

**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**

**Tuesday, February 6, 2007 – 8:30 a.m. to 5:30 p.m. Eastern Time  
Wednesday, February 7, 2007 – 8:00 a.m. to 3:00 p.m. Eastern Time**

**Marriott at Research Triangle Park  
4700 Guardian Drive, Durham, North Carolina 27703**

**CASAC Review of EPA's: (1) Draft Lead Exposure and Risk Assessments  
Technical Support Document; and (2) 1<sup>st</sup> Draft Lead Staff Paper**

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 *Draft Review of the National Ambient Air Quality Standards for Lead: Policy Assessment of Scientific and Technical Information* (1<sup>st</sup> Draft Lead Staff Paper, December 2006) and a related draft technical support document, *Lead Human Exposure and Health Risk Assessments and Ecological Risk Assessment for Selected Areas: Pilot Phase, Draft Technical Report* (Draft Lead Exposure and Risk Assessments, December 2006).

Attendees: Chair: Dr. Rogene Henderson

CASAC Members: Dr. Ellis Cowling  
Dr. James Crapo  
Dr. Douglas Crawford-Brown  
Mr. Richard Poirot  
Dr. Armistead (Ted) Russell  
Dr. Frank Speizer

Panel Members: Dr. Joshua Cohen  
Dr. Bruce Fowler  
Dr. Andrew Friedland (via phone)  
Dr. Robert Goyer  
Mr. Sean Hays  
Dr. Bruce Lanphear  
Dr. Samuel Luoma  
Dr. Frederick J. Miller  
Dr. Paul Mushak  
Dr. Michael Newman  
Dr. Joel Schwartz (via phone)

Panel Members: Dr. Ian von Lindern  
(Cont.) Dr. Barbara Zielinska

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

Other EPA Staff: Dr. Tim Benner, ORD, OSP  
Mr. John Hannon, OGC, ARLO  
Ms. Beth Hassett-Sipple, OAR, OAQPS  
Ms. Marion Hoyer, OAR, OTAQ  
Dr. Tim Lewis, ORD, NCEA-RTP  
Dr. Robert MacPhail, ORD, NHEERL  
Dr. Karen Martin, OAR, OAQPS  
Dr. Deirdre Murphy, OAR, OAQPS  
Mr. David Orlin, OGC, ARLO  
Mr. Tom Pace, OAR, OAQPS  
Dr. Zachary Pekar, OAR, OAQPS  
Dr. Mary Ross, ORD, NCEA-RTP  
Dr. Erika Sasser, OAR, OAQPS  
Ms. Lydia Wegman, OAR, OAQPS  
Dr. Lori White, ORD, NCEA-RTP

#### Convene Meeting, Call Attendance, Introduction and Administration

Mr. Fred Butterfield, Designated Federal Officer (DFO) for the CASAC, opened the meeting and the teleconference line, called attendance, and welcomed all attendees. He noted the 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. He mentioned that six individuals would be making public comments today. Mr. Butterfield said a transcript of this meeting's minutes will be taken and available within 2 weeks after the meeting, however, the Science Advisory Board (SAB) does not certify the accuracy of the transcript. He also said a summary of the meeting will be posted on the SAB Web Site (<http://www.epa.gov/sab/>) within 90 days after the meeting. He noted that all panelists had earlier submitted documentation with respect to possible financial conflicts-of-interest or appearances of a lack of impartiality, which was reviewed by the SAB staff prior to the teleconference meeting and found to be satisfactory.

Dr. Vanessa Vu, SAB Staff Office Director, thanked the CASAC members and the EPA Office of Air Quality Planning and Standards (OAQPS) officials for their participation in the meeting. She acknowledged that two new CASAC members were joining the meeting today, Dr. Armistead (Ted) Russell, Georgia Institute of Technology, Atlanta, Georgia, and Dr. Douglas Crawford-Brown, University of North Carolina at Chapel Hill, Chapel Hill, North Carolina. She also said two existing CASAC members would be retiring from the Committee after 6 years of service, Dr. Fred Miller, Consultant, Cary, North Carolina, and Dr. Barbara Zielinska, Desert Research Institute, Reno, Nevada. On behalf of the EPA Administrator, Dr. Vu presented EPA

Distinguished Service Awards to Dr. Miller and Dr. Zielinska for their SAB CASAC service for the period 2000-2006.

### Purpose of Meeting and Welcome

Dr. Rogene Henderson, CASAC and Lead Review Panel Chair, reiterated Dr. Vu's recognition of the CASAC service provided by Dr. Miller and Dr. Zielinska and thanked them for their distinguished efforts. She also welcomed Dr. Russell and Dr. Crawford-Brown to the CASAC. Dr. Henderson briefly stated the purpose of the meeting, which was to conduct a peer review of the "Review of the National Ambient Air Quality Standards for Lead: Policy Assessment of Scientific and Technical Information (1<sup>st</sup> Draft Lead Staff Paper, December 2006) and the related draft Lead Exposure/Risk Assessment Technical Support Document (TSD), prepared by OAQPS.

Prior to the start of the technical discussion on the 1<sup>st</sup> Draft Lead Staff Paper (Staff Paper) and the related TSD, several CASAC members raised questions about the January 30, 2007, *New York Times* (NYT) article, "Bush Directive Increases Sway on Regulation." The NYT article reviewed a recent amendment to Executive Order (EO) 12866 on Regulatory Planning and Review that requires each federal agency to have a regulatory policy office led by a political appointee to supervise development of rules for regulated industries. Members were concerned that the EO 12866 amendment would compromise their independence in providing advice to the EPA Administrator on regulations. Although a Regulatory Impact Analysis, which includes an economic assessment, is included in all EPA proposed rulemakings, members were concerned, based on the EO 12866 amendment, that the EPA Administrator would soon be considering cost and science in setting National Ambient Air Quality Standards (NAAQS) for criteria air pollutants.

To address some of the CASAC member concerns, Dr. Henderson referred to her January 12, 2007, memorandum to the members that reviewed the implementation of EPA's revised process for reviewing NAAQS and the CASAC Lead NAAQS Review. In the revised NAAQS process, Dr. Henderson stressed that the CASAC must be more proactive than reactive in their deliberations. Some of the specific issues and concerns about the revised NAAQS process expressed by Panel members were:

- CASAC is most valuable in the late stages of Staff Paper development. Has CASAC been removed from the rulemaking process?
- In the revised process, where does EPA staff work end and the policy process begin?
- The Advance Notice of Proposed Rulemaking (ANPRM) allows Agency political views, not Agency staff views, to be known.
- Since 1978, "heavy lifting" (*e.g.*, scientific analysis) has been done by EPA staff in their Staff Papers; with the ANPRM, the CASAC will miss this level of analysis.
- Lead is a unique criteria pollutant and should not be delisted as a criteria air pollutant.

- Lead should continue to be included in the NAAQS rulemaking process. The revised process may make lead more relevant as a regulated hazardous air pollutant, which is less environmentally preferable.

### Overview of EPA's 1<sup>st</sup> Draft Lead Staff Paper and Draft Lead Exposure and Risk Assessment Technical Support Document

Dr. Lydia Wegman, Director, Health and Environmental Impacts Division, OAQPS, and her staff (Dr. Karen Martin, Dr. Zachary Pekar, Dr. Deirdre Murphy, and Ms. Ginger Tennant) provided overview presentations on EPA's Lead Staff Paper and the Lead TSD. Dr. Wegman thanked CASAC members for their earlier comments on the draft Lead Air Quality Criteria Document (AQCD) Work Plan. Responding to CASAC questions, she outlined the court-ordered schedule that governs the completion of the lead NAAQS review. Basically, the Court ordered EPA to issue the notice of proposed rulemaking for lead no later than May 1, 2008, and a final rulemaking notice by September 1, 2008. Dr. Wegman discussed the interim steps in this schedule that included:

- The Lead ANPRM will be published by September 1, 2007; the ANPRM will include two documents: the 2<sup>nd</sup> Draft Exposure and Risk Assessments Lead Report, which will include a full-scale assessment (human exposure and risk), and the Lead Policy Assessment Document, which will include a range of policy options.
- A 60-day ANPRM public comment period and the CASAC review will follow the release of the ANPRM.
- A Final Exposure and Risk Assessments Report will be completed in late Fall 2007.
- A proposed note of proposed rulemaking for Lead is planned for release in early Spring 2008, with a Final Rule by September 1, 2008.

Drs. Martin, Murphy and Pekar, and Ms. Tennant, OAQPS, provided details about the Lead Staff Paper and TSD. They pointed out that the draft Staff Paper is organized around three main parts: characterization of ambient lead (Chapter 2); lead-related health effects and primary NAAQS (Chapter 3-5); and lead-related welfare effects and secondary NAAQS (Chapter 6). The purpose of the Staff Paper is to evaluate the policy implications of the key scientific and technical information contained in the Lead AQCD, and to identify critical elements that EPA staff believe should be considered in the review of the lead NAAQS. The TSD describes the methodology and results of the pilot phase human exposure and health risk assessments and ecological risk assessments for a several case studies. Five case studies were selected for the pilot phase. For the ecological risk assessment, the case studies were supplemented by a national-scale ecological screening risk assessment. In the Staff Paper, the pilot phase methodology and results are summarized in Chapter 4, and the ecological risk assessment methodology and results are summarized in Chapter 6.

### Characterization of Ambient Lead

This section contains data on lead emissions, lead air monitoring, and non-air media lead concentrations. There has been a historic reduction in emissions and ambient air concentrations. Based on a 2002 emissions inventory, the current lead emission levels are 1,600 tons per year from more than 12,000 point sources plus non-point, mobile sources. On a cumulative national basis, the primary lead air emissions are from mobile sources, boilers, and iron and steel foundries. Lead smelters are the next highest source of emissions. On an individual source basis, the metals industry is the primary source of lead air emissions. OAQPS staff cautioned that the National Emissions Inventory (NEI) does *not* include near-roadway re-suspension of soils/dust that may contain historically-deposited lead. Based on the 2003-2005 ambient air concentrations, three sites exceeded the NAAQS for lead. However, it was noted that many of the highest lead emitting sources in the 2002 NEI may not have nearby lead NAAQS compliance monitors.

Lead emitted into the air is distributed to other media; nonetheless, human and ecological exposures are dominated by the ingestion route. Lead is accumulative and lead emitted yesterday (or years ago) can remain available for human and ecological exposure. Re-entrainment and re-suspension of deposited lead contribute to this situation. Lead dynamics in soils and aquatic systems vary, with surface concentrations declining in quiet forest soils and lake sediments. Trends are less clear in systems near lead sources and with energy intensive and turbulent sources.

### Health Effects Evidence

This section assesses key policy-relevant information on the known and potential health effects associated with exposure to lead. It summarizes data contained in the Lead AQCD. There is strong evidence that lead has multiple health effects on a variety of tissues and organ systems, across a range of exposure levels extending well below 10 µg/dL. In this document, blood lead is used as an internal exposure or dose metric. Neurocognitive impacts, specifically decrements in Intelligence Quotient (IQ) in young children, are the focus of the quantitative risk assessment in this review.

### Human Exposure and Risk

The lead risk assessment is being conducted in two phases. The first phase (the pilot) is reflected in this first draft document, the second phase (the full-scale assessment) will be reflected in the second draft, which will be included in the ANPRM. In the pilot analysis, three case studies have been selected: (1) a primary lead smelter (in Herculaneum, Missouri); (2) a secondary lead smelter (in Troy, Alabama); and a near roadway (urban) in Houston, Texas. Additional case studies may be evaluated for the full-scale analysis based on results from the pilot assessment, as well as comments from the public and CASAC. The various steps in the risk methodology were reviewed including media concentrations, modeling multi-pathway exposures, blood lead level modeling, and concentration-response functions (IQ loss modeling).

Based on the risk assessment data contained in the Lead AQCD, two biokinetic models — the Leggett Model (Leggett, *et al.*, 1993) and the Integrated Exposure Uptake Biokinetic (IEUBK) Model (EPA, 1994) — and an empirical model (Lanphear, *et al.*, 1998) were selected for use. In

late January 2007, an error was found in the Leggett-based blood lead modeling completed for the pilot analysis. A “corrected” application of the Leggett model has now been developed with recalculated Leggett results being substantially larger than the IEUBK model results. For a given set of exposures, risk assessment results indicate that the Leggett model will likely generate individual blood lead estimates that are about two- to three-fold higher, and population blood lead percentile distributions about three- to four-fold higher, than the corresponding IEUBK estimates. Rather than regenerating all of the Leggett-based blood lead level and IQ loss estimates presented in the pilot analysis, OAQPS has opted to regenerate a subset of those results. Specifically, they will re-run the Leggett analysis for the Primary Lead Smelter Case Study and update the sensitivity analysis results to reflect the corrected application of the Leggett model. OAQPS noted that all blood lead level and IQ loss estimates on the IEUBK model are not affected by the Leggett model error.

In addition to the Leggett model problem, a data error also was identified in the Lanphear, et al., 2005, Pooled Analysis Study. Specifically, the error involves blood lead concentrations ranges presented in Table 4 from the Lanphear article entitled “Low-Level Environmental Lead Exposure and Children’s Intellectual Function: An International Pooled Analysis,” *Environmental Health Perspectives*, Volume 113, No. 7, July 2005. A corrected copy of Table 4 has been received but the degree to which the errors impact the pilot risk results is not clear without re-running the risk analysis for both the concurrent and lifetime average blood lead metrics. In the full-scale analysis, OAQPS asked that CASAC focus on three areas: (1) characterizing lead media concentrations; (2) exposure analysis; and (3) IQ loss modeling.

### The Primary Lead NAAQS

This section covers the adequacy of the current lead standard and the policy options to be considered in retaining or revising the standard. The current lead NAAQS is  $1.5 \mu\text{g}/\text{m}^3$ , total suspended particulate matter (TSP), with a quarterly monitoring average time and ceiling. Policy options include a wide range of alternatives, including revising the standard in the  $0.5\text{-}1.5 \mu\text{g}/\text{m}^3$  range, TSP, with a monthly monitoring average time or more frequent sampling for shorter averaging times. The upcoming Policy Assessment in the ANPRM will include the adequacy of the current standards, preliminary risk/exposure information for alternative options, and a range of policy options, considering all aspects of the standard setting.

### Welfare Effects and Risk Assessment

This section presents information in support of the review of the secondary NAAQS for lead and an overview of the pilot assessment. Effects evidence indicates that lead may remain in soils and sediments for extended periods of time depending on the type and disturbance level of the ecosystem. However, there is sparse quantitative data on lead-related ecosystem level effects. The pilot analyses identified the potential for ecological risk to various receptors and did not quantify risk. Ecological effects screening values are based on established criteria and methods for soils, surface water, and sediment. Exposure concentrations for total lead in soil, dissolved lead in surface waters, and total lead in freshwater sediments were estimated for the three case studies and the national-scale screening analyses. Pilot analysis results indicate that the potential for adverse effects from air-derived lead exists in all three case studies and in several watersheds identified in the national-scale database. Quantitative ecological analysis will be limited to the pilot results due to the lack of funding.

### Public Comment Period

Six speakers made presentations during the public comment period. Two speakers provided their comments via teleconference, and the remaining four speakers provided their comments in person. Following are some of the specific issues and concerns raised by these speakers.

#### Dr. Dorr Dearborn, American Thoracic Society (via teleconference)

Dr. Dearborn, a practicing medical doctor, member of the Greater Cleveland Lead Advisory Council, and representative of the American Thoracic Society, said the Cleveland, Ohio, area had the highest concentration of lead-toxic children in the United States. Although the lead standard has not been achieved in many areas, Dr. Dearborn said that the primary lead standard should be retained. With more than 28 percent of the children seen in the Cleveland area having blood lead concentrations greater than 10 µg/dL, now is not the time to reverse this health standard. Dr. Dearborn said the American Thoracic Society urges EPA to: (1) retain lead as a criteria pollutant with a lower standard at 0.5 µg/m<sup>3</sup> with an average monitoring time of one month; and (2) improve point source compliance monitoring. Currently, 90 percent of primary lead emitters do not have adequate monitors within one mile of their facilities.

#### Mr. Larry O'Leary, EPA Community Advisory Group, Herculaneum, Missouri (via teleconference)

As a seven-year member of the Community Advisory Group in Herculaneum, Mr. O'Leary asked that EPA go beyond science in reviewing the lead NAAQS standard and consider the "day-to-day" experience of people living within close proximity of primary lead smelters. He urged EPA to retain and lower the lead standard. He pleaded that EPA "don't abandon us" since the lead NAAQS standard is the only leverage people have to confront lead-emitting plants. EPA should lower the lead NAAQS standard to 0.5 µg/m<sup>3</sup>. EPA should realize that property values are significantly affected by lead-emitting plants; hundreds of thousands of people across the country are living with daily exposure from lead-emitting sources at the same time that their property is depreciating.

#### Ms. Kathleen Logan Smith, Missouri Coalition for the Environment

Ms. Smith said that Missouri is the number one source of lead mining in the United States and home to the only primary U.S. lead smelter. Two hundred thousand acres of the Big River watershed in Missouri also are affected by lead pollution. On behalf of the Missouri Coalition, she urged EPA to: (1) retain lead as a NAAQS standard; (2) retain the original NAAQS review process; (3) investigate lead health effects such as Amyotrophic Lateral Sclerosis (ALS), "Lou Gehrig's Disease;" (4) don't rely on technology-based standards, such the Maximum Achievable Control Technology (MACT) Standards to protect people from lead emissions; (5) investigate new sources of lead emissions, such as the soon to be completed, "largest in the U.S." cement plant in Missouri; and (6) in the lead risk assessment, consider children living near lead-emitting facilities.

Ms. Leslie Warden, former resident, Herculaneum, Missouri

Ms. Warden said she and her family lived in Herculaneum for many years. Their house was located within two blocks of the Herculaneum Lead Smelter Plant. Elevated lead emissions from the plant affected every aspect of their family life, including her son whose health has deteriorated due to lead. She said EPA should: (1) reject any suggestion to revoke the lead NAAQS; (2) strengthen the lead MACT requirements; (3) revise the lead monitoring network; (4) align the current lead blood action levels to the Centers for Disease Control and Prevention requirements; and (5) lower the lead NAAQS. This is the only way to lower lead concentrations in communities that are being “bathed” in lead.

Dr. Teresa S. Bowers, Gradient Corporation, representing the Association of Battery Recyclers

Dr. Bowers made several comments about the OAQPS Lead Staff Paper and the TSD. She summarized her comments on these documents as follows: (1) EPA underestimates the impact of historic lead emissions, other lead sources, and general anthropogenic background lead on lead levels in soil in all three case studies; (2) EPA underestimates or ignores the impact of other lead sources on house dust, such as lead-based paint; (3) EPA must clearly distinguish between policy-relevant lead sources versus policy-relevant background; (4) there are a large number of calculation errors in the IQ decrement section of the documents; and (5) the ecological risk assessment case studies provide no basis for a review of the lead NAAQS because none of the case studies relate estimated ecological effects to levels of lead in air.

Dr. Craig Borioko, International Lead Zinc Research Organization (ILZRO)

Dr. Borioko’s comments focused on differences between the OAQPS Staff Paper and the lead AQCD. He said there were a number of conclusions drawn in the Staff Paper that are at odds with data presented in the lead AQCD. One example is how elevated blood lead levels affect the IQ of children. The Staff Paper recommends a blood lead level of 2.5 µg/dL; however, it needs to recognize that the nature of the science and the level of technology do not support this conclusion. Another example of the differences between the documents is the immune system characterizations. There also is an overstatement of the end point of concern between the two documents.

Summary of the CASAC Discussion on the Draft Lead Exposure and Risk Assessments  
Technical Support Document**Chapter 2: Overview of Risk Assessment**

In general, CASAC members thought the overall description of the risk assessment and the technical approach taken was good. However, members had specific questions and concerns about the case study sites and conceptual model for lead human exposure and health risk assessments. Some of these issues and concerns were:

- Why were some of the case study sites chosen? The criteria for selection of some of these sites were not clear.

- The case studies do not go far enough or deep enough technically to adequately provide the scientific basis to review the national standard; more data from other sites are needed to better represent national exposure.
- The conceptual model needs a complete and independent validation. What are the goals for choosing this model? What are the correct inputs? The model needs to be completely defined.
- In the uncertainty analysis, multivariate sensitivity analysis should be used.
- Describe in better detail the strategy used to separate background and source to blood lead levels; specifically, the distribution of this information is unclear.

#### **Chapter 4: Estimates of Media Concentrations**

The CASAC thought there was too much modeling across the case studies to provide reasonable estimates of the media concentrations from these studies. Some of their specific concerns were:

- The dispersion modeling markedly underestimates air lead, monitored versus modeled, as distances increase beyond 0.5 miles from the stack; similarly, for air data results for distances beyond 1.7 miles, the modeled air lead values underestimate the measurement data significantly.
- Media concentration estimations need to be improved; there is a difference between the measurements and the model estimates.
- The dispersion model under captures fugitive emissions.
- Particle size distribution data for lead from point sources need to be added to the models.
- The dust concentration of lead from soil and background is underestimated.
- The portion of inhalation data from direct and indirect sources needs to be better clarified.

#### **Chapter 5: Human Exposure Assessment and Blood Lead Estimation**

The CASAC was supportive of the overall analytical structure of the exposure assessment and blood lead estimation; however, they had various concerns and issues about the models used. Some of these concerns and issues were:

- The construction of the original Leggett model should be reviewed in light of the SAB All-Ages Lead Model (AALM) Review Panel that analyzed various models and their usefulness for EPA's regulatory use.
- The differences in the predictive levels of lead absorption between the Leggett and IEUBK models need to be clarified.

- In the models, the water intake concentrations versus the air intake concentrations need to be better clarified.
- The biological significance of the blood lead value needs to be reviewed and incorporated into the application of these models.
- Protection of vulnerable portions of the sub-population needs to be better analyzed and incorporated into the assessment.

### **Chapter 6: Estimation of Human Health Risk**

CASAC members had questions about inter-comparisons of the predictive capabilities of the models. Some of the specific questions were:

- How was the cut point issue chosen in the models? This issue needs to be better described.
- Some estimates between the models are off by several orders of magnitude; the size of the safety factor in setting of standards needs to accommodate the magnitude of these differences.
- The calculation of how the mean and variances is derived between the models needs to be clarified.
- The expected value for certainty is not zero.

### **Chapter 7: Ecological Risk Assessment**

CASAC members thought this chapter was well written and reasoned. It provides a connection between lead in the atmosphere and ecological risk. Some suggestions for improving the chapter were:

- The chapter would benefit from a clear conceptual model that ties atmospheric lead to terrestrial and aquatic environments.
- Terms need to be clearly defined (*e.g.*, what population of U.S. surface waters do the selected sites represent?).
- The link between sample site results and the intended surface water population is not clear.
- Some information is presented on ecosystem effects but an in-depth evaluation and synthesis is needed to better describe the uncertainties in all the standards.

## Summary of the CASAC Comments on the 1<sup>st</sup> Draft Lead Staff Paper

### **Chapter 2: Characterization of Ambient Lead**

CASAC members found that this chapter had a great deal of information about ambient lead concentrations, along with emissions, loss processes and physical characterization. Some specific comments the members had were:

- Re-suspended dust is a major source of lead contamination and needs to be added to the analyses.
- A more comprehensive characterization of lead levels nationally is needed, as well as a distribution plot of high-end lead concentrations.
- Modeling estimate results are limited and more data needs to be presented.
- Some pie charts would be helpful in describing lead as a multi-media pollutant; airborne lead is only a source. Lead exposure is the result of a combination of sources that include drinking water, diet, and other occupational and household environmental issues.
- There is little in the analyses about what might be a safe or, at least, an acceptable ambient air lead level; some discussion of this issue should be added.

### **Chapter 3: Policy-Relevant Assessment of Health Effects Evidence**

CASAC members agreed that this chapter integrated material from the lead AQCD reasonably well. Organizationally, the chapter allows readers to follow the basis for which endpoints and sub-populations should be focused on in the risk assessment. Some individual member comments were:

- The inclusion of a “hypothetical threshold or cut point” in the pilot quantitative risk assessment is confusing and should be further clarified.
- The shape of the blood lead dose-response relationship is nonlinear, and a log-linear model provides a better fit for the data than a linear one.
- The potential importance of chronic versus acute exposure should not be ignored, and the blood lead metric should not be the only value to consider.

### **Chapter 4: Characterization of Health Risks**

The methodology and results of the pilot phase human exposure and health risk assessments, which are described in the TSD, are summarized in this chapter. CASAC discussion on the TSD will not be repeated here. Nonetheless, some additional member comments were:

- Examine additional case studies and air quality scenarios; the case studies and scenarios described had limited data.

- Data generated using the biokinetic models need to be consistent with epidemiologic data.
- Blood lead levels below 1 µg/dL should be examined for additional benefits because the NAAQS standard is intended to provide a margin of safety.

### **Chapter 5: The Primary Lead NAAQS**

CASAC members found that this chapter systematically reviews the basis for the 1978 lead standard but does not provide enough current information about lead exposure problems. Some issues and concerns expressed by members were:

- New information about the risk of neurological effects to the fetus and possible developmental effects during the neonatal period from lead in maternal milk has been identified and need to be included.
- New information about lead effects on other organ systems, such as the immune system, skeletal system and reproductive system, should be included.
- The difference between “evidence based” and “quantitative exposure—and risk-based considerations” is confusing and needs to be clarified.
- There is ambiguity as to what is meant by a “maximum arithmetic mean;” the term needs to be defined.

### **Chapter 6: Policy Relevant Assessment of Welfare Effects**

This chapter presents information in support of the review of the secondary lead NAAQS. The ecological risk assessment methodology and results, which are described in the TSD, are summarized in this chapter. CASAC discussion on the TSD will not be repeated here. Nonetheless, some additional member comments were:

- Indicators of the trajectory of lead in the environment, such as the accumulation of lead in ocean sediments, need to be considered.
- As air lead emissions decrease, more attention through indicators and monitoring needs to be made on lead contamination in soils and sediments.
- More data on the link between atmospheric disposition and remote lake sediment would improve the uncertainty estimate of lead in soil and sediments.

### Summary and Next Steps

EPA revised the process for reviewing the NAAQS and the Panel Chair suggested that members take a more proactive role in making recommendations to the EPA Administrator on revising the lead NAAQS. To support this proactive role and prepare an integrated CASAC recommendation to EPA prior to the release of the lead ANPRM, the Chair asked members to form four subgroups (*i.e.*, Preamble, Primary Standard, Secondary Standard, and Indicator/Monitoring) to

draft clear, concise, and scientifically based recommendations. The DFO proposed that the subgroups submit to the Chair and himself their draft recommendations by February 16, 2007, in the form of a section for the CASAC letter to the Administrator on the lead NAAQS. A public CASAC Lead Review Panel teleconference will be held in early March to review an integrated version of the draft CASAC subgroup recommendations. A copy of these draft recommendations will be posted on the SAB Web Site prior to the teleconference. Following the teleconference, a final draft version of the CASAC recommendations will be distributed to members for review, with an expected submission of the letter to the Administrator by late March.

The DFO adjourned the meeting at approximately 2:00 p.m. on February 7, 2007.

**[Update:** The CASAC Lead Review Panel met via a public teleconference on Friday, March 9, 2007 to review and approve the CASAC's draft letter to the EPA Administrator resulting from its February 6-7, 2007 meeting to conduct a peer review of the Agency's 1<sup>st</sup> Draft Lead Staff Paper and Draft Lead Exposure and Risk Assessments technical support document. The CASAC's final letter/report (EPA-CASAC-07-003, dated March 27, 2007) from the CASAC Lead Review Panel's February 6-7, 2007 meeting was transmitted to the Administrator on March 27, 2007, and was posted on March 29, 2007 on the SAB Web site at the following URL: <http://www.epa.gov/sab/pdf/casac-07-003.pdf>.]

Respectfully Submitted:

Certified as True:

/s/

/s/

*Fred A. Butterfield, III*

*Rogene Henderson, Ph.D.*

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Fred A. Butterfield, III  
CASAC DFO

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Rogene Henderson, Ph.D.  
CASAC Chair

Date: April 17, 2007

## Appendix A – Roster of the CASAC Lead Review Panel

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### 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**, Research Associate Professor of Medicine, Tufts University School of Medicine, Institute for Clinical Research and Health Policy Studies, Center for the Evaluation of Value and Risk, Tufts New England Medical Center, Boston, MA

**Dr. Deborah Cory-Slechta**, Director, Environmental and Occupational Health Sciences Institute, a joint Institute of the Robert Wood Johnson Medical School, University of Medicine and Dentistry of New Jersey, and Rutgers 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. Douglas Crawford-Brown\***, Director, Carolina Environmental Program; Professor, Environmental Sciences and Engineering; and Professor, Public Policy, Department of Environmental Sciences and Engineering, University of North Carolina at Chapel Hill, Chapel Hill, NC

**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. Armistead (Ted) Russell\***, Georgia Power Distinguished Professor of Environmental Engineering, Environmental Engineering Group, School of Civil and Environmental Engineering, Georgia Institute of Technology, Atlanta, GA

**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](mailto:butterfield.fred@epa.gov))

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

## Appendix B – Meeting Agenda

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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

**Tuesday, February 6, 2007 – 8:30 a.m. to 5:30 p.m. Eastern Time**  
**Wednesday, February 7, 2007 – 8:00 a.m. to 3:00 p.m. Eastern Time**

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

### Peer Review of EPA's: (1) Draft Lead Exposure and Risk Assessments Technical Support Document; and (2) 1<sup>st</sup> Draft Lead Staff Paper

#### Meeting Agenda

#### Tuesday, February 6, 2007

8:30 a.m.	<b>Convene Meeting; Call Attendance; Introductions and Administration; and Overview of Meeting Agenda</b>	Mr. Fred Butterfield, CASAC Designated Federal Officer (DFO)
8:40 a.m.	<b>Welcome &amp; Opening Remarks from EPA Science Advisory Board (SAB) Staff Office</b>	Dr. Vanessa Vu, Staff Director
8:45 a.m.	<b>Purpose of Meeting</b>	Dr. Rogene Henderson, Chair
8:50 a.m.	<b>Welcome from EPA's Office of Air Quality Planning and Standards (OAQPS)</b>	Ms. Lydia Wegman, Director, Health and Environmental Impacts Division, OAQPS
	<b>Review Process for Lead NAAQS</b>	Dr. Karen Martin, OAQPS staff
	<b>Summary Presentation on 1<sup>st</sup> Draft Lead Staff Paper and Draft Lead Exposure and Risk Assessments Technical Support Document</b>	Dr. Zachary Pekar, Dr. Deirdre Murphy & Ms. Ginger Tennant, OAQPS staff
10:00 a.m.	<b>Formal Public Comment Period</b>	Mr. Butterfield (Facilitator)
11:00 a.m.	<b>Break*</b>	
11:15 a.m.	<b>CASAC Lead Review Panel Discussion in Response to Charge Questions on Draft Lead Exposure and Risk Assessment TSD, Chapter 2: <i>Overview of Risk Assessment</i></b>	Dr. Henderson, Panel Members (Drs. James Crapo, Ted Russell, Joshua Cohen, Andrew Friedland & Robert Goyer)

Notes:

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

**Tuesday, February 6, 2007 (continued)**

12:00 p.m.	<b>Lunch</b>	
1:00 p.m.	<b>Lead Panel Discussion on Draft Lead TSD, Chapter 4, <i>Estimates of Media Concentrations</i></b>	Dr. Henderson, Panel Members (Drs. Paul Mushak, Fred Miller, Ian von Lindern & Barbara Zielinska)
2:00 p.m.	<b>Lead Panel Discussion on Draft Lead TSD, Chapter 5: <i>Human Exposure Assessment and Blood Pb Estimation</i></b>	Dr. Henderson, Panel Members (Drs. Douglas Crawford-Brown, Bruce Lanphear & Bruce Fowler)
3:00 p.m.	<b>Break*</b>	
3:15 p.m.	<b>Lead Panel Discussion on Draft Lead TSD, Chapter 6: <i>Estimation of Human Health Risk</i></b>	Dr. Henderson, Panel Members (Drs. Frank Speizer, Deborah Cory-Slechta, & Joel Schwartz, and Mr. Sean Hays)
4:15 p.m.	<b>Lead Panel Discussion on Draft Lead TSD, Chapter 7: <i>Ecological Risk Assessment</i></b>	Dr. Henderson, Panel Members (Dr. Ellis Cowling, Mr. Rich Poirot, and Drs. Samuel Luoma & Michael Newman)
5:15 p.m.	<b>Summary, Wrap-Up and Next Steps</b>	Dr. Henderson
5:30 p.m.	<b>Adjourn Meeting for the Day</b>	Mr. Butterfield

**Wednesday, February 7, 2007**

8:00 a.m.	<b>Reconvene Meeting; Call Attendance</b>	Mr. Butterfield
8:05 a.m.	<b>Re-cap of Previous Day's Meeting</b>	Dr. Henderson
8:10 a.m.	<b>Public Comment Period**</b>	Mr. Butterfield (Facilitator)
8:25 a.m.	<b>Additional OAQPS Comments</b>	Dr. Martin
8:30 a.m.	<b>CASAC Lead Review Panel Discussion on 1<sup>st</sup> Draft Lead Staff Paper, Chapter 2: <i>Characterization of Ambient Lead</i></b>	Dr. Henderson, Panel Members (Drs. Ted Russell, Barbara Zielinska, & Ian von Lindern)
9:15 a.m.	<b>Lead Panel Discussion on 1<sup>st</sup> Draft Lead Staff Paper, Chapter 3: <i>Policy-Relevant Assessment of Health Effects Evidence</i></b>	Dr. Henderson, Panel Members (Drs. Fred Miller, Joshua Cohen & Bruce Fowler, and Mr. Sean Hays)

Note:

\*\*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.

**Wednesday, February 7, 2007 (continued)**

10:15 a.m.	<b>Break*</b>	
11:30 a.m.	<b>Lead Panel Discussion on 1<sup>st</sup> Draft Lead Staff Paper Lead SP, Chapter 5, <i>The Primary Lead NAAQS</i></b>	Dr. Henderson, Panel Members (Drs. Frank Speizer, Deborah Cory-Slechta, Robert Goyer & Joel Schwartz)
12:30 p.m.	<b>Lunch</b>	
1:30 p.m.	<b>Lead Panel Discussion on 1<sup>st</sup> Draft Lead Staff Paper Lead SP, Chapter 6, <i>Policy-Relevant Assessment of Welfare Effects</i></b>	Dr. Henderson, Panel Members (Dr. Ellis Cowling, Mr. Rich Poirot, and Drs. Andrew Friedland, Samuel Luoma & Michael Newman)
2:30 p.m.	<b>Summary, Wrap-Up, Next Steps and Closing Remarks</b>	Dr. Henderson
3:00 p.m.	<b>Adjourn Meeting</b>	Mr. Butterfield

Notes:

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