



April 18, 2005

MEMORANDUM

SUBJECT: CASAC Consultation on Draft Ozone Health Assessment Plan: Scope and Methods for Exposure Analysis and Risk Assessment

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

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

Attached is a draft document, *Ozone Health Assessment Plan: Scope and Methods for Exposure Analysis and Risk Assessment* (draft Health Assessment Plan), 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). This draft Health Assessment Plan 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 Research Triangle Park, NC, on May 5, 2005. I am requesting that you forward this draft Health Assessment Plan, as well as a related document described below, *Plan for Review of the National Ambient Air Quality Standards for Ozone*, to the CASAC O₃ Panel to prepare for that consultation.

The purpose of this draft Health Assessment Plan is to outline the scope and approaches that staff is planning to use to conduct a quantitative exposure analysis and human health risk assessment for O₃, and to highlight key issues involved in these assessments so as to facilitate consultation with the CASAC O₃ Panel, as well as public comment. OAQPS staff intends to take into consideration the CASAC O₃ Panel's advice and public comments on this Health Assessment Plan in conducting these quantitative exposure and risk assessments. As noted in the draft Health Assessment Plan, these quantitative assessments will draw upon information presented in the *Air Quality Criteria for Ozone and Related Photochemical Oxidants* (O₃ AQCD), a document being prepared by EPA's National Center for Environmental Assessment, Research Triangle Park, NC (NCEA-RTP), which is also undergoing review by the CASAC O₃ Panel and the public. The results of the exposure and risk assessments will be documented in separate reports and summarized and considered as part of an O₃ Staff Paper, *Review of the National Ambient Air Quality Standards for Ozone: Policy Assessment of Scientific and Technical Information*, to be prepared by OAQPS staff and reviewed by the CASAC O₃ Panel and the public. The O₃ Staff Paper evaluates the policy implications of the key studies and

scientific information contained in the O₃ AQCD and presents staff conclusions and recommendations for standard-setting options for the EPA Administrator to consider in determining whether to retain or revise the O₃ NAAQS.

The schedule for conducting and documenting the exposure and risk assessments; the preparation, review, and completion of the O₃ AQCD and O₃ Staff Paper; and the proposed and final rulemaking in the Agency's review of the O₃ NAAQS is now governed by a consent decree. As discussed in a related document, *Plan for Review of the National Ambient Air Quality Standards for Ozone*, this schedule calls for completion of the O₃ AQCD by February 28, 2006, completion of the exposure and risk assessments and the O₃ Staff Paper by September 2006, and issuance of a notice of proposed rulemaking by March 28, 2007 and a final rulemaking notice by December 19, 2007.

Documents for Consultation

The following documents are being made available to the CASAC O₃ Panel in the form of attached electronic files. These documents are also available from the EPA website http://www.epa.gov/ttn/naaqs/standards/ozone/s_o3_index.html under "Planning Documents." Printed copies of these documents are available by contacting Mr. Harvey Richmond (richmond.harvey@epa.gov; 919-541-5271).

- ▶ **Attachment 1:** *Ozone Health Assessment Plan: Scope and Methods for Exposure Analysis and Risk Assessment* (draft Health Assessment Plan, April 2005)

This document is the focus of the scheduled consultation with the CASAC O₃ Panel, to be guided by the charge questions listed below. Following an introductory section, this document discusses air quality considerations that are relevant to both the planned exposure analysis and human health risk assessment. The next two sections present the planned scope and approach for the exposure analysis and the health risk assessment. Throughout these sections, key issues are discussed and staff's plans for addressing these issues are noted. The final section summarizes the schedule and interim milestones related to these assessments.

- ▶ **Attachment 2:** *Plan for Review of the National Ambient Air Quality Standards for Ozone* (OAQPS, March 2005)

This plan for the overall O₃ NAAQS review presents the schedule for key milestones in this review and provides background information on the NAAQS review process, a brief summary of past O₃ NAAQS reviews, and the status of current review activities. This document also focuses on the development of a key document in the review process, the O₃ Staff Paper, and discusses the planned organization and content of that document. As such, this plan is intended to serve as an informational document to help the CASAC O₃ Panel and other interested parties understand the status and plans for EPA's ongoing O₃ NAAQS review.

Charge to the CASAC O₃ Panel

Within each of the main sections of the draft Health Assessment Plan, questions that we ask the Panel to focus on in their review include the following:

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's 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.

We look forward to discussing these issues with the CASAC O₃ Panel at our upcoming meeting. Should you have any questions regarding the draft Health Assessment Plan, please contact me (919-541-5274; email martin.karen@epa.gov) or Mr. Harvey Richmond (919-541-5271; email richmond.harvey@epa.gov).

Attachments

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