

**U.S. Environmental Protection Agency
EPA Science Advisory Board (SAB) Staff Office
Clean Air Scientific Advisory Committee (CASAC)
CASAC Ozone Review Panel**

Summary Meeting Minutes of the CASAC's Public Advisory Meeting

**Tuesday, December 6, 2005 – 9:00 a.m. to 5:30 p.m. Eastern Time
Wednesday, December 7, 2005 – 8:30 a.m. to 5:30 p.m. Eastern Time
Thursday, December 8, 2005 – 8:30 a.m. to 3:00 p.m. Eastern Time**

Hilton Durham near Duke University, 3800 Hillsborough Road, Durham, NC 27705

Meeting to Conduct a: (1) Peer-Review of EPA's 2nd External Review Draft Air Quality Criteria Document (AQCD) for Ozone and Related Photochemical Oxidants; and (2) Consultation on EPA's 1st Draft Ozone Staff Paper and Related Draft Technical Support Documents

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

Agenda: See Meeting Agenda – Appendix B

Purpose: The purpose of this meeting was for EPA's Clean Air Scientific Advisory Committee (CASAC) to conduct a peer review of the *Air Quality Criteria for Ozone and Related Photochemical Oxidants (Second External Review Draft), Volumes I, II, and III* (second draft Ozone AQCD, August 2005); and a consultation on the *Review of the National Ambient Air Quality Standards for Ozone: Policy Assessment of Scientific and Technical Information* (first draft Ozone Staff Paper, November 2005) and two related draft technical support documents, *Ozone Health Risk Assessment for Selected Urban Areas: First Draft Report* (first draft Ozone Risk Assessment, November 2005) and *Ozone Population Exposure Analysis for Selected Urban Areas: Draft Report* (first draft Ozone Exposure Assessment, October 2005).

Attendees:

Chair:	Dr. Rogene Henderson
CASAC Members:	Dr. Ellis Cowling Dr. James Crapo Dr. Frederick Miller Mr. Richard Poirot Dr. Frank Speizer [via telephone] Dr. Barbara Zielinska
Panel Members:	Dr. John Balmes Dr. William (Jim) Gauderman Dr. Henry Gong Dr. Paul Hanson [via telephone]

Panel Members: Dr. Jack Harkema
(cont.) Dr. Philip Hopke
Dr. Michael Kleinman
Dr. Allan Legge
Dr. Morton Lippmann
Dr. Maria Morandi
Dr. Charles Plopper
Dr. Armistead (Ted) Russell
Dr. Elizabeth (Lianne) Sheppard
Dr. James Ultman
Dr. Sverre Vedal
Dr. James Zidek

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

Other EPA Staff: Dr. Tim Benner, ORD, OSP
Dr. James Brown, ORD, NCEA-RTP
Dr. Lester Grant, ORD, NCEA-RTP
Dr. Brooke Hemming, ORD, NCEA-RTP
Dr. Gary Hatch, ORD-NHEERL
Mr. Jeffrey Herrick, ORD, NCEA-RTP
Dr. Jee Young Kim, ORD, NCEA-RTP
Dr. Dennis Kotchmar, ORD, NCEA-RTP
Dr. John Langstaff, OAR, OAQPS
Dr. Karen Martin, OAR, OAQPS
Dr. David McKee, OAR, OAQPS
Dr. Anuradha Mudipalli, ORD, NCEA-RTP
Dr. Sri Nadadur, ORD, NCEA-RTP
Dr. Zachary Pekar, OAR, OAQPS
Dr. Paul Reinhart, ORD, NCEA-RTP
Dr. Mary Ross, ORD, NCEA-RTP
Ms. Vicki Sandiford, OAR, OAQPS
Ms. Susan Stone, OAR, OAQPS
Dr. David Svendsgaard, ORD, NCEA-RTP
Ms. Ginger Tennant, OAR, OAQPS
Dr. Lori White, ORD, NCEA-RTP
Dr. John Vandenberg, ORD, NCEA

(1) Peer-Review of EPA's 2nd External Review Draft Air Quality Criteria Document (AQCD) for Ozone and Related Photochemical Oxidants

Meeting Summary

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

TUESDAY, DECEMBER 6, 2005 & WEDNESDAY, DECEMBER 7, 2005

Convene Meeting, Call Attendance, Introduction and Administration

Mr. Fred Butterfield, Designated Federal Officer (DFO) for the CASAC, opened the meeting, called attendance, and welcomed all attendees. He noted that 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. Meeting minutes were taken for this meeting. The minutes will be certified by the Clean Air Scientific Advisory Committee (and Ozone Review Panel) Chair and made available on the SAB Web site (www.epa.gov/sab). In addition, a full transcription of this meeting is being taken at the request of the EPA program office to capture the discussions at the meeting; however, the DFO noted that the Science Advisory Board (SAB) Staff Office does not certify the accuracy of transcripts of its meetings. All Panelists have earlier submitted documentation with respect to possible financial conflicts-of-interest, which was reviewed by a SAB staff member prior to the meeting and found to be satisfactory.

Dr. Vanessa Vu, Staff Director, EPA Science Advisory Board (SAB), thanked the Chair and members of the CASAC Ozone Review Panel for taking part in this review. She also thanked Dr. Grant and his National Center for Environmental Assessment (NCEA-RTP) staff, Dr. Karen Martin and the staff of the Office of Air Quality Planning and Standards (OAQPS), and the SAB staff members who were present.

Purpose of the Meeting

Dr. Rogene Henderson, CASAC and Ozone Review Panel Chair, briefly stated the purpose of the meeting, the peer review of EPA's 2nd External Review Draft Air Quality Criteria Document (AQCD) for Ozone and Related Photochemical Oxidants.

Overview of Presentation on EPA's 1st Draft Ozone Air Quality Criteria Document

Dr. Les Grant, Director, NCEA in Research Triangle Park, NC (NCEA-RTP), within EPA's Office of Research and Development (ORD), thanked the members of the Ozone Panel, members of the public, and other EPA staff. Dr. Grant thanked the panel members for their efforts in reviewing both the 1st and now 2nd draft of the Ozone AQCD for Ozone and Related Photochemi-

cal Oxidants. Dr. Grant and members of the NCEA-RTP staff gave an overview presentation on the Agency's 2nd Draft AQCD, focusing on the changes that were made to the second-draft document in response to ASAC and other comments on the 1st draft. (A hard-copy of NCEA-RTP's presentations is located in FACA file for this meeting.) This included questions-and-answers between Ozone Panel and NCEA-RTP staff members.

Public Comment Period

Mr. Butterfield, CASAC DFO, facilitated the formal public comment period. He kicked-off the public comment period by reminding speakers to limit their oral statements to no more than five minutes. The following eight (8) individuals offered oral public comments on December 6: Dr. Allen Lefohn, A.S.L. & Associates; Dr. Samuel Oltmans, National Oceanic and Atmospheric Administration (NOAA); Dr. Paul Switzer, Stanford University; Mr. Jon Heuss, Air Improvement Resource, Inc. (AIR), speaking on behalf of the General Motors Corporation (GMC); Dr. Deborah Dreschler, California Environmental Protection Agency, Air Resources Board (CARB); Ms. Deborah Shprentz, consultant, speaking on behalf of the American Lung Association (ALA); Dr. Will Ollison, American Petroleum Institute (API); and Dr. Jay Turim, Sciences International, Inc., speaking on behalf of the Alliance of Automobile Manufacturers (AAM). In addition, the following three (3) individuals offered oral public comments on December 7: Mr. John Blair, Valley Watch, Inc.; Mr. Joel Schwartz, American Enterprise Institute (AEI); and Dr. Richard Dey, West Virginia University School of Medicine, speaking on behalf of the American Thoracic Society (ATS). (See Appendix C for a summary listing of all public speakers; copies of public commenters' oral statements are located in the FACA file for this meeting.) Ozone Panel members were permitted to ask follow-up questions after each public speaker had finished delivering his or her oral public statement.

Summary of the CASAC Ozone Review Panel's Discussion and Deliberations re: EPA's 2nd Draft AQCD for Ozone

Members of the CASAC Ozone Review Panel were generally pleased with the improvement in the 2nd Draft Ozone AQCD and found that EPA staff had been responsive to the Panel's comments on the review of the first draft. In general, the Panel expressed two general concerns, the first of which related to consistency within the document, noting that some of the same information is now given in three places: the Executive Summary, the main text, and the annexes. The Ozone Panel noted that Agency staff members should check carefully to ensure there is consistency across all three parts of the documents. A second concern was that both "positive" and "negative" studies of associations between ozone concentrations and health outcomes should be given the same careful consideration in the Ozone AQCD. Panel members noted that it is important that this document not contain an inappropriate bias emphasizing positive studies over equally well-designed studies that report a negative result in terms of adverse health effects. Avoiding this kind of selective "publication bias" becomes increasingly important as the gap between ozone ambient air quality standards and policy-relevant background (PRB) concentrations decreases. Significant points and conclusions from Ozone Panel members' discussion concerning the individual chapters of the 2nd Draft Ozone AQCD include the following:

- Ozone Panel members commented that the revised version of Chapter 2 (*Physics and Chemistry of Ozone in the Atmosphere*) of the Ozone AQCD is a substantial improve-

ment on what was a good first draft. Nevertheless, this document should focus on related photochemical oxidants in addition to ozone, adding that O₃ is only one of many photochemical oxidants that collectively dominate tropospheric chemistry. Panelists pointed-out that changes in ozone precursor emissions result in changes to ozone, other oxidants and their many various reaction products — including organic and inorganic acids — and the formation of secondary organic and inorganic aerosols. Several Panel members also emphasized the importance of discussing oxidants in both gaseous and particle-bound phases. With respect to ozone monitoring, the members of the Ozone Panel felt that there needs to be better discussion of the precision and accuracy of current generation monitors, and how the averaging process should be reflected in the setting of how attainment is determined, in the O₃ AQCD. The Panel pointed-out that rounding to the nearest 10 parts per billion (ppb) also needs to be reviewed, and noted that, in particular, the shift to an 8-hour average standard reduces uncertainty as compared to a one-hour average measurement.

- With respect to Chapter 3 (*Environmental Concentrations, Patterns, and Exposure Estimates*), the Ozone Panel commented that both the AQCD and the associated Annex have been greatly improved in this second draft. Nonetheless, the Panel identified some areas that would benefit from further improvements, the most important of which would be improved integration between Chapter 3, its Annex, and the Ozone AQCD's Executive Summary. The Panel also expressed some concerns about the use of the single global model (GEOS-CHEM) for the PRB estimation. The comparison of model outputs with actual measurements should be included in the main chapter, providing convincing evidence that this global model is suitable for the PRB estimation, particularly on the regional and local scale. Panel members commented that, to the extent possible, the bias and prediction error of the models should be quantified. The section in this chapter regarding trends in emissions and concentrations of ozone precursors, mainly VOCs and NO_x (Section 3.5), needs additional work, and it was noted that it might also be useful to include some illustrations of trends in different percentiles of the ozone distribution over the past 15 years. Furthermore, information should be provided concerning how the Air Pollutants Exposure (APEX) model outputs compare with personal exposures and its role in health risk assessment in the section on human exposures to ozone.
- The Ozone Panel judged that Chapter 4 (*Dosimetry, Species Homology, Sensitivity, and Animal-to-Human Extrapolation*) in the 2nd Draft Ozone AQCD is greatly improved from the first draft. In particular, the formation on ozone dosimetry, species homology, sensitivity and animal-to-human extrapolation provides a good basis for the integration of animal toxicological, human clinical and epidemiological studies to assess the potential for adverse effects in humans exposed to ozone. Nevertheless, the Panel identified several topics that still need to be addressed, including: (1) temporality of ozone exposures (*i.e.*, single, repeated, acute, chronic), and how such exposures related to biological effects; (2) location of the primary sites of tissue damage by ozone; and (3) an examination of the chemical reaction kinetics and rate constants appropriate for predicting sites of epithelial injury when modeling the dosimetry of ozone.

- Panelists noted that Agency staff have done an excellent job with Chapter 5 (*Toxicological Effects of Ozone and Related Photochemical Oxidants in Laboratory Animals and In Vitro Test Systems*) of incorporating into the comments and recommendations that the Panel had made with its review of the 1st Draft Ozone AQCD in May 2005. The Panel found this chapter to be well-written, well-organized, and adequately reflective of the published literature since the last version of the Ozone AQCD; specifically: the added figures clearly enhance the written text (although more descriptive figure legends are needed); the summaries and interpretations provided at the end of each subsection are also well done and informative; and revised chapter presents a more integrated assessment of the *in vivo* animal data and the *in vitro* studies. Nevertheless, members of the Panel suggested that a short summary of what is known from earlier studies would strengthen the chapter.
- Overall, the Ozone Panel found that Chapter 6 (*Controlled Human Exposure Studies of Ozone and Related Photochemical Oxidants*) represented a comprehensive scientific update and summary, noting that the majority of previous comments from Panel members have been satisfactorily incorporated into this draft. The Panel's suggestions for additional improvements included the following: (1) revise the section on the genetic modulation of ozone responses and the cardiovascular effects of ozone exposure in humans; (2) restate, for foundation and perspective, the most important human data from EPA's 1996 Ozone AQCD; (3) consider new study data reflecting controlled human exposures to low ozone concentrations, *e.g.*, less than 0.08 ppm.
- The Ozone Panel found Chapter 7 (*Epidemiologic Studies of Human Health Effects Associated with Ambient Ozone Exposure*) to be significantly improved from the previous draft and noted that EPA staff have incorporated most of the Panel's previous comments, — adding that, in general, the Ozone AQCD is now a relatively balanced review of the specific topics and presents a well-formulated and logical progression of summarizing the available data. Nonetheless, Panel members made several specific suggestions for improving this chapter, including: (1) exploring more fully the risk to outdoor workers, with Panel members noting that this additional discussion can help to explain the relatively large responses in the outdoor workers, who are also exposed to ozone as part of a complex mixture, which can also be tied to the revisions that that the Ozone Panel called-for in Chapter 2 concerning ozone as a surrogate measure for all of the photochemical oxidants; (2) further developing the chronic effects section; (3) providing better linkage between the figures presented and the actual annex tables from which the figures are taken; and (4) including the appropriate criteria that the Agency uses for selective inclusions of recently-published papers that add significantly to the body of scientific data on critically-important issues.
- With respect to Chapter 8 (*Integrative Synthesis: Exposure and Health Effects*), Ozone Panel members judged that this chapter needs to be shortened and more focused on the application of data and conclusions to health effects relevant to ozone exposure levels near or below the current ozone national ambient air quality standard (NAAQS); and specifically, EPA staff should add a table that lists all studies that demonstrate possible adverse health effects occurring at or below the current standard, following which there

should be a discussion of the strengths, weaknesses and overall value of each of the studies. Agency staff should also include a second table listing studies that show no adverse health effects at exposure levels at or below the current O₃ NAAQS, with the strengths and weaknesses of these particular studies also clearly identified. In addition, the summary and conclusions section of the integrative synthesis chapter needs to identify the relevance of the reported studies or conclusions to ozone exposure levels at or below the current air quality standard. The Panel also commented that this chapter needs to better address the plausibility of the more recent observational findings on mortality, especially cardiovascular mortality associated with low level ozone exposure. Specifically, this will require addressing the adequacy of ozone concentrations at central urban monitors as a measure of exposure in a population (*e.g.*, the inactive, debilitated, or elderly) at the low end of the distribution of population ozone exposure concentrations. Moreover, the discussions of cardiovascular effects and chronic effects of ozone also need to be improved in this chapter, including the presentation of more-relevant experimental findings to support the cardiovascular effects observed in the epidemiological studies. EPA staff also need to clarify that the evidence for ozone effects on cardiovascular hospitalizations, at this time, is inconclusive, at best. Furthermore, the issue of the shape of the concentration-response function and of thresholds will be critical to the deliberations presented in the Ozone Staff Paper; and the apparent differences between the experimental and epidemiological findings pertaining to the issue of thresholds need to be addressed. Finally, the Ozone Panel noted the critical importance of the exposure and human health effects integrative synthesis chapter in the development of EPA's 2nd Draft Ozone Staff Paper.

- The Ozone Panel commended EPA staff authors for their revision of Chapter 9 (*Environmental Effects: Ozone Effects on Vegetation and Ecosystems*), commenting that a significant improvement was achieved in this chapter by presenting the major conclusions and scientific findings in three different formats: a very brief Executive Summary; a relatively short main chapter; and a very thorough and detailed annex that represents a comprehensive compilation of scientific information published both prior to and following the EPA's publication of the 1996 Ozone AQCD. Panel members also noted that the main chapter provides a balanced and thoughtful summary with emphasis on current scientific knowledge about ozone effects on vegetation and ecosystems. Nonetheless, the Panel judged that the authors need to ensure that the most important aspects of current knowledge are dealt with in both the main chapter and the Executive Summary.
- Ozone Panelists remarked that Chapter 10 (*Tropospheric Ozone Effects on UV-B Flux and Climate Change Processes*) provides an informative, qualitative discussion of the potential interactions between ozone, UV-B radiation and global climate change. In particular, the Panel was pleased to see that EPA staff considered these complex indirect effects in the 2nd Draft Ozone AQCD, and notes substantial improvement from the first draft. Panel members commented that increasing UV exposures could lead to increases in the incidence of cataracts, skin cancers, and other adverse effects from suppression of immune system responses, but may also provide beneficial protective effects, including reductions in the incidence of several other forms of cancer, through increased production of vitamin D. They also noted that complex and poorly-understood climate feedback interactions preclude our current ability to make reliable quantitative estimates of climate

change effects that might result from small local or regional reductions in tropospheric ozone, adding that additional research efforts by EPA and others will be needed to allow the Agency to provide better, more quantitative estimates of effects of tropospheric ozone on (and from) UV-B radiation and climate change in the future.

- The Ozone Panel had no concerns with respect to Chapter 11 of the 2nd Draft Ozone AQCD (*Effect of Ozone on Man-Made Materials*).

Closing Remarks

Dr. Rogene Henderson thanked all Ozone Panel members for their participation in this review of the 2nd draft Ozone AQCD. She requested that the “chapter leads” (*i.e.*, the first person named among the lead discussants for each chapter) provide their consolidated inputs — reflecting the comments from their co-lead discussants — for the Panel’s draft letter concerning its peer review of the 2nd draft Ozone AQCD to her and Mr. Butterfield, as DFO, by close of business on Monday, December 19. In order to meet this deadline, of course, co-lead discussants should have their supporting remarks in to their respective chapter leads by no later than the middle of next week.

In addition, Dr. Henderson asked that all Panel members provide their revised or initial individual written review comments on the 2nd draft Ozone AQCD as soon as practicable, but also by 12/19. In addition, she requested that Panel members tailor their individual comments to the Agency charge questions found in the background and charge memos from NCEA-RTP

Mr. Butterfield, CASAC DFO, adjourned this peer-review portion of the meeting at approximately 5:00 p.m. on Wednesday, December 7.

(2) Consultation on EPA’s 1st Draft Ozone Staff Paper and Related Draft Technical Support Documents

Meeting Summary

The discussion followed the issues and general timing as presented in the meeting agenda.

THURSDAY DECEMBER 8, 2005

Convene Meeting, Call Attendance, Introduction and Administration; Opening Statement by CASAC Chair

Mr. Fred Butterfield, CASAC DFO, opened the meeting, called attendance, and welcomed-back all attendees. Mr. Butterfield stated that the purpose of the meeting was for the Ozone Panel to conduct a consultation on EPA’s 1st Draft Ozone Staff Paper and two related draft technical support documents prepared by OAQPS, within EPA’s Office of Air and Radiation (OAR). Dr. Rogene Henderson, the CASAC Chair, noted that this consultation on the 1st Draft Ozone Staff Pa-

per was a real opportunity for the Ozone Panel to offer its advice to the Agency early in the development of this very important document. Additionally, she complimented the Agency staff on the quality of the first draft staff paper.

Public Comment Period

Mr. Fred Butterfield kicked-off the public comment period by reminding speakers to limit their oral statements to no more than five minutes — and to keep them to three minutes if possible. The following seven (7) individuals offered oral public comments on December 8: Dr. Allen Lefohn, A.S.L. & Associates; Dr. Annette Rohr, Electric Power Research Institute (EPRI); Mr. Jon Heuss, Air Improvement Resource, Inc. (AIR), speaking on behalf of the General Motors Corporation (GMC); Dr. David Riker, CRA International, speaking on behalf of the Utility Air Regulatory Group (UARG); Dr. Larry Gephart, ExxonMobil Biomedical Sciences, Inc.; Ms. Deborah Shprentz, consultant, speaking on behalf of the American Lung Association (ALA); and Dr. Will Ollison, American Petroleum Institute (API). (See Appendix C for a summary listing of all public speakers; copies of public commenters' oral statements are located in the FACA file for this meeting.) Ozone Panel members were permitted to ask follow-up questions after each public speaker had finished delivering his or her oral public statement.

Overview of Presentation of EPA's 1st Draft Ozone Staff Paper and Related Draft Technical Support Documents

Dr. Karen Martin and members of her OAQPS staff gave overview presentations on EPA's 1st Draft Ozone Staff Paper and two related draft technical support documents: *Ozone Health Risk Assessment for Selected Urban Areas: First Draft Report* (first draft Ozone Risk Assessment, November 2005) and *Ozone Population Exposure Analysis for Selected Urban Areas: Draft Report* (first draft Ozone Exposure Assessment, October 2005). (A hard-copy of OAQPS' presentations is located in FACA file for this meeting.) This included questions-and-answers between Ozone Panel and members of the OAQPS staff.

Summary of the CASAC Ozone Review Panel's Discussion and Deliberations re: EPA's 1st Draft Ozone Staff Paper and Related Draft Technical Support Documents

The members of the CASAC Ozone Review Panel were generally pleased with EPA's 1st Draft Ozone Staff Paper and the two related draft technical support documents. Significant points raised by Ozone Panelists during this consultation on these documents include the following:

- One Panel member commented that a major problem with this 1st Draft Staff Paper is that it loses the focus on other photochemical oxidants, noting that chemistry in the atmosphere is almost exclusively photochemistry. He added that the purpose of regulating ozone is the overall control of photochemical oxidants, and that the breadth of the influence of photochemical oxidants is diminished too far by restricting the discussions in the staff paper to ozone. In addition, control of photochemical oxidants (including ozone and its reaction products) would also provide controls on pollutants that include inorganic acids (sulfuric and nitric), particles formed from these inorganic acids, and secondary or-

ganic aerosols and their associated oxidants such as peroxides. This Panel member also remarked that the role of ozone in the formation of secondary particles particularly secondary organic aerosol (SOA) is neglected in the document, and strongly suggested that a significant added benefit in controlling ozone is that it will reduce the oxidant burden in the atmosphere leading to lower rates of formation of secondary inorganic (sulfate and nitrate) as well as organic particles.

- Another Panelist similarly remarked that, although the section in chapter 2 that covers chemical and physical properties and the formation and transport of ozone mentions “other oxidants,” it does not include any information regarding this topic. She noted that it would be important to summarize briefly the discussion in this chapter regarding other photochemical oxidants and the role of ozone in the atmospheric transformation processes that may result in the formation of more toxic gas- and particle-phase products. She added that the ambient O₃ levels, its temporal and spatial variability, long-term trends, and characterization of ozone episodes, do seem to be adequately summarized in this chapter. However, she also pointed-out that there is no information regarding relationships between ambient O₃ and human exposures. Moreover, while the modeling of human exposure to ozone is discussed in Chapter 4 of the 1st Draft Staff Paper, there is no information in both chapters how the actual personal human exposures compare to the ambient central monitoring data.
- With regard to ozone air quality information and analyses discussed in Chapter 2 of the Staff Paper, another Ozone Panel member noted that the results of the air quality characterizations and analyses are generally clear and very well communicated with regard to the review of the primary and secondary Ozone NAAQS. He added that, in particular, the Staff Paper provides a good characterization of the concentration field of the current criteria metrics, while noting that some improvements are still needed. With regard to the extent to which the properties of ambient ozone are appropriately characterized, including policy-relevant background (PRB), this Panelist remarked that some indication is needed of the level of uncertainty associated with the estimates of the PRB field, adding that the relationship between ambient and personal exposures is very well discussed in qualitative terms. Another Panel member also commented that the issues surrounding PRB are not very well characterized, and noted that the statement that policy-relevant background cannot be derived from measurements and must be based on modeling is somewhat controversial.
- Another Panelist noted that the Air Pollutants Exposure (APEX) model that the Agency used to estimate exposures both currently, and in the future appears to be both technically appropriate and feasible model, while noting that the Staff Paper still suffers from a lack of discussion on model evaluation in this document, along with historical applications and quantitative uncertainty analysis.
- With regard to Chapter 3 (Health Effects) of the 1st Draft Ozone Staff Paper, a Panel member commented that, in general, the chapter takes a well-balanced approach to summarizing and integrating the available health evidence, although there are some exceptions. He also noted that defining adversity based on level of lung function is compli-

cated in the context of ozone because it is not clear that the acute decrease in inspiratory capacity (hence the major determinant of the decline in FVC and FEV₁) is not beneficial in preventing more marked exposure. With respect to the Agency's treatment of policy-relevant assessment of health effects evidence, another Panelist judged that Chapter 3 represents a good start toward serving as the basis for characterizing the health risks in humans from exposure to ozone. Nevertheless, the chapter could be shortened by less repetition of material from the Ozone AQCD. In addition, he commented that there are a number of areas where revisions are needed based upon technical aspects and interpretation of the existing data. Some of these areas are listed below according to their appearance in the chapter.

- Another Ozone Panel member commented that the use of a linear exposure-response function for the FEV₁ calculations should be revisited since this has the undesirable statistical property of providing negative risk estimates at low exposures, adding that a logistic function would be a good alternative. He also noted that, at a minimum, a demonstration that the calculations provided in the current draft staff paper are relatively insensitive to the choice of linear versus logistic risk function would go a long way to reducing concern about the general use of the linear function.
- A Panel member remarked that the decisions to exclude respiratory symptoms in children in risk assessment and to dispute the use of inner city asthmatic subjects are problematic. With respect to the Draft Ozone Risk Assessment, this Panelist commented that Chapter 3 of this draft technical support document constitutes a foundation for Chapter 5 (Health Risks) of the Staff Paper, adding that, in some ways, the technical support document actually reads better than Chapter 5. However, he also noted that Chapter 3 is shorter because it evaluates controlled human exposures only.
- Another member of the Ozone Panel commented that, with regard to the exposure analysis and the *Ozone Population Exposure Analysis for Selected Urban Areas: Draft Report* technical support document, the approach is, in general, state of the art in probabilistic exposure modeling, in that it combines accepted ambient air pollution models with residential characteristic and personal activity variables that impact exposure. She also noted that, as with any model that incorporates a broad range of input variables, uncertainties are inherent to the validity of the model assumptions and the quality and comprehensiveness of the input data. This Panelist also remarked that, while the limitations of the data are fairly well-described, the assumptions of the model need to be stated clearly upfront.
- Commenting on the *Ozone Health Risk Assessment for Selected Urban Areas: First Draft Report*, another Panel member remarked that the logic of this presentation is well presented but from his perspective was easier to read for the epidemiology aspects after reading the clinical studies. He added that the problem will be that to do a series of potential different standards the issue will become confusing simply by the mass of numbers, and that unless a method is presented that would allow for a graphic view of multiple standards in the same graph it will be hard to grasp the value of each change. Still another member of the Panel noted that there was no mention of how distributed lag coefficients are incorporated into the risk assessment. She added that, since these are the sum

of coefficients over multiple days, it should be noted how this is treated in the risk assessment.

- With respect to the welfare effects in the 1st Draft Ozone Staff Paper, another Panel member commented that he was disappointed at not seeing any Agency staff recommendations with respect to a possible secondary standard with a different metric, also pointing-out that the value of ecosystem function and services is inadequately presented. He remarked that he joined the others on the Ozone Panel who believe it is time that EPA demonstrates its commitment to protecting the environment by setting an appropriate, separate secondary standard for ozone.

Closing Remarks

Dr. Rogene Henderson thanked all Ozone Panel members for their participation in this consultation on EPA's 1st Draft Ozone Staff Paper and related technical support documents. Dr. Henderson asked that all Panel members provide their revised or initial individual written review comments on the 1st draft Ozone Staff Paper, *etc.* as soon as practicable, but also by close of business on Monday, December 19.

Mr. Butterfield, CASAC DFO, adjourned the meeting at approximately 2:45 p.m. on Thursday, December 8.

Respectfully Submitted:

Certified as True:

/s/

/s/

Fred A. Butterfield, III

Rogene F. Henderson, Ph.D.

Fred A. Butterfield, III
CASAC DFO

Rogene F. Henderson, Ph.D.
CASAC Chair

Appendices

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

Appendix B – Meeting Agenda

**U.S. Environmental Protection Agency
EPA Science Advisory Board (SAB) Staff Office
Clean Air Scientific Advisory Committee (CASAC)
CASAC Ozone Review Panel
Public Advisory Meetings**

Hilton Durham near Duke University, 3800 Hillsborough Road, Durham, NC 27705

9:00 a.m. Tuesday, December 6 to 5:30 p.m. Wednesday, December 7, 2005: Meeting to Conduct a Peer Review of EPA's 2nd Draft Ozone AQCD

Thursday, December 8, 2005 (8:30 a.m. – 3:00 p.m.): Meeting to Conduct a Consultation on EPA's 1st Draft Ozone Staff Paper & Technical Support Documents

Meeting Agenda

Tuesday, December 6, 2005

9:00 a.m.	Convene Meeting; Call Attendance; Introductions and Administration; and Overview of Meeting Agenda	Mr. Fred Butterfield, CASAC Designated Federal Officer (DFO)
9:10 a.m.	Welcome from EPA Science Advisory Board Staff Office	Dr. Vanessa Vu, Director
9:15 a.m.	Opening Remarks & Purpose of Meeting	Dr. Rogene Henderson, Chair
9:20 a.m.	Welcome from NCEA-RTP; Overview Presentation on EPA's 2nd External Review Draft Air Quality Criteria Document (AQCD) for Ozone and Related Photochemical Oxidants	Dr. Les Grant, Director, National Center for Environmental Assessment-RTP; & NCEA-RTP Staff
10:30 a.m.	Break*	
10:45 a.m.	Public Comment Period (Ozone AQCD)	Mr. Butterfield (Facilitator)
11:45 a.m.	Lunch (Hotel)	
1:00 p.m.	CASAC Ozone Review Panel Discussion in Response to Charge Questions: 2nd Draft Ozone AQCD (<i>Atmospheric Physics and Air Quality</i>, Chapters 2-3)	Dr. Henderson, Ozone Review Panel Members
2:30 p.m.	Break	
2:45 p.m.	CASAC Panel Discussion on 2nd Draft Ozone AQCD (<i>Atmospheric Physics and Air Quality</i>, Chapters 2-3) [Continued]	Dr. Henderson, Ozone Review Panel Members

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

Tuesday, December 6, 2005 (continued)

4:00 p.m.	CASAC Panel Discussion on 2nd Draft Ozone AQCD (<i>Human Health Effects</i>, Chapters 4-8)	Dr. Henderson, Ozone Review Panel Members
5:30 p.m.	Adjourn Meeting for the Day	Dr. Henderson, Mr. Butterfield

Wednesday, December 7, 2005

8:30 a.m.	Reconvene Meeting; Call Attendance	Mr. Butterfield
8:40 a.m.	Re-cap of Previous Day's Meeting	Dr. Henderson
8:45 a.m.	Public Comment Period (Ozone AQCD)*	Mr. Butterfield (Facilitator)
9:00 a.m.	Additional NCEA-RTP Comments	Dr. Grant
9:05 a.m.	CASAC Panel Discussion on 2nd Draft Ozone AQCD (<i>Human Health Effects</i>, Chapters 4-8) [Cont.]	Dr. Henderson, Ozone Review Panel Members
10:15 a.m.	Break**	
10:30 a.m.	CASAC Panel Discussion on 2nd Draft Ozone AQCD (<i>Human Health Effects</i>, Chapters 4-8) [Cont.]	Dr. Henderson, Ozone Review Panel Members
12:00 p.m.	Lunch (Hotel)	
1:00 p.m.	CASAC Panel Discussion on 2nd Draft Ozone AQCD (<i>Environmental/Welfare Effects</i>, Chapters 9-11)	Dr. Henderson, Ozone Review Panel Members
2:00 p.m.	Break	
2:30 p.m.	CASAC Panel Discussion on 2nd Draft Ozone AQCD (<i>Environmental/Welfare Effects</i>, Chapters 9-11) [Continued]	Dr. Henderson, Ozone Review Panel Members
5:15 p.m.	Summary, Wrap-Up, and Next Steps	Dr. Henderson
5:30 p.m.	Adjourn Meeting for the Day	Dr. Henderson, Mr. Butterfield

Notes:

*The purpose of the public comment period on the second day of the meeting is to permit members of the public who were unable to provide their oral comments on the first day with an opportunity to do so.

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

Thursday, December 8, 2005

8:30 a.m.	Reconvene Meeting; Call Attendance	Mr. Butterfield
8:40 a.m.	Purpose of Consultative Meeting	Dr. Henderson
8:45 a.m.	Overview Presentations on EPA's 1st Draft Ozone Staff Paper, Exposure Analysis & Risk Assessment Technical Support Documents	Dr. Karen Martin, Dr. David McKee, OAQPS & Staff
9:45 a.m.	Public Comment Period (Ozone Staff Paper, etc.)	Mr. Butterfield (Facilitator)
10:00 a.m.	Break*	
10:15 a.m.	CASAC Ozone Review Panel Discussion in Response to Charge Questions: 1st Draft Ozone Staff Paper (<i>Air Quality</i>, Chapter 2 and <i>Human Health Effects</i>, Chapter 3)	Dr. Henderson, Ozone Review Panel Members
11:00 a.m.	CASAC Panel Discussion on 1st Draft Ozone Staff Paper (<i>Health Risks</i>, Chapter 5) & Risk Assessment Technical Support Document	Dr. Henderson, Ozone Review Panel Members
11:45 a.m.	Lunch (Hotel)	
12:45 p.m.	CASAC Panel Discussion on 1st Draft Ozone Staff Paper (<i>Human Exposure</i>, Chapter 4) & Exposure Analysis Technical Support Document	Dr. Henderson, Ozone Review Panel Members
1:30 p.m.	CASAC Panel Discussion on 1st Draft Ozone Staff Paper (<i>Primary O₃ NAAQS</i>, Chapter 6)	Dr. Henderson, Ozone Review Panel Members
2:00 p.m.	CASAC Panel Discussion on 1st Draft Ozone Staff Paper (<i>Environmental Effects/Secondary O₃ NAAQS</i>, Chapter 7)	Dr. Henderson, Ozone Review Panel Members
2:50 p.m.	Summary, Wrap-Up, Next Steps and Closing Remarks	Dr. Henderson
3:00 p.m.	Adjourn Meeting	Mr. Butterfield

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

Appendix C –List of Public Speakers

List of Public Speakers

U.S. Environmental Protection Agency ❖ Clean Air Scientific Advisory Committee (CASAC) ❖ CASAC Ozone (O₃) Review Panel

Tuesday, December 6 & Wednesday, December 7, 2005: Peer Review of EPA’s 2nd Draft Ozone AQCD

Thursday, December 8, 2005: Consultation on EPA’s 1st Draft Ozone Staff Paper & Technical Support Documents

Public Meetings ❖ December 6-8, 2005 ❖ *Hilton Durham near Duke University* ❖ 3800 Hillsborough Road, Durham, NC 27705

#	Speaker’s Name	Organizational Affiliation(s)	Organization(s) Represented (comments offered on behalf of)	Document(s)	Day(s) Speaking
1	Dr. Allen Lefohn	A.S.L. & Associates	same	O ₃ AQCD & O ₃ Staff Paper	Tuesday, 12/6 Thursday, 12/8
2	Mr. John Blair*	Valley Watch, Inc.	same	O ₃ AQCD & O ₃ Staff Paper	Wednesday, 12/7
3	Dr. Annette Rohr	Electric Power Research Institute (EPRI)	same	O ₃ Staff Paper	Thursday, 12/8
4	Dr. Samuel Oltmans*	National Oceanic and Atmospheric Administration (NOAA)	none (representing himself)	O ₃ AQCD	Tuesday, 12/6
5	Dr. Paul Switzer*	Stanford University	none (representing himself)	O ₃ AQCD	Tuesday, 12/6
6	Mr. Joel Schwartz*	American Enterprise Institute (AEI)	same	O ₃ AQCD & O ₃ Staff Paper	Wednesday, 12/7
7	Mr. Jon Heuss	Air Improvement Resource, Inc. (AIR)	General Motors Corporation (GMC)	O ₃ AQCD & O ₃ Staff Paper	Tuesday, 12/6 Thursday, 12/8
8	Dr. Deborah Dreschler*	California Environmental Protection Agency, Air Resources Board (CARB)	same	O ₃ AQCD & O ₃ Staff Paper	Tuesday, 12/6
9	Dr. David Riker	CRA International	Utility Air Regulatory Group (UARG)	O ₃ Staff Paper	Thursday, 12/8
10	Dr. Larry Gephart	ExxonMobil Biomedical Sciences, Inc.	same	O ₃ AQCD & O ₃ Staff Paper	Thursday, 12/8

*Note: Will present oral comments via teleconference (phone) line

#	Speaker's Name	Organizational Affiliation(s)	Organization(s) Represented (comments offered on behalf of)	Document(s)	Day(s) Speaking
11	Dr. Richard Dey*	West Virginia University School of Medicine	American Thoracic Society (ATS)	O ₃ Staff Paper	Wednesday, 12/7
12	Ms. Deborah Shprentz	Consultant	American Lung Association (ALA)	O ₃ AQCD & O ₃ Staff Paper	Tuesday, 12/6 Thursday, 12/8
13	Dr. Will Ollison	American Petroleum Institute (API)	same	O ₃ AQCD & O ₃ Staff Paper	Tuesday, 12/6 Thursday, 12/8
14	Dr. Jay Turim	Sciences International, Inc.	Alliance of Automobile Manufacturers (AAM)	O ₃ AQCD	Tuesday, 12/6

*Note: Will present oral comments via teleconference (phone) line