

07-19-11 Preliminary Draft Comments from Clean Air Scientific Advisory Committee (CASAC) Lead Review Panel. These preliminary pre-meeting comments are from individual members of the Panel and do not represent CASAC consensus comments nor EPA policy. Do not cite or quote.

**Preliminary Comments from Members of the CASAC Lead Review Panel on
EPA’s Review of the National Ambient Air Quality Standards for Lead: Risk and
Exposure Assessment Planning Document (June 2011)
(Updated July 19, 2011)**

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Comments from Dr. Herbert E. Allen

I have reviewed the Ecological Risk Assessment portion of the document and am in agreement with the Key observations and conclusions.

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Comments from Dr. Deborah Cory-Slechta

The intent of the document was to summarize the approach to Risk Assessment adopted by the 2006 AQCD on lead including the limitations that were inherent in each of the steps of the process and to evaluate whether data collected since that time could be used to inform any of those limitations and, if so, the extent to which that information would influence the final risk assessment.

The limitations inherent in the previous derivation of both the primary and the secondary NAAQS were thoroughly and completely laid out in this document. For each of those limitations, the document presented the extent of new information related to that limitation that had been reported since the 2006 document. In addition, it addressed the extent to which the information would alter or influence the prior risk assessments.

For both the primary and secondary NAAQS, the conclusion arrived at is that there is insufficient new information that would reduce these specific limitations of the risk assessment and would have thus warranted a new risk assessment. Based on the reading of the Integrated Assessment Documents and the Risk and Exposure Assessment Planning Document, I would concur with those conclusions.

Comments from Dr. Chris E. Johnson

In reviewing the Risk and Exposure Assessment (REA) Planning Document, I focused my efforts on the welfare risk assessment. Others on the CASAC are much better equipped to judge the health risk assessment.

1. Overview of the previous ecological risk assessment and the presentation of results from the last review of the Pb NAAQS.

The REA Planning Document does a good job of describing the design and conduct of the ecological risk assessment done for the 2008 NAAQS process. The REA Planning document does not present any results from that assessment, aside from the limitations and uncertainties that were identified.

2. Evaluation of new evidence and information in light of limitations and uncertainties of the risk assessment from the previous review.

The authors of the REA Planning Document highlighted several areas where recent studies have added to our understanding of key issues related to ecological risk assessment. While there is much new material that supports the previous work, the authors conclude that few of the limitations and uncertainties identified in the previous assessment have been adequately addressed.

3. Staff assessment of the new information and conclusions regarding the use of critical loads modeling.

The REA Planning Document highlights the many difficulties in carrying out a comprehensive critical loads based assessment for Pb in terrestrial and aquatic ecosystems. In addressing new information, the REA Planning Document refers to the ISA, which considered three studies of critical loads in terrestrial systems, and claimed that there is no new significant information regarding critical loads in aquatic systems. It is, in my opinion, a bit narrow-minded to conclude that the state of science in critical loads modeling has not advanced because few have tried it. The many, many studies carried out since 2005 on toxicological effects, Pb fate and transport, and bioaccumulation, cited in the ISA, all contribute to a better knowledge base for critical loads modeling. Are there gaps? Of course. But there is no question that we are better equipped to do it now than we were six years ago.

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4. The decision to rely on the quantitative ecological risk assessment from the previous review, placed within the context of newly available evidence and information.

This is, all things considered, probably the right decision. An ecological risk assessment carried out today, and incorporating insights from studies published since 2005, would be better than the one done for the 2008 NAAQS process. But it would probably not result in any substantially different conclusions. The bioconcentration factors for aquatic plants in the current ISA are much lower than the ones in the 2006 AQCD. Using lower BCF values would reduce the hazard quotient at both the organism and ecosystem level.

On a more general note, I fear that the EPA is placing unreasonably high expectations on the data needs for performing a new quantitative ecological risk assessment. For example, in discussing critical loads modeling, the REA Planning Document says, "...however, application of this methodology at a national scale requires localized data across a wide range of ecosystems, which are currently unavailable or inadequate." Frankly, the United States will probably never have localized data on fluxes, soil fractions, groundwaters, floral and faunal bioaccumulation, and toxicity adequate for a proper critical loads assessment, or other ecological risk assessment for that matter. The amount of work required, coupled with the dearth of funding for research on metal biogeochemistry, makes the development of such a database very unlikely indeed. I do think that it is probably too soon to do another ecological risk assessment at this time, but the tone of this document concerns me.

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Comments from Dr. Michael Rabinowitz

What follows are comments prompted by the text of the documents, arranged by page, some bearing on the questions in the EPA charge, particularly related to the Health Risk Assessment. More comments may come post-meeting.

Page 2-1, line 5 - I suggest replacing "different" with "improved" (although 2-30 addresses this issue well in detail)

Page 2-1, end of 2nd paragraph – suggest adding ... along with a host of other miscellaneous sources such as ceramics, cosmetics, and plastic venetian blinds.

Page 2-3, para 2, line 5 - suggest adding ...processing, such as bearing metals in machinery and solder seals)

Page 2-3, para 4, last line - ...metric, in part because PbB is viewed as more biologically active and more homogenous than bone.

Page 2-5, Fig 2-1 - Please re-label pools of internal deposition so that "blood" appears in the middle box. Then, you can also add two-way arrows from that middle blood pool left and right to the bone and other indicating exchange between those pools via the blood. Otherwise, a useful and concise diagram.

Section 2.1.2 - perhaps have a table listing the 5 studies, sort of a convolution of Table 2-1.

List by study and provide scenario time and level for each. Not really new information, just another way to show it.

Figure 2-2 - A+ good explanatory power

Page 2-11, note 10 - I do concur that using concurrent and some lifetime average is the way to go. At these levels, the paradigm of "windows of vulnerability" appears to have been overcome by the tendency for recovery. So, the effects of any earlier insults go un-noticed given subsequent lifetime exposures.

Table 2-3 - Maybe repetitive and long, but very useful

Page 2-32 - first full para, I agree

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Page 3-1 - just curious, is reduced atmospheric visibility a welfare effect?

Page 3-1, para 3, line 7 - suggest ...other pollutants, such as ozone or NOX, adding these examples might add strength

Page 3-4 - good discussion of critical load, which I needed

Page 3-10, note 19 - good presentation, only afraid it might be lost in footnote.

Comments from Dr. Gail Wasserman

Section on Health Risk Assessment

Overall, this section reads well and clearly states both its conclusions and the limitations in model-development.

Figure 2-1. The text on page 2-2 indicates that the boxes that are relevant to air-related pathways are indicated in bold, while in my version they are shaded. I believe shading works better, actually. The Figure clearly presents the focus of the earlier document to which it refers.

Figure 2-2. There is a typo in the lower right-hand box.

p.2-12. Although the 4 models are described, some more text about the justification and implications of each would be helpful for connecting these dots. Useful would also be an indication that the cutpoint in the “log-linear with cutpoint” model in the Lanphear meta-analysis was selected but of too few observations below this point to warrant inferences.

Figure 2-3. I think some other designation for either the first or third model in the legend would be helpful. The patterns of dots and dashes is quite similar. The legend on the Y axis should indicate that there are “points” lost.

I am not sure whether this is a comment that belongs in this section, but somewhere there needs to be a discussion of the metrics of IQ scoring and the clinical significance of small deficits. As a practicing psychologist, I find the parsing of IQ scores into “points lost” that translates into fractions of a single point very uncomfortable, especially given that the standard error of measurement for most IQ tests is 5 points. There needs to be some risk/benefit awareness of the policy implications of interventions at very low blood lead levels.

Table 2-3 nicely lays out the new evidence and where the important gaps remain.

There appear some inconsistencies between the conclusions made in this table, and those apparent in Table 2-5 (and section 2.5.1) in the ISA. As examples, the ISA underscores the causal connection between exposure and both child behavior and adult cardiovascular concerns, outcomes for which the REA Planning Document notes unclear evidence. If the issue is that the existing data are insufficient to result in quantitative risk assessments (but sufficient to result in decisions about causality), that should be explicitly stated. In other words, more cross-talk between these documents would be helpful.