



February 3, 2014

**MEMORANDUM**

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

**FROM:** Erika Sasser, Acting Director /s/  
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**TO:** Holly Stallworth  
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The draft documents, *Health Risk and Exposure Assessment for Ozone: Second External Review Draft* and *Welfare Risk and Exposure Assessment for Ozone: Second 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>), are being made available on EPA's website for review by the Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel (the Panel) at a public meeting to be held in Chapel Hill, NC on March 25-27, 2014. The documents 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). Charge questions for the Panel to consider in its review of these documents are attached to this memorandum. I am requesting that you forward this memorandum and the attached charge questions to the Panel members to prepare for the March meeting.

As part of the review of the current NAAQS for O<sub>3</sub>, EPA's OAQPS staff has prepared second draft risk and exposure assessments (REAs) for both health and welfare effects. These draft REAs evaluate the risks to human populations and to agricultural and forest ecosystems when O<sub>3</sub> concentrations just meet the current primary O<sub>3</sub> standard and several alternative primary and secondary standard levels. The REAs are based on applications of results of scientific studies summarized in the final *Integrated Science Assessment of Ozone and Related Photochemical Oxidants*. 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). The REAs include descriptions of the scope of the assessments and the methodologies used as well as key results, observations, and related uncertainties associated with the quantitative analyses conducted.

The second draft REAs incorporate a number of changes from the first drafts of these documents. One important change is that the assessments now provide estimates of the changes in risks resulting from just meeting alternative standard levels relative to just meeting the existing standards. Many of the other changes in the assessments are in response to comments offered by the Panel following their peer review of the first draft documents. The Panel presented its comments on the first draft assessments in a letter to the Administrator dated November 19, 2012.<sup>1</sup> We are appreciative of the Panel's review, which contributed to improvements in the second draft assessments. Some of the most significant changes made in consideration of CASAC comments on the first draft REAs are summarized below.

Responses to CASAC comments on the first draft health risk and exposure assessment:

- We have restructured Chapter 2 to more fully describe the conceptual steps in the exposure and risk assessment, identifying the important elements and types of methods and tools that are used. We have included additional conceptual diagrams throughout the REA connecting each analytical component back to the overall conceptual framework.
- We have implemented a model-based approach to adjust O<sub>3</sub> concentrations to just meet the existing standard and several alternative standard levels.
- We have performed model input and output data evaluations including among others evaluations of historical trends in CHAD activity pattern data and comparison of CHAD data with recent American Time Use Survey (ATUS) data, comparison of APEX estimated exposures with personal exposure measurement data, and comparison of APEX estimated ventilation estimates with independent methods used to estimate ventilation.
- Consistent with CASAC recommendations, we have implemented the McDonnell, Stewart, and Smith (2012) lung model of FEV1 decrements, using the threshold model specification. We have explored the model in detail and provide a number of sensitivity analyses exploring aspects of the model including the impact of age related factors.
- We are providing estimates of risks for the entire range of O<sub>3</sub> concentrations down to zero, as well as providing the distributions of risk and risk changes along the full range of ozone concentrations.
- We have substantially expanded our discussion of the potential role of exposure measurement error to include a detailed discussion of the sources of exposure measurement error and the ways in which exposure measurement error can add uncertainty to effect estimates.
- To reduce repetition and consolidate and prioritize results, we have made several changes to the way we present and summarize risk estimates (both in tabular and graphical form) and the way in which we discuss the results in the text. Specifically, we have modified the color scheme on the heat maps to make them easier to interpret and added line charts which allow readers to evaluate trends in risk reduction for short-term exposure-related mortality across the standard levels we evaluated. We have also reduced the total number of tables, focusing on those risk metrics most informative to policy-relevant questions.

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<sup>1</sup> Frey, C. and Samet, J. (2012). Letter from Clean Air Scientific Advisory Committee to the Honorable Lisa P. Jackson, Administrator, US EPA. CASAC Review of the EPA's Health Risk and Exposure Assessment for Ozone (First External Review Draft-Updated August 2012) and Welfare Risk and Exposure Assessment for Ozone (First External Review Draft-Updated August 2012) November 19, 2012.

- We have included risk estimates for long-term exposure-related mortality. We have also included sensitivity analyses exploring the impact of using regionally differentiated effect estimates to model this endpoint, instead of a single national-scale effect estimate.
- We have restructured Chapter 9 (Synthesis) to focus more on comparing and contrasting exposure and risk results to identify common patterns, or important differences. The comparisons focus on patterns across urban areas, across years of analysis, and across alternative standards. Chapter 9 provides an overall integrated characterization of exposure and risk in the context of key policy-relevant questions introduced in Chapter 2 and assesses the degree to which the integrated results are representative of national patterns of exposure and risk.

Responses to CASAC comments on the first draft welfare risk and exposure assessment:

- We have implemented a model-based approach to adjust O<sub>3</sub> concentrations to reflect just meeting the existing standard and alternative W126-based standards. This approach uses national reductions in NO<sub>x</sub> to adjust O<sub>3</sub> concentrations at monitors throughout a region such that the highest monitor in the region meets a specified W126 concentration. Resulting W126 concentrations are interpolated to provide national surfaces of W126 concentrations for use in the risk analyses.
- We have restructured the chapters to provide a more integrated treatment of ecosystem functions, e.g. biomass loss and ecosystem services, including the dollar value of changes in commercial timber and crops.
- We have added a number of additional analyses of risks of yield loss for agricultural crops. These include analyses of county level patterns of yield loss for individual species remaining after just meeting the existing standard and yield gains from meeting alternative standards.
- We have added analyses of forest ecosystem impacts based on biomass loss weighted by species basal area.
- We have added an analysis of uncertainties associated with use of seedling biomass loss to represent biomass loss in mature trees.
- We have restructured Chapter 8 (Synthesis) to focus more on comparing and contrasting exposure and risk results to identify common patterns, or important differences, focusing on patterns across different geographic areas of the U.S., across years of analysis, and across alternative W126 standard levels. Chapter 8 provides an overall integrated characterization of risk in the context of key policy-relevant questions raised in Chapter 2 and assesses the degree to which the integrated results are representative of national patterns of risk.

The CASAC and public comments on the draft REAs will be taken into consideration in making revisions to the draft document. Final REAs will be released in Summer 2014. Draft documents are being made available to the Panel in the form of electronic files, available from the EPA website at [http://www.epa.gov/ttn/naaqs/standards/ozone/s\\_o3\\_2008\\_rea.html](http://www.epa.gov/ttn/naaqs/standards/ozone/s_o3_2008_rea.html).

A set of charge questions related to the draft REAs are attached. These charge questions focus on the overall design of the analyses and the methods, results, and interpretations of the different analytical elements of the assessments.

We look forward to discussing the second draft health and welfare risk and exposure assessments with the Panel at our upcoming meeting. Should you have any questions regarding the REAs, please contact me (919-541-3889; email [sasser.erika@epa.gov](mailto:sasser.erika@epa.gov)) or Dr. Bryan Hubbell (919-541-0621; email [hubbell.bryan@epa.gov](mailto:hubbell.bryan@epa.gov)).

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**Attachments**

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

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

## **Attachment**

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

The second draft Health Risk and Exposure Assessment (REA) provides estimates of human exposures and health risks associated with O<sub>3</sub> concentrations adjusted to just meet the existing primary O<sub>3</sub> standard and several alternative standard levels. The assessment also provides descriptions of the data and methods used to develop the estimates. 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 lung function 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, 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). Also included is an Executive Summary for the information presented in chapters 1-9.

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

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

1. To what extent 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 and clearly reflect the air quality, health effects, exposure and risk considerations relevant for quantitative exposure and risk assessment, building from information contained in the final ISA? What are the views of the Panel on the additional flowchart provided for the overall assessment and the additional information regarding specific elements of the exposure and risk assessments?

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

3. To what extent does the Panel find the scope of the health risk and exposure assessment is clearly communicated? To what extent does the panel find the additional flowcharts for each analytical component to be useful additions?

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

4. What are the views of the Panel on the appropriateness of the methods used to characterize O<sub>3</sub> air quality for the exposure and risk assessment? What are the views of the Panel on the HDDM-based adjustment methodology used to adjust O<sub>3</sub> concentrations to just meet the existing O<sub>3</sub> standard and alternative standards?
5. To what extent does the Panel find that the discussion of uncertainty related to the air quality inputs to the exposure and risk assessment appropriately covers important sources of uncertainty?

#### **Chapter 5: Characterization of Human Exposure to Ozone**

6. To what extent does the Panel find the assessment, interpretation, and presentation of the methods and results of the updated and expanded population-based exposure analysis to be technically sound, appropriately balanced, and clearly communicated?
7. Chapter 5 includes several evaluations of key APEX inputs and model outputs, including for example analysis of time-activity data and comparison of actual personal exposures with modeled exposures. What are the views of the Panel on the appropriateness and usefulness of these evaluations and the conclusions drawn from these evaluations?
8. Chapter 5 includes several scenario-based exposure simulations that focus on specific populations or behaviors. What are the views of the Panel on the design, results, and interpretation of these additional scenario-based exposure simulations?
9. To what extent does the Panel find that the discussion of uncertainty and variability have covered important sources of uncertainty and variability and appropriately characterized their relationship to the exposure estimates?

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

10. To what extent does the Panel find the assessment, interpretation, and presentation of the methods and results of the updated and expanded lung function risk analysis to be technically sound, appropriately balanced, and clearly communicated?
11. What are the views of the Panel on the implementation of the McDonnell-Stewart-Smith model to specify the exposure-response function linking the change in FEV<sub>1</sub> to O<sub>3</sub> exposure?
12. To what extent does the Panel find that the discussion of uncertainty and variability have covered important sources of uncertainty and variability and appropriately characterized their relationship to the risk estimates?

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

13. To what extent does the Panel find the assessment, interpretation, and presentation of the methods and results of the updated epidemiology-based risk assessment to be technically sound, appropriately balanced, and clearly communicated?
14. To what extent does the Panel find that the 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?
15. Adjusting the distributions of O<sub>3</sub> concentrations based on decreasing NO<sub>x</sub> emissions to just meet the existing and alternative O<sub>3</sub> primary standards resulted, in some cases, in substantial shifts in the spatial and temporal patterns of O<sub>3</sub> across case study urban areas relative to patterns of O<sub>3</sub> that existed for recent air quality, and presumably relative to the patterns present in the study locations of the epidemiology studies from which the concentration-response functions were drawn (see section 7.1.1 of the TSD, USEPA, 2012). What are the views of the Panel on the characterization of the degree to which these changes in spatial patterns of O<sub>3</sub> introduce uncertainty in risk estimates when effect estimates based on one spatial/temporal pattern of O<sub>3</sub> (the pattern in the epidemiology study) are applied to a substantially different spatial/temporal pattern of O<sub>3</sub> concentrations?
16. In particular, what are the views on the Panel on the characterization of the level of uncertainty associated with estimates of risk associated with days with relatively lower composite (area-wide average) O<sub>3</sub> concentrations and those with relatively higher composite O<sub>3</sub> concentrations?

## **Chapter 8: National Scale Mortality Risk Burden Based on Application of Results from Epidemiological Studies**

17. To what extent does the Panel find the assessment, interpretation, and presentation of the methods and results of the updated national-scale risk analysis to be technically sound, appropriately balanced, and clearly communicated?
18. To what extent does the Panel find the risk and air quality representativeness analyses to be technically sound and clearly communicated?

## **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 assessment?
20. To what extent does the Panel find that the discussion of overall uncertainty provides an appropriate context for interpretation of the exposure and risk results?

## **Executive Summary**

21. To what extent does the Panel find the Executive Summary to be a useful summary of the data and methods used to estimate human exposures and health risks and the key results of the assessment?

## **Attachment**

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

The second draft Welfare Risk and Exposure Assessment (WREA) 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 adjusted to just meet the current secondary O<sub>3</sub> standard of 75 ppb and alternative W126 standard levels of 15, 11, and 7 ppm-hrs. For the WREA, 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), introduces the ecosystem services framework to help define how the damage to ecosystems informs determinations of the adversity to public welfare associated with changes in ecosystem functions (chapter 5), presents analyses that characterize ambient O<sub>3</sub> exposures on two important ecological effects – biomass loss and foliar injury – and estimate impacts to the following ecosystem services: supporting, regulating, provisioning, and cultural services (chapters 6 and 7), and provides a synthesis of the assessment including key results and observations (chapter 8). Also included is an Executive Summary for the information presented in chapters 1-8.

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

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

1. To what extent 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 and clearly reflect the air quality, ecosystem effects evidence, ecosystem services, and exposure and risk considerations relevant for quantitative assessment, building from information contained in the final ISA?

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

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

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

4. What are the views of the Panel on the appropriateness of the methods used to characterize O<sub>3</sub> air quality for the exposure and risk assessment? What are the views of the Panel on the HDDM-based adjustment methodology used to adjust O<sub>3</sub> concentrations to just meet the existing O<sub>3</sub> standard and levels for average W126 scenarios, coupled with the interpolation method used to create a national surface of W126 concentrations for all scenarios?
5. To what extent does the Panel find that the discussion of uncertainty related to the air quality inputs to the exposure and risk assessment appropriately includes important sources of uncertainty?

#### **Chapter 5: O<sub>3</sub> Risk to Ecosystem Services**

6. To what extent does the Panel find the assessment, interpretation, and presentation of the methods and results of the updated ecosystem services assessment to be technically sound, appropriately balanced, and clearly communicated?
7. To what extent does the Panel support the revised structure of the ecosystem services discussions, including integrating ecological effects analyses directly with the ecosystem services assessments?
8. To what extent is the combination of O<sub>3</sub> exposure data with other data sources (e.g. fire data, bark beetle maps, trail maps) to link areas of concern/interest with areas of higher vegetation risk due to O<sub>3</sub> technically sound?
9. To what extent does the Panel find that the discussion of uncertainty and variability has included all important sources of uncertainty and variability and appropriately characterized their relationship to the ecosystem services estimates?

#### **Chapter 6: Biomass Loss**

10. To what extent does the Panel find the assessment, interpretation, and presentation of the methods and results of the biomass loss risk assessment to be technically sound, appropriately balanced, and clearly communicated?
11. To what extent does the Panel find the carbon sequestration estimates from the Forest and Agricultural Sector Optimization Model Greenhouse Gas version (FASOMGHG) (Section 6.6.1) to be technically sound and appropriately characterized?
12. To what extent does the Panel find the weighted biomass loss analysis in Section 6.8 to be a technically sound approach to assess potential ecosystem-level effects nationwide and in Class I areas?

13. To what extent does the Panel find that the discussion of uncertainty and variability has included all important sources of uncertainty and variability and appropriately characterized their relationship to biomass loss estimates?

### **Chapter 7: Foliar Injury**

14. To what extent does the Panel find the assessment, interpretation, and presentation of the methods and results of the foliar injury risk assessment to be technically sound, appropriately balanced, and clearly communicated?
15. What are the views of the Panel on the analysis of the Forest Health Monitoring data in Section 7.2, including the finding of the lack of a statistical relationship between the severity of foliar injury and W126 index values or soil moisture levels?
16. What are the views of the panel on the appropriateness of the characterization of vegetation strata (i.e., herb, shrub, tree) for the analyses of sensitive species cover in the three national park case studies (Section 7.4)?
17. What are the views of the Panel on the usefulness of the screening-level assessment of visible foliar injury in national parks in Section 7.3? Specifically, what are the views of the Panel regarding conclusions appropriate to draw from applying the W126 benchmark scenarios derived from the national-scale Forest Health Monitoring data analysis in the screening-level assessment?
18. To what extent does the Panel find that the discussion of uncertainty and variability have covered important sources of uncertainty and variability and appropriately characterized their relationship to foliar injury risks?

### **Chapter 8: 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 welfare exposure and risk analyses?

### **Executive Summary**

20. To what extent does the Panel find the Executive Summary to be a useful summary of the data and methods used to estimate exposures and risks to ecosystems and the key results of the assessment?