



March 20, 2009

MEMORANDUM

SUBJECT: CASAC Review of the Second Draft Risk and Exposure Assessment to Support the Review of the SO₂ 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 SO₂ Primary National Ambient Air Quality Standard: Second Draft* (henceforth referred to as the second draft REA). 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 standards (NAAQS) for sulfur oxides (SO_x). The second draft assessment document will be the focus of a review by the Clean Air Scientific Advisory Committee (CASAC) Sulfur Oxides Primary NAAQS Review Panel (the Panel), scheduled for a public meeting to be held in Chapel Hill, NC on April 16-17, 2009. I am requesting that you forward this memorandum and the attached electronic file containing the second draft REA to the Panel members to prepare for that review.

The purpose of this second draft REA document is to convey the approach taken by staff to characterize human exposures and health risks associated with ambient SO₂ and to present the results of those analyses. In preparing this second draft REA, OAQPS staff has made a number of changes from the first draft, which was reviewed by the Panel at a public meeting on July 30-31, 2008. For example, this second draft REA identifies the potential alternative standards for which analyses were conducted and presents the results of those analyses. In addition, this second draft REA also contains additional information and analyses in response to comments from the Panel on the first draft document. For example, this draft includes: (1) analyses of exceedences of potential health effect benchmark levels as low as 100 ppb, (2) additional model evaluations, (3) expanded characterization of uncertainties, and (4) a policy assessment that considers epidemiological, human exposure, and animal toxicological evidence presented in the ISA (available at: http://www.epa.gov/ttn/naaqs/standards/so2/s_so2_cr_isa.html), as well as the exposure and risk characterization results presented in this document, as they relate to the adequacy of the current SO₂ NAAQS and potential alternative primary SO₂ standards. The version of the second draft REA document being sent to you today contains exposure and risk analyses

conducted in St Louis and Green Counties in Missouri (MO). EPA is also attempting to extend its exposure and risk analyses to Alleghany County (Pittsburgh), Pennsylvania and Cuyahoga County (Cleveland), Ohio. However, as of this date we are still working to rectify technical issues involving disparities between dispersion model predicted SO₂ concentrations and measured SO₂ concentrations at fixed site monitors. If EPA is successful in resolving these technical issues, additional exposure and risk estimates for these areas will be included in the presentation to the Panel at the April 16-17 meeting.

Completion of this second draft REA will be followed by Agency rulemaking. This process will be informed by the risk and exposure information contained in the final REA, as well the scientific evidence described in the final ISA. The rulemaking process will also take into account CASAC advice and recommendations, as well as public comment on any policy options under consideration. EPA is under a consent decree to complete its review of the SO₂ primary NAAQS by issuing a proposed rule no later than November 16, 2009 and a final rule by June 2, 2010.

Document for Review

We are sending printed copies of the second draft REA 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/so2/s_so2_cr_rea.html

- **Attachment:** *Risk and Exposure Assessment to Support the Review of the SO₂ Primary National Ambient Air Quality Standard: Second Draft*

The second draft REA is the focus of the scheduled review with the 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 SO₂. Chapter 3 provides information on at-risk populations. Chapter 4 provides information on key health effects associated with SO₂ exposures. Chapter 5 identifies potential alternative standards that have been examined in the risk and exposure analyses, 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 presents the approach and results of the exposure assessment conducted in St. Louis and Greene Counties in MO, as well as the approach and results of the risk characterization that is based on the exposure assessment. Chapter 9 presents a quantitative risk assessment for lung function responses based on the results of the exposure analyses conducted in St Louis and Greene Counties in MO. Chapter 10 integrates the scientific evidence from the final ISA with the risk and exposure information in this second draft REA as it relates to the adequacy of the current standards, and to potential alternative standards.

Charge to the CASAC Sulfur Oxides Primary NAAQS Review Panel

Within each of the main sections of the second draft REA 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, 5, 6, and 7)

1. Does the Panel find the results of the air quality analyses to be technically sound, clearly communicated, and appropriately characterized?
2. In order to simulate just meeting potential alternative 1-hour daily maximum standards, we have adjusted SO₂ air quality levels using the same approach that was used in the first draft to simulate just meeting the current standards. What are the Panel's views on this approach? To what extent does this approach characterize the public health implications of the current standards? Does the Panel have technical concerns with this approach?
3. In this second draft document, the locations selected for detailed analyses were expanded from twenty to forty counties, using ambient SO₂ monitoring data for years 2001-2006. What are the views of the Panel regarding the appropriateness of these locations and time period of analysis? To what extent is the rationale for selection of these locations and time periods clear and sufficient to justify their use in detailed air quality and exposure analyses?
4. What are the views of the Panel regarding the adequacy of the assessment of uncertainty and variability? To what extent have sources of uncertainty been identified and the implications for the risk characterization been addressed? To what extent has variability adequately been taken into account?

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

1. The presentation of the SO₂ health effects evidence is based on the information contained in the final ISA for Sulfur Oxides. Does the draft REA accurately reflect the overall characterization of the health evidence for SO₂ contained in the final ISA? Does the Panel find the presentation to be clear and appropriately balanced?
2. The specific potential alternative standards that have been selected for analysis are based on both controlled human exposure and epidemiological studies. To what extent is the rationale for selection of these potential alternative standards clear and sufficient to justify their use in the air quality, exposure and risk analyses? What are the views of the Panel regarding the appropriateness of these potential alternative standards for use in conducting the air quality, exposure, and risk assessments?

Characterization of Exposure (Chapters 6 and 8):

1. Does the Panel view the results of the exposure analyses to be technically sound, clearly communicated, and appropriately characterized?
2. The second draft REA evaluates exposures in St Louis and Greene County, MO. What are the views of the Panel on the approach taken? To what extent does this approach help to characterize the public health implications of the current standards? Does the Panel have technical concerns with this approach?
3. What are the views of the Panel regarding the approaches taken to model SO₂ emission sources? Does the Panel have comments on the comparison of the model predictions to ambient monitoring data?
4. What are the views of the Panel regarding the adequacy of the assessment of uncertainty and variability? To what extent have sources of uncertainty been identified and the implications for the risk characterization been addressed? To what extent has variability adequately been taken into account?
5. What are the views of the Panel regarding the staff's characterization of the representativeness of the St. Louis and Greene County, MO exposure and risk estimates?

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

1. Based on conclusions in the ISA regarding decrements in lung function in exercising asthmatics following 5-10 minute SO₂ exposures, we have adjusted our range of 5-minute potential health effect benchmark values to 100 – 400 ppb. To what extent does this range of benchmark values appropriately reflect the health effects evidence related to 5-10 minute SO₂ exposures evaluated in the ISA?
2. Does the Panel view the results of the risk characterization in Chapters 7 and 8 and the lung function quantitative risk assessment in Chapter 9 to be technically sound, clearly communicated, and appropriately characterized?
3. A quantitative risk assessment has been conducted with respect to two indicators of lung function response in exercising asthmatics in St. Louis and Greene County, MO. 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 adequacy of the discussion of uncertainty and variability? To what extent have sources of uncertainty been identified and the implications for the risk characterization been addressed? To what extent has variability adequately been taken into account?

Policy Assessment (Chapter 10):

1. The policy chapter has integrated health evidence from the final ISA and risk and exposure information in this second draft REA as it relates to the adequacy of the current and potential alternative standards. Does the Panel view this integration to be technically sound, clearly communicated, and appropriately characterized?
2. What are the views of the Panel regarding the staff's discussion of considerations related to the adequacy of the current standards? To what extent does the draft policy chapter adequately characterize the public health implications of the current standards?
3. To what extent does the draft policy chapter adequately characterize the public health implications of the potential alternative 1-hour daily maximum SO₂ standards?
4. Staff believes that the evidence presented in the final ISA and the exposure and risk information presented in this second draft REA supports a potential alternative 1-hour daily maximum standard within a range of 50- 150 ppb. To what extent does the draft policy chapter provide sufficient rationale to justify this range of levels?

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. Michael J. Stewart (919-541-7524; email stewart.michael@epa.gov).

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