



November 23, 2005

**MEMORANDUM**

**SUBJECT:** CASAC Review of Second External Review Draft Ozone Air Quality Criteria Document (2<sup>nd</sup> Draft Ozone AQCD)

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In support of the Environmental Protection Agency's (EPA) ongoing periodic review of the National Ambient Air Quality Standards (NAAQS) for Ozone (O<sub>3</sub>), a first draft of an updated revision of the EPA document, *Air Quality Criteria for Ozone and Related Photochemical Oxidants*, was prepared by EPA's National Center for Environmental Assessment, Research Triangle Park, NC (NCEA-RTP). That First External Review Draft (January 2005) of the revised Ozone Air Quality Criteria Document (1<sup>st</sup> Draft Ozone AQCD) was made available for public comment in early 2005 and subsequently underwent peer review by the Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel at a public meeting which took place in RTP on May 4-5, 2005. Based on the public comments received and that CASAC review, revisions were incorporated into a Second External Review Draft (2<sup>nd</sup> Draft) of the Ozone AQCD, which consists of three volumes (EPA/600/R-05/004aB-cB, August 2005). The 2<sup>nd</sup> Draft Ozone AQCD was released for public comment by posting on the Agency's NCEA Web site at: <http://cfpub.epa.gov/ncea/> under "Risk Assessments (Ozone)" and circulated in CD-ROM form to all members of the CASAC Ozone Review Panel in early October 2005 in preparation for their review at an upcoming (December 6-8, 2005) public meeting.

A June 15, 2005 letter to the EPA Administrator summarized the consensus views expressed by the CASAC Ozone Review Panel regarding their review of the 1<sup>st</sup> Draft Ozone AQCD and their advice on recommended revisions to further improve the document. In that letter, the Panel indicated that it was generally pleased with the high quality of the 1<sup>st</sup> Draft Ozone AQCD and complimented Agency staff on their efforts. The Panel noted that they were appreciative of the new format, in which key information from the previous Ozone AQCD was typically summarized at the outset of each chapter or main section and then interpretive evaluation of newly-available information was discussed in the remainder of the chapter, with

detailed supporting information being described in annexes to the main chapters. However, despite the high overall quality of the 1<sup>st</sup> Draft AQCD, the CASAC Ozone Review Panel also identified several important areas that needed to be improved and provided both general and specific advice for strengthening of the document.

EPA staff and expert consultants to NCEA-RTP have undertaken extensive efforts to incorporate into the 2<sup>nd</sup> Draft Ozone AQCD a number of changes made in response to public comments and CASAC review of the 1<sup>st</sup> Draft Ozone AQCD. In the materials that follow below, some of the more salient revisions made in response to public and CASAC comments are concisely summarized in relation to various chapters or subsections; and, in addition, associated charge questions are posed to help focus the discussions at next month's CASAC Ozone Review Panel meeting.

We look forward to interacting with the CASAC Ozone Review Panel in Durham, NC during its December 6-8 public meeting and to receiving further constructive advice on how to improve the revised Ozone AQCD in bringing it to its final form during the next few months, in time for publication by a court-ordered deadline of February 28, 2006. Thank you.

## **SUMMARY OF SALIENT REVISIONS INCORPORATED INTO AUGUST 2005 SECOND EXTERNAL REVIEW DRAFT OF OZONE AQCD AND ASSOCIATED CHARGE QUESTIONS FOR DECEMBER 2005 CASAC PUBLIC MEETING**

### **A. GENERAL REVISIONS**

**Re-sequencing of Main Chapters and Annexes.** One overarching modification seen in the 2<sup>nd</sup> Draft Ozone AQCD is a restructuring of the three volumes which comprise it. Specifically, in contrast to the placing of annex materials immediately after the particular chapter to which they are related as was done in the 1<sup>st</sup> Draft (and, therefore, their being interspersed across each of three volumes), all of the main chapters of the revised Ozone AQCD (including the Executive Summary and Chapters 1 through 11) now all appear in Volume I, whereas Volumes II and III of the 2<sup>nd</sup> Draft AQCD include the annexes to the main chapters. In keeping with CASAC's advice, this emphasizes EPA's shift toward a new approach (as embodied in the newly developed Ozone AQCD) of focusing the main criteria document chapters on shorter, interpretive evaluations of literature and the inclusion of more-detailed descriptive information in annexes to the main criteria document.

**Charge Questions – Overall.** Does this new format meet Panel members' expectations in terms of facilitating reading and comprehension of the evaluations and conclusions that are communicated in the overall criteria document materials, *i.e.*, in the AQCD's main chapters and accompanying annexes? Or, would alternative sequencing of materials to have a given annex immediately follow its relevant main chapter be more "reader friendly" and effective?

**Addition of an Executive Summary.** A newly-developed Executive Summary has been added to the 2<sup>nd</sup> Draft Ozone AQCD; specifically, at the beginning of Volume I. That summary is provided mainly in terms of concise bullets characterizing key findings and conclusions drawn from various main chapters of the document.

**Charge Question – Executive Summary.** What are the Panel’s views with regard to the format of the newly-provided Executive Summary and the soundness of its scientific content, including consistency of the restatement of key findings and conclusions stated in the main chapters of the document?

## **B. REVISIONS TO SPECIFIC CHAPTERS**

**Chapter 2.** In addition to responding to comments on specific technical or grammatical points, a sub-section on possible mechanisms of formation of reactive oxygen species (ROS) in particulate matter (PM) was added. Studies of the formation of ROS in PM are sparse. Material from new studies of the effects of interference on ozone measurements was also added. The results of these studies indicate that effects of interfering substances can be substantial in highly-localized environments, but are not likely to be a cause for concern in typical ambient environments.

**Chapter 3.** Sections of Chapter 3 characterizing ozone air quality across the United States were almost entirely rewritten. Discussion of ambient air quality analyses focused on ozone in the twelve urban areas to be considered in risk assessments in the Ozone Staff Paper. Information for ozone across the range of concentrations found in ambient air was included. Additional material on observations for oxidants other than ozone, present in both gas and particulate phases, was added, based mainly on results of limited field studies for those “other” oxidants.

**Charge Questions – Chapters 2 & 3.** Given the expanded information related to “other photochemical oxidants” in response to earlier CASAC advice, what are the Panel members’ views with regard to the scope and scientific adequacy of Chapters 2 & 3? Are there any other important topics that should be addressed?

**Chapter 4.** Based on earlier review of this chapter on dosimetry of ozone in the respiratory tract in the 1<sup>st</sup> Draft Ozone AQCD, the CASAC recommended increased discussion about (and inclusion of more figures illustrating) basic dosimetric principles related to ozone uptake and effects. The organization of the chapter also caused some confusion as to summarization of the state of knowledge at the time of the 1996 Ozone AQCD and the evaluation of new dosimetry-related advances since then. In response to CASAC Ozone Review Panel comments, extensive revisions were made to Section 4.2 to better clarify information related to these areas.

**Charge Question – Chapter 4.** Are there any further revisions that should be made beyond the new figures, associated discussions, and reorganization of Section 4.2 and its constituent discussions in order to adequately address the Panel’s earlier concerns?

**Chapter 5.** In response to CASAC comments, three figures were added to Chapter 5 to better illustrate mechanisms of ozone toxicity and genetic susceptibility. NCEA staff also removed discussions of studies using high, non-ambient levels of O<sub>3</sub> and added caveats informing readers that events and mechanisms observed at higher concentrations may differ from those observed at near-ambient levels. Better descriptions were added of research covered in the previous O<sub>3</sub> AQCD. Redundancy was eliminated by placing only tables in the annex and discussions and interpretations of the research in the main chapter.

**Charge Question - Chapter 5.** Do these added figures, additional discussions, and general reorganization of the material adequately address the concerns expressed regarding the first draft? Does the Panel have any further recommendations to improve the chapter?

**Chapter 6.** Numerous minor corrections and coverage of some more references were added throughout Chapter 6 (on Controlled Human Exposures to Ozone) and its associated annex in response to the first CASAC review. However, more notable revisions were made to a few sections. First, in response to concerns that genetic factors were not adequately discussed, Section 6.5.7 and its annex on genetic factors were completely revised and expanded to include a number of newer studies. Second, Section 6.9.3 on inflammatory responses in the lower respiratory tract was considered by the CASAC Ozone Review Panel to be too lengthy relative to other inflammatory response sections; in response, that section (6.9.3) has been substantially rewritten and shortened, despite inclusion of a new figure illustrating temporal patterns for various responses and coverage of several new references. Third, given the CASAC's review comments noting that Section 6.10 did not adequately address cardiovascular effects of ozone exposure, Section 6.10 and its annex on extrapulmonary effects were revamped to include more discussion of relevant studies of ozone cardiovascular effects.

**Charge Questions – Chapter 6.** Although there is a paucity of clinical studies concerning human genetic factors in relation to ozone effects, do revised Sections 6.5.7 and AX 6.5.7 adequately discuss the current state of knowledge and uncertainty related to the existing pertinent studies? Also, does the Panel find that Section 6.9.3 on inflammatory responses to more succinctly, yet adequately, summarize pertinent information than the previous draft? Moreover, do revisions to Section AX6.10 adequately characterize the intimate relationship between the pulmonary and cardiovascular systems, and do materials in Sections 6.10 and AX6.10 provide sufficient background information to adequately address potential cardiovascular effects of ozone as evidenced by clinical studies?

**Chapter 7.** The acute ozone mortality discussion has been updated and enhanced in response to comments from CASAC and the public. In addition, new literature, including three published meta analyses, has been incorporated. The examination of CVD mortality and associated morbidity studies have been updated and expanded with published literature. Efforts were also made to incorporate limitations of assessing the presence of thresholds of ozone effects.

**Charge Questions – Chapter 7.** Do the current discussions adequately present the relationship between ozone exposure and acute mortality, and the strength and robustness of the evidence base? Are the discussions on the concentration-response relationships and the potential existence of thresholds of ozone effects improved? Are the summary statements regarding the concentration-response relationship and threshold of effects substantiated?

Are acute and chronic pulmonary function outcomes clearly presented? For individual studies, are % changes in FEV<sub>1</sub> or PEF more uniformly presented to enhance comparison of effects among the various studies? Are presentations of the chronic studies informative and summary statements on the chronic effects appropriate?

Are the revisions of Chapter 7 responsive to comments made by CASAC and the public with regard to the 1st ERD? Specifically, has the prior focus on statistical significance been redirected to effect estimates with confidence intervals or SD and include pertinent data such as sample size when necessary? Have repetitive, overly fundamental background information and cross-references to the previous PM AQCD been revised appropriately in the introduction and the interpretive sections? Are the summary of key findings and the conclusions derived from the ozone epidemiology studies focused and substantiated? In addition, have the Annex Tables been improved in regard to presentation of ozone levels and ranges, study design and limitations?

**Chapter 8.** This critical Integrative Synthesis chapter of the Ozone AQCD has been extensively revised in the 2<sup>nd</sup> Draft Ozone AQCD so as to present a more coherent discussion on the overall health effects associated with ambient ozone exposures. Extensive efforts have been made to characterize important pertinent information for assessing the consistency between experimental findings in human and animal toxicology studies with observational findings reported in the epidemiologic studies for both acute and chronic exposures. The discussions in section 8.2 have also been revised to present current ambient ozone air quality trends, including new information on factors affecting human exposures (section 8.3).

This information has been utilized to integrate exposure issues in the synthesis of health effects discussed in section 8.4 based on experimental toxicology studies in humans and laboratory animals (biochemical, physiological inputs) together with the epidemiologic observations. The scientific information synthesized here was utilized to evaluate and highlight biological plausibility associations presented in section 8.5 for the important epidemiological observations: respiratory morbidity; mortality (particularly with additional new discussions on cardiovascular effects); and potential susceptibility factors including potential ozone-allergen interactions associated with these observations (Section 8.6). The last section presents an overall summary and conclusions for ozone health effects.

**Charge Questions – Chapter 8.** How well does the revised Integrative Synthesis chapter in the 2<sup>nd</sup> Draft Ozone AQCD accomplish the desired integration of key findings and conclusions from Chapters 2 through 7, and in what ways might that chapter be further improved? In particular, are the discussions on ozone-allergen interactions sufficiently clear with regard to potential susceptibility issues? Also, how well does the revised draft of Chapter 8 provide an integrated health effects assessment for chronic effects of O<sub>3</sub>? Do the

discussions in the biological plausibility section adequately capture and synthesize pertinent key scientific information from Chapters 5 and 6 (as also summarized in Table 8-1 and Figures 8-9 and 8-10) to characterize the extent to which various O<sub>3</sub>-induced pulmonary function/respiratory symptom effects may be considered adverse for various types of exposed human population groups (*i.e.*, as a function of age and respiratory disease status)? Lastly, are there any other important topics or issues that need to be addressed in the Chapter 8 Integrative Synthesis?

**Chapter 9.** An overarching recommendation from the CASAC’s earlier review of this chapter on ozone vegetation/ecosystem effects pertinent to scientific bases for secondary ozone NAAQS was that it be revamped to encompass a structure analogous to that used for other chapters, *i.e.*, the focusing of the main AQCD chapter on short, interpretive evaluation of information of most relevance for derivation of criteria supporting NAAQS decisionmaking and allocation of more extensive, detailed descriptive materials to accompanying annexes. Appropriate revisions were done to accomplish this, with the discussions in the body of Chapter 9 in the 2<sup>nd</sup> Draft Ozone AQCD being restricted to a much shorter interpretive summary of key information and more detailed descriptive information being placed in accompanying annex materials.

A key issue addressed in the revised chapter deals with derivation of several different metrics or indices reflective of exposure-response relationships for ozone-induced vegetation damage. In its earlier review, the CASAC also recommended that EPA undertake a re-analysis of NCLAN data to determine whether 8-hour moving average ozone metrics exhibit similar vegetation exposure- response surfaces as the SUM06 ozone metric presented in the 1<sup>st</sup> Draft Ozone AQCD. In response to the CASAC’s advice, statistical analyses of NCLAN data have been undertaken as a complement to the current draft of section 9.5 entitled “Ozone Exposure – Plant Response Relationships.” Also of note is the addition of discussion in Chapter 9 and/or accompanying annex materials of a number of so-called Free Air Control Exposure(FACE) studies published since those covered in the 1<sup>st</sup> Draft Ozone AQCD. Besides the first charge question listed below focusing on evaluation of the adequacy of such just-noted revisions, many of the original charge questions posed for the earlier CASAC review of the 1<sup>st</sup> Draft AQCD still apply.

**Charge Questions – Chapter 9.** What are the CASAC Ozone Panel’s views on the adequacy of the much shorter evaluative discussion now comprising Chapter 9 of the 2<sup>nd</sup> Draft Ozone AQCD? Have any crucially important new FACE studies or other crucially important types of ecological effects studies been missed? Are there any additional modifications to the main body of Chapter 9 or accompanying annex materials that would further strengthen the overall coverage and interpretation of findings related to ozone vegetation/ecosystem effects?

**Chapter 10.** Chapter 10, on UV-B flux and climate change, has undergone further revision to provide a concise but clear overview of key information regarding tropospheric O<sub>3</sub> effects on UV-B flux at the earth’s surface, factors governing human exposure to UV-B and its potential human health effects. In particular, the CASAC called for — and changes were made in the chapter — to provide:

(a) tighter links between the detailed information provided on human factors governing UV-B exposure and the summary and conclusions concerning scientific basis for evaluating the role of pollutant O<sub>3</sub> and UV-B health effects;

(b) tighter links between Chapter 3 discussions on policy-relevant background (PRB) concentrations and patterns of elevated O<sub>3</sub> levels and Chapter 10 discussion of role of ozone in climate change (with text reviewing this being introduced where appropriate in Chapter 10 discussion of regional and local O<sub>3</sub> concentrations and trends in the context of climate forcing); and

(c) stronger statements on the evidence for and impacts of climate change (with discussion of studies concerning the evidence of GHG-linked sea surface warming published in *Science* being added, and the reader being referred to several detailed studies on the potential climate change impacts — given that a greatly-expanded discussion of this subject is seen as beyond the scope of this Ozone AQCD).

Overall, the Chapter continues to find that available evidence is insufficient to allow trustworthy quantification of the direct role of surface-level O<sub>3</sub> on UV-B flux and that no reasonable estimates of risks of UV-B-related human health effects due to the reduction of surface-level O<sub>3</sub> can be made at this time. Chapter 10 also concludes that, while it is well known that O<sub>3</sub> is a very effective greenhouse gas, quantification of its role as a climate forcing agent is uncertain due to its relatively short atmospheric lifetime and incomplete information on its global sources. Evidence indicates that the global atmospheric background levels of O<sub>3</sub> are increasing, leading to its increasing role in global-scale climate change. It seems likely, however, that due to its tendency to exist at high concentrations adjacent to the sources of its precursors, the climate impacts due to anthropogenic O<sub>3</sub> may be most important at regional scales.

**Charge Questions – Chapter 10.** Does Chapter 10 effectively discuss issues associated with quantifying: (a) the role of surface-level O<sub>3</sub> in determining the UV-B to which humans may be exposed; and (b) the available information on factors governing human exposure to UV-B and specific health consequences associated with UV-B exposure? Also, does Chapter 10 adequately describe the role of tropospheric O<sub>3</sub> in the climate system and summarize the available evidence concerning ozone's role in changing climate? Are there any additional modifications that would strengthen Chapter 10?