



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

March 10, 2008

OFFICE OF
RESEARCH AND DEVELOPMENT

MEMORANDUM

SUBJECT: CASAC Review of Integrated Science Assessment for Oxides of Nitrogen – Health Criteria: Second External Review Draft

FROM: Ila Cote, Ph.D, Acting Director */Signed/*
National Center for Environmental Assessment –
Research Triangle Park Division (B243-01)

TO: Angela Nugent, Designated Federal Officer
Clean Air Scientific Advisory Committee
EPA Science Advisory Board Staff Office (1400F)

Attached is the draft *Integrated Science Assessment for Oxides of Nitrogen – Health Criteria: Second External Review Draft* (draft 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 nitrogen dioxide (NO₂). The purpose of the draft ISA is to identify, evaluate, and summarize scientific information on the health effects associated with gaseous nitrogen oxides. 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)). The draft ISA will be reviewed by the Clean Air Scientific Advisory Committee (CASAC) Nitrogen Oxides Primary NAAQS Panel at a public meeting to be held in Research Triangle Park in May 2008. I am requesting that you forward the draft ISA to the CASAC Panel to prepare for that review.

This second external review draft includes revisions based on the comments and advice provided by the CASAC panel on the second external review draft ISA. One of the key issues on which EPA has focused in revising the draft ISA includes more detailed characterization of the process of study selection and evaluation in preparation of the ISAs. The introduction includes a more comprehensive discussion of the framework for evaluation of health evidence, including characterization of the criteria for causality determination, and the concepts are carried through the evaluation of evidence in subsequent chapters.

The draft ISA is supported by a series of Annexes that provide more comprehensive and detailed information on the relevant evidence available from the disciplines of atmospheric science, human exposure, toxicology, clinical studies and epidemiology. These Annexes are provided with the ISA for the Panel's information. The CASAC Panel is being asked to review the draft ISA. NCEA-RTP will also address comments received on supporting material in the Annexes, to the extent that Panel members wish to review and provide comments on the Annexes.

Following the review of this second draft ISA, NCEA-RTP staff will prepare a final ISA that addresses comments received during CASAC; the court-ordered deadline for the final ISA is July 11, 2008.

Charge to the CASAC Nitrogen Oxides Primary NAAQS Review Panel

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

1. What are the views of the Panel on the characterization of the search strategy for identifying literature, criteria for study selection, the the framework for scientific evaluation of studies and causality determination?
2. To what extent are the atmospheric chemistry and air quality characterizations clearly communicated, appropriately characterized, and relevant to the review of the primary NO₂ NAAQS? Are the properties of ambient oxides of nitrogen appropriately characterized, including spatial and temporal patterns and relationships between ambient oxides of nitrogen and human exposure? Does the information in Chapter 2 provide a sufficient atmospheric science and exposure basis for the evaluation of human health effects presented in later chapters?
3. To what extent is the discussion and integration of evidence from the animal toxicology and controlled human exposure studies and epidemiologic studies technically sound, appropriately balanced, and clearly communicated? What are the views of the Panel on the conclusions drawn in the draft ISA regarding the strength, consistency, coherence and plausibility of NO₂-related health effects?
4. What are the views of the Panel on the characterization of groups likely to be susceptible or vulnerable to NO₂ and the potential public health impact of NO₂ exposure?
5. What are the Panel's views on the adequacy of this second external review draft ISA to provide support for future exposure and policy assessments?

We look forward to discussing these issues with the CASAC NOx and SOx Primary Panel at our upcoming meeting. Should you have any questions regarding the draft ISA, please feel free to contact me (919-541-4173, email cote.ila@epa.gov), or Dr. Dennis Kotchmar (919-541-4158; email kotchmar.dennis@epa.gov).

Attachments

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