



THE ADMINISTRATOR OF THE ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OCT - 8 2014

H. Christopher Frey, Ph.D.  
Chairman  
Clean Air Scientific Advisory Committee  
U.S. Environmental Protection Agency  
1200 Pennsylvania Avenue, NW  
Washington, D.C. 20460

Dear Dr. Frey:

I want to thank you and the other members of the Clean Air Scientific Advisory Committee's Ozone Review Panel for your comments on the U.S. Environmental Protection Agency's *Health Risk and Exposure Assessment for Ozone, Second External Review Draft; Welfare Risk and Exposure Assessment for Ozone, Second External Review Draft*; and the *Second Draft Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards*. My staff and I are grateful for the review and advice provided during the public meetings on March 25, 26 and 27, 2014; the teleconferences on May 28, 2014, and June 4, 2014, and in your letters dated July 1, 2014, June 18, 2014, and June 26, 2014.

We carefully considered your comments and recommendations as well as those submitted by the public. On August 29, 2014, we transmitted the final documents to the Science Advisory Board's staff office, along with memorandums highlighting the revisions made to the draft documents in response to CASAC comments. Your contributions are extremely valuable to the EPA as we move to the next stage of the ozone National Ambient Air Quality Standards review.

I appreciate the advice the panel provided throughout this review of the ozone National Ambient Air Quality Standards, including the multiple drafts of the *Health Risk and Exposure Assessment for Ozone*, the *Welfare Risk and Exposure Assessment for Ozone* and the *Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards*.

Thank you all for your hard work, and I look forward to continuing to work with you on important public health and environmental challenges.

Sincerely,

A handwritten signature in black ink, appearing to read "Gina McCarthy".

Gina McCarthy



August 29, 2014

**MEMORANDUM**

**SUBJECT:** The Health Risk and Exposure Assessment for Ozone, Final and the Welfare Risk and Exposure Assessment for Ozone, Final

**FROM:** Erika Sasser, 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

During the March 25-27, 2014 public meeting and the May 28 and June 4, 2014 teleconference meetings, the Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel (the CASAC O<sub>3</sub> Review Panel) discussed their findings and recommendations on the *Health Risk and Exposure Assessment for Ozone: Second External Review Draft* and *Welfare Risk and Exposure Assessment for Ozone: Second External Review Draft*.<sup>1</sup> As part of the Environmental Protection Agency's (EPA's) ongoing review of the national ambient air quality standards (NAAQS) for ozone (O<sub>3</sub>), staff from the EPA's Office of Air Quality Planning and Standards (OAQPS) addressed the CASAC O<sub>3</sub> Review Panel's recommendations and prepared the *Health Risk and Exposure Assessment for Ozone: Final* and *Welfare Risk and Exposure Assessment for Ozone: Final*. I am requesting that you place these final documents in the appropriate location on the Science Advisory Board website. Also, please notify the CASAC members about the availability of the final risk and exposure assessment documents on the EPA Technology Transfer Network website: [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 final risk and exposure assessments 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 risk and exposure assessments 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

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<sup>1</sup> The documents can be found at <http://yosemite.epa.gov/sab/sabproduct.nsf/bf498bd32a1c7fdf85257242006dd6cb/84006d7423b29d9b85257b96004a8381!OpenDocument&Date=2014-03-25>.

[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 risk and exposure assessments 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 final risk and exposure assessments incorporate a number of changes from the second draft documents. The CASAC O<sub>3</sub> Review Panel presented its comments on the second draft health and welfare risk and exposure assessments in letters to the Administrator dated July 1, 2014 and June 18, 2014, respectively,<sup>2</sup> and many of the revisions to the assessments are in response to comments offered by the CASAC O<sub>3</sub> Review Panel. Some of the most significant changes made in consideration of the CASAC O<sub>3</sub> Review Panel's comments on the second draft assessments are summarized below.

Responses to CASAC O<sub>3</sub> Review Panel comments on the second draft health risk and exposure assessment:

- Throughout the final health risk and exposure assessment and associated appendices, we incorporated recommendations to clarify references, figures, tables, and discussions to improve overall document navigation and readability.
- In Chapter 1 – *Introduction*, we included an illustrative summary of existing O<sub>3</sub> air quality.
- In Chapter 2 – *Conceptual Model*, we added brief definitions regarding the strength of evidence categories used in characterizing the short- and long-term O<sub>3</sub>-related health effects. Further, we clarified the discussion of how background O<sub>3</sub> concentrations are accounted for in the exposure and risk calculations.
- In Chapter 3 – *Scope*, we added discussion of additional health responses that may be related to the FEV<sub>1</sub> health metric used in our controlled human exposure-based risk calculations and also stressed that the limited number of health endpoints used in our risk assessment is directly a function of the measured health outcomes provided in the peer-reviewed health studies.
- In Chapter 4 – *Air Quality Characterization*, we added discussion of the regression approach used as being empirically based. We expanded the discussion of the selected emissions reductions scenarios and their associated justifications. The NO<sub>x</sub>/VOC sensitivity analysis discussion was also expanded to include the comparison of emissions reductions needed for NO<sub>x</sub>/VOC vs. NO<sub>x</sub> only and a brief summary of air quality results associated with these scenarios. Details were added regarding the HDDM-adjustment methodology, including the alternate approach used for NY and LA study areas, for improved clarity and completeness. And finally, we clarified and expanded the discussion of uncertainties, improved the description of the propagation of uncertainty calculations, and also extended the propagation of regression uncertainty calculations to 8-hr maximum ozone concentrations.

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<sup>2</sup> Frey, H.C. (2014). Letters from Clean Air Scientific Advisory Committee to the Honorable Gina McCarthy, Administrator, US EPA. CASAC Review of the EPA's *Health Risk and Exposure Assessment for Ozone (Second External Review Draft)* July 1, 2014 and CASAC Review of the EPA's *Welfare Risk and Exposure Assessment for Ozone (Second External Review Draft)* June 18, 2014.

- In Chapter 5 – *Characterization of Urban-scale Human Exposure*, we performed an analysis of CHAD time spent outdoors considering four U.S. regions (section 5.4.1.6), discussed differences between APEX modeled exposures and estimated personal exposure concentrations from available measurement studies (section 5.4.4.1), compared exposure results using either the 2000 or 2010 U.S. Census data as an APEX input (section 5.4.4.4), and added results summary figures and tables to include numbers of people exposed and person-days of exposure (e.g., Figure 5-10 and Table 5-13).
- In Chapter 6 – *Characterization of Health Risks Based on Controlled Human Exposure Studies*, we expanded the results to include number of people experiencing an adverse health response (Appendix 6B). We expanded discussion and evaluation of the modified age term in MSS model. (In section 6.2.4 the modified age term is described; in section 6.4.2 and Appendix 6D model results are compared with a clinical study with children; in section 6.5.1.1 the statistical significance of the age term is discussed; Section 6.5.3 and Appendix 6E have results about the effect of the age term, age-relevant factors (e.g., time spend outdoors, ventilation rates), and a sensitivity analysis with an alternative age term). APEX model results were also compared using the 2000 and 2010 U.S. Census data for input (section 6.5.6). Further, we conducted a sensitivity analysis of inter-subject variability in response and expanded the discussion of inter- and intra-subject variability and performed a sensitivity analysis using the most recent MSS model (section 6.5.1). Finally, the discussion of uncertainties was expanded to include those related to inter- and intra-subject variability (Table 6-20).
- In Chapter 7 - *Characterization of Health Risk Based on Epidemiological Studies*, we included a sensitivity analysis evaluating the effect thresholds have on long-term mortality estimates (section 7.5.3) and added additional discussion of uncertainties associated with the modeling of long-term mortality (section 7.4.2). We expanded the discussion of potential sources of variability in risk to include micro-scale variations in O<sub>3</sub> levels near roadways and the potential implications of this source of variability for exposure misclassification in epidemiology-based studies (section 7.4.2). And finally, we clarified the discussion regarding the consistent patterns in short-term mortality incidence reductions observed across alternative air quality standard levels (section 7.5.2).
- In Chapter 8 – *Characterization of National-scale Mortality Risk Based on Epidemiological Studies and Urban-scale Representativeness Analysis*, we included a sensitivity analysis evaluating the effect thresholds have on estimates of mortality associated with long-term O<sub>3</sub> concentrations (section 8.1.3).
- In Chapter 9 – *Summary and Synthesis*, we added Table 9-1 which summarizes exposure and risk results in tabular form. We extended the discussion of uncertainties in modeling O<sub>3</sub> responses to meeting standards, in particular addressing the regression approach relating O<sub>3</sub> responses to emissions changes with ambient O<sub>3</sub> concentrations (section 9.5.1). The discussion of uncertainties related to epidemiology-based risks was modified to clarify the nature of uncertainties from using community-wide O<sub>3</sub> exposure surrogates, and to add additional information about the effect of using alternative threshold models for estimates of mortality associated with long-term O<sub>3</sub> concentrations (section 9.5.3).

And finally, we added two new conclusory paragraphs reflecting overall findings and overall confidence in the results.

Responses to CASAC O<sub>3</sub> Review Panel comments on the second draft welfare risk and exposure assessment:

- Throughout the final welfare risk and exposure assessment, we incorporated recommendations to clarify references, figures, tables, and discussions. We also streamlined the uncertainty discussions and further emphasized the strength of the underlying evidence.
- In Chapter 4 – *Air Quality Considerations*, we added an explanation for the use of the nine climate regions. We also included an assessment of the bias and error estimates resulting from the use of the HDDM-adjustment methodology and added a quantitative analysis of uncertainty associated with applying modeled O<sub>3</sub> responses to ambient data. Lastly, we investigated the implications of the regionally derived “across-the-board” NO<sub>x</sub> emissions reduction scenarios.
- In Chapter 5 -- *Ecosystem Services*, we clarified language related to the bark beetle infestations and fire risk to emphasize the correlational nature of these spatial analyses.
- In Chapter 6 – *Biomass Loss*, we assessed the responsiveness of relative biomass loss estimates to changes in W126 values. We summarized the number of tree species exceeding two percent relative biomass loss under recent O<sub>3</sub> conditions, as well as when O<sub>3</sub> is adjusted to just meet the existing standard and potential alternative standard levels of 15, 11, and 7 ppm-hrs. Because Cottonwood and Black Cherry are highly sensitive species and to provide a reference for the effect of these species, these data were also presented excluding Cottonwood, as well as excluding Cottonwood and Black Cherry.
- In Chapter 7 – *Foliar Injury*, we substantially clarified section 7.3 -- *Screening-Level Assessment of Visible Foliar Injury in 214 National Parks*, including clarifying the discussion of the W126 benchmarks for foliar injury. Because the CASAC O<sub>3</sub> Review Panel noted that it was an arbitrary level of injury, we removed the “elevated injury” scenario. In addition, throughout section 7.3 we also clarified much of the information contained in the figures and tables.

We appreciate the advice and recommendations the CASAC O<sub>3</sub> Review Panel provided throughout this review of the O<sub>3</sub> NAAQS. Please accept my gratitude for the advice the CASAC O<sub>3</sub> Review Panel has provided throughout our review of the O<sub>3</sub> NAAQS, including the multiple drafts of the *Health Risk and Exposure Assessment for Ozone*, and the *Welfare Risk and Exposure Assessment for Ozone*. We greatly appreciate the Panel's time and dedicated effort, which have been instrumental in helping us improve the quality of these assessments. Should you have any questions regarding the risk and exposure assessments, 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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