

**Summary Minutes of the
U.S. Environmental Protection Agency (EPA)
Clean Air Scientific Advisory Committee (CASAC)
Ozone Review Panel
Public Teleconference
November 5, 2012**

Date and Time: Monday, November 5, 2012, 9:00 AM – 1:00 PM ET

Location: Teleconference Only

Purpose: To discuss the CASAC Ozone Review Panel's draft reports on EPA's Integrated Science Assessment for Ozone and Related Photochemical Oxidants (Third External Review Draft – June 2012) (ISA), Health Risk and Exposure Assessment for Ozone (First External Review Draft - Updated August 2012) (HREA), Welfare Risk and Exposure Assessment for Ozone (First External Review Draft - Updated August 2012) (WREA), and Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards (First External Review Draft – August 2012) (PA).

Participants: Ozone Review Panel (for full roster, see Attachment A)

Dr. H. Christopher Frey, CASAC Chair

Mr. George Allen

Mr. Ed Avol

Dr. Michelle Bell

Dr. David Chock

Dr. Ana Diez-Roux

Dr. W. Michael Foster

Dr. David Grantz

Dr. Jack Harkema

Dr. Daniel Jacob

Dr. Frederick Miller

Dr. Armistead (Ted) Russell

Dr. Jonathan Samet

Dr. Helen Suh

Dr. James Ultman

Dr. Sverre Vedal

Dr. Kathleen Weathers

Dr. Peter Woodbury

Dr. Ronald Wyzga

Mr. Aaron Yeow, Designated Federal Officer (DFO)

Other Attendees (See Attachment B)

Monday, November 5, 2012

Opening Remarks

Mr. Aaron Yeow, the DFO for the public teleconference of the CASAC Ozone Review Panel took roll and opened the meeting. He welcomed Dr. Chris Frey as the new Chair of CASAC and Drs. Jack Harkema and Ronald Wyzga as new Chartered CASAC members. He thanked Drs. Jonathan Samet and Ted Russell for their past CASAC service and for their agreeing to stay on the Ozone Panel as consultants. 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 Register¹, and the meeting minutes will be made publicly available after the meeting. He noted that the Panel received several written public comments and requests from the public to present oral comments. He stated that the SAB Staff Office has reviewed information provided by the panel members to determine if there are any issues with conflict-of-interest or appearance of a lack of impartiality for any of the advisory panel members participating in this review. As a result of this review, the SAB Staff Office asked Dr. Michelle Bell and Dr. Jonathan Samet not to comment on the use of their studies as the basis for the Health Risk and Exposure Assessment, and its implications for the Policy Assessment.

He then turned the meeting over to Dr. Chris Frey, Chair of the CASAC.

Dr. Frey welcomed everyone, stated the purpose of the teleconference was to review the Panel's draft review of 4 EPA Ozone documents, and reviewed the Agenda². He pointed out that at the end of the Panel's discussion of each report, the Chartered CASAC members would provide a disposition of each report.

Public Comments

There were 11 registered public speakers and they presented according to the order in the List of Public Speakers³.

Roger McClellan summarized his written comments⁴ and stated that the EPA documents do not adequately consider multi-pollutant health effects, need further improvement in describing background ozone, and that the CASAC should not reach premature conclusions on the science or assume the policy-making role of the EPA Administrator.

Sonja Sax, on behalf of the American Petroleum Institute, presented her oral statement⁵, which focused on three main issues with the risk assessment based on the epidemiology evidence in the first draft REA: the calculation of effects down to a zero ozone level, the use of alternative concentration-response functions in the core and sensitivity analyses, and whether results are informative for purposes of the policy assessment.

Julie Goodman, on behalf of the American Forest & Paper Association, presented her oral statement⁶, which focused on two main issues: the weight of evidence for cardiovascular effects associated with ozone in the ISA, and the use of the McDonnell *et al.* (2012) model for the risk assessment based on controlled exposure studies in the REA.

Ed Hopkins presented comments on behalf of the Sierra Club and indicated that the current standard is insufficient, according to the scientific evidence.

Christopher Emery, on behalf of ENVIRON International Corporation, presented his oral statement⁷, which focused on two topics: the issue of background tropospheric ozone and the consistent theme to downplay the role of the stratosphere as a source; and the appropriate application and evaluation of CMAQ/HDDM as a methodology to replace the quadratic rollback technique for the health risk calculations.

Samuel Oltmanns presented oral comments⁸ that focused on the need to provide a balanced view on the contributions to background ozone.

Allen S. Lefohn, presented oral comments⁹ and stated that a more balanced perspective concerning the importance of the stratospheric contribution in respect to background ozone concentrations is needed in the draft CASAC Panel Reports.

William McDonnell presented oral comments¹⁰ that addressed specific issues raised about the McDonnell et al. (2012) model in the CASAC review of the HREA and to point out some inconsistencies in the underlying HREA and ISA documents

Nicole Downey, on behalf of Earth System Sciences, presented her oral statement¹¹ which focused on the significant level of confusion with respect to background ozone, the risk ‘in excess of background’ and how background ozone is taken into account in the risk assessments.

Jeffrey Holmstead, Bracewell & Giuliani, summarized his written comments¹² and stated that in the Clean Air Act, Congress gave CASAC a specific list of responsibilities, but CASAC has largely overlooked two of the responsibilities, to advise the Administrator on the relative contribution to air pollution concentrations of natural as well as anthropogenic activity and to advise the Administrator of any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of such national ambient air quality standards.

Deborah Shprentz, on behalf of the American Lung Association, summarized her written comments¹³ and made 4 main points: 1) it is important for any proposed standard to protect against both short-term and long-term adverse effects; 2) concur with EPA’s statement in the PA that the current standard is not adequate to protect public health with an adequate margin of safety; 3) that it is unacceptable for the PA to dismiss the broad spectrum of epidemiological studies as irrelevant to standard setting; 4) and are concerned that the draft risk assessment does not evaluate impacts on children ages zero-five.

Discussion of the Consensus Responses in the Draft ISA Report

Dr. Frey and the Panel members went through each section of the Draft ISA Report. For the response to charge question for Chapter 3, the Panel agreed to revisions to item 6 and to add a statement regarding background ozone. For the response to the charge question for Chapter 5, the Panel agreed to an added statement regarding the Devlin et al. (2012) study. The panel agreed to

revisions to items 3 and 5 under the response to the charge question for Chapters 6-7. Lastly, the panel agreed to revisions to the response to the charge question for Chapters 9-10 pertaining to recent proteomics results.

Discussion of the Letter to the Administrator for the Draft ISA Report

The Panel members agreed to adding in a statement with respect to Chapter 5 that the title should be changed to reflect species homology and agreed that a section on Chapter 4 should be added to the letter.

Disposition of the Draft ISA Report

The Chartered CASAC members approved the report with the revisions discussed.

Discussion of the Consensus Responses in the Draft REA Report

Dr. Frey and the Panel members went through each section of the Draft REA Report. For the response to charge question 2 (HREA Chapter 2), the Panel agreed to make revisions to refer only to the conceptual framework. The Panel agreed to revisions to the response to charge question 5 (HREA Chapter 4). For the HREA Chapter 6, the panel agreed to revisions to the response to charge questions 4 and 5. The Panel agreed to revisions to the response to charge question 16 (HREA Chapter 8) and charge question 19 (HREA Chapter 9). For the response to charge question 5 (WREA Chapter 4), the panel agreed to revisions pertaining to clarifying the term “fused data”. The Panel agreed to revisions for clarity to the response to charge question 9 (WREA Chapter 5).

Discussion of the Letter to the Administrator for the Draft REA Report

The Panel members agreed that the wording changes regarding conceptual framework should be reflected in the letter as well.

Disposition of the Draft REA Report

The Chartered CASAC members approved the report with the revisions discussed.

Discussion of the Consensus Responses in the Draft PA Report

Dr. Frey and the Panel members went through each section of the Draft PA Report. The Panel agreed to delete the last paragraph to the response to charge question 1 (Chapter 2) and to revise the response to charge question 3 (Chapter 2). There was some discussion about the response to charge question 2 (Chapter 4) regarding whether the PA provided adequate justification for considering levels 60 ppb. The Panel agreed to revising the response. There was some discussion on EPA’s justification of ignoring crop yield data. The Panel agreed to revisions to the response to charge question 5 (Chapter 5).

Discussion of the Letter to the Administrator for the Draft PA Report

The Panel members agreed to strike the sentence on page 2, line 5 of the letter and agreed to make the same revision to lines 14-15 of page 2 regarding levels below 60 ppb that was discussed for charge question 2 of Chapter 4.

Disposition of the Draft PA Report

The Chartered CASAC members approved the report with the revisions discussed.

Additional Clarifying Public Comment

Roger McClellan was given an opportunity to provide an additional clarifying public comment. He stated that discussion of the statistical form of the standard should not be limited to the PA and that the PA draws from the scientific evidence from the ISA and REA, so discussion of the statistical form is appropriate and necessary in those documents.

With business concluded, the meeting was adjourned by the DFO at 1:00 pm.

Respectfully Submitted:

/signed/

Mr. Aaron Yeow
Designated Federal Officer
EPA SAB Staff Office

Certified as Accurate:

/signed/

Dr. H. Christopher Frey
Chair
CASAC

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.

References Cited

Devlin, R. B., Duncan, K. E., Jardim, M., Schmitt, M. T., Rappold, A. G., and Diaz-Sanchez, D. (2012). Controlled exposure of healthy young volunteers to ozone causes cardiovascular effects / clinical perspective. *Circulation*, 126(1):104-111.

McDonnell, W. F., Stewart, P. W., Smith, M. V., Kim, C. S., and Schelegle, E. S. (2012). Prediction of lung function response for populations exposed to a wide range of ozone conditions. *Inhalation Toxicology*, 24(10):619-633.

Materials Cited

The following meeting materials are available on the CASAC website:

<http://www.epa.gov/casac>, at the [November 5, 2012 CASAC Ozone Review Panel Meeting page](#):

¹ Federal Register Notice Announcing the Meeting

² Agenda for November 5, 2012 Public Meeting

³ List of Public Speakers

⁴ Roger McClellan comments

⁵ American Petroleum Institute comments presented by Sonja Sax

⁶ American Forest & Paper Association comments submitted by Julie Goodman

⁷ ENVIRON comments submitted by Christopher Emery

⁸ Samuel Oltmans comments on the ISA, REA, and PA

⁹ Allen S. Lefohn comments

¹⁰ William McDonnell comments

¹¹ Earth System Sciences, LLC comments submitted by Nicole Downey

¹² Jeffrey Holmstead comments

¹³ American Lung Association comments on the PA

ATTACHMENT A - ROSTER

U.S. Environmental Protection Agency Clean Air Scientific Advisory Committee Ozone Review Panel

CHAIR

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

IMMEDIATE PAST CHAIR

Dr. Jonathan M. Samet, Professor and Flora L. Thornton Chair, Department of Preventive Medicine, Keck School of Medicine, University of Southern California, Los Angeles, CA

CASAC MEMBERS

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

Dr. Ana Diez-Roux, Professor of Epidemiology, School of Public Health, University of Michigan, Ann Arbor, MI

Dr. Jack Harkema, Professor, Department of Pathobiology, College of Veterinary Medicine, Michigan State University, East Lansing, MI

Dr. Helen Suh, Associate Professor, Bouve School of Health Sciences, Northeastern University, Boston, MA

Dr. Kathleen Weathers, Senior Scientist, Cary Institute of Ecosystem Studies, Millbrook, NY

Dr. Ronald Wyzga, Technical Executive, Electric Power Research Institute, Palo Alto, CA

CONSULTANTS

Mr. Ed Avol, Professor, Preventive Medicine, Keck School of Medicine, University of Southern California, Los Angeles, CA

Dr. Michelle Bell, Professor, School of Forestry and Environmental Studies, Yale University, New Haven, CT

Dr. Joseph D. Brain, Cecil K. and Philip Drinker Professor of Environmental Physiology,

Department of Environmental Health, Harvard School of Public Health, Harvard University, Boston, MA

Dr. David Chock, Independent Consultant, Bloomfield Hills, MI

Dr. William Michael Foster, Professor, Pulmonary and Critical Care Medicine, Duke University Medical Center, Durham, NC

Dr. David A. Grantz, Department of Botany and Plant Sciences, University of California at Riverside, Kearney Agricultural Center, Parlier, CA

Dr. Daniel Jacob, Professor, Atmospheric Sciences, School of Engineering and Applied Sciences, Harvard University, Cambridge, MA

Dr. Steven Kleeberger, Professor and Lab Chief, Laboratory of Respiratory Biology, National Institute of Environmental Health Sciences, National Institutes of Health, Research Triangle Park, NC

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

Dr. Howard Neufeld, Professor, Department of Biology, Appalachian State University, Boone, NC

Dr. Armistead (Ted) Russell*, Professor, Department of Civil and Environmental Engineering, Georgia Institute of Technology, Atlanta, GA

Dr. James Ultman, Professor, Chemical Engineering, Bioengineering Program, Pennsylvania State University, University Park, PA

Dr. Sverre Vedal, Professor, Department of Environmental and Occupational Health Sciences, School of Public Health, University of Washington, Seattle, WA

Dr. Peter Woodbury, Senior Research Associate, Department of Crop and Soil Sciences, College of Agriculture and Life Sciences, Cornell University, Ithaca, NY, U.S.A.

* Immediate Past CASAC Member

SCIENCE ADVISORY BOARD STAFF

Dr. Holly Stallworth, Designated Federal Officer, U.S. Environmental Protection Agency, Science Advisory Board (1400R), 1200 Pennsylvania Avenue, NW, Washington, DC 20460

Mr. Aaron Yeow, Designated Federal Officer, U.S. Environmental Protection Agency, Science Advisory Board (1400R), 1200 Pennsylvania Avenue, NW, Washington, DC, 20460

ATTACHMENT B – Other Attendees
CASAC Ozone Panel Public Teleconference

(Persons who requested the teleconference call-in number or indicated they were on the call)

November 5, 2012

Name	Affiliation
Aucoin, Vivian	Louisiana Department of Environmental Quality
Austin, Doug	Institute of Clean Air Companies
Bass, Ben	CQ Transcriptions
Brown, James	EPA
Buckley, Barbara	EPA
Downey, Nicole	Earth System Sciences, LLC
Dutton, Steve	EPA
Emery, Christopher	ENVIRON International Corporation
Eswald, Steve	Southern Company
French, Timothy	Chicago Law Partners
Goodman, Julie	Gradient
Gouze, Steve	California Air Resources Board
Herrick, Jeff	EPA
Hilton, Roger G.	Alstom
Hines, Erin	EPA
Hoertz, John	US Air Force
Holmstead, Jeffrey	Bracewell & Giuliani
Hopkins, Ed	Sierra Club
Hopkinson, Jenny	InsideEPA
Hubbell, Bryan	EPA
Jenkins, Scott	EPA
Kalisz, Cathe	American Petroleum Institute
Kotchmar, Dennis	EPA
Lefohn, Allen	A.S.L. & Associates
Long, Tom	EPA
Luben, Tom	EPA
Martin, Karen	EPA
McClellan, Roger	Toxicology and Human Health Risk Analysis
McDonnell, William	William McDonnell Consulting
Miranda, Ayanna	No Affiliation given
Nichols, Jen	EPA
Ollison, Will	American Petroleum Institute
Oltmans, Samuel	University of Colorado
Owens, Beth	EPA
Parker, Stuart	InsideEPA

Patel, Molini	EPA
Pavlich, David	Phillips 66 Company
Pekar, Zachary	EPA
Pinto, Joe	EPA
Ross, Mary	EPA
Rostker, David	U.S. Small Business Administration
Sacks, Jason	EPA
Sax, Sonja	Gradient
Shprentz, Deborah	Consultant to the American Lung Association
Smith, J. Travis	EPA
Smith, Richard L.	University of North Carolina
Steichen, Ted	American Petroleum Institute
Stevens, Tina	EPA
Stone, Susan	EPA
Vandenberg, John	EPA
Wegman, Lydia	EPA
Wells, Benjamin	EPA
Wesson, Karen	EPA
Wilson, Linda	New York State Attorney's Office
Woods, Clint	U.S. House of Representatives
Zawacki, Margaret	EPA