



May 31, 2006

**MEMORANDUM**

**SUBJECT:** CASAC Consultation on the Draft Analysis Plan for Human Health and Ecological Risk Assessment for the Review of the Lead National Ambient Air Quality Standards

**FROM:** Karen M. Martin, Group Leader  
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**TO:** Fred Butterfield  
Designated Federal Officer  
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Attached is the *Analysis Plan for Human Health and Ecological Risk Assessment for the Review of the Lead National Ambient Air Quality Standards* (the analysis plan) prepared by the Environmental Protection Agency's (EPA) Office of Air Quality Planning and Standards (OAQPS) staff as part of EPA's current review of the national ambient air quality standards (NAAQS) for lead. This analysis plan will be the focus of a consultation by the Clean Air Scientific Advisory Committee (CASAC) Lead NAAQS Review Panel (the CASAC Lead Panel), scheduled for a public meeting to be held in Durham, NC, on June 28-29, 2006. I am requesting that you forward the attached document together with this memorandum to the CASAC Lead Panel to prepare for that review.

The purpose of the analysis plan is to outline the scope, approaches, and methods that staff is planning to use for the human health and ecological risk assessments to be conducted as part of the review of the lead NAAQS. This document also serves to highlight key issues in the estimation of human health and ecological exposure and risks posed by lead. This plan is intended to facilitate consultation with the CASAC Lead Panel, as well as public review, 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.

This analysis plan draws from the current draft of the Air Quality Criteria Document (AQCD) for Lead; the health and ecological assessments will be based on information in the final AQCD for Lead to be completed later this year. With regard to certain aspects of the human exposure and health risk assessment, this plan recognizes several possible options for analysis. The human exposure and health risk assessment will be conducted in two stages, with the first or "pilot" phase having a primary focus on testing and refining the assessment approaches. The first draft of the human exposure and health risk assessment report will

document the results of the pilot phase and plans for completion of the second phase or “full-scale” assessment. Panel members will have an opportunity to comment on the approaches implemented in the pilot phase and on plans for the full-scale assessment in conjunction with their review of the first draft assessment report early next year. The full-scale assessment will be presented in the second draft of the human exposure and health risk assessment report, which we intend to complete in mid-2007.

The ecological risk assessment will also be conducted in two phases (tiers). In the tier 1 assessment, concentrations of lead in environmental media will be compared to screening values to determine the potential for adverse effects under the current standard. The tier 2 assessment will further refine exposure values for susceptible species, as identified in the tier 1 assessment, and compare these results to known concentration effects as well as address alternative NAAQS scenarios. The first draft of the ecological exposure and risk assessment report will describe the tier 1 assessment and plans for the tier 2 assessment. In parallel with the human health assessment, Panel members will have an opportunity to comment on the approaches implemented in the tier 1 assessment and on plans for the tier 2 assessment in conjunction with their review of that draft assessment report early next year. The tier 2 ecological risk assessment will be presented in the second draft of the ecological exposure and risk assessment report.

### **Charge to the CASAC Lead Panel**

Within each of the main sections of the analysis plan, we ask the CASAC Lead Panel members to focus their review on the following questions:

#### **Human Exposure and Health Risk Assessment:**

Do the Panel members have any general comments on the approach presented in the analysis plan for completing the human health exposure and risk assessment?

#### ***Exposure Assessment (estimating media concentrations)***

1. The draft plan describes the use of ambient monitoring data combined with a range of modeling tools to characterize lead concentrations in ambient air across modeled study areas under specific NAAQS scenarios (e.g., current conditions, current NAAQS, alternate NAAQS).
  - a. What are the Panel members’ views on the general approach of using monitor data when sufficient, augmented by air quality modeling as needed in particular study areas to characterize air quality?
  - b. What are the Panel members’ views regarding the use of source-apportionment to estimate contribution to ambient concentrations by particular emissions categories (e.g., reentrainment vs. ongoing point-source emissions)?
  - c. Do the Panel members have any comments regarding the options presented in the plan for estimating re-emission of historically deposited lead (reentrainment)?
2. The draft plan describes the use of available soil measurements (either site-specific or obtained from a similar surrogate site), combined with a range of approaches, including

modeling tools to characterize soil lead concentrations in modeled study areas associated with specific NAAQS scenarios (e.g., current conditions, attaining the current NAAQS, alternate NAAQS).

- a. What are the Panel members' views on the general approach and tools being considered for use in the assessment?
- b. Do the Panel members have any comments regarding the use of a simple soil reservoir model to predict soil concentrations of lead associated with different air quality scenarios?
- c. Furthermore, what are the Panel members' views regarding the alternative use in the full-scale assessment of a more sophisticated dynamic, mass-conserving fate and transport model such as TRIM.FaTE to predict soil concentrations for different air quality scenarios?
- d. Do the Panel members have any comments on the magnitude of the simulation period duration required to identify changes in soil given changes in ambient air concentrations and related deposition?

3. The draft plan describes the use of a similar approach to that used in the IEUBK blood lead model for predicting indoor dust concentrations (i.e., depending on contributions from outdoor soil lead, outdoor ambient air lead, and other sources).

- a. Do the Panel members generally agree with using this approach?
- b. Furthermore, the staff is planning to consult the literature (e.g., as cited in the Lead AQCD) to obtain updated outdoor *soil-to-indoor dust* and *ambient air-to-indoor dust* factors. Do the Panel members have any comments regarding estimates for the outdoor *soil-to-indoor dust* and *ambient air-to-indoor dust* factors?

4. The draft plan describes various sources of information for characterizing background lead exposures (e.g., diet, drinking water, lead paint). Do the panel members have any recommendations for additional or preferred sources of information?

### ***Exposure Assessment (blood lead modeling)***

1. The draft plan describes the potential use of multiple models for estimating child and adult blood lead levels.

- a. What are the Panel members' views regarding the suite of blood lead models being considered for children, and their potential combined use to inform model uncertainty? Do the Panel members generally agree with the preference the plan assigns to the IEUBK model for children's blood level estimates?
- b. Similarly, for adults, what are the Panel members' views regarding the suite of models being considered for estimating adult blood lead levels?
- c. What are the Panel members' views on the staff's plans for deriving a geometric standard deviation for blood lead in adults and children which reflects the latest information on inter-individual variability in exposure factors and biokinetics?
- d. What are the Panel members' views regarding the option of employing Monte Carlo methods to develop exposures for a set of simulated individuals reflecting variability in exposure factors that are then used to generate a distribution of blood lead levels for that simulated population via a blood lead model?

### ***Effects Assessment and Risk Assessment***

1. Do the Panel members generally agree with the three main endpoints being considered for quantitative risk assessment: IQ (children) and blood pressure and renal effects (both for adults)?
2. In considering the assessment of risks to children:
  - a. What are the Panel members' views on the set of studies the staff is considering for use in estimating childhood IQ decrement associated with blood lead levels, and the preference assigned to Lanphear et al. (2005)?
  - b. Furthermore, do Panel members have any comments or advice regarding the types of models (linear, non-linear) to be used to reflect individual study findings on IQ loss for children at exposure levels below 10 µg/dL (concurrent measurement)?
  - c. Regarding the specific blood lead level metrics to use in modeling child IQ, do the Panel members have any recommendations regarding the metrics (e.g., lifetime-averaged, concurrent) being considered for use with specific studies?
3. In considering the assessment of blood pressure effects in adults:
  - a. What are the Panel members' views on the set of studies the staff is considering for use in estimating blood pressure effects in adults, and the preference assigned to Nawrot et al. (2002)?
  - b. Furthermore, do the Panel members have comments or advice regarding the nature of the model (e.g., linear, log-linear) which should be used for this endpoint?
4. In considering assessment of renal effects in adults, what are the Panel members' views on the set of studies the staff is considering for use in modeling this endpoint?
5. What are the Panel members' views on the use of the same blood level metric (e.g., average blood lead during adult exposure period) for both adult endpoints?
6. Do Panel members generally agree with the various risk measures that staff is considering?

### ***Uncertainty and Variability Assessment***

The analysis plan describes the use of an integrated approach for addressing uncertainty and variability associated with exposure and risk estimates generated in this assessment. This integrated approach combines sensitivity analysis techniques (for addressing model and parameter uncertainty) and probabilistic techniques (for addressing exposure-related variability). The integrated approach will use a modeling options "tree" to represent the different combinations of modeling options under consideration with the maximum, minimum and central-tendency branches being identified and subject to more intensive analysis including consideration for variability (through probabilistic simulation) and parameter uncertainty (through sensitivity analysis techniques).

- a. What are the Panel member's views concerning this approach of combining sensitivity analysis methods (for examining uncertainty) with probabilistic simulation (to consider variability)?
- b. Specifically, what are the Panel members' views regarding the approach of identifying maximum, minimum and central-tendency modeling branches for focused analysis regarding uncertainty and variability?
- c. Do the Panel members have any recommendations regarding specific sources of uncertainty and/or variability that should be included in this examination of uncertainty and variability?

### **Ecological Risk Assessment**

Do the Panel members have any general comments on the approach presented in the analysis plan for conducting the ecological risk assessment? Do Panel members think that uncertainty and variability are adequately characterized? Are there additional ways to characterize uncertainty and variability that should be considered as part of this assessment?

### ***Data Sources for Determining Media Concentrations***

The analysis plan describes the variety of data sources available for determining current levels of lead in air, soil, freshwater, and sediment.

- a. Are there other datasets (air, soil, water, sediment) not mentioned that should be considered for the analysis (either national or region in scale)?
- b. Does the age of the USGS soil data present a significant concern to the analysis?
- c. What are the Panel members' opinions on using regional or national-scale data to estimate media concentrations at study locations without site-specific data?
- d. Do the Panel members feel that sediment data as described in the plan are useful for this analysis, given that it is not available for all regions of the country and is not standardized?

### ***Case Study Selection***

The draft plan describes the criteria and process by which case study locations will be selected.

- a. What do the Panel members feel are the most important ecological criteria for establishing case study locations?
- b. What low-level exposure scenarios might be important to consider if additional case study locations are chosen for tier 2?

### ***TRIM.FaTE Model***

The draft plan discusses the use of the TRIM.FaTE model for estimating future media concentrations.

- a. Do the Panel members feel that either MPE or TRIM.FaTE is more appropriate for determining future media concentrations?

- b. In the Panel members' opinions, is ten years an appropriate time step for future media concentrations for the model under the current ambient air scenario?

### ***Ecotoxicity Screening Values***

The analysis plan discusses ecotoxicity screening values for soil, freshwater, and sediment and their uses in this assessment.

- a. Do the Panel members feel this is an appropriate use for screening values given the larger scale application?
- b. Which option regarding bird Eco-SSL values do the Panel members feel is most appropriate?
- c. Do Panel members feel that the current AWQC are useful given that they do not currently factor in pH but are based on water hardness?
- d. Given the current state of development of the sediment criteria, is it appropriate to use them in this analysis?

### ***Modeling of Intake Rate or Body/Tissue Concentration***

1. Do the Panel members have any additional input into modeling intake rates for susceptible receptors?
2. Do the Panel members feel that it is more appropriate to use NOAELs or LOAELs for comparing concentration effects?