



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
NATIONAL CENTER FOR ENVIRONMENTAL ASSESSMENT  
RESEARCH TRIANGLE PARK, NC 27711

OFFICE OF  
RESEARCH AND DEVELOPMENT

March 3, 2011

**MEMORANDUM**

**SUBJECT:** CASAC Review of First External Review Draft Integrated Science Assessment for Ozone and Related Photochemical Oxidants

**FROM:** John Vandenberg, Ph.D.  
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**TO:** Holly Stallworth, Ph.D.  
Designated Federal Officer  
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EPA Science Advisory Board Staff Office (1400R)

The *First External Review Draft Integrated Science Assessment for Ozone and Related Photochemical Oxidants* (O<sub>3</sub> ISA) prepared by the Environmental Protection Agency's (EPA) National Center for Environmental Assessment – Research Triangle Park Division (NCEA –RTP) as part of EPA's ongoing review of the national ambient air quality standards (NAAQS) for ozone (O<sub>3</sub>) was released on March 3, 2011. Electronic copies are available for download at <http://www.epa.gov/ncea>. The draft ISA will be reviewed by the Clean Air Scientific Advisory Committee (CASAC) O<sub>3</sub> NAAQS Review Panel (the O<sub>3</sub> CASAC Panel) at a public meeting to be held in Chapel Hill, NC on May 19-20, 2011. We are in the process of distributing the draft O<sub>3</sub> ISA to the O<sub>3</sub> CASAC Panel. I am requesting that you forward our charge to the O<sub>3</sub> CASAC Panel.

The purpose of the draft ISA is to identify, evaluate, and summarize scientific information on the health and welfare effects associated with O<sub>3</sub> and related photochemical oxidants. The ISA is intended to "accurately reflect the latest scientific knowledge useful in indicating the kind and extent of identifiable effects on public health which may be expected from the presence of [a] pollutant in ambient air" (Clean Air Act, Section 108; 42 U.S.C. 7408). This first external review draft ISA integrates the scientific evidence for review of the primary (health-based) and secondary (welfare-based) NAAQS for O<sub>3</sub> and provides draft findings, conclusions and judgments on the strength, coherence and plausibility of the evidence. Chapter 2 of the O<sub>3</sub> ISA provides an integrative summary and conclusions of this assessment. This chapter is supported

by detailed information on the relevant evidence available from the multiple disciplines and approaches related to the causal framework (Chapter 1); atmospheric sciences (Chapter 3) and human exposure (Chapter 4); dosimetry and mode of action (Chapter 5); human health effects from short-term (Chapter 6) and long-term exposures (Chapter 7); susceptible populations (Chapter 8); effects on vegetation and ecosystems (Chapter 9); and O<sub>3</sub> effects on climate and UV-B exposure (Chapter 10). The final O<sub>3</sub> ISA, in conjunction with additional technical assessments, will provide the scientific basis for EPA's decision regarding the adequacy of the current standards for O<sub>3</sub> to protect human health, public welfare, and the environment.

In September 2009, a draft Integrated Review Plan for the Ozone National Ambient Air Quality Standards Review (EPA/452/P-09/001) was made available for public comment and was discussed by the CASAC via a publicly accessible teleconference consultation on November 13, 2009 (74 FR 54562). In August 2010, EPA held a workshop to discuss, with invited scientific experts, initial draft human health materials prepared in the development of the ISA (75 FR 42085). Preparation of the First Draft O<sub>3</sub> ISA benefitted both from that 2009 CASAC consultation and from peer-consultative workshop review of preliminary materials. NCEA followed past advice from the CASAC to streamline the format of the document to facilitate timely CASAC and public review by focusing more clearly on those issues most relevant to policy assessment.

The main purpose of this "background and charge memo" is twofold, both: (a) to help orient the O<sub>3</sub> CASAC Panel to the overall structure and content of the first draft O<sub>3</sub> ISA, and the key issues addressed in it; and (b) to help focus their review on matters of most importance to assist EPA in improving the quality of the document. Accordingly, brief overviews concerning certain key features and issues addressed by the First Draft O<sub>3</sub> ISA are concisely characterized below, and pertinent charge questions are posed in relation to a number of important topics. Following the CASAC and public review of the draft ISA, NCEA-RTP staff will produce a second draft ISA, which will be released in September 2011.

### **Charge to the O<sub>3</sub> CASAC Panel**

We ask the Panel to focus on the following questions in their review:

1. This first external review draft O<sub>3</sub> ISA is of substantial length and reflects the copious amount of research conducted on O<sub>3</sub>. EPA has attempted to succinctly present and integrate the policy-relevant scientific evidence for the review of the O<sub>3</sub> NAAQS. The panel may note that per CASAC consultation on November 13, 2009, considerable discussion has focused on older literature. The panel emphasized that important older studies should be discussed in detail to reinforce key concepts and conclusions if they are open to reinterpretation in light of newer data and where these older studies remain the definitive works available in the literature. In considering subsequent charge questions and recognizing an overall goal of producing a clear and concise document, are

there topics that should be added or receive additional discussion? Similarly, are there topics that should be shortened or removed? Does the Panel have opinions on how the document can be shortened without eliminating important and necessary content?

2. The framework for causal determination and judging the overall weight of evidence is presented in Chapter 1. Is this framework appropriately applied for this O<sub>3</sub> ISA? How might the application of the framework be improved for O<sub>3</sub> effects?
3. Chapter 2 presents the integrative summary and conclusions from the O<sub>3</sub> ISA with detailed discussion of evidence in subsequent chapters. Is this a useful and effective summary presentation? How does the Panel view the appropriateness of the causal determinations?
4. In relation to Chapter 3 and its associated appendix, to what extent are the atmospheric chemistry and air quality characterizations clearly communicated, appropriately characterized, and relevant to the review of the O<sub>3</sub> NAAQS? Does the information on atmospheric sciences provide useful context and insights for the evaluation of O<sub>3</sub> effects on human health, vegetation, ecosystems, and climate in the ISA?
  - a. Is accurate and appropriate information provided regarding techniques for measuring O<sub>3</sub> and its components, and spatial and temporal patterns of O<sub>3</sub> concentration?
  - b. Policy Relevant Background (PRB) O<sub>3</sub> concentrations are necessary to estimate risks to human health and environmental effects associated with exposures to O<sub>3</sub> concentrations attributable to anthropogenic sources of precursors emitted in the United States, Canada and Mexico (i.e., to O<sub>3</sub> concentrations above PRB levels). As such, estimates of PRB are key to the NAAQS process for O<sub>3</sub>. Is the evidence related to estimation of and uncertainty in PRB presented clearly, succinctly, and accurately? Are there issues related to uncertainties in methods for estimated PRB concentrations that have not been addressed or should be expanded?
  - c. Does the discussion of ambient O<sub>3</sub> concentrations adequately describe the variability attributed to diurnal patterns, seasonal patterns, and spatial differences in both urban and non-urban locations? Are the analyses and figures presented in Chapter 3 and its associated appendix (section 3.7) effective in depicting ambient O<sub>3</sub> characteristics?
  - d. Is there additional information regarding oxidants, other than O<sub>3</sub>, that should be included, or is the current emphasis on O<sub>3</sub> adequate?

5. Chapter 4 describes human exposures to O<sub>3</sub>. Is the evidence relating human exposure to ambient O<sub>3</sub> and errors associated with exposure assessment presented clearly, succinctly, and accurately? Are the results of field studies evaluating indoor-outdoor and personal-ambient exposure relationships, and factors affecting those relationships, presented in a manner that is useful for interpretation of epidemiologic results? Is the information on modeling O<sub>3</sub> concentration surfaces and population exposures appropriate for evaluating the utility of these modeling approaches? Do the characterizations of temporal and spatial variability of O<sub>3</sub> in urban areas provide support for better understanding and interpreting epidemiologic studies discussed later?
6. The dosimetry and modes of action of O<sub>3</sub> are discussed in Chapter 5. The primary focus of the dosimetry discussion is to highlight factors that might lead to differences in dose between individuals and between species. Some potential modes of action that may underlie a number of health outcomes and that may contribute to the biological plausibility of health effects of short- and long-term exposures are described in detail. Is the review of basic dosimetric principles of O<sub>3</sub> uptake presented accurately and in sufficient detail? What are the views of the Panel on the approach taken in Chapter 5 to characterize modes of action for O<sub>3</sub>-related effects?
7. Chapter 6 is intended to support the evaluation of human health effects evidence for short-term exposures to O<sub>3</sub>. To what extent are the discussion and integration of evidence on the health effects of O<sub>3</sub> from the animal toxicological, controlled human exposure, and epidemiologic studies, technically sound, appropriately balanced, and clearly communicated? Does the integration of health evidence focus on the most policy-relevant studies or health findings? What are the views of the panel regarding the balance of emphasis placed on evidence from previous and recent epidemiologic studies in deriving the causal determination for short-term O<sub>3</sub> exposure and respiratory effects (in particular, additional epidemiologic evidence for lung function and respiratory symptoms and new evidence for biological indicators of airway inflammation and oxidative stress that previously has been largely limited to human controlled exposure and toxicological studies)? The majority of new studies that examine the association between short-term O<sub>3</sub> exposure and mortality focus on specific issues that have been previously identified. Does the structure of the chapter adequately highlight the breadth of studies (both older and new) that indicate an association between O<sub>3</sub> exposure and mortality and provide the underlying rationale for the causal determination? Are the data properly presented regarding the credibility of newly reported findings being attributable to O<sub>3</sub> acting alone or in combination with other co-pollutants and regarding the extent that toxicological study findings lend support to the biological plausibility of reported epidemiologic associations in reaching a causal determination? Are the tables and figures presented in Chapter 6 appropriate, adequate and effective in advancing the interpretation of these health studies?

8. Chapter 7 presents important new findings from studies published since the 2006 O<sub>3</sub> AQCD including studies that examine the relationship between long-term O<sub>3</sub> exposure and new onset asthma in children, first childhood asthma hospital admissions, increased asthma severity, bronchitic symptoms and respiratory-related school absences. These studies provide evidence in this regard based on different genetic variants. What are the views of the Panel on the conclusions drawn in the draft ISA regarding the strength, consistency, coherence and plausibility of the evidence for health effects for long-term O<sub>3</sub> exposure on respiratory morbidity? Limited new data also suggest a link between long-term O<sub>3</sub> exposure and respiratory mortality; what weight should be placed on this evidence in causal determinations? What are the views of the Panel on the conclusions drawn in the draft ISA regarding the strength, consistency, coherence and plausibility of the evidence for neurological effects resulting from long-term O<sub>3</sub> exposure? Are the data properly presented regarding the credibility of newly reported findings being attributable to O<sub>3</sub> acting alone or in combination with other co-pollutants and regarding the extent that toxicological study findings lend support to the biological plausibility of reported epidemiologic associations in reaching a causal determination?
9. Chapter 8 is a discussion of potential susceptibility factors. Are the characteristics included within the broad susceptibility categories appropriate and consistent with the definitions used? Are there any key susceptibility factors that were not included and need to be added?
10. Chapter 9 describes effects of O<sub>3</sub> on vegetation and ecosystems. Are the major effects of O<sub>3</sub> exposure on vegetation and ecosystems identified and characterized? To what extent do the discussions and integration of evidence across scales (e.g., species, communities and ecosystems) correctly represent and clearly communicate the state of the science? Has the ISA adequately characterized the available information on the relationship between O<sub>3</sub> exposure and effects on individual plants and ecosystems? Are there subject areas that should be added, expanded upon, shortened or removed?
11. Chapter 10 provides a concise overview of key information regarding O<sub>3</sub> effects on climate and UV-B exposure. What are the views of the Panel on the scientific soundness and usefulness of the discussion in Chapter 10 on the role of O<sub>3</sub> in global climate change and changes in mean global temperatures? Is there any information regarding the climatic effects of domestically produced O<sub>3</sub> on climate in the U.S. that should have been included? Is there important new information on UV-B effects or other welfare effects such as materials damage that have been overlooked and should be incorporated into this chapter?

We look forward to discussing these issues with the O<sub>3</sub> CASAC Panel at our upcoming meeting. Should you have any questions regarding the draft O<sub>3</sub> ISA, please

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