



November 14, 2005

MEMORANDUM

SUBJECT: CASAC Consultation on Draft Ozone Staff Paper and Related Analyses

FROM: Karen M. Martin, Group Leader
Health and Ecosystems Effects Group
Office of Air Quality Planning and Standards

A handwritten signature in black ink, which appears to read "Karen M. Martin", is written over the typed name in the "FROM:" field.

TO: Fred Butterfield
Designated Federal Officer
Clean Air Scientific Advisory Committee
EPA Science Advisory Board Staff Office (1400F)

Attached are materials prepared by the Environmental Protection Agency's (EPA) Office of Air Quality Planning and Standards (OAQPS) staff as part of EPA's ongoing review of the national ambient air quality standards (NAAQS) for ozone (O₃). These materials will be the focus of a consultation by the Clean Air Scientific Advisory Committee (CASAC) O₃ NAAQS Review Panel (the CASAC O₃ Panel), scheduled for a public meeting to be held in Durham, NC, on December 7-8, 2005. These materials include the first draft of the O₃ Staff Paper, *Review of the National Ambient Air Quality Standards for Ozone: Policy Assessment of Scientific and Technical Information*, and other documents as identified below. I am requesting that you forward these materials to the CASAC O₃ Panel to prepare for that review.

The purpose of the O₃ Staff Paper is to evaluate the policy implications of the key scientific and technical information contained in EPA's second external review draft Air Quality Criteria Document (CD) for O₃ (August 2005) and to identify critical elements that EPA staff believes should be considered in the review of the O₃ NAAQS. The O₃ Staff Paper is intended to "bridge the gap" between the scientific review contained in the O₃ CD and the public health and welfare policy judgments required of the Administrator in reviewing the O₃ NAAQS. This first draft O₃ Staff Paper is based on the information in the second external review draft O₃ CD, which will be reviewed by the CASAC O₃ Panel on December 6-7, 2005.

Following completion of this consultation on the first draft O₃ Staff Paper, OAQPS staff will produce a second draft O₃ Staff Paper, which will be released for CASAC and public review in the spring of 2006. Following completion of the O₃ Staff Paper, EPA will conduct a rulemaking with regard to its review of the O₃ NAAQS. Consistent with the terms of a consent decree, the EPA Administrator will sign a notice of proposed rulemaking by March 28, 2007 and a final rulemaking notice by December 19, 2007.

Documents for Review

The following documents are available for review by the CASAC O₃ Panel in the form of attached electronic files or by downloading the documents from the EPA website:

http://www.epa.gov/ttn/naaqs/standards/o3/s_o3_cr_sp.html. Printed copies of these documents or a CD containing these electronic files are also available by contacting Dr. David McKee (mckee.dave@epa.gov; 919-541-5288).

- ▶ **Attachment 1:** *Review of the National Ambient Air Quality Standards for Ozone: Policy Assessment of Scientific and Technical Information* (First draft O₃ Staff Paper, November 2005)

Following an introductory chapter (Chapter 1), this document is organized into three main sections:

- characterization of ambient O₃ (Chapter 2);
- O₃-related health effects and primary NAAQS, including a policy-relevant assessment of O₃ health effects evidence (Chapter 3), initial results of quantitative assessments of human exposures (Chapter 4) and human health risks (Chapter 5), and a preliminary review of some of the elements of the primary standard for O₃ (Chapter 6); and
- O₃-related welfare effects and secondary NAAQS, including a policy-relevant assessment of O₃ welfare effects evidence and description of a planned quantitative vegetation-related environmental assessment (Chapter 7). A review of the secondary standards for O₃ will be presented in Chapter 8, to be included in the next draft O₃ Staff Paper.

Staff conclusions and recommendations for consideration in the review of the primary and secondary O₃ NAAQS are not included in this first draft O₃ Staff Paper, although primary standard options are identified for the purpose of conducting additional exposure analyses and health risk assessments for potential alternative primary standards. The next draft of the O₃ Staff Paper will contain initial staff conclusions and recommendations on the primary and secondary O₃ NAAQS. These initial staff conclusions and recommendations will be based on the final O₃ CD and will be informed by comments from the CASAC O₃ Panel and the public on this document and by the results of additional human exposure and health risk assessments and an environmental assessment.

The attached electronic files include the entire draft O₃ Staff Paper and appendices.

- ▶ **Attachment 2:** *Ozone Population Exposure Analysis for Selected Urban Areas: First Draft Report* (EPA, 2005)

The first draft Exposure Analysis technical support document describes the methodology and presents initial results of an O₃ human exposure analysis in a number of U.S. cities. The exposure analysis methodology and initial results are summarized and discussed in Chapter 4 of the first draft O₃ Staff Paper.

The attached electronic file contains the entire first draft Exposure Analysis report and printed copies are available by request from Mr. John Langstaff at langstaff.john@epa.gov.

- ▶ **Attachment 3:** *Ozone Health Risk Assessment for Selected Urban Areas: First Draft Report* (Abt Associates, Inc., 2005)

The first draft Risk Assessment technical support document describes the methodology and presents the initial results from an O₃ health risk assessment for health risks associated with exposure to O₃ in a number of U.S. cities. The risk assessment methodology and initial results are summarized and discussed in Chapter 5 of the first draft O₃ Staff Paper.

The attached electronic file contains the entire first draft Risk Assessment report and printed copies are available by request from Mr. Harvey Richmond at richmond.harvey@epa.gov.

Listed below are several technical support documents prepared by OAQPS staff and cited in the draft O₃ Staff Paper that are also being made available to the CASAC O₃ Panel to facilitate their review of the above documents.

- ▶ **Attachment 4:** *Analysis of 2004 Ozone Data for the Ozone NAAQS Review* (Fitz-Simons et al., 2005)

This technical support memorandum provides documentation for the analyses of air quality data presented in the draft Staff Paper and used in the Exposure Analysis and Health Risk Assessment. The extensive data files that make up this memorandum are available from Mr. Terence Fitz-Simons at fitz-simons.terence@epamail.epa.gov.

- ▶ **Attachment 5:** *Evaluation of a quadratic approach for adjusting distributions of hourly ozone concentrations to meet air quality standards* (Rizzo, 2005)

This technical support memorandum describes the quadratic air quality procedure used to adjust recent O₃ air quality data to simulate just meeting the current and alternative O₃ standards. This memorandum also describes an evaluation of the quadratic approach based on observed historical reductions in ambient levels.

Charge to the CASAC O₃ Panel

Within each of the main sections of the first draft Staff Paper, questions that we ask the Panel to focus on in their review include the following:

O₃ air quality information and analyses Chapter 2):

1. To what extent are the air quality characterizations and analyses clearly communicated, appropriately characterized, and relevant to the review of the primary and secondary O₃ NAAQS?
2. To what extent are the properties of ambient O₃ appropriately characterized, including policy-relevant background, spatial and temporal patterns, and relationships between ambient O₃ and human exposure?
3. Does the information in Chapter 2 provide a sufficient air quality-related basis for the human health and environmental effects and assessments presented in later chapters?

O₃-related health effects (Chapter 3):

1. To what extent is the presentation of evidence assessed in the O₃ CD from the animal toxicology and controlled-exposure human experimental studies and epidemiologic studies, as well as the integration of information from across the various health-related research areas, technically sound, appropriately balanced, and clearly communicated?
2. What are the views of the Panel on the appropriateness of staff's discussion and conclusions on key issues related to quantitative interpretation of the epidemiologic study results, including, for example, exposure error, the influence of alternative model specification, potential confounding by co-pollutants, and lag structure?
3. What are the views of the Panel on the adequacy and clarity of staff discussions on the issue of potential thresholds in concentration-response relationships?
4. What are the views of the Panel on the appropriateness of the staff's characterization of groups likely to be sensitive to O₃?

Exposure Analysis (Chapter 4 of the draft O₃ Staff Paper and draft Exposure Analysis technical support document):

1. To what extent is the assessment, interpretation, and presentation of the initial results of the exposure analysis in Chapter 4 technically sound, appropriately balanced, and clearly communicated?
2. Are the methods used to conduct the exposure analysis technically sound? Does the Panel have any comments on the methods used?
3. Are the exposure analysis methods and results fully and clearly communicated in the draft Exposure Analysis technical support?

4. To what extent are the uncertainties associated with the exposure analysis clearly and appropriately characterized in both Chapter 4 and the draft Exposure Analysis technical support document?
5. What are the views of the Panel on sensitivity analyses that should be conducted to evaluate the influence of uncertainties in the exposure analysis?

Health Risk Assessment (Chapter 5 of the draft O₃ Staff Paper and draft Health Risk Assessment technical support document):

1. To what extent is the assessment, interpretation, and presentation of the initial results of the health risk assessment in Chapter 5 technically sound, appropriately balanced, and clearly communicated?
2. In general, is the set of health endpoints and concentration-response and exposure-response functions used in the risk assessment appropriate for this review?
3. Are the methods used to conduct the health risk assessment technically sound? Does the Panel have any comments on the methods used?
4. Are the methods and results fully and clearly communicated in the draft Health Risk Assessment technical support document?
5. To what extent are the uncertainties associated with the health risk assessment clearly and appropriately characterized in both Chapter 5 and the draft Health Risk Assessment technical support documents?
6. What are the views of the Panel on sensitivity analyses that should be conducted to evaluate the influence of uncertainties in the health risk assessment?

Staff Conclusions and Recommendations on Primary O₃ NAAQS (Chapter 6):

1. What are the views of the Panel on the alternative primary standards identified by staff to be included in additional human exposure analyses and health risk assessments for the next draft O₃ Staff Paper?

O₃-related welfare effects (Chapters 7):

1. To what extent is the presentation of evidence drawn from the O₃ CD related to the various welfare effects considered in this review technically sound, appropriately organized and balanced, and clearly communicated?
2. To what extent does this first draft Chapter 7 appropriately take into account the range of views of the Panel members that were expressed orally and in writing during and after the consultation on the Environmental Assessment Plan?

3. To what extent do the figures aid in clarifying the text? Should more or less information of this type be included in the second draft?
4. To what extent does this draft recognize important sources of uncertainty associated with the various component analyses?
5. While recognizing the lack of quantitative information on O₃-related ecosystem effects, what are the Panel's views on the appropriateness of how this topic is addressed in this draft?

We look forward to discussing these issues with the CASAC O₃ Panel at our upcoming meeting. Should you have any questions regarding the first draft O₃ Staff Paper, please contact me (919-541-5274; email martin.karen@epa.gov) or Dr. David McKee (919-541-5288; email mckee.dave@epa.gov); questions about the exposure analysis can be directed to John Langstaff (919-541-1449; email langstaff.john@epa.gov); questions about the risk assessment can be directed to Harvey Richmond (919-541-5271; email richmond.harvey@epa.gov).

Attachments

cc: Vanessa Vu, SAB, OA
Les Grant, ORD/NCEA-RTP
Lydia Wegman, OAQPS/AQSSD
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