

**Summary Minutes of the  
U.S. Environmental Protection Agency (EPA)  
Clean Air Scientific Advisory Committee (CASAC)  
Lead Review Panel  
Public Meeting  
July 20 - 21, 2011**

Date and Time: Wednesday, July 20, 2011, 9:00 AM – 5:30 PM ET; Thursday, July 21, 2011, 8:30 AM – 12:30 PM ET

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

Purpose: The purpose of the meeting was to conduct a peer review of EPA's *Integrated Science Assessment for Lead (First External Draft - May 2011)* and a consultation on EPA's *Review of the National Ambient Air Quality Standards for Lead: Risk and Exposure Assessment Planning Document (June 2011)*.

Participants: CASAC Lead Panel (for full roster, see Attachment A)

Dr. H. Christopher Frey, Chair

Mr. George Allen

Dr. Herbert Allen

Dr. Deborah Cory-Slechta

Dr. Cliff Davidson

Dr. Philip Goodrum

Dr. Sean Hays

Dr. Chris Johnson

Dr. Susan Korrick

Dr. Michael Kosnett

Dr. Roman Lanno

Mr. Richard Poirot

Dr. Joel Pounds

Dr. Michael Rabinowitz

Dr. William Stubblefield

Dr. Ian von Lindern

Dr. Gail Wasserman

Dr. Michael Weitzman

Mr. Aaron Yeow, Designated Federal Officer (DFO)

Dr. John Vandenberg, EPA National Center for Environmental Assessment (NCEA)

Dr. Ellen Kirrane, EPA NCEA

Ms. Debra Walsh, EPA NCEA

Dr. Bryan Hubbell, EPA Office of Air Quality and Planning Standards

Dr. Zachary Pekar, EPA OAQPS

Other Attendees (See Attachment B)

**Wednesday, July 20, 2011**

## **Opening Remarks**

Mr. Aaron Yeow, the DFO for the CASAC Lead Review Panel, opened the meeting. He noted that as required under the Federal Advisory Committee Act (FACA), the Panel's deliberations are held in public with advanced notice given in the Federal Register<sup>1</sup>, and the meeting minutes will be made publicly available after the meeting. He noted that the Panel received one request from the public to present oral comments, and received one set of written public comments. He also noted that the Panel members are subject to compliance with federal ethics regulations and conflict-of-interest laws that pertain to them. He then turned the meeting over to Dr. Vanessa Vu, the Director of the SAB Staff Office, who welcomed everyone and thanked them for their public service. She indicated that the purpose of the meeting was for the Panel to peer review EPA's *Integrated Science Assessment for Lead (First External Draft - May 2011)*<sup>2</sup> and to provide consultative advice on EPA's *Review of the National Ambient Air Quality Standards for Lead: Risk and Exposure Assessment Planning Document (June 2011)*<sup>3</sup>. She then turned the meeting over to Dr. Chris Frey, Chair of the CASAC Lead Review Panel.

Dr. Frey welcomed everyone, and had the Panel introduce themselves. He reiterated the purpose of the meeting and the expectations of the results from the meeting. He reviewed the Agenda<sup>4</sup>, and introduced Dr. John Vandenberg, from EPA's National Center for Environmental Assessment (NCEA) for his presentation.

## **EPA Presentation**

Dr. John Vandenberg, EPA NCEA, made a presentation<sup>5</sup> to the Panel. He provided a description of the Integrated Science Assessment (ISA) document, the National Ambient Air Quality Standard (NAAQS) review process, and reviewed the schedule for the current NAAQS review. He then turned it over to Dr. Ellen Kirrane, who provided an overview of the ISA and the charge questions. Ms. Debra Walsh then provided an overview of the Health and Environmental Research Online (HERO) system.

## **Public Comment**

Dr. Craig Boreiko, International Lead Zinc Research Organization, made an oral statement and indicated that he also submitted written comments<sup>6</sup>. He indicated that the causality criteria set forth in the ISA were not rigorously applied. He noted that little attention was paid to the causality criteria, particularly with respect to confounders in the lead epidemiology studies.

## **Charge Question 1 - Causal Framework / Study Selection**

The Panel members generally agreed that the criteria of using epidemiological studies within one order of magnitude at the general population blood lead range was reasonable, especially for a document that intends to focus on environmental lead exposures. The members found the Health and Environmental Research Online (HERO) system to be helpful. One member expressed concern that limiting the analysis to just one order of magnitude of current exposure excludes

90% of the world. There was discussion on the NAAQS process and that the role of the ISA is to aid the development of the Lead NAAQS for the United States.

### **Charge Question 3 - Ambient Air**

The Panel members generally found the document to be well written and comprehensive. Some of the Panel members noted that there was not any discussion on what EPA is doing to develop a better high-volume sampler. Although the ISA might not be the best place to discuss the development of a new high-volume sampler, the members wanted to reiterate CASAC's previous recommendations for the need for such a sampler, early on in the NAAQS review process, and not wait until the implementation stage, at which point it would be too late to develop it. It was also noted that the shutdown of the Herculaneum smelter presents an opportunity to prospectively study the impacts of air lead to soil lead. Other members recommended that the chapter needs to briefly summarize the current state of the science to provide context to the new studies. The Panel members had several issues with the accuracy of some of the particle size Pb comparisons and recommends that EPA screen the data for very low concentrations that may have poor precision and re-check the calculations. The members also had concerns about several aspects of the reported Pb emissions inventory data, including the relative importance of resuspended Pb from soils near historical sources (including roadways), and emissions from aviation gasoline combustion.

### **Charge Question 4 – Exposure, Biomarkers, Toxicokinetics**

#### *Charge Question 4a – Exposure and Toxicokinetics*

The Panel members noted that this chapter was pretty well-put together and found that the discussion of the effects of the reduction in air lead levels from the phase out of gasoline to be good. However, little emphasis is given to attributing the reductions in air lead levels to the shutdown of stationary sources throughout the country that was occurring at the same time. The members also thought it would be useful for the chapter to include a summary of how lead concentrations in other media have changed over the years.

Following the lunch break, EPA provided some clarification of the NAAQS process and the roles of the ISA and Risk and Exposure Assessment (REA).

#### *Charge Question 4b – Biological Markers*

The Panel recommended that the ISA provide greater distinction in the definition of the terms absorption and bioavailability and to use the terms consistently according to that distinction. The members also recommended defining the distinction between validation and application of biomarkers for exposure, body burden, dose, and risk. There was discussion regarding several figures pertaining to biokinetic modeling and it was recommended that greater explanation be given to the biokinetic modeling assumptions and comparisons to epidemiological data as validation.

### *Charge Question 4c – Empirical Modeling*

The Panel members found that inclusion of additional studies from which to estimate air Pb to blood Pb slope factors was a positive advancement from the previous NAAQS, which relied on just one or two studies, but would like to see how these slope factors compared to the one used in the previous NAAQS review. One member developed several figures to illustrate the potential change (reduction) in blood Pb concentrations as a function of reductions in the current NAAQS and recommended that the ISA contain similar figures.

### **Charge Question 5 – Integrated Health Effects of Lead Exposure**

#### *Charge Questions 5a and 5e – Modes of Action and Dose-Response*

The Panel members generally found that the discussion of the potential modes of action underlying the health effects of Pb exposure was thorough and inclusive of the current scientific literature and that no known modes of action have been left out. They found that some cases studies were not presented in sufficient detail to make conclusions regarding the mechanisms of action. They found that the additional evidence since 2006 for a non-linear dose-response curve was appropriately cited and provides further support for the non-linearity of the dose response curve. They noted that the non-linear dose-response curve is also supported by the animal literature.

#### *Charge Questions 5b and 5c – Health Endpoints*

The Panel members generally found the discussion of specific health endpoints in this chapter to be sufficiently broad in scope, and inclusion of additional health endpoints was not required. The members recommended a more rigorous and transparent “weight of the evidence” analysis to establish the extent of any causal relationship and that the analysis should devote more attention to the limitations of the existing studies with respect to consistency, reproducibility, bias, control for confounders, and shortcomings in statistical methodology.

#### *Charge Question 5d – Integration of Epidemiological and Toxicological Evidence*

The members found the chapter provided a comprehensive review of the human epidemiologic and toxicological evidence of Pb’s health effects but recommended a number of modifications to the chapter and identified several ways to improve the application of causal determination criteria to the Chapter’s conclusions.

### **Charge Question 7 – Ecological Effects of Lead**

The Panel members generally found the ecological effects chapter to be an excellent synthesis of the available environmental toxicity data for Pb. The chapter focused on post-2006 data, but some of the values that are relied upon are somewhat dated (e.g., the 1985 Ambient Water Quality Criteria and the 2003 terrestrial ecological soil screening level values). It was suggested that high quality data might be available from non-published sources, such as data generated for the European Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regulations and recommendations were made that these be evaluated. The members

recommended consistent use of the terms bioconcentration factor (BCF) and bioaccumulation factor (BAF) and also noted that BCF is an inappropriate measure to assess the hazard of Pb. Causal conclusions were only weakly supported by limited exposure data and thus should be reevaluated.

### **Charge Question 6 – Susceptible Populations and Life Stages**

The members generally found that the ISA’s discussion on susceptible populations was well written and useful. However, they recommend that EPA be very clear on the strength of the literature and cautious in inferring causality. They found that the ISA would be strengthened with more discussion of nutritional aspects that serve to increase susceptibility, differences in effects by gender, more discussion of gene-environmental interactions, and more mention of epigenetic implications. They noted that although early development is a vulnerable time period, significant data also show that later periods in life are associated with significant adverse effects.

### **Charge Question 2 - Integrative Health and Ecological Effects Overview**

The members generally supported the integrated summary being placed towards the beginning of the ISA as opposed to the end of the document. Overall, they found the integrated overview to be very helpful and well written, and the framework for characterizing the degree of causality is particularly useful. They recommended that care be taken to ensure that the most important points and key features from the health effects chapter are mentioned in this overview chapter.

Dr. Frey discussed action items and the DFO recessed the meeting until the next day.

### **Thursday, July 21, 2011**

The Panel reconvened at 8:30 am and Dr. Frey went over some scheduling items related to the draft letter on EPA’s ISA that the Panel will be developing. He then went over the agenda and turned it over to EPA for their presentation.

### **EPA Presentation**

Dr. Zachary Pekar and Dr. Bryan Hubbell from EPA’s OAQPS presented an overview<sup>7</sup> of the Risk and Exposure Assessment Planning Document. Some of the topics discussed included the purpose of the document, an overview of the of the prior Lead NAAQS review, key areas of uncertainty and limitations in the prior review, and an overview of key observations in the current planning document.

There was some discussion between the Panel members and EPA about whether there was going to be an REA document. EPA indicated that they did not plan on producing an REA document because the recent scientific information did not warrant a new quantitative risk assessment. They explained that this would be documented in the policy assessment document (PAD). Several members indicated that the documentation in the PAD is too late in the process and wanted to see something sooner. Several members also indicated that they would like to see

additional modeling, particularly in regards to an airport case study to assess the impact of aviation gasoline.

**Public Comment**

There were no public comments on the REA Planning document.

**Health Risk Assessment Issues**

The Panel proceeded to discuss their comments on the human health risk assessment issues in the REA Planning Document. Several members commented that the document was well-written and coherent. Some members agreed with EPA that there is not sufficient new data to warrant a new quantitative risk assessment. Other members raised the issue of airports and aviation gasoline and perhaps the need for some additional case studies/modeling.

**Welfare Assessment Issues**

The members generally found the document to be well-written and well-organized. Some members pointed out that there is a huge difference in terms of perspective of the importance of lead in health risk assessment versus ecological risk assessment. They did not consider lead to be in the top list of things that reduce the functioning of ecosystems and the production of ecosystem services. Some members agreed that the critical loads approach was the way to go, but were concerned that there would ever be enough sufficient data. Another member indicated that the weakest link in the risk assessment was the linkage between air concentrations of lead and media concentrations of lead.

**Summary and Action Items**

With the discussion on the REA Planning Document concluded, Dr. Frey then proceeded with a summary of the Panel’s consensus responses to the charge questions on the ISA. He presented a summary of the major points discussed and agreed upon by the Panel. He then discussed the next steps and action items.

With the business concluded, the Designated Federal Officer adjourned the meeting at 11:55 AM ET.

Respectfully Submitted:

Certified as Accurate:

*/Signed/*

*/Signed/*

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Mr. Aaron Yeow  
Designated Federal Officer  
EPA SAB Staff Office

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Dr. H. Christopher Frey  
Chair  
CASAC Lead Review Panel

NOTE AND DISCLAIMER: The minutes of this public meeting reflect diverse ideas and suggestions offered by Panel members during the course of deliberations within the meeting. Such ideas, suggestions and deliberations do not necessarily reflect consensus advice from the Panel members. The reader is cautioned to not rely on the minutes to represent final, approved, consensus advice and recommendations offered to the Agency. Such advice and recommendations may be found in the final advisories, commentaries, letters or reports prepared and transmitted to the EPA Administrator following the public meetings.

## Materials Cited

The following meeting materials are available on the CASAC website:

<http://www.epa.gov/casac>, at the [July 20 - 21, 2011 CASAC Lead Review Panel Meeting page](#):

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<sup>1</sup> Federal Register Notice Announcing the Meeting

<sup>2</sup> Integrated Science Assessment for Lead (First External Draft - May 2011)

<sup>3</sup> Review of the National Ambient Air Quality Standards for Lead: Risk and Exposure Assessment Planning Document (June 2011).

<sup>4</sup> Agenda for July 20-21, 2011 Public Meeting

<sup>5</sup> EPA Presentation on the Lead Integrated Science Assessment (ISA)

<sup>6</sup> Public Comments from Craig Boreiko, International Lead Zinc Research Organization (ILZRO)

<sup>7</sup> EPA Presentation on the Lead Risk and Exposure Assessment (REA) Planning Document

## ATTACHMENT A - ROSTER

### U.S. Environmental Protection Agency Clean Air Scientific Advisory Committee CASAC Lead Review Panel (2010-2013)

#### CHAIR

**Dr. H. Christopher Frey**, Professor, Department of Civil, Construction and Environmental Engineering, College of Engineering, North Carolina State University, Raleigh, NC

#### MEMBERS

**Mr. George A. Allen**, Senior Scientist, Northeast States for Coordinated Air Use Management (NESCAUM), Boston, MA

**Dr. Herbert Allen**, Professor Emeritus, Department of Civil and Environmental Engineering, University of Delaware, Newark, DE

**Dr. Richard Canfield\***, Senior Research Associate, Division of Nutritional Sciences, Cornell University, Ithaca, NY

**Dr. Deborah Cory-Slechta**, Professor, Department of Environmental Medicine, School of Medicine and Dentistry, University of Rochester, Rochester, NY

**Dr. Cliff Davidson**, Professor, Civil and Environmental Engineering, Syracuse University, Syracuse, NY

**Dr. Philip E. Goodrum**, Senior Project Manager, Environmental Resources Management (ERM), Dewitt, NY

**Dr. Sean Hays**, President, Summit Toxicology, Allenspark, CO

**Dr. Philip Hopke**, Bayard D. Clarkson Distinguished Professor, Department of Chemical and Biomolecular Engineering, Clarkson University, Potsdam, NY

**Dr. Chris Johnson**, Professor, Department of Civil and Environmental Engineering, Syracuse University, Syracuse, NY

**Dr. Susan Korrick**, Assistant Professor of Medicine, Department of Medicine, Brigham and Women's Hospital, Channing Laboratory, Harvard Medical School, Boston, MA

**Dr. Michael Kosnett**, Associate Clinical Professor, Division of Clinical Pharmacology and Toxicology, Department of Medicine, University of Colorado Health Sciences Center, Denver, CO

**Dr. Roman Lanno**, Associate Professor and Associate Chair, Department of Evolution, Ecology, and Organismal Biology, Ohio State University, Columbus, OH

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

**Dr. Joel Pounds**, Laboratory Fellow, Cell Biology & Biochemistry, Biological Sciences Division, Pacific Northwest National Laboratory, Richland, WA

**Dr. Michael Rabinowitz**, Geochemist, Marine Biological Laboratory, Newport, RI

**Dr. William Stubblefield**, Senior Research Professor, Department of Molecular and Environmental Toxicology, Oregon State University, Corvallis, OR

**Dr. Ian von Lindern**, President, TerraGraphics Environmental Engineering, Inc., Moscow, ID

**Dr. Gail Wasserman**, Professor of Clinical Psychology in Child Psychiatry, Division of Child and Adolescent Psychiatry, College of Physicians and Surgeons, Columbia University, New York, NY

**Dr. Michael Weitzman**, Professor, Pediatrics; Psychiatry, New York University School of Medicine, New York, NY

\*Did not participate in this review.

**SCIENCE ADVISORY BOARD STAFF**

**Mr. Aaron Yeow**, Designated Federal Officer, U.S. Environmental Protection Agency, Science Advisory Board (1400R), 1200 Pennsylvania Avenue, NW, Washington, DC, Phone: 202-564-2050, Fax: 202-565-2098, (yeow.aaron@epa.gov)

**ATTACHMENT B – Other Attendees  
CASAC Lead Panel Public Meeting**

**July 20, 2011**

<b>Name</b>	<b>Affiliation</b>
Boreiko, Craig	International Lead Zinc Research Organization
Brightwell, Holly*	Texas Commission on Environmental Quality
Brown, James	EPA
Datko, Laura	EPA
Davis, Allen	EPA
Dietert, Rodney	Cornell University
Dubois, Jean-Jacques	EPA
Dutton, Steve	EPA
Dzubow, Rebecca*	EPA
Fairbrother, Anne	Exponent
Gandy, Jay	University of Arkansas for Medical Sciences
Gonick, Harvey	UCLA
Hines, Erin	EPA
Hoyer, Marion	EPA
Hubbard, Heidi	ICF
Johns, Doug	EPA
Kotchmar, Dennis	EPA
Lassiter, Meredith	EPA
Long, Thomas*	EPA
Lorang, Ellen	EPA
McDow, Steve	EPA
Meacham, Connie	EPA
Mendez, Bill	ICF
Murphy, Deirdre	EPA
Nystrom, Marci*	California Air Resources Board
Orlin, David	EPA
Owens, Beth	EPA
Parker, Stuart*	InsideEPA
Patel, Molini	EPA
Pedde, Meredith*	EPA
Pinto, Joseph	EPA
Rajan, Pradeep	EPA
Richmond-Bryant, Jennifer	EPA
Ross, Mary	EPA
Rothenberg, Stephen	National Institute of Public Health

Selgrade, Mary Jane	ICF
Sheedy, Keith*	Texas Commission on Environmental Quality
Shumake, Katie	EPA
Siporin, Kaylyn	EPA
Stanek, Lindsay	EPA
Svendsgaard, Dave	EPA
Tennant, Ginger	EPA
Tonne, Jay*	Texas Commission on Environmental Quality
Vanderpool, Robert	EPA
Vinikoor-Imler, Lisa	EPA
Volpe, Rosalind	ILZRO
Walsh, Debra	EPA
Weaver, Virginia	Johns Hopkins University
Wiesskopf, Marc	EPA
Wise, John	University of Southern Maine
Wright, Robert	Harvard University
Wright, Rosalind	Harvard University
Young, Brianna	EPA

\*Participated via teleconference

**July 21, 2011**

<b>Name</b>	<b>Affiliation</b>
Boreiko, Craig	ILZRO
Brightwell, Holly*	Texas Commission on Environmental Quality
Deitert, Rodney	Cornell University
Dubois, Jean-Jacques	EPA
Dzubow, Rebecca*	EPA
Fairbrother, Anne	Exponent
Hines, Erin	EPA
Hoyer, Marion	EPA
Hubbard, Heidi	ICF
Kotchmar, Dennis	EPA
Lassiter, Meredith	EPA
Long, Thomas*	EPA
Mendez, Bill	ICF
Murphy, Deirdre	EPA
Nystrom, Marci*	California Air Resources Board
Orlin, David	EPA
Owens, Beth	EPA

Parker, Stuart*	InsideEPA
Patel, Molini	EPA
Pedde, Meredith*	EPA
Rajan, Pradeep	EPA
Richmond-Bryant, Jennifer	EPA
Ross, Mary	EPA
Rothenberg, Stephen	National Institute of Public Health
Sheedy, Keith*	Texas Commission on Environmental Quality
Tennant, Ginger	EPA
Tonne, Jay*	Texas Commission on Environmental Quality
Volpe, Rosalind	ILZRO
Weaver, Virginia	Johns Hopkins University
Wise, John	University of Southern Maine

\*Participated via teleconference