



August 14, 2008

MEMORANDUM

SUBJECT: CASAC Review of the Second Draft Risk and Exposure Assessment to Support the Review of the NO₂ Primary National Ambient Air Quality Standard

FROM: Lydia Wegman, Director
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TO: Angela Nugent
Designated Federal Officer
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Attached is the current version of the document, *Risk and Exposure Assessment to Support the Review of the NO₂ Primary National Ambient Air Quality Standard: Second Draft* (henceforth referred to as the second draft assessment document). This draft document has been 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 primary national ambient air quality standard (NAAQS) for nitrogen oxides (NO_x). The version of the second draft assessment document being sent to you today is complete with the exception of chapter 8, which will discuss an exposure analysis that is being conducted for the city of Atlanta, GA. This exposure analysis chapter, as well as associated materials that will be included in appendix B, will be sent separately within the next week. The second draft assessment document will be the focus of a review by the Clean Air Scientific Advisory Committee (CASAC) Oxides of Nitrogen Primary NAAQS Review Panel (the Panel), scheduled for a public meeting to be held in Research Triangle Park, NC on September 9-10, 2008. I am requesting that you forward this memorandum and the attached electronic file containing the second draft assessment document to the Panel members to prepare for that review.

The purpose of this second draft assessment document is to convey the approach taken by staff to characterize human exposures and health risks associated with ambient NO₂ and to present the results of those analyses. In preparing this second draft assessment document, OAQPS staff has made a number of changes from the first draft, which was reviewed by the Panel at a public meeting on May 1 and 2, 2008. For example, this second draft assessment document identifies the potential alternative standards for which analyses were conducted and presents the results of those analyses. The analysis of these alternative standards will help to inform future policy decisions that will be made during the Agency's policy assessment and rulemaking process; it is not the purpose of the risk and exposure assessment document to make any policy recommendations. This second draft assessment document also contains additional information and analyses in response to comments from

the Panel on the first draft document. For example, this draft includes (1) a comparison of predicted on-road NO₂ concentrations generated by the air quality assessment (based on roadway-to-ambient ratios) and the exposure assessment (based on AERMOD outputs in Philadelphia and Atlanta); (2) a comparison of modeled and monitored NO₂ concentrations in Philadelphia (included in appendix B) and Atlanta (to be sent next week); and (3) a quantitative risk assessment for respiratory emergency department visits in Atlanta, GA. OAQPS staff intends to take into consideration the Panel's advice and public comments on this second draft document in preparing the final risk and exposure assessment document for NO₂. The final risk and exposure assessment document is scheduled for completion in November 2008.

Completion of this assessment document will be followed by Agency rulemaking, which is scheduled to begin with the issuance in the Federal Register of an advance notice of proposed rulemaking (ANPR) by December, 2008. The ANPR will present the Agency's policy assessment which will be based on the evaluation of scientific evidence presented in the final Integrated Science Assessment (ISA) as well as the information presented in the final risk and exposure assessment document. Additional rulemaking steps include issuance of a proposed rule by May 28, 2009 and a final rule by December 18, 2009, consistent with the schedule in the consent decree that governs the completion of this review.

Document for Review

We are sending printed copies of the following document to members of the Panel who have not expressed a preference for electronic copies only. In addition, we request that you forward to the Panel members the attached electronic file containing this document. This document is also available on the EPA website:

http://www.epa.gov/ttn/naaqs/standards/nox/s_nox_cr_rea.html

- **Attachment:** *Risk and Exposure Assessment to Support the Review of the NO₂ Primary National Ambient Air Quality Standard: Second Draft*

The second draft risk and exposure assessment document is the focus of the scheduled review with the CASAC NO_x/SO_x Panel, to be guided by the charge questions listed below. Chapter 1 includes information on the background, history, and scope for the assessment. Chapter 2 provides information on sources, ambient levels, and exposures associated with NO₂. Chapter 3 provides information on at-risk populations. Chapter 4 provides information on key health effects associated with ambient NO₂ and NO₂ exposures. Chapter 5 identifies potential alternative standards that have been analyzed as well as our rationale for selecting those specific standards for analysis. Chapter 6 presents an overview of the goals and approaches to assessing exposures and risks. Chapter 7 presents the approach and results of the air quality analysis as well as the approach and results of the risk characterization that is based on the air quality analysis. Chapter 8 (to be sent next week) presents the approach and results of the exposure assessment as well as the approach and results of the risk characterization that is based on the exposure assessment. Chapter 9 presents a risk assessment for emergency department visits in Atlanta, GA.

Charge to the CASAC NO_x/SO_x Primary Review Panel

Within each of the main sections of the second draft assessment document, we ask the Panel to address the following questions, taking into consideration changes and additions since the first draft:

Characterization of Air Quality (Chapters 2, 6, and 7)

1. To what extent are the air quality characterizations and analyses technically sound, clearly communicated, appropriately characterized, and relevant to the review of the primary NO₂ NAAQS?
2. In order to simulate just meeting potential alternative 1-hour daily maximum standards, we have adjusted NO₂ air quality levels using the same approach that was used in the first draft to simulate just meeting the current annual standard. To what extent is this approach clearly communicated and appropriately characterized?
3. Because of the impact of mobile sources on ambient NO₂, we have estimated on-road NO₂ concentrations. To what extent is the approach taken technically sound, clearly communicated, and appropriately characterized? Do Panel members have comments on the relevance of this procedure for reviewing the primary NO₂ NAAQS?
4. What are the views of the Panel regarding the adequacy of the assessment of uncertainty and variability?

Characterization of Health Effects Evidence and Selection of Potential Alternative Standards for Analysis (Chapters 3, 4, 5)

1. The presentation of the NO₂ health effects evidence is based on the information contained in the NO₂ Integrated Science Assessment. What are the views of the Panel on the overall characterization of the health evidence for NO₂? To what extent is the presentation clear and appropriately balanced?
2. The specific potential alternative standards that have been selected for analysis are based on both controlled human exposure studies and on epidemiological studies conducted in the United States. What are the Panel's views on the appropriateness of these potential alternative standards (in terms of indicator, averaging time, form, and level) for the purpose of conducting air quality, exposure, and risk assessments and on the rationale used to select them for that purpose?

Characterization of Exposure (Chapters 6 and 8):

1. To what extent is the assessment, interpretation, and presentation of the results of the exposure analysis technically sound, clearly communicated, and appropriately characterized?

2. The second draft assessment document evaluates exposures in Atlanta. What are the views of the Panel on the approach taken and on the interpretation of the results of this analysis?
3. What are the views of the Panel regarding the adequacy of the assessment of uncertainty and variability?

Characterization of Health Risks (Chapters 7, 8, 9):

1. Based on conclusions in the final ISA regarding airway responsiveness, we have expanded the range of potential health effect benchmark values to include 0.1 ppm. Do Panel members have comments on the range of potential health effects benchmark values chosen to characterize risks associated with 1-hour NO₂ exposures?
2. To what extent are the assessment, interpretation, and presentation of health risk results technically sound, clearly communicated, and appropriately characterized?
3. A focused risk assessment has been conducted for emergency department visits in Atlanta, GA. To what extent are the assessment, interpretation, and presentation of health risk results technically sound, clearly communicated, and appropriately characterized? What are the views of the Panel on the approach taken and on the interpretation of the results of this analysis?
4. What are the views of the Panel regarding the clarity and adequacy of the discussion of uncertainty and variability with respect to the characterization of health risks.

We look forward to discussing these issues with the Panel at our upcoming meeting. Should you have any questions regarding the second draft risk and exposure assessment document, please contact Dr. Scott M. Jenkins (919-541-1167; email jenkins.scott@epa.gov).

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