

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

Summary Meeting Minutes of the CASAC’s Public Advisory Meeting

Wednesday, June 28, 2006 – 8:30 a.m. to 6:00 p.m. Eastern Time

Thursday, June 29, 2006 – 8:00 a.m. to 12:00 p.m. Eastern Time

Marriott at Research Triangle Park, 4700 Guardian Drive, Durham, NC 27703

**Meeting to Conduct: (1) Peer Review of EPA’s 2nd External Review
Draft Air Quality Criteria Document (AQCD) for Lead; and
(2) Consultation on Agency’s Draft Lead Risk Assessment Plan**

Panel Members: See CASAC Lead Review Panel Roster – Appendix A

Agenda: See Meeting Agenda – Appendix B

Purpose: The purpose of this public meeting was for the CASAC Lead Review Panel to conduct: a peer review of the Agency’s *Air Quality Criteria for Lead (Second External Review Draft), Volumes I and II* (EPA/600/R-05/144aB–bB) (2nd Draft Lead AQCD, May 2006); and a consultation on EPA’s *Analysis Plan for Human Health and Ecological Risk Assessment for the Review of the Lead National Ambient Air Quality Standards* (Draft Lead Risk Assessment Plan, May 2006).

Attendees: Chair: Dr. Rogene Henderson

CASAC Members: Dr. Ellis Cowling
Dr. James Crapo
Dr. Frederick Miller
Mr. Richard Poirot
Dr. Frank Speizer
Dr. Barbara Zielinska

Panel Members: Dr. Deborah Cory-Slechta
Dr. Bruce Fowler
Dr. Andrew Friedland
Dr. Robert Goyer
Mr. Sean Hays
Dr. Bruce Lanphear
Dr. Paul Mushak
Dr. Michael Newman
Dr. Michael Rabinowitz
Dr. Ian Von Lindern

EPA SAB Staff: Mr. Fred Butterfield, CASAC Designated Federal Officer (DFO)
Dr. Vanessa Vu, Staff Director, SAB Staff Office

Other EPA Staff: Tim Benner, ORD, OSP
James Brown, ORD, NCEA-RTP
J. Michael Davis, ORD, NCEA-RTP
Lester Grant, ORD, NCEA-RTP
Dennis Kotchmar, ORD, NCEA-RTP
Tim Lewis, ORD, NCEA-RTP
Karen Martin, OAR, OAQPS
Thomas McCurdy, ORD, NERL
Deirdre Murphy, OAR, OAQPS
David Orlin, OGC, SWERLO
Zachary Pekar, OAR, OAQPS
Andreas Pfahles-Hutchens, OPPTS, OPPT
Mary Ross, ORD, NCEA-RTP
Jennifer Seed, OPPTS, OPPT
David Svendsgaard, ORD, NCEA-RTP
Kevin Teichman, ORD, OSP
Ginger Tennant, OAR, OAQPS
Lori White, ORD, NCEA-RTP
Lindsay Wichers, ORD, NCEA-RTP

Meeting Summary

The discussion followed the issues and general timing as presented in the meeting agenda (Appendix B).

WEDNESDAY, JUNE 28, 2006

Convene Meeting, Call Attendance, Introduction and Administration

Mr. Fred Butterfield, Designated Federal Officer (DFO) for the CASAC, opened the meeting and the teleconference line at 8:30 a.m., called attendance, and welcomed all attendees. He noted that CASAC is a Federal advisory committee chartered under the Federal Advisory Committee Act (FACA) to provide advice and recommendations to the EPA Administrator. Consistent with FACA regulations, its deliberations are held as public meetings and teleconferences for which advance notice is given in the *Federal Register*. The DFO is present at all such meetings to assure compliance with FACA requirements. Meeting minutes were taken (by DFOs from the SAB Staff Office) for this teleconference. The minutes will be certified by the CASAC (and Lead Review Panel) Chair and made available on the SAB Web site (<http://www.epa.gov/sab>). All Panelists have earlier submitted documentation with respect to possible financial conflicts-of-interest, which was reviewed by a SAB staff member prior to the meeting and found to be satisfactory.

Dr. Vanessa Vu, SAB Staff Director, welcomed and thanked the members of the CASAC Lead Review Panel for taking part in this review. She also thanked the managers and staff from the Agency's National Center for Environmental Assessment (NCEA), Research Triangle Park (RTP), NC.

Purpose of Meeting

Dr. Rogene Henderson, CASAC and Lead Review Panel Chair, briefly stated the purpose of the meeting, which was to conduct a peer review of EPA's 2nd Draft Lead AQCD and a consultation on the Agency's Draft Lead Risk Assessment Plan.

Welcome by EPA's National Center for Environmental Assessment and Summary Presentation on the Major Revisions Incorporated into EPA's 2nd Draft Lead AQCD

Dr. Les Grant, Director of EPA's National Center for Environmental Assessment in Research Triangle Park, NC (NCEA-RTP), gave a welcome from NCEA and also thanked the members of the Lead Panel for their participation in this review. Dr. Grant and members of his staff then gave a detailed presentation that addressed the *Air Quality Criteria for Lead (Second External Review Draft) – Chapter Highlights and Issues*. Panel members engaged Dr. Grant and his staff with questions and answers throughout this overview presentation. (A hard-copy of the NCEA-RTP presentation is located in FACA file for this meeting.)

Public Comment Period

Mr. Butterfield facilitated the formal public comment period. (A summary listing of the public speakers is found in Appendix C.)

- Mr. Lawrence Wiseman, Washington University in St. Louis Interdisciplinary Environmental Clinic – Speaking on behalf of the Missouri Coalition for the Environment and Jack and Leslie Warren, Mr. Wiseman's comments covered three areas: (1) changes in the CDC's level of concern for blood lead concentration over the past quarter century, and the EPA's role in establishing health-based standards; (2) EPA's use of sophisticated models to examine lead uptake via multiple pathways; and (3) protection of at-risk populations living or working near significant stationary sources. On the first concern, Mr. Wiseman noted that the Draft Lead AQCD makes the point clearly that there is no level of lead exposure that can be clearly identified with confidence as safe. Given the importance of reducing lead poisoning, both the EPA and the CDC conclude that prevention of exposure to lead is the only effective means of dealing with lead toxicity — a strong conclusion regarding the importance of maintaining a strict NAAQS for Lead. Their second concern is with the prediction of lead uptake and blood lead levels by mathematical models. The current techniques for the modeling of air lead's effect on population blood lead levels are much more sophisticated than the methods used in the original lead NAAQS. Instead of relying on the outdated linear-slope model used in 1978, EPA has now proposed using models that account for dust loadings, bioavailability, and age-related behaviors. Mr. Wiseman noted that the EPA must use these models as a guide, but not as an absolute predictor, since by themselves, these models do not provide an adequate margin of safety for predicting public health outcomes, and must allow for a

significant degree of error in the outputs from these models. Thirdly, EPA must spend more time addressing the issues regarding specific, significant stationary sources, such as primary and secondary lead smelters, battery recycling plants, and the mining sites, all of which represent some of the high intensity sources for lead. Given the very high concentrations of air lead near emissions sources, young children, who demonstrate mouthing behaviors, are at increased risk for lead poisoning. The EPA must spend more time analyzing these high-risk areas, and must take steps to set Lead NAAQS that provide an adequate margin of safety for children in those areas. (A hard-copy of Mr. Wiseman’s comments is located in FACA file for this meeting.)

- Dr. Craig Boreiko, International Lead Zinc Research Organization (ILZRO) – Speaking on behalf of ILZRO, Dr. Boreiko noted as a general comment that most of that organization’s concerns with the 1st Draft Lead AQCD have not been addressed in the second draft. Their principal comments are as follows: (1) a significant amount of scientific literature is being ignored or relegated to annexes on key issues, including critical reviews and meta-analyses; (2) there is a lack of transparent criteria for evaluation of study quality and relevance, and large sections of the document still consists of narrative reviews that compile within a single paragraph or a single sentence; (3) studies that are of highly-uneven quality; (4) the issues raised by the CDC “effects under ten” working group are ignored, analysis that combines data from IQ studies conducted in different countries, in different assessment methods; (5) ILZRO also sees significant emphasis being placed upon renal effects in the general population; and (6) the latest studies of NHANES III and lead and blood pressure show little relationship between blood lead and blood pressure at the current blood lead levels in the U.S. (A hard-copy of Dr. Boreiko’s comments is located in FACA file for this meeting.)
- Dr. Teresa Bowers, Gradient Corporation – Speaking on behalf of the Association of Battery Recyclers (ABR), Dr. Bowers presented brief comments on two different areas. First, she noted that there is a need for more quantitative information in this 2nd Draft Lead AQCD on the relationship between air lead concentrations, lead and other environmental media, and blood lead concentrations in order to form the basis of the information necessary for the risk assessment that is detailed in OAQPS’ project plan. Dr. Bowers notes that there is some indication in this Lead AQCD that EPA intends to rely on the old blood-lead air-lead slope factor approaches. However, the relationship between air lead and blood lead should not be evaluated with the simplistic slope factor model approaches that were used twenty years ago for a number of reasons. Second, Dr. Bowers commented on the non-linear dose response curves observed between blood levels and IQ. In particular, she issued an appeal to the epidemiological community to look for departures from this shape of a dose-response curve, adding that the 2nd Draft Lead AQCD needs to address these issues. (A hard-copy of Dr. Bower’s comments is located in FACA file for this meeting.)

There was opportunity for questions for the presenter from the members of the Lead Panel following each of public commenter’s presentation.

Summary of CASAC Lead Review Panel Discussion and Deliberations re: the 2nd Draft Lead AQCD

Chapter 7 (Integrative Synthesis)

Since NCEA-RTP staff did not complete the integrative synthesis chapter in time for the release of the 1st Draft Lead AQCD, this was the first opportunity for the Lead Panel to review Chapter 7. Overall, members of the Panel found the chapter to be concise and well-written, although they noted specific issues and concerns with the integrative synthesis that included the following:

- The chapter needs to be amended to include an evaluation of welfare effects of lead as well as health effects. Once this is accomplished, it will be more appropriate to place this chapter following the environmental effects chapter (Chapter 8).
- Agency staff could improve the chapter by standardizing the format in which data are presented, that is, leading with the discussion of human data, then including animal data that either support the conclusions of the human studies or are suitable for extrapolation; and, importantly, by focusing on biologic effects that occur at relatively low levels of exposure to lead.
- The Lead Panel recommends that EPA incorporate data tables that summarize the multi-exposure sources of lead and its multi-organ system effects, to include a table that covers key lead contamination and lead exposure issues, and an additional table that focuses on major dose-response relationships.
- While the neurotoxic effects of lead are appropriately identified as a major concern, given the lower levels of lead exposure and total burdens that are commonly experienced today, this needs to be extended to identify and assess the relative importance of adverse effects on other organ systems at such low-level lead exposures.

Finally, given the importance of this chapter to OAQPS' forthcoming Staff Paper for Lead, the CASAC requested to review an updated version of the integrative synthesis — along with an Executive summary for the Lead AQCD — to be scheduled for Tuesday, August 15, 2007, approximately seven weeks from now — via a public teleconference.

Chapter 2 (Chemistry, Sources, and Transport of Lead)

Overall, the Lead Panel felt that Chapter 2 of the 2nd Draft Lead AQCD represented a significant improvement from the first draft of the document, both in the chapter's content and how it was presented. Specifically, there was an improved discussion concerning the chemistry and physical properties of lead, and its transport and transformation processes that affect migration, deposition and behavior in environmental reservoirs. Nevertheless, the empirical data relating to emissions, production, use, environmental release, and fate of lead are still inadequate; and, additionally, there are numerous references that remain throughout the "Sources of Lead" section that relate to data from prior to 1990. Agency staff need to acknowledge the degree to which they lack up-to-date information in these areas and instead present an evaluation of the emission-related data that are available in order to inform OAQPS' forthcoming lead analysis and risk assessment.

Chapter 3 (Routes of Human Exposure to Lead and Observed Environmental Concentrations)

Similarly, Lead Panel members judged that Chapter 3 had been greatly improved-upon since the 1st Draft Lead AQCD. Specifically, the treatment of the contribution of airborne lead to total body lead burden has been significantly strengthened, although the Panel noted that Chapter 3 would still benefit by the inclusion of a methodology that describes the relative contribution of various sources of lead to dust lead loading, and, additionally, to be able to better understand: the contribution of airborne lead on surface deposition of lead (and, as a corollary, the relationship between airborne lead and oral lead intake); and the degree to which historically-deposited, environmentally-persistent airborne lead contributes to current lead exposures, particularly for at-risk populations. In addition, the primary sources of lead exposure should be more explicitly identified in Chapter 3.

The Panel also commented that the levels of airborne lead are still high compared with those found in the pre-industrial period, although these levels are relatively low by contemporary standards (*i.e.*, since the removal of lead from gasoline). Nonetheless, lead-based paint remains as a major source of lead exposure in at-risk populations, particularly children, and should be given greater emphasis in Chapter 3. Finally, there still remain questions regarding what is really considered a “background” level of airborne lead that the Agency could control.

Chapter 4 (Models of Human Exposure That Predict Tissue Distribution of Lead)

The members of the Lead Panel were noted that Agency staff had also significantly-improved Chapter 4 in the 2nd Draft Lead AQCD, having incorporated Panel members’ on the first draft document. In particular, the chapter contains a much better discussion of lead kinetics with respect to internal dose assessment and, therefore, the lead human-health risk assessment. The discussion of the details of the dosimetry models that are used to predict blood Pb levels was also expanded and enhanced.

However, Panel members noted that the chapter still contains inconsistencies in terminology, numbers, and discussions. Importantly, there is no summary of the salient points in Chapter 4 that should be brought forward into the integrative synthesis (Chapter 7). The discussion of lead particulate inhalation by the uptake route in this chapter remains inadequate, with the deposition fractions cited differing significantly from what current particulate dosimetry models predict for children. Members of the Lead Panel also noted that the chapter does not adequately address uncertainty associated with blood lead levels, which impairs the ability to accurately-predict blood lead levels at current ambient lead exposure levels. Chapter 4 also lacks a discussion of how the Agency would use slope-factor (*i.e.*, epidemiologic) models compared with biokinetic and physiologically-based models.

Chapter 6 (Epidemiological Studies of Human Health Effects Associated with Lead Exposure)

The Lead Panel judged that the revised Chapter 6 is well-written and thorough in its review of the epidemiological health-related literature, and particularly in presenting the limitations of the health-based research studies. Panel members noted that the summaries of each section of the

chapter were use, as well the overall chapter summary in the final section. Members of the Lead Panel discussed whether the epidemiological evidence points to a threshold in blood lead levels below which adverse health effects are not observed, noting that, while there is no evidence of such a threshold, it is also reasonable to state that there is no evidence to say definitively that there is *not* a threshold. Nevertheless, there are clearly significant neurocognitive impacts in young children who have lead blood levels in the range of 1–10 µg/dL, and the weight of the evidence suggests these adverse continue down to blood lead levels at the lowest end of that range (*i.e.*, 1–2 µg/dL).

The Panel also noted that the effects of lead on blood pressure in adults, while small, are highly-consistent and statistically-significant (albeit not always biological relevant) across the breadth of epidemiologic studies. Specifically, as indicated in a 1985 study found in the cardiovascular literature, a national reduction of 1 mm Hg of blood pressure can result in several thousand fewer cardiovascular deaths per year.

Chapter 8 (Environmental Effects of Lead)

The members of the Lead Panel did not feel that the updated version of this chapter in the 2nd Draft AQCD represented a significant improvement over what Agency staff had presented in the first draft of this document. In particular, Panelists advise that this information in Chapter 8 be presented in a way that is more directly relevant to the issue of whether the Administrator should alter the present primary (human health-related) and secondary (welfare-based) Lead standards. It was noted that secondary NAAQS are frequently set as equivalent to the primary standards, and that therefore EPA needs to address the important question as to whether the environmental impacts of lead occur at airborne concentrations of the pollutant that are lower than — or have different indicators, statistical forms, or averaging times than — those that adversely affect human health.

Lead Panel members commented that these negative effects on terrestrial and aquatic ecosystems are not solely due to present ambient lead emissions, but rather in very large measure (*i.e.*, roughly three orders of magnitude) by historically-deposited, cumulative, environmentally-persistent lead that is redistributed in soils, sediments, and surface waters. Accordingly, if EPA maintains a secondary NAAQS for lead that is set equal to the primary Lead NAAQS, this will not provide adequate protection for ecosystems. Furthermore, Panel members noted that present and future monitoring needs are still not adequately addressed in Chapter 8, although Lead Panelists were pleased that the discussion of “Critical Loads” in the 2nd Draft Lead AQCD was improved over what appears in the first draft of the document.

The DFO adjourned the meeting for the day at approximately 6:00 p.m.

THURSDAY, JUNE 29, 2006

Reconvene Meeting, Call Attendance

Mr. Butterfield reopened the meeting and the teleconference at 8:00 a.m., called attendance, and welcomed all attendees back to the second day of the meeting.

Re-cap of Previous Day's Meeting

Dr. Henderson suggested that the Panel move directly into the second day's public comment period, the purpose of which is to permit members of the public who were unable to provide their oral comments on the first day with an opportunity to do so.

Additional Public Comment Period

There were no public commenters on the second day of the Lead Panel's meeting..

Additional NCEA-RTP Comments

Dr. Grant did not have any additional comments, other than thanking Panel members for yesterday's discussions.

Summary of CASAC Lead Review Panel Discussion and Deliberations re: the 1st draft Lead AQCD

Chapter 5 (Toxicological Effects of Lead in Laboratory Animals, Human, and *In Vitro* Test Systems)

Lead Panel members felt that this chapter had been improved significantly over the 1st Draft Lead AQCD, in terms of defining its objectives, chapter organization and inclusion of relevant materials. The one exception to this is the inclusion of the human data in Section 5.3 related to neurotoxicology, in that the introduction to this section does not seem to clearly define what its purpose is in this chapter, especially since it is supposed to provide conclusions for chapter 6 on epidemiological studies of human health effects. Lead Panel members had only several other, relatively-minor issues with this chapter, including the fact that there are some redundancies in the last section (5.11) of the chapter that are not needed in this document, as well as missing units and references.

Summary, Wrap-up, Next Steps and Closing Remarks

The Chair thanked all members of the Lead Panel for their participation in this meeting. She asked that, by no later than Friday, July 7, all Panel members provide their individual inputs for the CASAC's draft/letter report from the Lead Panel's review of the 2nd Draft Lead AQCD to the chapter lead discussants inputs for the draft/letter report from this meeting, with a copy to both her as the Chair and to Fred Butterfield as DFO. In addition, the Chair requested that Panel members send her and the DFO their initial or revised individual review comments, which will be appended to the CASAC's final letter/report for this meeting, by the same date. In turn, the chair requested that chapter lead discussants provide their integrated, summary paragraph(s) for the draft/letter report from this meeting to her by no later than that following Monday, July 10.

Finally, the DFO is scheduling a public teleconference meeting of the Lead Panel for Tuesday, August 15 from 12:00 to 4:00 p.m. Eastern time for the Lead Panel to conduct additional review of the updated Integrative Synthesis chapter and the Executive Summary for the Lead AQCD.

Overview Presentation of EPA's Draft Lead Risk Assessment Plans (OAQPS)

Dr. Zachary Pekar and other staff from EPA's Office of Air Quality Planning and Standards (OAQPS) gave a brief overview presentation of the Agency's *Analysis Plan for Human Health and Ecological Risk Assessment for the Review of the Lead National Ambient Air Quality Standards* (Draft Lead Risk Assessment Plan, May 2006). Panel members engaged Dr. Pekar and his colleagues on the OAQPS staff with questions and answers throughout this overview presentation.

Summary of CASAC Lead Review Panel Consultation on OAQPS' Draft Lead Risk Assessment Plan

Section 3 (Human Exposure and Health Risk Assessment: Overview of Analysis Plan)

The Lead Panel felt that this section provides an appropriate overall general approach to this problem, and that it is suitable for estimating human exposure and health risk assessment. In addition, the case-study approach, initially focusing on three cases that represent particular types of ambient lead emissions and exposure scenario (primary lead smelter, other significant stationary sources and near roadway re-entrainment), is excellent. It is recommended that the introduction include a more detailed discussion of the history of EPA Lead NAAQS revisions including recommendations of previous CASAC groups. It is recommended that this section also include the chronology of international policies on lead air quality standards.

One Panel member also noted that it is clear that the most extensive, complete data sets available to the EPA for risk assessment purposes are those regarding IQ decrements and neurobehavioral endpoints for blood lead levels in children. These data sets are robust, appropriate for modeling for risk assessment, and most relevant to current lead exposures. However, although highly quantitative, the magnitude of change in blood pressure effects is low and its clinical significance questionable. Moreover, renal effects in adults also have substantial uncertainties that reduce the value of this endpoint for risk modeling. Therefore, it is recommended that for pilot analysis, the agency place its primary focus on modeling IQ loss for children. An additional case study that should be considered is modeling the effects of soil in and around residential dwellings since this can serve as a direct source of oral lead exposure for children. Finally, the Panel commented that the modeling approach needs to consider the lead burden in the environmental, both in terms of its historical accumulation and current lead uses that contribute to the lead burden both through air and water emissions.

Section 4 (Human Exposure and Health Risk Assessment: Exposure Assessment)

Overall, the Lead Panel saw no particular problems with the general approach taken. However, it was acknowledged that the Agency would encounter data-availability and -quality challenges, especially in terms of monitored blood lead data. For example, it is expected that the data from the primary lead smelter site (Herculaneum, MO) would be comparatively robust, but that the

other case-study sites would have much more limited empirical data sets. Notwithstanding, it was pointed-out that, although the uncertainties encountered in the current case-study scenarios may prevent definitive conclusions leading to regulatory decision-making (*i.e.*, the establishment of NAAQS for lead), the strategy that OAQPS proposes here will prove only more useful should additional, pertinent data become available in the future,

Section 5 (Human Exposure and Health Risk Assessment: Effects Assessment)

Lead Panel members commented that, in terms of adults, OAQPS has identified two endpoints, blood pressure and the renal. Blood pressure has many epidemiologic and experimental studies, and there are plausible and reasonable mechanisms for adverse effects of low-level exposures to lead. However, with the renal it was noted there are only one or two epidemiologic studies and, furthermore, there have been no defined or reported experimental studies that would suggest a mechanism for such a low-level effect. Thus, the Panel has much less confidence in quantifying risk associated with renal effects.

Section 6 (Human Exposure and Health Risk Assessment: Risk Assessment)

One Panel member noted that the overall plan for the Lead Risk Assessment generally adheres implicitly and explicitly to the usual conceptualization of the four elements in a risk assessment: hazard characterization, dose-response relationships, exposure assessment, and risk characterization. The section of this draft OAQPS document that describes the planned analyses for IQ change in children, blood-pressure risk in adults, and potential renal function change further suggests that these three, really quite-different risks (and risk groups) will be combined in some sort of overall risk estimate. However, no details are provided on how this will be done, which is of concern.

In addition, another Lead Panelist commented that the challenge for EPA will be extrapolating what is learned from the case studies into a generalization of a NAAQS for Lead. From the standpoint of dealing with both the availability of data, the complication of not having “time specific” data on prior exposure (the changes in environmental lead levels would suggest that a different background level would be needed for each cohort for about each 10 years of age), and the different pathophysiological interpretation of exposure of brain, cardiovascular and renal effects by age and different background exposures, it would seem impossible to realistically think about a combined assessment. The Panel member went on to comment that perhaps this is why no model for such was offered.

Section 7 (Human Exposure and Health Risk Assessment: Uncertainty and Variability Assessment)

One Lead Panel member made the following specific comments with respect to this section in Draft Lead Risk Assessment:

- There does not appear to be adequate data to include renal effects in the risk assessment; thus, priority should be given to completing all tasks involving children as a susceptible group before attention is possibly paid to cardiovascular effects in adults.

- In 1990, the CASAC recommended that the averaging time for the Lead NAAQS be reduced from 90 days to 30 days, in order to better address the short-term exposure implications for children’s health. Nothing has changed to alter the recommendation that the averaging time of the standard be based up 30 days.
- There is insufficient time to do a full probabilistic risk assessment. Agency staff have appropriately identified the types of sensitivity analyses that will be useful to provide insights on uncertainty and variability. Similarly, EPA staff are considering Monte Carlo modeling, but again the timeframe for completing the requisite analysis to meet the court-ordered deadline likely precludes these types of analyses.
- OAQPS staff should be aware that the data neither support nor refute that there is a threshold below which adverse effects of lead are not seen. As such, some policy-relevant background is probably going to be needed for the lead risk assessment.
- Predictions of the biokinetic models for some of the case specific pilot-study locations should be compared to predictions from any slope-ratio models that have been developed for these areas. This would help to determine the extent to which the biokinetic models can be applied on a national scale because the slope ratio models can definitely not be extrapolated in this manner.
- Finally, the ecological risk assessment approach needs further refinement. There are too many potential pathways that could be explored, such that staff needs to prioritize their efforts.

Sections 8-9 (Ecological Risk Assessment: Overview of Analysis Plan/Ecological Risk Analysis Plan)

One Panel member commented that he hoped that the draft analysis plan would place greater emphasis on things that are directly relevant to what the Administrator must consider in making a choice about how to establish or modify the Lead NAAQS standard. Another Lead Panelist member cautioned that Agency staff might find areas of the country with sensitive soils and water bodies that might be of concern for ecological effects that may be completely irrelevant or completely disconnected from the scenarios that the Agency selected for human health.

Finally, a third Lead Panel member noted that there is a recent body of literature demonstrating that, although lead is stable in soil, lead-organic matter complexes are not stable and that their mobilization rates are dependent on the mobilization of organic matter. Thus, in the temperate north-central and northeast U.S., organic matter can have a response time of 25-50 years, during which time lead may in fact be mobile. Therefore, this Panelist recommended that OAQPS staff reconsider the section of the Draft Lead Risk Assessment Plan stating that lead is “very stable in soil,” and that, as a result, “these data are probably still the best available for large areas of the country.”

Summary, Wrap-up, Next Steps and Closing Remarks

The Chair thanked all members of the Lead Panel for their participation in this consultation, and asked that, by no later than Friday, July 7, all Panel members send her and the DFO their initial

or revised individual written comments on the Draft Lead Risk Assessment Plan, which will be appended to the CASAC’s final letter to the EPA Administrator acknowledging that this consultative meeting took place.

The DFO adjourned the meeting at approximately 12:15 p.m.

Respectfully Submitted:

Certified as True:

/s/

/s/

Fred A. Butterfield, III

Rogene Henderson, Ph.D.

Fred A. Butterfield, III
CASAC DFO

Rogene Henderson, Ph.D.
CASAC Chair

Appendix A – 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

SCIENCE ADVISORY BOARD STAFF

Mr. Fred Butterfield, CASAC Designated Federal Officer, 1200 Pennsylvania Avenue, N.W., Washington, DC, 20460, Phone: 202-343-9994, Fax: 202-233-0643 (butterfield.fred@epa.gov)

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

Appendix B – Meeting Agenda

**U.S. Environmental Protection Agency
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CASAC Lead Review Panel**

Public Advisory Meeting

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**Meeting to Conduct: (1) Peer Review of EPA’s 2nd External Review
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Meeting Agenda

Wednesday, June 28, 2006

8:30 a.m.	Convene Meeting; Call Attendance; Introductions and Administration; and Overview of Meeting Agenda	Mr. Fred Butterfield, CASAC Designated Federal Officer (DFO)
8:40 a.m.	Welcome & Opening Remarks from EPA Science Advisory Board (SAB) Staff Office	Dr. Vanessa Vu, Staff Director
8:45 a.m.	Purpose of Meeting	Dr. Rogene Henderson, Chair
8:50 a.m.	Welcome from EPA’s National Center for Environmental Assessment (NCEA); Summary Presentation on Major Revisions Incorporated into 2nd Draft Lead AQCD	Dr. John Vandenberg (tentative), Acting Associate Director for Health, EPA-NCEA; Dr. Les Grant, Director, NCEA-RTP; NCEA-RTP Staff
9:30 a.m.	Formal Public Comment Period	Mr. Butterfield (Facilitator)
10:30 a.m.	Break*	
10:45 a.m.	CASAC Lead Review Panel Discussion in Response to Charge Questions on 2nd Draft Lead AQCD – Chapter 7: <i>Integrative Synthesis</i>	Dr. Henderson, Panel Members
12:00 p.m.	Lunch (Hotel)	

Note:

*Periodic breaks will be taken as necessary and at the call of the Chair.

Wednesday, June 28, 2006 (continued)

12:50 p.m.	Continue CASAC Lead Review Panel Discussion on Chapter 7	Dr. Henderson, Panel Members
1:15 p.m.	CASAC Lead Review Panel Discussion on Chapter 2: <i>Chemistry, Sources, and Transport of Lead</i>	Dr. Henderson, Panel Members
2:00 p.m.	CASAC Lead Review Panel Discussion on Chapter 3: <i>Routes of Human Exposure to Lead and Observed Environmental Concentrations</i>	Dr. Henderson, Panel Members
2:45 p.m.	CASAC Lead Review Panel Discussion on Chapter 4: <i>Lead Toxicokinetics and Measurements/Modeling of Human Exposure Impacts on Internal Tissue Distribution of Lead</i>	Dr. Henderson, Panel Members
3:30 p.m.	Break*	
3:45 p.m.	CASAC Lead Review Panel Discussion on Chapter 6: <i>Epidemiologic Studies of Human Health Effects Associated with Lead Exposure</i>	Dr. Henderson, Panel Members
4:30 p.m.	CASAC Lead Review Panel Discussion on Chapter 8: <i>Environmental Effects of Lead</i>	Dr. Henderson, Panel Members
5:55 p.m.	Summary, Wrap-Up and Next Steps	Dr. Henderson
6:00 p.m.	Adjourn Meeting for the Day	Mr. Butterfield

Thursday, June 29, 2006

8:00 a.m.	Reconvene Meeting; Call Attendance	Mr. Butterfield
8:05 a.m.	Re-cap of Previous Day's Meeting	Dr. Henderson
8:10 a.m.	Public Comment Period**	Mr. Butterfield (Facilitator)
8:25 a.m.	Additional NCEA-RTP Comments	Dr. Grant
8:30 a.m.	CASAC Lead Review Panel Discussion on Chapter 5: <i>Toxicological Effects of Lead in Laboratory Animals, Humans, and In Vitro Test Systems</i>	Dr. Henderson, Panel Members

Notes:

*Periodic breaks will be taken as necessary and at the call of the Chair.

**The purpose of the public comment period on the second day of the meeting is to permit any members of the public who were unable to provide their oral comments on the first day with an opportunity to do so.

Thursday, June 29, 2006 (continued)

9:15 a.m.	Break*	
9:30 a.m.	Overview Presentation on EPA’s Draft Lead Risk Assessment Plans from OAQPS	Dr. Zachary Pekar, Office of Air Quality Planning & Standards
9:50 a.m.	CASAC Lead Review Panel Consultation on OAQPS’ Draft Lead Risk Assessment Plans	Dr. Henderson, Panel Members
11:50 p.m.	Summary, Wrap-Up, Next Steps and Closing Remarks	Dr. Henderson
12:00 p.m.	Adjourn Meeting	Mr. Butterfield

Note:

*Periodic breaks will be taken as necessary and at the call of the Chair.

Appendix C – List of Public Speakers

List of Public Speakers

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

Public Advisory Meeting

Wednesday, June 28, 2006 – 8:30 a.m. to 6:00 p.m. Eastern Time

Thursday, June 29, 2006 – 8:00 a.m. to 12:00 p.m. Eastern Time

Marriott at Research Triangle Park, 4700 Guardian Drive, Durham, NC 27703

**Meeting to Conduct: (1) Peer Review of EPA’s 2nd External Review
Draft Air Quality Criteria Document (AQCD) for Lead; and
(2) Consultation on Agency’s Draft Lead Risk Assessment Plan**

#	Speaker’s Name	Organizational Affiliation(s)	Organization(s) Represented (i.e., comments offered on behalf of)
1	Mr. Lawrence Wiseman	Washington University in St. Louis, MO Interdisciplinary Environmental Clinic	Missouri Coalition for the Environment, and Jack and Leslie Warren
2	Dr. Craig Boreiko	International Lead Zinc Research Organization (ILZRO)	same
3	Dr. Teresa S. Bowers	Gradient Corporation	Association of Battery Recyclers (ABR)