

02-01-13 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 Do not cite or quote.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 Policy Assessment for the Review of the Lead National Ambient Air Quality Standards
(External Review Draft – January 2013)**

Received as of 02-01-13

Mr. George Allen	2
Dr. Deborah Cory-Slechta.....	3
Dr. Chris Johnson	5
Dr. Roman Lanno	7
Mr. Richard Poirot	10
Dr. Ian von Lindern.....	15
Dr. Gail Wasserman	19
Dr. Michael Weitzman.....	20

02-01-13 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 Do not cite or quote.

Mr. George Allen

Comments on Chapter 2

Response to specific Charge Questions:

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?

Overall, Chapter 2 provides a concise and well-organized summary of the relevant material from the ISA. Minor note: the boxplots in section 2.2.2 need to have the whisker defined - is it 95th percentile?

2. With regard to information on ambient Pb monitoring (section 2.2.1), to what extent is this information appropriately characterized and clearly communicated?

2.2.1.3.1, pg 2-20, lines 4-9: this paragraph is a well written description of the process being taken towards a better FRM sampler. It states that known limitations in wind-tunnel aerosol generation and particle sampling of ultra-coarse particles will limit the upper range of any new FRM to 18-20 microns. I would suggest that EPA consider the practical aspects of sampler design and testing, and (at least initially) constrain the project goals to an upper limit of 15 microns, a size noted in the ISA as being appropriate (sufficiently large enough) for exposure assessment in a NAAQS context.

2.2.1.3.3, Pg. 2-22, lines 17-18: The Pb NAAQS form is “never to be exceeded” – a unique form. How is the Pb design value calculated - is it the highest 3-month running average over the 3-year period?

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Dr. Deborah Cory-Slechta

Comments on Chapter 4 – Primary Standard for Lead

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

The application of the evidence-based framework from the last review seems appropriate, particularly given that new literature since the prior 2006 review provides further support for the health effect conclusions presented in the prior review. Additionally, new studies do not fundamentally alter the uncertainties for air-to-blood ratios or C-R functions for IQ decrements in young children.

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?

The use of exposure-risk information from the prior review appears appropriate given the absence of significant new information that could fundamentally change the interpretation.

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

The document states repeatedly that no threshold for lead effects on IQ can be identified. In some respects, the ability to define a threshold may already be a moot issue. Reductions in IQ in children are being reported at blood lead values as low as 2 ug/dl. In essence, these effects are being reported at the lowest levels of lead in blood that can be reliably measured by most laboratories doing such analyses.

While the regulations do not require that zero risk be achieved, neither does it prevent it. Given the above statement, and the fact that the supra-linear C-R curve has now been demonstrated in several studies, it becomes increasingly difficult to support a standard based on 1-2 IQ point loss. From a biological perspective, a standard based on some degeneration of function does not seem appropriate. From a public health perspective, communicating to the public that a regulatory standard is based on exposures that provide no more than a 1-3 point IQ reduction would seem less than ideal and contradictory to their expectations.

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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?

Yes, given the evidence-based framework. However, given that we are now down to the lowest blood lead levels that can be reliably measured, it is not clear that all of these arguments are in fact requisite.

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?

As noted above, statements about the threshold do not seem warranted given that IQ reductions now occur at the lowest blood lead levels that can be reliably measured in most laboratories. It was for this reason that the ACCLPP committee recommended to CDC a complete elimination of the phrase 'level of concern' and stated that no safe level of blood lead can be identified.

Dr. Chris Johnson

Comments on Chapter 5: Welfare Effects and Exposure/Risk Information

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?

Section 5.1 does a good job of summarizing the evidence for ecological effects from the Third Draft ISA. Each sub-section includes a brief description of our understanding in the 2006 Air Quality Control Document, and commentary on how research undertaken since then has (or has not) changed our understanding. The general conclusion is that recent research has added depth and nuance to our understanding of the fate and transport of Pb in ecological systems, and to our understanding of effects on organisms in terrestrial and aquatic ecosystems, but has not changed our understanding in a way that merits reconsideration of relationships used to assess risk.

Two persistent themes in the ecological effects sections of the ISA and this PA document are: (1) it is difficult to isolate the effects of air Pb on ecosystems from other sources, including “legacy” Pb accumulated in soils and sediments; and (2) it is difficult to isolate the effects of Pb from other metals and stressors. It is distressing to see the degree to which these explanations are used to justify no-action conclusions. The threat of release of legacy Pb in soils and sediments, for example, whatever the source (atmospheric or geologic), may necessitate a lower secondary air quality standard than would be warranted in the absence of the legacy Pb.

The overall impression left in reading section 5.1 is that the authors are working very hard to justify a no-action conclusion, even if that means forcing some round pegs into square holes.

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?

The results of the 2006 risk and exposure assessment (REA) are summarized in section 5.2. The summary is concise and clear, both in the explanation of the model employed and in the case studies used in the assessment.

The interpretation of the results from the 2006 REA is appropriate insofar as it re-states the conclusions from that document, and there have been no fundamental changes to our understanding of key thresholds or ecological receptors in the intervening years. However, after reading section 5.2 of the draft PA, one is left with serious doubts about the value of the original work for the purpose of establishing a secondary standard. Of four case studies employed, the results from two (the primary and secondary smelter cases) are judged to be “not informative.” The relevance of a third case study (non-urban near-

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roadway conditions) is deemed “highly uncertain” due to the presence of legacy Pb in roadside soils. The only case study that is deemed relevant is the Hubbard Brook case, where ambient Pb concentrations are far below the current (and proposed) standard. Results from analysis of surface water and sediment data are judged to be inconclusive because of possible non-air sources to waters and legacy Pb in sediments.

Overall, four of the five major efforts in the 2006 REA are judged to be of limited or no value for the purposes of this policy assessment. Yet the Agency considers another REA unnecessary. Perhaps new information since the 2006 REA does not warrant a new REA, but the apparent inadequacy of the 2006 REA would certainly seem to warrant another try.

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?

As discussed above in my comments to the other charge questions, I believe that the limitations and uncertainties presented in chapter 5 of the Draft PA are somewhat overstated. Issues such as legacy Pb, multi-stressor effects, and lab-to-field applicability do create uncertainty, but do not make data uninformative.

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Dr. Roman Lanno

The Policy Assessment document (did not read chapter 4) is well written and summarizes evidence justifying retaining the current standard without revision. Retaining the current standard is warranted given the lack of significant additional data that has become available since the last AQCD. The US EPA nicely describes that the new data adds to an existing database, refines some key concepts (e.g., bioavailability, critical loads), but is not yet ready for application in the development and revision of a new secondary standard. Additionally, uncertainties in Pb exposure/risk are addressed. The magnitude of the contribution of Pb from air to the total environmental Pb load and the fate and distribution of airborne Pb to other environmental media is discussed. Figure 1-1 provides a nice backdrop for discussing these issues. The confounding effects of other sources of Pb (e.g., surface runoff to waters near industries) and the “challenge of disentangling of atmospheric deposition contributions from those associated with surface runoff” are discussed. Uncertainties related to screening values used in the risk assessment are also discussed.

Page 2-1, line 11 – change “depending on their size” to “depending on particle size”

Page 2-20, lines 26 and 27 – change “adsorption” to “absorption”

Page 2-38, line 5 – What is meant by “substantially”? Is this a statistically significant decrease and if so, by how much? Half, ten-fold? Specifics would help here.

Page 2-40, line 7 – remove underscore in 20 ug/kg

Page 2-40, line 12 – Should this be Figure 2-14, not 2-16?

Page 2-41 – Figure 2-14 shows very nicely the drop in environmental Pb due to the phasing out of leaded gasoline

Chapter 2 provides an excellent summary of temporal trends in Pb exposure, especially the influence of removing Pb from automotive gasoline.

Comments on Chapter 5 - Welfare Effects and Exposure/Risk Information

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?

Section 5.1 adequately summarizes the key aspects of evidence assessed and integrated in the ISA.

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

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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?

The information in section 5.2 adequately integrates and communicates the information from the screening-level risk assessment and provides an appropriate interpretation and decision on the adequacy of the current secondary standard.

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?

The limitations and uncertainties of both the data and the screening levels used in risk assessment of case studies are adequately discussed.

Page 5-2, lines 28-31 – another major issue is that Pb rarely occurs alone but in mixtures with other metals

Pages 5-8 and 5-9, lines 35 and 1 – in addition to the issue of single species toxicity tests not capturing the complexity of bioavailability in natural systems, there is a lack to models that integrate bioavailability information that would allow prediction of toxicity among soils varying in physical and chemical characteristics

Page 5-10, line 7 – If this data is based only upon nominal concentrations, then it should only be considered as secondary data and should be used very cautiously in a PA document. I would suggest omitting it, unless there are actual measurements of Pb in the test medium.

Page 5-15, line 5, end of line – change “summarizes” to “summarizing”

Comments on Chapter 6 - Review of the Secondary Standard for Lead

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)?

Yes, the preliminary staff conclusions provide a good assessment of the available evidence and the previous risk assessment in light of the current secondary standard.

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?

At this point in time, the discussion provides appropriate and sufficient rationale to support retaining the current standard without revision.

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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 the chapter?

Not at this point.

Mr. Richard Poirot

Comments on Chapter 2

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?

With a few minor exceptions (see specific comments) the information on Pb emissions, air quality and concentrations in other media is appropriately characterized and clearly presented. Historical and recent (2008) emissions data are summarized quantitatively in clear charts and tables, with additional detail on the 2008 NEI inventory data sources and limitations provided in Appendix 2A. There are also some (qualitative) discussions and an informative Appendix (2B) on recent regulatory actions, indicating that current emissions have declined since 2008, with additional reductions pending. In a future PAD, it would be useful if quantitative estimates of some of these emissions reductions could be presented.

The Information on ambient air concentrations (through 2011) is also clearly presented in maps, charts and in a detailed appendix (2D). There are more recent data (including near airports) that were initiated following the previous Pb NAAQS review, and which would be informative for the current Pb NAAQS review, as well as for the separate Section 231 avgas review. It would be useful if some of these more recent data can be presented in (or as a supplement to) the next Pb PAD. While it may take 3-years of data to calculate an official design value, an exceedance of the Pb NAAQS and other potentially useful information can be provided by as few as 3 months of new data.

The Information on Pb concentrations in other media is clearly presented. The sections (2.3.2.1 and 2.3.2.2) on indoor and outdoor dust (and air contributions to) are highly relevant to exposure assessments and would benefit from some added discussion (also missing in the ISA) of how dust Pb concentration, loading, and loading rates are measured. In particular, information relating to the differences in particle sizes in dust samples and ambient air samples would be helpful.

With regard to information on ambient Pb monitoring (section 2.2.1), to what extent is this information appropriately characterized and clearly communicated?

The information on ambient Pb monitoring is appropriately characterized and clearly communicated. It is understood that we are “stuck” with the Hi-Vol TSP sampler as an imperfect historical artifact, and that there is not time to develop and fully test alternative samplers that would consistently capture particles greater than 10 microns with appropriate collection efficiencies and size ranges under varying wind speeds and directions. The draft PAD notes that the Agency expects a new, improved sampler to be “available for consideration in a future review”. Given that the Agency had also expressed an interest in developing an alternative “TSP” sampler (low-volume TSP FRM) in the previous 2008 NAAQS revision, it would be desirable at some point to see a commitment to expend the resources needed to have an alternative sampler “available for consideration in the next Pb NAAQS review”.

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Toward this goal, it would also be useful to see some discussion indicating what the desirable cut size characteristics of an alternative sampler might be. Information provided in the 3rd draft ISA could be cited here, for example (page 3-67) of the ISA: “The relevant particle size distribution for ambient sampling is smaller than the size distribution of the settled dust. Particles larger than about 20 µm are generally considered too large to be transported for more than a few seconds under typical conditions... It follows that 15 to 20 µm may be a practical limit for both good sampling data quality and representative sampling in a limited area.”

Along similar lines, the term TSP is used broadly and imprecisely to mean several different things – including what the Hi-Vol collects, what other currently available so-called TSP samplers collect, and what a future alternative TSP sampler might collect (all of which differ from each other). Development and usage of more precise terminology could be helpful. No wonder our sampling technology remains so imprecise...

Specific Comments

P 2-1, line 11: Change “their” to “particle”, or add “particles” after “Pb” in line 10.

P 2-2, lines 13,14: It might be helpful to provide a few examples here of the recent or pending Pb emissions reductions, or at least a pointer to Appendix 2B.

P 2-3, lines 13 and generally in this paragraph: Since you have previously emphasized the considerable emissions reductions since the 2008 NEI, why not use the past tense consistently (as in the last sentence of this paragraph), or “...largest source sector emitting Pb into the atmosphere in 2008 was aviation gasoline...”, etc.

P 2-3, line 14: A minor point, but combining mining and metal working into a single category seems a bit odd, and makes for an awkward following sentence, in which fuel combustion is identified as the second largest source category. I wonder if you might instead say something like “Following avgas, which accounted for almost 60% of 2008 Pb emissions, the general metal working and mining, fuel combustion and miscellaneous source categories each contributed 10% to 15% of the 2008 total.”

P 2-5, line 13: Would it be possible to provide some indication of how large these pending emissions reductions will be?

P 2-6, lines 15-28: This separate CAA Section 231 review process is interesting and unusual, and would seem to emphasize the importance of the recently initiated airport Pb monitoring. If any exceedances were observed in that monitoring (and/or given the results of the recent Miranda et al. (2011) study), it would seem impossible for EPA to conclude that avgas could not be reasonably anticipated to endanger public health. Hopefully it will be possible for EPA to report any available results from the recent airport monitoring in a subsequent PAD.

Miranda, M.L., R. Anthopolos, and D. Hastings (2011) A Geospatial Analysis of the Effects of Aviation Gasoline on Childhood Blood Lead Levels, *Environmental Health Perspectives* 119: # 10, 1513-1516.

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P 2-7: lines 3-8: Could you provide a quantitative indication of the reduction (in tons or %) of NASCAR Pb emissions that have resulted from switching to unleaded fuels in the “major” race series? Is there some schedule for elimination of Pb fuels for the remaining “minor” race series?

P 2-7, lines 21 and 28: Can you provide averaging times for these concentrations?

P 2-7, line 33: You could add “historical” before “sources”.

P 2-11: There seems to be a slight discrepancy (airport monitoring sites in TX) between the airport monitors indicated in Figure 2-2 and in Figure 2.4. Remind me why airport monitoring is not required at airports emitting > 1 ton?

P 2-12, line 15: Seeing the words “accessible” and “AQS” in the same sentence always brings a smile.

P 2-13, line 20: Has any such additional monitoring been required by the Regional Administrators?

P 2-16, lines 1-3: But presumably some airport sites were operational on or before 12/27/11 and have now collected a year – or at least multiple 3-month periods – of data, which would be of great interest to see in the next PAD.

P 2-16, Figure 2-4: As noted previously, the airport monitor in eastern TX in Fig. 2-4 is not indicated in Fig. 2-2, and a northern TX airport monitor in Fig 2-2 is not indicated in Fig. 2-4.

P 2-18, line 3: You could add “currently” before “quantified” since IMPROVE Pb analysis was conducted by PIXE prior to 6/1/92.

P 2-18, lines 4-5: The VIEWS reference is currently functional. However VIEWS is no longer funded or updated (except for the IMPROVE database). To assure future functionality, you could change “VIEWS website” and link to “FED website (<http://views.cira.colostate.edu/fed/>)”.

P 2-18, line 5: You could add “currently” before “operated” since IMPROVE did not operate on a 1-in-3 day schedule prior to 2000.

P 2-18, lines 7-13: To fix several small inaccuracies, I suggest replacing these 3 sentences with: “The original IMPROVE network began sampling in 1988, with 36 monitors located in or near “Class I” federal areas (including National Parks and Wilderness Areas, which are afforded special visibility protection under the Clean Air Act). The network underwent major expansions in in the early 1990s and 2000s, and currently includes 110 sites located in or near Class I visibility areas, virtually all of these being rural. Approximately 60 additional “IMPROVE protocol” sites at various urban and rural locations, requested and funded by various parties, have also been included as part of the IMPROVE network (Figure 2-6).”

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P 2-19, line 17: As noted in comments on the 3rd draft ISA, I think the term “TSP” is vaguely defined, and used to mean many different things. In this case an “alternative TSP” sampler would not collect the same TSP as the current “Pb-TSP” FRM sampler. If it did there would be no need for it. To clarify the intended meaning, I suggest adding a text box with wording something like: TSP is an acronym for Total Suspended Particles, an hypothetical and un-measurable concept. In this document, we use the term TSP to mean “particles with the size characteristics of those collected by the high volume (Hi Vol) TSP sampler” and Pb-TSP to mean “Pb in particles collected by the Hi Vol TSP sampler”. When referring to alternative existing or future samplers with an upper 50% particle cut size larger than 10 microns, but not identical to the Hi Vol TSP sampler, we use the term “TSP” in quotes.

P 2-20, line 7, or elsewhere: This might be an appropriate place to add discussion similar to that recently added to the ISA suggesting that there is some convergence between the practical limits on largest particle cut sizes for size-selective sample technologies and the upper size limits for spatially representative sampling of “airborne” particles that remain suspended for more than a few seconds. For example on page 3-67 of the ISA:

The relevant particle size distribution for ambient sampling is smaller than the size distribution of the settled dust. Particles larger than about 20 µm are generally considered too large to be transported for more than a few seconds under typical conditions... It follows that 15 to 20 µm may be a practical limit for both good sampling data quality and representative sampling in a limited area.

P 2-22, lines 18-21 and 32-33: Hopefully some of this new data can be presented in the next PAD. While 3 years of data may be needed to develop complete design values for the new monitors, exceedances of the NAAQS could be observed with as few as 3 months of data – and would be informative to see as (or if) they occur.

P 2-24, Figure 2-8: Use of a lower scale (max of 1 µg/m³) would help, if feasible.

P 2-28, lines 6, 7, and Figures 2-11 to 2-13: Could “previous source-oriented sites” be defined? Assuming this means “sites near sources which have shut down”, the implication is that this second highest concentration category (where it appears some sites are approaching the NAAQS) would seem to be heavily influenced by fugitive emissions of historically deposited Pb. Or is it possible this category includes Pb sources that have changed operations or controlled emissions below some threshold level? Could the category include sources that were shut down during the 2009-2011 period?

P 2-28, line 9: Switch “additional” and “indicate”.

P 2-28, line 15: Change “Pb” to “Pb-TSP”.

P 3-34, line 1: Delete the “0” before “air”.

P 3-34, line 2: Change “at” to “near”.

P 3-34, line 5: Maybe change “arises” to “originates” to make it clear you’re not necessarily talking about dust suspended in the air.

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P 3-35, line 1: I must be missing something, but can't understand how controls could reduce ambient concentrations by 75%, but only reduce outdoor dust concentrations and loading rate by 50% - unless maybe dust concentration and loading rate were "measured" by methods that included larger particles (from resuspension of historical Pb deposits) than the ambient air sampling measured.

P 3-36. Line 4: Add "Pb" before "occurring".

P 2-36, line 9: You could add "spatial patterns and" before "documented reductions".

P 2-37, lines 5-27: This is a nice summary, but the little bit of discussion of rates of soil Pb decline as a function of distance from sources like roadways or smelters reminds me that the general topic of Pb gradients (soil, dust, or ambient air concentration) near sources, is not much discussed in the PAD or ISA – but could be useful in terms of exposure assessments, monitor siting, etc. This is also a subject area where some modeling – evaluating concentration and deposition patterns of different particle sizes – could be informative. Maybe next review cycle...

P 2-38, line 12: Can you report how far from the road this "greater distance" was?

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Dr. Ian von Lindern

Comments on the 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.

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?

The Introduction provides a clear and concise description of the new Integrated Science Assessment/Risk and Exposure Assessment/Policy Assessment (ISA/REA/PA) process; providing the purpose, background, history, and scope of the review and summary of the document's organization and structure. It is well written and does avoid excessive jargon, so as to be readable and understandable to a general audience.

However, I believe it overdoes the conclusion that no information justifying reconsideration of the NAAQS has accumulated in the last five years, without caveats to convey the level of uncertainty and lack of information in some areas important to consider in the formulation of US lead regulatory policy.

PURPOSE AND SCOPE: The PA does indicate one purpose is to "bridge the gap" between the scientific assessments in the ISA and REA, but a concise description and purpose and scope of the ISA and REA would be helpful. With regard to purpose, my understanding in reading the PA, is that analysis and synthesis are limited to the question as to whether any information has accumulated in the previous 5 years that would prompt reconsideration of the primary and secondary NAAQS; and that, in turn, is limited to indicator, averaging time, form and level.

The general conclusion is that no new information has surfaced through the ISA process that would prompt reconsideration of the indicator, averaging time, form and level. I would generally agree with that conclusion.

However, this conclusion should be conveyed with an assessment of the adequacy of the old information. With respect to health effects, large volumes of new information have come forward to supplement an already rich database. However, for other areas there are significant unknowns and uncertainties associated with the lack of information available for the last review. Those inadequacies and uncertainties should be conveyed to policy makers. A finding that no new data have come forward to assist in reviewing the previous decision based on a paucity of information - sends a different message to policy evaluators, than stating that the new studies don't refute the analysis of the existing database.

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With regard to scope, the PA uses the term to accentuate that lead is a multimedia contaminant and the scope of the document goes beyond air. The ISA and REA extend to other media that are impacted by or impact air lead, and project and integrate the effect of lead exposures from other media on human and ecological receptors. This is appropriate and necessary to effectively evaluate the role and impact of air lead regulation and is accomplished in the context of the other media. Apparently, this is in contrast to other priority pollutants as the PA notes.

However, with respect to subject area and geography, the ISA and PA are limited in scope, both in contrast to the former CD/ Staff Paper process; and with respect to the potential impacts of policy decisions to other components of the environment and beyond the US. These limitations are not conveyed in the PA.

With regard to the ISA, it is not clear in the PA that the ISA is limited only to exposures and data sources considered currently relevant to the US population. And that the significance of new studies is assessed only as to how these relate to conclusions drawn in the past review; and then only to studies in the peer reviewed literature. This has resulted in an ISA that is more than 70% dedicated to toxicology, health effects, bio-kinetics, and causal determinations. These are areas that were data rich in the last review, and continue to produce volumes of new peer reviewed information. In contrast, in areas where the least is known and EPA relies on past findings, uncertainty is becoming greater as the existing information becomes outdated; and some areas important to policy determinations have been eliminated from the review and no information is assessed or conveyed.

The areas of great uncertainty include any consideration of information relative to the production, use, and disposition of lead in the US. The last CD noted that lead use in the US by 2006 was nearing the record levels observed during the tetra-ethyl lead gasoline-additive years. Demand for lead for in batteries and electronics is ever increasing. Lead prices have been at record highs despite the global recession. Where the previous CD contained and acknowledged inadequate data on production, use, and disposition of lead in the US – the ISA doesn't mention it, not even as background discussion.

With regard to the REA, the purpose is not described in the PA; but there is an indication that both the staff and CASAC felt a new REA was not warranted. However, the PA fails to note that the 2006-8 REA was less than ideal. The 2006-8 REA was based on modeling exercises; that necessarily had high levels of uncertainty, due to the paucity of production, monitoring and emissions data. As no potentially useful new model input data were identified in the staff literature search in 2010-11, attempting a new REA would have been superfluous. The policy-makers and evaluators should be informed of this lack of data, levels of uncertainty, and decreasing confidence that the REA is reflective of current conditions. Failure to distinguish between no data and supportive data in these decisions could perpetuate the use of these outdated analyses 5, 10, 15 etc. years in future reviews.

In the previous ISA Draft review, I offered comments regarding the change in procedures from developing CDs and Staff Papers to the current ISA/REA/PA. My opinion was, and remains, that this results in insular and less comprehensive review process. In that regard, the historic discussion fails to note that previous reviews were not so limited, and that EPA policy makers and policy critics were provided with scientifically vetted information regarding the role of lead in US commerce, and data obtained and analyzed from other EPA Offices to use in effecting more comprehensive and holistic

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policy. A 1990 Staff Paper reviewed by CASAC specifically addressed the consistency and impacts of lead regulation across the EPA and other agencies, resulting in a comprehensive inter-agency policy. No such communication is evident in the new process.

The failure to collect and or assess information relative to the production, use and disposition of lead in US commerce, and the decision to exclude globally representative exposures, precludes the Agency from considering the effects of policy decisions in media other than air, and beyond the boundaries of the US.

As a result, it is inaccurate to indicate that no new information has accrued relevant to the impact of US air lead policy on exposures, health effects, and health and economic damage outside the US. It is more accurate to say that new ISA/PA process excludes consideration of impacts on populations outside the US; that these studies, databases, and other potentially pertinent information was not sought, assessed, nor reported on by the Agency; and that this is a significant change from previous NAAQS reviews.

It would be more comforting to know that information relevant to consideration of the potential harm done overseas by US policy with regard to lead in the air, other media and commerce regulated by the EPA is being vetted, and used somewhere within the Agency to acknowledge or alleviate global suffering.

Historically Emitted Lead is given special consideration in both the ISA and the PA as a residual contaminant in various media, a source of potential emissions, a potential steady-state component of different ecosystems, and a continuing exposure to humans. There is considerable discussion dedicated to the reduction of lead in air and other media in the US over the last four decades.

The analysis notes significant reductions and attributes the decline to various factors. Most of the decline in emissions and ambient air exposures was achieved through the elimination of tetra-ethyl lead gasoline additives. Another major component was substantial decreases in emissions from primary and secondary smelters, and metals processing industries. In the case of gasoline-related emissions, these ceased and other non-lead products were substituted in commerce. This resulted in decreased lead emissions and health and environmental effects in both the US and globally.

In the case of lead production and secondary recovery, however, this production and recovery were exported overseas. The ISA analyses extensively noted the declines in air lead concentrations and past accumulations in soils, sediments and other sinks. However, there is no mention, consideration or assessment of the impact of the “avoided emissions” in their new locales, much of which may be sequestered in repositories in the US, or exported and released in other countries. The ISA and PA did note that these excessive emissions in Asia are detectable in the US, and that contaminated cocoa beans have been observed from Africa, but not at health significant concentrations.

However, in the developing world, these emissions are of considerable significance and, too often, have tragic health consequences. Much of the lead produced in these countries, finds its way to US consumers, is eventually disposed of back to the developing countries; setting up a recycling of exposure. It seems that EPA policy makers should be made aware that these conditions result from the

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same policy decisions so favorable to US population and the environment, if for no other reason than to convey the findings to other regulatory or legislative functionaries.

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Dr. Gail Wasserman

Comments on Chapter 3

(1) How well do sections here map onto conclusions and evidence of ISA?

Sections on both “Public Health Implications and At-Risk Populations” and “Concentration response functions for child IQ decrements” are clearly written, and these sections map well onto the information presented in the ISA.

Smaller edits

P3-28 L 22 “behavioral [and] physiological factors”

P 3-31 L 19. Differences between black and white individual betoken racial, and not ethnic backgrounds. Differences across subgroups of Hispanics would be “ethnic” differences. The most general way to aggregate these comparisons would be to refer to “different racial or ethnic groups” in L 19.

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Dr. Michael Weitzman

Comments on Chapter 3 - Health Effects and Exposure/Risk Information

In my opinion this is an extremely good chapter, and my comments and suggestions are largely editorial or minor in nature.

3-1, line 17 and 18: should the order be changed to “gastrointestinal tract and the respiratory system” as most absorption is via the GI tract although the focus of our work is on ambient air lead?

3-1, line 19-21: This sentence, I believe, is unclear.

3-2, line 19: substitute “one” for “a”

3-2, line 28: I suggest changing “current maternal exposure” to “...to exogenous sources of lead during pregnancy.”

3-2, line 31: after “umbilical cord” change wording to “which is representative of newborn blood lead levels”

3-3, line 16: do we know when blood lead levels begin to rise in infancy...I believe it is usually stated that they begin to rise around age 6 months but I am not sure of this.

3-3, line 24: can we cite specific national, i.e. CDC, HUD, EPA, and international health agencies ?

3-4 I have difficulty understanding Figure 3-1

3-5, line 21: I suggest adding “or lead contaminated soil”

3-8, line 14: I suggest adding “their more rapid respiratory rates

3-8, line 27: Mention is made of Table 3-1, I believe the Table should be moved up several pages.

3-14, line 10: Is it possible to estimate the % of blood lead from air by age or to mention that this is not possible to do because of multiple variables, including the intensity of exposure to other sources?

3-14, line 27: I suggest adding “strengthens and extends” conclusions.....

3-16, line 13: do we intentionally mean “is associated with” here or should it be “causes?”

3-21 Under **Measure** some are bolded and others are not bolded—it is unclear to me is this is due to footnote C *Studies discussed in ISA....*

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3-23, line 16: I suggest changing “One exception” to “In addition, one...”

3-27, line 5: I suggest adding after population IQ “and neurocognitive and behavioral”

3-27, line 19: do we mean to say “associated with” or should it be “causes?”

3-29: should we mention very low birth weight, in utero cocaine, heroin, alcohol or tobacco exposure, or head trauma as examples of potentially vulnerable populations, or populations for which we currently have no data regarding the possibility of heightened vulnerability?