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

Summary Meeting Minutes of the CASAC's Public Advisory Teleconference

Friday, May 12, 2006 – 1:00 to 4:00 p.m. Eastern Time

EPA Science Advisory Board (SAB) Staff Office
1025 F. Street, N.W., Washington, DC 20004

CASAC Ozone Review Panel Teleconference to Provide Additional Advice to EPA Concerning Chapter 8 (Integrative Synthesis) of EPA's Final Air Quality Criteria Document (AQCD) for Ozone and Related Photochemical Oxidants

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

Agenda: See Meeting Agenda – Appendix B

Purpose: The purpose of this public teleconference meeting was for the CASAC Ozone Review Panel to provide additional advice to the Agency concerning Chapter 8 (Integrative Synthesis) of EPA's Final Ozone AQCD (February 2006).

Attendees:

Chair:	Dr. Rogene Henderson
CASAC Members:	Dr. Ellis Cowling Dr. James Crapo Dr. Frederick Miller Dr. Frank Speizer
Panel Members:	Dr. John Balmes Dr. William (Jim) Gauderman Dr. Henry Gong Dr. Paul Hanson Dr. Philip Hopke Dr. Michael Kleinman Dr. Allan Legge Dr. Morton Lippmann Dr. Maria Morandi Dr. Charles Plopper Dr. Elizabeth (Lianne) Sheppard Dr. Armistead (Ted) Russell Dr. James Ultman Dr. Sverre Vedal
EPA SAB Staff:	Mr. Fred Butterfield, CASAC Designated Federal Officer (DFO)

Other EPA Staff:
Ms. Lea Anderson, OGC, ARLO
Dr. Tim Benner, ORD, OSP
Dr. James Brown, ORD, NCEA-RTP
Dr. Lester Grant, ORD, NCEA-RTP
Dr. Dennis Kotchmar, ORD, NCEA-RTP
Dr. Karen Martin, OAR, OAQPS
Dr. David McKee, OAR, OAQPS
Dr. Sri Nadadur, ORD, NCEA-RTP
Mr. Harvey Richmond, OAR, OAQPS
Mr. Michael Rizzo, OAR, OAQPS
Dr. Mary Ross, ORD, NCEA-RTP
Ms. Susan Stone, OAR, OAQPS
Ms. Lydia Wegman, OAR, OAQPS
Dr. Lori White, ORD, NCEA-RTP

Meeting Summary

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

Convene Meeting, Call Attendance, Introduction and Administration

Mr. Fred Butterfield, Designated Federal Officer (DFO) for the Clean Air Scientific Advisory Committee, opened the teleconference meeting, 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, the deliberations of CASAC 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 there was only one individual offering public comments today. Mr. Butterfield said a transcript of this teleconference is not being taken. However, summary minutes were taken (by the DFO) for this teleconference meeting. These minutes will be certified by the CASAC (and Ozone Review Panel) Chair and posted on the SAB Web Site (http://www.epa.gov/sab/). Mr. Butterfield 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.

Purpose of Meeting and Welcome

Dr. Rogene Henderson, CASAC and Ozone Review Panel Chair, welcomed Panel members and briefly stated the purpose of the meeting (see above), which is to provide the Agency with additional advice concerning Chapter 8 (Integrative Synthesis) of the Agency's *Final Air Quality Criteria for Ozone and Related Photochemical Oxidants* (Final Ozone AQCD, EPA/600/R-05/004aF-cF, February 2006).

Public Comment Period

There was one public commenter during this teleconference, Ms. Deborah Shprentz, consultant, speaking on behalf of the American Lung Association (ALA); (Ms. Shprentz's written statement is attached as Appendix C, and a copy of her public comments is located in the FACA file for this meeting.)

Summary of the Ozone Panel's Discussion on Chapter 8 (Integrative Synthesis) of the EPA's Final Ozone AQCD

The members of the CASAC Ozone Review Panel were in general agreement that EPA has been reasonably successful in assembling the relevant information and incorporating findings from atmospheric sciences, toxicology, human clinical studies and epidemiology, in its development of the Integrative Synthesis chapter in the Agency's Final Ozone AQCD. Nonetheless, Panel members comments that there are some very important issues that are not presented well, or at all, in Chapter 8, including: the utility of time-series studies in assessing the risks from ozone exposure; the problem of exposure measurement error in ozone mortality time-series studies; use of ozone as a surrogate marker for other toxic photochemical pollutants; a general downplaying of animal-to-human extrapolation studies; and the need for inclusion of welfare issues (*i.e.*, leading to the establishment of secondary standards for criteria air pollutants) in an integrative synthesis chapter. These major points are discussed as follows:

- With respect to how time-series studies are used in assessing the risks from ozone exposure, members of the Ozone Panel noted that the epidemiological evidence on the health effects of ozone, while only constituting a fraction of the total scientific knowledge, nevertheless plays a disproportionately large role in the policymaking process. Therefore, Panel members commented on the *utility* of these time-series studies in the NAAQS-setting process. In particular, Ozone Panelists noted that, while the time-series study design is a powerful tool, it is also a "blunt" tool, in that the findings of mortality time-series studies apparently do not permit researchers to confidently attribute observed effects specifically to individual pollutants. Since time-series studies typically make use of data from available air pollution monitoring network sites in which concentrations of various subsets of the criteria pollutants are measured, in which the pollutants are often part of a large and highly-correlated mix of pollutants, only a very few of which are measured. Panel member highlighted that, for the Ozone NAAQS, this pollutant mix includes a large number of both gas- and particle-phase photochemical oxidant pollutants, adding that, unfortunately, only limited information is available concerning the specific chemical composition, toxicity and population exposure of oxidant pollutants other than ozone.

- Ozone Panel members recommended that the Ozone Staff Paper consider the problem of exposure measurement error in ozone mortality time-series studies. Panelists commented that it is well-know that personal exposure to ozone is not reflected adequately (if at all) by ozone concentrations measured at central outdoor monitoring sites. Rather, personal exposures to ozone are typically much lower than the ambient concentrations, and can even be dramatically lower depending on time-activity patterns, housing characteristics and season. In addition, Panel members remarked that there can be no correlation between personal concentrations of ozone measured over time and concentrations measured

at central outdoor sites, and that it therefore seems unlikely that observed associations between short-term ozone concentrations and daily mortality are due solely to ozone itself. Panel members added that another implication of ozone measurement error relevant to the NAAQS-setting process is that this degree of measurement error would be expected to have a substantial impact on the ability to detect a threshold of the concentration-response relationship below which no ozone effects are discernible, an issue that will need to be addressed.

- With respect to the issue of ozone acting as a surrogate for other toxic agents, Panel members identified at least two questions that are relevant to the ozone NAAQS-setting process: (1) What chemical agent or agents are at least partly responsible for the observed associations between ozone and mortality in the time-series studies?; and (2) Do we require an immediate answer to this question of whether ambient ozone adequately serves as a surrogate marker that, when controlled, effectively mitigates health impacts of this entire mix of pollutants? Ozone Panelists also noted that observed associations of ozone with mortality pertain to *total* mortality, which implies that ozone is causing acute effects on the cardiovascular system, and not merely on the respiratory system, adding that the collective scientific understanding of the cardiovascular effects of ozone is currently very limited compared to our understanding of ozone's effects on the lung.

- Panel members remarked that, while Chapter 8 touches upon animal-to-human extrapolation issues in a number of places, they did not agree with the extent to which these extrapolations are downplayed, offering detailed comments to Agency staff with respect to the development of EPA's 2nd Draft Ozone Staff Paper. Ozone Panelists commented that the integrative synthesis chapter inconsistently presents the case for and against animal-to-human extrapolation —first by contending that physiological differences lead to large uncertainties in such extrapolations, and subsequently stating the agreement between the species is sufficient to support a common mode of action for ozone in producing biological effects.

- Finally, Ozone Panel members expressed their disappointment with regard to failing to include welfare issues in the integrative synthesis chapters of EPA's air quality criteria documents. While Panelists understand that the exposures and adverse effects of criteria pollutants on public health have been the principal focus of the Agency's traditional sense of responsibility to the people of the United States, they noted that the Clean Air Act establishes that both public-health-based (primary) standards *and* public-welfare-based (secondary) standards for criteria air pollutants should be set as part of the Agency's review of the NAAQS. Therefore, the issues related to the setting of the both the primary and secondary standards need to be included in AQCD integrative chapters.

Summary and Next Steps

Dr. Henderson requested that Ozone Panel members send her and Mr. Butterfield any inputs into the draft letter to the EPA Administrator containing the Ozone Panel's additional advice to the Agency concerning the Final Ozone AQCD — as well as any initial or revised individual written comments on Chapter 8 (Integrative Synthesis) — as soon as possible. The Chair thanked eve-

ryone on the conference call for their participation. Mr. Butterfield thanked also all participants, after which the CASAC DFO adjourned the meeting at approximately 2:40 p.m.

Respectfully Submitted:

/s/

Fred A. Butterfield, III

Fred A. Butterfield, III
CASAC DFO

Certified as True:

/s/

Rogene F. Henderson, Ph.D.

Rogene F, Henderson, Ph.D.
CASAC Chair

Appendices

Appendix A – Roster of the CASAC Ozone Review Panel

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

CHAIR

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

MEMBERS

Dr. John Balmes, Professor, Department of Medicine, University of California San Francisco, University of California – San Francisco, San Francisco, California

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

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

Dr. William (Jim) Gauderman, Associate Professor, Preventive Medicine, Medicine, University of Southern California, Los Angeles, CA

Dr. Henry Gong, Professor of Medicine and Preventive Medicine, Medicine and Preventive Medicine, Keck School of Medicine, University of Southern California, Downey, CA

Dr. Paul J. Hanson, Senior Research and Development Scientist, Environmental Sciences Division, Oak Ridge National Laboratory (ORNL), Oak Ridge, TN

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

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

Dr. Michael T. Kleinman, Professor, Department of Community & Environmental Medicine, University of California – Irvine, Irvine, CA

Dr. Allan Legge, President, Biosphere Solutions, Calgary, Alberta, Canada

Dr. Morton Lippmann, Professor, Nelson Institute of Environmental Medicine, New York University School of Medicine, Tuxedo, NY

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

Dr. Maria Morandi, Assistant Professor of Environmental Science & Occupational Health, Department of Environmental Sciences, School of Public Health, University of Texas – Houston Health Science Center, Houston, TX

Dr. Charles Plopper, Professor, Department of Anatomy, Physiology and Cell Biology, School of Veterinary Medicine, University of California – Davis, Davis, California

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

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. Elizabeth A. (Lianne) Sheppard, Research Associate Professor, Biostatistics and Environmental & Occupational Health Sciences, Public Health and Community Medicine, University of Washington, Seattle, WA

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

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

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

Dr. James (Jim) Zidek, Professor, Statistics, Science, University of British Columbia, Vancouver, BC, Canada

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) (Physical/Courier/FedEx Address: Fred A. Butterfield, III, EPA Science Advisory Board Staff Office (Mail Code 1400F), Woodies Building, 1025 F Street, N.W., Room 3604, Washington, DC 20004, Telephone: 202-343-9994)

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

Appendix B – Meeting Agenda

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

Public Advisory Teleconference Meeting

Friday, May 12, 2006 – 1:00 to 4:00 p.m. Eastern Time

EPA Science Advisory Board (SAB) Staff Office
1025 F. Street, N.W., Washington, DC 20004

Objective: To Provide Additional Advice EPA Concerning Chapter 8 (Integrative Synthesis) of the Final Air Quality Criteria Document (AQCD) for Ozone and Related Photochemical Oxidants

Meeting Agenda

Friday, May 12, 2006

1:00 p.m.	**Convene Teleconference; Call Attendance; Introductions and Administration**	Mr. Fred Butterfield, CASAC DFO
1:10 p.m.	**Purpose of Meeting**	Dr. Rogene Henderson, Chair
1:15 p.m.	**Public Comment Period**	Mr. Butterfield (Facilitator)
1:45 p.m.	**Members' Discussion and Deliberation**	CASAC Ozone Review Panel Members

Discussion Topic	**Lead Discussant**
• Plausibility and the time-series studies	Dr. Sverre Vedal
• Exposure measurement errors with ozone	Dr. Barbara Zielinska
• Animal-to-human extrapolations	Dr. Fred Miller
• Inclusion or exclusion of photochemical pollutants in general	Dr. Phil Hopke
• Other discussion items	—

3:50 p.m.	**Summary and Next Steps**	Dr. Henderson
4:00 p.m.	**Adjourn Meeting**	Mr. Butterfield

Appendix C – Public Comments

Statement of Deborah Shprentz
Consultant to the American Lung Association
CASAC Ozone Review Panel
May 12, 2006

The World Health Organization (W.H.O.) is engaged in a review of its air quality guidelines. Earlier this year, the W.H.O. Working Group reported its consensus recommendations to revise the air quality guidelines. Eighty distinguished scientists from around the world were involved in this effort as authors, reviewers, or participants, including several members of CASAC.

The Working Group recommended revising the current guideline for 8-hour average ozone concentrations of 120 $\mu g/m^3$ (61 ppb), to 100 $\mu g/m^3$ (51 ppb).

The basis for this recommendation is twofold.

1) First, the report states that "Since the mid 1990's … there has been a marked increase in health effects evidence from epidemiological time-series studies. Combined evidence from those studies show convincing, though small, positive associations between daily mortality and ozone levels, independent of the effects of particulate matter. Similar associations have been observed in both North America and Europe. These time-series studies have shown effects at ozone concentrations below the previous guideline of 120 $\mu g/m^3$ without clear evidence of a threshold."

2) Second, the report states that "Evidence from both chamber and field studies also indicate that there is considerable individual variation in response to ozone."

Thus the W.H.O. Working Group found the evidence of the ozone-mortality link to be convincing and recommended lowering their air quality guideline, which was already far below the current U.S. standard, even further, in part because of this new evidence.

It is also worth noting that the W.H.O. report specifically indicates that an 8-hour average concentration of 160 $\mu g/m^3$, or 82 ppb, (still below the effective U.S. standard of 85 ppb with rounding) does not provide adequate protection of public health. The basis for this conclusion is that :

1) this is the lower level of 6.6 hour chamber exposures of healthy exercising young adults where physiological and inflammatory lung effects have been observed;

2) this is the ambient level at various summer camp studies showing effects on health of children; and

3) this level is associated with an estimated 3-5% increase in daily mortality, based on the findings of daily time-series studies.

I will submit a full copy of the W.H.O. report for the record.