



July 16, 2012

**MEMORANDUM**

**SUBJECT:** CASAC Review of *Health Risk and Exposure Assessment for Ozone: First External Review Draft* and *Welfare Risk and Exposure Assessment for Ozone: First External Review Draft*

**FROM:** Lydia N. Wegman, Director /s/  
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**TO:** Holly Stallworth  
Designated Federal Officer  
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EPA Science Advisory Board Staff Office

Attached are the draft documents, *Health Risk and Exposure Assessment for Ozone: First External Review Draft* and *Welfare Risk and Exposure Assessment for Ozone: First External Review Draft*, 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 (O<sub>3</sub>). These documents will be the focus of a review by the Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel (the CASAC O<sub>3</sub> Panel) at a public meeting to be held in Durham, NC on September 11-13, 2012. I am requesting that you forward these draft documents to the CASAC O<sub>3</sub> Panel to prepare for the September meeting.

As part of the review of the current NAAQS for O<sub>3</sub>, EPA's OAQPS staff has prepared first draft risk and exposure assessments for both health and welfare effects. These draft risk and exposure assessments evaluate the risks to human populations and to forest ecosystems from exposures to recent levels of O<sub>3</sub>, and the risks that would exist upon just meeting the current primary and secondary O<sub>3</sub> standards. Subsequent drafts of the risk and exposure assessments will also evaluate alternative primary and secondary O<sub>3</sub> standards. The risk and exposure assessments are based on applications of results of scientific studies summarized in the *Integrated Science Assessment of Ozone and Related Photochemical Oxidants (Third External Review Draft)*, which the CASAC PM Panel will review at the same meeting. This document, along with EPA's Integrated Review Plan, can be found at [http://www.epa.gov/ttn/naaqs/standards/ozone/s\\_o3\\_index.html](http://www.epa.gov/ttn/naaqs/standards/ozone/s_o3_index.html). These risk and exposure assessments include descriptions of the scope of the assessments and the methodologies used as well as the initial key results, observations, and related uncertainties associated with the quantitative analyses conducted.

Chapter 6 (Characterization of Health Risk Based on Controlled Human Exposure Studies) of the Health REA is still under development, along with several appendices and technical memos. These documents include the following:

- Three appendices related to Chapter 6 (Characterization of Health Risk Based on Controlled Human Exposure Studies) of the Health REA:
  - Appendix 6-A. The Risk Methodology of the Previous Review
  - Appendix 6-B. The McDonnell-Stewart-Smith Model
  - Appendix 6-C. Detailed Risk Assessment Results
- Four appendices related to Chapter 5 (Ecological Effects) of the Welfare REA:
  - Appendix 5-A. Summary of Analyses of Tree Species
  - Appendix 5-B. Summary of Analyses of Class I Areas
  - Appendix 5-C. Summary of Analyses of Designated Critical Habitat Areas
  - Appendix 5-D. Supplemental Information for Assessment of Visible Foliar Injury risk in National Parks
- Three appendices related to Chapter 6 (Ecosystem Services) of the Welfare REA:
  - Appendix 6-A. i-Tree Model: Methodology and Summary
  - Appendix 6-B. Details for Economic Valuation Analyses
  - Appendix 6-C. FASOM Model: Methodology and Summary
- Two air quality technical memos supporting both the Health and Welfare REAs:
  - Analysis of Recent U.S. Ozone Air Quality Data to Support the O<sub>3</sub> NAAQS Review and Quadratic Rollback Simulations
  - Model-based rollback using the higher order direct decoupled method (HDDM)

The above listed documents will be made available to the Panel for review no later than August 13, 2012.

The CASAC and public comments on the draft risk and exposure assessments will be taken into consideration in developing the second drafts of the assessments. We plan to release second drafts of the risk and exposure assessments in January of 2013. The assessments are being made available to the CASAC O<sub>3</sub> Panel in the form of attached electronic files. The documents are also available from the EPA website at

[http://www.epa.gov/ttn/naaqs/standards/ozone/s\\_o3\\_index.html](http://www.epa.gov/ttn/naaqs/standards/ozone/s_o3_index.html). Printed copies of the main bodies of the documents have been sent to CASAC O<sub>3</sub> Panel members via UPS. The appendices are included in the attached electronic documents and can also be accessed via the internet as noted above. Printed copies of the appendices will be made available to Panel members upon request. Appendices include three appendices related to Chapter 5 (Characterization of Population Exposure), one appendix related to Chapter 7 (Characterization of Health Risk Based on Epidemiological Studies) and one appendix related to Chapter 8 (National Scale Risk Assessment and Representativeness Analysis). Attached to this memorandum are charge questions to guide the Panel's review of these documents.

We look forward to discussing the first draft risk and exposure assessments with the CASAC O<sub>3</sub> Panel at our upcoming meeting. Should you have any questions regarding the first draft risk and exposure assessments for O<sub>3</sub>, please contact me (919-541-5505; email [wegman.lydia@epa.gov](mailto:wegman.lydia@epa.gov)) or Dr. Bryan Hubbell (919-541-0621; email [hubbell.bryan@epa.gov](mailto:hubbell.bryan@epa.gov)).

## Attachments

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## ATTACHMENTS

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

The first draft Health Risk and Exposure Assessment (REA), conveyed to the CASAC Ozone Panel on July 16, 2012, provides preliminary estimates of human exposures and health risks associated with recent ambient levels of ozone (O<sub>3</sub>) and with O<sub>3</sub> levels simulated to just meet the current primary O<sub>3</sub> standard. The assessment also provides descriptions of the data and methods used to develop the estimates. The EPA staff is continuing to evaluate the data and methods used in this first draft REA. Revisions to data or methods in this first draft will be made based on this evaluation and comments received from CASAC or the public on this first draft REA.

For the Health Risk and Exposure Assessment, following an introductory chapter (Chapter 1), the document provides a conceptual framework for considering exposures and risks associated with ambient O<sub>3</sub> (Chapter 2), discusses the scope of the risk assessment (Chapter 3), the air quality information used to inform the exposure and risk assessments (Chapter 4), methods used to estimate population exposure to O<sub>3</sub> and results of the exposure analysis (Chapter 5), methods used to estimate risk based on controlled human exposure studies and results of the risk analysis (Chapter 6), methods used to estimate risks based on results of epidemiology studies and results of the urban case study risk analyses (Chapter 7), a national-scale assessment of premature mortality associated with recent O<sub>3</sub> levels, and an evaluation of the representativeness of the urban study areas in a national context (Chapter 8), and a synthesis of the assessment including key results and observations (Chapter 9).

We ask the CASAC Ozone Panel to focus on the charge questions below in their review of the first draft REA, but we would appreciate comments on any other topics as well.

#### **Chapter 1: Introduction**

1. Does the Panel find the introductory and background material, including that pertaining to previous reviews of the O<sub>3</sub> standards and the current review, to be clearly communicated and appropriately characterized?

#### **Chapter 2: Conceptual Model**

2. To what extent does the Panel find that the discussions accurately reflect and clearly communicate the currently available health effects evidence, and the relevance of that evidence for quantitative exposure and risk assessment, as characterized in the 3<sup>rd</sup> Draft ISA?

#### **Chapter 3: Scope**

3. Does the Panel find the scope of the health risk and exposure analysis is clearly communicated?

4. *Based on information in the 3<sup>rd</sup> draft ISA indicating lack of evidence for a threshold in O<sub>3</sub> concentration-response functions, we have included risk estimates down to zero O<sub>3</sub> concentrations. Based on further discussion in the ISA regarding the decreased confidence in the shape and magnitude of population health response at very low O<sub>3</sub> concentrations, we have also included risk estimates based on applying concentration-response (C-R) functions only down to the lowest measured level (LML) in the underlying epidemiology studies.*
  - a) To what extent does the Panel support the use of two different risk estimates, one applying the C-R function down to zero, and one applying the C-R function down to the LML, to characterize the range of risk estimates to balance comprehensiveness of the estimates with confidence in the estimates?
  - b) What are the views of the Panel on alternative cutoffs based on other points within the distribution of O<sub>3</sub> concentrations used in the underlying epidemiology studies?

#### **Chapter 4: Air Quality Considerations**

5. To what extent does the Panel consider the years of air quality data to be appropriate for use in the exposure and risk assessment?
6. Regarding the methods for simulating just meeting the ozone standard:
  - a) To what extent does the Panel find that the quadratic rollback approach used in the first draft REA for simulating just meeting the current standard (including application of US background as a lower-bound on rollback) is a reasonable approach?
  - b) To what extent does the Panel support using an air quality model based approach for simulating just meeting the standard in future drafts as a replacement for the current quadratic approach?
  - c) What are the views of the Panel on the strengths and limitations of the proposed approach using the Higher-order Direct Decoupled Method?

*[The air quality technical support memos will be submitted for review in August]*

#### **Chapter 5: Characterization of Population Exposure**

7. To what extent does the Panel find the methods used to conduct the exposure analysis technically sound? Does the Panel have any recommendations on the methods used?
8. To what extent does the Panel find the assessment, interpretation, and presentation of the results of the exposure analysis as presented technically sound, appropriately balanced, and clearly communicated?
9. Regarding the characterization of uncertainties and variability:
  - a) To what extent does the Panel find that the uncertainties associated with the exposure analysis are clearly and appropriately characterized?
  - b) To what extent does the Panel find that the uncertainty assessment is technically sound? Are there other important uncertainties which are not covered?

10. What are the views of the Panel on the sensitivity analyses that EPA plans to conduct as part of the second draft REA to evaluate the influence of uncertainties in the exposure analysis?

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

*[Charge questions related to this chapter will be submitted under separate cover accompanying Chapter 6, which is expected to be provided in August]*

### **Chapter 7: Characterization of Health Risk Based on Epidemiological Studies**

11. Regarding the epidemiologic studies used in the analysis:
- a) What are the Panel's views on the set of epidemiological studies selected for use in specifying C-R functions and on the set of C-R functions specified for use in the risk assessment?
  - b) To what extent does the Panel find the detailed descriptions of rationales for the selection of the epidemiological studies and the selection of the set of C-R functions specified using those studies to be appropriate and complete?
12. To what extent does the Panel find that the qualitative discussion of uncertainty and variability have covered important sources and appropriately characterized the relationship of those sources of uncertainty and variability to the risk estimates?
13. Regarding the results of the risk analysis:
- a) What are the views of the Panel on the presentation and discussion of risk estimates, including the key observations presented in section 7.6.2?
  - b) What are the views of the Panel on the presentation of the distribution of O<sub>3</sub>-related mortality across daily O<sub>3</sub> levels for each city as “heat maps”?
14. To what extent does the Panel agree with the characterization of overall confidence, including the degree to which the conclusions reached regarding overall confidence are supported by available information?
15. What are the views of the Panel on EPA’s discussion of potential refinements to the REA for the second draft, including the plans for quantitative sensitivity analyses, additional refinements to the core risk estimates, and plans for assessment of long-term mortality and morbidity (i.e., plans to model risk for mortality and the decision not to model risk for morbidity endpoints, given data limitations)?

### **Chapter 8: National Scale Risk Assessment and Representativeness Analysis**

16. What are the views of the Panel on the overall approach used for the national scale risk analysis, including the O<sub>3</sub> concentration methods and metrics, the use of city-specific and national average concentration-response relationships derived by Bell et al. (2004) and Zanobetti and Schwartz (2008)?

17. What are the views of the Panel on the approach identified for quantifying long-term mortality using the Jerrett et al. (2009) two-pollutant model national respiratory mortality effect estimate?

18. Regarding the representativeness analysis:

- a) What are the views of the Panel on the methods and presentation of results for the representativeness analyses?
- b) Does the Panel have suggestions for additional risk characteristics that would be useful to include in the analysis?

### **Chapter 9: Synthesis**

19. To what extent does the Panel find the synthesis to be a useful integration and summarization of key results and insights regarding the overall health exposure and risk analysis?

## **Charge to the CASAC Ozone Review Panel for Review of the First Draft Welfare Risk and Exposure Assessment for Ozone**

The first draft Welfare Risk and Exposure Assessment (REA), conveyed to the CASAC Ozone Panel on July 16, 2012, includes descriptions of the data and methods used to estimate exposures and risks to ecosystems associated with recent O<sub>3</sub> levels and with O<sub>3</sub> levels simulated to just meet the current secondary O<sub>3</sub> standard. The assessment also includes preliminary results of the assessment, recognizing that data and methods are still being evaluated and as thus results will be updated based on changes to data or methods resulting from the evaluation and also based on any changes to data or methods resulting from comments received during CASAC review or from public comments on the first draft REA.

For the Welfare Risk and Exposure Assessment, following an introductory chapter (Chapter 1), the document provides a conceptual framework for considering exposures and risks to ecosystems associated with ambient O<sub>3</sub> (Chapter 2), discusses the scope of the risk assessment (Chapter 3), the air quality information used to inform the risk assessment (Chapter 4), methods used to estimate risks to forest ecosystems and vegetation, and results of the risk analysis (Chapter 5), methods used to characterize impacts on ecosystem services and results of ecosystem service modeling (Chapter 6), and a synthesis of the assessment including key results and observations (Chapter 7).

We ask the CASAC Ozone Panel to focus on the charge questions below in their review of the first draft REA, but we would appreciate comments on any other topics as well.

### **Chapter 1: Introduction**

1. Does the Panel find the introductory and background material, including that pertaining to previous reviews of the O<sub>3</sub> standards and the current review, to be clearly communicated and appropriately characterized?

### **Chapter 2: Conceptual Model**

2. To what extent does the Panel find that the materials accurately reflect and clearly communicate the currently available welfare effects evidence, and the relevance of that evidence for quantitative exposure and risk assessment, as characterized in the 3<sup>rd</sup> Draft ISA?

### **Chapter 3: Scope**

3. To what extent does the Panel find the scope of the welfare risk and exposure assessment to be clearly communicated?

### **Chapter 4: Air Quality Considerations**

4. To what extent does the Panel consider the years of air quality data to be appropriate for use in the exposure and risk assessment?



5. What are the views of the Panel on the approach used to develop a national scale surface of W126?
6. Regarding the methods for simulating just meeting the ozone standard:
  - a) To what extent does the Panel find that the quadratic rollback approach used in the first draft REA for simulating just meeting the current standard is a reasonable approach?
  - b) Does the Panel have suggestions for alternative approaches for simulating just meeting the current secondary standard or alternative standards based on the W126 metric?

*[The air quality technical support memos will be submitted for review in August]*

## **Chapter 5: Ecological Effects**

7. Regarding the assessment of relative biomass loss (RBL) for individual species:
  - a) What are the views of the Panel on the use of the linear model forced through the origin to assess the proportional relationship between the relative biomass loss (RBL) values for each species comparing the RBL at recent ambient conditions to the RBL under the scenario modeling O<sub>3</sub> just meeting the current standard?
  - b) To what extent does the Panel find that this an appropriate analysis to compare the proportional changes in RBL? Does the Panel have suggestions for alternative approaches that provides a comparable result and maintains the cell-by-cell approach to help control for environmental variability?
  - c) To what extent does the panel agree with the approach used to combine the 11 tree species into one analysis?
8. Regarding the assessment of RBL for combined species:
  - a) To what extent does the Panel support the use of the Importance Values from the U.S. Forest Service to weight the RBL values in extrapolating from individual trees to larger ecosystem level effects?
  - b) What are the views of the Panel on the use of the summed-RBL as a metric to use for assessing effects at the larger ecosystem scale?
  - c) Does the panel have any recommendations for methods to include a wider range of tree species (beyond the 8 species included)?
9. What are the views of the Panel on the use of federally designated Class I and Critical Habitat areas as endpoints for this analysis? Does the Panel have any suggestions for additional parks beyond Rocky Mountain National Park and Sequoia/Kings Canyon National Park that should be analyzed? Does the panel have recommendations for additional or alternative geographic analysis areas that could be used?
10. To what extent does the Panel find that the vegetation mapping data from USGS and NPS used to generate a scaled-RBL surface in Great Smokey Mountain National Park is appropriate?
11. Regarding the screening level foliar injury risk assessment:

- a) To what extent does the Panel find the updated assessment of foliar injury risk in national parks originally performed in Kohut (2007) to be an appropriate screening level risk assessment?
  - b) What are the views of the Panel regarding the potential methods for estimating O<sub>3</sub> exposure at additional parks?
  - c) What are the Panel's views regarding the appropriateness of requiring that two criteria must be satisfied (i.e., based on both W126 and N100) in order to receive higher risk ratings?
  - d) Is the Panel aware of any assessments of foliar injury in national parks conducted between 2006 and 2010 that could potentially be used to validate the updated risk ratings?
12. Regarding the assessment of cover of O<sub>3</sub> sensitive species:
- a) To what extent does the Panel find the preliminary analysis of sensitive species cover to be an appropriate and useful approach to highlight areas of potentially higher risk due to the presence of sensitive species?
  - b) To what extent does the Panel find the vegetation mapping data appropriate to assess the cover of O<sub>3</sub> sensitive species in GSMNP?
  - c) What are the views of the Panel on the decision to not distinguish between vegetation strata (i.e. herb, shrub, tree)? To what extent does the Panel agree with this methodology relative to analyzing the strata individually?
  - d) What are the views of the panel on using benchmarks, similar to those used in the Kohut analysis of foliar injury risk, to allow estimates of change between exposure scenarios?

## **Chapter 6: Ecosystem Services**

13. To what extent does the Panel find that EPA has adequately characterized the range of ecosystem services that are potentially adversely affected by O<sub>3</sub>?
14. To what extent does the Panel agree with EPA's ecosystem services framework, connecting O<sub>3</sub> exposure, through ecological effects to ecosystem services?
15. Does the panel agree with EPA's use of combined O<sub>3</sub> exposure data with other data sources (e.g. fire data, bark beetle maps, trail maps) to link areas of concern or interest with areas of higher vegetative risk due to O<sub>3</sub>? Does the Panel have any recommendations for additional datasets and ecosystem services that could add to or improve these analyses?
16. Regarding the analysis of forest yield impacts:
- a) To what extent does the Panel agree that the Forest and Agricultural Sector Optimization Model (FASOM) model is appropriate to assess timber and crop yield changes and the effects of those changes on additional ecosystem services?
  - b) What are the views of the Panel on the extrapolation of concentration-response functions across similar species?

*[The appendix detailing the FASOM analysis will be submitted for review in August]*

17. Regarding the analysis of urban forest impacts:

- a) To what extent does the Panel feel that the i-Tree model is appropriate for assessing changes to urban forest ecosystem services based on O<sub>3</sub> exposure?
- b) In order to increase the number of tree species covered by the iTree model, does the Panel have recommendations for additional species that could be included, based on estimates from similar species?

*[The appendix detailing the i-Tree analysis will be submitted for review in August]*

18. Regarding the use of PnET-CN:

- a) What are the views of the Panel on the potential use of the PnET-CN model in the 2nd draft to assess impacts on larger scale ecosystem services (e.g. hydrologic changes, c sequestration)?
- b) Does the Panel have recommendations of other models that are accessible to EPA that could be used instead of PnET-CN?

19. Regarding ecosystem services related to foliar injury:

- a) To what extent does the Panel agree that potential visible foliar injury is appropriate to use as a metric to assess potential loss of cultural services associated with recreation in national parks?
- b) Does the Panel feel that there are O<sub>3</sub> benchmarks that could be used to assess changes in foliar injury potential between exposure scenarios similar to those used by Kohut (2007)?

## **Chapter 7: Synthesis**

20. To what extent does the Panel find the synthesis to be a useful integration and summarization of key results and insights regarding the overall welfare exposure and risk analysis?

## **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?