



MEMORANDUM

SUBJECT: CASAC Consultation on Draft Sulfur Dioxide Health Assessment Plan: Scope and Methods for Exposure and Risk Assessment

FROM: *Karen M. Martin*
for Lydia N. Wegman, Director
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TO: Holly Stallworth
Designated Federal Officer
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Attached is a draft document, *Sulfur Dioxide Health Assessment Plan: Scope and Methods for Exposure and Risk Assessment* (draft Health Assessment Plan), 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 standards (NAAQS) for sulfur dioxide (SO₂). This draft Health Assessment Plan will be the focus of a consultation by the Clean Air Scientific Advisory Committee (CASAC) NO_x/SO_x Primary NAAQS Review Panel (the CASAC NO_x/SO_x Panel), scheduled for a public meeting to be held in Research Triangle Park, NC, on December 5-6, 2007. I am requesting that you forward this draft Health Assessment Plan to the CASAC NO_x/SO_x Review Panel to prepare for that consultation.

The purpose of this draft Health Assessment Plan is to outline the scope and approaches that staff is planning to use to conduct an exposure analysis and human health risk assessment for SO₂, and to highlight key issues involved in these assessments so as to facilitate consultation with the CASAC NO_x/SO_x Panel, as well as public comment. OAQPS staff intends to take into consideration the CASAC NO_x/SO_x Panel's advice and public comments on this Health Assessment Plan in conducting these exposure and risk assessments. As noted in the draft Health Assessment Plan, these assessments will draw upon information presented in the *Integrated Science Assessment for Oxides of Sulfur – Health Criteria* (SO_x ISA), a document being prepared by EPA's National Center for Environmental Assessment, Research Triangle Park, NC (NCEA-RTP), which is also undergoing review by the CASAC NO_x/SO_x Panel and the

public. The results of the exposure and risk assessments will be documented in a report to be prepared by OAQPS staff and reviewed by the CASAC NO_x/SO_x Panel and the public.

The schedule for conducting and documenting these assessments is discussed in a related document, *Integrated Review Plan for the Primary National Ambient Air Quality Standard for Sulfur Dioxide*, which was the subject of a consultation by the CASAC NO_x/SO_x Panel earlier this year (available at the website listed below). This schedule calls for completion of the SO_x ISA by September 2008 and completion of the exposure and risk assessments by January 2009. These assessments will be followed by Agency rulemaking, which will include the issuance in the Federal Register of an advance notice of proposed rulemaking (ANPR) by February 2009, a proposed rule by July 2009, and a final rule by March 2010.

Document for Consultation

The following document is being made available to the CASAC NO_x/SO_x Panel in the form of an attached electronic file. The document is also available from the EPA website http://www.epa.gov/ttn/naaqs/standards/so2/s_so2_index.html under "Planning Documents." Printed copies of this document will be sent to Panel members via Federal Express.

- ◆ Attachment: *Sulfur Dioxide Health Assessment Plan: Scope and Methods for Exposure and Risk Assessment* (draft Health Assessment Plan, November 2007)

This document is the focus of the scheduled consultation with the CASAC NO_x/SO_x Panel, to be guided by the charge questions listed below. Following an introductory section, this document discusses air quality considerations that are relevant to both the planned exposure and human health risk assessments. The next two sections present the planned scope and approach for the exposure analysis and the health risk assessment. Throughout these sections, key issues are discussed and staff's plans for addressing these issues are noted. The final section summarizes the schedule and interim milestones related to these assessments.

Charge to the CASAC NO_x/SO_x Primary Review Panel

Within each of the main sections of the draft Health Assessment Plan, questions that we ask the Panel to focus on in its review include the following:

Air Quality Considerations:

1. Based on the low estimated contribution of policy-relevant background SO₂ to overall ambient SO₂ levels, staff is considering a proportional (i.e., linear) approach to adjusting air quality to simulate just meeting potential alternative SO₂ standards that are below recent air quality concentrations. Do the Panel members have comments on adopting a proportional approach to simulate just meeting more stringent alternative air quality standards?

2. Recognizing that current ambient air quality concentrations are lower than the current standards, the draft Health Assessment Plan discusses two alternative approaches to simulating ambient SO₂ levels associated with just meeting the current SO₂ standards: use of historical air quality data (e.g., possibly pre-2000) when ambient levels were at or above the current standards, or use of a proportional (i.e., linear) approach to adjust SO₂ levels upward. Do the Panel members have advice or comments on these two alternative approaches to simulating air quality just meeting the current SO₂ standards?

Exposure Analysis:

1. In considering the exposure analysis broadly:
 - a. Do Panel members have any comments on the general structure and overall two-tier approach that staff plans to use for the exposure analysis? Are the criteria that staff plans to use for deciding whether to conduct a Tier II analysis clear and appropriate?
 - b. Have the most important factors influencing exposure to SO₂ been clearly accounted for and described?
 - c. The draft plan describes the basis for and selection of population groups of interest (i.e., children, asthmatics (children and adults), and the elderly) for which SO₂ exposure estimates are to be developed. Do Panel members generally agree with the groups of interest identified in the draft plan?
2. In considering the Tier I exposure assessment:
 - a. Do Panel members agree that a statistical model using available ambient 5-minute monitoring data is appropriate for estimating expected exceedances of very short-term (5-minute) potential health effect benchmarks?
 - b. Do Panel members agree with the approach of applying a statistical model to estimate 5-minute concentration exceedances at monitoring locations where only 1-hour monitoring was performed for evaluating the extent of 5-minute peaks associated with meeting alternative standards with longer averaging times?
3. In considering a potential Tier II exposure assessment:
 - a. Do Panel members agree with the combined emissions/dispersion modeling approach to estimate short-term (hourly) SO₂ concentrations in close proximity to SO₂ emission sources?
 - b. Do Panel members have comments or advice regarding the described binning of sources and development of prototype stacks/facilities?
 - c. Do Panel members agree with the approach using peak-to-mean ratio cumulative density functions (PMR CDFs) to estimate very short-term peak concentrations from the 1-hour modeled concentrations?
 - d. Do Panel members generally agree that the approach described using APEX is reasonable and appropriate to estimate the occurrence of very short-term (5 minute) SO₂ peak exposures?

4. Do Panel members have any comments or advice regarding the general approach to addressing uncertainty and variability in each Tier of the exposure assessment as described in the draft plan?

Health Risk Assessment:

1. Do Panel members have any comments on the general structure and overall three-tier approach that staff plans to use for the risk assessment? Are the criteria that staff plans to use for deciding whether to conduct a Tier III risk assessment clear and appropriate?
2. In considering the Tier I risk assessment:
 - a. Do Panel members agree with the approach of having a qualitative assessment of health endpoints to identify which are likely candidates for a more sophisticated and quantitative tier of assessment?
 - b. Do Panel members agree with our initial observation that controlled human exposure studies demonstrate strong evidence for bronchoconstriction in exercising asthmatics following 5-10 minutes SO₂ exposure?
 - c. Do Panel members agree with staff's initial observation that the strongest epidemiologic evidence is for respiratory symptoms in asthmatic children and respiratory-related hospital admissions and respiratory-related emergency department visits in asthmatics and others with respiratory conditions?
3. In considering the Tier II risk assessment:
 - a. In general, are staff plans to use potential health effect benchmarks to address respiratory effects demonstrated in exercising asthmatics in controlled human exposure studies clear and appropriate?
 - b. Do Panel members generally agree with the tentatively identified potential health effect benchmark of 0.5 to 0.6 ppm for exercising asthmatics following 5-10 minutes SO₂ exposure?
 - c. Do Panel members generally agree with the staff's approach of focusing on areas around major sources of SO₂ with respect to concerns about 5-10 minute peak exposures related to the respiratory effects observed in controlled human exposure studies?
 - d. Do Panel members generally agree with staff's approach of focusing on urban areas with respect to concerns about 1- and 24-hr and annual SO₂ concentrations related to respiratory effects observed in epidemiologic studies?
 - e. Do Panel members have any comments or advice with respect to staff's approach of gathering additional information to characterize the SO₂ ambient air quality that existed at the time various key U.S. and Canadian studies addressing respiratory effects were conducted to see if the concentration-response relationships observed in these epidemiologic studies are related to particular SO₂ levels and associated averaging times, geographic location and/or season, and the inclusion of various co-pollutants?

4. In considering a potential Tier III risk assessment:
 - a. Do Panel members generally agree that there is insufficient information to develop credible exposure-response relationships for use in a quantitative risk assessment based on the controlled human exposure evidence?
 - b. Do Panel members have any comments or advice with respect to the general approach or specific factors to be considered in deciding whether or not to proceed to a Tier III quantitative risk assessment for the respiratory-related health endpoints based on epidemiologic evidence discussed in the draft plan?
5. Do Panel members have any comments or advice with respect to the general approach to addressing uncertainty and variability in each Tier of the risk assessment as described in the draft plan?

We look forward to discussing these issues with the CASAC NO_x/SO_x Primary NAAQS Review Panel at our upcoming meeting. Should you have any questions regarding the draft Health Assessment Plan, please contact Dr. Karen Martin (919-541-5274; email martin.karen@epa.gov) or Dr. Stephen E. Graham (919-541-4344; email graham.stephen@epa.gov).

Attachment

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