Draft Assessment Plan
To Support the
Lead Renovation, Repair, and Painting Rule

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Introduction

The U.S. Environmental Protection Agency (EPA) has proposed new requirements to reduce exposure to lead hazards created by renovation, repair, and painting activities that disturb lead-based paint. The Federal Register Notice for the Lead Renovation, Repair, and Painting (LRRP) proposed rule is available at: http://edocket.access.gpo.gov/2006/06-71.htm. This action supports the attainment of the Federal government's goal of eliminating childhood lead poisoning by 2010. The proposal would establish requirements for training renovators and dust sampling technicians; certifying renovators, dust sampling technicians, and renovation firms; accrediting providers of renovation and dust sampling technician training; and for renovation work practices. These requirements would apply in "target housing," defined in section 401 of the Toxic Substances Control Act (TSCA) as any housing constructed before 1978, except housing for the elderly or persons with disabilities (unless any child under age 6 resides or is expected to reside in such housing) or any 0-bedroom dwelling. Initially the rule would apply to all renovations for compensation performed in target housing where a child with an increased blood lead level resides, rental target housing built before 1960 and owner-occupied target housing built before 1960, unless, with respect to owner-occupied target housing, the person performing the renovation obtains a statement signed by the owner-occupant that the renovation will occur in the owner's residence and that no child under age 6 resides there. EPA proposed to phase in the applicability of this proposal to all rental target housing and owner-occupied target housing built in the years 1960 through 1977 where a child under age 6 resides.

The EPA is presently developing the final LRRP rule. In support of this rule, EPA's Office of Pollution Prevention and Toxics (OPPT) is developing an assessment of the effect of lead exposure following specific RRP activities on the neurocognitive function in children (as measured by IQ). This assessment will also include RRP activities conducted in child-occupied facilities (COF).[1] The purpose of this draft assessment plan is to outline the scope, approaches, and methods being proposed for this assessment. This proposed assessment plan is intended to facilitate consultation with the CASAC for the purpose of obtaining advice on the overall scope, approaches, and key issues in advance of the completion of such analyses and presentation of results in the first draft of the assessment. Subsequent to CASAC review, the proposed assessment plan may be revised by EPA to reflect EPA's understanding of CASAC comment.

Scope of the Assessment

The purpose of this assessment is to characterize the effects of lead exposure following specific RRP activities on the neurocognitive function in children (as measured by IQ). The EPA recently released the final Air Quality Criteria Document (AQCD) for lead (US EPA, 2006) that provides an extensive analysis of the health effects associated with lead exposure. The AQCD is used as the source for the hazard assessment in the current assessment. The exposure assessment focuses on dust lead levels created by specific RRP activities such as door or window replacements, or paint removal by scraping, burning or sanding. The assessment will include an

[1] COFs are defined (see 40 CFR 745.223) as a building, or a portion of a building, constructed prior to 1978, visited regularly by the same child, under age 6, on at least two different days within any week, provided that each day's visit lasts at least 6 hours and the combined weekly visit lasts at least 6 hours, and the combined annual visits last at least 60 hours. Examples of COFs are day-care centers, preschools, and kindergarten classrooms.

analysis of dust lead levels created by specific RRP activities with and without the requirements of the LRRP rule. For each RRP activity, a distribution of blood lead levels will be estimated for children under age 6. Finally, for each of the specific RRP activities, the assessment will characterize the distribution of IQ loss due to the resultant lead exposure. It is important to note that the assessment is not intended to provide a characterization of IQ loss on a population basis. It is only intended to provide estimations of IQ loss associated with specific RRP activities. This information will then provide the basis for the subsequent economic analysis for the final LRRP rule.

Uncertainty and variability analyses will be undertaken as the assessment is developed. For example, analyses of exposure approaches will be presented in the exposure assessment, analyses of the blood-lead models will be presented with the blood lead estimation, and analyses of IQ models will be presented in the characterization of changes in children's IQ.

Hazard Identification

A detailed analysis of the health hazards associated with lead exposure is presented in the Air Quality Criteria Document for Lead (EPA, 2006), and has been extensively peer-reviewed. This assessment will utilize the AQCD, and will focus only on neurocognitive effects in children. As described in the AQCD (EPA, 2006), neurocognitive effects in children are of particular concern due to the levels at which they occur and the potential for lifelong impact. Neurocognitive effects have been reported with remarkable consistency across numerous studies of various study designs, populations studied, and developmental assessment protocols, even following adjustment for many confounding factors. Consistently, studies have demonstrated dose-response relationships. Children are particularly at risk due to sources of exposure, mode of entry, rate of absorption and retention, and partitioning of lead in soft and hard tissues. The neurocognitive effects reported in children appear to persist into adolescence and young adulthood in the absence of marked reductions in environmental exposure to lead. In view of these considerations, the effect of lead exposure on neurocognitive function in children (as measured by IQ) has been selected as the endpoint for this assessment.

Exposure Assessment

The *Environmental Field Sampling Study* (EFSS) and the *Characterization of Dust Lead Levels After Renovation, Repair, and Painting* (OPPT Dust Study) are the current and planned, respectively, sources of information for the exposure assessment of lead. Another potential source is the *Lead-Safe Work Practices Survey Project Report* recently submitted by the National Association of Home Builders (NAHB).

The overall purpose of the EFSS was to assess lead disturbance and exposure associated with various types of renovation and remodeling activities by measuring lead in air and dust before, during, and after the conduct of targeted activities within housing units with confirmed lead-based paint (EPA 1997). The EFSS was split into two primary components: one in which real world RRP jobs, such as carpet removal and window replacement, were monitored; and one involving a controlled study in which various RRP activities such as sawing, drilling, demolition, sanding, and duct removal were monitored on surfaces containing lead-based paint. The controlled study also investigated the degree to which settled dust-lead loadings could be reduced using either broom or standard vacuum cleanup on smooth cleanable surfaces. In total, 31 different workers participated in this study, with the real-world RRP jobs including workers from the window and carpet removal/replacement industry, and with the controlled study including certified abatement contractors. The results of the EFSS demonstrated that significant lead loadings were generated by most of the different RRP activities pursued.

The OPPT Dust Study is currently in progress, and is anticipated to be completed in January, 2007. The OPPT Dust Study is investigating the comparative impact on dust lead levels from use of the lead-safe work practices EPA has proposed and from baseline activities. The study is also investigating the effectiveness of different components of the lead-safe work practices EPA has proposed. There is an internal job component and an external job component. For interior jobs, settled dust wipe samples and air monitoring samples will be taken for each job, each cleaning step, and each cleaning verification step. For exterior jobs, dust wipe samples will be collected.

The NAHB submitted the *Lead-Safe Work Practices Survey Project Report* in November 2006. Its objective was to measure the lead dust levels generated during typical renovation/remodeling (the *Report's* "R&R" is the equivalent of "RRP") activities to determine if routine RRP activities increase lead dust levels in the work area and environs. In this project, air and surface wipe samples were collected during 60 RRP activities performed by local professional RRP contractors at five residential properties.

The first draft of the exposure assessment includes 1) exposure scenarios based on existing data (without the OPPT dust study) and 2) exposure scenarios based on the OPPT dust study (to be completed in full in the second draft of the exposure assessment). The RRP activities included in the first draft of the exposure assessment are: renovating kitchen; three cutouts; replacing windows; replacing exterior doors; scraping lead-based paint (LBP), interior flat component; scraping LBP, interior door; replacing fascia boards; exterior LBP removal.

The specific exposure scenarios for the second draft of the exposure assessment are yet to be determined, but scenarios that were used for the proposed LRRP rule were based on the EFSS data and other existing data. These included:

Kitchen
Remodeled kitchen

Bathroom
Remodeled bathroom

Additions
Added Bathroom onto home
Added Kitchen onto home
Added Bedroom onto home
Added other inside room onto home
Bedroom created through structural changes
Other room created through structural changes
Bathroom created through structural changes

Non-Room-Specific Wall/Ceiling
Added/replaced internal water pipes in home
Added/replaced electrical wiring, fuse boxes, or breaker switches in home
Added/replaced plumbing fixtures in home
Installed paneling or ceiling tiles
Added/replaced central air conditioning
Added/replaced built-in heating equipment
Other major improvements or repairs
Added/replaced security system in home

Non-Room-Specific Window/Door
Added/replaced doors/windows to home

Interior Painting

Whole Exterior
Added/Replaced siding on home

Contained Exterior
Added attached garage onto home
Added porch onto home
Added deck onto home
Added carport onto home
Added/replaced shed, detached garage, or other building

Exterior Painting

Exposure scenarios will include background soil and dust exposure pathways, as well as exposures following various renovation, repair, and painting activities. Calculation of the amount of exposure will follow a review of relevant literature/documents that pertain to changes in lead loadings after abatement and renovation activities, though few abatement studies are likely to be relevant to the RRP exposure assessment. The exposure assessment will fully describe all assumptions, e.g., how dust/soil lead loadings were converted into lead concentrations. The results of the exposure assessment will be suitable for use as input to the blood lead models. If exposures change over time, (e.g., in the time following renovation, repair, and painting activities), the exposure assessment will reflect this change.

The first draft of the exposure assessment will be available in time for a CASAC consultation in early 2007. The first draft estimates exposures based on two methods for control of lead released during the selected RRP activity scenarios: baseline controls, and full rule implementation controls. Baseline control consists of basic sweep and vacuum cleaning, while full rule control requires the use of plastic sheeting to protect surfaces and prevent dust migration, and HEPA vacuum followed by wet wipe/mop cleaning.

The second draft of the exposure assessment will update the first draft of the exposure assessment to address comments received from the CASAC review and to include data from the OPPT Dust Study, the NAHB study, and other relevant data. The second draft of the exposure assessment will complete in full the exposure scenarios based on the dust study that were identified in the first draft of the exposure assessment.

Estimating Blood Lead

The assessment will estimate blood lead level metrics for the specific RRP activities with and without the requirements of the LRRP, and will, to the extent possible, include characterization of uncertainty in these estimates. Once exposure levels in the form of either modeled intake rates (e.g., for dietary items and indoor dust) or exposure concentrations (e.g., for ambient air) have been generated, the next step is to model blood lead levels. The concentration of lead in whole blood is the most commonly used measure, or biomarker, primarily because it is most convenient and easily measured, but also because blood lead tends to be a good indicator of recent exposures. Lead in long-term body stores (primarily bone) may also contribute to blood lead concentrations and to the risk of adverse effects. Thus, most approaches for estimating adverse effects take into account the biokinetics (i.e., uptake, deposition, mobilization, and excretion) of lead in the body. Empirical approaches bypass the explicit modeling of biokinetics and predict blood lead levels directly based on measures of lead exposure or intake.

Three models are being considered to estimate blood lead levels in children, the IEUBK model (EPA, 1994), the Leggett model (Leggett et al., 1993), and an empirical model (Lanphear et al., 1998). The IEUBK model (EPA 1994) is a well-evaluated and widely used EPA model for predicting blood lead levels in children when exposures are expected to exceed 3 months to a year. The Leggett et al. (1993) model, which is also a biokinetic model, can accommodate shorter term exposures. The important features of the IEUBK and Leggett models are highlighted in Table 1. Both models calculate time-averaged lead uptake (dose absorbed into blood) over specified time periods, and model the transfer of the absorbed dose among various biokinetic compartments. In the IEUBK, intake and uptake calculation modules for a range of exposure pathways are built-in, with default exposure factors and absorptions fractions already supplied. Multi-source and multi-pathway exposures are automatically combined to generate estimated lead uptake. The intake module for the Leggett model is less refined than that for the IEUBK; the user is required to supply estimates of total ingestion and inhalation pathway intake (administered dose), summed across all exposure sources and media, although the computer implementation has been adapted so that input is comparable to that for the IEUBK. Both the IEUBK and Leggett have uptake modules that include pathway-specific absorption fractions, as well as modules that simulate model respiratory tract deposition and ciliary transport of particulate to the gastrointestinal tract. The Leggett model’s treatment of both inhalation and ingestion pathway absorption is somewhat more complex than that in the IEUBK.

Table 1. Comparison of IEUBK and Leggett Model Characteristics

Biokinetic Model	Model Inputs	Multipathway Uptake Estimation	Model Outputs	Support for Probabilistic Estimates/Sensitivity Analyses
IEUBK	Age-specific (annual) air, water, dietary, soil/dust lead concentrations, age-specific inhalation and ingestion exposure factors	Multi-source and multi-pathway intake/uptake assessment integral to model	Age-, pathway-specific lead uptakes, age-specific individual blood lead levels (annual); age specific blood lead distributions	Lognormal approximation of blood lead distribution, batch processing, automated sensitivity analyses for individual variables
Leggett	Age-specific acute or chronic ingestion and inhalation lead intake, (daily) age-specific ingestion, inhalation absorption process parameters	Ingestion and inhalation exposures from different sources must be combined external to model; front-end module exists	Daily (or shorter) Concentrations, masses of lead in blood and other compartments, lead excretion, clearance for exposed individual	None, must be done external to model algorithm

As noted earlier, an empirical model (the Lanphear model) for estimating blood lead levels in children is also being considered. The Lanphear model (Lanphear et al., 1998) uses a regression-based approach for predicting blood lead levels on the basis of environmental concentrations and other variables. Application of the Lanphear model, if undertaken, will not be parallel to applying the IEUBK or Leggett models. This model is being considered as a complement to the biokinetic models, at the suggestion of the Science Advisory Board.

Regardless of the specific model(s) used, a distribution of blood lead levels will be estimated for children under age 6 years for each specific RRP activity.

IQ Changes in Children

This assessment will characterize IQ changes in children for each specific RRP activity with current cleanup conditions and those that would be in place following the LRRP rule. The outputs from the blood lead models described above will be profiles of blood lead levels across the ages of interest. The models will be summarized appropriate to the scenarios being considered. The model outputs will be converted to metrics that can serve as suitable inputs for the dose-response models. The dose-response models of Lanphear et al. (2005) and Canfield et al. (2003) studies will be used for the modeling of IQ. As discussed in the AQCD (EPA, 2006), these studies have high quality, good size, and have the potential for generalizability. In addition, they have been subjected to rigorous peer and other external review.

Non-linearity in the relationship between blood lead levels and IQ scores, suggestive of higher slopes at lower blood lead levels, has been identified. The form of the relationship is one feature that may be explored in model uncertainty analyses, as will adjustment for covariates and other model characteristics. Potential impacts of the most important covariates on change estimates for particular RRP activities may be assessed through sensitivity analyses.

Modeling of lead-related exposure and IQ is subject to a variety of sources of variability (e.g., residential location, type of renovation, dietary ingestion rates, lead uptake rates) as well as sources of uncertainty (e.g., different blood lead models, different blood lead/IQ functions). Because of data limitations and constraints, it is not feasible to develop confidence distributions for many of the sources of parameter and model uncertainty identified for this analysis. Therefore, rather than a comprehensive probabilistic uncertainty analysis, sensitivity analysis techniques will be used to examine the impact of sources of uncertainty on exposure and IQ results. Such techniques (entailing one-at-a-time variation) can be applied to examining the contributions of different parameters, different models, and different sources and renovation methods. Characterizing the impact of variability (e.g., of exposure magnitude, of exposure duration) can also be explored via such techniques; probabilistic simulation is an adjunct that can illuminate the impact of such intermediate steps as blood lead level derivation on the final calculations.

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