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)

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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.

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.

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.

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

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. Ian von Lindern

Overview: The draft Integrated Science Assessment (ISA) is organized, comprehensive, and presented in a logical, transparent manner. It is an impressive well-edited document that is convenient to read and digest, despite its size. The document is structured as a follow up to the EPA 2006 criteria review document and presents many of the conclusions as affirmations or supplements to the 2006 edition. The questions outlined in Section 1 are all keyed to the implications of new evidence that has evolved since the last review and how those studies inform the Agency in meeting its responsibilities.

This is an appropriate approach in light of the EPA ISA strategy, which seems to be to examine whether any new information developed since 2006 provides justification for modifying the earlier analyses.

This works well for those familiar with the previous review. However, this format i) may be challenging for uninitiated readers and reviewers, ii) does not inform the reviewer as to the historic conditions and accomplishments (in some areas), and iii) does not address weaknesses (in some areas) in the information base identified or analyses conducted in the last review.

Historic Perspective: There were challenges encountered in the previous review that indicated significant gaps in the knowledge base. These information gaps introduced uncertainties into the process that should be revisited. The last NAAQS review showed that EPA had, in maintaining the irrelevant standard from 1978-2007, "lost track" of key parameters necessary to effectively assess the health and ecological risks of airborne lead in the U.S. Relatively little data were available in several key areas for performing a responsible risk assessment.

It seems EPA intends to conclude in the Risk Assessment Planning document that, although substantive information has accumulated, little of this information changes the analyses or conclusions developed and presented in 2006. Based on the information presented, this conclusion does appear to be justified. However, there seems to be a disconnect in that i) significant data deficiencies were identified in 2006, ii) EPA is the Agency responsible to collect the data to fill these data gaps, iii) now EPA concludes the data continue to be unavailable to appropriately assess lead exposure in the country, and iv) the old risk analyses will be continued to be relied upon for another five years.

The current exposure and risk assessment strategy evaluates pilot examples representing real situations prevalent in the country. These analyses are modeling exercises based on outdated empirical relationships and little concurrent ambient data. These situations show substantial probability of exceeding the new NAAQS and attendant levels of excess risk to surrounding populations. The major problem with respect to current exposure and risk analyses is that EPA is

unable to estimate how much of the country is subject to these excessive levels.

The ISA should point this deficiency out and ascertain whether there are technological or scientific barriers to developing the requisite information from existing sources, or through new program activities. The subsequent policy analyses should examine whether relevant databases are being developed, both internal and external to the EPA. Should EPA be developing, supporting, or implementing programmatic activities to make it possible to move from the near total reliance on risk modeling to observational and empirical analysis of contemporaneous data?

Several questions should be answered with respect to monitoring and surveillance. What data base is accumulating with respect to compliance with the new standard? Is a network established, is it adequate and effective, and are there detectable blood lead levels associated with any gradient in exposure? Have there been excursions? Certain U.S. sub-populations (e.g. immigrants and inner city children) are at substantially greater risk of exposure due to co-factors associated with different cultures, climates, dietary and nutritional regimes, as are being encountered in the global lead poisoning epidemic. Are these venues being monitored?

ISA Exposure Assessment Review: Evaluation of the Exposure Assessment portion of the document begins with Chapter 1 and extends through Chapter 4.

Chapters 1 and 2 Introduction and Integrative Health and Ecological Overview, respectively, are well organized, edited to provide a clear and transparent presentation of the intent and structure, and effectively summarize the document. Section 1.6 on causality and EPA's Framework for Causal Determination is particularly strong and organized to clearly present EPA's conclusions and justifications with respect to health issues. Section 2.7 and 2.8 are also especially pertinent additions and improvements to the Criteria Document process. Overall, the causation and health effects sections are impressive, comprehensive, and well-supported.

In contrast, there is little discussion and few conclusions presented regarding sources, uses, ambient concentrations, exposure or populations at risk. Only 4 of 72 pages in the summary Chapter 2 discuss Ambient Lead and Exposure, followed by 2 pages of Toxicokinetics and Biomarkers, compared to 16 pages of Human Health Effects and 15 pages of Ecological Effects summary. This is followed by an 18 page summary dedicated to Integration of Human Health and Ecological Effects.

The latter is a particularly good presentation and the Agency should be commended for beginning to make these connections formally in policy support documents. It is a step forward in environmental regulatory approach that will well serve both the environment and U.S. health and ecological policy. Table 2.8 in the Chapter 2 summary is particularly strong in making this point.

Unfortunately, the relative amount of attention paid to exposure in the summary is appropriate to the makeup of the document as a whole, with more than 70% of the ISA dedicated to health effects and causality. This is also likely reflective of where research and monitoring attention and publication resources have been focused in recent years. With regard to the AQCD it is also points out the greatest deficiencies in the last NAAQS process have not been addressed and are perhaps being compounded and extended in this revision.

Developing effective exposure estimates was the weakest point in the analyses that supported the current NAAQS. This was due to the lack of monitoring data available to assess contemporary exposures in the U.S., or to support the modeling analyses relied on in subsequent development of the NAAQS. Unfortunately, in the last review, the EPA was challenged in effectively estimating the extent of potential damage in the general population; the relationship between air lead levels, emissions and absorption; a safe air lead concentration; or the number of citizens exposed to potentially dangerous levels.

This weakness was identified in the 2006 AQCD and the OAQPS made the best of a poorly characterized situation. There were insufficient data to characterize active emissions and emission rates, ambient concentrations and the degree, extent and severity of ongoing redistribution of residual lead in the nation's environment. As a result, EPA relied on modeling and decades-old empirical relationships to quantify exposures. This resulted in considerable uncertainty inherent in the overall process.

Chapter 3 Ambient Lead: Source to Concentration: Chapter 3 addresses the areas identified as data gaps in the last review, and presents the information that will eventually be relied upon in developing exposure risk assessments for the U.S. population. There has been some additional ambient monitoring conducted since 2007 that better informs the Agency with respect to population exposure.

Formal and Informal Uses of Lead in the U.S.: Prior to discussing the adequacy of available ambient lead data, it is critical to note that there is no information relative to trends of commercial use and disposition of lead in U.S. commerce in the entire document. That 2006 AQCD indicated that use and consumption of lead in the U.S. were approaching levels near the peak utilization seen before the gasoline additive phase down. Yet, it seems the EPA has little or no information on the current life-cycle of lead in either the formal or informal industrial sector in the U.S. Does the Agency know how much or where this lead is being produced, used, consumed, recycled, recovered, reused, disposed of, or if it is being exported as waste? Is this information obtainable? Are any data bases available? Is the information reliable? It seems these data would inform the Agency as to where appropriate monitoring and testing should be undertaken.

Sources of Atmospheric Lead: Sections 3.1 and 3.2 discuss sources of lead and summarize the National Emissions Inventory and discuss other anthropogenic sources of airborne lead. This discussion provides a good overview of the larger airborne sources in the U.S. and provides a county-by-county database to characterize the magnitude and extent of these sources across the country. These sections indicate that there are some quantitative data regarding larger point sources in the country and a basic understanding of source behavior with respect to numerous smaller lead sites in which the airborne pathway plays a significant role in human and ecologic exposure. However, there does not seem to be an inventory of the latter sites. How many are there? Where are these located? Is the list complete? Are there populations nearby? Are health risks in these areas addressed in other regulatory programs?

Fate and Transport: Section 3.3 provides good discussion of lead fate and transport in the environment and recognizes that the majority of environmental lead is potentially air lead in waiting, or once was air lead, and can easily be transferred to other environmental compartments of exposure significance.

Air Quality Monitoring / Surveillance: Section 3.4 is an informative discussion of lead monitoring techniques and appropriately covers the available technology to effectively monitor air lead in the U.S.

Section 3.5 does provide some new information to address the data gaps identified in 2006. There have been additional monitoring data collected in the interim that provide some concurrent information regarding airborne exposures in the U.S. Although a fair quantitative discussion and an extensive Appendix are provided, no conclusions are drawn with regard to the quality, representativeness and degree of compliance with the NAAQS as currently implemented.

With regard to compliance or implied risk, this information is confusing. It seems that “Source Oriented TSP monitors” indicate the NAAQS is being exceeded in 14 of 22 counties being monitored across the U.S. Conversely, non-source oriented monitors show levels generally well below the new NAAQS standard. Additional discussion is provided with regard to PM10 and PM2.5 monitors analyzed for lead. These networks generally seem to show overall compliance with the new NAAQS, even when TSP monitoring shows the same areas at-risk.

However, there seems to be no “take away” message with regard to these data and analyses. This is in stark contrast to the health issues presented and discussed in the document that are clearly conclusion oriented. Questions that come to mind include:

What is the appropriate monitoring technique? One method shows 2/3rds of all source oriented sites are out of compliance across the U.S.; the other method shows 3 of 323 sites exceed the criteria, but does not specify source type. Does the latter method appropriately reflect the risk associated with these sources?

If 2/3rds of source oriented sites are out of compliance, how many of these sites are there in the country? Are there only 22 that are being effectively monitored, or hundreds or thousands not being monitored? What populations are exposed by these sites? How do these sites relate to the National Emissions Inventory presented earlier in the Chapter, or are these the other anthropogenic sites, for which there is no inventory? It seems there should either be answers provided to these questions to support a national risk assessment, or an indication that the problem is not appropriately characterized by current source inventory and monitoring efforts.

Particle Size: Section 3.5.3 addresses particle size distribution of lead-bearing particulate and seems to be oriented toward eventual monitoring and health risk assessment of lead particulate. Doubtless particle size is a critical parameter with respect to collection efficiency and transport, solubility, chemical-transformation and toxicological properties. However, it must be remembered that lead in any particle size seen within these discussions is, or soon can be, hazardous to children and other receptors.

Concentrations in Other Media: The remainder of Chapter 3 is dedicated to summarizing lead concentrations observed in various environmental media. These are good and informative discussions. The air lead discussion does a good job of describing the large decreases noted with the gasoline phase down. It would also be important to note the decreases associated with point sources in the same time frame, particularly with respect to smelting, mineral processing and secondary recycling. The ambient air lead decreases in the vicinity of these sources were significantly greater than those achieved in urban areas through the phase down. Moreover, many of these industries were shutdown and were replaced in the global sense outside the U.S.

The document would also benefit from a larger historic perspective to the other media similar to that developed for air. Other media and biota have seen significant concentration decreases since the phase down and industry shutdown and cleanups. However, the pattern, length of time, relative magnitude and toxicological significance of these declines vary by media. It would be beneficial to note these patterns, particularly in light of the increasing interest in ecological response and potential secondary standard considerations.

Chapter 3 should develop a conclusion oriented format similar to that employed for the causality associations made in Chapter 2 and the other subject areas of the document.

Chapter 4 Exposure, Toxicokinetics and Biomarkers:

Pathways and Exposure Parameters: Chapter 4 addresses Exposure Assessment in Section 4.1 and begins with an appropriate discussion of pathways. There appears to be a typo on line 4 regarding the gasoline phase down date, but the text notes the associated historic reductions in air lead exposures. It is always good to note that significant air lead reductions also were noted in the vicinity of point sources, and other media concentration decreases were observed, both attendant to and independent of the phase down and curtailments in industrial emissions.

This is followed by a discussion of indoor versus outdoor versus personal exposure that does not quite reach a conclusion. It seems that personal exposures are generally higher than the ambient exposures, which is important to note, and indoor versus outdoor tends to vary with site specifics and season and cannot be generalized. Soils and dusts are discussed next. The complexity and interrelationship of these variables and the role of air media in the continual exchange between these media is emphasized, but it might be noted that a clear empirical relationship between soil and dust has yet to be demonstrated, as it also likely tends to vary with specific site conditions, seasonality, etc.

The remainder of this section discusses other media and effectively summarizes the current state of knowledge with respect to relative significance of these media in acting as sources in pathways common to North America, Europe and Australia, where almost all of these studies have derived. A limited amount of discussion is provided for China. However, it should be noted that exposure sources and pathways are moderated by behavior, housing, lifestyle and cultural patterns. These patterns vary immensely for developing and middle-income countries and cultures, as compared to the U.S. Also many immigrant populations in the U.S. may engage in ethnic and cultural behaviors leaving them more susceptible to lead intake and uptake.

All of these sections would benefit from a brief description of how the concentrations and relative intakes have decreased in association with the phase down, industrial source curtailment, and decrease in lead content of consumer goods over the past three decades. Table 4.5 could benefit from some additional description of dry weight versus wet weight considerations for dietary crops and how that relates to ingestion of lead from soils versus foodstuff. Description of how concentrations and intakes from these same media can vary dramatically in cultural, ethnic and socio-economic situations differing from Europe and North America would be a benefit to the document.

In Table 4.6, one study shows lead content in ug as opposed to a concentration. A footnote would be appropriate to allow comparison to other entries in the Table.

Toxicokinetics: The toxicokinetics discussion is concise and well-developed and reflective of the current understanding and practice in risk assessment activities. The discussion could be amplified with respect to the uncertainties associated with uptake and excretion in populations outside of North America and European populations.

Biomarkers: The discussion in Section 4.3.2 Blood Lead measurements has a confusing transition from analytical techniques to ALAD from page 4-35 to 4-36. Perhaps the analytical discussion could be expanded and some transition language be inserted, or the discussion of the significance of ALAD be moved or combined with Section 4.3.4.4.

Relationship of Lead in Blood and Lead in Bone: The overall discussion of the health significance and interrelationship of these biomarkers is informative and well presented. It might

be useful to discuss the relevance of these biomarkers in terms of internal exposure to organs and tissue and the relevance to immediate toxic health effects.

Exposure-Blood Lead Relationships: Section 4.5 through the Summary in Section 4.7 provides a concise summary of this topic area that has been well vetted in several previous SAB reviews and represents the current scientific consensus for this important segment of risk assessment process.

Chapter 4 should develop a conclusion oriented format similar to that employed for the causality associations made in Chapter 2 and the other subject areas of the document.

Policy Implications: The ISA is reflective of a long history of lead health and risk assessment and attendant regulatory programs. These actions have reduced lead exposures and health effects in the U.S. and other developed countries by orders of magnitude over the past four decades. As the populations in these countries attain ever lower blood lead levels and body burdens, investigators are observing previously undetected adverse outcomes. In the last decade, lead-related research has continued to concentrate on investigating and defining adverse effects at ever-lower exposure levels. Similarly the ISA is heavily weighted toward assessing and characterizing new information regarding health effects.

However, during this time, the EPA and other environmental regulators have diminished the monitoring and programmatic attention paid to lead, as the overt health risks have subsided. This has occurred because the ambient exposures have decreased dramatically to levels unimaginable in previous decades, and other health risks have taken priority.

Nevertheless, the demand for and consumption of lead in the U.S. have increased markedly in this century, accompanied by substantial price increases in the domestic and world market. As noted above, other general exposure considerations related to market and use factors; (i.e. emission sources, commercial uses, waste, recovery, recycling and disposition and fate of lead) in the U.S. today are poorly understood, nor have exposure parameters been quantified. There is no treatment of these factors in the ISA. It is unclear if there are any data, or whether EPA sought such information. Several other issues, generally considered in policy decisions, not included in the ISA are advancements in pollution control capacity, best available technologies, and best practices for source control.

Data Sources: Unfortunately, the best information for production data, emission information, industry transition and economic indicators is more likely to be found in the trade literature and government agency records. Much of the practical knowledge that has been developed in applying scientific findings and methods to remedial and regulatory activities is generated and housed in programmatic activities within EPA and the States.
In 2006, the CASAC urged the Agency to mine these data sources in the last review. The sources cited in the ISA review seem to have been limited to the peer reviewed literature and the national

air quality monitoring network. Perhaps in developing the attendant policy recommendations, the Agency will explore the life cycle and economic impacts of lead regulation in both this country and overseas.

Global Considerations: Although U.S. lead demand has increased, domestic production and recycling and recovery of many discarded lead products have been diverted to developing countries. Much of this is diversion results from EPA policies. On the international scene, the increased price and demand observed in the last five years has had devastating effects, substantially more severe than those observed in the 1970s. Environmental exposures and lead poisoning are increasing with several incidences of severe morbidity and substantial mortality associated with the increased demand and high price of metals. Hundreds of children have died at some sites and thousands suffer irreversible health effects that their families and communities must cope with for decades.

More children in the world die and suffer irreversible, dysfunctional brain damage due to lead poisoning today than in the last fifty years. Although air lead levels in the U.S. are at an all time low, the implications for regulation of lead releases and the impact of U.S. policies in the global environment and human health are substantial. If not in the ISA, it seems the EPA has an obligation to inform the policy makers of the global consequences of lead regulation, or lack thereof. Similarly the U.S. has an obligation to export the scientific knowledge base, consequences of irresponsible practices, and information regarding mitigation of adverse effects. The subsequent regulatory policies when implemented have ramifications, not only beyond ambient air lead levels, but throughout the world.

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.