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Environmental
Protection Agency

EPA Science Advisory
Board (1400F)
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EPA-SAB-CASAC-CON-05-001
June 2005
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EPA's Draft Ozone Health Assessment Plan: Scope and Methods for Exposure Analysis and Risk Assessment (April 2005)

*A Consultation by the Ozone Review Panel of the
EPA Clean Air Scientific Advisory Committee*



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460**

June 8, 2005

EPA-SAB-CASAC-CON-05-001

**OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD**

Honorable Stephen L. Johnson
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Subject: Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel's
Consultation on EPA's Draft Ozone Health Assessment Plan (April 2005)

Dear Administrator Johnson:

EPA's Office of Air Quality Planning and Standards (OAQPS), within the Office of Air and Radiation (OAR), is conducting technical analyses and assessments in consideration of revising the National Ambient Air Quality Standards (NAAQS) for ozone and related photochemical oxidants. As part of this process, the Agency's National Center for Environmental Assessment, Research Triangle Park, NC (NCEA-RTP), within the EPA Office of Research and Development (ORD), is revising the air quality criteria document for ozone; and OAQPS has developed a draft Ozone Health Assessment Plan: Scope and Methods for Exposure Analysis and Risk Assessment (April 2005).

EPA's Clean Air Scientific Advisory Committee (CASAC) was asked to provide early expert input on this draft Ozone Health Assessment Plan in the form of a consultation. Accordingly, the CASAC, supplemented by subject-matter-expert Panelists — collectively referred to as the CASAC Ozone Review Panel ("Panel") — met in a public meeting held in Research Triangle Park (RTP), NC, on May 5, 2005, to conduct a consultation with staff from OAQPS on this draft Ozone Health Assessment Plan. The current Panel roster is found in Appendix A of this report. The charge questions provided to the Panel by EPA are found in Appendix B to this report.

The SAB Staff Office has developed the consultation as a mechanism for an advisory body such as the CASAC to advise EPA on technical issues that should be considered in the development of regulations, guidelines, or technical guidance before the Agency has taken a position. Consultations are conducted under the normal requirements of the Federal Advisory Committee Act (FACA), as amended (5 U.S.C., App.), which include advance notice of the public meeting in the *Federal Register*.

Since a consultation represents non-consensus advice — with experts providing their individual input which was summarized in technical minutes for Agency consideration — there will be no formal report from the CASAC or the SAB as a result of this consultation, nor do we expect any formal response from the Agency. Nevertheless, we hope that the individual Panel member comments expressed during the meeting were helpful to EPA, and we look forward to reviewing the Agency's ozone health risk assessment in the near future.

Sincerely,

/Signed/

Dr. Rogene Henderson, Chair
Clean Air Scientific Advisory Committee

Appendix A – Roster of the CASAC Ozone Review Panel

Appendix B – Charge to the CASAC Ozone Review Panel

cc: Steve Page (MD-10)
John Bachmann (MD-10)
Lydia Wegman (MD-15)
Karen Martin (MD-15)

Harvey Richmond (MD-15)
Anthony Maciorowski (1400F)
Fred Butterfield (1400F)

Appendix A – Roster of the CASAC Ozone Review Panel

U.S. Environmental Protection Agency Science Advisory Board (SAB) Staff Office 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

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

**Immediate past CASAC Chair

Appendix B – Charge to the CASAC Ozone Review Panel

Air Quality Considerations:

1. The importance of characterizing policy-relevant background O₃ levels for both the exposure analysis and risk assessment is described in the draft plan.
 - a. What are the Panel members' views on the general approach described for characterizing policy-relevant background levels, considering both regional and seasonal differences?
 - b. In particular, what are the Panel members' views on using the global tropospheric O₃ model GEOS-CHEM to estimate monthly average policy-relevant background O₃ levels for different geographic regions across the U.S.?
2. The draft plan notes that staff is currently considering various approaches to adjusting air quality to simulate just meeting the current and alternative O₃ standards. The results of this evaluation will be described in the first draft Exposure Analysis Report; Panel members will have an opportunity to comment on this issue in conjunction with their review of that draft report and the first draft O₃ Staff Paper later this Fall.

Exposure Analysis:

1. Do Panel members have any comments on the overall approach to be used for the exposure analysis, including the use of the APEX model (as depicted in Figure 1 in the draft plan)?
2. The draft plan notes that staff is currently developing a methodology for constructing longitudinal human activity patterns based on cross-sectional human activity diary data contained in the Consolidated Human Activity Data Base (CHAD). Are Panel members aware of sources of information or approaches developed by others that could help inform our development of this methodology?
3. The draft plan describes the basis for and selection of population groups of interest (*i.e.*, all school-age children, active children, asthmatic children, and the general population) for which ozone exposure estimates are to be developed.
 - a. Do Panel members generally agree with the groups of interest identified in the draft plan?
 - b. In particular, what are the Panel members' views on the approach of using the median of daily PAI values for characterizing "active" children?
4. An overall strategy and general approach for addressing uncertainty and variability in the exposure analysis is described in the draft plan, including the use of 2-dimensional Monte Carlo analysis to separately characterize uncertainty and variability for the most important input parameters.

- a. What are the Panel members' views on this overall strategy and approach for addressing uncertainty and variability in the exposure analysis?
- b. Staff plans to describe in more detail the approach for quantitatively addressing uncertainties in the first draft Exposure Analysis Report; Panel members will have an opportunity to comment on these more detailed plans in conjunction with their review of that draft report and the first draft O₃ Staff Paper later this Fall.

Health Risk Assessment:

1. Do Panel members have any comments on the general structure and overall approach that staff plans to use for the risk assessment, considering the different parts of the assessment based on controlled human exposure studies (as depicted in Figure 2 in the draft plan) and on epidemiologic and/or field studies (as depicted in Figure 3 in the draft plan)?
2. In considering the part of the risk assessment to be based on controlled human exposure studies:
 - a. In general, are the criteria that staff plans to use for the selection of health endpoints and exposure-response functions clear and appropriate?
 - b. Do Panel members generally agree with focusing on lung function decrements in the quantitative risk assessment?
 - c. What are the Panel members' views on the methodology and specific studies that staff plans to use to estimate probabilistic exposure-response relationships for lung function decrements?
 - d. Do Panel members generally agree with the various risk measures that staff plans to generate in this part of the risk assessment?
3. In considering the part of the risk assessment to be based on epidemiologic and/or field studies:
 - a. In general, are the criteria that staff plans to use for the selection of health endpoints, urban areas, studies, and concentration-response functions clear and appropriate?
 - b. In particular, based on these criteria and the information in the first draft O₃ AQCD, what are the Panel members' views on the specific choices considered for inclusion in the risk assessment as discussed in the draft plan (*e.g.*, the locations and health endpoints listed in Table 1 and the specific studies listed in Table 2 of the draft plan)?
4. Do Panel members have any comments or advice with respect to the general approach to addressing uncertainty and variability in each part of the risk assessment as described in the draft plan?
 - a. What are the Panel members' views on the scope of the various sensitivity analyses that staff has planned to evaluate the influence of various uncertainties in both parts of the risk assessment?

- b. With respect to mortality associated with short-term exposures to O₃ in epidemiologic studies, the plan describes the use of an Empirical Bayes technique to more efficiently make use of the city-specific and overall estimates for the concentration-response relationships to be incorporated in the risk assessment. What are the Panel members' views of this approach?
- c. Staff notes that several meta-analyses addressing the impact of various factors on estimates of mortality associated with short-term exposures to O₃ will be published in June 2005. Staff plans to review these analyses and explore whether they provide additional information that can be used to assist in characterizing the uncertainties for this health outcome. The first draft Risk Assessment Report will describe any additional plans to expand the uncertainty analyses based on these new publications; Panel members will have an opportunity to comment on any such additional plans in conjunction with their review of that draft report and the first draft O₃ Staff Paper later this Fall.

NOTICE

This report has been written as part of the activities of the U.S. Environmental Protection Agency's (EPA) Clean Air Scientific Advisory Committee (CASAC), a Federal advisory committee administratively located under the EPA Science Advisory Board (SAB) Staff Office that is chartered to provide extramural scientific information and advice to the Administrator and other officials of the EPA. The CASAC is structured to provide balanced, expert assessment of scientific matters related to issue and problems facing the Agency. This report has not been reviewed for approval by the Agency and, hence, the contents of this report do not necessarily represent the views and policies of the EPA, nor of other agencies in the Executive Branch of the Federal government, nor does mention of trade names or commercial products constitute a recommendation for use. CASAC reports are posted on the SAB Web site at: <http://www.epa.gov/sab>.