



August 15, 2012

MEMORANDUM

SUBJECT: CASAC Review of the *Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards: First External Review Draft*

FROM: Lydia N. Wegman, Director /s/
Health and Environmental Impacts Division (C504-02)
Office of Air Quality Planning and Standards
United States Environmental Protection Agency

TO: Holly Stallworth
Designated Federal Officer
Clean Air Scientific Advisory Committee
EPA Science Advisory Board Staff Office

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 reviewed by the Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel (the CASAC O₃ Panel) at a public meeting to be held in Raleigh, NC on September 11-13, 2012. These materials include the first draft O₃ Policy Assessment, *Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards: First External Review Draft*. Also attached are additional materials related to the first drafts of the Health and Welfare Risk and Exposure Assessments (REAs),¹ sent to you on July 16, 2012, including revised versions of Chapters 5, 6 and 9 of the Health REA and Chapters 4, 6 and 7 of the Welfare REA and appendices for these chapters. Three related technical memos are also attached which support the Policy Assessment and the REAs. I am requesting that you forward these draft documents to the CASAC O₃ Panel to prepare for the September meeting.

As part of the current O₃ NAAQS review, the Policy Assessment is intended to help bridge the gap between the relevant scientific information and assessments and the judgments required of the EPA Administrator in determining whether, and if so how, it is appropriate to revise the primary (health-based) and secondary (welfare-based) NAAQS for O₃. The first draft Policy Assessment builds upon information presented in the third draft *Integrated Science Assessment of Ozone and Related Photochemical Oxidants* and the first drafts of the Health and Welfare REAs, which the CASAC O₃ Panel will review at the same meeting. The first draft Policy Assessment presents and discusses EPA staff's preliminary conclusions regarding the adequacy

¹ These documents are titled *Health Risk and Exposure Assessment for Ozone, First External Review Draft* and *Welfare Risk and Exposure Assessment for Ozone, First External Review Draft*.

of the current O₃ standards set in 2008 and identifies additional analyses that would be appropriate to help inform consideration of potential alternative O₃ standards in the second draft Policy Assessment, including additional exposure and risk analyses for the second drafts of the Health and Welfare REAs. Attached to this memorandum are charge questions to guide the Panel's review of the first draft Policy Assessment. The CASAC and public comments on the first draft Policy Assessment will be taken into consideration in developing the second draft Policy Assessment, which we anticipate releasing in early 2013.

The first draft Policy Assessment is being made available to the CASAC O₃ Panel in the form of attached electronic files. Printed copies of the document have also been sent to CASAC O₃ Panel members via UPS. This document, as well as the other materials discussed below, can also be found at EPA's Technology Transfer Network (TTN) website, at: http://www.epa.gov/ttn/naaqs/standards/ozone/s_o3_index.html.

Complete drafts of the Health REA and Welfare REA, including the revised Chapters 5, 6, and 9 of the Health REA and revised Chapters 4, 6, and 7 of the Welfare REA, are being made available to the CASAC O₃ Panel in the form of attached electronic files. Printed copies of the revised Chapters 5, 6 and 9 of the Health REA and Chapters 4, 6, and 7 of the Welfare REA have also been sent to CASAC O₃ Panel members via UPS. Chapters 6 and 9 of the Health REA and Chapters 6 and 7 of the Welfare REA include new information that was not released with the draft REAs released on July 16, 2012. Chapter 5 of the Health REA has also been revised to provide corrected table numbers throughout the document and Chapter 4 of the Welfare REA has been revised to provide a corrected Figure 4-3. The appendices to the REAs can be accessed electronically as noted above and printed copies of the appendices will be made available to Panel members upon request. Attached to this memorandum are charge questions to guide the Panel's review of the new Chapter 6 of the Health REA. The CASAC and public comments on the draft Health and Welfare REAs will be taken into consideration in developing second drafts of these documents, which we anticipate releasing in early 2013.

The following technical memos are included in the attached electronic documents and can also be accessed via the TTN as noted above:

- *Analysis of Recent U.S. Ozone Air Quality Data to Support the Ozone NAAQS Review and Quadratic Rollback Simulations to Support the First Drafts of the Risk and Exposure Assessments*
- *Model-based Rollback Using the Higher-order Direct Decoupled Method (HDDM)*
- *Regional and Seasonal Analysis of North American Background Ozone Estimates from Two Studies*

Printed copies of these technical memos will be made available to Panel members upon request.

We look forward to discussing the first draft Policy Assessment and the first drafts of the Health and Welfare REAs with the CASAC O₃ Panel at our upcoming meeting. Should you have any questions regarding the first draft Policy Assessment, please contact me (919-541-5505; email wegman.lydia@epa.gov) or Dr. Karen Martin (919-541-5274; email martin.karen@epa.gov). Should you have any questions regarding the first draft REAs, please contact me (919-541-5505;

email wegman.lydia@epa.gov) or Dr. Bryan Hubbell (919-541-0621; email hubbell.bryan@epa.gov).

Attachments

cc: Vanessa Vu, SAB, OA
Rosalina Rodriguez, OAQPS/HEID
Richard Wayland, OAQPS/AQAD
John Vandenberg, ORD/NCEA-RTP
Mary Ross, ORD/NCEA-RTP
Karen Martin, OAQPS/HEID
Bryan Hubbell, OAQPS/HEID
Darryl Weatherhead, OAQPS/HEID
Susan Lyon Stone, OAQPS/HEID
Scott Jenkins, OAQPS/HEID
Vicki Sandiford, OAQPS/HEID
Karen Wesson, OAQPS/HEID
John Langstaff, OAQPS/HEID
Zachary Pekar, OAQPS/HEID
Stephen Graham, OAQPS/HEID
Charles Fulcher, OAQPS/HEID
Neal Fann, OAQPS/HEID
Susan Anenberg, OAQPS/HEID
Travis Smith, OAQPS/HEID
Christine Davis, OAQPS/HEID
Amy Lamson, OAQPS/HEID
Souad Benromdhane, OAQPS/HEID
Farhan Ahktar, OAQPS/HEID
Tyler Fox, OAQPS/AQAD
Pat Dolwick, OAQPS/AQAD
James Hemby, OAQPS/AQAD
Norm Possiel, OAQPS/AQAD
Heather Simon, OAQPS/AQAD
Halil Cakir, OAQPS/AQAD
Benjamin Wells, OAQPS/AQAD
Joann Rice, OAQPS/AQAD

Charge to the CASAC Ozone Panel in Reviewing the First Draft Policy Assessment for Ozone

The first draft Policy Assessment begins with an introductory chapter that provides background information as well as an overview of O₃ monitoring and air quality characterizations. The remainder of the document is organized into two main parts. Chapters 2 through 4 focus on the review of the primary O₃ NAAQS while chapters 5 through 7 focus on the review of the secondary O₃ NAAQS. Staff's preliminary considerations of the scientific evidence and exposure/risk information related to the primary standard are discussed in chapters 2 and 3, respectively. Staff's preliminary conclusions on the adequacy of the current primary O₃ standard are discussed in chapter 4, which also includes discussion of additional analyses that would be appropriate to help inform consideration of potential alternative primary standards in the second draft Policy Assessment. Staff's preliminary considerations of the scientific evidence and exposure/risk information related to the secondary standard are discussed in chapters 5 and 6, respectively. Staff's preliminary conclusions on the adequacy of the current secondary O₃ standard are discussed in chapter 7, which also includes discussion of additional analyses that would be appropriate to help inform consideration of potential alternative secondary standards in the second draft Policy Assessment.

The second draft Policy Assessment will reflect consideration of comments received during CASAC review and from public comments on this first draft document. In its review of the first draft Policy Assessment, we ask the CASAC O₃ Panel to focus on the charge questions below, but we would appreciate comments on any other topics as well.

Chapter 1: Introduction

1. To what extent are the ambient O₃ monitoring network, spatial and temporal patterns of ambient O₃ concentrations, and background O₃ concentrations (section 1.3) appropriately characterized and clearly communicated?

Chapter 2: Overview of the Health Evidence

1. To what extent does the presentation of the evidence appropriately reflect the assessment of the evidence, including the weight-of-evidence conclusions, in the third draft ISA?
2. To what extent is the presentation of the health effects evidence, including evidence for effects following short-term (section 2.2) and long-term (section 2.3) O₃ exposures, technically sound, appropriately balanced, clearly communicated, and presented at an appropriate level of detail?
3. What are the views of the Panel on the appropriateness of staff's characterization of controlled human exposure studies, in particular those studies reporting respiratory effects following exposures to O₃ concentrations below the level of the current O₃ standard (section 2.2.1)?

4. What are the views of the Panel on the appropriateness of staff's discussion of key issues related to the interpretation of epidemiologic study results, including confounding by co-pollutants, effect modification, lag structure, the nature of concentration-response relationships, and the potential for thresholds (sections 2.2.1.6, 2.2.1.7, and 2.2.2)?
5. What are the views of the Panel on the appropriateness and level of detail of the staff's characterization of the public health implications of the health evidence (section 2.4), including the discussions of adversity, populations at-risk, averting behavior, and the size of populations at-risk from O₃?

Chapter 3: Overview of Health Exposure and Risk Assessments

1. To what extent are the assessment, interpretation, and presentation of the initial results of the exposure and risk analyses clearly communicated and appropriately focused to support considerations presented in chapter 4?
2. To what extent does the Panel feel that this chapter is useful for inclusion in the Policy Assessment, given the summary of the policy-relevant findings presented in the draft Health REA?

Chapter 4: Staff's Preliminary Conclusions on the Primary O₃ NAAQS

1. What are the views of the Panel on how this chapter characterizes and considers the available health evidence and air quality information in reaching a preliminary staff conclusion on the adequacy of the current primary O₃ standard (section 4.2)?
2. Beyond the exposure and risk analyses of air quality adjusted to simulate just meeting the current standard in the first draft REA, what range of alternative O₃ levels would be appropriate for further exposure and risk analyses in the second draft Health REA? To what extent does the information presented in section 4.3.1 help inform this consideration?
3. What are the views of the Panel on the preliminary approaches outlined in section 4.3.2 for considering air quality information from epidemiologic studies that characterized O₃-related morbidity or mortality concentration-response relationships across the entire or restricted distributions of ambient O₃ concentrations? What are the views of the Panel regarding how such air quality information can appropriately be considered in the context of drawing conclusions on potential alternative standards in the second draft Policy Assessment?

Chapter 5: Consideration of the Welfare Evidence

1. To what extent does the presentation of the evidence appropriately reflect the assessment of the evidence, including the weight-of-evidence conclusions, in the third draft ISA?
2. To what extent is the presentation of the evidence related to mechanisms governing plant response to O₃ (section 5.2) and on O₃-related effects on vegetation (section 5.3) technically sound, appropriately balanced, clearly communicated, and presented at an appropriate level of detail?

3. What are the views of the Panel on the appropriateness of staff's discussions and conclusions on biologically relevant exposure metrics and staff's focus of the W126 form (section 5.4)?
4. 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 (section 5.5)?
5. What are the views of the Panel on the considerations regarding adversity in the public welfare context as discussed in section 5.6?
6. What are the views of the Panel on the considerations regarding other welfare effects as briefly summarized in section 5.7?

Chapter 6: Consideration of the Welfare Exposure and Risk Assessments

1. To what extent are the assessment, interpretation, and presentation of the initial results of the exposure and risk analyses clearly communicated and appropriately focused to support considerations presented in chapter 7?
2. What are the views of the Panel on the appropriateness and usefulness of including a qualitative discussion of potential O₃-related impacts on ecosystem services in this document?
3. To what extent does the Panel feel that this chapter is useful for inclusion in the Policy Assessment, given the summary of the policy-relevant findings presented in the draft Welfare REA?

Chapter 7: Staff's Preliminary Conclusions on the Secondary O₃ NAAQS

1. What are the views of the Panel on how this chapter characterizes and considers the currently available vegetation evidence and the exposure and risk information from the first draft Welfare REA in reaching preliminary staff conclusions on the adequacy and appropriateness of the current secondary O₃ standard (section 7.2)?
2. What are the views of the Panel on the elements and range of levels of a cumulative, seasonal standard identified in section 7.3 that would be appropriate for further analyses in the second draft Welfare REA? To what extent does the information presented in this section help inform this consideration?

Charge to the CASAC Ozone Review Panel for Review of the First Draft Health Risk and Exposure Assessment for Ozone

Chapter 6: Characterization of Health Risk Based on Controlled Human Exposure Studies

1. To what extent does the Panel find the methods used to conduct the risk analysis to be technically sound? What are the views of the Panel members on the methods used?
2. To what extent does the Panel find the assessment, interpretation, and presentation of the results of the risk analysis as presented in Chapter 6 to be technically sound, appropriately balanced, and clearly communicated?
3. To what extent does the Panel find the focus of the assessment on lung function decrements in the quantitative risk assessment to be appropriate and informative?
4. What are the views of the Panel on the use of the two different modeling approaches for specifying the exposure-response function linking the change in FEV1 to ozone exposure?
5. What are the views of the Panel on the treatment of the relationship between age and dFEV1 in the McDonnell-Stewart-Smith model?
6. To what extent does the Panel find that the qualitative discussion of uncertainty and variability has covered important sources of uncertainty and variability and has appropriately characterized the relationship of those sources of uncertainty and variability to the risk estimates?
7. What are the views of the Panel on additional sensitivity analyses or other approaches to addressing uncertainty and variability?