Concepts.

Relationship to TSCA §403 Hazard Standards

Residential soil lead cleanups under the Superfund, RCRA Corrective Action and Toxic Substances Control Act (TSCA) programs seek to protect the health of the most vulnerable populations (children). The studies that take place at CERCLA or RCRA Corrective Action sites involve multiple hazardous substances with potentially numerous sources of contamination and multiple pathways of exposure that require cleanup levels be developed with site-specific information. In contrast, the TSCA §403 hazard standards for bare residential soil only apply to pre-1978 target housing and certain child-occupied facilities. These hazard standards are minimum national standards that apply to lead-based paint activities (i.e., inspections, lead-hazard screens, risk assessments and abatements) to help prioritize the cleanup of residential and child-occupied facilities affected by lead based paint.

Applicability to Superfund Site Assessment and Listing

RSLs and RMLs are not used in the Hazard Ranking System (HRS) scoring calculations.[13] Sites not eligible for the NPL are assigned a no further remedial action planned (NFRAP) decision. A change in RSLs or RMLs itself will not affect HRS scoring at sites with prior NFRAP decisions or result in additional NPL sites from the NFRAP universe. EPA can reassess a NFRAP site for potential NPL eligibility if

[12] See NCP 40 CFR 300.430(e)(2)(i).

[13] The Superfund site assessment program determines if a site is eligible for placement on the NPL primarily based on application of criteria contained in the Hazard Ranking System (HRS) (40 CFR Part 300 – Appendix A- The Hazard Ranking System). The HRS is a scoring system that uses information from initial, limited investigations to assess the relative threat posed by sites for NPL listing.

additional information arises and generally relies on states and tribes to inform EPA of the need to reassess a NFRAP site for potential response action.

The EPA site assessment program also considers whether involvement by the Superfund removal program is needed at any point during the site assessment process. EPA regions should be aware of this revised guidance on RMLs when reviewing lead sampling results associated with site assessments and should consult with the Superfund removal program as appropriate.

CONCLUSION

Reducing exposure to lead can improve communities' health and wellbeing. EPA residential soil lead cleanups —combined with the education and action of individuals and communities—have proven to be an effective part of an overall strategy for reducing blood-lead levels in children. With this guidance, EPA is updating its approach for reducing lead exposure in a manner consistent with the best available science.

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