



January 8, 2013

**MEMORANDUM**

**SUBJECT:** CASAC Review of the *Draft Policy Assessment for the Review of the Lead National Ambient Air Quality Standards*

**FROM:** Lydia Wegman, Director  
Health and Environmental Impacts Division  
Office of Air Quality Planning and Standards

**TO:** Aaron Yeow  
Designated Federal Officer  
Clean Air Scientific Advisory Committee  
EPA Science Advisory Board Staff Office

This memorandum conveys the draft document, *Policy Assessment for the Review of the Lead National Ambient Air Quality Standards, External Review Draft*, prepared by the Environmental Protection Agency's (EPA) Office of Air Quality Planning and Standards (OAQPS) staff as part of EPA's ongoing review of the national ambient air quality standards (NAAQS) for Lead (Pb). This draft Policy Assessment (PA) document will be the focus of a review by the Clean Air Scientific Advisory Committee (CASAC) Lead Review Panel (the Panel), scheduled for a public meeting to be held in Cary, NC on February 5-6, 2013. Charge questions for the Panel to consider in its review of this draft PA are attached to this memorandum. I am requesting that you forward this memorandum and the accompanying electronic file containing the draft PA to the Panel members to prepare for that review.

This draft PA presents analyses and preliminary staff conclusions regarding the policy implications of the key scientific and technical information that informs this review of the current primary (health-based) and secondary (welfare-based) Pb standards. When final, the PA is intended to help "bridge the gap" between the relevant scientific and technical information, presented in the Integrated Science Assessment (ISA) and Risk/Exposure Assessments (REAs) considered in this review, and the judgments required of the EPA Administrator in determining whether it is appropriate to retain or revise the Pb NAAQS.

This draft document draws upon information presented in the third draft *Integrated Science Assessment for Lead* (US EPA, 2012), which will also be reviewed by the Panel at the February 5-6, 2013 public meeting. It also draws upon information from the human exposure and health risk assessment (US EPA, 2007) and the screening ecological risk assessment from

the last Pb NAAQS review (ICF, 2006).<sup>1</sup> Based on analysis of this information in the draft PA, the preliminary staff conclusions are that it is appropriate to consider retaining the current primary and secondary standards, without revision. Accordingly, this draft PA does not identify potential alternative standards for consideration.

In light of the preliminary staff conclusions reached in this draft PA, we do not envision preparing a second draft of this document. Rather, we anticipate taking CASAC and public comments on this draft PA into consideration in preparing a final PA. We note that in NAAQS reviews in which the newly available information calls into question the adequacy of the current standard(s), a second draft PA is typically prepared to include staff consideration of potential alternative standards, generally drawing from analyses of alternative standards presented in a second draft REA. In this case, however, a new REA has not been developed and staff has preliminarily concluded that it is appropriate to consider retaining the current standard, without revision. Thus, there is no new substantive information that we would intend to add that would provide a basis for preparing a second draft PA in this review.

Our current schedule anticipates completion of a final PA this summer. Subsequently, the EPA's review of the Pb NAAQS will conclude with Agency rulemaking. Our current rulemaking schedule anticipates a proposed rule early in 2014, followed by a public comment period, with final rulemaking anticipated in late 2014.

We will send printed copies of the draft PA to members of the Panel. In addition, we request that you forward to the Panel the attached electronic file containing this document. This document will also be available on the EPA website:  
[http://www.epa.gov/ttn/naaqs/standards/pb/s\\_pb\\_index.html](http://www.epa.gov/ttn/naaqs/standards/pb/s_pb_index.html).

We look forward to discussing this draft PA with the Panel at our upcoming meeting. Should you have any questions regarding this draft document, please contact Dr. Deirdre Murphy (919-541-0729; email [murphy.deirdre@epa.gov](mailto:murphy.deirdre@epa.gov)).

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**Attachment:**

Charge to the CASAC Lead Review Panel for Review of the Draft Pb Policy Assessment

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<sup>1</sup> These documents are available at [http://www.epa.gov/ttn/naaqs/standards/pb/s\\_pb\\_2010\\_rea.html](http://www.epa.gov/ttn/naaqs/standards/pb/s_pb_2010_rea.html). Based on the analysis in the *Risk and Exposure Assessment Planning Document* (US EPA, 2011; [http://www.epa.gov/ttn/naaqs/standards/pb/s\\_pb\\_2010\\_pd.html](http://www.epa.gov/ttn/naaqs/standards/pb/s_pb_2010_pd.html)), which was the subject of a consultation with CASAC in spring 2011, staff concluded, with CASAC concurrence, that the information newly available in this review did not warrant development of new risk assessments.

## Attachment

### Charge to the CASAC Lead Review Panel for Review of the draft Pb Policy Assessment

The draft Policy Assessment (PA) includes six chapters following an executive summary. Charge questions for the Panel's consideration are presented below for each of these chapters. Chapters 1 and 2 provide general information relevant to review of both the primary and secondary standards. Chapters 3 and 4 provide information specific to review of the primary standard. Chapters 5 and 6 provide information specific to review of the secondary standard.

***Introduction (Chapter 1):*** This chapter provides context for the review, including the background of past reviews, as well as the scope for the current review. This includes discussion of fate and multimedia pathways of ambient air Pb and other nonair sources of Pb in the environment.

1. Does the Panel find the introductory and background material, including that pertaining to previous reviews of the Pb standard and the scope of the current review to be appropriately characterized and clearly communicated?

***Ambient Air Lead (Chapter 2):*** This chapter provides an overview of current information on air Pb emissions and monitoring data, consideration of the current air Pb monitoring requirements and an overview of current information on Pb in nonair media.

1. To what extent does the Panel agree that the most relevant information on emissions (section 2.1), air quality (section 2.2.2), and Pb concentrations in other media (section 2.3) is presented, and to what extent is the information presented appropriately characterized and clearly communicated?
2. With regard to information on ambient Pb monitoring (section 2.2.1), to what extent is this information appropriately characterized and clearly communicated?

***Health Effects and Exposure/Risk Information (Chapter 3):*** This chapter discusses key policy-relevant aspects of the health effects evidence and exposure/risk information.

1. To what extent does the information in sections 3.1 (Internal Disposition and Biomarkers of Exposure and Dose), 3.2 (Nature of Effects) and 3.3 (Public Health Implications and At-Risk Populations) capture and appropriately characterize the key aspects of the evidence assessed and integrated in the ISA?
2. To what extent is the newly available evidence on air-to-blood ratios appropriately characterized and considered in light of information previously available in past reviews?
3. To what extent is the newly available evidence on concentration-response functions for IQ decrements in young children appropriately characterized and considered in light of information previously available in past reviews?

4. With regard to the exposure and risk information, to what extent is the information drawn from the human exposure and health risk assessment in the last review sufficiently characterized and clearly communicated? To what extent is the information appropriately interpreted in light of the currently available information and for the purpose of assessing the adequacy of the now current standard?
5. Are the limitations and uncertainties in the exposure/risk information appropriately characterized and considered in our interpretation of the information in the context of this current review?

***Review of the Primary Standard for Lead (Chapter 4):*** This chapter describes the basis for the current primary standard and consideration of the current evidence and exposure/risk-based information with regard to reaching preliminary staff conclusions about the adequacy of the current standard.

1. In this chapter, staff applies the same evidence-based air-related IQ loss framework as developed and used in the last review, which has fundamentally two key inputs: an air-to-blood ratio and the slope of a concentration-response (C-R) function for IQ decrements in young children.

To what extent does the Panel agree with application of the evidence-based framework from the last review, particularly with regard to consideration of the currently available information, and related limitations and uncertainties, for air-to-blood ratios and C-R functions for IQ decrements in young children?

2. As previously discussed with CASAC, staff concluded that the current information does not warrant development of a new REA in this review. Thus, exposure/risk information was drawn from the REA conducted in the last review.

What are the Panel's views on staff's interpretation of the exposure/risk information, and on staff's conclusions that the information is generally supportive of conclusions drawn from the evidence-based framework as to the adequacy of the current standard?

3. In reaching preliminary staff conclusions, staff notes that, like any NAAQS review, this Pb NAAQS review requires public health policy judgments. The public health policy judgments for this review include the public health significance of a given magnitude of IQ loss in a small subset of highly exposed children (i.e., those likely to experience air-related Pb exposures at the level of the standard), as well as how to consider the nature and magnitude of the array of uncertainties that are inherent in the evidence and in the application of this specific framework.

What are the Panel's views on public health policy judgments that inform staff's preliminary conclusions with regard to the adequacy of current standard and a lack of support for consideration of potential alternative standards?

4. In the Panel's view, does the discussion in section 4.3 provide an appropriate and sufficient rationale to support staff's preliminary conclusion that it is appropriate to consider retaining the current standard (including the indicator, level, averaging time, and form) without revision?
5. Does the Panel have any recommendations regarding additional interpretations and conclusions based on the available information that would be appropriate for consideration beyond those discussed in this chapter?

***Welfare Effects and Exposure/Risk Information (Chapter 5):*** This chapter discusses key policy-relevant aspects of the environmental evidence and exposure/risk information.

1. To what extent does the information in section 5.1 (Welfare Effects Information) capture and appropriately characterize the key aspects of the evidence assessed and integrated in the ISA?
2. With regard to the exposure and risk information in section 5.2 (Exposure and Risk Information), to what extent is the information drawn from the screening-level risk assessment in the last review sufficiently characterized and clearly communicated? To what extent is the information appropriately interpreted in light of the currently available information and for the purpose of assessing the adequacy of the current standard?
3. Are the limitations and uncertainties in the exposure/risk information appropriately characterized and considered in our interpretation of the information in the context of this current review?

***Review of the Secondary Standard for Lead (Chapter 6):*** This chapter describes the basis for the current secondary standard and consideration of the current evidence and exposure/risk-based information with regard to reaching preliminary staff conclusions about the adequacy of the current standard.

1. Does the Panel agree with preliminary staff conclusions about the evidence and previous risk assessment in light of current standards as presented in section 6.2 (Adequacy of the Current Standard)?
2. In the Panel's view, does the discussion in this chapter provide an appropriate and sufficient rationale to support preliminary staff conclusions that it is appropriate to consider retaining the current standard (including the indicator, level, averaging time, and form) without revision?
3. Does the Panel have any recommendations regarding additional interpretations and conclusions based on the available information that would be appropriate for consideration beyond those discussed in this chapter?