UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

September 6, 2006

EPA-CASAC-06-010

Honorable Stephen L. Johnson
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Subject: Clean Air Scientific Advisory Committee's (CASAC) Review of the 2nd Draft Lead Air Quality Criteria Document

Dear Administrator Johnson:

In June, EPA's Clean Air Scientific Advisory Committee (CASAC), supplemented by subject-matter-expert Panelists — collectively referred to as the CASAC Lead Review Panel (Lead Panel) — reviewed EPA's *Air Quality Criteria for Lead (Second External Review Draft), Volumes I and II* (EPA/600/R-05/144aB–bB, May 2006) (2nd Draft Lead AQCD). The CASAC's report to you on this subject is found in a letter (EPA-CASAC-06-008) dated July 26, 2006. In this letter, the CASAC had requested to review an updated version of the integrative synthesis (Chapter 7), which was only available as a first draft in the 2nd Draft Lead AQCD, and the Executive Summary. The CASAC Lead Panel met in a public teleconference on August 15, 2006 to review these updated documents.

The Lead Panel found the two documents much improved, in response to the Panel's previous recommendations. The Panel was pleased to see that the integrative synthesis chapter was revised to include a discussion of the science to be considered for setting both the primary and the secondary lead standards, and that the integrative synthesis was reordered in the Lead AQCD to follow the environmental effects chapter. The Lead Panel also agreed that the newly-available study by Schober *et al.* regarding lead-related mortality that was submitted by EPA's Office of Research and Development (ORD) for the Panel's review was important enough to be incorporated into both the integrative synthesis chapter and the Executive Summary of the Lead AQCD. However, the study should be included with the appropriate caveats, as discussed in the Lead Panel's teleconference and in individual comments of the panelists. The Panel also felt that the Schober *et al.* paper should be mentioned, once again with appropriate caveats, in Chapter 6 (Epidemiologic Studies of Human Health Effects Associated with Lead Exposure).

Furthermore, the Panel felt that the interaction between air quality standards and the large reservoirs of lead in other media such as water, soil, dust, plants and food, should be discussed in

the Executive Summary in relation to Figure 7-1 regarding principal pathways of lead from the environment to human consumption. In addition, the Panel notes that multimedia exposure pathways are critical for the determination of projected human subject lead levels. Therefore, a discussion of this topic, as well as Figure 7-1, should be included in both the integrative synthesis chapter and the Executive Summary. Finally, the CASAC recommends that a number of changes be made to the ecological section of the Executive Summary in order to more clearly state the important findings of the Agency (see Lead Panel members' individual review comments, particularly those of Dr. Andrew Friedland and Dr. Paul Mushak).

The Panel members agreed that the Lead AQCD will be adequate for rulemaking after EPA incorporates the above recommendations and also makes a good-faith effort to address Panel members' suggested changes as found in their individual review comments. The CASAC Lead Panel was pleased to complete the review of the 2nd Draft Lead AQCD and looks forward to the review of the 1st Draft Lead Staff Paper. As always, the CASAC wishes the Agency staff well in this important endeavor.

Sincerely,

/Signed/

Dr. Rogene Henderson, Chair
Clean Air Scientific Advisory Committee

Appendix A – Roster of the Clean Air Scientific Advisory Committee

Appendix B – Roster of the CASAC Lead Review Panel

Appendix C – Review Comments from Individual CASAC Lead Review Panel Members

Appendix A – Roster of the Clean Air Scientific Advisory Committee

U.S. Environmental Protection Agency
Science Advisory Board (SAB) Staff Office
Clean Air Scientific Advisory Committee (CASAC)

CHAIR

Dr. Rogene Henderson, Scientist Emeritus, Lovelace Respiratory Research Institute, Albuquerque, NM

MEMBERS

Dr. Ellis Cowling, University Distinguished Professor-at-Large, North Carolina State University, Colleges of Natural Resources and Agriculture and Life Sciences, North Carolina State University, Raleigh, NC

Dr. James D. Crapo, Professor, Department of Medicine, National Jewish Medical and Research Center, Denver, CO

Dr. Frederick J. Miller, Consultant, Cary, NC

Mr. Richard L. Poirot, Environmental Analyst, Air Pollution Control Division, Department of Environmental Conservation, Vermont Agency of Natural Resources, Waterbury, VT

Dr. Frank Speizer, Edward Kass Professor of Medicine, Channing Laboratory, Harvard Medical School, Boston, MA

Dr. Barbara Zielinska, Research Professor, Division of Atmospheric Science, Desert Research Institute, Reno, NV

SCIENCE ADVISORY BOARD STAFF

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Appendix B – Roster of the CASAC Lead Review Panel

U.S. Environmental Protection Agency
Science Advisory Board (SAB) Staff Office
Clean Air Scientific Advisory Committee (CASAC)
CASAC Lead Review Panel

CHAIR

Dr. Rogene Henderson*, Scientist Emeritus, Lovelace Respiratory Research Institute, Albuquerque, NM

MEMBERS

Dr. Joshua Cohen, Faculty, Center for the Evaluation of Value and Risk, Institute for Clinical Research and Health Policy Studies, Tufts New England Medical Center, Boston, MA

Dr. Deborah Cory-Slechta, Director, University of Medicine and Dentistry of New Jersey and Rutgers State University, Piscataway, NJ

Dr. Ellis Cowling*, University Distinguished Professor-at-Large, North Carolina State University, Colleges of Natural Resources and Agriculture and Life Sciences, North Carolina State University, Raleigh, NC

Dr. James D. Crapo [M.D.]*, Professor, Department of Medicine, National Jewish Medical and Research Center, Denver, CO

Dr. Bruce Fowler, Assistant Director for Science, Division of Toxicology and Environmental Medicine, Office of the Director, Agency for Toxic Substances and Disease Registry, U.S. Centers for Disease Control and Prevention (ATSDR/CDC), Chamblee, GA

Dr. Andrew Friedland, Professor and Chair, Environmental Studies Program, Dartmouth College, Hanover, NH

Dr. Robert Goyer [M.D.], Emeritus Professor of Pathology, Faculty of Medicine, University of Western Ontario (Canada), Chapel Hill, NC

Mr. Sean Hays, President, Summit Toxicology, Allenspark, CO

Dr. Bruce Lanphear [M.D.], Sloan Professor of Children's Environmental Health, and the Director of the Cincinnati Children's Environmental Health Center at Cincinnati Children's Hospital Medical Center and the University of Cincinnati, Cincinnati, OH

Dr. Samuel Luoma, Senior Research Hydrologist, U.S. Geological Survey (USGS), Menlo Park, CA

Dr. Frederick J. Miller*, Consultant, Cary, NC

Dr. Paul Mushak, Principal, PB Associates, and Visiting Professor, Albert Einstein College of Medicine (New York, NY), Durham, NC

Dr. Michael Newman, Professor of Marine Science, School of Marine Sciences, Virginia Institute of Marine Science, College of William & Mary, Gloucester Point, VA

Mr. Richard L. Poirot*, Environmental Analyst, Air Pollution Control Division, Department of Environmental Conservation, Vermont Agency of Natural Resources, Waterbury, VT

Dr. Michael Rabinowitz, Geochemist, Marine Biological Laboratory, Woods Hole, MA

Dr. Joel Schwartz, Professor, Environmental Health, Harvard University School of Public Health, Boston, MA

Dr. Frank Speizer [M.D.]*, Edward Kass Professor of Medicine, Channing Laboratory, Harvard Medical School, Boston, MA

Dr. Ian von Lindern, Senior Scientist, TerraGraphics Environmental Engineering, Inc., Moscow, ID

Dr. Barbara Zielinska*, Research Professor, Division of Atmospheric Science, Desert Research Institute, Reno, NV

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* Members of the statutory Clean Air Scientific Advisory Committee (CASAC) appointed by the EPA Administrator

Appendix C – Review Comments from Individual CASAC Lead Review Panel Members

This appendix contains the preliminary and/or final written review comments of the individual members of the Clean Air Scientific Advisory Committee (CASAC) Lead Review Panel who submitted such comments electronically. The comments are included here to provide both a full perspective and a range of individual views expressed by Panel members during the review process. These comments do not represent the views of the CASAC Lead Review Panel, the CASAC, the EPA Science Advisory Board, or the EPA itself. The views of the CASAC Lead Review Panel and the CASAC as a whole are contained in the text of the report to which this appendix is attached. Panelists providing review comments are listed on the next page, and their individual comments follow.

Panelist **Page #**

Dr. Joshua Cohen

Dr. Joshua Cohen
September 5, 2006

Comments on Chapter 4

EPA has made a number of clarifications to Chapter 4 (Lead Toxicokinetics and Measurement/Modeling of Human Exposure Impacts on Internal Tissue Distribution of Lead) that greatly enhance the report.

There is one issue that I would encourage the Agency to consider further. Section 4.4.4.2 of the report cites a 1998 paper by Hogan et al. to support the contention that IEUBK model-predicted PbB levels are close to empirically measured values. Although the report notes that Bowers and Mattuck (2001) found the degree of agreement depends on various factors, EPA does not mention or otherwise contend the finding by Bowers and Mattuck that the IEUBK model predictions can substantially diverge from empirically measured PbB values.

More generally, consider the use of the IEUBK model to predict individual PbB values based on child-specific environmental measurements. If the IEUBK model accurately reproduces the GM and GSD PbB values for that population (as reported by Hogan et al., 1998) and if the correlation between the empirical and IEUBK-predicted values is less than perfect, then it follows that the low-end PbB values predicted by the IEUBK model will underestimate the corresponding empirical values, while the high-end IEUBK-predicted values will overestimate the corresponding empirical values. A simulation will demonstrate this phenomenon, which may have regulatory implications.

Dr. James Crapo

James D. Crapo, M.D.
Professor of Medicine
National Jewish Medical and Research Center
August 18, 2006

Both Chapter 7 on Integrative Synthesis and the Executive Summary have been substantially revised and have appropriately addressed the primary scientific concerns. Both chapters are ready for closure with regard to the scientific data and issues required for this phase of the Lead Review.

The Executive Summary is well written. The use of bullets provides clarity for the presentation of the primary issues as well as highlighting the primary scientific data relevant to lead air quality standards. My primary recommendation with regard to this chapter is that it would benefit from including an additional section addressing the interaction between air lead quality standards and the large reservoirs of lead in other media such as water, soil, dust, paint, and foods. Multimedia exposure pathways are critical for the determination of projected human subject lead levels. While airborne lead is a small component of this reservoir, it plays a central role in the movement of lead between multimedia and the ultimate exposure of human subjects. This topic needs to be more completely addressed in the Executive Summary to lay the appropriate platform for consideration of the appropriate air quality standard for lead to be done in the subsequent staff paper.

I compliment the EPA staff on preparing an outstanding document summarizing a very complex field.

Dr. Andrew Friedland

Andy Friedland, Ph.D.
Dartmouth College
16 August 2006

Brief specific comments related to the Executive Summary and Chapter 7 (Synthesis Chapter) made after the 15 August 2006 conference call

Executive Summary

Page E-15, lines 32 forward: Methodologies Used in Terrestrial Ecosystem Research. We really need to ask how much of this section on methods belongs in the Executive Summary. I would say maybe one or two bullets including the material on BLM, but not all of this.

Page E-16 lines 28-29: I want to draw attention to these lines as an important place to reorder the sources of Pb based on the new information presented in the new table in Chapter 2. These lines currently read: waste incineration first and coal-fired power plants last.

Page E-16 lines 35-39: We discussed this bullet as one that could be shortened or deleted. I recommend that it read:
"Dry deposition can account for anywhere from 10% to 90% of total Pb deposition. Because CAA Legislation has preferentially reduced Pb associated with fine particles, relative contributions of dry deposition have changed in the last few decades."

Page E-17 line 18: "had" should be changed to "have".

Chapter 7

Page 7-86 lines 29-30: I want to draw attention to these lines as an important place to reorder the sources of Pb based on the information in Chapter 2. These lines currently read: waste incineration first and then metal smelting and production…."

Page 7-88 line 8: "After deposition, most all Pb species are…." DELETE "all".

Dr. Robert Goyer

Robert Goyer, M.D.
August 18, 2006

The Integrative Synthesis Chapter (Chapter 7) is an accurate and comprehensive synthesis of the 2nd draft of the Lead-AQCD update, particularly if comments make by various panel members at the 8/15 teleconference are incorporated into the chapter. The integrative synthesis of the Toxicological Effects of Lead as contained in chapter 5 is appropriately summarized in Chapter 7. The major health effects are accurately presented particularly with emphasis on the neurological, cardiovascular and renal effects and appropriate recognition of other health effects.

I do not have expertise to comment on the Schober et al. paper but agree that it may introduce a new dimension to the risk of lead exposure. Because of its significance it must be corroborated and the data analyzed by others. I agree with the suggestion that the paper be recognized but only with appropriate caveats.

The second draft of the Lead AQCD with suggested amendments and additions will provide a accurate and up to date scientific basis for future EPA decisions

Dr. Bruce Lanphear

Bruce Lanphear, M.D.
August 21, 2006

Comments on Chapter 7 (Lanphear)

Page 7-15, line 28: It is true that "bone measurements likely constitute a better indication of overall past cumulative exposure history" in adolescents and adults, but this sentence should be modified because it is not a better biomarker in younger children (e.g., < 10 years of age). Indeed, it cannot be measured reliably in these children.

Table 7-3, Page 7-24: The consensus of the CASAC advisory committee was that there was evidence of lead-associated IQ deficits at blood lead concentrations of 5 µg/dL. This table is inconsistent with this consensus.

Page 7-37, line 25-27: A related problem is that the conclusion "possibly as low as 5 µg/dL". This statement is inconsistent with the consensus of the Committee. We indicated that there was evidence of adverse consequences at blood lead levels of 5 µg/dL and, although the data are less certain, there is most likely adverse effects at blood lead levels below 5 µg/dL.

Page 7-59, lines 26-27: The conclusion "and are of likely public health concern" sounds much less definitive than the Committee's consensus. My understanding from the Committee meeting is that "blood lead levels < 10 µg/dL *are a major* public health concern".

Page 7-62: As written, the discussion about the Bowers & Beck manuscript was confusing and inconclusive. The authors should refer to the commentaries by Joel Schwartz and Richard Horning.

7-86, line 13-14: The term "risk-free" is not what was intended by the Committee. Please refer to our August 15th, 2006 conference call minutes for the modified sentence suggested by Fred Miller. This modified sentence should be the concluding sentence and the last sentence (lines 17-19), which doesn't fit in this paragraph, should be deleted.

Comments on Executive Summary (Lanphear)

Page E-8, lines 13-15: The reference to the animal studies should be deleted from this paragraph; it belongs in the subsequent paragraph on animal studies.

Page E-15, lines 6-7: The term "risk-free" is not what was intended by the Committee. Please refer to our August 15th, 2006 conference call minutes for the modified sentence suggested by Fred Miller.

Page E-23: A concluding paragraph(s) would be extremely valuable to help the reader understand the conclusions and implications of the CASAC recommendations. As written, the reader is left hanging.

Dr. Samuel Luoma

Samuel N. Luoma, Ph.D.
U.S. Geological survey (USGS)
August 18, 2006

The updated versions of Chapter 7 and the Integrated Synthesis are both improved. The agency has responded to some of the previous comments made by the panel, especially the editorial comments. But they have not responded to others; perhaps some of the most important. There are also contradictions between the new Chapter 7 and the Synthesis.

From the broadest view, EPA has missed an opportunity in these summaries to characterize what is different between ecological risks of lead vs. other metals; and specifically between atmospheric lead and other sources. I believe our subcommittee comments provided some direction in that regard; to that there was little meaningful response. Characterizing the unique aspects of the ecological risks of (atmospheric) lead could begin a basis for a more informed generation of regulation; this document will not begin that transition. The iterations of this document verify that agency is clearly comfortable with the simplistic source identification and toxicity test approach they have used for decades as the basis for characterizing ecological risk of a chemical; and uncomfortable with advanced testing techniques, models and field evidence (multiple lines of evidence); even though the consensus in the scientific community is that the latter is the only way to address the uncertainties in ALL approaches. Until that changes, we can expect continued uneven treatment of these complex subjects and regulations that are at least sometimes difficult to justify.

As I noted earlier, the report understated the uncertainties in the BLM and AVS approaches. Chapter 7 responded to this by eliminating all mention of the BLM; but the synthesis retains an endorsement of its development. The latter is appropriate under the heading “developing area of research” (this is how AVS should be explained as well); but the summary and the synthesis should be consistent with one another. Some detailed comments have also been ignored. For example, their generic bioaccumulation model (three types of bioaccumulation) is taken from a general metal model, as I noted in my first detailed comments; all three models don't apply to lead. Lead also follows specific detoxification pathways in at least some invertebrates (extra-cellular granule formation - Brown, ~1977). The synthesis does not include recognition of either of these points. This is not the most important flaw, by itself, but it contributes to the general impression that the agency is not especially well informed about important aspects of the ecological risks specific to this element. In short, I don't have any comments to add to those I made in previous additions, other than the feeling of a missed opportunity described above.

Dr. Paul Mushak

CASAC PANEL REVIEW COMMENTS: POST TELECONFERENCE

Paul Mushak, Ph.D.
August 18, 2006

I believe that the Executive Summary and the 2nd Draft of the Integrative Synthesis Chapter 7 (Chapter 8 in the final) — after changes indicated by members in the Panel's teleconference review of 8/15 are made — will be scientifically acceptable and can go forward to complete the updated Pb AQCD.

I also believe the completed AQCD-Pb Update will not only serve as a scientific underpinning for the needs of OAQPS and other Agency offices, but will also serve as the most recent expert consensus treatise for use by the international scientific community.

Recapitulating some of my comments and those of others given Tuesday, for clarification and emphasis:

- The Executive Summary (ExSum) would benefit quite a bit from having EPA's standard lead environmental cycling schematic, now appearing as Figure 7.1, also appear in the ExSum.

- I believe that the ExSum Figure should in fact reflect the nature of "air Pb" as a multimedia pollutant rather than present all "Pb" per se in the Figure. There's a key distinction here. Both the former and the latter obviously have multimedia dimensions, but the former directly addresses ambient air Pb NAAQS assessment.

- A key issue for air lead NAAQS facing OAQPS and the policy makers is the extent to which regulating lead in air, for risks other than from direct inhalation, affects or does not affect the total air Pb-driven exposure picture. Consequently, non-air Pb sources such as paint lead should not appear in the Figure. The Figure legend, however, should make it clear it is basically air Pb-driven.

- The Figure should also be updated to show an arrow to local air Pb from dust Pb re-entrainment.

- Separating the Special Risk groups and the Potential Public Health Impacts from the health effects summaries in the ExSum was a good move. These topics are given better highlighting.

- Chapter 7 should also separate out the public health impacts as a section for highlighting. That is, make public health impacts, especially those impacts on the known risk groups, a new section 7.6.

- Chapter 7, perhaps in the fate/transport and media lead levels section or even in the section on measurement and modeling of human lead exposures as sprung from Chapter 4, should include some Tables on dust lead loadings for both interior and exterior hard surfaces as I did for illustration after the 2/28-3/1/06 CASAC Pb panel meeting. Using equations already in EPA/NCEA documents, such as the '96 EPA Integrated Report for the three-city soil lead abatement demonstration project, one finds that even air Pb levels of 0.1 $\mu g/m^3$ produce dust lead loadings onto surfaces such as floors in children's play areas that will become hazardous in the near term.

- The newly published cardiovascular (CV) epidemiological study by Schober et al. that had considerable discussion presumably could be handled in several ways. The present proposed paragraph insert could include some qualifying statements. I leave that to the regression jockeys on the Panel to thrash out with NCEA. EPA could do an internal reanalysis, but it's doubtful time would allow that, using the data sets relied upon by the authors along the lines discussed. Alternatively, the paper can be treated as something requiring consideration as a factor that may have public health impact without spelling our firm numbers. It could then be evaluated by OAQPS within the confines of new information that, while not quantifiable as to risk enumerations, will qualify as defining a need for "an adequate margin of safety" as spelled out in Sec. 109 of the CAA and the 1990 CAAA.

- The need for replicating this study was noted. That would have to await a comparable data set for analysis, which would in fact be another more recent NHANES survey. NHANES surveys are unique national surveys in that they incorporate blood lead levels within fairly rigid statistical designs and study execution for multiple national health assessments. The only candidate for a new data set is the most recent NHANES data segment, quasi-NHANES 4, spanning the period 1995 to 2004. The Schober group followed 9757 individuals out to 2000 but there was only the single, baseline Pb-B measured in the 88-94 time frame.

- That alternative, however, requires years in the doing. The Schober et al. study did a follow-up of subjects post-Pb-B at a median span of almost 9 years.

- Does any more recent NHANES data set raise the potential biostatistical conundrum that subjects in more recent NHANES testings (post-NHANES 3) will have accumulated lower bone lead burdens and lower lead releases back to blood, given the nature of the CV risk population as to age and exposure history? A null outcome with any newer NHANES survey data analysis would arguably not rule out likelihood that subjects in the Schober et al. analysis had a Pb-B vs. CV mortality association and were presenting with a real risk for CV mortality. The extent to which there is this lead release dependency or latency will depend on the cardiotoxic, vasoactive and vasotoxic mechanisms operating in older humans.

- Some quick comparisons can be made. First, for Schober et al., the youngest subjects would have had the least amount of bone lead accumulation. The youngest subjects in

Schober et al. were 40 years of age. At the midpoint of NHANES 3, i.e., 1991, 40 year olds tested that year were born in 1951. People born in 1951 were still to see the peak of their lead exposures from various lead sources, and certainly from ambient air levels linked to leaded gasoline consumption in the 1960s and 1970s, to, say, 1976. This would be long after their somatic development reached the point, i.e., post-5 years of age, where their bone lead accumulations with net bone formation would exceed bone lead releases from rapid turnover (e.g., O'Flaherty, 1993, 1995, 1998).

- We would expect that even the youngest subjects in the Schober et al. study would have had the opportunity to accumulate significant bone lead burdens and endogenous lead releases over the period 1956 (5 years of age) to 1976, a span of 20 years.

- For the period 1994-2004, a 40-year old at the mid-point would only have had a bit more than half as much time for bone lead accumulation, all exposure factors remaining the same. This might be enough reduction in the lead exposure biomarker variable to reduce its statistical power. On the other hand, it is critical to keep in mind that the shorter time frame of bone Pb accumulation is still capturing many of the high lead exposure years applicable to the subjects in Schober et al.

- The above applies to the youngest age defining a lower bound to bone lead release rates to Pb-B and then any Pb-B vs. CV risk associations. Individuals in all the older age bands, >40 years of age, would have increasingly more overlap of the highest national lead exposure years for both Schober et al. and any newer NHANES data sets. This assumes also that the subject numbers in the age cells used in the NHANES strata are proportionately the same in NHANES III and NHANES IV.

Dr. Michael Rabinowitz

Michael Rabinowitz, Ph.D.
August 15, 2006
Comments on 2nd Draft Pb AQCD

Having reviewed the Executive Summary and Chapter 7, my comments follow:

1- This is a much improved version. It should be sufficient as a basis for the regulation of environmental lead exposure, assuming you have added the few concrete suggestions which I offered previously dealing with earlier chapters, mostly related to blood lead trajectories.

2- It seems like a good time to offer suggestions about future research needs which would improve our understanding of some critical areas. Let me suggest 3.

a) Lead as an independent risk factor for poor child development. Much data has been collected from numerous human studies of lead burden and child development, and more are in the pipeline. In every population, confounders are present. What I would like to see is a clearer exposition of lead as an independent risk factor. Specifically I would like to see the regression model of each study with and without the lead term, to assess the models goodness of fit. Lead could be taken to be an independent risk factor if the model fits significantly better with a lead term added, and also if adding the lead term does not significantly change the coefficient of any of the other risk factors. From this approach we could better see how important lead can be compared to the other risk factors.

b) Transport of soil lead into dust and hence to humans. This topic has been investigated, but since it has become a central feature of human exposure, we would benefit from improved knowledge of those factors which influence the transport of lead by this route: the range, amount, and form of lead. Those factors might be related to the soil type, the chemical and physical forms of the lead pollution in the soil, and a host of meteorological factors such as wind, humidity, and temperature. Factors related to the residence might also be important. We should know more about how much and how far the lead in soil can travel.

c) Lead as a factor in mortality. The recent examinations of the relationship between adult blood lead and subsequent length of life deserve close attention. In that population wide blood leads have fallen by an order of magnitude over the last generation, we should have cause to expect longer lifes. Tobacco smoking is a strong confounder in the general popultion; smoking causes premature deaths from heart disease and cancers as well as elevating blood lead levels. Statistically adjusting for smoking is a usefull tool in examining the popultion wide effects, but let me suggest that to more exactly look at the role of lead as an independent risk factor, we should stratify for smoking and look at the relationship between lead and age at death in a popultion of non-smokers.

3- I must thank my fellow board members who have vigorously applied there varied expertise. Because they have each done so much of the heavy lifting, I found my task was much easier. Thank you.

Dr. Frank Speizer

Dr. Frank Speizer
August 14, 2006

Comments on the Revised Chapter 7 Integrated summary and Executive Summary

In general I found both documents to be acceptable and with additions made ready for closure. I am left with a few minor editorial changes, which are offered simply to add to clarity and set the background straight.

Chapter 7

Page 7.2, line 30. End of historical background. This presents the facts as we heard them, but does not give us any indication as to why, in the face of the data available, the administrator chose not to change the standard. There clearly must be additional information to document going against at least the recommendation to move to a 30 day average from the 120 day average. The statement that air levels were already below the existing standard is part of the answer but it seems incomplete. Perhaps additional administrative historical background should be added. (In the final analysis it may have been a political decision, and if so, so be it. But what we have here is only part of the history.)

Page 7.24, Table 7.3. For clarity I think the labels of effects at 5µg/dl need to be moved down to indicate that they are seen at the 5ug level and are uncertain (?) below that level. That is what the footnote says, but not what might be interpreted by looking a t the table. Ditto for Table 7.4 for blood pressure.

Executive Summary

Page E.2, paragraph beginning line 23: Suggest somewhere in this paragraph indicate that the averaging time for the standard is 3 month. Since this will be a consideration in a revised standard it should be specified here.

Dr. Ian von Lindern

Dr. Ian von Lindern
August 21, 2006

Final Comments of Ian von Lindern re: Executive Summary and Synthesis Chapter

I have reviewed the latest draft of Section 7 and the Executive Summary of the 2nd Draft Air Quality Criteria Document for lead and was a participant in the August 15, 2006 conference call regarding these documents. I believe these Chapters are significantly improved and this document is appropriate to meet the statutory, regulatory and scientific requirements of the criteria process. Dr. Grant and his staff should be commended for a job well done, notwithstanding the difficult schedules and sheer volume of material to be reviewed and synthesized. I concur with the committee's recommendations and consensus agreements reached on the call. My individual comments are minor and editorial.

I would like to see it explicitly stated in the Executive Summary, that the current standard of 1.5 $\mu g/m^3$ Pb is not protective of human health, due to subsequent deposition of lead dusts that accumulate in acceptable amounts in homes (house dust) and soils.

As we were not able to review Chapter 2, I accept Dr. Grant's explanation that references to source and emissions inventories indicated in the Synthesis Chapter and the Executive Summary are consistent with and reflective of modifications made since the June meeting. There were some inconsistencies and caveats suggested for incorporation in the committee's and individual comments that I trust have been addressed.

It might be worthwhile to double check that all points made in the Executive Summary can be found in the Synthesis Chapter, as well, and are traceable to presentation and discussion in the individual Chapters.

I believe a word may be missing in line 3, p E-6.

Perhaps section E-7 could point out that the lead accumulation, residence time and many of the ecological effects resulting from past practices are likely to endure for decades or centuries, may effectively permanently alter ecosystems, and that natural recovery processes will require several human lifetimes.

Dr. Barbara Zielinska

Dr. Barbara Zielinska
August 21, 2006

Comments on Chapter 7 and Executive Summary of Lead AQCD – 2nd Draft

In my opinion, both the 2nd Draft of Chapter 7 on the Integrative Synthesis and the Executive Summary are adequate and can be included in the final version of lead AQCD. I agree with the other Lead Panel's members that the Executive Summary should emphasize the "air lead" as a multimedia pollutant. The inclusion of updated Figure 7-1 in the Executive Summary would be beneficial.

As far as Chapter 7 is concerned, I believe that it is important to list the current sources of lead in the correct order (see also the memo from the Battery Council International regarding this subject). Figure 7-1 should be updated to reflect the importance of soil and dust reentrainment as sources of ambient and inhaled Pb. In the discussion of dry deposition (page 7-7) the size ranges of "very small," "large" and "intermediate" particles should be given. Also, the sentence line 11-13 on this page is not clear – the reference to the original paper or to Chapter 2 where the study is discussed should be given.

NOTICE

This report has been written as part of the activities of the U.S. Environmental Protection Agency's (EPA) Clean Air Scientific Advisory Committee (CASAC), a Federal advisory committee administratively located under the EPA Science Advisory Board (SAB) Staff Office that is chartered to provide extramural scientific information and advice to the Administrator and other officials of the EPA. The CASAC is structured to provide balanced, expert assessment of scientific matters related to issue and problems facing the Agency. This report has not been reviewed for approval by the Agency and, hence, the contents of this report do not necessarily represent the views and policies of the EPA, nor of other agencies in the Executive Branch of the Federal government, nor does mention of trade names or commercial products constitute a recommendation for use. CASAC reports are posted on the SAB Web site at: http://www.epa.gov/sab.