UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

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MEMORANDUM

SUBJECT: CASAC Consultation on the Draft Assessment in Support of the Lead Renovation, Repair, and Painting Rule

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TO: Fred Butterfield, Designated Federal Officer
Clean Air Scientific Advisory Committee
EPA Science Advisory Board Staff Office

Attached are the draft Assessment Plan, draft Hazard Assessment, and draft Exposure Assessment being developed to support the Lead Renovation, Repair, and Painting (LRRP) Rule prepared by the Environmental Protection Agency's (EPA) Office of Pollution Prevention and Toxics. In addition, two completed dust studies, and the study design of a third study which is underway, are also attached. The three dust studies are being evaluated for potential use in the exposure assessment. These documents are being made available to the CASAC Panel as attached electronic files. These documents are also available from the EPA website http://www.epa.gov/lead/pubs/casac.htm. These documents will be the focus of a consultation by the Clean Air Scientific Advisory Committee (CASAC) Lead Review Panel, scheduled for a public meeting to be held in Research Triangle Park (RTP), NC, on Monday, February 5, 2007. The Charge questions to be used to focus the discussion of the CASAC Panel are included below. We request that you forward the attached document(s), together with this memorandum to the CASAC Lead Panel to prepare for that review.

The draft Assessment Plan provides materials needed to address Questions 1 and 4; the draft

Hazard Assessment, plus the Air Quality Criteria Document provided by the Office of Air, includes materials to address Question 2; the draft Exposure Assessment, plus the two dust studies and the study design of a third dust study provide materials needed to address Questions 1, 3, 4, 5, and 6. A summary of the scope of the assessment is included below, followed by a list of issues for the CASAC consultation, and the corresponding charge questions.

Scope of the Assessment

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 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 6 years of age 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 Lead Renovation, Repair, and Painting (LRRP) rule for lead. In support of this rule, 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 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. This assessment will also include RRP activities conducted in child-occupied facilities (COF).[1]

[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.

Charge Questions

Issue 1. Draft Assessment Plan

OPPT has developed a draft Assessment Plan. This is intended to provide an overview of the approaches that will be used for the hazard assessment, exposure assessment, blood lead modeling, and determination of changes in children's IQ.

Question 1. Please comment on the reasonableness of the approach outlined in the draft Assessment Plan.

Issue 2. Draft Hazard Assessment

EPA recently finalized its Air Quality Criteria Document (AQCD) for Lead, which was extensively reviewed by the CASAC. This document provides an all-encompassing analysis of the current lead literature. In an effort not to duplicate efforts, OPPT has adopted portions of the AQCD for the hazard section of the risk assessment for the LRRP rule.

Question 2. Please comment on the transparency and completeness of the draft hazard assessment.

Issue 3. Environmental Monitoring Studies

There are two existing studies and one ongoing study which contain environmental monitoring data on dust levels in buildings during renovation, repair and painting activities. The three studies are described below.

Issue 3a. Environmental Field Sampling Study (EFSS)

The purpose of the EFSS (USEPA 1997) was to assess lead disturbance and exposure associated with various types of RRP activities by measuring lead in air and dust before, during, and after RRP activities in housing units with confirmed lead-based paint. The EFSS had two 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.

The EFSS demonstrated that significant lead loadings were generated by most of the RRP activities. Some important limitations of the EFSS include: most of the work activities were simulated RRP activities, not "real world" RRP activities; the housing units chosen for the study were generally vacant units in poor condition with high paint-lead levels.

Question 3a. Please comment on the usefulness of this study in the context of this particular exposure assessment.

Issue 3b. Lead-Safe Work Practices Survey Project Report. November 9, 2006.

The Lead-Safe Work Practices Survey was conducted by the National Association of Home Builders to measure the amount of lead dust generated during typical RRP activities and assess whether routine RRP activities increase lead dust levels in the work area and property. Both air samples and surface dust wipe samples were collected during RRP activities conducted in five separate residential properties included in the study. The Study's stated objectives were to answer the following three questions: 1) Do typical renovation and remodeling activities create lead hazards? 2) When applying EPA's lead-safe work practices to a set of typical renovation and remodeling activities, are surface lead hazards (>40 ug/ft^2 on floors, >250 ug/ft^2 on window sills), or airborne hazards (>50 ug/m^3 in the air) created? 3) Do modified lead-safe work practices reduce lead exposures below the PEL?

Some potential limitations of the NAHB survey include: 1) the properties in the study were old (approximate construction dates were between 1800 and 1950), and it is unclear to what extent the site preparation included cleaning; 2) the report is unclear about the difference between EPA/HUD Lead Safety Work Practices (LSWP) and Modified LSWP; we were unable to determine whether either of these was intended to be similar to the provisions of the RRP proposed rule; and 3) dust levels were only measured before RRP activities were conducted and after clean-up following the RRP activities. No measurements post RRP activity and pre-cleaning were taken.

Question 3b. Please comment on the usefulness of this study in the context of this particular exposure assessment.

Issue 3c. Characterization of Dust Lead Levels After Renovation, Repair, and Painting (Ongoing.)

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 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. Specifically, for interior jobs, the study is investigating 1) using plastic coverings during RRP work and 2) using a more extensive clean up routine than that which is typically conducted by RRP workers. The four phases of the interior jobs to be completed are 1) use of plastic coverings and cleaning per the proposed rule after work completion, 2) use of plastic coverings and baseline cleaning after work completion, 3) no plastic coverings and cleaning per the proposed rule after work completion, and 4) no plastic coverings and baseline cleaning after work completion. For exterior jobs, a single phase will be used with plastic sheeting, and collection trays will be placed above and below the plastic to assess the differential amounts of lead. 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 from collection trays placed underneath the rule plastic, on top of the rule plastic, and near the rule plastic.

Analysis of sample results will assess the impact of the proposed techniques for reducing lead levels of the dust left behind from RRP activities.

Question 3c. Please comment on the usefulness of this study in the context of this particular exposure assessment.

Issue 4. **General Approach for the Sensitivity Analysis in the Exposure Assessment**

As described in the draft exposure assessment, sensitivity analysis techniques are being used to examine the impact of sources of uncertainty on exposures. Assumptions have had to be made for a variety of parameters to apply these techniques. The indoor parameters include 1) post-activity cleanup efficiency, 2) percent house workspace, and 3) lead loading. The outdoor parameters include 1) background soil concentration, 2) lead loading, 3) percent of house perimeter involved in project, and 4) soil depth. At the moment, the sensitivity analyses suggest that cleaning efficiency is one of the most important variables in determining dust levels over time (see Issue 5 below). In addition, lead loading and percent of space involved (indoors and out) seem to be important. Most of the analyses conducted to date have assumed that cleaning efficiency is constant over time. However, an exploration of varied cleaning efficiency in kitchen remodeling indicates that the duration of elevated exposure may vary sufficiently to have an impact on the choice of the appropriate pharmacokinetic model as discussed in Issue 7.

The sensitivity of the estimated exposures to assumptions about different scenario conditions can reflect the differential scales in which those conditions are measured. Many of the assumptions are entered as percents, which have a limited range of values; some are lead concentrations, which are orders of magnitude greater. A sensitivity score is based on absolute units. OPPT has also chosen to express sensitivity by an "elasticity" measure, which normalizes the inputs.

Question 4a. Please comment on whether the appropriate variables have been evaluated in the sensitivity analysis. Please comment on whether the assumptions for other variables should be explored.

Question 4b. Please comment on OPPT's plan to use both elasticity and sensitivity scores to evaluate the impact of changes in assumptions to likely exposures.

Issue 5. Cleaning Efficiency Considerations in the Exposure Assessment.

Review of the cleaning efficiency literature suggests that the most relevant factors for cleaning efficiency differences are the following: 1) floor type, e.g., hard surface and carpet; 2a) for the hard surfaces, the dust level, which varies by whether the dust has been added recently or has settled (i.e., been "ground-in"), and by the effect of cleaning iterations; 2b) for carpet, the cleaning iteration after RRP activity.

Generally, hard surfaces with recently added dust have higher baseline levels that correspond to higher cleaning efficiencies in the initial cleaning efforts. Efficiency results for hard surface floors with settled dust varied considerably. Different cleaning methods, floor types and floor conditions may be responsible for these differences. Initial effort carpet cleaning efficiency with recently added dust was quite variable, whereas settled dust initial efficiencies were similar.

Typical RRP activity may add lead dust to previously settled lead dust. This was the case for the EFSS 1997 hard surface study, which clearly shows differences in cleaning efficiency due to the baseline dust levels. For hard surface cleaning, we propose that cleaning efficiency values from the EFSS baseline-dust ranges be matched to the results of the Dust Study for the four test Phases, e.g., a Phase with results near 1000 $\mu g/ft^2$ would use cleaning efficiencies in the 25% to

68% range.

Neither different baseline levels nor added versus settled dust appear relevant for carpet cleaning efficiency. However, there are several studies with sequential cleaning results. Perhaps these could be combined and used to plot a function that could then extrapolate beyond the maximum of ten cleanings presented in the data.

Limited evidence suggests that lead flooring dust loading can increase over longer time periods because there will be a near-field reservoir that will contribute to lead dust gain, especially from carpet.

Question 5. Please comment on the proposed approach for establishing cleaning efficiency in the exposure assessment.

Issue 6. Conversion of Dust Loadings to Dust Concentrations

Appendix C of the draft exposure assessment describes the approach for converting lead loadings to lead concentrations. The relationship between house dust loading and lead concentration for the draft exposure assessment report comes from the ICF (2006) analysis of a data set developed as part of HUD's 1997 National Survey. The ICF (2006) analysis was used because it appears to use the largest, most nationally representative source completed to date of both house dust loading and concentration data taken simultaneously from the same households.

The regression analysis relating lead loading and lead dust concentrations in the exposure assessment differs from the Battelle (2005) regression analysis cited in USEPA (2006a). It is important to note that the ICF (2006) analysis was not complete prior to the development of the USEPA (2006a) report.

Question 6. Please comment on the adequacy of the method used in the draft exposure assessment to convert dust loadings to dust concentrations. Are there other methods that should be explored?

Issue 7. Blood Lead Modeling

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. 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. 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.

The current draft exposure assessment indicates that exposures to lead following renovation

activities are variable over time, and mostly occur for a time period less than one year. OPPT plans to use the Leggett model for these exposures of short duration and the IEUBK model for exposures greater than one year.

Question 7a. Please comment on whether the empirical model should be considered.

Question 7b. The draft exposure assessment indicates that exposures decline through time until background levels are reached. Please comment on the adequacy of using a mean (weighted or otherwise) or some other summary input of exposure to the Leggett or IEUBK models.

Question 7c. The IEUBK model yields activity-specific distributions of individual values at different (geometric) mean levels of blood lead. Please comment on how the level-specific upper tails and the variability can be determined when using the Leggett model.

Issue 8. Characterization of Changes in Children's IQ

The assessment will characterize IQ changes in children for the specific RRP activities with current cleanup conditions and those that would be in place following the rule. For each RRP activity, a distribution of IQ loss will be estimated, based on a log-linear model presented in the pooled analysis by Lanphear, et al. (2005). It is possible that the change in blood lead concentrations associated with each of the renovation activities will be small.

Question 8. If the analyses do indicate that the changes in blood lead concentrations are small, please comment on how to extrapolate the data from the Lanphear study at very low doses.